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## **HOW TO REGULATE?**

A handbook presenting regulatory techniques of nine jurisdictions and a basic universal method

Version INT 1.1

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## *Foreword and project history*

By identifying the topic of „regulatory techniques“ in 2008, I thought to have found a small uncharted island. Now I incline to thinking that it is a continent. The territory that I saw in front of me seemed to grow bigger and bigger over time. Ever more regulatory questions and matching solutions appeared. From 2008 to 2013, I studied regulation of the European Union in sectors other than those I was familiar with. I encountered proof of remarkable intelligence laid down in regulation. Since the end of 2013, I have also examined regulation of jurisdictions other than my domestic one. The regulatory techniques which I encountered there are just as interesting as the ones I know from my domestic jurisdiction. By gaining both a cross-sector and a cross-jurisdiction perspective, my undertaking became an intellectual adventure. I hope that some readers will experience the same intellectual thrill when discovering intelligent regulatory techniques in other sectors and jurisdictions than those they are familiar with.

Officials in possession of an inventory of regulatory techniques have more choices and can conceive of better regulation. A good deal of regulation has been improved with the help of the predecessor text of this handbook, despite its very limited dissemination in a kind of pilot project. Several hundred officials have thanked me for my initiative and have recognized the practical value of the predecessor text. Accordingly, I suppose that the much more complete, balanced and really international handbook in front of you will be at least equally useful. I compiled the handbook out of interest and a clear sense that an inventory of regulatory techniques should exist, to the benefit of officials and of the citizens of their jurisdictions. However, I do not think that the regulatory method and the inventory of regulatory techniques displayed in this handbook should necessarily be further developed by myself. Other persons and above all some institutions might be better qualified and better placed. Therefore, I would be happy to grant the right to further develop the handbook to public institutions (administrations, scientific institutes, think-tanks etc.) and persons working for them. Please contact me if you know an institution or a person possibly interested in further developing the handbook or developing a new text based on it.

### **DISCLAIMER AND CONDITIONS OF USE**

1. This handbook has been drafted under my own responsibility as a private person. The views taken in this handbook are exclusively my personal views. They are not intended to reflect the views of my current or any previous employer or sections thereof. In particular they are not intended to reflect the view of any institution of the European Union or sections of these institutions.
2. This handbook has been developed as a pro bono knowledge sharing initiative and is made available free of charge, outside any commercial context. Accordingly, users cannot claim liability rights.

#### **The author:**

(Mr) Manfred KOHLER holds two German degrees in law and a French degree in public administration. Since 1989, he has been working for three administrations in two nation states (at the local level and in a national ministry), for a national and an international NGO, for two institutions of the European Union and for two institutions of the United Nations. Throughout his 25 years of professional activity in the field of regulation, he has strengthened more than 150 regulatory acts. From 2010 to 2013, he trained around 300 officials who were working in many different policy fields.

## 1. Introduction

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*Ruling the country is like cooking a small fish.*

*Lao Tse*

### 1.1. Purpose and use of this text

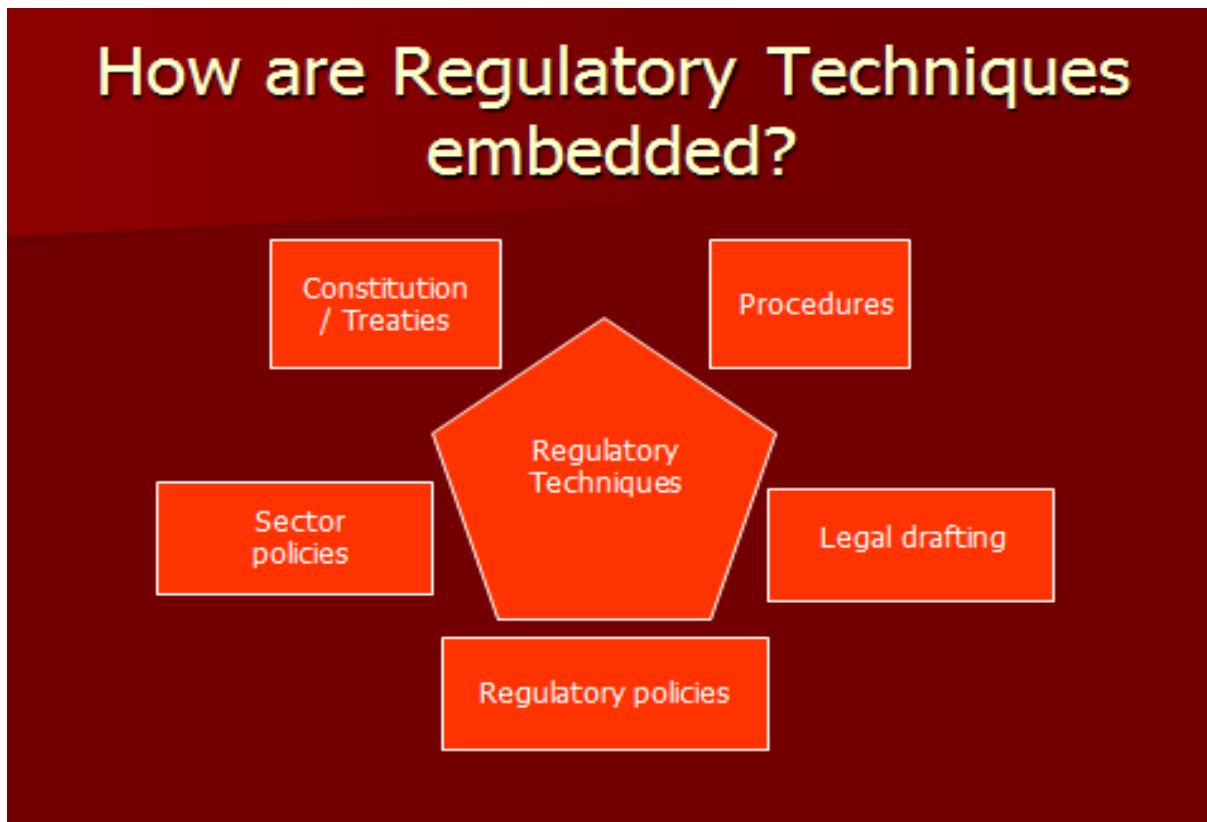
The purpose of this text is mainly to serve as a handbook for officials involved in regulatory activities. Furthermore, it can be used as a basis for training courses or for self-training.

This text is not intended to be read from A to Z. Instead readers are invited to pick and choose the sections that are relevant to them. [As a consequence, it is sometimes necessary to repeat some content. Some content is relevant under different aspects and therefore needs to be displayed in different Sections.]

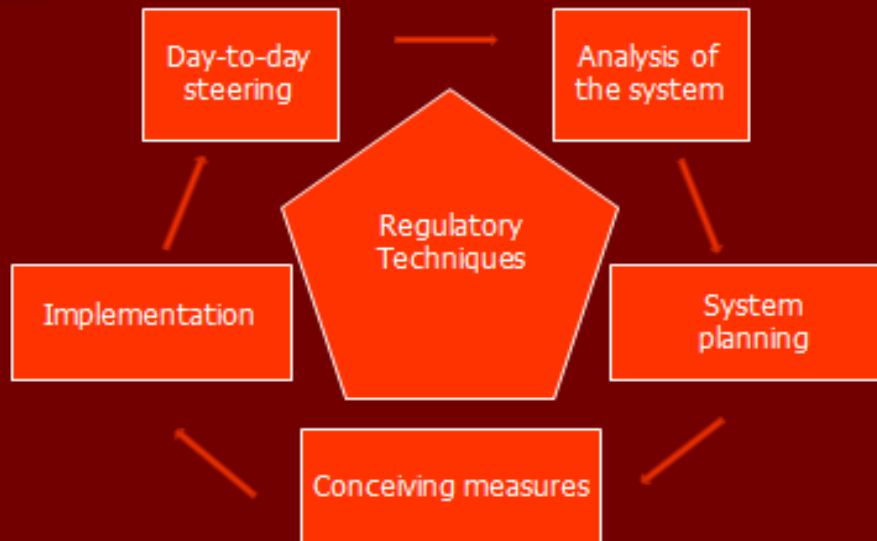
The text is not deemed to be authoritative. Instead, it should be used as a first orientation and as an intellectual sparring partner. As such it can help to reflect one's own practice where there is little formal instruction.

The text explores the empty space between:

- the constitution or similar documents setting the legal frame, like the treaties founding conglomerates of nation states with own jurisdiction,
- the sector specific policies followed by the government, administration or institution,
- the impact assessment, better regulation, simplification and other regulatory policies,
- applicable drafting instructions or recommendations, and
- the procedural settings of the respective jurisdiction.



# Knowing Regulatory Techniques can help in these processes



## 1.2. Terminology

In this handbook, we use the following expressions:

- “Jurisdiction“ means a nation state or a conglomerate of nation states which has its own regulatory empowerments.
- “Geographic entities“ are parts of a jurisdiction. Geographic entities can mean the various states in a federal state like the U.S, Brazil, Canada or Argentina or the member states of the Mercosur, the ECOWAS, the EU, ASEAN or of another conglomerate of nation states with their own regulatory empowerments. But it could also mean „région“ if the handbook were to be used in the national French legislative context.
- We borrow the expression “Centre” from the Indian political and administrative practice to refer to the central government in the case of a nation state or to the central organs in case of a conglomerate of nation states with their own regulatory empowerments.
- We call a “sector“ a certain rather limited regulatory subject matter, which however encompasses a variety of particular issues, e.g. the safety of cars, telephone services, or organic farming. The issues of a certain sector are usually the same across various jurisdictions. The expression “sector“ is thus not related to one single jurisdiction.
- The expression “field“ refers to several parallel sectors which fall under the same generic term of (next) higher order, e.g. environmental protection, product safety, or financial services. The expression “field“ is not related to one single jurisdiction either.

We strive for a consistent use of the following terms which fit for various jurisdictions:

- Regulation: Legal acts of general applicability (thus not only for individual cases). Regulation consists of either legislation or of regulatory acts.



- Legislation: regulation adopted by the respective parliament.
- Regulatory acts: regulation adopted by the administration (ministry, department, agency etc.).
- Regulatory measures: Regulation or other measures that influence behaviour in more than just individual cases.

We sometimes also use the expression “Regulatory measures other than regulation” which is self-explanatory on the basis of the previous definitions.

Decisions on individual cases are mostly not dealt with in this handbook, though they might, in exceptional cases, also have a regulatory effect, e.g. if they are published and thereby influence the behaviour of operators others than those formally addressed. We sometimes refer to them as “administrative acts”.

### 1.3. Developing of a method and science of regulating

There are millions of lawyers in the world. However, only a very small fraction of them are involved in law-making or regulating in general. Law-making or regulating in general is mostly not part of university law-studies. Law-studies focus on the application of law, not on regulating. Studies of political science do not prepare either for the activity of regulating at an operational level. Only some administrative schools do so. However, most of them only offer training for specific aspects. Hardly any school deals with the general method and with the tools (regulatory techniques). There is accordingly a vacuum at the level of professional training.

The vacuum at the level of training is mirrored by a vacuum at the level of research. Methods of regulation are subject to scientific research either for specific sectors or for specific aspects, if ever. To the knowledge of the author, there is no comprehensive research analysing and presenting methods and tools of regulating.

From this situation, the author started from the other end: he listed questions that were raised by officials or that arose in his day-to-day practice and tried to develop answers to these questions. To his surprise, new questions constantly arose. Today, he still identifies new questions every month. The handbook attempts to respond to these ever multiplying questions.

Whilst being in contact with many officials who were in charge of a wide variety of regulatory sectors, the author noted that some officials were also looking for methodological guidance on how to regulate. To respond to that need, the handbook includes new methodological recommendations. The handbook presents a basic universal method encompassing the following branches:

- analysis of the sector (Section 2.1),
- identification of possible goals, objectives, measures, requirements, incentives, and information or enforcement tools (Sections 2.2 and 2.3 and Chapter 7),
- conception of regulatory measures with focus on regulation (from Section 2.3 to Chapter 10),
- basic quality verification (Chapter 11).

The method presented here is admittedly basic. The four branches are not yet equally developed. They could be extended by ever more details and alternatives. The author refrained from presenting more details for a specific reason: some jurisdictions have developed regulatory policies. If the author had presented more details, the presented method would come into conflict with the regulatory policies of the various jurisdictions. By tackling only the top of the methodology pyramid and the detailed regulatory techniques which are below the radar of regulatory policies, this conflict is hopefully avoided. Readers are of course invited to complement or even to correct the method in view of the practice and the regulatory policies of their jurisdiction.

There should be an international debate of regulators with scientists. A scientific observation of regulatory activities could detect elements and characteristics that the regulators themselves cannot see. Having analysed these elements, the method of regulation presented here could be substantially improved.

The establishment of dedicated institutes would favour the emergence of a new scientific field, “the science of

regulation”<sup>1</sup>. Such institutes could undertake research on regulatory techniques and the methodology of regulating, train regulators and offer consultancy services. They should be recognised as being of public interest. Each jurisdiction should have one institute to cover specific aspects.

Why is it so important to further develop regulatory techniques and the methodology of regulating? Knowing about them could strengthen public policies. Public authorities are falling behind rogue and other egoistic operators who develop ever cleverer business constructions and methods to escape authority verification. The competition is likely to be lost on the authorities’ part if the authorities do not use their opportunities to regulate more efficiently. At the same time, only full knowledge of regulatory techniques enables authorities to regulate as lightly as possible. E.g., the freedom of citizens and of economic operators should of course not be limited by stringent mandatory law if less compelling tools can serve the given goals better. The regulatory techniques presented in this handbook can be helpful in both directions: protecting the primacy of state ruling and thereby the common interest of societies and protecting individual liberties.

#### 1.4. The selection of jurisdictions

Jurisdictions have been selected according to a variety of criteria: internet accessibility of the jurisdiction's regulation, geographic distribution of the various jurisdictions (aim: covering different continents), income distribution of jurisdictions (aim: covering high, medium and low-income jurisdictions), different religious and societal backgrounds, supposed regulatory quality (sub-criterion: strong tradition of comparing regulation), and respect of the rule of law and of basic democratic principles.

The handbook contains a certain share of EU regulation, carried over from its predecessor text and recognisable by the letters “EU” or “EC” before or after the number of the act. The substantial, but not dominant share of EU regulation<sup>2</sup> is justified. EU regulation is based on many different regulatory traditions. It is thus very rich in terms of regulatory techniques.

South-American jurisdictions have a long tradition of comparing law, selecting amongst the best reference regulation and adding innovative elements thereto. This is in particular the case for Argentina which has been influenced by not only Spanish, but also Italian law. We supposed that Brazil would select from the best elements of EU and U.S. product and service regulation. Indeed we found improved elements of EU law combined with a highly intelligent overall architecture and interesting detailed regulatory solutions. Canada seemed promising because it has both British and French law roots and an extremely powerful neighbour whose regulation automatically serves as regulatory benchmark. Confirming the expectation, we found high quality regulation that can perhaps serve even better as an international reference, for aspects of regulatory techniques, than the often extremely complex U.S. regulation<sup>3</sup>.

We selected India and Singapore for South and South-East Asia. Both jurisdictions provide for full access to their regulation and use particular regulatory techniques. India seemed interesting insofar as it has, besides the British influence, a long-standing autonomous administrative tradition. We supposed India to have the courage to

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<sup>1</sup> This expression and the equivalent expression „regulatory science“ are today mostly used for products falling under the competence of the U.S. authority FDA (Food and Drugs Administration), see e.g. <http://regulatoryscience.georgetown.edu>. The author thus pleads for an extension of the meaning from FDA regulated products to all products, services or processes. A broader use of the expression was already common practice in the 1990ies; see e.g. Alan IRWIN et al, “Regulatory Science – Towards a sociological Framework”, in: *Futures* Vol. 29 No. 1 pp 17-33, Elsevier Science Limited 1997. Wikipedia defines “regulatory science” in a third, also too restrictive meaning though not being limited only to FDA regulated products: “Regulatory science refers broadly to the scientific and technical foundations upon which regulations are based in various industries - particularly those involving health or safety.” Thus, according to Wikipedia, the expression does not relate to the methods of regulating as such. More on the emergence of the expression “regulatory science” in 1987 and the use of this expression can be found here. Outside the world of law and regulation, the expression “regulatory science” is used in the field of engineering for the science of (often cybernetic) electronic steering.

<sup>2</sup> About 2/7 of all the references to regulatory examples points to EU regulation.

<sup>3</sup> It is likely that we will screen some U.S. regulation for innovative regulatory techniques for the next edition of this handbook. It goes without saying that the U.S. regulation is technically a top-level reference in most sectors. Therefore it is recommended that sector specialists also look at the respective U.S. regulation. In Annex III, we will show how to find U.S. regulation for a specific sector.

go its own way for certain questions, and indeed it does so. Singapore demonstrates that a small jurisdiction, too, can reach the very top in terms of regulatory quality. We initially wished to add an East-Asian jurisdiction, but unfortunately the East-Asian jurisdictions that we investigated make their regulation not or not speedily available in English. Thus we drifted slightly south and found fascinating regulatory techniques in the Philippines.

For Africa we had more difficulties in identifying appropriate candidates that would complement the panel. Amongst those few jurisdictions committed to democracy and the rule of law, we were in particular looking for French-speaking jurisdictions. We selected one west- and one north-African jurisdiction, Senegal and Tunisia. They complete the panel well insofar as they are rather Islamic and not amongst the richest jurisdictions. Unfortunately, both jurisdictions did not adopt a high quantity of regulation recently. Wishing to cite predominantly recent regulation, we could therefore not present a high number of acts of these two jurisdictions<sup>4</sup>. However, reading the Official Journal of Senegal, we took note of some interesting regulation elaborated by the Economic Community Of West African States [ECOWAS](#).

Overall, we reached quite a balanced selection of references. The Americas provide for slightly more than 30% of the references. The EU and Asia each provide for slightly less than 30% of the references. Africa, ECOWAS and UNECE provide for the remainder.

Suggestions for further appropriate jurisdictions are welcome. The next edition of this handbook might cover a few more.

## 1.5. The missing chapters 4 to 6

There are no chapters 4 to 6 in this edition of the handbook. These chapters are consciously left open. Readers in the various jurisdictions might find that there are, in their respective jurisdiction, regulatory questions which should be addressed. Readers who wish to complete the handbook in view of the needs of their respective jurisdiction are invited to contact the author. The following outline illustrates what the chapters could look like.

### **Chapter 4: The types of regulation in jurisdiction X**

This chapter could for instance describe:

- the various types of regulation that regulators could use in the specific jurisdiction,
- the conditions for using the different types of regulation,
- the respective advantages and disadvantages of the different types of regulation,
- the links between the different types of regulation that are to be respected and those which might need to be created,
- what has to be borne in mind when using the different types of regulation.

### **Chapter 5: International aspects in regulation**

Chapter 5 could for instance provide the necessary advice on how to avoid frictions between the international setting and the domestic jurisdiction. Regulation in a certain jurisdiction relates in at least two ways to international legal, political or administrative instruments:

- It stipulates how to adopt the international instruments;
- It stipulates how to integrate the international instruments into the jurisdiction.

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<sup>4</sup> Furthermore, many of the regulatory techniques used by Senegal and Tunisia seemed quite familiar to us: they are derived from the French tradition which is also the strongest influence of the EU regulation. The percentage of regulatory techniques worth being presented was therefore rather low. This does not imply any statement on their quality.

The basics for both are often set out at the level of the constitution or other very fundamental law. However, many practical aspects can come into play. They are not necessarily dealt with at the level of the law. E.g., it can be advisable to adopt the international instrument only when it is ensured that it can be integrated into the respective jurisdiction. In some jurisdictions, it is even possible to adopt the international instrument and the integration measure together “in one strike”.

### **Chapter 6: Other jurisdiction specific aspects of regulation**

This chapter can respond to all questions that do not fit under the other chapters and for which the responses must be specific to the respective jurisdiction. This chapter could for instance deal with issues like translation requirements for regulation (e.g. can international standards be referred to without translation?), publicity requirements applicable to new regulation which need to be addressed in the regulation itself, requirements for regulation that serve to fulfil procedural requirements of regulating, constitutional constraints for the content of regulation, and the transmission of tasks to specialised agencies.

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## 2. Laying the ground

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*“It must be considered that there is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to handle, than to initiate a new order of things. For he who innovates will have for his enemies all those who are well off under the existing order of things, and only lukewarm supporters in those who might be better off under the new.”*  
*Niccolo Machiavelli*

Once asked to draft new regulation, we tend to start drafting immediately, mostly on the basis of a previous example. Thereby we risk being set on the wrong track. Readers might find it useful to check at least some of the items and the fundamental questions listed in Chapter 2 prior to drafting measures.

### **PART A: Applicable to all regulatory measures (regulation and other)**

#### 2.1. Analysing the issues of the sector

Taking regulatory measures without proper prior analysis of the issues resembles prescribing a medical treatment without diagnosis. Both in the regulatory and the medical world, it is risky to omit the analysis / diagnosis. The instinct of the physicist or of the regulator might be right in most cases. But in some other cases, s/he would have detected by a proper analysis / diagnosis that the issue identified by her/him is not the real one, not the most important one or at least not the only important one. Consequently, s/he might have taken other measures than the ones s/he took or s/he might have modified elements of the measure taken.

Hereafter, readers will find a list of questions which may help to get a more complete picture of the situation of their sector. Ideally, readers will take time for each of the questions raised – a slow approach ensures a deeper insight. Furthermore, readers might consult stakeholders on their views with regard to the identified questions and the sector as a whole. Stakeholders often have a different perspective than the officials in charge. A stakeholder consultation can take place in a classic written form or in more modern, participatory forms. More on the latter is to be found in Sections 2.5. and 10.1.

##### 2.1.1. The questions helping to analyse the sector

###### **2.1.1.1. Up-coming developments – presenting the future**

Which new developments are to be expected for your sector in the years to come, e.g. in terms of:

- technology?
- economy?
- behaviour of today’s actors?
- entry into play and behaviour of new actors?

###### **2.1.1.2. The landscape of political operators**

Describe the landscape of political actors!

- Who has some control or influence? Describe the control or influence!
- Who are the leaders? What are their interests?
- What are the interests of the „heavy-weights“ amongst the followers?

- What are the interests of the other followers?

### 2.1.1.3. The state of the current regulation

Is the regulation complete? Does it deal with all relevant aspects?

Is the regulation up-to-date? Does it take account of recent and upcoming technological, economical or other developments?

Is the regulation precise?

Is the regulation clear?

Is the regulation simple to apply?

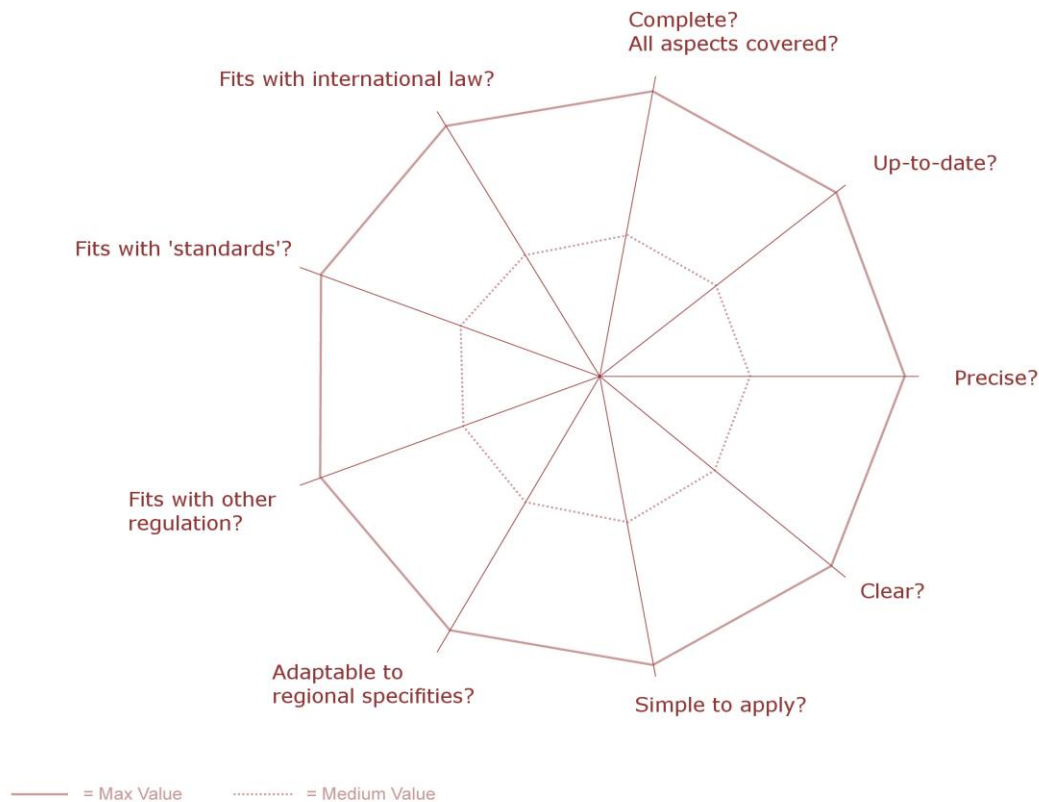
Is the regulation optimised as to its adaptability to regional specificities?

Is its relationship to other regulation optimised?

Is its relationship with or reference to international standards or similar documents optimised?

Is its relationship to international treaties optimised?

Insert your estimations into the following graph – the better the performance, the further to the outside:



### 2.1.1.4. Knowledge, compliance and responsiveness

How well do geographic entities know their rights and obligations?

How well do operators know their rights and obligations?

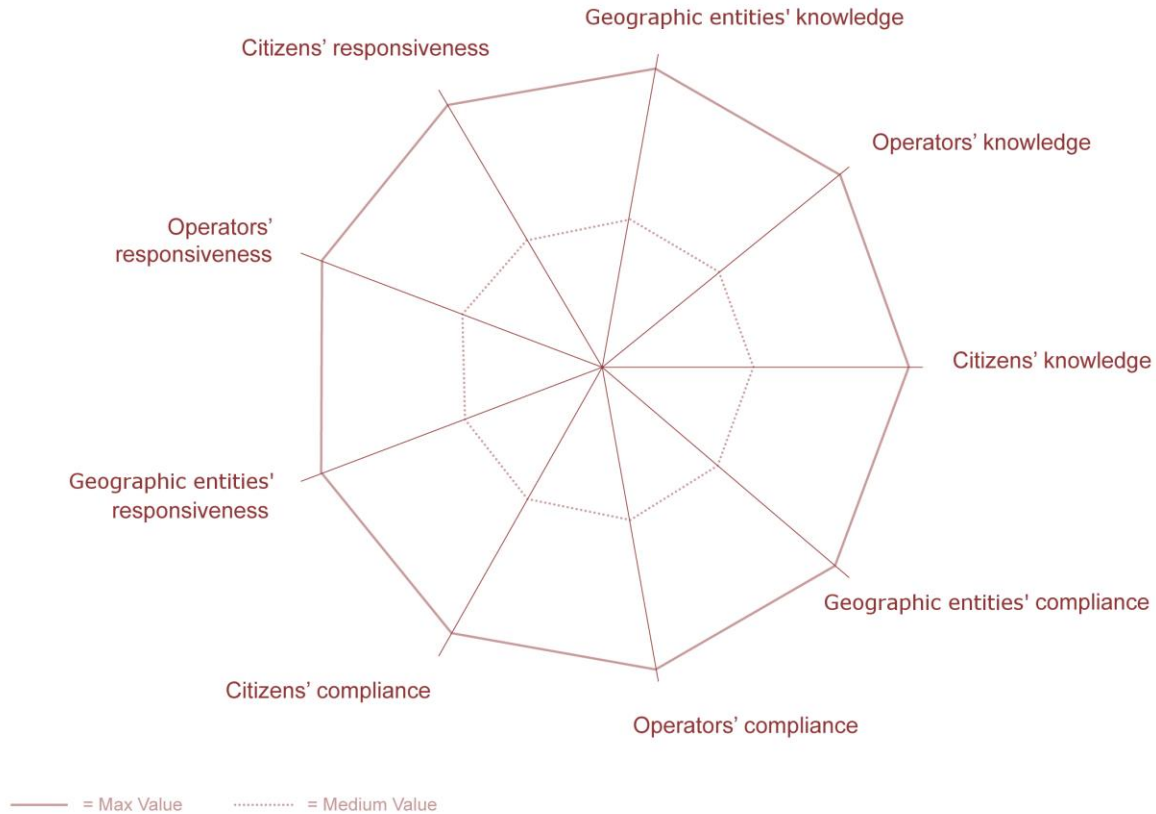
How well do citizens know their rights and obligations?

To what extent do geographic entities comply with their obligations?

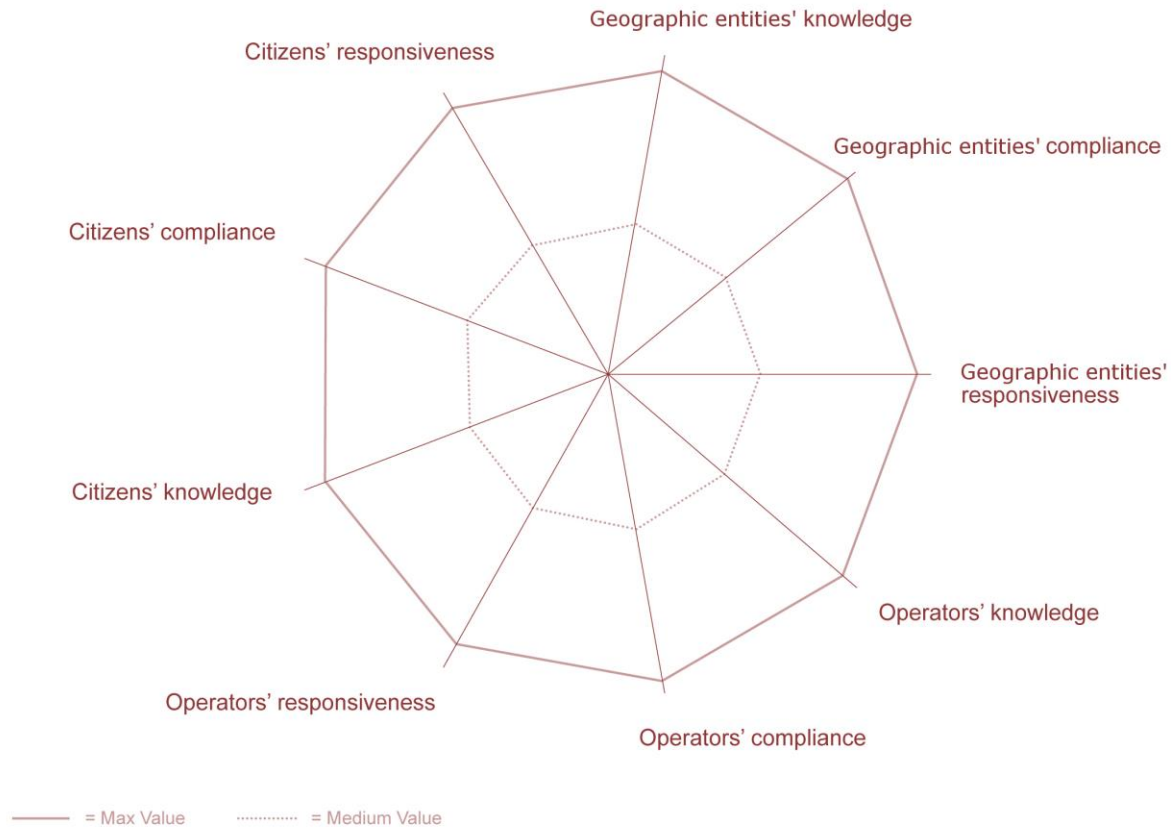
To what extent do operators comply with their obligations?

To what extent do citizens comply with their obligations?  
 How responsive are geographic entities to soft steering (e.g. via guidance, recommendations and information)?  
 How responsive are operators to soft steering (e.g. via guidance, recommendations and information)?  
 How responsive are citizens to soft steering (e.g. via guidance, recommendations and information)?

Insert your estimations into the following graph – the better the performance, the further to the outside:



In order to see whether the deficiencies are specific to a certain target audience, also insert your estimations into the following graph – the better the performance, the further to the outside:



### 2.1.1.5. Verification

Is the verification of compliance of operators and of citizens:

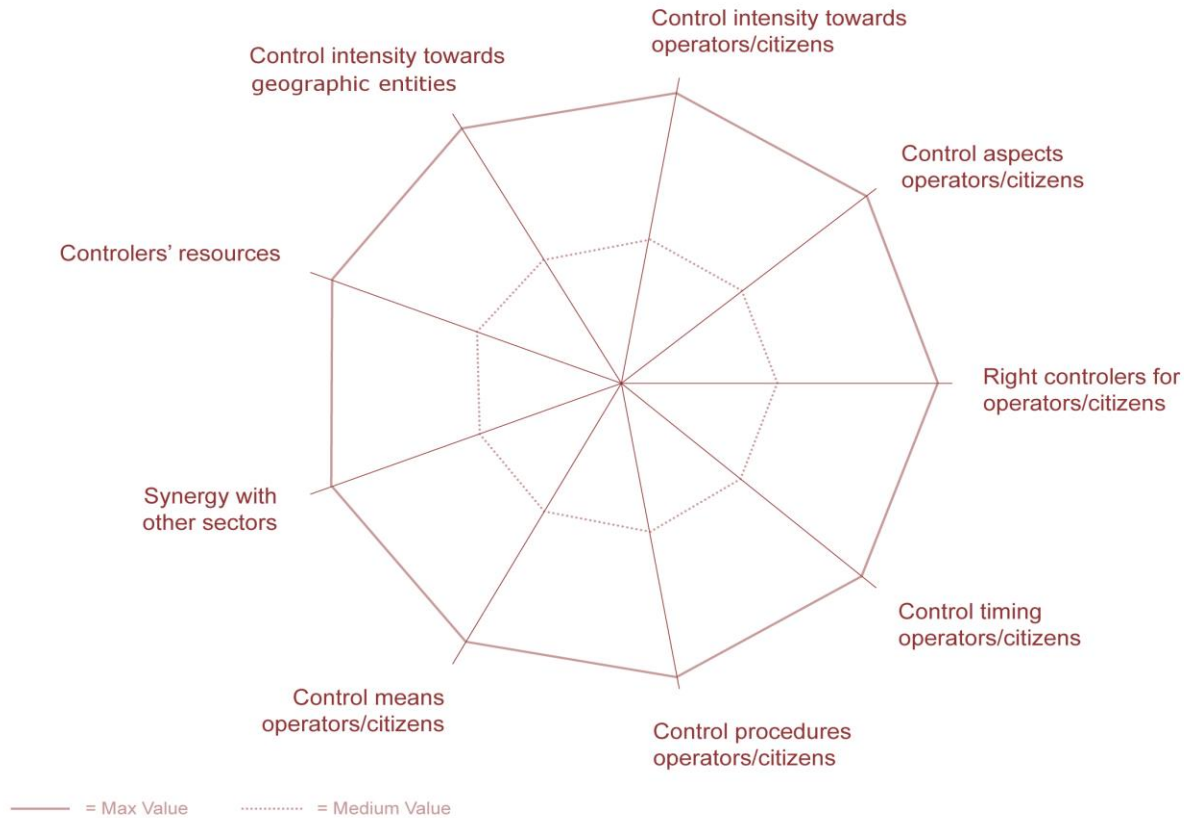
- intense enough?
- targeting the right aspects?
- executed by the right authorities or entrusted to the right private bodies?
- executed at the right time and the right step of the processes regulated?
- executed in the right procedure?
- provided by the right means?
- optimised in terms of synergy with other sectors' verification and supervision?

Do the authorities or entrusted private bodies have enough staff, equipment and money at their disposal to efficiently execute their verification and supervision function?

Is the verification of compliance of geographic entities intense enough?

Insert your estimations into the following graph – the better the performance, the further to the outside:





### 2.1.1.6. Top problems and potentials

Looking back at the answers to questions listed in 1. to 5. or other weak points identified:

What are the top five problems of the sector?

What are the top three development potentials for the sector, taking upcoming developments into particular account (see 1.)?

### 2.1.2. Follow-up to the analysis: first steps towards a response

There are many ways to find responses to the outcome of the analysis. Basically, all management approaches can be applied. We present here one approach which is item-oriented and an integral approach. Both approaches can also be combined. One can also use one method to verify the result of the other.

#### 2.1.2.1. The items-oriented approach

What are the necessary political, legal, managerial, and informational systems or other steps and means to solve each of the top five problems?

Which of the steps and means identified for the previous question are useful or even necessary to resolve more than one problem?

What are the necessary political, legal, managerial, and informational systems or other means to realise each of the top three potentials?

Which of the steps and means identified for the previous question are useful or even necessary to seize more than one potential?

How can the means best be combined so as to strengthen one another?

Can some of the non-top-five-problems also be elegantly solved?

Is it even necessary to integrate solutions to the non-top-five-problems, e.g. to avoid negative repercussions on the system?

What resources do we have at our disposal, at the level of the Centre and in the geographic entities?

How can the available resources be used so as to optimise the system?

The items-oriented approach is the one that many of us instinctively apply. It provides a feeling of “being in control of things”. However, we tend to limit the number of problems that we are willing to analyse or process. Accordingly, there is a risk of overlooking “secondary”, non-top-five-problems, or to underestimate the systemic relevance thereof. To illustrate it with an image: if you have to repair a pot with many holes, it might give you a good feeling to repair the five biggest holes, but the pot still cannot be used after your attempt to repair it.

### 2.1.2.2. The integral approach

What would be the best scenario that you can imagine for your sector for the next five and for the next ten years?

What would be the second best?

What resources are needed to ensure that these two scenarios will become a reality?

Which elements of the scenarios are important, but can be realised with few resources?

Which elements of the scenarios are important, but need many resources?

Which elements of the scenarios are less important, but can be realised with few additional resources?

What resources do we have at our disposal, both at the level of the Centre and in the geographic entities?

How shall we use the available resources so as to optimise the system?

If readers find it difficult to answer the questions raised in Section 2.1.2. without thinking of concrete measures, they are invited come back to these questions once they have read the other parts of Chapter 2 in which the various types of measures are presented.

### 2.1.3. Examples

The author’s training sessions on regulatory techniques contained a practical part. In this practical part, one, two or three real cases were presented by the participants and analysed in group work. Though this type of mini-analysis is not as systematic and comprehensive as the previously outlined sector analysis, the experience gained in the group work illustrates why a sector analysis is useful: it triggers a new perspective on the issues. During the group work, the primary topic was often shifted and always complemented by secondary topics. Mostly new candidate measures were identified. The following, partly fictive<sup>5</sup> examples can illustrate this.

#### 2.1.3.1. Example 1: “The method gap”

When the training course participant presented her case to her peers, she feared that the parliament would accuse her department of being inactive with regard to risks linked to the size of particles used as coating to certain devices falling under the sector regulation. The sector regulation indeed had no provisions on micro- and nanoparticles, but contained general clauses which could be understood as obliging one to reduce risks linked to particle size. Evidently, no specific risk evaluation methods were set out. Individual manufacturers have

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<sup>5</sup> The real cases were modified in such a way (e.g. by changing topics and merging similar cases) that the text presented here cannot be regarded as representing a real situation whilst still exemplifying the learning effects of analysing the system.

undertaken research both on risks and risk assessment, but were reluctant to share the results. They feared that their products would be regarded as unsafe by authorities. To anticipate pressure from the parliament, the superior of the participant wanted to launch an amending regulatory act. The participant felt uncomfortable: what should the regulatory act be about given that risk assessment methods were not yet well established? And how could the method, once laid down in the future regulatory act, be updated given that science was still evolving so fast? Despite these questions, she was constantly thinking in terms of an amending regulatory act.

After the discussion with her peers, the participant came to the conclusion that, instead of adopting a new regulatory act, it would be more appropriate to draft a short guidance document explaining why and how risks linked to particle size were to be evaluated under the current regulation. In parallel thereto, she envisaged developing, together with the industry and stakeholder associations, a website that would inform users of the methodological state of the art. Beyond scientific literature, industry methodological instructions, so far kept secret, would also be made available in an anonymised form by the respective industry association. The sector could thus defend itself against pressure from the parliament by demonstrating that law cannot contain more than the general safety requirement which already exists, that this general safety requirement is basically sufficient and that the crucial issue of methodology can best be dealt with by a dynamic internet based information platform.

### **2.1.3.2. “Example 2: “No empowerment for the real thing”**

The participant presented a dilemma: she had to deal with a three-step decision making and information process. There was an empowerment to regulate by regulatory acts the second and the third step which both dealt with pure information transmission. However, there was no empowerment to regulate on the first which was the crucial step in the process. The crucial first step fell under the competence of geographic entities. Geographic entities were extremely vigilant as to their prerogatives in this respect. Unfortunately, the steps 2 and 3 could not be correctly processed unless the communication regarding step 1 is standardised and channelled. Otherwise there would be a high risk of misunderstandings and mistakes.

In the discussion with her peers, the view was broadened. Instead of simply reflecting in terms of instruments (“Which tool to choose?”), the entire process was looked at. The question arose: How to convince geographic entities to manage all three steps in an integral way? A solution consisted in developing a form and making it mandatory for steps 2 and 3. But this form should also cover the communication needs of step 1! Geographic entities could of course decide not to use the form for step 1, but the form would allow them to economise in terms of time and human resources. Furthermore, it would be risky for them to use another form just for step 1: mistakes could occur when transferring data from this other form to the form to be mandatorily used for steps 2 and 3. Thus it would be simply irrational for geographic entities not to also use the form for step 1. Finally, by presenting the criteria relevant for step 1 in a non-binding way in the form, it might even influence the substantive decision making for step 1. Although there is no formal empowerment to regulate for step 1 and the criteria to be applied therein, the simple informal listing of all relevant criteria might have a harmonising effect on the practice of the various geographic entities.

### **2.1.3.3. Example 3: “Not only clarification needed”**

According to the initial view of the participant, there was a need for legal clarification with regard to certain rules. This was perceived as the major issue by the course participant when he presented his case. The clarification could be achieved by new legislation or by guidance. A deeper analysis showed that some operators, namely those based outside the jurisdiction, were not willing to comply with the existing rules or were not even aware of them. Nor would they respect new guidance. Clarification by new legislation would not be better unless the enforcement by certain geographic entities was strengthened. Thus the enforcement came into the focus of the course participant.

At the end of the case study, the participant recognised that new legislation would further deepen the already

uneven playing field, unless the new legislation were to set up minimum resource and activity requirements for authorities in charge of ensuring compliance. The participant seemed more inclined to investigate possibilities of exerting pressure on certain geographic entities with weak authorities so as to get them to increase their enforcement efforts. The question of whether new legislation was needed for purposes of clarification or whether guidance would be sufficient remained open for the time being. But the participant could not exclude the fact that, with stronger enforcement, guidance might be sufficient. Thus he left the course with the intention (1) to firstly check possibilities of exerting pressure on geographic entities to address the enforcement issue. If this was successful, he would (2) need to assess whether guidance would be sufficient to reach the clarification goal. Only if (1) or (2) turned out not to work would he suggest to his superiors the proposal of new legislation (3). But this legislation would have a second chapter on the geographic entities' enforcement obligations to address the newly identified issue of enforcement.

## 2.2. Identifying the policy goals

Policy goals can either be predetermined, e.g. by politicians or superiors in the administration (2.2.1), or still to be determined (2.2.2).

### 2.2.1. Analysing predetermined policy goals

Officials working for administrations are often told to follow a certain policy goal. In this case it is useful for identifying the appropriate regulatory measures to analyse what is behind the set policy goal: the „goals behind the goals“, so to speak. Some of the „goals behind the goals“ build chains. The goals which do not depend on other goals, at the end of the chains, shall be called primary goals in this text. The goals which are between the primary goals and the officially set goals shall be called intermediate goals.

Let us take a simple example: politicians may declare the following goal to be pursued: „to reduce tobacco smoking as much as possible“. Behind the declared goal we can identify two other goals: to reduce casualties and to reduce illness.



But these two goals might just be intermediate goals. They might have, subject to the views of the politicians, a common primary goal: to increase the number of healthy years in life. Behind the second intermediate goal is another intermediate goal: to reduce public spending on health. Behind this goal, there is another goal: to achieve a healthy public budget. This goal can be regarded as a primary goal.



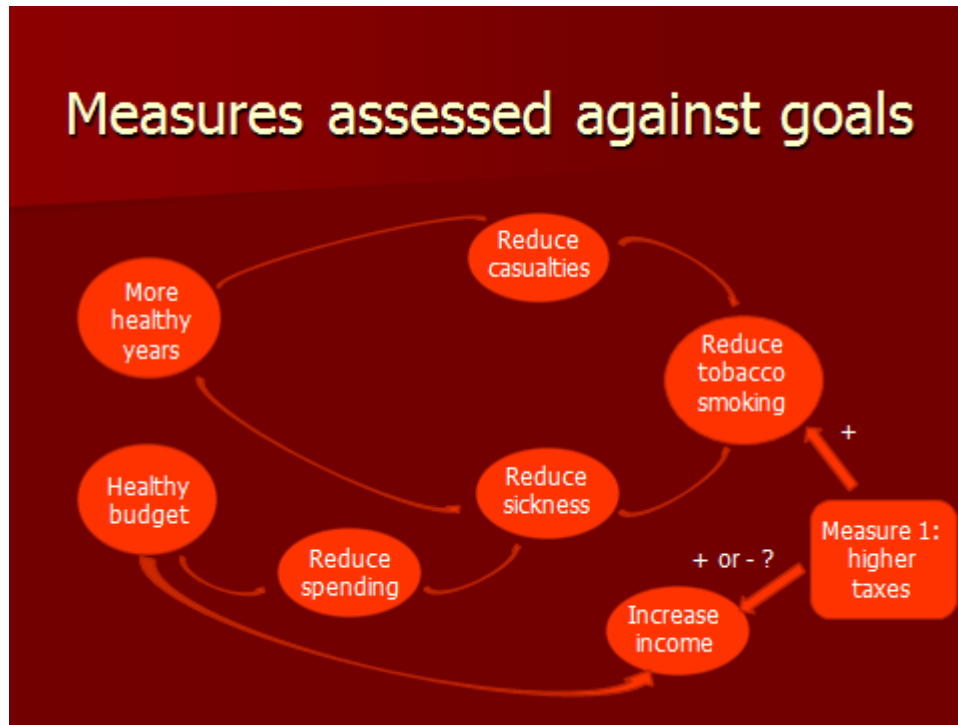
To see how the analysis of primary and intermediate goals can widen the range of policy choices, let us examine an imagined case. Imagine that an official in an autonomous nation state's ministry is in charge of proposing measures „to reduce as much as possible the use of smoking tobacco“. S/he has so far considered a panel of possible measures:

- Increase taxes<sup>6</sup> on tobacco products, creating a financial incentive to smoke less;
- Offer lower health insurance rates for non-smokers, creating another financial incentive to smoke less;
- Oblige manufacturers of tobacco products to place warnings and deterring images on the packaging with a view to deterring smokers;
- Launch information campaigns managed by media, health insurances and schools;
- Offer anti-addiction courses (e.g. managed by health insurances).

Let us look at the first of the possible measures. Increasing taxes on tobacco will increase the overall tax revenue, but it will only increase it up to a certain taxation rate. From a certain taxation rate onwards, any further increase will decrease the overall revenue, as economists have found out and as the political reality in some high tax states has also proven. This is because the taxation rate becomes either too prohibitive or because it becomes too appealing to commit tax fraud when taxes are extremely high. Accordingly, from a certain level onwards there can be a conflict between “creating by higher taxes a financial incentive for not smoking” and “increasing the overall revenue”. As the official has detected this potential conflict, the official may quantify the two contrary financial effects. When doing so, the official can also analyse secondary financial effects of the measure, namely the effect of the costs of less smoking on the health insurances. Different theories have been circulated in this respect: subject to the overall costs triggered by an increased longevity, health insurances

<sup>6</sup> We use here the commonly used expression “taxes” although “excises” would be the right expression in most states.

might win or lose with the increased taxes.



Even when higher taxes have a negative financial effect overall, it might be good for the health of the population to increase the taxes beyond the critical level. Thus the official can offer the politicians a useful choice to make: optimise revenue or optimise positive health effects or choose a compromise in between.

A similar analysis can be undertaken for the four other measures that our official is considering. All the other four measures will evidently cost money. Their respective benefit-cost-ratio merits can be examined individually and comparatively (comparing the measures against each other) so that the politicians (or the administrative decision maker) can select the most cost-efficient ones.

Thus we can deduce already from this relatively simple example that knowing the primary goals of the politicians can trigger second thoughts. The official can offer the decision maker(s) a wider range of measures and thus a wider choice. S/he can point out trade-offs that nobody would have detected without analysing the primary goals of the politicians.

In a second example, we will go further and show that the analysis of the goals can even trigger collateral measures which are useful to optimise the pursuit of the goals. Let us imagine a fully autonomous nation state with some domestic oil production and the power to fix oil prices on the internal market. In this state, politicians are in favour of the goal: „reduce private transport in cars“. The politicians are in favour of this goal for a wide range of reasons:

- Some politicians wish to reduce congestion with a view to reducing the loss of working-time of employees.
- Some wish to slow down climate change.
- Some wish to reduce toxic pollution and noise in cities to avoid illness and casualties.
- Some wish to reduce the number of accidents in order to avoid injuries and casualties.
- Some wish to keep the internal fuel prices low. In this group, the politicians follow different primary goals:

some wish to keep industry production costs low, some have the same wish for agricultural production costs, and other politicians aim at keeping food prices low so that the poor can afford their food<sup>7</sup>.

The immediate response to the request of the politicians could consist of suggesting the following measures:

- Increase the price of petrol and diesel on the internal market;
- Establish a vehicle taxation system which is based on fuel consumption as primary or sole parameter;
- Limit the right to circulate in a certain car to every second working day in order to promote commuter communities;
- Tax or circulation right privileges for electric cars or for cars with fuel consumption at least 50% below the average.

But in view of the primary goals pursued by the politicians, more (groups of) measures could be offered:

- In view of local noise and toxicity reduction: Introduce limitations for car circulation subject to noise and fuel consumption (no cars with medium or high noise or toxic emissions in the inner city, no cars with high noise or toxic emissions in cities at all);
- In view of reduction of cancer provoking fine particles mainly emitted by diesel engines: give an incentive to use petrol instead of diesel cars, either by tax incentives or by extended circulation rights;
- In view of industry and agricultural production costs: determine different price levels for oil, subject to its use.

In addition, the official can inform his superiors or the politicians of the subtle trade-off which has to be made in order to optimise the result in view of the different, partly conflicting goals. Here are two of them:

- Weight is an important factor for fuel consumption of vehicles. But safety features increase weight.
- NOx optimisation of engines is to a certain, limited extent counter-productive for fuel consumption reduction and vice-versa.

We stop the analysis here as we do not aim at presenting all possibilities and side-effects. We simply aimed to show that the analysis of primary and intermediate goals can lead to new measures and to the optimisation of measures.

### 2.2.2. Determining further policy goals

Even if some goals are pre-determined by politicians or the head of the administration, officials should examine whether further goals need to be determined or spelled out (sometimes goals have not been consciously set, but are implicitly expected). It is very unlikely that the politicians or the head of the administration have undertaken a complete analysis of the sector, that they are aware of all the problems and that they see all the possible positive developments (potentials). By examining whether further goals should be set, officials can inform their superiors and/or the politicians of further possibilities to improve the sector.

The best basis for setting goals is the analysis of the sector. Each of the problems identified in the sector analysis can be turned into a goal. But one should not limit oneself to the problems. As we have also seen in the sector analysis, there can be potentials for improvement which are not linked to a problem.

If properly done, a sector analysis will detect so many problems and potentials for improvement that it is hardly possible to manage them all in the regulatory process. Therefore, it can be advisable to split problems and potentials into two groups: major and minor issues.

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<sup>7</sup> There is a double correlation between food and oil prices: a high oil price makes food production more costly and agricultural surfaces can be used either for food or bio-fuel production, thus both markets are linked.

## 2.3. Determining objectives, measures, requirements and incentives

To illustrate what is meant by “objectives”, “measures”, “requirements” and “incentives”, let us use an example. Imagine that local politicians have decided to pursue the political goal “to reduce the number of traffic accidents in town”. Together with the local administration, they have developed different objectives that are deemed to concretise the goal. One of the objectives is to ensure that vehicles are not too fast. One of the requirements concretising this objective could be: vehicles should not be faster than 30 km/h in an area of 100 meters surrounding schools. Respect of the requirement shall be ensured by three measures:

- Establishment of a zone with reduced maximum speed by speed limit indications;
- Enforcement of the speed limit by radar surveillance, vehicle identification and financial sanctions;
- Establishment of radars displaying: “Thank you for respecting the speed limit”.

The first two measures are based on the incentive “avoid sanctions”. The last measure uses the incentive “praise”.

### 2.3.1. The right order for determining objectives, measures, requirements and incentives

Once the goals have been determined, officials might think of determining the objectives. Objectives are, like goals, determining targets, but they are more concrete and measurable than goals. Determining objectives can be mandatory according to the planning or impact assessment mechanism of the respective jurisdiction. However, objectives are not always necessary for the identification of measures, requirements and incentives. If the goals are already quite concrete, it might be easier to skip the level of objectives and think immediately in terms of measures, requirements and incentives. Furthermore, it is sometimes impossible to establish ambitious but realistic objectives without having examined requirements, their incentives and the measures which are to refer to them. If the enumeration of objectives is mandatory according to applicable regulatory policies, but the official does not need them for his personal planning, the official might also proceed without enumerating the objectives and might deduce the objectives later, thus filling in the gap for the official planning process or impact assessment.

Is it best to start with the measures, requirements or the incentives? It is difficult to establish an order that is valid and best for all cases. Instinctively, one might think that measures come first. But starting with the measures might focus the view automatically to the requirements and incentives that fit with the measures identified. Other requirements and incentives are lost to sight. Accordingly, it might be better to note the measures which have come to mind naturally when doing the system analysis or the analysis of the goals, but to put these measures “into the fridge” until the requirements and incentives have been analysed and cast into measures.

As for the order in which requirements and incentives should come, it is advisable to undertake two exercises:

- Examining requirements and attributing to them the appropriate incentives;
- Identifying suitable incentives and inventing appropriate requirements. These requirements invented on the basis of incentives may differ from the requirements so far identified under the first indent. They may differ in nature or in terms of stringency.

Once the requirements and incentives have been identified, one can think anew on the measures. It is possible to deduce appropriate measures from the requirements and incentives. During this exercise, one may also reflect on the measures “put into the fridge”. If some of the latter do not match with the requirements and incentives whilst still felt to be worthwhile, there is a certain likelihood that some requirements and incentives have been missed in the previous step. Here again, the double-eyes movement may help to identify loopholes.

Whatever order has been chosen, it is always advisable to try, in addition, a different starting point. Different starting points usually lead to the identification of additional requirements, incentives and even measures. By using different starting points, there is a wider choice and thereby more possibilities to get positive policy results. The use of this method reduces the likelihood of missing opportunities.

### 2.3.2. The requirements



Some requirements are appropriate for certain incentives and not for others. Requirements for positive incentives are mostly more stringent than requirements for negative incentives of the type „sanction“.

The requirements and measures should be set up in view of the goals or objectives, the empowerment(s), and the incentives which are most appropriate to influence the behaviour of the targeted natural or legal persons. In the case of regulation, the enforcement capacities and possibilities and other elements discussed under sector analysis (Section 2.1) may also play a role. Above all the enforcement aspect should not be overlooked: it is of no help to set up the most wonderful requirements if the requirements will not be fulfilled voluntarily and if they cannot be enforced either.

It goes without saying that on one hand reasonable requirements can only be set up in the light of the specific sector. On the other hand, regulators sometimes overestimate the specificity of their requirements. Many regulators of specific sectors think that their sector requirements are extremely specific. They often do so because they have not extensively studied the requirements set up in other sectors. The more one reads regulation of different sectors, the more one recognises that requirements are basically similar. Differences are to a certain extent due to the sector's specificities. But often they are also due to the fact that the regulators of one sector conceive of requirements better or worse than in another. Brazil has drawn a radical consequence from this. It has set up basic generic documents containing requirements for products and others for services. The sector specific regulation builds on these. It can deviate, but automatically does not fall below the level of the generic documents. See as an example Section 10 of the [Brazilian Portaria INMETRO / MDIC Number 247](#)<sup>8</sup> of 26/05/2014 on the conformity assessment for the retreading of tires. It refers to the generic act, but also contains certain add-ons:

*„The criteria for responsibilities and obligations must follow the ones below and those established by the RGDF Services“* (one of the generic acts).

Jurisdictions that do not wish to go the radical Brazilian way should encourage their regulators to look into other sectors' regulation. Furthermore, it can help to study which requirements have been set up by other jurisdictions for the respective sector. Annex III shows a simple search technique which helps to find the latter.

Even before looking into the past measures, other sectors or other jurisdictions, one can start developing requirements on his/her own, directly based on the sector analysis and the analysis of policy goals. This can ensure that one's own creativity is not steered into habitual paths too early. To reach the best possible result, it is advisable to start thinking independently (alone or with others), then to study examples of the past, of other sectors or other jurisdictions, and then to restart independent thinking again, this time with the inspiration of the examples.

Of course, it is not easy to develop requirements "from scratch". To get some inspiration, please find in the following a typology of requirements.

We can distinguish the following types of requirements:

- Procedural requirements („Operators must be registered.“)
- Substantial requirements.

Substantial requirements can be qualitative or quantitative:

- Qualitative requirements („Clinical trials shall only be authorised if the medicine is based on an innovative approach.“)
- Quantitative requirements. To be sub-divided into requirements establishing minimum and/or maximum values, average values, and balance values.

Both procedural and substantial requirements can *inter alia* refer to organisations, natural persons, geography / physical presence, objects or processes or a combination thereof:

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<sup>8</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.

- Organisational requirements („Applicant companies must be independent from any authority. “), therein in particular: system requirements („Applicants must set up and maintain a quality management system. “<sup>9</sup>),
  - Personal requirements („4.1 In order to qualify and acquire a license to own and possess a firearm or firearms and ammunition, the applicant must be: a) a Filipino citizen; b) at least twenty-one (21) years old at the time of the filing of his/her written application ... “)<sup>10</sup>,
  - Geographic / physical presence requirements („A high risk facility may not be established more than 20 Km away from the next fire brigade.“),
  - Object requirements („Life-vests must be marked with the following symbol: ... “),
  - Process requirements („The manufacturing of explosives must fulfil the following conditions: ...“);
- Amongst the conditions to be fulfilled may be another process, e.g. „... shall be managed in accordance with a quality system fulfilling the conditions of ISO ...“.

Section 10.B of the [Implementing Rules and Regulations of the Anti-Bullying Act of 2013 of the Philippines](#)<sup>11</sup> contains an interesting case of a procedural requirement that contains built-in process requirements and thereby illustrates the difference between procedural and process requirements:

*„B. Procedures.*

*Consistent with Sections 3 and 4 of the Act, all public and private kindergarten, elementary and secondary schools shall adopt procedures that include:*

*a. Immediate Responses*

*...*

*g. Due Process*

*In all cases where a penalty is imposed on the bully or offending student, the following minimum requirements of due process shall be complied with:*

*a) The student and the parents or guardians shall be informed of the complaint in writing;*

*b) The student shall be given the opportunity to answer the complaint in writing, with the assistance of the parents or guardian;*

*c) The decision of the school head shall be in writing, stating the facts and the reasons for the decision; and*

*d) The decision of the school head may be appealed to the Division Office, as provided in existing rules of the Department.*

See as an example of how different personal and geographic conditions/requirements can be combined the following extract of the [Canadian Customs Act - Accounting for Imported Goods and Payment of Duties Regulations](#):

*„Paragraphs 10.5(2) (a) and (b):*

*(a) if the importer is an individual, the importer ordinarily resides in Canada or the United States or, if the importer is a partnership, the importer has at least one partner who is an individual who ordinarily resides in Canada or the United States;*

*(b) if the importer is a corporation, the importer has its head office in Canada or the United States or operates a branch office in Canada or the United States;*

*Paragraph 10.5(3) (b):*

*(b) if the carrier is a corporation, the carrier has its head office in Canada or the United States or operates a branch office in Canada or the United States; “*

<sup>9</sup> See as examples Sections 93 to 97 of the [Canadian Food and Drugs Act, Blood Regulations, P.C. 2013-1065 October 9, 2013](#) or Sections 6.1 to 6.6 of the [Canadian Regulations Amending the Onshore Pipeline Regulations](#), 1999, P.C. 2013-308 March 21, 2013. The latter is slightly more comprehensive than the first, but still manageable.

<sup>10</sup> Section 4 of the Philippine [Implementing Rules and Regulations of Republic Act No. 10591](#) (the “Comprehensive Firearms and Ammunition Regulation Act”), published on December 7, 2013.

<sup>11</sup> Act No. 10627, published on December 13, 2013

In addition to this typology, we can distinguish the following types of requirements:

- Requirements may be timed: limit value X until ... and limit value Y thereafter.
- Requirements may be dynamic and evolve over time without any predetermination: examples of such conditions are clauses like “best available techniques”, “state-of-the-art”, and dynamic reference to documents under control of other institutions such as Codices elaborated by the UN.
- Requirements may be subject to a review process.

Requirements may be applicable under certain circumstances and thus be subject to conditions.

- Conditions used as part of requirements may be all positive ( $A \text{ and } B \rightarrow C$ ) or partly positive and partly negative ( $A \text{ and not } B \rightarrow C$ ) or all negative ( $\text{not } A \text{ and not } B \rightarrow C$ ).
- Conditions may be interlinked by “and” or by two types of “or”: “A or B  $\rightarrow$  C” usually means “If there is A or B or both A and B, there will be C”; “A or B” may exceptionally also mean “A or B but not A and B”.

Likewise, requirements themselves can be interlinked by “and” or by two types of “or”.

### 2.3.3. The behavioural incentives

Incentives can be provided in two ways:

Firstly, regulation can establish incentives.

Secondly, measures other than regulation can provide for incentives. E.g. contracts and subsidies can be alternatives to unilaterally imposed obligations. An administration may be able to give an advantage by simple administrative decision. It can thereby create an incentive. E.g. an administration can decide to process those requests of operators or citizens faster that are based on a fully filled-in form and for which a certification body has already verified basic requirements.

The two ways of providing incentives constitute two overlapping circles. Some advantages can lawfully only be provided if regulation provides for a specific legal basis. Some advantages can, by their nature, only be provided by measures other than regulation. Regulators who exclusively reflect in terms of unilateral obligations to be imposed by regulation are likely to miss opportunities. Therefore it is very important to analyse the right behavioural incentives in conjunction with appropriate requirements before deciding on the measures to be taken.

*Inter alia* the following advantages can constitute incentives:

- The risk of reputational disadvantages (possible “naming and shaming” by authorities<sup>12</sup>, business associations, NGOs etc.);
- Reputational advantages (e.g. in the context of marketing of products fulfilling highest level requirements instead of the legal minimum requirements – positive publicity / praising by authorities or business associations);
- Feeling fashionable or morally good (e.g. millions of Europeans classify their daily garbage without being obliged to simply because it is common practice and good for the environment);
- Praise, going from a simple “thank you for respecting the speed limit” to formal awards;
- Status advantages (e.g. safer market access, like presumption of conformity with legal requirements provided by the fulfilment of standards under the New Approach, or access to a broader market);
- Longer validity of certificates or approvals;
- More legal certainty (e.g. by an optional state authorisation procedure instead of self-certification);
- Better protection of rights;
- Better control of competitors or opponents (e.g. via the voluntary accession to a self-regulatory body having a Code of Conduct and enforcement mechanisms)

<sup>12</sup> E.g. the UK is naming and shaming employers who do not pay the minimum wage, see <http://www.bbc.com/news/uk-27751722>

- Lower insurance rates;
- Lower liability risks;
- Lower damage risk; Lower risk of future compensation claims or of claims aiming at the internalisation of external costs;
- Access to valuable know-how (consultants, handbooks and training);
- Exclusion from public tenders or contracts;
- Privileged access to public tenders or contracts (e.g. for green procurement);
- Privileged access to subsidies / grants;
- Tax incentives.

Several of these incentives can be combined. The voluntary application of “the top world standard” may give access to the area of various jurisdictions at the same time, may prolong the validity of approvals and may provide for a better reputation (with or without labelling) and thus better marketing opportunities. There are situations in which the three incentives combined trigger a shift of the production whereas one of the incentives alone doesn't. These incentives sometimes permit the design of a package of non-coercive measures which have the same or more effect than unilateral coercive measures.

The [Canadian Food and Drugs Act – Marketing Authorization for Maximum Residue Limits for Veterinary Drugs in Foods](#) provides for an intelligent procedural incentive not to use certain substances beyond certain limit values:

*„2. When a veterinary drug that is set out in column I of the List or one of its metabolites — and that is analysed as being the substance named in column II — is present in a food that is set out in column III, the food is exempt from the application of paragraphs 4(1)(a) and (d) of the Food and Drugs Act in respect of the drug and its metabolites, if the amount of the substance present in the food does not exceed the maximum residue limit that is set out in column IV for that food and if any other condition that is set out in that column is met.“*

For more information on behavioural incentives, see this OECD document: Regulatory Policy and Behavioural Economics:

[http://www.oecd-ilibrary.org/governance/regulatory-policy-and-behavioural-economics\\_9789264207851-en](http://www.oecd-ilibrary.org/governance/regulatory-policy-and-behavioural-economics_9789264207851-en)

## 2.3.4. The regulatory measures: typology, comparison and selection

### 2.3.4.1 Typology

Being aware of the full range of available measures is a precondition for making the right choice. Therefore, it is advisable to invest some time into the question: which measures are at my disposal? The answer to this question is of course different from one jurisdiction to the next, and often from one sector to the next in the same jurisdiction. However, it is possible to set up a typology of measures.

The first important distinction to be made is between regulation (a) and other measures other than regulation (b)<sup>13</sup>.

#### (a) Regulation:

Subject to the jurisdiction and the legal setting for the sector in that jurisdiction, there are one or more types of legislation for which the respective parliament needs to be involved. Furthermore, there are one or more types of regulation adopted by the administration, that is non-legislative regulation, also called regulatory acts. These measures are of general applicability, thus not only targeting a pre-defined limited number of natural or legal persons. They are thus to be distinguished from decisions on individual cases. Decisions on individual cases are not dealt with in this handbook though they might, exceptionally, also have a regulatory effect, e.g. if they are

<sup>13</sup> See our terminology explained in Section 1.2.

published and thereby influence the behaviour of all operators.

(b) Regulatory measures other than regulation:

Once confronted with a new issue, those who are familiar with regulation tend to immediately think of new regulation as a solution. Alternatives to regulation are regarded as less valuable, though they might better serve the pursued goal(s). Due to this attitude, alternatives to regulation are quite often not examined.

Measures other than regulation can be subdivided into those dealing with information and others. The importance of information can hardly be overestimated. Information as such can influence behaviour, as we will see in some of the following examples. Even when we have fully-fledged regulation and enforcement thereof, information measures should be considered. Informing natural and legal persons of their obligations is cheaper than enforcement and sometimes even a precondition for enforcement. Here is a basic typology of measures other than regulation (as so far defined):

aa) Voluntary agreements / self-regulation / co-regulation<sup>14</sup>

Industry and other professional associations often claim that they are able to reach a certain political goal just by an agreement concluded on behalf of their members. Regarding the co-operation of social partners, voluntary agreements are common practice and work well in quite a few jurisdictions. However, in other regulatory sectors experiences are less positive. – The following means can trigger readiness to adopt voluntary agreements / self-regulation: (1) Letters to business associations, suggesting voluntary agreements / self-regulation and indicating that otherwise regulation will be adopted (2) public consultations or announcements indicating the readiness to adopt regulation. – An intermediate form of regulation is co-regulation. Co-regulation is a form of self-regulation with involvement of / validation by an authority. One specific form of co-regulation consists in making a self-regulatory agreement between social partners mandatory for all workers or for all workers who wish to apply the rules of the agreement. An example of the latter can be found in the Argentinian Decree 110/2014 of 29 January 2014 Homologación del Acta Acuerdo de la Comisión Negociadora del Convenio Colectivo de Trabajo General para la Administración Pública Nacional<sup>15</sup>.

bb) Voluntary labelling and marking

Labelling and marking can be introduced on a mandatory basis<sup>16</sup>. But they can also be introduced on a voluntary basis by a private initiative. E.g. some of the organic farming labels are based on initiatives of private associations. Labels can also be developed by a private-public partnership, e.g. based on a joint analysis of quality issues in a certain sector. As with many other alternatives to regulation, financing may help to initiate voluntary labelling and marking.

Both mandatory and voluntary labelling can be linked to incentives, e.g. with regard to public tenders<sup>17</sup>. In order to reach a high-standard voluntary labelling and marking, it is sometimes necessary to develop severe draft regulation.

cc) Naming, shaming, praising and rating mechanisms

Public rating creates an incentive for operators to perform better, even when the rating is made by a private institution (see e.g. [Euroncap](#)). Subject to the legal system, public rating undertaken by an authority may require a legal basis. Some types of ratings will hardly require a legal basis in any jurisdiction. E.g., authorities are normally free to rate chemicals according to their respective risk, and it can nonetheless have a strong regulating effect, steering away from certain products and favouring others (in the same way as specialised information systems do). We have seen under “incentives” that rewards can also constitute a behavioural incentive. Thus praising as a positive counter-part to shaming should not be neglected.

dd) Training measures for operators, professionals or citizens

Training for operators, professionals or even citizens can be cheaper and more effective than enforcement,

<sup>14</sup> Self-regulation is the regulation established by those to be regulated. Co-regulation is a variant of self-regulation in which the authority validates the result of the self-regulatory process.

<sup>15</sup> Official Journal of 4.2.2014.

<sup>16</sup> See e.g. [Regulation EC/106/2008](#) of 15 January 2008 on a Community energy-efficiency labelling programme for office equipment.

<sup>17</sup> See again [Regulation EC/106/2008](#) of 15 January 2008 on a Community energy-efficiency labelling programme for office equipment.

above all if the number of operators or professionals is rather limited and if the legal or technological setting is complicated. Training can be provided by authorities, by business associations, by other associations, by conformity assessment bodies or by independent service providers.

ee) Guidelines/interpretative documents

In some sectors, geographic entities, authorities and private actors apply guidance as if it were regulation. If this is the case, it is no longer always necessary to develop regulation which is cumbersome to adopt and to update.

ff) Supervision of geographic entities / authorities

Supervision of geographic entities or authorities can also help to reach policy goals. If the geographic entities or authorities interpret the legislation differently, the supervision can be used to enforce one of the possible interpretations. A supervision measure against one geographic entity or authority can be perceived as a warning by others. There can be a harmonisation effect. A supervision measure blaming understaffing can increase the degree to which the geographic entities / authorities or operators comply with legal obligations if the lack of compliance is due to insufficient resources on the part of the enforcement administrations.

gg) Empowering authorities

Empowering authorities can take place in different ways, e.g. by training, by defending the independence of the authorities and by engaging in favour of a sufficient staffing of the enforcement authorities, above all if they are influenced by politicians or by other administrations in the geographic entities. Authorities of geographic entities sometimes wait for the support of the central authority to defend their budgetary interests against the regional or local finance department. If the lack of staff at the regional or local level is the major system deficiency, such support measures by the Centre are of utmost importance.

hh) Administrative bench-marking

Administrative bench-marking is a tool by which administrations are compared to each other with regard to parameters or good practices. Manifold examples of administrative bench-marking can be found in the remit of the OECD.

ii) Coordination of geographic entities / authorities / conformity assessment bodies

Coordination of geographic entities, of authorities and of conformity assessment bodies can help to reach a harmonised interpretation of law, a harmonised and equally stringent administrative or decision-making practice, an increase of average knowledge, better verification techniques (e.g. to counter fraud), more exchange of data so as to avoid double verification by different geographic entities, different authorities, or different conformity assessment bodies. Coordination can happen by means of more or less advanced electronic tools (from emails through wikis to databases). The fewer tasks are centralised, the more coordination will be needed. However, coordination is also needed within big central authorities if different departments start developing their own practices and policies. The statement „different people have different views“ also applies to central authorities even if the people are only half a corridor apart. - Who is best placed to coordinate? The answer is to be given taking account of the concrete situation, once available human resources, impartiality, abilities and system oversight of the candidates have been analysed. Often the central administration or agency acting on behalf of the central administration is best placed to coordinate. Sometimes coordination is better ensured by one of the geographic entities or administrations to be coordinated, e.g. if specific knowledge is required and if that knowledge is only available in a particular geographic entity or administration. Sometimes coordination happens by open P2P processes. Very rarely, external service providers are used to ensure coordination.

jj) Declarations announcing a political or regulatory intention

These declarations can have an effect similar to regulations, though they are only intentions, not cast in law, and modifiable at any moment. An announcement stating that „in future public tenders, special attention will be paid to aspects of ...“ or a press release indicating that “market access will be more severely regulated with regard to criterion X“ will deter certain operators from investing and invite others to invest more, but on the basis of the anticipated future criteria. It goes without saying that the influencing effect will vanish if the institution or person making the declaration has lost its credibility. Reliability and trust is of the utmost importance. Declarations can be made publicly or in private towards representatives of the targeted persons or operators.

kk) Press releases (e.g. on risks linked to products, services or behaviours)

Press releases can provide information which influences behaviour of operators, of professionals or even of

citizens. Many governments launch alerts regarding products which are disseminated via the media. Some of these alerts, e.g. those of the U.S. agency [FDA](#), have repercussions worldwide.

#### ll) Classic awareness raising campaigns (e.g. regarding risks linked to products, services or behaviours)

If a consumer is informed by classic awareness raising campaigns about the risk linked to the use of a certain type of toy, he will probably not buy it anymore. Even a shopkeeper might stop ordering that type of toy. Coming to know about potentially unsafe, though not yet banned products or chemicals and their comparatively safe alternatives might make manufacturers move away from unsafe substances without any regulation obliging them to do so. Unlike regulation, awareness raising campaigns can also deter from using products or chemicals which are suspected to be harmful, but cannot yet be banned as some evidence is still missing. Equally, they can deter from using products or chemicals during the ban procedure. Classic awareness raising campaigns use the classic media like television, radio, and printed material disseminated by authorities, schools, trade unions, associations, NGOs etc. Classic awareness raising campaigns are nowadays deemed to be less efficient than internet campaigning, though internet campaigning does not reach certain parts of the population.

#### mm) Internet campaigning

The internet offers a large and ever expanding variety of tools to influence the behaviour of citizens and of operators. Besides classic websites and databases accessible online, authorities could, in theory, use short message services like Twitter. They could also proactively use social media to disseminate information that influences behaviour. They could share their views on fora and independent mailing lists. They could post comments here and there to draw attention to risks, legal requirements and indicators for non-compliance. Through all these tools they could also direct people to their domestic website which contains more solid and comprehensive information than what normally circulates via social media and the other tools mentioned thus far. However, subject to the legal system of the respective jurisdiction, there are legal constraints. Authorities might become liable for information that is not fully correct, not comprehensive or not totally fair. The legal benchmark for information activity of authorities might be very high. How can they circumvent the risk of liability? An elegant solution can consist of paying NGOs or media for undertaking information work. In many jurisdictions, NGOs and media have a lower liability risk as long as they act in good faith and in the boundaries of their mandate. But even in case of severe liability risks authorities should not necessarily shy away from alerting citizens or economic operators via the range of internet media listed. If the facts clearly indicate a high risk for persons, alerts are justified. In some jurisdictions there might even be a legal obligation to inform the public or operators of risks and non-compliances by all appropriate means, and this will include the internet media listed.

#### nn) Information systems

Information systems can be an excellent tool to influence the behaviour of certain target groups, be they professionals, operators, administrations or even citizens. See as an example [www.ecoi.net](http://www.ecoi.net) which has influenced the decision making of asylum and refugee administrations, judges and attorneys on four continents since 1999. If information is clearly presented and is of interest to the target groups to make use of it, information may have the same behaviour-influencing effect as a legal obligation. As information can be presented faster than legal measures can be adopted, the behaviour influencing effect can even occur earlier. More on information systems is to be found in Annex II.

#### oo) Financial instruments

Financial instruments can complement and partly replace regulatory tools. Accordingly, they should be integrated into the regulatory picture for a certain sector<sup>18</sup>.

### 2.3.4.2 Comparing the measures

To compare the various potential measures, it is useful to assess the measures according to a variety of criteria which should include at least the following:

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<sup>18</sup> Financial instruments have, on purpose, not been integrated into this handbook. They constitute a field on their own and are very much subject to jurisdiction specific rules.

	Measure 1	Measure 2	Measure 3	Measure 4	Measure 5	Measure 6	Measure 7	Measure 8
Months needed to generate effects								
Longevity of effects								
Degree of binding effect								
Flexibility for adaptation								
Short term resources needed (launch)								
Medium term resources needed (implementation)								
Long term resources needed (maintenance)								
Type and availability of human resources needed								
Best to be used for								



The following chart indicates how some measures available in a certain nation state could be assessed:

	Legislation	Regulatory acts	Self-regulation	Supervision of geographic entities	Guidance documents	Information services / awareness raising campaigns	Voluntary labelling and marking	Press releases and alerts
Months needed to generate effects	12 to 48	6 to 24	12 to 36	3 to 24	3 to 24	6 to 18	12 to 36	1
Longevity of effects	very long	very long	medium	short to medium	short to medium	Medium	long	short
Degree of binding effect	high	high	low to medium	high	low to medium	Low	low	low
Flexibility for adaptation	low	medium	medium	low	high	High	medium	high
Short term resources needed (launch)	high	medium to high	low	medium	low to medium	medium	low to medium	low
Medium term resources needed (implementation)	medium to high	medium	low	medium	low	medium	low	low
Long term resources needed (maintenance)	medium	medium	low	low	low	low	low	low
Type of human resources needed	subject matter specialists lawyers negotiator	subject matter specialists lawyers negotiator	subject matter specialists negotiator	lawyers	subject matter specialists	subject matter specialists communication experts	subject matter specialists negotiators	communication experts
Best to be used for	setting a long-lasting legal framework	creating binding rules	setting binding targets whilst keeping the ways open	if reality lags behind a good legal standard	for legal interpretation or if guidance is followed as if it was law	fast evolving, complex information that can influence behaviour immediately	situations in which the public application of stable criteria influence operators	provoking ad hoc action of autonomous decision makers

The resource needs depend very much on the concrete measure.

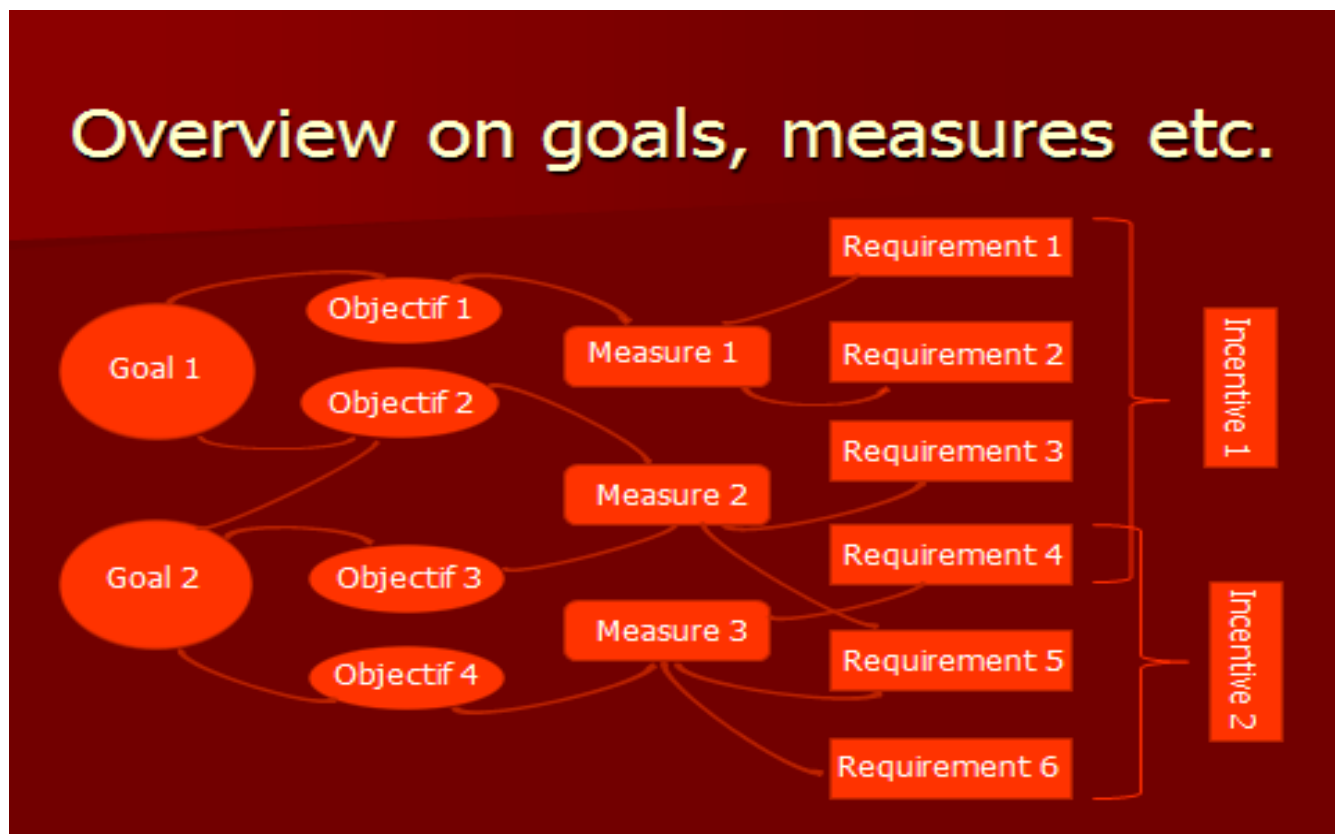
#### 2.3.4.3 Selecting the right measures

In addition to the aspects listed under 2.3.4.2, what are the aspects that might or should influence the selection of measures? The measures taken should evidently not overstretch the available budget, one's own management or administrative capacity, or the enforcement capacities of geographic entities or administrations. If these aspects set limits, it is advisable to select the measures which are most cost-efficiently or capacity-efficiently pursuing the goals. Of course, the measures should not either overstretch the adaptation capacity of those who will be targeted by the measures and should not constitute a disproportionate burden for them. Finally, the selection of measures will have to respond to political needs such as acceptability by lobby-groups, decision making organs or committees and the wishes of politicians or of the heads of the administration.

## 2.4. Keeping the oversight on goals, objectives, measures, requirements and incentives

We have seen, by the sheer number of parameters presented in so far, how complex decision-making can be. We will see throughout the handbook how so many more different aspects have to be taken into account content-wise and how they are interlinked. How can one maintain oversight and perspective?

One way to maintain oversight and perspective is to write the different goals, objectives, measures, requirements and incentives on cards and to pin the cards on a wall, board or big sheet of paper. Goals would be placed on the left, objectives on the medium left, measures in the middle, requirements on the medium right and incentives on the right<sup>19</sup>. All five should be linked by lines or arrows going from left to right or right to left to express relationships and impacts. Accordingly, the best vertical arrangement is the one with the least crossing of lines. The least crossing of lines can often best be achieved if similar goals are close to each other, if similar objectives are also close to each other etc. A similar picture can of course also be developed electronically. The downside of the method is: one needs a lot of space. The major advantage is the visual impression.



<sup>19</sup> It is possible to extend the graph even further so as to include information and enforcement tools. These tools will be dealt with in Section 7.1.

Another, more classic way consists of numbering and listing the different goals, objectives, measures, requirements and incentives in separate charts and indicating how they are linked:

#### The chart of goals

Goal No	Goal title / description	Rationale / remark	Concretised by objective(s)	Leading to measure(s)
G1			e.g. O1, O2	e.g. M1, M3, M4
G2				
G3				
G4				
G5				
G6				

#### The chart of objectives

Objective No	Objective title / description	Rationale / remark	Serving goals	Leading to measure(s)	Applying requirement(s)
O1			e.g. G3	e.g. M5, M6	e.g. R2, R5, R6
O2					
O3					
O4					
O5					
O6					

**The chart of measures**

Measure No	Measure title / description	Rationale / remark	Serving goals	Serving objective(s)	Applying requirement(s)
M1			e.g. G3	e.g. O5, O6	e.g. R2, R5, R6
M2					
M3					
M4					
M5					
M6					

For all charts presented so far: Subject to whether objectives are used or not in the planning process of the respective jurisdiction, the column on objectives can be skipped or deleted.

**The chart of requirements**

Requirement No	Requirement title / description	Rationale / remark	Set up in measure	Applying incentive(s) (describe e.g. based on following typology)
R1			e.g. M3	
R2				
R3				
R4				
R5				
R6				

### The chart of incentives

Incentive No	Incentive title / description	Rationale / remark	Used in measure(s)	Used in conjunction with requirement(s)
I1			e.g. M3	
I2				
I3				
I4				
I5				
I6				

## 2.5. Finding the right regulatory process

To the knowledge of the author, there is not yet a commonly recognised process for regulating. The author cannot validly establish a method either. However, he can describe what happens in practice once the political goals have been set or identified and once the sector has been analysed (2.5.1). Based on the description, we will identify a range of approaches with regard to different parameters (2.5.2).

### 2.5.1. Description of regulatory processes

Regulatory processes can focus on major issues (problems and potentials) or on dealing with all issues.

They can be run „top-down“ (by deduction) or „bottom-up“ (by induction) in terms of their content. The „top-down“-approach consists in determining the abstract political goals first, then more concrete objectives. From the objectives individual measures and particular requirements in the measures can be deduced. The „top-down“-approach is often followed when there are pre-determined political goals. But even when there are predetermined political goals, there can be some openness to arguments derived from the sector analysis. There can also be openness as to the fine-tuning of the political goals. All this very much depends on the political context and leadership of the administration. Only very rarely are regulatory processes run 100% top-down.

A process without predetermined political goals is more likely to follow the opposite inductive method „bottom-up“. It consists in identifying what could be required to improve the sector (e.g. based on the sector analysis and examples of other jurisdictions and examples of other sectors of the same jurisdiction). The attribution of the requirements to various measures comes next. Therefrom officials can deduce the political goals, with or without passing by the intermediate step of „objectives“. The political goals and measures are thereafter offered to the persons politically responsible for decision-making.

The regulatory process can be more or less driven by political considerations. To give an example of a political consideration: politically responsible persons sometimes prefer to take ineffective measures rather than no measures simply to give the impression that „something is being done about the problem“. This happens in the field of security policy<sup>20</sup>. Politicians must care about the feeling of insecurity because this constitutes a political risk. They tend to be in favour of visible measures even if the security specialists are of the view that security is not improved by the measure, e.g. because the measures can be easily circumvented. This attitude of politicians is legitimate – they have to care about the political risks as well as the actual risks. The sector specialists have

<sup>20</sup> See Fiona HAINES, *The Paradox of Regulation*, Edward Elgar Publishing, Cheltenham (UK) 2012.

naturally the actual risks in mind. Political considerations come second.

The regulatory processes can be open to options or be directed towards a predetermined result (which can either be political or not). The more they are open to options, the higher the likelihood that the processes overstretch the working and processing capacities of those involved. In case of complex issues or in cases in which a high number of issues need to be dealt with, the intellectual and psychological absorption capacity of those involved also plays a role. Above all, in comprehensive legislative projects the participants sometimes cannot bear more complication or options and therefore agree to proposals without checking alternatives or additions. The capacity limitations of the persons involved can become the decisive factor in the outcome of a process, above all if there was not wise budgeting of the capacities at the beginning of the process.

Very often both the decision on the measure(s) to be taken and the content of the measure(s) are influenced by one single example of the past, of other sectors or even of other jurisdictions. This might lead to a biased approach unless one strives for a broader comparison of the measures and requirements of different sectors or even of different jurisdictions.

Regulatory processes can be fast or slow and thus more reflective. Most regulatory processes accelerate. But some processes accelerate fast, some slowly.

Regulatory processes can have one single track, one single track with various (auxiliary) sub-tracks or several tracks that go their own way<sup>21</sup>. A single-track approach facilitates the overview of all representatives on what is going on. A multi-track approach can speed up the overall process. But it can also lead to mismatches, frictions and duplication. The single-track approach combined with sub-tracks seems to be the best intermediate solution, but it can also lead to duplication. What has been stated by a group of delegates in charge of a sub-track is often questioned by the delegates of the main track. Discussions may start again.

Regulatory processes can have more or less cross-references, e.g. amongst different tracks, or loop-backs (sometimes this is useless duplication, but sometimes it is necessary for adjustment).

Regulatory processes can be more or less influenced by requirements for impact assessments or planning instruments used in the administration.

The regulatory processes can be more or less open for stakeholders and be more or less participatory, meaning open to contribution based on equality of all participants. For these aspects of regulatory work, see Section 10.1.

Finally, regulatory processes can be based on electronic working tools like wikis or be prepared in classic ways.

### 2.5.2. Developing a tailor-made regulatory process

The various parameters can be listed in a chart. By marking crosses between the extremes, readers can determine in advance how their regulatory process should look. They thus develop their own tailor-made regulatory process. Readers can also use the chart during the process to benchmark the reality of the process against the planned process.

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<sup>21</sup> In the extreme case, the separate tracks have additional sub-tracks.



## PART B: Applicable to regulation only

### 2.6. Selection of the legal basis

The “legal basis” is the provision which empowers to adopt regulation. The legal basis is therefore also referred to as the “empowerment”.

Once the regulators have identified the goals they wish to achieve for their sector and once they decide that new regulation is needed, the regulators need to find an appropriate legal basis. There is a bilateral relationship between the goals and the legal basis. The legal basis determines what can be done with the legal act and which goals can be lawfully pursued. Example: If the legal basis says “In order to achieve a high level of safety, the authority may ...”, the authority may not pursue the goal of environmental protection. The legal basis determines what content can be placed in a measure. Sometimes the legal basis also determines the level of detail, the type of regulation to be adopted, or, in an international context, the harmonisation approach to be chosen.

### 2.7. Types of scope

We use the following definition: “The subject matter is what the act deals with, whilst scope refers to the categories of situations of fact or of law and the persons to which the act applies.” Let us read some examples of scopes. Scopes can be simple (like the first one) or complex (like the last) or in-between (2<sup>nd</sup> and 3<sup>rd</sup>).

Commission Regulation [EC/642/2009](#) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for televisions:

*“Article 1 - Subject matter and scope:*

*This Regulation establishes ecodesign requirements for the placing on the market of televisions.”*

The [Philippine “Lemon Law” on the protection of consumers buying motor vehicles](#)<sup>22</sup>:

*“SEC. 4. Coverage. – This Act shall cover brand new motor vehicles purchased in the Philippines reported by a consumer to be in nonconformity with the vehicle’s manufacturer or distributor’s standards or specifications within twelve (12) months from the date of original delivery to the consumer, or up to twenty thousand (20,000) kilometers of operation after such delivery, whichever comes first. The following causes of nonconformity shall be excluded:*

- (a) Noncompliance by the consumer of the obligations under the warranty;*
- (b) Modifications not authorized by the manufacturer, distributor, authorized dealer or retailer;*
- (c) Abuse or neglect of the brand new motor vehicle; and*
- (d) Damage to the vehicle due to accident or force majeure.”*

The Senegalese Law No. 2014-01 of January 6, 2014 relating to the treatment of dormant accounts in the books of financial institutions of the Member States of the West African Monetary Union (WAMU):

*Art. 2. - La présente loi a pour objet de fixer les règles applicables aux comptes dormants détenus dans les livres des organismes financiers des Etats membres de l’UMOA, tels que définis à l’article premier ci-dessus.*

*Ne sont pas visés par la présente loi :*

- le compte qui n’a subi aucune intervention de la part de son titulaire depuis au moins dix (10) ans, lorsque celui-ci a effectué, pendant cette période, une intervention sur les autres comptes qu’il détient dans les livres du même organisme financier ou a eu un contact avec ledit organisme ;*
- le compte soumis à une surveillance particulière du fait d’une décision de justice ou de l’administration ;*
- les dépôts à terme sur la période contractuelle de dix (10) ans ou plus.*

*Amended machine translation:*

*Art. 2 -. This Act aims to establish the rules for dormant accounts in the books of financial institutions of member states of WAMU, as defined in Article 1 above.*

*Not covered by this law:*

- The account that has not undergone any intervention on the part of the holder for at least ten (10) years, when he has performed, during this period, an intervention on other accounts held in the books of same financial institution or has had contact with said body;*

<sup>22</sup> Republic Act No. 10642, published on [July 15, 2014](#).



- The account subject to particular scrutiny because of a court or administration decision;
- Term deposits over the contractual period of ten (10) years or more.

Regulation EC/1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006:

*“Article 1: Purpose and scope*

*1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles as referred to in Article 4(8) by:*

*(a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;*

*(b) providing an obligation for:*

*(i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market;*

*(ii) suppliers to label and package substances and mixtures placed on the market;*

*(iii) manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006;*

*(c) providing an obligation for manufacturers and importers of substances to notify the Agency of such classifications and label elements if these have not been submitted to the Agency as part of a registration under Regulation (EC) No 1907/2006;*

*(d) establishing a list of substances with their harmonised classifications and labelling elements at Community level in Part 3 of Annex VI;*

*(e) establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements referred to in points (c) and (d).*

*2. This Regulation shall not apply to the following:*

*(a) radioactive substances and mixtures within the scope of Council Directive 96/29/Euratom ...”*

The last example demonstrates that it is possible to express the purpose together with the scope in one single article. But there is a downside of this approach: the content of the articles following the scope article is partly reflected in the scope article. This makes it quite long. Furthermore, it is necessary to check whether an extensive scope like this one is fully in line with the subsequent, more detailed articles. To avoid misinterpretation, an extensive scope needs to be checked for compatibility with the articles.

Scopes can comprise personal, geographic, temporal, legal, situational, process or activity related elements.

With regard to the persons, various additional criteria can be applied:

- nationality,
- origin,
- residence (legal presence),
- physical presence,
- economic and other functions.

In terms of geography, scopes can relate to activities or situations which take place:

- inside the jurisdiction: all activities or situations (covered by the subject matter) within the respective jurisdiction;
- outside the jurisdiction: activities or situations that involve persons or objects outside of the territory of the jurisdiction;
- inside *or* outside the jurisdiction: activities or situations that involve persons or objects either inside or outside of the territory of the jurisdiction;
- inside *and* outside the jurisdiction (cross-border): activities or situations that involve persons or objects being both inside and outside of the territory of the jurisdiction.

We thus have a multi-dimensional structure in which many combinations are possible – too many to be displayed here. It is preferable to start the process of scope determination with a first draft combining the most evident elements of the three dimensions. In a second step, extensions and restrictions to the provisional scope should be examined until the scope seems to be optimised. The listed terms can be used to make sure that all parameters are consciously decided upon.

Whatever scope is chosen, it should not be defined with reference to subjective or changing conditions. Clauses like “as defined by the manufacturer” or “in accordance with regional law” trigger disputes on the right interpretation and an unequal application.

Regulation can explicitly foresee its extra-territorial application. See e.g. the new Section 2B of the Air Navigation

Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#):

*“Extra-territorial application of Act  
2B.*

—(1) Except as otherwise expressly provided by sections 2D and 2E, this Part and Part II also extend to —

- (a) every foreign registered aircraft specified in any 83 bis agreement that has the effect of transferring functions or duties to Singapore;
- (b) every Singapore registered aircraft outside Singapore, subject to any 83 bis agreement that has the effect of transferring functions or duties to another Contracting State;
- (c) every holder of an aviation safety instrument while outside Singapore and exercising or purporting to exercise privileges accorded by that instrument;
- (d) every person in, or any of the crew of, any Singapore registered aircraft or aircraft operated by a Singapore operator, wherever they may be, in so far as this Act prohibits, requires or regulates the doing of anything by such persons in, or by any of the crew of, Singapore registered aircraft or aircraft operated by a Singapore operator; and
- (e) every other person wherever they may be, in so far as any provision of this Act prohibits, requires or regulates the doing of anything in relation to any Singapore registered aircraft or aircraft operated by a Singapore operator, by such other persons.”

Regulation should sometimes exempt the military, police or customs or the government, e.g. the new Section 2D of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#) in which „state aircraft“ is defined as an aircraft of the military, the police or the customs:

*“2D. This Act, with the exception of Part IIA and the provisions of any aviation safety subsidiary legislation shall not apply to any state aircraft or navigation by state aircraft; and shall not limit the privileges or immunities of any foreign state aircraft and the officers and crew of any foreign state aircraft.”*

It can make sense to clarify explicitly whether certain aspects are part of the scope or not. See the 2<sup>nd</sup>, the 3<sup>rd</sup> and the last example from this Section. See furthermore the [Status of Children \(Assisted Reproduction Technology\) Act 2013 of Singapore](#) which clarifies, in its Section 3 Subsections (4), (5) and (6), various collateral aspects of applicability:

*„(4) This Act shall not apply to a child to the extent that the child is treated by virtue of adoption as not being the child of any person other than the adopter or adopters.  
(5) The application of this Act shall not by itself affect the citizenship of a child.  
(6) For the avoidance of doubt, nothing in this Act shall affect any right or remedy that a person may have against any other person in relation to a fertilisation procedure which resulted in the birth of a child.“*

The [Status of Children \(Assisted Reproduction Technology\) Act 2013 of Singapore](#) contains, in its Section 3 Subsection (2), legal presumption as part of the scope with a view to ensuring the applicability of an act:

*„(2) For the purposes of this Act, a citizen of Singapore shall be presumed to be domiciled in Singapore, unless the contrary is proved.“*

In other parts, the act turns out to be a masterpiece for the intelligent use of rebuttable and non-rebuttable presumptions, including rules on priorities in case of conflicting presumptions (the purpose being to avoid double-parenthood).

The case of reference to or integration of other regulation has to be distinguished from simple statements on the applicability / non-applicability of other regulation; see Section 9.4.

## 2.8. Subject matter and purpose

In addition to the various scopes, regulation sometimes contains a description of its content. This description is sometimes also called "scope", but the term "subject matter" is more frequently used. See as example Article 1 of Regulation [EC/479/2008](#) of 29 April 2008 on the common organisation of the market in wine ...:

*“1. This Regulation lays down specific rules applying to the production and marketing of the products referred to in part XII of Annex I to Regulation (EC) No 1234/2007.  
2. As regards the products referred to in paragraph 1, this Regulation provides for:  
(a) support measures;  
(b) regulatory measures;  
(c) rules on trade with third countries;  
(d) rules governing production potential.”*

This extract is followed by definitions of the scopes for each letter (a-d).

To indicate the subject matter, as in paragraph 2, helps the reader to know what the regulation is about. It can also limit the potential legal effect of detailed prescriptions contained in the regulation to those items mentioned in the scope.

However, drafting a subject matter is risky. The risk is twofold:

- It happens that the regulation, via its subject matter, pretends to completely regulate a certain area whilst not doing so in reality. The over-broad subject matter creates a kind of void where there are no legal provisions whereas, to judge from the subject matter, there should be some. This creates legal uncertainty.
- It happens that a regulation covers a wider area than the one indicated in the subject matter.

Given the two opposite risks, the utmost care must be applied when drafting the subject matter at the very beginning of the process. A second verification should take place at the end of the negotiation process: Is the content of the final draft of the legislative measure still correctly covered by the subject matter and vice versa? In the regulatory process amendments might have been introduced that require a modification of the subject matter.

The two risks referred to above also extend to the scope. Accordingly, the verification exercise recommended for the subject matter should also take place with regard to the scope: the content of the act may have been modified in the regulatory process so that the scope also needs to be revised.

The risk of inconsistencies is not as high if the purpose(s) of the regulation is indicated at the beginning of the regulation. Above all in jurisdictions influenced by the U.S. we can find, in the main part of regulation, a paragraph on the purpose(s). See for example the [Graphic Health Warnings Law of the Philippines](#)<sup>23</sup>:

*"SEC. 3. Purposes. – The purposes of this Act are:*

*(a) to have Graphic Health Warnings that effectively warn of the devastating effects of tobacco use and exposure to second hand smoke;*

*(b) to remove misleading or deceptive numbers or descriptors like "low tar", "light", "ultra lights" or "mild" which convey or tend to convey that a product or variant is healthier, less harmful or safer; and*

*(c) to further promote the right to health and information of the people."*

## 2.9. Overlapping with other regulation

To establish a scope that overlaps with the scope of other regulation is not desirable. Such an overlap is often unnecessary or even involuntary. If new regulation partly overlaps with existing regulation, this may have negative effects in terms of legal uncertainty as well as double procedures. The key to avoiding involuntary double coverage is the precise analysis of the scopes, the subject matter and of the risks covered (for the latter: see Section 3.1). Very exceptionally, however, an overlap is unavoidable, e.g. if the regulator wishes to cover, in new regulation, a slightly different aspect than the one covered by the existing regulation.

It is not always easy to fit a new piece of regulation into a regulatory landscape. [Directive 2004/108/EC](#) on electromagnetic compatibility gives a good example of how this can be done without creating overlaps:

*"4. Where, for the equipment referred to in paragraph 1, the essential requirements referred to in Annex I are wholly or partly laid down more specifically by other Community directives, this Directive shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of implementation of those directives.*

*This Directive shall not affect the application of Community or national legislation regulating the safety of equipment."*

## 2.10. Referring to or integrating other regulation

Regulation can declare other regulation to be applicable. If the other regulation is already applicable by itself, the declaration is just confirmatory. If it is not, the declaration constitutes the applicability. A declaration of

<sup>23</sup> Republic Act No. 10643, published on [July 15, 2014](#).

applicability can be partly confirmatory and partly constitutive. Again, see as an example [Regulation EC/479/2008](#) of 29 April 2008 on the common organisation of the market in wine ...:

*"Article 58 - Applicability of horizontal rules*

*Save as otherwise provided for in this Regulation, Directive 89/104/EEC, Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs (1), Directive 2000/13/EC and Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products (2) shall apply to the labelling and presentation of products falling within their scopes."*

Regulation can also integrate substantial or procedural requirements of a pre-existing regulation by referring to it, whether the pre-existing regulation is applicable by itself or not. Once the reference is made, the pre-existing regulation might still be applicable by itself. This means that pre-existing and new regulation might be applicable in parallel. The parallel applicability is not necessarily superfluous. For instance the requirements of the pre-existing regulation might be looked at under a slightly different angle. The additional applicability by reference can also be meaningful if the act referred to is about to be repealed. However, it is usually better to avoid the parallel application of pre-existing and new regulation if they deal with the same requirements.

The [Argentinian Law 26.906 of 13 November 2013 on the Rules on Traceability and Verification of Technical Abilities of Used Active Medical Devices](#)<sup>24</sup> contains, in its Article 5, an explicit dynamic reference to future ordinances (*"... o la que en un futuro se dicte."*). As elegant as this might seem at first sight, such explicit references may raise legal questions for other parts of the same act: lawyers may argue that as there is no such explicit dynamic reference in other parts, future ordinances shall not be applied.

## 2.11. Harmonisation approaches

Harmonisation approaches are hereafter explained for the international context, such as UN conventions, and for conglomerates of nation states such as the EU. However, the harmonisation approaches can also be used within Federal States. The following list of harmonisation approaches is not deemed to be complete. In addition, there are many variants. The harmonisation approaches can be combined in many ways.

### 2.11.1. Notification procedures

Notification procedures give other jurisdictions the possibility of scrutinizing the national measure envisaged or taken. One famous example of this procedure is the notification obligation for new technical regulation under the WTO Technical Barriers to Trade (TBT) Agreement.

The advantage of notification procedures is that no substantial harmonisation is needed, but that a certain harmonisation effect can still be observed as soon as some kind of scrutiny criteria are set up. The disadvantage is that the supervision of these notifications is very work-intensive. Furthermore, without any kind of scrutiny criteria the supervision is meaningless.

Despite their weakness, notification procedures can be regarded as a first step towards harmonisation. Therefore it is useful to think of them as part of the harmonisation toolbox.

### 2.11.2. Mutual recognition of decisions

This harmonisation principle sets out that decisions of other jurisdictions are recognised as being equivalent to domestic decisions. As an example, see Chapter IV of the [UNECE Convention on Road Traffic](#) which provides, under certain conditions, for the recognition of driving licences.

Mutual acceptance creates a common legal space without cumbersome or impossible harmonisation. The major disadvantage is the frequency of disputes on the precise interpretation.

The mutual recognition can be made subject to an administrative condition such as the translation of the respective document.

<sup>24</sup> „Régimen de Trazabilidad y Verificación de Aptitud Técnica de los Productos Médicos Activos de Salud en Uso“.

Mutual recognition can also be made subject to conditions to be fulfilled by contracting parties (in the international context) or by geographic entities. If this is done, the mutual recognition integrates optional harmonisation (see just below). The Economic Community of West-African States (ECOWAS) Regulation C/REG.4/05/2008 of 18 May 2008 on the harmonization of rules governing quality control, certification and marketing of vegetable seeds and seedlings in the ECOWAS Space provides for an example of such a construction:

*„Article 5. - Principe de libre circulation des semences*

*Afin de contribuer à l'organisation du marché commun prévu par la politique agricole de la Communauté, les semences circulent librement sur le territoire des Etats membres dès lors qu'elles sont conformes aux normes de qualité en vigueur dans la CEDEAO.*

*Article 6. - Principe de reconnaissance mutuelle et d'équivalence*

*1. Les Etats membres mettent en oeuvre le principe de reconnaissance mutuelle des certifications fondées sur des prescriptions techniques et normes communautaires en matière de semences végétales ainsi que des procédures de contrôle et d'homologation en vigueur dans la CEDEAO, en les reconnaissant comme équivalentes.*

*2. Chaque Etat membre accepte sur son territoire les semences conformes aux normes techniques adoptées par un autre Etat membre.“*

*Amended machine translation<sup>25</sup>:*

*“Article 5 -. Principle of free movement of seeds*

*To contribute to the organization of the common market under the agricultural policy of the Community, seeds circulate freely within the territory of the Member States if they comply with quality standards in force in ECOWAS.*

*Article 6 -. Principle of mutual recognition and equivalence*

*1. Member States implement the principle of mutual recognition of certificates which are based on technical requirements and community standards for plants and seeds and on control procedures and approvals in force in ECOWAS, by recognizing the certificates as equivalent.*

*2. Each Member State accepts on its territory seed complying with technical standards adopted by another Member State.”*

### 2.11.3. Optional harmonisation

Optional harmonisation obliges jurisdictions to legislate in a certain way, but allows them to set up or to maintain alternative requirements in parallel. This type of harmonisation legislation could be observed in the field of product safety legislation, e.g. in UNECE Regulations on wheeled vehicles under the [Agreement concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles](#)<sup>26</sup> of 1958. Contracting parties of the so-called 1958 Agreement are obliged to accept on their market cars that fulfil certain requirements and their regulation must be constructed accordingly. But they are free to admit cars based on another set of national requirements.

The advantage of optional harmonisation is that the free circulation of products or services can be ensured relatively easily even if full harmonisation cannot be reached. The disadvantages are twofold. Obviously, regulation based on the principle of optional harmonisation does not fix a minimum level of stringency. Therefore, it cannot ensure a minimum level of environmental, consumer, health or workers' protection. Instead such regulation sets a stringency ceiling for jurisdictions: manufacturers can always refer to the content of the optionally applicable (UNECE or other optional harmonisation) law as an alternative to more stringent national law, if it exists. Furthermore, a lower level of protection in some jurisdictions, authorised by optional harmonisation, can have negative overspill effects on other jurisdictions. E.g. emissions in one jurisdiction may affect the territory of other jurisdictions, and products fulfilling only the low level requirements of one jurisdiction might be sold as used / 2<sup>nd</sup> hand products to other jurisdictions which have a higher level protection. Despite these disadvantages, optional harmonisation has a role to play if more ambitious forms of harmonisation cannot (yet) be achieved.

Optional harmonisation will thus always play an important role in the framework of international harmonisation if the discrepancies between jurisdictions are large. Combining the highest standards of the jurisdictions can provide for mutual recognition of product or service authorisation or certificates whilst increasing the average quality of these products and services. The reason for this positive effect is that economic operators strive for big scale and uniform production. They also have marketing advantages when fulfilling “the top world standard” for a

<sup>25</sup> Unfortunately, we only found the French version of this regulation via the Official Journal of Senegal. Therefore, we had to translate the French version although an English original is extremely likely to exist as well.

<sup>26</sup> The Agreement itself is to be found in the second row of that webpage (follow the link there).

certain product or service. Therefore they sometimes fulfil “the top world standard” though they are legally not obliged to do so.

#### 2.11.4. Minimum harmonisation

Minimum harmonisation obliges jurisdictions to take certain measures, but gives them leeway to take more stringent measures. There is no specific advantage only of going for minimum harmonisation. It is better than nothing, and sometimes the only achievable harmonisation – especially if jurisdictions have very different levels of stringency.

The major disadvantage is that it sets only a ground, minimum level. To allow jurisdictions to maintain or to introduce a higher level of stringency can lead to friction with other jurisdictions.

#### 2.11.5. Total harmonisation

Total harmonisation establishes all requirements within the given scope. It gives jurisdictions no leeway upwards or downwards.

The advantage of total harmonisation is that free circulation of products and services amongst the jurisdictions is ensured and that the same level of protection or performance is also ensured, to the benefit of the users, consumers etc. The disadvantage of total harmonisation is that it is rarely possible to take local conditions into account. Jurisdictions wishing to protect their citizens by more stringent criteria are hampered in doing so. Sometimes, they try to bypass the international legislation by regulating side-aspects. This triggers cumbersome negotiations on the lawfulness of these national regulations.

### 2.12. Density of regulation

Evidently, regulation can go more or less into detail. The less it goes into detail, the more room it leaves for implementing or complementing measures of geographic entities and for legal interpretation. These advantages are to be weighed against more legal uncertainty and the risk of an uneven playing field for operators. Detailed law is not always preferable. It very much depends on the concrete circumstances. It is often preferable not to regulate on details, especially if the regulatory topic is influenced by technological progress or similar fast modifications,. In these cases, it is more practical to just set the general principles at legislative level and leave it to regulatory acts, to standardisation or to informal guidance documents to fill in the gaps and to provide for updates thereof. In some cases, it can even be preferable to have a three- or even four-level-approach: legislation for the basic principles, regulatory acts for the 1<sup>st</sup> level of concretisation and standardisation and/or guidelines for the further concretisation.

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### 3. Risks and performances

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*There is good government when those who are near are made happy, and when those who are afar are attracted.*

Confucius

Much regulation tries to limit risks emerging in certain situations of life, be they linked to activities or to objects. Often, this regulation also tries to fix performance requirements. Dealing with risks and performances is key in some sectors, but not necessary in many others. If risks and performances are not of relevance to them, readers are invited to skip this chapter.

We have seen in Section 2.3.2 how requirements are constructed and what they may contain. In Chapter 3 we examine more thoroughly certain substantive elements of requirements. We focus in this Chapter on risks and performance requirements and issues connected thereto. We also deal with the selection of measures if different risks are at stake.

Some parts of this Chapter refer to mathematics which is, admittedly, slightly unusual in a law-making context. Risks and performance requirements can be described in a very precise way in mathematical terms. Sometimes mathematics is even the only way to express them appropriately. The use of mathematics in this chapter is not intended to endorse the use of quantification in all situations. The purpose is simply to improve the understanding of quantitative expressions and correlations.

#### 3.1. Responding to various types of risks

There is a double reflection to be made with regard to the integration of different risks:

- Which risks shall be covered by the regulation? This question should be dealt with in the same way as the determination of the scope: by a precise analysis of what should be covered and by double-checking that readers interpret the description of the covered risks in the same way. Special care must be taken with abstract terms like “safety”.
- How shall the covered risks be balanced against one another if one risk can only be reduced at the expense of another?

The question of which risks shall be covered can be linked to the issue of integration of other regulation (see also Sections 2.9. and 2.10). Regulators can decide:

- a) to only cover risks that are not covered by other regulation;
- b) to cover also the risks that are covered by other regulation and to make the other regulation non-applicable;
- c) to keep the other regulation applicable, but complement it, e.g. by requirements which are more targeted for the specific scope.

It is useful to list all the risks that might appear to be covered and to verify whether these risks are really fully covered or more appropriately dealt with in other legislation or regulatory measures. In case of doubt, the solution c) should be favoured.

Inappropriate risk coverage can evidently be observed with regard to horizontal legislation (e.g. on chemicals or the environment). Horizontal regulation is hardly ever as fine-tuned to cover risks in a tailor-made way. It can also exist in relation to vertical legislation. E.g. it happens that legislation on one big product group only incompletely covers certain risks which are specific to certain types of products falling into the group.

### 3.2. Full safety principle or other fixed risk limits

We return to what regulators can require in their regulation. Regulators can try to fix a limit of acceptable risk. E.g., the legislator can request to reduce the risk:

- as much as possible, or
- as much as reasonably possible which implies an economic consideration: disproportionate efforts to reduce the risk are not needed<sup>27</sup>, or
- to zero (full-safety principle).

For products that have no other use or utility than entertainment or providing fun the full-safety principle can be applied (e.g. for toys). However, some people question whether there can ever be “zero risk”.

Though it is not always possible to reach full safety, the idea of full safety should be kept for certain products and services. Especially if the potential damage is high (e.g. for bungee ropes), it might be a wise legislative decision to require full safety. If the full safety cannot be ensured for bungee ropes, bungee ropes should not be placed on the market. A manufacturer who is not able to ensure full safety should not place bungee ropes on the market. Views are different if goods or services imply a certain risk, but are still seen as an expression of one’s personality. Piercing and tattooing are to some extent risky, but free societies would not like to ban them.

In theory, it might be possible to fix a quantified risk limit. E.g. it would be possible to require that a certain hazard does not become reality in more than one out of 1000 or one out of 1000000 cases.

### 3.3. Risk-benefit analysis

There is an alternative to the full-safety principle. It is called risk-benefit analysis. The risk-benefit analysis requires comparing the benefit with the risks. More precisely, the benefit is weighed against an individual risk or the sum of the risks (all types of risks combined). A risk can be defined as the hazard (damage) multiplied by the likelihood of the hazard becoming a reality.

A benefit is evidently difficult to state if a product or service only provides for well-being, fun or pleasure. Accordingly, the risk-benefit principle is so far not applied to products that only provide for well-being, fun or pleasure<sup>28</sup>.

The risk-benefit principle is often regarded and applied as a rough assessment without a proper methodology, examination points etc. However, it is possible to develop a precise risk-benefit assessment methodology. As an example, see the guidance developed by the US Food and Drug Administration: “[Making Benefit-Risk Determinations in Medical Device Premarket Review](#)”. This guidance contains elements which could be transposed into other sectors’ guidance or even regulation.

### 3.4. Basic risk management obligations of operators

What kind of risk management obligations should regulation impose on operators? It might help to have a look at international standards. On average, international standards clearly spell out what an operator needs to do:

- Risk identification,
- Risk evaluation,
- Risk avoidance, e.g. by inherently safe design, manufacturing and service providing,
- Risk reduction / mitigation,

<sup>27</sup> The so-called ALARP principle is frequently used in standards, sometimes in contradiction with the legal requirements. ALARP stands for “as low as reasonably possible”.

<sup>28</sup> This might change in the future. Improving the subjective well-being correlates with the reduction of pain on the other side of the scale. Therefore, there is no obstacle to the application of the risk-benefit analysis. It is thus a political question whether positive feelings shall be regarded as benefit.



- Providing information on the residual risk,
- Instructing customers on how to minimise residual risk.

Risk management obligations for operators in regulation should follow this simple logic sequence. It is thus useful for regulators to check what has been done in the parallel world of standardization. At the same time, an automatic incorporation of the sets of obligations contained in the standards should be avoided. Industry and other lobbyists try to push for such incorporation. However, a simple incorporation can be against the common interest: the standards do not necessarily cover all risk aspects. Furthermore, they can contain deficiencies that should not be incorporated. E.g. industry often lobbies for rather limited risk reduction obligations, namely for the so-called ALARP concept (risk reduction as low as reasonably possible) which includes economic aspects. International standards also tend to give operators a discretionary power regarding the question of whether a risk is negligible. It is thus advisable to review the content of standards critically.

### 3.5. Risk uncertainty and the precautionary principle

Certain jurisdictions apply the so-called precautionary principle. The precautionary principle authorises regulators to take a preventive measure which cannot (yet) be 100 percent justified by science. According to this principle, the regulators may take account of societal, economic, cultural, ethical and environmental factors in case of uncertainty. The precautionary principle is a derivate of the discretionary power of the regulator. But is it always wise to apply the precautionary principle?

In the view of the author, it depends on the situation:

Situation A: All possible measures deal with just one single risk or cause just one single risk.

Situation B: The possible measures deal with different risks or cause different risks.

In Situation B, a complex assessment is needed. Situation B is more frequent than one may initially think. Here are some examples:

- Which of the different exhaust gases of cars, each of them triggering different risks, should the legislator primarily try to reduce? Or which type of fuel should the fiscal system privilege? Diesel engines produce less CO<sub>2</sub> for consuming less fuel. However, NO<sub>x</sub> emissions of Diesel engines are higher.
- Everywhere in the legislation regarding chemicals we are confronted with uncomfortable choices to be made: The ban of a certain substance as conservative, e.g. colour, plasticiser etc. might trigger the use of another substance which is not necessarily safe in view of the same or another risk.
- Are Genetically Modified Organisms (GMO) more or less risky than pesticides and herbicides that would otherwise be used?

At least in situations in which different measures deal with or cause different risks, a precise analysis of the impacts and of affected legal positions and interests is needed. To "blindly" apply the precautionary principle with regard to one risk can tragically backfire on other risks, and may thus cause more harm than good.

### 3.6. Choosing amongst measures that deal with or cause one single risk

If the possible measures deal with or cause only one single risk, risk managers should compare the effects of each potential measure against the scenario of doing nothing in order to find the best possible scenario. To make this comparison more precise, it might be useful to refer to mathematics:

Risk managers are invited to firstly assess the hazard "H" (how big is the damage at stake?) and the likelihood "L" of the hazard to occur if no measure is taken. Secondly, hazard and likelihood need to be multiplied ("H x L"). As this is the scenario in which no measure is taken, we can call it "H<sub>0</sub> x L<sub>0</sub>". In a third step, the product "H x L" is to be assessed under the assumption that different possible measures (M<sub>1</sub>, M<sub>2</sub>, M<sub>3</sub>, ...) are taken. Let us call the result for M<sub>1</sub> "H<sub>1</sub> x L<sub>1</sub>", the result for M<sub>2</sub> "H<sub>2</sub> x L<sub>2</sub>", the result for M<sub>3</sub> "H<sub>3</sub> x L<sub>3</sub>" etc. To decide whether one of these measures should be taken, it is advisable to subtract from "H<sub>0</sub> x L<sub>0</sub>" (the product hazard x likelihood of the situation without any measure) first "H<sub>1</sub> x L<sub>1</sub>", in a second operation "H<sub>2</sub> x L<sub>2</sub>", in a third operation "H<sub>3</sub> x L<sub>3</sub>" ...

etc.. "H0 x L0" minus "H1 x L1" thus measures the safety gain if the measure M1 is taken. "H0 x L0" minus "H2 x L2" thus measures the safety gain if the measure M2 is taken. The higher the result, the more safety can be ensured by taking the respective measure. If the result is below 0, the risks are increased and no measures should be taken (unless the risks are outweighed by a benefit).

Let us imagine that "H0 x L0" minus "H1 x L1" is the highest figure (which means that the safety is best preserved) if the measure M1 is taken. If the different potential measures do not impact free circulation or other economic rights, the examination ends here. Risk managers just need to take the measure for which the difference is highest.

If economic or other rights or simple interests are impacted by one of the potential measures, the safety won is to be weighed against the negative impact on these rights and interests. New measures usually impact at least economic interests.

It is reasonable to take the measure if "H0 x L0" minus "H1 x L1" > ERI, ERI being an abbreviation for legitimate "economic rights and interests".

One might argue that the mathematical model presented here does not really help insofar as the effect of the different potential measures cannot be estimated. Indeed, there might be situations in which it is impossible to estimate the effect of potential measures. However, if the measure is not at least with a certain likelihood deemed able to reduce H x L, it simply should not be considered. In all other cases, some effect is likely. Accordingly, there is an effect that needs to be quantified both in terms of hazard reduction and likelihood reduction. A rough estimate is still better than no estimate and blind decision-making. Accordingly, it is preferable to maintain a mathematical model to set estimations on the right track.

### 3.7. Choosing amongst measures that deal with or cause different risks

The assessment to be made is basically the same. But we need to compare the possible measures not just with regard to one hazard and its likelihood, but several. It is a situation of communicating tubes. Each of the various measures will impact several risks. We have to ask ourselves: do we really increase the overall safety by applying the measure?

Data is of the utmost importance for reasonable decision-making in situations involving different risks. If I cannot assess the consequences of a measure against the use of Substance A as plasticizer in products X, the regulator runs the risk of doing more harm than good. It might well be that the alternative Substance B does more harm as plasticizer in products X, though linked to another type of toxicity.

The need for comparative data is, legally speaking, not given in areas where the full-safety principle is applied. Under the full-safety principle, a product (or technology or substance) is deemed to be legal if, with a certain safety margin, a risk can be excluded. If a risk cannot be excluded, the product (or the technology or substance) cannot be lawfully marketed. This is very clear from the legal perspective. However, if the alternative (product, technology or substance) cannot be fully assessed as to its risks, authorities might cause more harm than good by applying the law.

To come back to the initial example of substances, there is a need for comparative risk assessments and data collection combining the parameters (1) substance with (2) function and with (3) product type. This seems to be burdensome. But the effect of comparative data would go far beyond the mere legal sphere. If made public, industry would extensively use such comparative data. There are three reasons why industry would look for substances with comparatively good risk assessments. To use substances with comparatively good risk assessments prevents future damage of reputation, future liability claims and the need to modify the products when the use of the substance has become unsustainable. To provide a public platform for the collection of comparative data could thereby be a valid and effective non-legislative measure that influences the behaviour of economic operators. Such a platform cannot substitute classic bans of substances, but can complement these bans. This measure makes sense, not only where the policy of bans fails to produce adequate results (be it due to a lack of resources or too high a scientific complexity).

### 3.8. Multi-dimensional impacts

As we can see in the case of "GMO versus herbicides and fertilisers", sometimes different potential impacts are to be weighed one against the other. These environmental impacts will appear with different time-scales. The decision on GMO versus herbicides and fertilisers may also have various economic consequences which are very difficult to assess. E.g. the GMO seeds are subject to patent rights. These patents might influence the economic structure of agriculture and, in the long term, maybe even the availability of seeds which are not protected by patent rights. A lack of cheap seeds may hamper the development of poorer regions in the world, but the large scale use of GMO could also favour the development of medium income countries. What we see here is just one chain of economic impacts. There are certainly many more, both positive and negative ones. Furthermore, there might be causal chains which are positive in the view of some and negative in the view of others.

This basic analysis of potential effects demonstrates that causal chains may go from one policy to the second and the third. Such causal chains and also feedback loops are extremely difficult to take into account in the decision-making process. Thus we can only slowly train ourselves in this type of multi-dimensional impact analysis. To learn, we need to get familiar with quantifying diagrams, close loop mechanisms and scenario simulations.

The last paragraph hints at what might be needed as future instruments for policy making. But we can now already identify a few tricky legal questions:

- In which cases must negative effects for other policy areas (than those the regulators are in charge of) be taken account of when evaluating a measure and when applying the proportionality principle?
- If these negative effects must be taken account of, another question arises: *to what extent* must a negative effect in another policy area be taken account of? Is there a "discounting factor" to be introduced?

Some regulation includes explicit obligations to take multi-dimensional impacts into account at the administrative level. These examples can help us to understand how the analysis and decision-making in case of multi-dimensional impacts of regulation can work. The [Indian right to fair compensation and transparency in land acquisition, resettlement and rehabilitation act](#), 2013, provides, in its Chapter II, for the obligation to undertake Social Impact Assessment studies in case of certain requisitions of land. The act contains detailed provisions on conditions to be fulfilled, including composition of the committee, publication and language requirements. It stipulates, in its Chapter II Article 8 Paragraph 1, that the legitimate purpose must outweigh the adverse social impact. Furthermore, the measure may not encompass more land than strictly necessary, and no previously confiscated alternative land must be available. How is the social impact integrated into the overall decision-making? Chapter II Article 6 states that the result of Social Impact Assessment is to be made available to the authority in charge of environmental impact assessment. Accordingly, we can presume that the social impact takes part in the overall weighing process undertaken by the latter authority. The multiple social impacts are thus integrated into the overall weighing process, though this weighing process was initially established merely for environmental impacts.

### 3.9. Translating risk assessment reports into measures (risk management)

The considerations of a risk manager go beyond these complex reflections if he receives a risk assessment. Subject to legal empowerments and to the measures that already exist, s/he has to choose the level of action. Sometimes there is a need to use several levels, e.g. an easy-to-implement but incomplete administrative measure and a measure that resolves the issue completely by regulation.

We have already mentioned two criteria for choosing the right level of intervention, the time-line and degree to which the measure resolves the issue. There are more, e.g. the availability of the human resources and the durability of the risk assessment. If the risk assessment is likely to be substantially revised in the next two years, it is risky to go for legislation. Risk management is thus a complex optimization task.

### 3.10. Safety margins in risk assessment and risk management

To apply a safety margin is sometimes possible and useful. For the assessment of risks with regard to chemical substances, a safety margin of factor 100 or 1000 is frequently used. This is adequate if the full safety principle is applied. If a substance should only be authorised when absolutely safe, a safety margin is normally appropriate.

However, a safety margin should not be applied if its application would disproportionately increase another risk or disproportionately reduce the benefit achieved with the substance, product or service in question. If such a downside is noted, a comparative risk-benefit analysis is needed.

In addition, the application of the precautionary principle might be simply disproportionate if measured against the economic interests or legal positions of those who would have to pay the price for it.

A special problem arises if applying a safety measure or a safety margin would overall be beneficial and the most cost-efficient, but the price is to be paid by somebody who has not caused the risk or who is not in an appropriate position to pay it. E.g., regulation may impose distributors or professional users certain maintenance or customer information obligations that they are not really able to comply with. The interest of the third party might be protected by formal rights or fundamental rights.

### 3.11. The proportionality principle

Contrary to the precautionary principle, the proportionality principle has to be applied on a mandatory basis in many jurisdictions. It is derived from fundamental rights. According to the proportionality principle, it must be established that new regulation is suitable to achieve the objective(s) sought, and that the same objective(s) may not be as effectively achieved by measures which are less restrictive. Furthermore the disadvantages caused may not be disproportionate to the objective(s) pursued.

The previously mentioned aspect of the proportionality principle is difficult to apply if there are multiple uncertainties and probabilities involved. Most regulators will rely on their rough appraisal when assessing whether the disadvantages of a measure are disproportionate. A rough appraisal is usually sufficient because the balance falls clearly on one side. However, regulators may also face situations that are not clear-cut. Regulators may wish to go for a precise analysis of effects in order to ensure that disadvantages are not disproportionate to the aim pursued (or reached).

Once again, mathematics can serve as an instrument to sharpen our judgement. To start, let us assume that there is only one disadvantage triggered. This disadvantage needs to be evaluated. According to the proportionality principle, this disadvantage has to be proportionate when weighed against the benefit that is pursued with the measure. If there is only one certain disadvantage, the formula is easy. Proportionality (P) is given if the benefit (B) is higher than the disadvantage (D).

$$P: B > D$$

In a second step, let us assume a case in which there is no certainty about the disadvantage taking place. There is only a certain likelihood. Let us also assume that there is only one theory on the likelihood of the disadvantage taking place. Proportionality is given if the benefit B is higher than the disadvantage D multiplied by the likelihood L of the disadvantage occurring.

$$P: B > D \times L$$

If there are different potential disadvantages (D1, D2, D3, ...), each of them being linked to a different likelihood, the formula becomes slightly more complicated:

$$P: B > D1 \times L1 + D2 \times L2 + D3 \times L3 \dots$$

If there are different theories about potential disadvantages, the same formula has to be applied for all theories Ta, Tb, Tc, ... . The result according to the different theories Ta, Tb, Tc, ... needs to be multiplied by the likelihood of the respective theory being right. The results shall be added up. Proportionality is given if the sum is still lower than the benefit B.

$$\begin{aligned}
 P: B &> LTa \times (D1 \times L1 + D2 \times L2 + D3 \times L3 \dots) \quad (\text{for } Ta) \\
 &+ LTb \times (D1 \times L1 + D2 \times L2 + D3 \times L3 \dots) \quad (\text{for } Tb) \\
 &+ LTC \times (D1 \times L1 + D2 \times L2 + D3 \times L3 \dots) \quad (\text{for } Tc) \\
 &+ \dots
 \end{aligned}$$

For each of these cases, it might be that the benefit is also uncertain. If this is the case, we just need to substitute, on the left side of the equation, the "B" by "B x L". If there are different potential benefits, we substitute, on the left side of the equation, the "B" by "B1 x L1 + B2 x L2 + B3 x L3 ...". The further split in accordance with different theories is equally possible.

### 3.12. Overview: the adaptation of risk and performance requirements to technical progress

Adaptation to technical progress can happen in many ways. It can be achieved by the constant drafting of new regulation. However, the constant drafting of new regulation is relatively cumbersome. Regulators can instead try to build in a kind of automatic adaptation to technical progress by using a variety of techniques:

- Expressions that imply an automatic update like "state of the art", "best available techniques", "technically most advantageous", "to reduce as much as possible the risk ...",
- Mandatory dynamic reference to international standards ("... comply with to the most recent international standards"<sup>29</sup>),
- Mandatory static reference to standards plus update of the reference once the standard has been updated,
- Mandatory dynamic references to international agreements, codices and other documents of high reputation,
- Mandatory static references to international agreements, codices and other documents of high reputation plus update of the reference once the reference text has been updated.

### 3.13. Quantitative and qualitative risk and performance requirements

Regulation can be more or less stringent. The right degree of stringency should be determined by a conscious decision and not simply by copying previous requirements. This statement seems to be evident for regulation fixing precisely performance requirements, e.g. via limit values or other quantitative targets (1.). It is less evident in the case of qualitative risk and performance requirements, meaning abstract terms fixing the targeted risk or performance level (2.). A third path consists in using abstract terms, but empowering for a definition thereof (3.).

1. The clearest way of setting performance requirements is to set quantitative limit values or other quantitative targets. At first sight this seems simple. The disadvantages appear after some time: the limit value might be impossible or too easy to be fulfilled so that an unforeseen adaptation procedure is needed. This is cumbersome, even if the adaptation can be made by regulation.

In some sectors, a limit value does not have any meaning as such without definition of the measurement methodology. Fuel consumption and emissions of vehicles is such a sector. Fuel consumption and emissions depend on the so-called test cycle and other testing parameters. To define these in regulation is extremely difficult, as they are extremely detailed and too comprehensive. This difficulty has led in some jurisdictions to the following practice: the legislator decides on limit values and obligations and the test method is determined by regulatory acts in parallel or even ex post. Such a practice is justified if the test method has to be adapted to the limit values in order to ensure that the limit values can be reached. However, feasibility arguments are often only put forward by industry to obtain a lenient test method. The intention of the legislator thus risks being undermined.

<sup>29</sup> Art. 7 of Commission Regulation (Euratom) No 302/2005 of 8 February 2005 on the application of Euratom safeguards, OJ L54/1 of 28.2.2005

An example of a regulatory act imposing a certain test method is to be found in Commission Regulation EU/10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (see its Article 18 and Annex V).

2. Regulators are often hesitant to use quantified criteria. Sometimes they are hesitant because they fear that each quantification might need to be updated, e.g. because there is technical progress. In such a situation, there can be a trade-off between legal preciseness and enforceability of legal requirements and the goal of automatic adaptation to technical progress that can be reached by vague expressions like “state of the art”. In such a trade-off situation, regulators sometimes prefer the abstract terms.

Especially when performance requirements are described in abstract terms, it seems to be normal to require the highest performance (e.g.: ...to reduce as much as possible the risk of...). However, it is sometimes not necessary, in view of the regulatory goal, to request the most stringent fulfilment, and sometimes it is even counter-productive for another goal. Thus a conscious decision is needed, as stated at the beginning of this Section.

As soon as the regulation does not simply require the most stringent fulfilment of a criterion, the margin of interpretation becomes wide. See as an example the term "state of the art" and its alternatives mentioned in Section 3.12. The term "state of the art" is so often used because it has two advantages:

- It aims at a high performance level;
- It is dynamic in time.

Unfortunately, there are uncertainties as to the use of this term: Does it mean that the highest possible performance level has to be fulfilled? Or is it sufficient to fulfil a fairly high, not sub-standard level?

This question of interpretation has sometimes led regulators to look for alternative formulations such as "technically most advanced". However, this is equally problematic. There might a very modern, "advanced" new technology which is nonetheless not especially well-performing in certain performance aspects. To refer to the "state of the art" would clearly permit the banning of this technology whereas it would be subject to legal debate whether it could be banned under the term "technically most advanced". There are also sectors in which a very old technology is still performing very well, be it in general or for some special purpose. In these cases it would be difficult to argue that the technology is "technically most advanced" whilst it would be deplorable to ban it.

Another alternative to the term "state of the art" is "technically most advantageous". This term makes quite sure that the highest performance level has to be sought for in the case of a one-dimensional performance scale. The term might nonetheless give rise to interpretative questions if there are different goals or performance scales and if the optimisation for one goal leads to lower results with regard to another. In this case, it is advisable that the regulator indicates how the two goals should be valued. The regulator should especially express to what extent economic considerations (or simply: cost) may influence the definition of "state for the art" or "technically most advantageous".

Moreover, the practice and the terms used so far in a given sector should be taken account of. If the term "state of the art" was so far understood in the best possible way, it might create useless legal uncertainty to replace this term by "technically most advanced". Introducing a different term might be misunderstood as a call for a different criterion. In such a situation, it might be a good option simply to fix the right legal interpretation of "state of the art" by a definition or by informal guidance documents.

The dynamic aspect (the “spiral upwards”) is better built-into the term "state of the art" than other terms. If another term than "state of the art" is used, it might be necessary to stress the dynamic aspect.

Furthermore, it can be clarified whether the criterion "state of the art" or "technically most advantageous" is to be applied only once for a given product or service type or whether it can also be stated later in the lifecycle that the product or service no longer fulfils the criterion (e.g. on the occasion of a authority surveillance operation). The regulator can refer, in the case of products, to the time the product type is designed, to the time that the individual product it is constructed, to the time it is sold or installed, to the time it is used, etc. For more on this, see Section 3.18.

3. There is an intermediate path between 1 and 2: establishing the criterion "best available technique" in legislation, but providing for an empowerment to define this term in a regulatory act. See as an example Commission Implementing Decision 2013/163/EU of 26 March 2013 establishing the best available techniques

(BAT) conclusions under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions for the production of cement, lime and magnesium oxide.

### 3.14. References to standards

Jurisdictions have developed two techniques on how to refer to standards:

- establishing a mandatory reference to a standard, thus integrating the content of the standard into the legal text;
- establishing a presumption of conformity for standards, meaning that products, services or other processes fulfilling the standard are presumed to comply with certain, precisely defined legal requirements.

Most jurisdictions create mandatory references to standards rather than providing for a presumption of conformity with legal requirements to those applying the standards. See as an example the U.S. Federal Motor Vehicle Safety Standards, Minimum Sound Requirements for Hybrid and Electric Vehicles:

„§ 571.5 Matter incorporated by reference. ...

(2) ISO 10844:2011 “Acoustics—Test Surface for Road Vehicle Noise Measurements,” into § 571.141.“

In certain jurisdictions, a mandatory reference to standards may even be dynamic, meaning to the version as last amended even if the last amendment takes place after the adoption of the regulation. See as example the [Canadian Regulations Amending the Onshore Pipeline Regulations](#), 1999<sup>30</sup>:

“CSA Z246.1” means CSA Standard Z246.1 entitled *Security Management for Petroleum and Natural Gas Industry Systems, as amended from time to time. (norme CSA Z246.1)*”

Both techniques of reference to standards require a good deal of work and time investment on the part of the authorities. In either case, the authorities need to verify whether the requirements set up by the standardisation bodies are in line with the legal requirements. The international standardisation machinery has become more and more disconnected from the legal requirements of the various jurisdictions. Therefore, standards are not necessarily aligned with requirements of regulation. It may help, in this case, to establish a rule of conflict, as provided for in the [Canadian Regulations Amending the Onshore Pipeline Regulations](#), 1999<sup>31</sup>:

„Subsection 4(3) of the Regulations is replaced by the following:

(3) If there is an inconsistency between these Regulations and a standard referred to in paragraph (1)(b), (c), (d) or (e), these Regulations prevail to the extent of the inconsistency.“

One major issue of standardisation is updating it. Updating a standard is not always less cumbersome than updating regulation. Standards should always reflect the "state of the art" or the otherwise abstractly defined performance requirements. Standards are mostly drafted by persons working for the respective industry. This is basically good inasmuch as these people have the best technical insight. However, the weak presence of other persons or institutions having a similarly high degree of technical understanding has downsides. To what extent is there still legitimacy if what is to be regarded as "state of the art" is (mainly) defined by industry representatives? Do these representatives have an interest in defining "state of the art" in a progressive way? Also, most standardisation bodies work by consensus, not only at the level of formal voting by states' delegates, but also at the working group level. One single active industry delegate can thereby prevent technical progress being reflected in a standard. Prior to referring to standards, the regulator should verify whether he has the administrative means to follow up the standard development and the means to successfully intervene in case of standards not completely reflecting the performance requirements defined by the term "state of the art" or by other terms.

The following questions might help regulators to make a conscious decision on whether to refer to a standard:

- Is the standard in contradiction with requirements set up by regulation?
- Does the standard concretise correctly the abstract expressions and requirements set up by regulation?
- Does the standard concretise correctly the discretionary powers set up by regulation?
- Does the standard provide for a discretionary power where the regulation does not foresee a discretionary power?

<sup>30</sup> SOR/2013-49 March 21, 2013 P.C. 2013-308 March 21, 2013.

<sup>31</sup> See previous footnote.

- Does the text of the standard reflect technical progress?
- Do the standards and other documents referred to in the standard reflect technical progress?
- Does the standard and the standards therein referred to refer to the same version of further/third standards?
- Does the standard refer to documents other than standards that cannot be referred to in a valid way? E.g. international standards sometimes refer to reports or national standards that cannot necessarily be accessed.
- If dynamic references in standards cannot be accepted for legal reasons: does the standard contain dynamic references?
- In jurisdictions like Brazil and the EU where standards can provide for a presumption of conformity with legal requirement: does the standard really fully cover (for all aspects and for all cases) the legal requirements that it claims to cover?
- In jurisdictions like Brazil and the EU where standards can provide for a presumption of conformity with legal requirement: does the standard distinguish between the specifications aiming to support the legal requirements and other specifications?

It goes without saying that the continuous supervision of standards under these aspects can become quite cumbersome.

### 3.15. References to non-legal documents other than standards

Regulators are often tempted to refer to non-legal documents to further specify requirements. References to other documents may help to set up requirements without much regulatory work, above all if the reference is dynamic. The [Brazilian draft Portaria INMETRO / MDIC Number 247 of 26/05/2014](#)<sup>32</sup> on the conformity assessment for the retreading of tires contains an undated and therefore probably dynamic reference to technical manuals of certain bodies:

*„A.3.1 Para qualquer um dos três processos de reforma de pneus (recapagem, recauchutagem e remoldagem), é respeitada a tolerância da diminuição do índice de velocidade conforme a Tabela “Símbolo de Velocidade” do Manual de Técnico da ALAPA.*

*Nota 1: podem ser utilizados dados dos Manuais Técnicos da ETRTO, TRA e da JATMA, no caso de serem omissos os constantes no Manual Técnico da ALAPA.“*

Amended machine translation:

*"A.3.1 For any of the three reform processes tires (retreading, retreading and remoulding) is respected the tolerance index decrease speed as Table" Speed Symbol "Technical Manual of ALAPA.*

*Note 1: data can be used from the ETRTO, TRA and JATMA Technical Manuals; if they are missing, those contained in the Technical Manual ALAPA can be used.*

Sometimes regulators make the reference to both standards and other non-legal documents in one strike. The Economic Community of West-African States (ECOWAS) Regulation C/REG.4/05/2008 of 18 May 2008 on the harmonization of rules governing quality control, certification and marketing of vegetable seeds and seedlings in the ECOWAS Space provides for an example of a dynamic and generic reference both to international standards and other international reference documents:

*“Article 7. En vue d’assurer la libre circulation des semences dans la Communauté et de favoriser leur commerce régional et international, les Etats membres fondent leurs règlements techniques en matière de semences, sur les normes, directives et recommandations internationales.”*

Amended machine translation<sup>33</sup>:

*“Article 7. In order to ensure the free movement of seeds within the Community and to promote their regional and international trade, Member States base their technical regulations on seeds on the international standards, guidelines and recommendations.”*

Generic reference clauses like the one of ECOWAS may cause disputes on which documents are to be

<sup>32</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.

<sup>33</sup> Unfortunately, we only found the French version of this regulation via the Official Journal of Senegal. Therefore, we had to translate the French version although an English original is extremely likely to exist as well.



regarded as referred to. Therefore, regulators may consider establishing a mechanism for the acceptance of reference documents (see below the example of Singapore).

Regulation can do more than just refer to non-legal documents. It can provide for explicit rules on the effect of respecting codes, standards, and guidance documents in procedures establishing the civil, penal or administrative responsibility of persons or operators. The most advanced example found is the new Section 3C of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#).

*“Use of code, standards, etc., in proceedings*

3C.

*—(1) This section applies to and in relation to any code, standard, rule, requirement, specification or other document issued by the Authority for the purpose of providing practical guidance or certainty in respect of any one or more of the requirements of this Part or any duty or other requirement prescribed in any aviation safety subsidiary legislation.*

*(2) Subsection (4) shall have effect where —*

*a person is alleged to have committed an offence under this Part or any aviation safety subsidiary legislation — by reason of a contravention of any provision of this Part or of any aviation safety subsidiary legislation; or by reason of a failure to discharge or perform a duty or other requirement imposed by this Part or any aviation safety subsidiary legislation; and*

*the matter to which the alleged contravention or failure relates is one to which, in the opinion of the court in the criminal proceedings, a code, standard, rule, requirement, specification or other document referred to in subsection (1) relates.*

*(3) Subsection (4) shall have effect where —*

*a holder of an aviation safety instrument is alleged to have not satisfied any requirement of this Part or any aviation safety subsidiary legislation applicable to holders of that aviation safety instrument —*

*by reason of a failure to discharge or perform a duty or other requirement imposed by this Part or any aviation safety subsidiary legislation; and*

*the matter to which the alleged contravention or failure relates is one to which, in the opinion of the Authority or Minister in any administrative proceedings involving the exercise of any power under section 4C, 4D, 4E, 4H, 4J, 4K, 4L or 4N, a code, standard, rule, requirement, specification or other document referred to in subsection (1) relates.*

*(4) In criminal proceedings referred to in subsection (2) or administrative proceedings referred to in subsection (3)*

*— compliance with a provision of such a code, standard, rule, requirement, specification or other document found by the court, Authority or Minister (as the case may be), to be relevant to a matter to which a contravention or failure alleged in the proceedings relates; or*

*a contravention of or a failure to comply with, whether by act or omission, any such provision so found, may be relied on by any party to those proceedings as tending to negative or establish any liability which is in question in those proceedings.”*

Instead of referring to non-legal texts itself, legislation can provide for an empowerment to incorporate, in subordinate regulation, non-legal text by reference. The advantage of this technique is that updating of the subordinate regulation is easier procedure-wise. The most advanced legal text found in this regard is the new Section 3B of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#). This Section 3B also contains detailed prescriptions on how non-legal texts can be referred to and how they must be made available. Even dynamic incorporation is possible, but accessibility to a certified copy must be ensured.

The [Fire Safety \(Petroleum and Flammable Materials\) Regulations 2013 of Singapore](#) replace, in Chapter 109A Section N 61(1), an old way of making reference to „codes of practice“ with a new one. Both ways are of interest. The previous version of the act apparently contained the concept of – presumably informal – „acceptance“ of a certain code of practice by the administrative authority; see the definition: ““accepted code of practice”, meaning any code of practice, standard, guide or handbook that is accepted by the Commissioner for the purpose of providing practical guidance to persons engaged in the storage, keeping, transport or dispensing, or conveyance by pipeline of any class of petroleum or flammable material. This concept of informal „acceptance“ makes management easy. Regardless of whether this was the case in Singapore, „acceptance“ can already be expressed by simple listing of certain Codes of Practice on a website of the authority, without any formal administrative procedure or decision-making. However, informal acceptance might, in some jurisdictions, be regarded as insufficient under aspects of legal certainty. This could have been the reason for Singapore to shift from mere „acceptance“ to the presumably rather formal „adoption“ of code of practices by the authority.

Section 55 of the act sets up a priority rule in case of conflict between different Codes of Practice by stipulating that one of them will prevail over the others:

*“(4) Unless otherwise provided in any regulations made under section 61, in the event that any code, standard, rule, specification or provision adopted under subsection (1) is inconsistent with the Code of Practice for Fire Precautions in Buildings published by the Commissioner, the Code of Practice for Fire Precautions in Buildings shall prevail.”*

Can there even be an obligation to use standards and similar non-legal documents? Both standards and other international non-legal documents are covered by the expression “standards” in the meaning of Article 2.4 of the TBT<sup>34</sup> Agreement; see the WTO dispute ruling “WT/DS231, EC Trade Description of Sardines”. The ruling was based on Article 2.4<sup>35</sup> of the TBT Agreement, which lays down an obligation to use international standards as a basis for domestic technical regulations except if such international standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued. In this ruling, a voluntary standard of the Codex Alimentarius Commission for the marketing of canned sardines and so-called sardine-type products (Codex Stan 94) has been regarded, by the WTO Appellate Body, as a standard in the meaning of the TBT Agreement. The WTO Appellate Body took the view that International Standards need not be adopted by consensus. As a result, all TBT signatories have to base their technical regulations on relevant international standards unless they are not effective or appropriate for the fulfilment of legitimate goals so that deviations are justified. The TBT signatories are even bound by standards that they formally opposed in the adoption process. The fact that the term “standard” has to be interpreted in a broad sense, also covering binding legal UN instruments, cannot be excluded.

### 3.16. High risk products and processes

High risk products and processes require particular care with regard to the substantial criteria to be applied. A good example of what can be required for high risk products and processes surrounding these products can be found in the [Canadian Explosives Regulations, 2013](#), P.C. 2013-1283 November 26, 2013. In addition to classic product-related requirements, these regulations require manufacturers to set up and to apply mandatory operating procedures to reduce accidents (Articles 86 to 89) and to consciously operate change management (Article 87). Articles 101 to 105 set up requirements for workers, visitors and other persons entering a manufacturing site. The Articles 186 onwards contain requirements for the transport and for the persons involved in this transport. The Articles 213 onwards contain rules for sellers and users of specific explosives.

We can see here an example of a general tendency: the riskier the product or process, the more groups of persons and side-processes need to be targeted by the regulation. Another example of this very tendency is the [Canadian Food and Drugs Act - Regulations Amending the Food and Drug Regulations](#) (1475 — Good Manufacturing Practices). It contains detailed obligations for packagers, labellers, distributors and importers. These obligations go up to the level of product testing.

The riskier a certain product or process is, the higher the likelihood that regulators deem it to be appropriate to require a quality management system. Quality management systems are required by some Canadian legislation. See as examples Sections 93 to 97 of the [Canadian Food and Drugs Act, Blood Regulations, P.C. 2013-1065 October 9, 2013](#) or Sections 6.1 to 6.6 of the [Canadian Regulations Amending the Onshore Pipeline Regulations](#), 1999, P.C. 2013-308 March 21, 2013. The latter is slightly more comprehensive than the first, but still manageable.

### 3.17. Bearing and causing risks

Those who bear certain risks are rarely exactly the same as those who cause them. If arms killed only those who manufacture them, who would continue to manufacture arms? If the risks caused by vehicles were concentrated in the cities where the vehicles are manufactured, would these cities still produce vehicles? If car manufacturers

<sup>34</sup> Technical Barriers to Trade

<sup>35</sup> Article 2.4 of the TBT Agreement says: “Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except if such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.”

were to bear the indirect costs and long-term damages that are caused by their cars, would they still find liability insurance?

Many economic operators let others pay for risks, but keep the profit for them. Some jurisdictions timidly react here and there against this business model; see e.g. in the banking sector where taxpayers' money is now better protected against rescue calls by "too-big-to-fail" banks than before 2008. However, there is still no general awareness as to the extent to which this business model is spread. In hardly any sector of regulation related to devices, products, chemicals or services is the principle of responsibility of the operator fully implemented. Classic tort law, requesting proof of causality and of negligence, usually fails in practice as it is too complicated. The principle of strict liability is applied in certain states for certain niche sectors (like oil drilling or nuclear activities), but not in all sectors. Mandatory collective insurance schemes, developed in Europe in the 19<sup>th</sup> century to protect workers against financial consequences of occupational accidents, often establish too high hurdles for the victims, namely in terms of burden of proof. Nonetheless only the principle of strict liability and mandatory insurance schemes may slightly remedy the unfairness of a situation where some make the profit and others bear the risks. Both are more successful if paired with a reduced/low burden of proof for causality or even a reversal of burden of proof once the damage has been proven. These techniques are still relatively rarely used. But from a cross-jurisdiction perspective, they are not exotic. They show up in quite a range of sectors (e.g. labour law, medical liability law, environmental liability law, animal liability law, copyright law, anti-corruption law, anti-trust law).

### 3.18. Reference time / reference stages

Requirements in regulation always have a reference time or reference stage, whether explicitly or implicitly. For services and other processes, the reference time/stage is usually the time when these are provided or take place. But sometimes an earlier time is referred to: the time of offer or the time of application for authorisation to an authority. To refer (also) to the time of offer can help to prove infringements. If a conformity assessment body professes in its publicity material to be very lenient in certain regards, it can counter authority remarks by claiming that its practice is more severe than indicated in the publicity or the offers. It cannot counter critical authority remarks if the legal requirements are at least also applicable to publicity or offers.

Some services or other processes take a long time. Thus the question arises of which legal requirements have to be applied if the legal requirements have been changed in the meantime: those applicable at the beginning or those at the end of the process? Transitional provisions should normally sort this question out unless it has been sorted out by the core text of the regulation.

For the purchase of products, devices, materials and substances we can distinguish different reference times: the time of advertisement/offer, the time when a purchase contract is concluded, the time when the contract is fulfilled, the time when the product, device, material or substance is handed over, the time when it is first used and the time when it is used thereafter, or even simply the time of inspection by an authority or entrusted body.

In all cases so far mentioned regulators also have the possibility of referring to the time span between the mentioned reference times / stages. Whatever the preference is, it makes sense to make a conscious choice regarding the reference time(s) or reference stage(s). It avoids complications and legal uncertainty at the level of enforcement.

### 3.19. Typology of risks related to devices, objects, substances

We have seen in the first Section of this Chapter that it is of the utmost importance to identify all the risks that should be covered by regulation. The following list might facilitate the task regarding risks related to devices, objects and substances, as it creates a kind of typology of risks:

- Mechanical risks (e.g. failing of brakes, failing of steering, squeezing mechanisms, cutting mechanisms),
- Software failure risks,
- Risks of software manipulation,
- Risks of electric failure,
- Risks linked to unintended charge of electricity,

- Risks linked to electricity supply breakdown,
- Risks of incompatibility of devices, connectors, chemical substances etc.
- Risks linked to electro-magnetic radiation (risk of interference with devices, risks for ultra-sensitive persons),
- Risk of radioactivity,
- Risk of other tissue destroying radiation (e.g. by protons or other parts of atoms),
- Risk of optical disturbance by beams and other light(s),
- Risk of too high or too low temperature,
- Risk of fire,
- Risk of spreading disease by use of human, animal or synthetic tissues,
- Risk of uncontrolled proliferation of living tissues or beings,
- Risks of bio-compatibility of chemicals,
- Risk of too high pressure (e.g. in case of explosion),
- Risk of not performing as intended (e.g. medicine),
- Risk of misunderstanding instructions for use,
- Risk of unintended inappropriate use,
- Risk of intended inappropriate use ("off-label use").

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## 7. Enforcement

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*"I have nothing but contempt for the kind of governor who is afraid, for whatever reason, to follow the course that he knows is best for the State."  
Sophocles*

The effectiveness of regulation is limited if its content is not put into practice. To ensure that its content is put into practice, enforcement is needed. Subject to the type of obligations contained in the regulation, the enforcement mechanisms have to be designed differently.

### 7.1. Information and enforcement

Regulatory measures other than regulation can become effective when they are made known to the target population. If an authority creates an administrative incentive, it must ensure that its target population comes to know about the incentive. Information is crucial.

For classic regulation which imposes obligations, the aspect of information tends to be regarded as secondary by regulators. Regulators instead tend to immediately reflect in terms of enforcement. Enforcement is, of course, necessary. However, informing the target population about legal obligations might be more cost-effective than only providing for enforcement. Many citizens, economic operators or professionals are ready to abide to the law. They just need to know about it. Instead of being expensively targeted by enforcement measures, it would suffice to inform them. Accordingly, regulators should think about information as a preliminary step to enforcement. For some measures of enforcement, e.g. for sanctions, preliminary information is also requested for reasons of fairness. One cannot expect everybody to read Official Journals.

The Economic Community of West-African States (ECOWAS) Regulation C/REG.4/05/2008 of 18 May 2008 on the harmonization of rules governing quality control, certification and marketing of vegetable seeds and seedlings in the ECOWAS Space contains basic provisions on information and is thereby one of the relatively rare examples of regulation that recognises the importance of preliminary information:

*"Article 8. - Principe de participation et d'information*

- 1. Les Etats membres assurent la pleine participation des différents acteurs du secteur semencier au processus de décisions publiques relatives aux semences.*
- 2. Les Etats membres organisent l'accès du public à l'information relative aux semences que détiennent les autorités publiques.*
- 3. Les Etats membres contribuent à la formation et à la sensibilisation des acteurs du secteur semencier."*

*Amended machine translation<sup>36</sup>:*

*"Article 8 - Principle of participation and information*

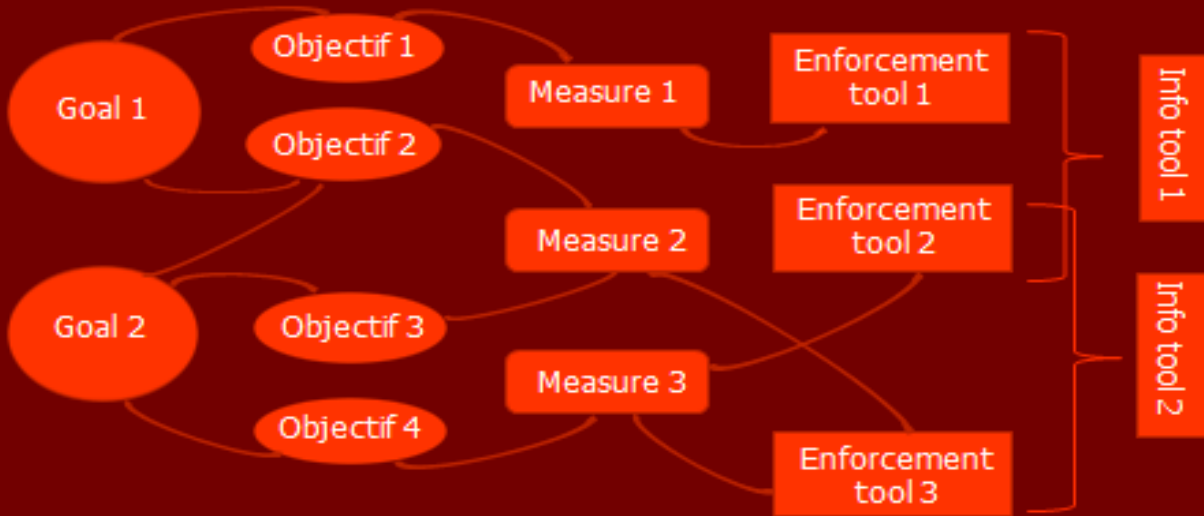
- 1. Member States shall ensure the full participation of different actors in the seed sector in the process of public decisions regarding seeds.*
- 2. Member States organize public access to information on the seeds held by public authorities.*
- 3. Member States contribute to the training and sensitization of stakeholders in the seed sector."*

We have seen in Chapter 2 how goals, objectives, measures, requirements and incentives interrelate. We can now build on the graph used there, and modify the graph so as to include two new types of items: information and enforcement.

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<sup>36</sup> Unfortunately, we only found the French version of this regulation via the Official Journal of Senegal. Therefore, we had to translate the French version although an English original is extremely likely to exist as well.

# Overview on goals, measures, enforcement and information tools



We can also develop charts similar to the ones presented in Chapter 2 to cover the aspects of information and enforcement. It is usually best for information and enforcement to be related to entire regulatory measures. However, in certain cases, information and enforcement need to relate to individual requirements. E.g. requirements can be addressed to different types of persons which need to be addressed separately. Accordingly, readers will find hereafter two charts: the measures-information-enforcement-chart and the requirements-information-enforcement-chart.

## The measures-information-enforcement-chart

Measure No	Measure title / description	Information tool(s) to be used to make the measure known	Enforcement tool(s) to be used
M1		e.g. internet campaign	e.g. supervision by competitors + right to sue at court
M2		e.g. press release	e.g. state in advance verification
M3			
M4			
M5			
M6			

**The requirements-information-enforcement-chart**

Requirement No	Requirement title / description	Information tool(s) to be used to make the requirement known	Enforcement tool(s) to be used
R1			
R2			
R3			
R4			
R5			
R6			

What to fill in? For the information column, readers might get some inspiration by the catalogue of regulatory measures in Section 2.3.4. Some of the information related to regulatory measures could well serve here for the chart, regardless of whether they are deemed and processed as independent regulatory measures or just as information means.

For the enforcement column, it is preferable to study first the full range of possibilities presented in this chapter. Considerations on enforcement can easily become very complex when all possibilities are really investigated prior to decision making. The chart can serve to resume the considerations, to keep the oversight and to ensure that nothing is forgotten.

Considerations on enforcement can even sometimes trigger the need to revisit goals, objectives, measures, requirements and incentives. This happens e.g. if it turns out that some requirements can hardly be enforced at all or that they can only be enforced for a part of the target population, thus causing an uneven playing field. Enforcement can also turn out to be disproportionately costly. It is thus risky both in terms of efficiency and costs not to integrate enforcement into the overall planning for a certain sector. The looping-back from considerations on enforcement to the overall planning and the development of the regulatory measures is often essential for a successful sector policy.

**7.2. Basic decisions to be taken with regard to the conformity verification**

One can set up a simple sequence of relevant questions to address the most important aspects of conformity verification and enforcement:

What needs to be verified?	When and under which conditions?	By whom?	In which procedure?

Please note that there can be logic feedback from the assessment of the third and fourth question into the assessment of the first two.

### 7.3. What needs to be verified

Basically, there are two approaches to verifying the conformity. The first is to verify the result, e.g. the final product or service. The second is to verify the steps leading to the result, e.g. the production and the quality verification which are part of the production process. Sometimes only one of the two approaches can or needs to be used. Sometimes both need to be combined to ensure conformity, e.g. if regulation sets up requirements both for the result and the way to the result or if the conformity of the result can only be verified on the way thereto.

At first sight it might appear strange that the verification of the way to the result can ensure the conformity of the result. And strictly speaking, we have to admit that it cannot do so to 100%. However, the verification of the way to the result can ensure a high likelihood of conformity. If a carefully working state authority or Conformity Assessment Body designated by the state finds the production process, including the quality verification, to be good, the risk of unintended deviations of the final products from the product type is very low. If, as part of the production process, the manufacturer has also set up a good system of verification of compliance of the product type with legal requirements, the likelihood of the product type to be in conformity with the legal requirements is also high. This can be verified by random checks of product documentation. Both elements together ensure a high likelihood of compliance of the final products with the legal requirements.

### 7.4. In advance versus ex-post conformity verification

The conformity with legal requirements can be ensured by in-advance (ex-ante) or ex-post verification. The in-advance and the ex-post conformity verification must, together, ensure compliance with the legal requirements, but should not go beyond what is necessary to ensure conformity with legal requirements. It is not proportionate to have an extensive in-advance state authorisation procedure that ensures the conformity of the product types with legal requirements and to verify this conformity again by ex-post conformity verification which is called "market surveillance" for products. However, there is room for ex-post conformity verification for the conformity of the individual product with its product type if this has not been ensured in the in-advance procedure. Even if the conformity of product types has been verified in advance, there is still room (and a need) for verifying that the products on the market are not counterfeit and that they are identical to the verified type. Similarly, it is sometimes not sufficient to verify the Standing Operating Procedures for services or other processes as the actual services and processes can easily deviate from the Standing Operating Procedures.

Accordingly, the legislator needs to decide what needs to be verified in advance and what ex post. The overall verification intensity should be sufficient to ensure conformity, but should not constitute a disproportionate burden. A first step towards this goal is to list what needs to be verified.

### 7.5. Conformity Assessment Bodies in advance versus state in advance verification

The right choice between Conformity Assessment Bodies' in-advance verification and state in-advance verification depends on the Conformity Assessment Bodies' designation and supervision practice and on the quality of the authorities and of the Conformity Assessment Bodies. The concrete situation has to be assessed. For instance, Conformity Assessment Bodies tend to be better placed for assessing the quality management of operators than authorities. Subject to the sector, either the authorities or again the Conformity Assessment Bodies have more technological knowledge.

To involve Conformity Assessment Bodies does not necessarily mean that the verification is weaker than that of a state agency / authority. The question of the stringency of the conformity assessment routes has to be distinguished from the question of who is verifying the conformity. Both authorities and Conformity Assessment Bodies can be stringent or can be too lenient.

The reason why Conformity Assessment Bodies are mostly deemed to be less severe is that they receive fees from their clients and are subject to competition amongst themselves. Therefore, some Conformity Assessment Bodies choose to be quite lenient with their clients. However, the same phenomenon can be observed in old-approach sectors where authorities receive substantial fees for authorisation procedures. Thus it is more the financial and the competitive situation that may lead to an over-lenient application of law and standards. This



pitfall could be remedied if the economic operators were to pay fixed fees to an authority in charge of deciding which Conformity Assessment Body will take over a certain economic operator<sup>37</sup>.

## 7.6. Mixed regimes

We are familiar with classic state authorisation procedures and with Conformity Assessment Bodies verifying the compliance of products or services. We are less familiar with procedures combining elements of the two procedures. Basically, there are two combinations possible:

**- Authorities are, for specific aspects, involved in a procedure run by Conformity Assessment Bodies.** See as example Art. 5-4 of the [Commission Regulation \(EU\) 722/2012](#) of 8 August 2012<sup>38</sup> concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin:

*"4. Before issuing an EC design-examination certificate or an EC type-examination certificate, the notified bodies shall, through their competent authority, hereinafter 'coordinating competent authority', inform the competent authorities of the other Member States and the Commission of their assessment carried out pursuant to paragraph 2 by means of a summary evaluation report in accordance with Annex II to this Regulation."*

This Regulation is an interesting example, because it obliges one to seek out not only the opinion of one authority of one geographic entity, but of different geographic entities together. Based on this model, a variety of further possibilities are imaginable:

- Geographic entities might obtain the right to veto the issuing of a certificate during a given period.
- Geographic entities might only be able to veto with a certain quorum, e.g. if one third of them oppose the issuing of the certificate.

**- Conformity Assessment Bodies are involved in a procedure run by authorities.** E.g. Regulation 168/2013/EU<sup>39</sup> of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles contains another interesting prototype of a mixed state-private authorisation regime; see Articles 61 to 71: technical services work on behalf of the approval authorities. They are assigned and supervised by the approval authorities. This authorisation regime is also used by other jurisdictions<sup>40</sup>.

## 7.7. Self-certification as alternative or complementing element

Both the in-advance verification undertaken by the Conformity Assessment Bodies and the in-advance verification undertaken by state authorities can be combined with elements of self-certification. Self-certification can also become an alternative to in-advance verification altogether, provided that the intensity of ex-post conformity verification is high enough to ensure compliance with the legal requirements. Even a very low intensity of ex post conformity verification may be sufficient if the operators in the sector are all very responsible, e.g. with a view of preserving their reputation or because the costs of an infringement stated by the authorities would be so high that there is a strong deterring effect. For this reason it was possible, in the U.S., to base the safety legislation for cars entirely on self-certification. In Europe too, self-certification has become an important element of product legislation. However, pure self-certification is mainly applied for low-risk products or services.

When should self-certification be applied? There cannot be a conclusive answer to the question without taking into account the situation of the respective sector. However, a few general statements can be made:

1. Self-certification is a good complementary tool for those elements of conformity that are not subject to an in-advance verification.

<sup>37</sup> The author has heard that India has at least intended to establish such a system.

<sup>38</sup> OJ L 212/3 of 9.8.2012

<sup>39</sup> OJ L60/52 of 2.3.2013

<sup>40</sup> To the knowledge of the author, this regulatory technique has been developed by the U.S.

2. If neither the state nor the Conformity Assessment Bodies have the capacity to ensure an in-advance verification for all products on the market, self-certification plus a relatively bold ex post verification based on random checks might be a good solution.

3. The same is true if the in-advance verification would substantially delay the market entry of life-saving products or services, e.g. for products of medical technology. The medical benefit of faster availability may outweigh the increase in safety triggered by verifying in advance.

4. The stronger the ex-post verification, the higher the likelihood that self-certification will be sufficient.

5. The bigger the disadvantage and the higher the likelihood of being sanctioned following ex post verifications, the higher the likelihood that self-certification will be sufficient.

6. The more the operators behave in a responsible way, the higher the likelihood that self-certification will be sufficient.

If self-certification has been chosen, it should be ensured that the economic operator consciously assesses the legal conformity of his product or service. Regulation may oblige making detailed declaration of conformity, as seen before in Commission Regulation EU/10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Regulation can also oblige the operator to establish a "product information file" which is based on a safety assessment as done in Article 10 of Regulation EC/1223/2009 of 30 November 2009 on cosmetic products.

An intermediate solution consists in letting the economic operator do the testing (and subsequent certification) himself, but to ensure that the testing is occasionally or systematically observed, be it by Conformity Assessment Bodies, state agencies, or accredited test laboratories (see the next Section 7.8). This solution is sometimes unavoidable, namely if the Conformity Assessment Bodies or the state agencies do not have the necessary test facilities at their disposal.

## 7.8. The procedure of in-advance verification

The advance verification is better executed if there is a verification procedure to be applied<sup>41</sup>. A common procedure makes the in-advance verification more reliable, faster and fairer.

What are the parameters of such a procedure (in addition to the questions already dealt with)?

- Regulation can determine the modalities of application / notification. E.g. it can foresee that the application has to be made in writing or by electronic means.
- Regulation can set up time-limits for applications / notifications (e.g.: at least three months before the start of the activity in question).
- Regulation can set up precise lists of what needs to be contained in the application / notification.
- Regulation can set up rules for the communication between the authority or the Conformity Assessment Body and the applicant (e.g. on the technical means of communication, the deadlines for responses).
- Regulation can set up rules on how conformity is to be verified (e.g. test procedures, verification limited to documentation).
- Regulation can set up time-limits for the authorisation / certification to be delivered, with or without "stop-the-clock" mechanisms when the applicant has to deliver more data or documents.
- The procedure can foresee that there is a formal authorisation by an authority or certification by a Conformity Assessment Body or that the operator only has to notify its intended activity. In the latter case, regulation can foresee that the authority may only intervene during a certain lapse of time in order to ban or restrict the activity in question.

In regulatory systems which use authorisations, authorities sometimes feel it to be inappropriate to provide a

<sup>41</sup> Exceptionally, the same may be true for ex post verification. However, ex post verification should instead be mostly unpredictable, in order to have the utmost deterrent effect. A reliable procedure might be counter-productive.

full/regular authorisation. For instance, authorities are sometimes not sure whether the applicant economic operator is really reliable or whether he possesses the adequate knowledge. To cope with these situations, the authorities may wish to provide for a temporally limited or conditioned authorisation instead of a full/regular authorisation. To do so they need, in many jurisdictions, a special empowerment. Such an empowerment should be foreseen by regulation. The empowerment might allow deviation from the rule of full authorisation, with or without specified conditions.

In some jurisdictions, it might even be necessary to enumerate precisely in the regulation the conditions that the authorities may refer to in a conditional authorisation. Regulation may empower authorities to set up one or more of the following conditions:

- Provide an additional certificate within X months;
- Employ a qualified person to close knowledge gaps;
- Undergo a specific training to close knowledge gaps;
- Review the quality system or the processes applied for certain items;
- Modify the physical installation for certain items;
- Exchange certain components or ingredients.

When enumerating conditions to be used for conditional authorisations, regulators need to keep in mind the conditions they have set for the full/regular authorisation. Do the two sets of conditions fit well together? Can the conditional authorisation be abused for circumvention of the minimum requirements of the full/regular authorisations? Furthermore, it is worth checking whether the conditional authorisations open the door to corruption.

Conditions can also be used with suspensive effect. Any kind of condition used for conditional authorisations can be combined in different ways with time limitations.

If the principle of authorisation is chosen, there is a variety of additional elements to be thought of:

- Shall authorisations be mandatory for the entire scope or only for a part of it?<sup>42</sup>
- Shall authorisations be delivered for each individual service or product or groups / families of services or products? See the Brazilian [Portaria INMETRO / MDIC No. 649](#) of 12/12/2012<sup>43</sup>, “General Requirements for Declaration of Conformity by Provider of Products”<sup>44</sup>, which defines:

*“4.9 Família de Produto*

*Agrupamento de modelos do produto, para um mesmo fim, de um mesmo fabricante, de uma mesma unidade fabril, de um mesmo processo produtivo, que possuem em comum alguma(s) da(s) seguinte(s) característica(s): memorial descritivo, projeto, dimensões, massa, matéria-prima, configuração, uso, entre outras, conforme definido em cada Requisito de Avaliação da Conformidade específico.”*

*Amended machine translation:*

*“4.9 Product Family*

*Grouping of product models for the same purpose, of the same manufacturer, of the same plant, of the same production process, having in common some of the following characteristic(s): technical description, design, size, weight, raw material, configuration, usage, among others, as defined in each specific requirement of Conformity Assessment.”*

- Can / must the documents relevant for the application be submitted electronically? See the Brazilian [Portaria INMETRO / MDIC No. 649](#)<sup>45</sup> of 12/12/2012, “General Requirements for Declaration of Conformity by Provider of Products”<sup>46</sup>, which provides:

<sup>42</sup> Voluntary authorisations can under certain circumstances make sense as well. We have not found any example of voluntary authorisations, but for voluntary certification. Brazil submitted for public consultation a draft ordinance (Portaria No. 8 of 10 January 2014) which foresees the voluntary certification of families of mineral water:

*“1.2.2 A certificação deve ser realizada para cada família de água mineral natural envasada, que se constitui como um agrupamento de modelos de água mineral natural de mesma classificação e oriunda de mesma fonte, envasados em uma mesma unidade fabril, com mesmo processo produtivo, e acondicionados em embalagens de mesma matéria prima.”*

Amended machine translation:

*“1.2.2 The certification must be made for each family of bottled natural mineral water, which is constituted as a grouping of models of natural mineral water with the same classification and coming from the same source, packaged in the same factory, with the same production process, and packaged in the same raw material.”*

<sup>43</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.

<sup>44</sup> Requisitos Gerais para Declaração da Conformidade do Fornecedor de Produtos.

*“6.1.1.6 A apresentação dos documentos relacionados é de responsabilidade do fornecedor e deve ser feita pelo Sistema Orquestra. Na impossibilidade de encaminhá-los por esse meio, o fornecedor deve entrar em contato com a Dipac / Dqual para receber orientações sobre a melhor forma de encaminhar os documentos.”*

*Amended machine translation:*

*“6.1.1.6 The presentation of related documents is the responsibility of the manufacturer and must be made by the Orchestra System. Failing to process through this, the manufacturer must contact the Dipac / Dqual to receive guidance on how best to forward the documents.”*

The respective database “Orchestra” can be visited under:  
[www.inmetro.gov.br/qualidade/regobjetos.asp](http://www.inmetro.gov.br/qualidade/regobjetos.asp)

- Shall there be deadlines for the decision-making or the authority?
- Shall the authorisation be automatically given if the administration does not decide in time?
- Shall there be fees as a precondition for the authorisation?
- What proof of authenticity shall be requested for the application (See Section 9.6)?
- Which information has to be provided with the application, and which information just on request?
- Which declarations (e.g. of good faith) have to be provided?
- What proof of authenticity shall be requested for these declarations (See Section 9.6)?
- What are the conditions under which the application must be rejected?
- What are the conditions under which the application may be rejected?
- May the authorisation be subject to certain conditions, imposed by the authority on the basis of its discretionary power? If so, what are the acceptable criteria and considerations?
- Can the authorisation be suspended (temporarily non-valid)? If so, what are the acceptable criteria and considerations?
- Can the authorisation be withdrawn (consequence: non-validity as from the moment of the withdrawal decision)? If so, what are the acceptable criteria and considerations?
- Under what conditions must the authorisation be withdrawn (consequence: non-validity as from the moment of the withdrawal decision)?
- Can the authorisation be revoked (consequence: non-validity from the beginning), e.g. in cases of fraud? If so, what are the acceptable criteria and considerations?
- Under what conditions must the authorisation be revoked (consequence: non-validity from the beginning)?
- Is the authorisation automatically invalid under certain conditions, e.g. in cases of fraud?
- For how long is the authorisation valid?
- What is the earliest moment for application for renewal?
- What is the latest moment for application for renewal?
- Which procedure applies to renewals?
- Shall there be intermediate inspections between the first authorisation and the renewal and between the renewals?
- For technical authorisations: should accredited test laboratories play a role in any of these steps?

Many of these aspects are illustrated in the [Accounting and Corporate Regulatory Authority \(Amendment\) Act 2014 of Singapore](#)<sup>47</sup>:

*“28G.*

*(1) An application to be registered by the Chief Executive as a registered qualified individual, or for the renewal of such registration, shall —*

- (a) contain such information and be made in such manner as the Chief Executive may determine;*
- (b) be accompanied by a declaration in such form as the Chief Executive may specify; and*
- (c) be accompanied by such application and registration fees as may be prescribed.*

*(2) A person shall not be registered as a registered qualified individual, or have his registration as such renewed, unless —*

<sup>45</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.

<sup>46</sup> Requisitos Gerais para Declaração da Conformidade do Fornecedor de Produtos.

<sup>47</sup> No. 18 of 2014.

- (a) the person is a qualified individual; and  
 (b) the person has completed such courses and training as may be prescribed.
- (3) The Chief Executive may refuse to register or renew the registration of an individual as a registered qualified individual if —
- (a) the individual has been convicted (whether in Singapore or elsewhere) of any offence involving fraud or dishonesty punishable with imprisonment for 3 months or more;  
 (b) the individual is an undischarged bankrupt, whether in Singapore or elsewhere; or  
 (c) the Chief Executive is otherwise not satisfied that the individual is a fit and proper person to be so registered.
- (4) In determining whether an individual is a fit and proper person under subsection (3)(c), the Chief Executive may consider such factors as may be prescribed.
- (5) The Chief Executive shall refuse to register a person as a registered qualified individual if —
- (a) that person's previous registration as a registered qualified individual had been cancelled because of —
- (i) a breach of a prescribed term or condition of registration; or  
 (ii) a failure to pay a financial penalty imposed because of a breach of a prescribed term or condition of registration; and  
 (b) less than 2 years has elapsed since the date on which the registration was cancelled.
- (6) The registration, or renewal of registration, of a registered qualified individual shall be valid for such period as the Chief Executive may specify.
- (7) An application for the renewal of registration of a registered qualified individual must be made not earlier than 60 days before the date of the expiry of registration.
- (8) The Chief Executive may impose on any registered qualified individual such restrictions pertaining to the use by that individual of the electronic transaction system as the Chief Executive thinks fit.
- (9) Every registered qualified individual shall comply with such terms and conditions as may be prescribed.
- (10) Without prejudice to subsections (12), (13) and (14), the Chief Executive may cancel the registration of a registered qualified individual —
- (a) if the person ceases to be a qualified individual;  
 (b) if there exists any ground on which the Chief Executive would have been entitled to refuse registration or renewal of registration under subsection (3); or  
 (c) if the registered qualified individual applies to the Chief Executive for his registration to be cancelled.
- (11) The Chief Executive may refuse to cancel a registered qualified individual's registration under subsection (10)(c) if the Chief Executive suspects that the registered qualified individual has breached any of the terms and conditions prescribed under subsection (9) and until —
- (a) the Chief Executive has investigated the suspected breach; and  
 (b) the Chief Executive —
- (i) has determined that there was no breach; or  
 (ii) has determined that there was a breach and has either —
- (A) taken action against the registered qualified individual under subsection (12) for the breach; or  
 (B) decided not to take action against the registered qualified individual under subsection (12) for the breach.
- (12) Where a registered qualified individual has breached any term or condition prescribed under subsection (9), the Chief Executive may —
- (a) cancel the registration of the registered qualified individual;  
 (b) suspend the registration of the registered qualified individual for a period not exceeding 12 months;  
 (c) restrict the registered qualified individual's use of the electronic transaction system to such extent as the Chief Executive thinks fit;  
 (d) require the registered qualified individual to pay, within such period as the Chief Executive may specify, a financial penalty not exceeding \$10,000 for each breach of such term or condition; or  
 (e) censure the registered qualified individual."

For much technical regulation, the use of accredited test laboratories has become a fashionable procedural step. Regardless of issues of control (which are basically the same as for Conformity Assessment Bodies), test laboratories are seen as a good tool for either outsourcing technical assessments of authorities or bringing neutrality and reliability into the applicants' self-certification. We present here as example the [Brazilian Portaria INMETRO / MDIC Number 247<sup>48</sup>](#) of 26/05/2014 on the conformity assessment for the retreading of tires. It contains the obligation to use accredited test laboratories. It contains provisions on

- who is in charge of accrediting (14.1 and 14.3),

<sup>48</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.

- what the test laboratories need to do (14.2), and
- under which conditions test reports of internationally accredited test laboratories can be accepted as equivalent (14.3):

*„14.1 Quando do uso de laboratório de ensaio, é responsabilidade do fornecedor a seleção do laboratório a ser contratado para a realização dos ensaios que serão utilizados no processo de registro da Declaração da Conformidade do Fornecedor, devendo ser contratado laboratório acreditado pela Cgcre, para o escopo específico.*

*14.2 Os laboratórios devem verificar, informando no relatório de ensaio, se a amostra do pneu reformado contém as seguintes informações gravadas no pneu:*

*I. Designação do pneu;*

*II. Índice de carga (exceto para pneus diagonais);*

*III. Índice de velocidade;*

*IV. Indicadores de desgaste da banda de rodagem (TWI) com altura mínima de 1,6 mm, com tolerância de + 0,6 mm, e com no mínimo 6 (seis) filas transversais de indicadores, exceto para pneus de diâmetro interno inferior ou igual a 304,8 mm (12”), que devem ter no mínimo 4 (filas) de indicadores.*

*14.3 Para os ensaios realizados por laboratórios estrangeiros devem ser observadas e documentadas a equivalência do método de ensaio e da metodologia de amostragem estabelecida. Além disso, esses laboratórios devem ser acreditados pela Cgcre ou por um acreditador que seja signatário de um acordo de reconhecimento mútuo do qual o Inmetro também faça parte. São eles:*

*a) Interamerican Accreditation Cooperation – IAAC;*

*b) International Laboratory Accreditation Cooperation – ILAC.“*

*Amended machine translation:*

*"14.1 Where there is use of a testing laboratory, it is the supplier's responsibility to select, amongst those laboratories which are accredited by Cgcre for the specific scope, the laboratory to be hired for the tests that will be used in the registration process of the Declaration of Conformity of the Manufacturer.*

*14.2 Laboratories must verify, stating in the test report, that the sample of the retreaded tire contains the following information written on the tire:*

*I. Description of the tire;*

*II. Load Index (except for diagonal tires);*

*III. Speed indication;*

*IV. Tread Wear Indicators (TWI) with a minimum height of 1.6 mm, with a tolerance of  $\pm 0.6$  mm, and at least six (6) transverse rows of indicators, except for tire inner diameter of less than or equal to 304.8 mm (12 "), which must be at least have 4 (rows) of indicators.*

*14.3 For the tests carried out by foreign laboratories, the equivalence of the test method and of the established sampling methodology should be observed and documented. In addition, these laboratories must be accredited by Cgcre or by an accreditor that is a signatory to a mutual recognition agreement to which INMETRO is also party. They are:*

*a) Interamerican Accreditation Cooperation - IAAC;*

*b) International Laboratory Accreditation Cooperation - ILAC ".*

The Portaria (ordinance) does not contain provisions on the criteria and the procedure for accreditation. This is probably a topic regulated elsewhere horizontally. Regulation on the criteria and the procedure for accreditation of test laboratories is often similar to regulation on the designation of Conformity Assessment Bodies. For both but more often for test laboratories, quite a few jurisdictions give an important role to national or international accreditation bodies. Some of these accreditation bodies work for a continent or part of it (see for example: IAAC) and most cooperate with a worldwide accreditation organisation (see for example: ILAC). For some sectors, the worldwide accreditation organisation itself provides for accreditation too. For others, the worldwide accreditation organisation just has the role of coordinating, training and supervising the accreditation bodies and developing common principles and guidelines etc. Accreditors mostly accredit against standards and the criteria contained therein, not against regulation. Regulators who rely on accreditation often give up their own power<sup>49</sup>. This can make sense in many cases and in particular if the regulators feel less competent than accreditors. However, it does not make sense if the technical competence requirements needed for a certain sector are so specific that the international standards or the accreditation bodies cannot grasp them.

The most complex and dense provisions on conformity assessment seen by the author are to be found in the Commission Regulation (EU) No 748/2012 of 3 August 2012<sup>50</sup> laying down rules to be implemented for the airworthiness and environmental certification of aircraft and related products, parts and appliances.

<sup>49</sup> Exceptionally, accreditation bodies accept to accredit against criteria set up by the regulator.

<sup>50</sup> OJ L 224 of 21.8.2012, p. 1

## 7.9. Implementation tasks: Centre, agency or geographic entities?

Four task assignment schemes are most frequently recommended:

- To centralise tasks with the Centre,
- To centralise tasks with a specialised agency, operating under control of the Centre but not necessarily located at the same place,
- To decentralise tasks to geographic entities,
- To partly decentralise to geographic entities.

The advantages and disadvantages of these four task assignments can, from the perspective of the Centre, be resumed as follows:

Responsibility assigned to:	Advantages:	Disadvantages:
Centre	<ul style="list-style-type: none"> <li>- Full control by the Centre,</li> <li>- Harmonised practice across the jurisdiction</li> </ul>	<ul style="list-style-type: none"> <li>- Administrative burden for the Centre,</li> <li>- Little knowledge with regard to the situation in the geographic entities, on the ground,</li> <li>- Highest degree of responsibility for errors</li> </ul>
Agency	<ul style="list-style-type: none"> <li>- High control by Centre,</li> <li>- Harmonised practice across the jurisdiction</li> </ul>	<ul style="list-style-type: none"> <li>- Financial and organisational burden for Centre,</li> <li>- Little knowledge with regard to the situation in the geographic entities, on the ground,</li> <li>- High degree of responsibility for errors</li> </ul>
Full decentralisation	<ul style="list-style-type: none"> <li>- No financial or organisational burden for Centre,</li> <li>- High level of knowledge with regard to the situation in the geographic entities, on the ground,</li> <li>- Low responsibility for errors</li> </ul>	<ul style="list-style-type: none"> <li>- Risk of disharmonised practice across the jurisdiction,</li> <li>- Low control by the Centre</li> </ul>
Partial decentralisation	Subject to the degree of decentralisation: row 1 or 3.	<ul style="list-style-type: none"> <li>- Subject to the degree of decentralisation: row 1 or 3</li> <li>- Risk of uncertainties with regard to the responsibilities</li> </ul>

There are alternatives to the classic assignment schemes based on decentralisation which have not yet been appropriately explored. The classic assignment schemes based on decentralisation contain an implicit assumption: all of the geographic entities have to do the same. But are all geographic entities identical? Do they really have the same capacities, strengths and weaknesses? Is it for instance realistic to expect a geographic entity with less than 3 million inhabitants to create and maintain the technical competence for performing market surveillance in the entire range of products? If the answer is still “yes” today, starting from which degree of further technological sophistication or reduction of tax income must the Centre give up this expectation?

New options are needed. One way to identify new options is to do away with the assumption that all the geographic entities necessarily have to do the same. An asymmetric assignment of tasks is to be considered. Geographic entities with few inhabitants or resources thus could take over some specialised tasks for the entire jurisdiction, but would be assisted by other geographic entities for all other tasks in return. Tasks would be attributed in accordance with specific strengths and weaknesses, avoiding duplication of resources and striving for an increase of the overall output by intelligent task sharing. If this type of co-operation works well in other spheres of life, be it research or industrial co-operation, it might well also work in inter-state co-operation, provided that it is based on a realistic assessment of strengths and weaknesses.

The asymmetric assignment of tasks can take place at two levels:

- Firstly, at the formal level of the legal act,
- Secondly, informally once the geographic entities are made responsible by the legal act.

In both cases the participation with the asymmetric task assignment can also be kept optional. If a few rich geographic entities prefer to trust only their own staff, so be it. For the other geographic entities, the asymmetric task assignment can still provide for a better (market) surveillance per invested staff or money.

As to the centralised assignment schemes, the following alternatives are sometimes worth examination. Firstly, tasks can be attributed via public tenders to public or private organisations that provide for the respective service. Secondly, if there are already organisations exerting the requested or a similar activity, grants might help to strengthen these organisations. Finally, the geographic entities and the Centre can also create a joint assignment of tasks to private operators whilst giving these operators the right to take fees for their services provided for third parties.

## 7.10. Content and density of state ex post verification

Most regulation does not determine precisely what the authorities have to do to supervise operators or citizens. The vagueness can be noted both with regard to the content of surveillance activities and their intensity. Not to determine the minimum verification intensity and the methods of supervision leads to disparities in verification intensity. At worst, the entire system is put at risk because some regional or local authorities do not supervise intensely enough or not in the same way as others. In this situation, a legal intervention of the Centre is not always an option. E.g. if the obligations for ex post verification (“surveillance”) are not precisely defined in the legal act, it would be hazardous for the Centre to intervene legally against geographic entities. To prevent these unfortunate situations, regulation should determine the content and the intensity surveillance obligations of the geographic entities’ authorities in as much detail as possible. Representatives of geographic entities are not always opposed to precise obligations. Precise obligations help them to claim more human resources.

There are relatively few examples of precise surveillance obligations. Commission Regulation EC/589/2008 of 23 June 2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs is a good example:

*“Article 24 - Checks*

1. *The Member States shall appoint inspection services to check compliance with this Regulation.*
2. *The inspection services referred to in paragraph 1 shall check the products covered by this Regulation at all stages of marketing. Apart from random sampling, checks shall be carried out on the basis of a risk analysis, taking into account the type and throughput of the establishment concerned, as well as the operator's past records as regards compliance with the marketing standards for eggs.*
3. *For Class A eggs imported from third countries, the checks provided for in paragraph 2 shall be made at the time of customs clearance and prior to the release for free circulation. Class B eggs imported from third countries shall be released for free circulation only after checking at the time of customs clearance that their final destination is the processing industry.*
4. *Apart from random sampling, operators shall be inspected at a frequency to be determined by the inspection services on the basis of a risk analysis as referred to in paragraph 2, taking account, at least, of:*
  - (a) the results of previous checks;*
  - (b) the complexity of the marketing channels followed by the eggs;*
  - (c) the degree of segmentation in the production or packing establishment;*
  - (d) the quantity of eggs produced or packed;*
  - (e) any substantial changes from previous years in the type of eggs*



*produced or processed or in the marketing method.*

*5. Inspections shall be conducted regularly and be unannounced. Records referred to in Articles 20, 21 and 22 shall be made available on first request to the inspection services.*

*Article 25 - Decisions on non-compliance*

*1. Decisions by inspection services following inspections provided for in Article 24 indicating non-compliance with this Regulation may only be taken for the whole of the batch which has been checked.*

*2. Where the checked batch is deemed not to comply with this Regulation, the inspection service shall prohibit its marketing, or importation if the batch comes from a third country, unless and until proof is forthcoming that it has been made to comply with this Regulation.*

*3. The inspection service which made the check shall verify whether the rejected batch has been or is being made to comply with this Regulation."*

This Regulation contains a complete surveillance system which is based on marking that ensures traceability. Another good example is Commission Regulation EC/642/2009 implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for televisions. It describes precisely what has to be tested and the consequences of negative tests:

*"ANNEX III - VERIFICATION PROCEDURE*

*When performing the market surveillance checks referred to in Article 3(2) of Directive 2005/32/EC, the authorities of the Member States shall apply the following verification procedure for the requirements set out in Annex I.*

*1. Authorities of the Member State shall test one single television unit.*

*2. The model shall be considered to comply with the provisions set out in Annex I, if:*

*(a) the result for on-mode power consumption does not exceed the applicable limit value set out in Annex I, points 1 and 2 of Part 1 by more than 7 %; and*

*(b) the results for off-mode/standby conditions, as applicable, do not exceed the applicable limit values set out in Annex I, points 1(a), 1(b), 2(a) and 2(b) of Part 2 by more than 0,10 Watt; and*

*(c) the result for the peak luminance ratio set out in Annex I, Part 3 does not fall below 60 %.*

*3. If the results referred to in point 2(a) or (b) or (c) are not achieved, three additional units of the same model shall be tested.*

*4. After three additional units of the same model have been tested, the model shall be considered to comply with the requirements set out in Annex I, if:*

*(a) the average of the results for the latter three units for on-mode power consumption does not exceed the applicable limit value set out in Annex I, points 1 and 2 of Part 1 by more than 7 %; and*

*(b) the average of the results for the latter three units for off-mode/standby conditions, as applicable, do not exceed the applicable limit values set out in Annex I, points 1(a), 1(b), 2(a) and 2(b) of Part 2 by more than 0,10 Watt; and*

*(c) the average of the results for the latter three units for the peak luminance ratio set out in Annex I, Part 3 does not fall below 60 %.*

*5. If the results referred to in point 4(a) and (b) and (c) are not achieved, the model shall be considered not to comply with the requirements.*

*6. For the purposes of checking conformity with the requirements, the authorities of the Member States shall use the procedure set out in Annex II and reliable, accurate and reproducible measurement procedures, which take into account the generally recognized state of the art measurement methods, including methods set in documents the reference numbers of which have been published for that purpose in the Official Journal of the European Union."*

Commission Implementing Regulation (EU) No 392/2013 of 29 April 2013 amending Regulation (EC) No 889/2008 as regards the control system for organic production contains a detailed program for enforcement with the help of entrusted private verification bodies, supervision of entrusted private verification bodies, exchange of information between these verification bodies and authorities, risk management, and percentage of verifications and of unannounced verifications.

A useful tool for facilitating the verification by authorities is to oblige operators to provide certain information on the occasion of registering themselves and/or their products, services or other activities. See as example the Brazilian Portaria INMETRO / MDIC No. 649<sup>51</sup> of 12/12/2012, "General Requirements for Declaration of Conformity by Provider of Products"<sup>52</sup> and the database "Orchestra" [www.inmetro.gov.br/qualidade/regobjetos.asp](http://www.inmetro.gov.br/qualidade/regobjetos.asp).

<sup>51</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.

<sup>52</sup> Requisitos Gerais para Declaração da Conformidade do Fornecedor de Produtos.

The Argentinian Law 26.905 of 13 November 2013<sup>53</sup> on the promotion or the reduction of the consumption of sodium by the population enumerates clearly, in its Article 5, the tasks incumbent on implementing authorities. Article 10 provides for the empowerment and duty to establish administrative provisions on the investigations of infringements and subsequent sanctions.

Sometimes it is useful to provide, in the regulation, for an empowerment for enforcement measures such as provided for by Article 20 of the Commission Implementing Regulation (EU) No 391/2013 of 3 May 2013 laying down a common charging scheme for air navigation services<sup>54</sup>.

*„Article 20 - Facilitation of compliance monitoring*

*Air navigation service providers shall facilitate inspections and surveys by the national supervisory authority concerned or by a qualified entity acting on the supervisory authority's behalf, including site visits. The authorised persons shall be empowered:*

*(a) to examine the relevant accounting documents, asset books, inventories and any other material relevant to the establishment of air navigation charges;*

*(b) to take copies of or extracts from such documents;*

*(c) to ask for oral explanations on site;*

*(d) to enter relevant premises, land or vehicles.*

*Such inspections and surveys shall be carried out in compliance with the procedures in force in the Member State in which they are to be undertaken.“*

Regulation EU/228/2013<sup>55</sup> of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006 contains, in its Article 8, an empowerment for the European Commission to determine by regulatory acts detailed provisions on the monitoring of operators:

*„The Member States shall conduct verifications by means of administrative and on-the-spot checks. The Commission shall adopt implementing acts regarding the minimum characteristics of the checks to be carried out by the Member States. The Commission shall also adopt implementing acts regarding the procedures and physical and financial indicators in order to ensure that the implementation of the programmes is monitored in an effective manner. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).“*

Whatever is regarded as the most suitable reference example, surveillance mechanisms need to be adapted to the respective sector and market. There cannot be a standard type of surveillance program for all sectors in all jurisdictions.

## 7.11. Policing by others than by authorities and by Conformity Assessment Bodies

Regulation can provide competitors or associations or other operators with the right to act in order to ensure the compliance of operators. These third parties may act because they are legally obliged to do so (7.10.1). Or they may act voluntarily (7.10.2).

### 7.11.1. Mandatory surveillance by third parties

For some products, it is possible to make importers and distributors responsible for the conformity of products. See as an example the Regulation EU/305/2011 laying down harmonised conditions for the marketing of construction products.

Another approach ensuring enforcement consists in obliging private operators to notify non-compliances or incidents and to publish these notifications thereafter so that other operators can react to these notifications as if they were warnings. Similar mechanisms are to be found in the Commission Regulation EU/16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed.

See as an example of a relatively modern enforcement regime involving economic operators the Commission

<sup>53</sup> The hyperlink broke and could not be replaced.

<sup>54</sup> OJ L128/31 9.5.2013

<sup>55</sup> L78/23 20.3.2013

Proposal for a [Regulation of the European Parliament and of the Council on medical devices](#)<sup>56</sup>. The proposal suggests that importers, distributors, Authorised Representatives of the manufacturers and so-called “responsible persons” are in charge of certain verifications and thus ensure the enforcement of manufacturers' obligations.

Commission Delegated Regulation EU/231/2013<sup>57</sup> of 19 December 2012 supplementing Directive 2011/61/EU of the European Parliament and of the Council with regard to exemptions, general operating conditions, depositaries, leverage, transparency and supervision contains an obligation not of the operators, but of its agents to verify that third parties fulfil their obligations; see its Art. 26(2) 2<sup>nd</sup> subparagraph.

With regard to the involvement of third parties, Argentina goes even further. The [Argentinian Law 26.912 on the legal regime for the prevention and Control of Doping in Sport of 13 November 2013](#) contains, in Article 2, the obligation of sports associations to incorporate certain provisions of a law into their statutes. The law also says that no financial or other public aid may be provided unless there is incorporation of the law into the statutes and full respect thereof.

### 7.11.2. Voluntary surveillance by third parties

It is difficult for state authorities to achieve high intensity surveillance, especially in sectors where there are many actors. Entrusted public utility associations, other associations or simply competitors can fill in the gap. They may exert intense surveillance in their own interests provided they have a powerful tool to enforce legal compliance. One way to achieve this is to give them the right to sue at court. To do this may trigger a completely new industry, like the law against unfair competition did in some jurisdictions. Less of an industry has emerged in the field of environmental law. In this field, some associations received the right to pursue goals of public interest without being themselves concerned (in legal terms) by a measure. A less radical step might consist in giving legal or natural persons the right to complain to and to alert authorities in a centralised procedure. The considerable workload triggered by these complaints has to be weighed against the compliance favouring effect.

A nice example of an effective complaint right provided by the UK government is “the right to contest” the use of public land and buildings; see [here](#). In this case, the state invites the citizens to control the state.

The first crucial element of a voluntary reporting or even whistle-blowing mechanism consists in providing everybody with the right to report, as done by the [Philippine “Free Mobile Disaster Alerts Act”](#)<sup>58</sup>:

“SEC. 5. Report of Violations. – Any natural or juridical person may report before the NTC any violation of this Act.”.

This first step should be accompanied by a clear indication of to whom and by which means the whistle-blowing mechanism can be initiated. See e.g. the standard text in Brazilian regulation under responsibility of the metrology institute INMETRO:

#### 14 DENÚNCIAS

*A Ouvidoria do Inmetro recebe denúncias, reclamações e sugestões, através dos seguintes canais:*

*e-mail: [ouvidoria@inmetro.gov.br](mailto:ouvidoria@inmetro.gov.br)*

*telefone: 0800 285 18 18*

*sítio: [www.inmetro.gov.br/ouvidoria](http://www.inmetro.gov.br/ouvidoria)*

*endereço para correspondência:*

*Ouvidoria - Instituto Nacional de Metrologia, Qualidade e Tecnologia (Inmetro)*

*Rua Santa Alexandrina, 416 – térreo*

*Rio Comprido - Rio de Janeiro – RJ*

*CEP 20261-232*

#### 14 COMPLAINTS

*The Ombudsman of INMETRO receives accusations, complaints and suggestions through the following channels:*

*email: [ouvidoria@inmetro.gov.br](mailto:ouvidoria@inmetro.gov.br)*

<sup>56</sup> COM(2012) 542 final, 2012/0266 (COD)

<sup>57</sup> OJ L83/1 of 22.3.2013

<sup>58</sup> Republic Act No. 10639, published on [June 20, 2014](#).

Phone: 0800 285 18 18  
 site: [www.inmetro.gov.br / ombudsman](http://www.inmetro.gov.br/ombudsman)

mailing address:  
 Ombudsman - National Institute of Metrology, Quality and Technology (INMETRO)  
 Rua Santa Alexandrina, 416 - ground  
 Long River - Rio de Janeiro - RJ  
 CEP 20261-232

A second step consists in ensuring confidentiality and protecting whistle-blowers against direct or indirect sanctions. Detailed empowerments for sophisticated voluntary reporting (and „whistle-blowing“) protection regimes are contained in the Sections 13F and 13G of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#)”

“Voluntary reporting scheme

13F.

—(1) Rules (referred to in this Act as the voluntary reporting rules) may be made by the Minister under this section to establish a scheme —

for the voluntary and confidential reporting of aviation safety issues;  
 to identify deficiencies and problems arising out of such reports; and  
 to provide data for safety improvements to the Singapore aviation system.

(2) The voluntary reporting rules must prescribe for —

the voluntary and confidential reporting of aviation safety issues to one or more persons designated in the rules (referred to in this Part as a designated person);  
 the manner in which such reports are to be made;  
 the use and disclosure by a designated person of information contained in such reports and information the designated person obtains or generates in the course of considering any such report, which shall not be inconsistent with section 13G; and

any other matters necessary or incidental to the establishment or operation of a scheme in accordance with subsection (1).

(3) All voluntary reporting rules made shall be presented to Parliament as soon as possible after publication in the Gazette.

Protection for reporting aviation safety issues

13G.

—(1) Subject to subsection (4), the following:

a report of an aviation safety issue made by a person (referred to in this section as the reporter) to a designated person in accordance with the voluntary reporting rules or any evidence of the contents of such a report; and  
 the fact that such a report of an aviation safety issue was made by the reporter to a designated person,  
 shall not be admissible in evidence against the reporter in any administrative proceedings before any tribunal in Singapore, any civil proceedings or any criminal proceedings before any court other than criminal proceedings for an offence under section 29C.

(2) A person is not entitled to take disciplinary action against his employee using information derived from a report of an aviation safety issue made by the employee to a designated person in accordance with the voluntary reporting rules.

(3) A tribunal is not entitled to make a decision of an administrative character (whether or not in the exercise of a discretion) under any written law against a reporter using information derived from a report of an aviation safety issue made by the reporter to a designated person in accordance with the voluntary reporting rules.

(4) For the avoidance of doubt, this section does not prevent the use of information derived from a source that is not a report of an aviation safety issue made to any designated person in accordance with the voluntary reporting rules.

(5) In this section, “tribunal” includes any person or body of persons constituted and vested by or under any written law to make a decision of an administrative character.”

A third, facultative step consists in creating an incentive. The U.S. has gone quite far in this respect. Their “whistle-blower bounty program” of the [Securities and Exchange Commission](#) promises an award of 10 to 30% of the perceived sanctions. Likewise the [Internal Revenue Service](#) gives substantive awards. More on the latter mechanism is to be found [here](#).

## 7.12. Catalogue of measures for enhanced enforcement

There are numerous possibilities to enhance enforcement beyond the habitual level. Readers might check the following measures:

1. A single complaints portal per region or geographic entity or unique complaints portal for the entire jurisdiction.
2. Connected thereto, an independent complaints investigation unit or institution.
3. A whistle-blowing mechanism that protects against direct or indirect (labour law or criminal) sanctions or discrimination if the whistle-blower acted in good faith (see the example of Singapore in Section 7.11.2 just above).
4. Entrusting one single NGO with receiving and processing complaints whilst ensuring anonymity of the complainant towards all authorities.
5. Provide competitors with the possibility of suing under private law if they suffer from a competitive disadvantage due to the non-fulfilment of duties.
6. Provide environmental organisations with the possibility of suing, as defenders of the public interest, non-compliant operators.
7. Provide for an exemption from sanctions or at least for reduction of sanctions in case one operator reveals a major infringement joint and commonly organised by different operators (classic competition law mechanism).
8. Obligation of regional or local authorities to publish stated infringements of operators („naming and shaming“).
9. Exclusion of companies from public tenders in case of non-fulfilment of duties<sup>59</sup>.
10. Creation of a label for those operators who undergo a voluntary compliance verification program managed by the chambers of commerce or similar semi-public organisations or by conformity assessment bodies engaged by them (entrusted certification).
11. Tax incentives for taking part in a voluntary compliance verification program managed by the chambers of commerce or similar semi-public organisations or by conformity assessment bodies engaged by them (entrusted certification).
12. Creation of a legal basis for redistribution of verification costs to operators or citizens, thereby improving the financial basis of the enforcement authorities.
13. Establishment of minimum resource requirements or at least of parameters for determining how many full-time equivalences (FTE) are needed for enforcement at the level of geographic entities. Parameters could include population, number of operators to be verified, or number of administrative districts. Quantified minimum resources could be, for example: 10 FTE per region and 1 FTE per million population at the central level for the overall management of enforcement (with no other tasks of course). 2 FTE per district and 1 per 100,000 inhabitants in each district.
14. Benchmark regional or local authorities, applying the naming and shaming principle to the geographic entities.
15. Creation of the legal possibility of steering grants away from authorities not willing to enhance enforcement of those which are strongly engaged.
16. Designation of reference laboratories so that evaluation practices in the technical field are de facto harmonised on a high level.
17. Establishment of an information system or information exchange ensuring that verification of compliance undertaken by one geographic entity can also be used by all other geographic entities.
18. Creation of a coordinating authority or of a coordination mechanism for geographic entities.

## 7.13. Limiting own-brand-labelling

In the case of some products, the so-called „Own-brand-labelling“ has become the nightmare of enforcement authorities: the same product appears under a different product name and under the responsibility of different

<sup>59</sup> This is called “debarment” in the U.S.; for examples, see the sources quoted on <http://www.acoel.org/post/2014/05/08/Beware-the-Specter-of-Debarment.aspx>

operators. Instead of one measure, several measures are needed to ban non-compliant products. Incident reporting hardly works because data attributed to one product name and operator are usually not linked to data regarding identical products with different names and their own respective responsible operators (e.g. manufacturers in accordance with the respective definition). Basically, own-brand-labelling can also occur for services and other processes. However, own-brand-labelling is more frequent for products.

How can regulators limit the negative effects of own-brand-labelling?

- A registration obligation and database system linking the various operators participating in own-brand-labelling prior to the marketing of the product or of the service can facilitate authority verification. See as example the Brazilian [Portaria INMETRO / MDIC No. 649](#)<sup>60</sup> of 12/12/2012, “General Requirements for Declaration of Conformity by Provider of Products”<sup>61</sup> and the database “Orchestra” [www.inmetro.gov.br/qualidade/regobjetos.asp](http://www.inmetro.gov.br/qualidade/regobjetos.asp).
- In the case of product legislation, a strict definition of „manufacturer“ can help. A strict definition can for instance consist of defining the „manufacturer“ as the natural or legal person physically manufacturing the product or assembling it at the final stage.
- Often legislation permits that a natural or legal person becomes the „manufacturer“ although the person never comes into contact with the product. In this case, tough obligations can help: if the „manufacturer“ must have full access to the entire technical documentation of the product and its manufacturing process, most of the own-brand-labellers are out of the game – provided that enforcement works. Other obligations that are difficult to be fulfilled by own-brand-labellers are: to be obliged to provide for post-market-follow-up-services with a certain/high degree of technical competence, and obligations to ensure traceability from the raw-materials to the final product and its distribution.
- If the own-brand-labellers have to undergo a complete new conformity assessment, the interest in own-brand-labelling might be reduced.

Of course it is not a goal in itself to eliminate own-brand-labelling. Instead, regulators should reflect in terms of: what needs to be done and which obligations have to be fulfilled without delegation in order to ensure the safety of products and services? And to what extent does own-brand-labelling hinder efficient conformity verification and enforcement? Once a precise analysis has been undertaken, it might turn out that own-brand-labellers do not provide for the same level of safety; hence the need to be very explicit as to the question of who has to fulfil all the obligations and whether / under which conditions the fulfilment of the obligations can be delegated or outsourced by the own-brand-labellers to others natural or legal persons, e.g. the real/physical manufacturers.

How can regulators counter the lobbyists’ call for accepting own-brand-labelling? The best response might consist in analysing whether there really is an economic need for own-brand-labelling. The following analytical questions might help to assess the situation:

- Is there a legitimate need to conceal who, in reality, has designed and/or manufactured a product or who provides a service?
- Wouldn't it be sufficient (for coping with the respective economic interests) for the brands of those who are marketing the product or the service to be affixed to the products or to the publicity material? Consumers will still take a certain product as the own-brand-labeller's product if the product is labelled as such; and this even if the real manufacturer is identifiable on the packaging of the product.
- Can the operator who wishes to become an own-brand-labeller really ensure that he fulfils all the legal obligations of a manufacturer or service provider as defined by the respective regulation? Does he really have the technical knowledge and the technical documentation?

## 7.14. Coping with rogue operators

There are many ways for rogue economic operators to circumvent obligations and state measures. One way is to change the company name or even to shift to another company identity. The same can be done just for the product or service identity. The easiest way is to rename a product or service in such a way that state measures

<sup>60</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.

<sup>61</sup> Requisitos Gerais para Declaração da Conformidade do Fornecedor de Produtos.

against the old product or service cannot be attributed anymore to the „new“ product or service. Operators thus start a "catch me if you can" game with the authorities. There are two measures that may help to counter this practice: (1) setting up comprehensive registration obligations and a database via which the identity of products can be detected (this is evidently problematic in the aspect of burden reduction for operators); (2) inviting or obliging geographic entities to take measures not only against an identified non-compliant product (or service), but also against products (or services) which are identical to the identified non-compliant product (or service). This technique requires careful application in order to respect the principle of legal certainty.

To cope with the phenomenon of changing product/service identities, it is necessary to determine what is to be regarded as one and the same product/service. The most differentiated legislation on this issue so far has been developed in Regulation 168/2013/EU<sup>62</sup> of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles. It contains, in its Article 3 (73) to (75), a precise definition of „type“, „variant“ and „version of a variant“. Furthermore, this Regulation contains detailed provisions on parts and components and provides for a staged approval thereof.

One of the most frequent weaknesses of regulation consists in permitting outsourcing without further conditions. Outsourcing of tasks makes enforcement more difficult, especially if the tasks are outsourced to natural or legal persons outside the respective jurisdiction. The supervision of outsourcing or delegation is therefore of the utmost importance for any legislation on products or services. [Commission Delegated Regulation EU/231/2013](#)<sup>63</sup> of 19 December 2012 supplementing Directive 2011/61/EU of the European Parliament and of the Council with regard to exemptions, general operating conditions, depositaries, leverage, transparency and supervision contains, in its Articles 75 to 82, very detailed conditions for the delegation of tasks.

If outsourcing is authorised without detailed conditions, rogue operators who have been identified by authorities can find a „proxy“ and operate officially as the outsourcing partner of the proxy. At the end of the day, they continue to manufacture products or to provide services, but they do so on behalf of the proxy who assumes the formal responsibility towards customers and authorities. Past authority measures against the rogue operators thereby become void. Even if they have been banned as operators offering the product or service to the clients, they can still operate as a supplier of services, of product components or even of the entire product to the proxy (if own-brand-labelling is authorised). All this does not mean that regulation should never authorise outsourcing – there is often an economic need for outsourcing. However, the regulators should be aware of the risks for enforcement triggered by outsourcing and, if they decide to permit outsourcing, should consider reducing these risks by setting up detailed conditions for outsourcing.

### 7.15. Rights for indemnities as regulatory mechanism

If clients or trade partners have the right to perceive a substantial indemnity in case of infringement of law, operators may refrain from not fulfilling their obligations. In order to have a deterring effect, the indemnity would need to be quite high, but the proportionality principle sets limits in many jurisdictions. Accordingly, this legislative instrument should rather be considered as a complement to enforcement, not as a substitute. See as an example of legislation establishing indemnities the [Indian right to fair compensation and transparency in land acquisition, resettlement and rehabilitation act](#), 2013. See furthermore Article 1(22) of [Regulation \(EU\) No 462/2013](#) of the European Parliament and of the Council of 21 May 2013 amending Regulation (EC) No 1060/2009 on credit rating agencies<sup>64</sup> introducing a new Article 35a into the latter. See also 7.11.2.

### 7.16. Administrative sanctions, fees and securities

Administrative sanctions can be a useful tool to enhance the fulfilment of obligations. Sanctions can target geographic entities, natural or legal persons. As they can also target legal persons, they can be effective in a sector where penal provisions do not suffice.

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<sup>62</sup> OJ L60/52 of 2.3.2013

<sup>63</sup> OJ L83/1 of 22.3.2013

<sup>64</sup> OJ L146/1 of 31.5.2013

See as an example of detailed provisions on administrative sanctions (administrative penalties and other administrative measures), Article 66 of [Directive 2013/36/EU](#) of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms...<sup>65</sup>:

*"Administrative penalties and other administrative measures for breaches of authorisation requirements and requirements for acquisitions of qualifying holdings*

*1. Member States shall ensure that their laws, regulations and administrative provisions provide for administrative penalties and other administrative measures at least in respect of:*

*(a) carrying out the business of taking deposits or other repayable funds from the public without being a credit institution in breach of Article 9;*

*(b) commencing activities as a credit institution without obtaining authorisation in breach of Article 9;*

*(c) acquiring, directly or indirectly, a qualifying holding in a credit institution or further increasing, directly or indirectly, such a qualifying holding in a credit institution as a result of which the proportion of the voting rights or of the capital held would reach or exceed the thresholds referred to in Article 22(1) or so that the credit institution would become its subsidiary, without notifying in writing the competent authorities of the credit institution in which they are seeking to acquire or increase a qualifying holding, during the assessment period, or against the opposition of the competent authorities, in breach of Article 22(1);*

*(d) disposing, directly or indirectly, of a qualifying holding in a credit institution or reducing a qualifying holding so that the proportion of the voting rights or of the capital held would fall below the thresholds referred to in Article 25 or so that the credit institution would cease to be a subsidiary, without notifying in writing the competent authorities.*

*2. Member States shall ensure that in the cases referred to in paragraph 1, the administrative penalties and other administrative measures that can be applied include at least the following:*

*(a) a public statement which identifies the natural person, institution, financial holding company or mixed financial holding company responsible and the nature of the breach;*

*(b) an order requiring the natural or legal person responsible to cease the conduct and to desist from a repetition of that conduct;*

*(c) in the case of a legal person, administrative pecuniary penalties of up to 10 % of the total annual net turnover including the gross income consisting of interest receivable and similar income, income from shares and other variable or fixed-yield securities, and commissions or fees receivable in accordance with Article 316 of Regulation (EU) No 575/2013 of the undertaking in the preceding business year;*

*(d) in the case of a natural person, administrative pecuniary penalties of up to EUR 5 000 000, or in the Member States whose currency is not the euro, the corresponding value in the national currency on 17 July 2013;*

*(e) administrative pecuniary penalties of up to twice the amount of the benefit derived from the breach where that benefit can be determined;*

*(f) suspension of the voting rights of the shareholder or shareholders held responsible for the breaches referred to in paragraph 1.*

*Where the undertaking referred to in point (c) of the first subparagraph is a subsidiary of a parent undertaking, the relevant gross income shall be the gross income resulting from the consolidated account of the ultimate parent undertaking in the preceding business year."*

The [Philippine "Free Mobile Disaster Alerts Act"](#)<sup>66</sup> provides an example of strong sanctions against companies in a quasi-penal context:

*"SEC. 6. Penalties. – (a) Any person who gives false or misleading data or information or willfully or through gross negligence, conceals or falsifies a material fact, in any investigation, inquiry, study, or other proceeding held pursuant to this Act, shall be punished with ...*

*(b) If the offender is a corporation, the penalties may range from the imposition of a fine of not less than One million pesos (P1,000,000.00) but not more than Ten million pesos (P10,000,000.00) and/or a suspension or revocation of its legislative franchise and other permits and licenses by the NTC. The maximum penalties prescribed in paragraph (a) shall also be imposed on the members of its board and/or management, as applicable."*

The beginning of (b) is, however, problematic: the formulation "If the offender is a corporation" suggests that persons acting on behalf of the corporation are not subject to punishment and the deterrent effect of the penal provision under (a) is reduced. If this is not intended, regulators should choose another formulation such as: "If the offence has been committed on behalf of a corporation, the corporation is subject to additional penalties. The penalties may range from ...".

Provisions on sanctions may include the right of the authority to confiscate:

<sup>65</sup> OJ L 176/338 of 27.6.2013

<sup>66</sup> Republic Act No. 10639, published on [June 20, 2014](#).



- profits generated by illegal activities, or
- the assets of the targeted natural or legal person.

Similar to administrative sanctions, fees for administrative procedures may be used not only to obtain funds for authorities, but also to influence the behaviour of private operators. E.g. manufacturers split their production into many differently labelled “products” which are basically identical; an administrative fee per product will trigger second thoughts on the part of the manufacturer. Fees for the verification of certain aspects by the authority can create an incentive to perform well and to limit the number of independently labelled “products” or “services”.

Financial sanctions and fees might be appropriate tools for natural persons and companies of small and medium size. But are they sufficient for multinational companies? Particularly in the U.S., there is a debate on how to deal with multi-national companies for purposes of enforcement. Some authors claim that classic sanctions like fines do not deter big multinational companies (“goliath-corporations”) from infringing the law. One author [suggests](#) that other sanctions are needed, namely suspending trading in a goliath-corporation’s stocks. However, the scepticism of this author might be exaggerated. Several banks were fined by the U.S. in unprecedented heights in 2014. Fines of 10 billion Dollars or more have even been imposed on the biggest multinational companies. Thus there is only one simple question: are the fines high enough?

It is sometimes preferable to foresee not just fees, but also securities/guarantees. [Regulation EU/228/2013](#)<sup>67</sup> of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006 contains, in its Article 12, an empowerment for the EU Member States to request securities:

*„2. No security shall be required when applying for import licences, exemption certificates or aid certificates. However, to the extent necessary to ensure the proper application of this Regulation, the competent authority may require a security to be lodged equal to the amount of the advantage as referred to in Article 13. In such cases, Article 34(1), (4), (5), (6), (7) and (8) of Commission Regulation (EC) No 376/2008 of 23 April 2008 laying down common detailed rules for the application of the system of import and export licences and advance fixing certificates for agricultural products shall apply.“*

## 7.17. Penal provisions / deterring managers of companies

Sanctions against companies do not always suffice to deter unlawful behaviour. Above all small companies can easily close business in case infringement of the law is detected. The managers or owners can get away without being harmed and may set up a new company next door to continue their unlawful business. To prevent this, it might be helpful to set up liability and even criminal responsibility for natural persons in charge of companies committing unlawful acts. This is done in Section 7 of the [Indian Unlawful activities \(prevention\) Amendment Act, 2012](#). This act places even the burden of proof for absence of knowledge and for the fulfilment of due care on the side of natural persons.

The [Graphic Health Warnings Law of the Philippines](#)<sup>68</sup> provides for precise provisions on penalties, also covering the case of repeated infringement:

*”SEC. 14. Penalties for Noncompliance. –*

*(a) The following penalties shall individually apply to manufacturers, importers, and distributors of tobacco products as well as their agents/representatives for any violation of Sections 6 and 7, and Section 11 insofar as they are responsible for providing display materials that are in violation of this Act:*

*(1) On the first offense, a fine of not more than Five hundred thousand pesos (P500,000.00);*

*(2) On the second offense, a fine of not more than One million pesos (P1,000,000.00); and*

*(3) On the third offense, a fine of not more than Two million pesos (P2,000,000.00) or imprisonment of not more than five (5) years, or both, at the discretion of the court: Provided, That the business permits and licenses, in the case of a business entity or establishment shall be revoked or cancelled.*

*If the guilty officer is a foreign national, he shall be deported after service of sentence and/or payment of applicable fines without need of further deportation proceedings and shall be permanently barred from re-entering the Philippines.*

<sup>67</sup> OJ L78/23 of 20.3.2013

<sup>68</sup> Republic Act No. 10643, published on [July 15, 2014](#).

*Each withdrawal or importation into the Philippine customs territory of noncompliant tobacco packages, regardless of size, for sale to the market, after the compliance date shall constitute one (1) offense. An additional penalty of One hundred thousand pesos (P100,000.00) per day shall be imposed for each day the violation continues after having received the order from the Department of Trade and Industry (DTI) notifying the company of the infraction.“*

The Senegalese Law No. 2014-01 of January 6, 2014 relating to the treatment of dormant accounts in the books of financial institutions of the Member States of the West African Monetary Union (WAMU) provides for a simple and precise sanction scheme. It also determines who shall decide on the sanctions and whereto the money shall go:

*“Art. 19. - Est passible d’une sanction pécuniaire dont le montant est égal au quart du montant du solde créditeur du compte dormant concerné, tout organisme dépositaire qui contrevient aux dispositions de la présente loi. En cas de récidive, la sanction visée à l’alinéa précédent est fixée à cent pour cent (100%) du solde dudit compte. Les sanctions pécuniaires à l’encontre d’un Etablissement de Crédit ou d’un SFD sont prises, selon le cas, par la Commission Bancaire, la BCEAO ou le Ministre chargé des Finances. Les sanctions pécuniaires à l’encontre d’un service financier de la Poste ou d’une Caisse Nationale d’Epargne sont prises par le Ministre chargé des Finances. Les sommes correspondantes sont recouvrées pour le compte du Trésor public du lieu de tenue du compte dormant, selon le cas, par la Banque Centrale ou par le Ministère chargé des Finances.“*

Amended machine translation:

*“Art. 19 -. Any depository body who contravenes the provisions of this Act shall be liable to a penalty of an amount equal to one quarter of the amount of the credit balance of the dormant account concerned. In case of recidivism, the penalty referred to in the preceding paragraph shall be one hundred percent (100%) of the balance of the account.*

*Monetary sanctions against a Credit Institution or SFD are taken, as appropriate, by the Banking Commission, the BCEAO or the Minister of Finance. Monetary sanctions against financial service of the Post or of a National Savings Bank are taken by the Minister of Finance.*

*The corresponding sums are collected on behalf of the Treasury of the place of holding of the dormant account, as appropriate, by the Central Bank or by the Ministry of Finance.”*

## 7.18. Responsibility of associated companies

The [Brazilian Lei N°- 12.846](#), of 1 August 2013 “Provisions on the administrative and civil liability of legal persons for the commission of acts against the national or foreign public administration, and other matters”<sup>69</sup> sets up, in its Article 4 Paragraph 2, a joint and common liability for controlling, controlled, affiliated, or consortium partners. Its Article 4 Paragraph 1 contains the liability rules for cases of merger or acquisition. Any liability in case of merger or acquisition is limited to the value of the company taken over:

*„Art. 4º Subsiste a responsabilidade da pessoa jurídica na hipótese de alteração contratual, transformação, incorporação, fusão ou cisão societária.*

*§ 1º Nas hipóteses de fusão e incorporação, a responsabilidade da sucessora será restrita à obrigação de pagamento de multa e reparação integral do dano causado, até o limite do patrimônio transferido, não lhe sendo aplicáveis as demais sanções previstas nesta Lei decorrentes de atos e fatos ocorridos antes da data da fusão ou incorporação, exceto no caso de simulação ou evidente intuito de fraude, devidamente comprovados.*

*§ 2º As sociedades controladoras, controladas, coligadas ou, no âmbito do respectivo contrato, as consorciadas serão solidariamente responsáveis pela prática dos atos previstos nesta Lei, restringindo-se tal responsabilidade à obrigação de pagamento de multa e reparação integral do dano causado.“*

Amended machine translation:

*„Article 4 There remains the responsibility of the legal entity in the event of contractual change, transformation, incorporation, merger or spin-off.*

*§ 1 In the event of a merger or amalgamation, the responsibility of the successor will be limited to the obligation to pay fines and full compensation for the damage done, up to the limit of the assets transferred. Other penalties provided in this Act arising out of acts and facts occurred before the date of the merger or consolidation, except for simulation or apparent intention of fraud, duly attested, are not applicable to him.*

*§ 2 The parent companies, subsidiaries, affiliates or the consortium partners of the respective contract will be jointly and severally liable for the performance of acts mentioned in this Act. This responsibility is limited to the obligation to pay fines and full compensation for the damage caused.“*

<sup>69</sup> „Dispõe sobre a responsabilização administrativa e civil de pessoas jurídicas pela prática de atos contra a administração pública, nacional ou estrangeira, e dá outras providências“.

## 7.19. E-commerce and private imports

### 7.19.1. Learning from extreme cases

The Internet has become a big challenge for authorities dealing with products and services. Confronted with the emergence of all kinds of cross-border internet trade and services, authorities tend to wait and see where problems arise, analyse them, think of measures and implement them. This is the classic method, appropriate for classic structures and mechanisms. However, is it appropriate in the case of fast evolving economic phenomena like internet business or financial markets? Doesn't it lead to a cat-and-mouse game that the economic operators always win? Readers might test another working method: the extreme case method. The extreme case method consists in identifying or imagining the worst that an operator could do, analysing the elements of his business model / construction and think about the means necessary to hinder a rogue operator from being efficient.

Let us take an example. The „meanest“ or trickiest business construction the author encountered so far was the following: an economic operator, presumably based in Mauritius, offered products via a website in several languages, amongst them German, to private households and businesses. In absence of other information we therefore must conclude that the operator was targeting the markets in Germany, Austria and Switzerland. In all three states, the respective products are regulated and submitted to a conformity assessment procedure. The manufacturers of the products came from all parts of the world. The products and their manufacturers have not undergone the respective conformity assessment procedure. The placing on the market in the three states would therefore be illegal for many of the products offered. The business conditions visible on the website stipulate that the purchase contract is concluded under the law of Mauritius, and Mauritius is the place of fulfilment of all obligations. The business conditions furthermore stipulate that the clients have to assess whether the import of the products into the clients' states is legal or not. The operator was aware of the fact that he might face sanctions either for being regarded as manufacturer placing products on the market or as their importer (as the products do not fulfil legal conditions of the targeted states). Therefore, it was stipulated that the operator does not ship the products anywhere. Instead, the clients had the possibility of ordering separately shipping services provided by a single service provider. Shipping was thus the subject of an additional contract for which the operator is at best liable as a kind of broker, but probably not liable at all under the law of Mauritius.

What else could the operator have done to protect himself? He could have had his web shop hosted by a hosting service provider outside the targeted states and not in Mauritius, making it even more difficult to get his web shop closed. He could have let the clients choose amongst various shipping services and their service providers to stress that the shipping contract is truly disconnected from the purchase contract. He could have offered only brokering services between the manufacturers or distributors and the clients instead of selling any products himself. If there were no manufacturers or distributors ready to sell under these conditions, he could have created a distributor company himself, placed in another state where there is a weak or corrupted judicial system or no applicable laws at all. For some of the products, he could have declared them to be components or spare parts, thus avoiding the formal applicability of the product legislation of the targeted states (most product legislation does not cover components and spare parts yet). For some other products, he might have decomposed them, selling the components separately (by separate contracts) and leaving it to the client to re-assemble the components so that a usable product is created by the client in the targeted states only. Thus, subject to the applicable product definition, no placing on the market of a product would take place. The cornerstone of product legislation, the placing on the market of a defined product, can be circumvented by this technique.

Another extreme case which is already occurring in the millions has to do with internet-based 3D-printing. „Manufacturers“ in or outside the jurisdiction in question may sell data-sets which allow their clients to 3D-print devices on any 3D-printer they have access to. Thus it is not a device that is sold, but a data-set or a blueprint. But not only are these data-sets or blueprints sold; many of them are even made available for free. This dissemination is part of a large citizens' movement for an alternative economy without patents. The dissemination often takes place in accordance with free licences like the creative commons licences. Those making the data-set or the blueprint available are mostly pure (professional or hobby) designers, architects or engineers, not manufacturers. And even worse: many of these data-sets or blueprints have been developed by P2P production, thus they have so many fathers and mothers that you cannot trace it back to an individual anymore. Accordingly the notion of “manufacturer“ dissolves as does the notion of „product“ and of the „placing on the market“ thereof.

Keeping these two extreme cases in mind, we can develop appropriate measures, countering key elements of current and to-be-expected business practices. We skip here the one-by-one analysis of the elements described in the two extreme cases to present immediately a package of measures which indeed counter many of the elements described and a few more enforcement difficulties that have emerged in the past.

### 7.19.2. Clarifying applicability

The first step for successfully countering problematic e-commerce practices consists in ensuring the applicability of the substantive requirements contained in regulation. Problematic e-commerce practices should not fall into a regulatory loophole. To reach that goal, a number of different measures can be considered. See here two examples:

- Regulation can establish distinct obligations for those bringing products into the jurisdiction, even if they do so for private use. This is common practice in customs law.
- Regulation can also clarify that it is applicable to products or services offered to clients on the territory of its jurisdiction.

The regulation of a certain jurisdiction is normally applicable as soon as a certain product or service is offered to clients in that jurisdiction. But how to determine whether a product or service has been offered to clients in a certain jurisdiction if the offer is made on the internet? Various criteria may be applied both at the level of legal interpretation or, preferably, when drafting the regulation:

- The broadest criterion is that the economic operator can only claim not to offer his products or services to clients from the respective jurisdiction if the clients are explicitly excluded.
- The most restrictive criterion is that the operator must offer the products or services explicitly to clients in that jurisdiction. Otherwise, he would not be regarded as targeting the jurisdiction.
- In between, one can imagine a variety of vague formulas like “appearing to target the jurisdiction”.

There are at least three subsidiary criteria which may in particular help if a vague formula has been established:

- If the products or services are also offered in a language which is specific enough to be linked to a jurisdiction, the economic operator cannot claim that he did not intend to target the jurisdiction.
- If the prices are also indicated in the currency of the respective jurisdiction, the jurisdiction is most probably being targeted.
- If the shipping of products to the respective jurisdiction is possible, the economic operator cannot claim that he did not intend to deliver to that jurisdiction.

Legislating on services provided outside the respective jurisdiction and on goods delivered from outside the jurisdiction to customers inside the jurisdiction does not normally go beyond the legislator's capacity / is not „ultra-vires“. This becomes clear if you look at examples in other legal fields: national penal laws punish acts committed outside the legislator's territory against its own citizens. Forgery of the legislator's currency and stamps is a sanctioned penalty regardless of where the act was committed and regardless of the nationality of the forger. Likewise, for taxes on services offered from abroad, the destination principle has been introduced recently in various national jurisdictions. The movement apparently started in India<sup>70</sup>, followed by China<sup>71</sup>. In these jurisdictions services are to be taxed at the place of residence or business of the customer.

### 7.19.3. Robust enforcement powers

To counter problematic practices and infringements in internet trade and services, authorities should, in a second step, receive comprehensive empowerments to do at least the following:

- to request from importers, wholesalers, retailers, trading platforms, website hosting services and domain

<sup>70</sup> see <http://www.servicetax.gov.in/imp-service-rules.htm>

<sup>71</sup> see <http://www.lexology.com/library/detail.aspx?g=e5c580b0-7432-445e-9615-2e9c6aa58303>

registrars the disclosure of data both on the identity of the economic operators offering goods or services and on individual transactions;

- to request from importers, wholesalers, retailers and trading platforms that they only offer products or services manufactured / provided by natural or legal persons with a clearly defined identity, place of business, internet and email address;
- to request from importers, wholesalers, retailers and trading platforms that they only offer products or services to natural or legal persons who disclose their identity, place of business, internet and email address of their suppliers and service providers upstream the supply chain;
- to request from importers, wholesalers, retailers and trading platforms that they only offer products or services to natural or legal persons who make accessible authorisations, certificates and other proof of conformity of their products or services (e.g. proof of registration in case of a registration obligation, proof of labelling in case of a labelling obligation, instructions for use);
- to request from importers, wholesalers, retailers and trading platforms access to real-time information about the shipment of goods, even if the shipment is operated by a service provider acting on behalf of the economic operator or on behalf of the client (so that the goods can be captured either when entering the jurisdiction or within the jurisdiction before reaching the client);
- to ban certain economic operators from trading platforms or to oblige the trading platforms not to display the offers of these operators to clients from one's own jurisdiction,
- to oblige trading platforms and other economic operators to display information on the rights of their costumers (e.g. consumer rights);
- to close the business of importers, wholesalers, retailers and trading platforms with the assistance of the website hosting service/operator;
- to confiscate the domain in case of continued fraudulent activity (otherwise the rogue operator can simply engage another website hosting operator and continue his business under the same domain);
- to open parcels unless the content is declared and, if it is a regulated product, information on its conformity assessment – e.g. via a web link - is provided;
- to radio-scan parcels to check whether the declared content is identical with the real content and presumably in conformity with substantial legal requirements;
- to open, to examine and to confiscate parcels when there is a suspicion that the product is not in conformity with legal requirements;
- to confiscate the payment made for a non-compliant product or service;
- to buy a product or to order a service “under cover” (as if the authority agent was a normal client);
- to impose financial sanctions against the operators and the natural persons acting on behalf of the operators, the latter being enforceable when the natural persons enter the territory;
- to impose penal sanctions against the natural persons acting on behalf of the operators, enforceable when the natural persons enter the territory.

Subject to the jurisdiction, most of the enforcement powers and empowerments to oblige economic operators need to be laid down in specific regulation. In some jurisdictions, it might be better to create within the regulation fully-fledged obligations of economic operators, paired with enforcement mechanisms, instead of empowering the authorities to create such an obligation by administrative acts. Above all for the first five indents this path will be often preferable. Further strengthening of enforcement can take place if enforcement by private operators is considered, as suggested above.

#### 7.19.4. International cooperation

The full enforcement of obligations in cross-border internet trade and services will require the cooperation of major or all jurisdictions by international conventions. This cooperation, hardly existing today, might, in the long run, resemble international cooperation in judicial matters. It will thus be extremely difficult to establish. Probably, it will only cover the severest cases of criminality. This perspective is admittedly not very attractive. But the only alternative thereto has to the knowledge of the author not yet been tested: several jurisdictions could establish, in their domestic legislation, empowerments for providing assistance to each other. If, at an administrative level, agreement on reciprocity has been reached amongst the administrations, cooperation could be initiated by regulatory acts other than legislation (adopted by the administration) or even by simple administrative acts in

individual cases. This construction is similar to the empowerments for unilateral recognition of foreign certificates which are often used only once an informal agreement on reciprocity has been reached amongst the administrations concerned. It would bring along with it flexible mutual enforcement assistance. However, it might be legally problematic in quite a few jurisdictions. Classic international public law providing for such mutual assistance will probably remain the default solution.

#### 7.19.5. Approaching trading platforms

Pending and upstream to formal or informal international agreements on cross-border internet trade and services, jurisdictions can separately or jointly approach the major trading platforms of the respective sector to agree informally on conformity ensuring measures with them. It might be that these trading platforms have an interest in responding positively to calls of authorities to counter certain practices of economic operators, above all if these practices may cause damage to the users of the trading platforms. The following measures could be applied by these trading platforms voluntarily via their business conditions and the programming of their websites; they could even be imposed on them by specific regulation:

- Obliging economic operators to display information on the conformity assessment of regulated products or services, e.g. by web link;
- Obliging operators to disclose (better online, but at least to the authorities) the major components and substances/materials used;
- Obliging operators to disclose (better online, but at least to the authorities) the supply chain for major components or service providers and for substances/materials used, ensuring traceability;
- Informing the clients of their rights;
- Informing the clients of the legal requirements applicable for the product in question, inviting them to verify compliance;
- Establishing an alert mechanism in case clients think they detect non-conformities.

#### 7.20. Covering de-constructed products

Some manufacturers sell components or ingredients, inviting the clients to compose the components or ingredients into the final product. Some manufacturers do so for legitimate reasons. E.g. voluminous furniture cannot be cheaply transported in one piece. Partly decomposing the furniture is justified. However, where does this end? A furniture market leader sells products partly so deconstructed that clients must possess certain crafting skills to assemble them. This example shows that a certain responsibility is shifted onto the clients. Assembling furniture is not without risks, both during the exercise of assembling and afterwards. Is the responsibility shift compatible with a legal requirement to reduce risks for clients? Should regulation set explicit limits for what can be shifted to the clients?

A further issue arises if the products can be assembled in different ways so that either a legal or an illegal product is created. E.g. there are cosmetics which are sold by ingredients. The proportion of a certain ingredient can be increased by the client so that the legal threshold is passed. Should this be tolerated? If not, explicit provisions hindering this practice are needed.

And what about the open source movement that provides for construction instructions for everything up to complicated machines? Shall devices produced in accordance with open source construction instructions be free of all legal requirements? See the [Global Village Construction Set](#) as an example of how far the movement has already gone.

Behind these cases, there is a more fundamental issue: when is a product a product? Starting from which degree of deconstruction can we not refer to a 'product' anymore? In the extreme case, only a set of components or ingredients or a set of instructions is made available, and it is up to the clients to decide what they do with them. At first one might think that this is not an issue for product legislation. However, one might have second thoughts when considering that certain ingredients of fertilizers can equally be used for creating explosives and that certain mechanical components can be used for manufacturing arms as well as civil products. At least in cases where the instructions for use give advice on how to create a problematic product, there are issues to be regulated on the fringe of classic product regulation.

These questions and the phenomena described in Section 7.19.1 (and in particular the example of 3D-printing) could trigger more general thoughts: we might need new legislative cornerstones if the notions “manufacturer“, „product“ and „placing on the market“ lose their meaning. Future legislation might instead set up requirements applicable to devices regardless of the existence of a manufacturer. Future legislation might also refer to another reference point for establishing legal requirements: instead of referring to the placing on the market, legislation might refer to the physical creation or to the putting into service / first use of a device (as some legislation already does today). Future legislation might also set up requirements for devices in use (which would include devices other than new ones). Requirements for devices in use already exist in some sectors, e.g. for vehicles.

## 7.21. Services and products provided from zones without state control

There are two developments which lead to the fact of services and products being provided from zones which are not under control of a state recognised by international public law:

- States losing control of a part of their territory, e.g. following a secession movement or civil war. Such zones outside the states' control currently exist in Moldavia (Transnistria, also called Trans-Dniestr or Transdnestrria), Georgia (Abkhazia), Somalia (Somaliland which ironically has more characteristics of a functioning state than the rest of Somalia).
- Internet and technology giants of Silicon Valley preparing the creation of huge swimming platforms in the international sea from which entrepreneurs can operate without being hindered by laws on privacy, worker protection etc. The strategic planning is made by the so-called Seasteading Institute. A first project of this kind is a transformed cruise ship swimming close to Silicon Valley in international waters, see <https://blueseeds.co>.

Services and products provided from outside any state-controlled areas raise a wide range of specific issues. Certain legal requirements, e.g. relating to a “state of origin”, cannot be applied to these entities. It might be difficult to find in these entities a negotiation counterpart to tackle issues. The entities are not recognised and not even recognisable under international public law. The entities do not necessarily have any interest in introducing requirements similar to the ones introduced by states, and even less so where they have an interest in applying requirements of states.

How can jurisdictions cope with this phenomenon? A range of instruments can be thought of, though none of them is a panacea:

- Stipulating by regulation that products and services must have a state of origin and attributing products and services by default to the closest recognised state or to the state to which the territory belonged in the past.
- Obliging shipping operators to alert customs authorities about parcels coming from non-state entities.
- Informing business and citizens of the particular risks when contracting with operators in non-state entities (e.g. absence of legal guarantees / no enforcement possible).
- Exerting pressure on shipping operators so that they do not deliver to or from non-state entities which are commonly used for circumventing legal requirements.
- Exerting pressure on financial service providers so that they do not transfer money to or from non-state entities which are commonly used for circumventing legal requirements.
- In extremely criminal cases, banning financial transactions with operators in non-state entities in order to oblige the operators to establish a place of business in a state. Of course, this is only efficient if many jurisdictions make this step together.

## 7.22. Consequences of non-conformities or negative test results

Enforcement authorities often struggle with cases in which there is doubtless non-conformity, but for which no clear consequence of the non-conformity has been determined by regulation. In these cases, the question often arises: is the non-conformity important enough to ban the product, service or activity in question? To avoid this uncertainty, it is useful to link in the regulation all different types of non-conformity with appropriately severe legal consequences. Legal consequences can e.g. be: rejection of the authorisation or certification, suspension of the authorisation or certification, prohibition to exert a certain activity, limitation of or conditions for exerting a certain

activity, additional verification measures, additional procedural obligations (like partial re-authorisation or re-certification), or undergoing special training courses.

A good example can be found in Section 6.2, table 2 of the [Brazilian Portaria n.º 576](#)<sup>72</sup>, of 28 November 2013 „Requirements for conformity approvals for baby bottles and nipples for baby bottles“ (Requisitos de avaliação da conformidade para mamadeiras e bicos de mamadeiras). This regulatory act determines exactly the number of tests to be undertaken and how many of the tests must be negative to justify the rejection of a product.

The [Brazilian Portaria INMETRO / MDIC Number 247](#)<sup>73</sup> of 26/05/2014 on the conformity assessment for the retreading of tires contains a shorter instruction on the number of tests to be conducted and what happens in case of negative test results. Furthermore, it highlights the relevance of doing the right sampling and determining the test setting:

*„D.1.1 Definição dos ensaios a serem realizados*

*D.1.1.1 Os ensaios devem ser realizados em laboratório acreditado, de acordo com os requisitos estabelecidos pelo RTQ para o Serviço de Reforma de Pneus e de acordo com a respectiva família descrita no subitem 4.5 deste RAC.*

*D.1.1.2 Os ensaios devem ser realizados em uma amostra de prova. No caso de reprovação desta amostra, o ensaio deve ser repetido nas amostras de contraprova e testemunha, devendo ambas serem aprovadas.*

*D.1.2 Definição da amostragem*

*A amostragem deve ser realizada por família de acordo com o subitem 4.5 deste RAC, composta por 01 (uma) unidade de prova, 01 (uma) unidade de contraprova e 01 (uma) unidade de testemunha.“*

*Amended machine translation:*

*"D.1.1 Definition of tests to be performed*

*D.1.1.1 The tests shall be conducted in an accredited laboratory in accordance with the requirements established by RTQ for Service Tyre Retreading and according to their families described in subsection 4.5 of this RAC.*

*D.1.1.2 The tests must be conducted with a test sample. In case of failure of this sample, the test must be repeated with a rebuttal and a witness sample, and both should be approved.*

*D.1.2 Definition of sampling*

*Sampling must be performed by family in accordance with subsection 4.5 of this RAC, consisting of 01 (one) unit test, 01 (one) unit of rebuttal and 01 (one) unit of witness.“*

<sup>72</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.

<sup>73</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.



### 7.23. Burden, means and degree of proof

Enforcement can easily fail if the applicable rules on the burden of proof are difficult to fulfill on the part of the authorities. Furthermore, the interpretation of the rules on the burden of proof may deviate from one state, region or district to the next. To avoid this, regulators may think about establishing rules on the burden of proof and the degree of likelihood requested to state whether a certain condition is fulfilled.

The [Argentinian Law 26.912 on the legal regime for the prevention and Control of Doping in Sport of 13 November 2013](#) contains, in its Article 16, rules on burden of proof and degree of likelihood requested for assuming doping. Article 17 of that act provides rules on means of proof, mixed with procedural elements. These two articles contain the most sophisticated provisions on proof that the author has come across in regulation outside criminal law:

*„ARTICULO 16.- Carga y grado de la prueba del dopaje. Recae sobre la organización antidopaje la carga de probar que se ha producido una infracción de la norma antidopaje. El grado de la prueba debe ser tal que la organización que haya establecido la infracción de las normas convenza al tribunal interviniente teniendo en cuenta la seriedad de la afirmación que hace. El grado de la prueba debe ser mayor al de un justo equilibrio de probabilidades pero inferior a la prueba más allá de cualquier duda razonable. Cuando el presente régimen haga recaer en un atleta o en cualquier otra persona que supuestamente hubiera cometido una infracción la carga de invertir tal presunción o de establecer la existencia de circunstancias o hechos específicos, el grado de la prueba debe ser el justo equilibrio de posibilidades, excepto en los casos contemplados en los artículos 26 y 32 del presente régimen, en los que recae sobre el atleta una mayor carga de la prueba.*

*ARTICULO 17.- Medios de establecer hechos y presunciones. Los hechos relativos a infracciones de la norma antidopaje pueden probarse por cualquier medio legítimamente obtenido, incluida la confesión. Las siguientes normas de prueba son de aplicación en los casos de dopaje:*

*a) Se presume que los laboratorios acreditados por la Agencia Mundial Antidopaje realizan análisis de muestras y aplican procedimientos de custodia de conformidad con la norma internacional para laboratorios. El atleta u otra persona pueden desvirtuar esta presunción demostrando que se ha producido una desviación, con respecto a la norma internacional, que podría haber causado razonablemente el resultado analítico adverso. En este caso, recae sobre la organización antidopaje la carga de demostrar que esa desviación no pudo haber sido el origen del resultado analítico adverso;*

*b) Toda desviación con respecto a cualquier otra norma internacional u otra norma o política antidopaje que no haya supuesto un resultado analítico adverso u otras infracciones a las normas antidopaje, no invalida tales resultados. Si el infractor demuestra que una desviación con respecto a otra norma internacional u otra norma o política de control del dopaje podría haber causado razonablemente el resultado analítico adverso, recae sobre la organización antidopaje la carga de establecer que esa desviación no ha originado la infracción a la norma antidopaje;*

*c) Los hechos demostrados en una sentencia firme del Tribunal Nacional Disciplinario Antidopaje constituyen una prueba irrefutable contra el atleta o la otra persona a los que afecte la sentencia sobre tales hechos, a menos que alguno de ellos demuestren que dicha sentencia contraviene los principios generales del derecho; ... “*

Amended machine translation:

*"ARTICLE 16 -. Burdens and standards of proof of doping. Anti-doping Organizations have the burden of proving that there has been a violation of an anti-doping rule. The standard of proof should be such that the organization which has established the infringement of the rules convinces the intervening court, considering the seriousness of the allegation. The degree of proof must be greater than a mere balance of probability but less than "proof beyond any reasonable doubt". When this scheme places on an athlete or anyone else who has allegedly infringed the law the burden of inverting such a presumption or of establishing the existence of special facts or circumstances, the standard of proof should be the right balance of probabilities, except in the cases specified in Articles 26 and 32 of this scheme, under which a greater burden of proof falls on the athlete.*

*ARTICLE 17 -. Means of establishing facts and presumptions. The facts relating to anti-doping rule violations may be proved by any means lawfully obtained, including admissions. The following rules of evidence are applicable in doping cases:*

*a) It is assumed that the laboratories accredited by the World Anti-Doping Agency conducted sample analysis and custodial procedures in accordance with the International Standard for Laboratories. The athlete or other person may rebut this presumption by establishing a deviation from the international standard, which could reasonably have caused the adverse analytical finding. In this case, the anti-doping organization has the burden of establishing that such deviation could not have been the origin of the adverse analytical finding;*

*b) Any deviation from any other International Standard or other anti-doping rule or policy which did not cause an adverse analytical finding or any other anti-doping rule violation does not invalidate such results. If the offender shows that a deviation from another International Standard or other standard or doping control policy could reasonably have caused the adverse analytical finding, the Anti-Doping Organization has the burden of establishing that such a deviation did not cause the violation of doping rule;*

c) *The facts established by a final determination of the National Anti-Doping Disciplinary Tribunal constitute irrefutable evidence against the athlete or the other person whom the judgment on those facts affects, unless any of them show that the judgment is contrary to the general principles of law; ... "*

## 7.24. Assistance by other administrations, public and private entities

Administrations need often assistance in order to find relevant information and means of proof. Sometimes they even need assistance for the enforcement of administrative acts. Unless it is already covered by existing law, it can be helpful to create an obligation for other administrations or public enterprises to assist in the fulfilment of tasks derived from the new regulation. See as an example the [Philippine "Lemon Law" on the protection of consumers buying motor vehicles](#)<sup>74</sup>:

*"SEC. 12. Assistance by Other Agencies. – The DOTC and other agencies, political subdivisions, local government units, including government-owned and/or controlled corporations, shall render such assistance as required by the DTI in order to effectively implement the provisions of this Act."*

We have seen in Section 7.19 that administrations sometimes even need assistance from private companies to enforce administrative acts and to obtain information or means of proof. Accordingly, regulators should check whether they need to build specific empowerments into their regulation so that the enforcement authorities can formally request support from other authorities or public or private entities.

## 7.25. Attributing responsibility to courts or administrations

It can be necessary to clarify which court or administration is in charge of tasks and responsibilities linked to the regulation. See as example Section 10.A of the [Implementing Rules and Regulations of the Anti-Bullying Act of 2013 of the Philippines](#)<sup>75</sup>:

*"Complaints of bullying and other acts under this IRR shall be within the exclusive jurisdiction of the Department or the private school and shall not be brought for amicable settlement before the Barangay, subject to existing laws, rules and regulations. Complaints for acts covered by other laws shall be referred to the appropriate authorities." ...*

*"If the bullying incident or retaliation resulted in serious physical injuries or death, the case shall be dealt with in accordance with the provisions of Republic Act 9344 or the "Juvenile Justice and Welfare Act," as amended, and its Implementing Rules and Regulations, in connection with other applicable laws, as may be warranted by the circumstances attendant to the bullying incident." ...*

*„ If the student, after an investigation, is found to have knowingly made a false accusation of bullying, the said student shall be subjected to disciplinary actions or to appropriate interventions in accordance with the existing rules and regulations of the Department or the private school."*

The Senegalese Law No. 2014-01 of January 6, 2014 relating to the treatment of dormant accounts in the books of financial institutions of the Member States of the West African Monetary Union (WAMU) determines who shall decide on the sanctions and whereto the money shall go:

*"Art. 19. - ...*

*Les sanctions pécuniaires à l'encontre d'un Etablissement de Crédit ou d'un SFD sont prises, selon le cas, par la Commission Bancaire, la BCEAO ou le Ministre chargé des Finances. Les sanctions pécuniaires à l'encontre d'un service financier de la Poste ou d'une Caisse Nationale d'Epargne sont prises par le Ministre chargé des Finances. Les sommes correspondantes sont recouvrées pour le compte du Trésor public du lieu de tenue du compte dormant, selon le cas, par la Banque Centrale ou par le Ministère chargé des Finances."*

*Amended machine translation:*

*"Art. 19. - ...*

*Monetary sanctions against a Credit Institution or SFD are taken, as appropriate, by the Banking Commission, the BCEAO or the Minister of Finance. Monetary sanctions against financial service of the Post or National Savings Bank are made by the Minister of Finance.*

*The corresponding sums are collected on behalf of the Treasury of the place of holding the dormant account, as appropriate, by the Central Bank or by the Ministry of Finance."*

<sup>74</sup> Republic Act No. 10642, published on [July 15, 2014](#).

<sup>75</sup> Act No. 10627, published on [December 13, 2013](#)

## 7.26. Enforcement powers

Legislation can provide for general or for explicit and detailed inspection and enforcement powers. General provisions keep the legal text short. More detailed provisions create more legal certainty, above all on the crucial question of how far the authorities may go. The downside of detailed provisions is the risk that some special cases fall through the grid of empowerments. A subsidiary general clause can reduce the risk. An example of very detailed inspection and enforcement powers can be found in the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#). This act contains a wide range of empowerments after the headline „Division 3 — Safety inspections and enforcement powers“ (Sections 4J to 4O). In addition thereto, it provides in the sections before that headline for empowerments to exempt, suspend and impose requirements in deviation from the legal text and to make provisional orders to avoid imminent danger; see the new Sections 4C, 4D, 4E and 4F of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#). The Section 4F contains a criteria list jointly for the Sections 4C, 4D and 4E, which is an elegant construction. Altogether the act constitutes an excellent reference for those jurisdictions which prefer the path of detailed empowerments – or are obliged to take this path for legal reasons.

Further examples of enforcement powers are to be found in Sections 7.10 and 7.20.3.

## 7.27. Provisional orders to avoid imminent danger

Regulation can provide for an explicit empowerment to make provisional orders to avoid imminent danger. See as a rather complex example the new Section 4E of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#):

*“4E.*

*—(1) Subject to subsection (4), where it appears to the Authority that a holder of an aviation safety instrument is contravening, or is likely to contravene, any condition of the aviation safety instrument, that there are reasonable grounds to believe there is a serious and imminent risk to air safety and that it is appropriate or requisite, to avoid any actual or imminent occurrence that endangers or threatens to endanger the safety of the public, that a provisional order be made under this section, the Authority shall, instead of taking any decision under section 4C or 4D, by provisional order make such provision as appears to it requisite for securing compliance with that condition.*

*(2) A provisional order —*

*shall require the holder of an aviation safety instrument to whom it relates (according to the circumstances of the case) to do, or not to do, such things as are specified in the provisional order or are of a description so specified; shall take effect at such time, being the earliest practicable time, as is determined by or under the provisional order; and*

*may be revoked at any time by the Authority.*

*(3) In determining whether it is appropriate or requisite that a provisional order be made, the Authority shall have regard, in particular, to the extent to which any person is likely to sustain loss or damage in consequence of anything which, in contravention of the condition of an aviation safety instrument, is likely to be done, or omitted to be done, before a decision under section 4C or 4D may be made.*

*(4) Subject to subsections (5), (6) and (7), the Authority shall, by notice in writing, confirm a provisional order, with or without modifications, if —*

*the Authority is satisfied that the holder of an aviation safety instrument to whom the order relates has contravened, or is likely to contravene any condition of its instrument; and*

*the provision made by the order (with any modifications) is requisite for the purpose of securing compliance with that condition.*

*(5) The Authority shall not confirm a provisional order in relation to a holder of an aviation safety instrument if it is satisfied —*

*that the duties imposed on the Authority under this Act or the Civil Aviation Authority of Singapore Act 2009 preclude the confirming of such a provisional order;*

*that the holder of an aviation safety instrument has agreed to take, and is taking, all such steps as it appears to the Authority for the time being to be appropriate for the holder of that instrument to take for the purpose of securing or facilitating compliance with the condition in question; or*

*that the contraventions were, or the apprehended contraventions are, of a trivial nature.*

*(6) Before the Authority confirms a provisional order, the Authority shall give notice to the holder of an aviation safety instrument concerned —*

*stating that the Authority proposes to confirm the provisional order and setting out its effect;*

*setting out —*

*the relevant condition of the aviation safety instrument for the purpose of securing compliance with which the provisional order is to be confirmed;*

*the acts or omissions which, in the Authority's opinion, constitute or would constitute contraventions of that condition; and*

*the other facts which, in the Authority's opinion, justify the confirmation of the provisional order; and specifying the period (being not less than 28 days from the date of service of the notice) within which representations or objections with respect to the proposed confirmation may be made, and shall consider any representations or objections which are duly made and not withdrawn.*

*(7) The Authority shall not confirm a provisional order with modifications except — with the consent of the holder of an aviation safety instrument to whom the order relates; or after — serving on that holder of an aviation safety instrument such notice of the proposal to confirm the provisional order with modifications and in that notice, specifying the period (being not less than 28 days from the date of service of the notice) within which representations or objections with respect to the proposed modifications may be made; and considering any representations or objections which are duly made and not withdrawn.*

*(8) In this section, "provisional order" means an order under this section which, if not previously confirmed in accordance with subsection (5), shall cease to have effect at the end of such period (not exceeding 3 months) as is determined by or under the order."*

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## 8. Other implementation questions

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*If you once forfeit the confidence of your fellow citizens, you can never regain their respect and esteem. It is true that you may fool all of the people some of the time; you can even fool some of the people all of the time; but you can't fool all of the people all of the time.*

*Abraham Lincoln*

As with surveillance, it is best to think of the other aspects of implementation of a future legislative or regulatory measure even before drafting. Some questions of implementation can influence the design of the measure.

### 8.1. Discretionary powers and vague legal expressions / margins of appreciation

Discretionary powers and vague legal expressions are tools to permit a fine-tuned implementation<sup>76</sup>.

A discretionary power exists if an authority or another entity has the right to decide freely, provided that certain conditions are fulfilled. Discretionary powers are often expressed by the words “can” or “may” or by leaving a choice to the authority. Examples: “In case of infringement of the obligation to notify changes of the quality system, the authority may withdraw its authorisation.” - “In case of infringement of the obligation to notify changes of the quality system, the authority must withdraw its authorisation or impose additional conditions.” The empowerment of the authority is only given if certain conditions are fulfilled. These conditions can be precise or not.

Regulation often gives a certain discretionary power to authorities with a view to ensuring an implementation which is adapted to the local needs or the needs of a specific case. This can make sense if the regulator cannot precisely list all of the requirements for the authority or another entity to act or if the regulator considers that flexibility is needed to cover atypical cases. However, discretionary powers bring risks. The first is the risk of diverging administrative practice. The second is corruption which is linked to the third: limited judicial control. The risks can to a modest extent be reduced by indicating in the regulation to what purpose the discretionary power has been conveyed. The purpose can, subject to the jurisdiction, for instance be expressed in the recitals or in the rationale. In some jurisdictions, it is even possible to indicate the purpose of a discretionary power in the core text of the regulation.

The disadvantages stated for discretionary powers are also to be noted for vague legal expressions. Vague legal expressions may be used as part of the conditions (“In case of infringement of the obligation to notify substantial changes of the quality system, ...”) or as part of the enacting part of a sentence (“... , the authority must take appropriate measures.”). Vague legal expressions open up a margin of appreciation which is, according to the rules of the respective jurisdiction, subject to full or limited judicial control. However, whilst opening up a margin of appreciation, they may be used to limit a discretionary power; see e.g. the fragment “... , the authority may take proportionate measures.”. Without the word “proportionate” the authority could take all measures, not just proportionate ones. The word “proportionate” thus has a limiting effect. Thus, there are many ways to combine the two instruments.

Taking account the disadvantages of the two instruments, it is advisable to use them in a restricted way. To examine whether their use is really necessary, regulators might carefully check whether the cases intended to be covered cannot be better framed by more precise regulatory text.

### 8.2. Ensuring harmonised interpretation

Sometimes, questions of interpretation can even be clarified by simple definitions. To avoid diverging interpretations, regulation can furthermore contain interpretation guidelines or provide for an empowerment to

<sup>76</sup> We address them here under the perspective of implementation, though they are evidently parts of the requirements.

adopt interpretation guidelines later on.

Commission Delegated Regulation EU/231/2013<sup>77</sup> of 19 December 2012 supplementing Directive 2011/61/EU of the European Parliament and of the Council with regard to exemptions, general operating conditions, depositaries, leverage, transparency and supervision contains, in its Article 56, an interpretation guideline:

*„In the absence of specific interpretation given by ESMA or by the Joint Committee of the European Supervisory Authorities, the provisions of this Section shall be interpreted in a consistent manner with the corresponding provisions of Directive 2006/48/EC and with the Guidelines to Article 122a of the Capital Requirements Directive of 31 December 2010 issued by the Committee of European Banking Supervisors and their subsequent amendments.“*

In some jurisdictions, it might be useful to establish as an “interpretative” or implementing rule that the law is to be applied in a strict way. See Section 18 of the [Graphic Health Warnings Law of the Philippines](#)<sup>78</sup>:

*SEC. 18. Strict Compliance and Inspections. – Absolutely no extensions of time to comply with the provisions of this Act shall be granted to tobacco manufacturers and importers or any other affected party.*

However, in some other jurisdictions, such a sentence could raise legal questions as to whether, in other cases, some leniency may be applied.

Sometimes the interpretation guidelines cannot be established in advance because it is, at the time of adoption of the regulation, not yet clear what questions will arise. In this case, it might be useful to provide for an empowerment to adopt interpretative measures. See as an example [Regulation EU/228/2013](#)<sup>79</sup> of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006. This Regulation contains, in its Article 12, an empowerment for the Commission to adopt regulatory acts necessary to ensure the uniform application by the Member States of a certain article. It is noteworthy that it does not contain any specific condition except that the act must be necessary:

*„3. The Commission shall adopt implementing acts regarding the measures necessary to ensure the uniform application by the Member States of this Article, specifically relating to the introduction of the system of certificates and the commitment undertaken by operators at the time of registration. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).“*

### 8.3 Ensuring the harmonized and stringent work of Conformity Assessment Bodies

The designation, supervision and de-designation processes are the key leverage for influencing the Conformity Assessment Bodies’ work. The design of these processes also determines to what extent Conformity Assessment Bodies are compliant with legal requirements and with instructions given by the authorities. There are many variables for the designation process:

- How many different authorities shall be involved? Subject to the degree of impartiality and to the competence of the main authority, it may make sense to involve more authorities.

Shall there be a right to be designated once certain conditions are met or is the designation based on a discretionary decision which is not subject to full judicial control?

- Shall there be detailed documentation requirements for the application, e.g. in relation to the fulfilment of designation criteria?

- Shall there be an assessment in the premises of the conformity assessment body or in the premises of an economic operator being assessed by the conformity assessment body (so-called “observed audits”)?

- Shall the Conformity Assessment Body be periodically assessed?

- Shall there be unannounced surveillance assessments?

- Shall the designation be based on accreditation or not? The weaker the authorities and the stronger the respective accreditation bodies, the more accreditation makes sense. However, accreditation is usually judged

<sup>77</sup> OJ L83/1 of 22.3.2013

<sup>78</sup> Republic Act No. 10643, published on [July 15, 2014](#).

<sup>79</sup> OJ L78/23 of 20.3.2013

against standards, not against requirements set up by regulation. If there is a mismatch between the requirements in the standards and the requirements in the regulation, accreditation is not extremely useful.

Besides the designation mechanism, there is a wide variety of other measures that can be used to strengthen and harmonise the work of Conformity Assessment Bodies (legal or paralegal control mechanisms, peer review, codes of conduct, informal co-ordination of decision making, etc.). The best example so far found in regulation: [Commission Implementing Regulation \(EU\) No 392/2013](#) of 29 April 2013 amending Regulation (EC) No 889/2008 as regards the control system for organic production. This Regulation contains a detailed program for enforcement. The program foresees assistance by entrusted private bodies, supervision of entrusted private bodies, exchange of information between the entrusted bodies and authorities, and risk management. The program determines a minimum percentage of verifications and of unannounced verifications.

#### 8.4. Ensuring that authorities decide in time

Many enforcement issues depend on timely decision-making by authorities. Likewise, operators or citizens who need an authorisation or certification depend on timely decision-making. For this reason it can be wise to establish deadlines for administrative decisions. On the other hand, the administrations cannot be made responsible for delays which are due to circumstances that are outside of their control. But it is possible to strike a balance between the legitimate interests of operators and citizens and the legitimate interests of authorities. See as an example the [Canadian Species at Risk Act - Permits Authorizing an Activity Affecting Listed Wildlife Species Regulations](#) 2013 which contains fine-tuned rules establishing deadlines for administrative decisions. These rules include various so-called „stop-the-clock-mechanisms“:

*„90-day time limit*

*3. (1) Subject to subsections (2) and (3), the competent minister must either issue a permit or notify the applicant of the refusal to issue a permit within 90 days after the date of the notice indicating that the application has been received.*

*Application incomplete*

*(2) The time limit set out in subsection (1) is suspended if the application is incomplete. The suspension begins on the day on which the competent minister notifies the applicant in writing that the information provided is insufficient to allow the competent minister to issue or refuse to issue a permit and ends on the day on which the competent minister receives all of the missing information.*

*Non-application of time limit*

*(3) The time limit set out in subsection (1) is not applicable in the following circumstances:*

- (a) additional consultations are necessary, including consultations held under subsections 73(4) and (5) of the Act;*
- (b) an Act of Parliament other than the Act or a land claims agreement requires that a decision be made before the competent minister issues or refuses to issue a permit under section 73 of the Act;*
- (c) the terms and conditions of a permit previously issued to the applicant under section 73 of the Act have not been met;*
- (d) the applicant requests or agrees that the time limit is not to apply; or*
- (e) the activity described in the permit application is modified before the competent minister issues or refuses to issue a permit under section 73 of the Act.“*

#### 8.5. Strengthening authorities

The implementation of regulation is often hampered by weak authorities. In order to require a minimum level of strength, regulators can set up various types of requirements, e.g.:

- Requirements on independence;
- Management requirements;
- Requirements on minimum resources (ideally with clear indication of minimum Full-time equivalences, not just vague clauses like „appropriate number of staff“ as the latter is difficult to enforce);
- Obligation to apply a quality system. The Argentinian Decreto Nacional 38/13 of 22 January 2013<sup>80</sup> obliges, in its Article 13, obliges the National Genetic Data Bank to undergo an annual quality system ISO certification.

<sup>80</sup> The hyperlink broke and could not be replaced.

Authorities can furthermore be strengthened by clearly defining their tasks and by explicitly providing for necessary empowerments to act. Without explicit empowerments, authorities risk being helpless before unlawful operators or citizens. Examples of such clear empowerments have been presented in Section 7.26.

## 8.6 Preventing corruption or other unlawful operations of authorities

The [Indian National Food Security Act](#) No. 20 of 2013, published on 10 September 2013, establishes, in its Chapter VII, a „Grievance Redress Mechanism“ with a State Commission operating similarly to a court or to an arbitral tribunal:

*„14. Every State Government shall put in place an internal grievance redressal mechanism which may include call centres, help lines, designation of nodal officers, or such other mechanism as may be prescribed. ...*

*20. (1) The State Commission shall, while inquiring into any matter referred to in clauses (b) and (e) of sub-section (6) of section 16, have all the powers of a civil court while trying a suit under the Code of Civil Procedure, 1908, and, in particular, in respect of the following matters, namely:—*

*(a) summoning and enforcing the attendance of any person and examining him on oath;*

*(b) discovery and production of any document;*

*(c) receiving evidence on affidavits;*

*(d) requisitioning any public record or copy thereof from any court or office; and*

*(e) issuing commissions for the examination of witnesses or documents.*

*(2) The State Commission shall have the power to forward any case to a Magistrate having jurisdiction to try the same and the Magistrate to whom any such case is forwarded shall proceed to hear the complaint against the accused as if the case has been forwarded to him under section 346 of the Code of Criminal Procedure, 1973.“*

The [Indian National Food Security Act](#) No. 20 of 2013 provides also, in its Chapter XI, for transparency and accountability by obliging to publish records, to undertake social audits, and by establishing supervising committees:

*„27. All Targeted Public Distribution System related records shall be placed in the public domain and kept open for inspection to the public, in such manner as may be prescribed by the State Government.*

*28. (1) Every local authority, or any other authority or body, as may be authorised by the State Government, shall conduct or cause to be conducted, periodic social audits on the functioning of fair price shops, Targeted Public Distribution System and other welfare schemes, and cause to publicise its findings and take necessary action, in such manner as may be prescribed by the State Government.*

*(2) The Central Government may, if it considers necessary, conduct or cause to be conducted social audit through independent agencies having experience in conduct of such audits.*

*29. (1) For ensuring transparency and proper functioning of the Targeted Public Distribution System and accountability of the functionaries in such system, every State Government shall set up Vigilance Committees as specified in the Public Distribution System (Control) Order, 2001, made under the Essential Commodities Act, 1955, as amended from time to time, at the State, District, Block and fair price shop levels consisting of such persons, as may be prescribed by the State Government giving due representation to the local authorities, the Scheduled Castes, the Scheduled Tribes, women and destitute persons or persons with disability.*

*(2) The Vigilance Committees shall perform the following functions, namely:—*

*(a) regularly supervise the implementation of all schemes under this Act;*

*(b) inform the District Grievance Redressal Officer, in writing, of any violation of the provisions of this Act; and*

*(c) inform the District Grievance Redressal Officer, in writing, of any malpractice or misappropriation of funds found by it.“*

Finally, the [Indian National Food Security Act](#) No. 20 of 2013 establishes, in its Chapter XIII, a state liability for any non-fulfilment of rights accorded by the act:

*„44. The Central Government, or as the case may be, the State Government, shall be liable for a claim by any person entitled under this Act, except in the case of war, flood, drought, fire, cyclone or earthquake affecting the regular supply of foodgrains or meals to such person under this Act: provided that the Central Government may, in consultation with the Planning Commission, declare whether or not any such situation affecting the regular supply of foodgrains or meals to such person has arisen or exists.“*

A good deal of corruption and other unlawful operations can be observed in connection with contracts and public tenders. Besides specific rules on the attribution of contracts and on public tenders, it might help to prescribe by regulation how the contracts shall look. An example of this practice is to be found in the [Argentinian Decree 271/2014](#) of 6 March 2014 “Aprobación de Modelo de Contrato de Préstamo CAF a celebrarse con la Corporación Andina de Fomento destinado a financiar parcialmente el "Programa de Obras Básicas de Agua



Potable 2012-2015 AySA - Fase I<sup>81</sup>.

## 8.7. Means for dispute resolution

Regulation often gives rise to disputes. Accordingly, it can be helpful to establish means for dispute resolution.

There are various mechanisms that can serve for purposes of dispute resolution:

- Arbitrator,
- Arbitrator Tribunals,
- Special Committees.

An example of special Committees in charge of settling disputes can be found at the beginning of the previous section. An example of an Arbitrator Tribunal can be found in the law of Argentina. Article 46 of the [Argentinian Decreto 1.023/2013](#) of 29 July 2013 „Transparency of markets and protection of investors: Regulation of the Law on Capital Markets - Transparencia de los mercados y protección de los inversores: Reglamentación de ley de Mercado de Capitales“ contains the empowerment and basic principles for the establishment of Arbitrator Tribunals:

*„Los reglamentos para la creación y funcionamiento de los Tribunales Arbitrales dictados por los mercados, deberán ser aprobados por la COMISION NACIONAL DE VALORES, debiendo dicha reglamentación contener, como mínimo, los siguientes aspectos:*

- a) Las condiciones de idoneidad, honorabilidad, integridad, experiencia, antecedentes académicos y profesionales que deben acreditar los miembros.*
- b) El Tribunal debe estar constituido por un número de miembros impar.*
- c) El contenido del laudo arbitral deberá ser exclusivamente de derecho.... “*

*Amended machine translation:*

*„The regulations for the establishment and operation of Arbitrator Tribunals dictated by the markets must be approved by the National Securities Committee; such regulation must contain at least the following:*

- a) The terms of suitability, honesty, integrity, experience, academic and professional background that the members have to demonstrate.*
- b) The Court must be composed of an odd number of members.*
- c) The content of the arbitrator’s award shall be exclusively legal. ... “*

The [Philippine “Lemon Law” on the protection of consumers buying motor vehicles](#)<sup>82</sup> provides for a sophisticated dispute settlement procedure to be managed by an ordinary administration:

*“SEC. 8. Remedies for Dispute Resolution. – The DTI shall exercise exclusive and original jurisdiction over disputes arising from the provisions of this Act. All disputes arising from the provisions of this Act shall be settled by the DTI in accordance with the following dispute resolution mechanisms:*

*(a) Mediation*

- (1) The principles of negotiation, conciliation and mediation towards amicable settlement between the manufacturer, distributor, authorized dealer or retailer and the consumer shall be strictly observed;*
- (2) In the course of its dispute resolution efforts, the DTI shall endeavor to independently establish the validity of the consumer’s outstanding complaint. The DTI shall likewise retain the services of other government agencies or qualified independent private entities in the ascertainment of the validity of the consumer’s complaint. Any cost incurred in establishing the validity of the consumer’s complaint shall be borne jointly by the consumer and the manufacturer, distributor, authorized dealer or retailer;*
- (3) The complaint shall be deemed valid if it is independently established that the motor vehicle does not conform to the standards or specifications set by the manufacturer, distributor, authorized dealer or retailer;*
- (4) Upon failure of the negotiation or mediation between the manufacturer, distributor, authorized, dealer or retailer and the consumer, the parties shall execute a certificate attesting to such failure; and*
- (5) At any time during the dispute resolution period, the manufacturer, distributor, authorized dealer or retailer and the consumer shall be encouraged to settle amicably. All disputes that have been submitted for mediation shall be settled not later than ten (10) working days from the date of filing of the complaint with the DTI.*

*(b) Arbitration*

*In the event there is a failure to settle the complaint during the mediation proceedings, both parties may voluntarily decide to undertake arbitration proceedings.*

<sup>81</sup> Official Journal of 13.3.2014

<sup>82</sup> Republic Act No. 10642, published on [July 15, 2014](#).

*(c) Adjudication*

*(1) In the event that both parties do not undertake arbitration proceedings, at least one of the parties may commence adjudication proceedings, administered by the DTI. The DTI shall rely on the qualified independent findings as to conformity to standards and specifications established herein. In no case shall adjudication proceedings exceed twenty (20) working days;*

*(2) In case a finding of nonconformity is arrived at, the DTI shall rule in favor of the consumer and direct the manufacturer, distributor, authorized dealer or retailer to grant either of the following remedies to the consumer:*

*(i) Replace the motor vehicle with a similar or comparable motor vehicle in terms of specifications and values, subject to availability; or*

*(ii) Accept the return of the motor vehicle and pay the consumer the purchase price plus the collateral charges.*

*In case the consumer decides to purchase another vehicle with a higher value and specifications from the same manufacturer, distributor, authorized dealer or retailer, the consumer shall pay the difference in cost.*

*In both cases of replacement and repurchase, the reasonable allowance for use, as defined in this Act, shall be deducted in determining the value of the nonconforming motor vehicle; and*

*(3) In case a nonconformity of the motor vehicle is not found by the DTI, it shall rule in favor of the manufacturer, distributor, authorized dealer or retailer, and direct the consumer to reimburse the manufacturer, distributor, authorized dealer or retailer the costs incurred by the latter in validating the consumer's complaints.*

*An appeal may be taken from a final judgment or order of the Adjudication Officer which completely disposes of the case within fifteen (15) days from receipt thereof. The appeal shall be taken by filing a Memorandum of Appeal with the Secretary of the DTI, with Notice of Appeal to the Adjudication Officer, and with a copy duly furnished the adverse party or parties on any of the following grounds:*

*(i) Grave abuse of discretion;*

*(ii) The decision/order is in excess of jurisdiction or authority of the Adjudication Officer; and*

*(iii) The decision/order is not supported by the evidence or there is serious error in the findings of facts.*

*The Secretary of the DTI shall decide on the appeal within thirty (30) days from receipt thereof. A party seeking further appeal from the decision of the Secretary of the DTI may file a case for certiorari to the Court of Appeals ..."*

## 8.8. Decision making by committees

It can make sense to attribute certain responsibilities to committees. If so, the question arises of how the committee shall operate. In many jurisdictions, the internal rules are left to the committee to decide upon. However, this can lead to manipulation, namely by the chair, or other unwanted results. As an alternative, regulators can consider setting up basic rules of operation themselves. This is done in the Tunisian [Decree No. 2014-2242 of 24 June 2014 fixing the amount and the procedures of allocation of pensions to resistants](#):

*„ Article 5 - Le président de la commission peut convoquer toute personne dont il juge la présence utile pour participer aux travaux de la commission sans prendre part au vote, et peut, le cas échéant, solliciter l'avis technique des organismes spécialisés. Les membres de la commission sont nommés par arrêté du chef du gouvernement, sur proposition des ministères et organismes concernés, pour une durée de trois ans renouvelable une seule fois.*

*Art. 6 - La commission se réunit sur convocation de son président quatre fois au moins par an et chaque fois que de besoin. Le Président établit l'ordre du jour de la commission et le transmet aux membres. La commission ne peut délibérer valablement qu'en présence de la moitié de ses membres au moins. Si le quorum n'est pas atteint lors de la première réunion, celle-ci est reportée à une date ultérieure. Une nouvelle convocation doit intervenir au moins une semaine avant la date de réunion. La deuxième réunion est réputée valable quel que soit le nombre des membres présents.*

*Les avis de la commission sont rendus à la majorité des voix de ses membres présents et en cas d'égalité, celle du président est prépondérante.*

*Les réunions de la commission sont consignées dans des procès-verbaux et signés par son président et ses membres présents.*

*Art. 7 - Le secrétariat permanent de la commission est assuré par les services chargés des affaires sociales relevant de la Présidence du gouvernement.“*

*Amended machine translation:*

*“Article 5 - The Chairman of the Committee may summon any person whose attendance he considers useful to participate in the work of the Committee without taking part in the vote. He may, if necessary, seek technical advice from the specialist agencies. The members of the Committee are appointed by order of the Head of Government, on the proposal of departments and agencies, for a period of three years, renewable once.*

*Art. 6 - The Committee shall be convened by its chairman at least four times a year and whenever necessary. The President sets the agenda of the Committee and sends it to members. The Committee may only validly deliberate in the presence of at least half of its members. If the quorum is not reached at the first meeting, the meeting is postponed to a later date. A new notice must be made at least one week before the meeting date. The second meeting shall be deemed valid whatever the number of members present.*

*The opinions of the Committee are made by majority vote of its members present and in case of a tie, the Chairman has the casting vote.*

*Meetings of the Committee shall be recorded in the minutes and signed by its President and members present.*

*Art. 7 - Permanent Committee secretariat is provided by the departments responsible for social affairs under the Presidency of the Government."*

## 8.9. De minimis clause

It is not necessarily very helpful that authorities sue all non-conformities, above all if their enforcement capacity is rather limited. A "De minimis clause" sets a limit under which a certain consequence is not or not necessarily to be pursued. A "De minimis clause" can sometimes be found in final dispositions. At any rate, the "De minimis clause" is an item to be checked at the end of the drafting exercise. Is it really worthwhile to apply all the mechanisms in the draft regulation in all cases covered by the scope? Is the necessary procedural effort still proportionate? If not, up to what limit can the application of the regulation be omitted? To raise this question helps to create better regulation.

See as an example of a "de minimis clause" Council [Regulation EC/479/2008](#) of 29 April 2008 on the common organisation of the market in wine... which sets such a limit at 50.000 hectolitres of yearly wine production per EU Member State:

*"Article 105 - De minimis: This Chapter shall not apply in Member States where wine production does not exceed 50000 hectolitres per wine year. This production shall be calculated on the basis of the average production during the previous five wine years."*

## 8.10. Regularisation

Regularisation is a process that permits natural or legal persons to legalise a situation that is unlawful under the currently applicable law. The regularisation clauses can temporarily suspend certain legal obligations in order to create an incentive for regularisation ("No penalties to be paid for the past if you declare your fortune and pay taxes."). Furthermore, they can set up conditions for regularisation, like the payment of a fee. See as an example Council [Regulation EC/479/2008](#) of 29 April 2008 on the common organisation of the market in wine...:

*"Article 86 - Obligatory regularisation of unlawful plantings planted before 1 September 1998*

*1. Producers shall, against the payment of a fee and not later than 31 December 2009, regularise areas planted with vines without a corresponding planting right, where applicable, before 1 September 1998."*

## 8.11. Co-operation amongst authorities

Most regulation contains little text on co-operation amongst authorities, as if it went without saying that authorities co-operate well. In practice, co-operation is not always excellent. Partly this is due to a lack of willingness. Partly it is due to the facts that there are no clear and detailed obligations for co-operation, that there is no legal empowerment for the exchange of data foreseen in the regulation, that there is no multi-lingual database for the exchange of detailed information<sup>83</sup> or that there is no other translation tool available. All this can be remedied by integrating issues of co-operation into the regulation.

Article 38 of [Directive 2009/72/EC](#) concerning common rules for the internal market in electricity... contains a good example of relatively detailed rules on co-operation. It even provides for the empowerment to create ever more detailed rules by regulatory acts:

*"1. Regulatory authorities shall closely consult and cooperate with each other, and shall provide each other and the Agency with any information necessary for the fulfillment of their tasks under this Directive. In respect of the information exchanged, the receiving authority shall ensure the same level of confidentiality as that required of the originating authority.*

*2. Regulatory authorities shall cooperate at least at a regional level to:*

*(a) foster the creation of operational arrangements in order to enable an optimal management of the network, promote joint electricity exchanges and the allocation of cross-border capacity, and to enable an adequate level of interconnection capacity, including through new interconnection, within the region and between regions to allow for*

<sup>83</sup> See as an example the EU "Internal Market Information System" (IMI) [http://ec.europa.eu/internal\\_market/imi-net/index.html](http://ec.europa.eu/internal_market/imi-net/index.html)

*development of effective competition and improvement of security of supply, without discriminating between supply undertakings in different Member States;*

*(b) coordinate the development of all network codes for the relevant transmission system operators and other market actors; and*

*(c) coordinate the development of the rules governing the management of congestion.*

*3. National regulatory authorities shall have the right to enter into cooperative arrangements with each other to foster regulatory cooperation.*

*4. The actions referred to in paragraph 2 shall be carried out, as appropriate, in close consultation with other relevant national authorities and without prejudice to their specific competencies.*

*5. The Commission may adopt Guidelines on the extent of the duties of the regulatory authorities to cooperate with each other and with the Agency. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 46(2)."*

For aspects of international cooperation of authorities, see the following Section.

## 8.12. Rules on international data-exchange and cooperation

As business and private behaviours become more and more international, jurisdictions can no longer afford not to cooperate with other jurisdictions. Authorities are sometimes hindered from cooperating with authorities of other jurisdictions due to confidentiality rules or rules on data-protection. In some jurisdictions, the transfer of data regarding a natural or legal person as such requires a legal basis, regardless of rules on confidentiality and of rules on data-protection. Accordingly, regulation should contain precise empowerments for exchanging data with authorities in other jurisdictions. These empowerments can be subject to the respect of rules of confidentiality and of data-protection rules by the other jurisdictions. When verifying the rules of other jurisdictions, special care should be applied to the question of whether rules on public access to documents or other transparency rules do not counter confidentiality or data-protection in the other jurisdictions.

Whilst the exchange of information is the most relevant issue of international administrative cooperation, it is to be noted that international administrative cooperation can go further. See e.g. Section 7.20.4 and this OECD document on international regulatory cooperation:

[http://www.keepeek.com/Digital-Asset-Management/oecd/governance/international-regulatory-co-operation\\_9789264200463-en#page1](http://www.keepeek.com/Digital-Asset-Management/oecd/governance/international-regulatory-co-operation_9789264200463-en#page1)

## 8.13. Rules on confidentiality

Law often needs to contain provisions on confidentiality. The provisions can oblige economic operators, professionals, authorities and conformity assessment bodies and their agents. Such provisions usually need to be adapted to the specific sector – general rules on data protection hardly match sector specific rules, but can be referred to as a baseline. Rules on confidentiality must be strong enough to counter rules on public access to documents and other transparency rules.

Section 11 of the [Implementing Rules and Regulations of the Anti-Bullying Act of 2013 of the Philippines](#)<sup>84</sup> provides an example of precise confidentiality rules, namely rules on who is authorised to have access to sensitive information:

*"Any information relating to the identity and personal circumstances of the bully, victim, or bystander shall be treated with utmost confidentiality by the Child Protection Committee and the school personnel, provided, that the names may only be available to the school head or administrator, teacher or guidance counselor designated by the school head, and parents or guardians of students who are or have been victims of bullying or retaliation."*

## 8.14. Verification on the territory of another jurisdiction

Any state verification on the territory of another jurisdiction / state needs of course to be authorised by an

<sup>84</sup> Act No. 10627, published on [December 13, 2013](#)

agreement under international public law. To foresee a state verification on the territory of another jurisdiction without authorisation of the host state could amount to an infringement of international public law. Nonetheless, there are such mechanisms foreseen in the law of several jurisdictions. See as an example the [Canadian Customs Act / CCOFTA Verification of Origin Regulations](#)<sup>85</sup>.

Audits or inspections undertaken by (usually private) entrusted Conformity Assessment Bodies are less problematic under aspects of international public law. If certain Conformity Assessment Bodies are entrusted by different jurisdictions, they can examine legal requirements of different jurisdictions on the same topic in one go, e.g. regarding the quality management systems.

See also this OECD document on international regulatory cooperation:

[http://www.keepeek.com/Digital-Asset-Management/oecd/governance/international-regulatory-co-operation\\_9789264200463-en#page1](http://www.keepeek.com/Digital-Asset-Management/oecd/governance/international-regulatory-co-operation_9789264200463-en#page1)

## 8.15. Recognition of foreign certificates and authorisations

The recognition of foreign certificates and approvals can be decided unilaterally or in conjunction with the state whose certificates or approvals shall be recognised. To reduce unnecessary burden for the exporting industry, it can be useful to negotiate with trade partners bilaterally on the recognition of certificates and approvals. The negotiations can lead to formal or informal bilateral agreements.

As formal bilateral agreements tie up a lot of resources and are not easy to manage, it is preferable to foresee an empowerment to decide upon the recognition of foreign certificates by regulatory acts. The empowerment should not be limited to the case of mutual recognition. According to theories of free trade, it is advantageous in all cases to recognise foreign certificates and approvals provided that these fulfil the same requirements and are based on an equal or higher level of stringency as the domestic certificates and approvals. Furthermore, if the domestic industry exports more to the third country than vice versa, the domestic industry will profit more from the recognition of the foreign certificates than the industry of the third country. It can substantially reduce costs by applying only for the certificate or the approval of the third country. The only necessary condition is that the certificate or the approval must be based on an assessment that is at least of an equivalent level of stringency as requested by domestic law.

We present here as an example of the recognition of foreign certificates the [Brazilian Portaria INMETRO / MDIC Number 247](#)<sup>86</sup> of 26/05/2014 on the conformity assessment for the retreading of tires:

*„14.3 Para os ensaios realizados por laboratórios estrangeiros devem ser observadas e documentadas a equivalência do método de ensaio e da metodologia de amostragem estabelecida. Além disso, esses laboratórios devem ser acreditados pela Cgcre ou por um acreditador que seja signatário de um acordo de reconhecimento mútuo do qual o Inmetro também faça parte. São eles:*

- a) Interamerican Accreditation Cooperation – IAAC;*
- b) International Laboratory Accreditation Cooperation – ILAC.“*

*Amended machine translation:*

*14.3 For the tests carried out by foreign laboratories, the equivalence of the test method and of the established sampling methodology should be observed and documented. In addition, these laboratories must be accredited by Cgcre or by an accreditor that is a signatory to a mutual recognition agreement to which INMETRO is also party. They are:*

- a) Interamerican Accreditation Cooperation - IAAC;*
- b) International Laboratory Accreditation Cooperation - ILAC ".*

The technique recognition of foreign certificates has also been used in the Canadian Environmental Protection Act, 1999 / [Heavy-duty Vehicle and Engine Greenhouse Gas Emission Regulations, 2013](#), P.C. 2013-160 February 22, 2013:

*„13. (1) Subject to subsections (4) and (8), a heavy-duty vehicle or heavy-duty engine of a given model year that is covered by an EPA certificate and that is sold concurrently in Canada and the United States must conform to the*

<sup>85</sup> P.C. 2013-1293 November 28, 2013

<sup>86</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.

*certification and in-use standards referred to in the EPA certificate instead of to the following standards, whichever apply: ..."*

Strictly speaking, this paragraph goes even further than a simple recognition in so far as this paragraph declares the domestic law inapplicable if the product is to be sold both in Canada and in the U.S.!

The recognition of foreign certificates can be subject to translation requirements for some or all foreign languages. See as an example Section 6.1.1.3 of the Brazilian [Portaria INMETRO / MDIC No. 649](#)<sup>87</sup> of 12/12/2012, "General Requirements for Declaration of Conformity by Provider of Products"<sup>88</sup>, which exempts English and Spanish documents from the requirement of translation:

*"6.1.1.3 Os documentos para a solicitação do Registro a serem anexados ao Sistema Orquestra são:*

*2) No caso de apresentação de Certificado do Sistema de Gestão da Qualidade emitido por OAC acreditado por signatários do acordo de reconhecimento mútuo (Multilateral Recognition Agreement – MLA) do International Accreditation Forum – IAF, este deve estar acompanhado de tradução juramentada no idioma português, quando este for emitido em idioma distinto do inglês ou espanhol. O Certificado deve ser válido para o processo produtivo na unidade fabril do objeto da Declaração da Conformidade do Fornecedor, de forma inequívoca. Os demais documentos referentes ao Sistema de Gestão da Qualidade, que estiverem em idioma distinto do inglês ou espanhol, devem estar traduzidos para o português."*

*Amended machine translation:*

*"6.1.1.3 The following documents must be uploaded to the Orchestra System in order to request registration:*

*2) In case of filing of the Certificate of Quality Management System issued by CABs accredited by signatories of mutual recognition (Multilateral Recognition Agreement - MLA) of the International Accreditation Forum - IAF, this must be accompanied by a sworn translation in Portuguese language when it is issued in a different language than English or Spanish. The certificate must be unequivocally valid for the production process in the factory of the object of the Declaration of Conformity Supplier. The other documents related to the Quality Management System which are in a language other than English or Spanish must be translated into Portuguese."*

If the recognition of foreign certificates and approvals is desired in international negotiations, several of the harmonisation approaches presented in this handbook can be used. In case of doubt, the Optional harmonisation gives the best chance of reaching an agreement. It does not hurt anyone's interests to recognise certificates and approvals if they are based on the top level of the world's product requirements or standards. For details see the Section 2.11.3.

If the recognition of foreign certificates is not possible, one might consider, as the second best possibility, joint conformity assessments so as to lower the burden for economic operators. Joint conformity assessments can be provided through legislation, by administrative arrangements or, if in one of the jurisdictions the conformity assessment tasks are delegated to private bodies, by intelligent company and contractual law arrangements.

## 8.16. Informatics tools

Quite a few regulations need informatics tools to be implemented. Their number is constantly increasing.

In some jurisdictions, regulation must contain provisions on the informatics tools necessary for its implementation. In others, this is not mandatory. There are at least three reasons why it can be useful to mention the informatics tools in the regulation:

- In some jurisdictions the regulation must create the legal basis for the expenditures needed to create the informatics tools.
- In other jurisdictions, there is no need to create such a legal basis for the expenditures, but the administration in charge will have better chances to receive the funds if the informatics tools are mentioned in the regulation as being necessary for the implementation of the regulation. Mentioning the informatics tools will thus strengthen the position of the administration in budgetary negotiations.
- In some jurisdictions, the storage of data regarding natural or legal persons is only lawful when empowered by regulation.

<sup>87</sup> Unfortunately, the hyperlinks to documents of INMETRO do not work in some computer settings. The documents are easily retrievable by copying the document number or a part of the quote into a search engine.

<sup>88</sup> Requisitos Gerais para Declaração da Conformidade do Fornecedor de Produtos.

Regardless of whether the regulation must or should refer to the informatics tools, there is an important question to be checked prior to adopting new regulation: Is the regulation easy to implement or at least implementable in terms of informatics?

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## 9. Miscellaneous

*The government is merely a servant -- merely a temporary servant; it cannot be its prerogative to determine what is right and what is wrong, and decide who is a patriot and who isn't. Its function is to obey orders, not originate them.*

Mark Twain

### 9.1. Transitional provisions and phasing in

Each jurisdiction uses one or more standard formulations for determining the entry into application of regulation. Sometimes, these standard formulations are sufficient. Frequently, however, more questions should be reflected on:

- **Shall the new law be introduced step by step for different parts of the scope or for all in one go?** See e.g. the [Canadian Electricity and Gas Inspection Act - Regulations Amending the Electricity and Gas Inspection Regulations](#)<sup>89</sup>.
- **For which stage in a process shall the new regulation be applied as from date X and for which other stage from date Y?** [For products, the stages can be determined with the help of the following questions: Is the relevant product already approved / certified? Has the product been created? Has it been sold to customers (placed on the market)? Has the product been handed over to the customer? Is the product already in use?] [For services, the stages can be determined with the help of the following questions: Has the service been approved / certified? Has the service been offered? Has the service been subject to a contract? Has the service been provided?] Regulation may also refer to different stages in one single provision. E.g., the [Tunisian Decree of the Minister of Health of 20 May 2014](#) amending the Decree of 24 February 1999 laying down the procedures for listing particulars which must be displayed on the outer cover of packets and packages containing tobacco products ...<sup>90</sup> refers both to the time of manufacturing and to the time of order:
 

*“Article 8 (nouveau) - Les paquets et les emballages destinés aux produits de tabac qui sont fabriqués ou commandés avant l'entrée en vigueur du présent arrêté, peuvent être utilisés jusqu'au 30 avril 2015.”*

*Amended machine translation:*

*“Article 8 (new) - Packages and packaging for tobacco products that are manufactured or ordered before the entry into force of this Order may be used until 30 April 2015.”*
- **Shall there be a period in which citizens / operators can choose between the old and the new law?** The anticipation of new law is, generally speaking, in the interest of the jurisdiction, as the new law is usually more advanced. However, it can create difficulties for the enforcement administrations. They have to distinguish between the products or services which are already fulfilling the new requirements and those which are not.
- **Should the geographic entities have the option of keeping the old law applicable for a period of time?** Normally, previously applied law shall cease to apply by a certain date. However, there might be a need to give geographic entities the possibility of maintaining the law, for a certain time at least.
- **Is there a need to redirect references?** If a legal act is repealed, there might be a need to ascertain that references to the repealed act are redirected / transferred to the new act.
- **Is there a need to repeal (parts of) other legal acts that have become obsolete with the repeal of the major act?**
- **Is there a need to stipulate the provisional application of certain parts of the measure?**

<sup>89</sup> SOR/2014-113 May 16, 2014, P.C. 2014-568 May 15, 2014, Vol. 148, No. 12 — June 4, 2014

<sup>90</sup> Full official title: Arrêté du ministre de la santé du 20 mai 2014, modifiant l'arrêté du 24 février 1999, fixant les modalités d'inscription des mentions qui doivent être portées sur la couverture extérieure des paquets et des emballages contenant des produits de tabac exposés directement au consommateur, les méthodes d'analyse permettant de mesurer la teneur en nicotine et en goudron dans lesdits produits ainsi que les modalités de vérification de l'exactitude de ces mentions.



Regulation needs to determine the date of its application. However, there can be, in very exceptional cases, a need to leave the date of application open for a certain time and to determine it later.

At the time of adoption, it is not necessarily clear (a) when the act will be published and (b) when the administration will be ready to apply the act. Accordingly, it can be advisable to empower the administration to determine the entering into force of the regulation within a certain lapse of time. The [Indian right to fair compensation and transparency in land acquisition, resettlement and rehabilitation act](#), 2013, provides in its Chapter I, Article 1 Paragraph 3 that the act shall enter into force once the Government has so decided, provided that the decision is taken within three months after the act being agreed to by the president. Canada too uses this technique, and does so even for specific sections of a regulation; see the [Canada Marine Act](#) – Order Fixing February 13, 2014 as the Day on which Sections 178 and 185 of the Act come into Force<sup>91</sup>.

The entry into force or application date of a regulatory act may be linked to the entry into force or application date of another regulatory act; see e.g. the [Canadian Electricity and Gas Inspection Act - Regulations Amending the Electricity and Gas Inspection Regulations](#)<sup>92</sup>:

*„8. These Regulations come into force on the day on which section 6 of the Fairness at the Pumps Act, chapter 3 of the Statutes of Canada, 2011, comes into force, but if they are registered after that day, they come into force on the day on which they are registered.“*

Normally, regulation should not come into force prior to its publication. However, there might be special reasons to foresee a limited retroactivity (e.g. to avoid manipulations in the transition phase). The [Indian National Food Security Act](#) No. 20 of 2013, published on 10 September 2013, stipulates in Chapter I Section 1.(3) that it shall be deemed to have come into force prior to its publication:

*„(3) Save as otherwise provided, it shall be deemed to have come into force on the 5th day of July, 2013.“*

The Senegalese law No. 2014-01 of January 6, 2014 relating to the treatment of dormant accounts in the books of financial institutions of the Member States of the West African Monetary Union (WAMU) also provides for an entry into force and supposedly of an application date earlier than the date of adoption:

*“Art. 23. - La présente loi entre en vigueur le 1er janvier 2014.  
Sont abrogées, à compter de cette date, toutes dispositions antérieures contraires.  
La présente loi sera exécutée comme loi de l'Etat.  
Fait à Dakar, le 6 janvier 2014”*  
*“Art. 23 - . This Act comes into force on 1 January 2014.  
All previous contrary provisions are repealed with effect from that date.  
This Act shall be enforced as state law.  
Made in Dakar, January 6, 2014”*

## 9.2. Validity of decisions, legal acts and certificates based on the previous law

Something that is sometimes forgotten when preparing new regulation is the question of whether decisions, legal acts and certificates taken or issued under the old law shall remain valid, and if so under which conditions and for how long. Forgetting this question causes a lot of legal uncertainty or difficulties, or both, in the transition.

Evidently, there is a conflict between the economic operators' wish to maintain their legal position for as long as possible and the regulator's interest in introducing the obligations of the new regulation as fast as possible.

## 9.3. Applicability of other regulation

There is a wide variety of clauses dealing with the applicability of other regulation:

- Repeal provisions;
- Provisions stipulating that other regulations remain unaltered;
- Provisions stipulating that other regulations prevail;

<sup>91</sup> SI/2014-12 February 26, 2014m P.C. 2014-145 February 10, 2014.

<sup>92</sup> SOR/2014-113 May 16, 2014, P.C. 2014-568 May 15, 2014, Vol. 148, No. 12 — June 4, 2014

- Provisions stipulating that the new regulation prevails over other regulations;
- Provisions stipulating that no other regulations apply.

Repeal provisions can be specific, targeting one or several regulatory acts, or general. Section 20 of the [Graphic Health Warnings Law of the Philippines](#)<sup>93</sup> repeals not just a specific regulatory act or parts thereof, but stipulates, in addition, in general terms: “*all other laws, decrees, executive orders and other administrative issuances and parts thereof which are inconsistent with the provisions of this Act are hereby modified, superseded or repealed accordingly.*”

The Senegalese Law No. 2014-01 of January 6, 2014 relating to the treatment of dormant accounts in the books of financial institutions of the Member States of the West African Monetary Union (WAMU) also provides for repeal of “contrary previous provisions”, and this is even combined with an application date earlier than the adoption date:

*“Art. 23. - La présente loi entre en vigueur le 1er janvier 2014.  
Sont abrogées, à compter de cette date, toutes dispositions antérieures contraires.  
La présente loi sera exécutée comme loi de l’Etat.  
Fait à Dakar, le 6 janvier 2014”*  
Amended machine translation:  
*“Art. 23 -. This Act comes into force on 1 January 2014.  
All previous contrary provisions are repealed with effect from that date.  
This Act shall be enforced as state law.  
Made in Dakar, January 6, 2014*

It is sometimes useful to clarify that other regulation should remain unaltered; see as an example Council [Regulation EC/428/2009](#) setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items:

*“Article 26 - This Regulation does not affect:  
the application of Article 296 of the Treaty establishing the European Community,  
the application of the Treaty establishing the European Atomic Energy Community.  
However, the most common place for such kind of clearance is rather at the beginning of the legislative measure.”*

Section 21 of the same [Graphic Health Warnings Law of the Philippines](#)<sup>94</sup> clarifies that the international obligations prevail over the new legislation:

*„SEC. 21. Compliance with Existing International Conventions. – Nothing in this Act shall modify the measures adopted to give effect to the obligations of the Philippines under international conventions existing at the time of the enactment of this Act.“*

Such a clarification is not necessary in jurisdictions where international law automatically prevails over domestic regulation.

An explicit statement that no other legal acts apply is contained in Section 3.(2) of the [Canadian Food and Drugs Act, Blood Regulations, P.C. 2013-1065 October 9, 2013](#):

*„(2) Except for section A.01.045 of the Food and Drug Regulations, no other regulation made under the Act applies to blood that is the subject of these Regulations.“*

We deal in this Section with simple statements on the applicability or non-applicability of other regulation. References to or integration of other regulation is dealt with in Section 2.10. See also Section 2.9 on “Overlapping with other regulation”.

#### 9.4. Authenticity of acts

Many regulations foresee declarations or other acts of the authorities, of operators or of citizens that trigger legal effects. If they do, the question arises as to how and whether the authenticity of these acts is to be proven. The acts can consist of:

- oral statements, to be made in front of an empowered official in a precise form and with appropriate minutes, and

<sup>93</sup> Republic Act No. 10643, published on [July 15, 2014](#).

<sup>94</sup> Republic Act No. 10643, published on [July 15, 2014](#).

- written statements.

For written statements, the first question that arises is that of the signature: Is it to be authenticated by an official? Can the signature be replaced by an electronic signature? If so, what are the requirements of authenticity? Regulation should establish these requirements. But electronic signatures are under threat from hackers. Therefore, the range of valid signatures must be established in a dynamic way. Apparently, this issue is becoming a business of its own. Canada has even set up regulation establishing the criteria for the regulator when determining requirements for electronic signature, thus setting up a kind of meta-requirements. The [Canadian Department of Employment and Social Development Act - Electronic Documents and Electronic Information Regulations](#)<sup>95</sup> provides:

*“8. The standard of reliability required with respect to any electronic signature must be established taking into account the following factors, including*

*(a) the purpose for which the electronic signature is required;*

*(b) a secure electronic signature, which has the same meaning as in subsection 31(1) of the Personal Information Protection and Electronic Documents Act; or*

*(c) a signature that results from the application of any technology or process that is determined by the Minister or the Commission as able to provide the same level of security as a secure electronic signature.”*

For written statements, the second question that arises is that of transmission. Transmission by classic letter is certainly the standard. But may transmission be made by e-mail or by fax? Or is it, on the contrary, necessary to request the letter to be sent as a “registered letter” or by bailiff?

All these questions can evidently arise both for acts of the authority and for acts of private persons.

## 9.5. Separability clause

Contracts contain often a clause stating that, if parts of the contract are invalid, the rest is deemed to remain valid. We found a similar clause applied to regulation in the [Graphic Health Warnings Law of the Philippines](#)<sup>96</sup>:

*“SEC. 19. Separability Clause. – If any clause, provision, paragraph or part thereof shall be declared unconstitutional or invalid, such judgment shall not affect, invalidate or impair any other part hereof but such judgment shall be merely confined to the clause, provision, paragraph or part directly involved in the controversy in which such judgment has been rendered.”*

## 9.6. Sunset clause

The sunset clause consists in fixing a date of cessation of applicability for a certain regulation. The sunset clause came out of fashion in some jurisdictions when it was discovered that problems do not necessarily disappear when a regulation ceases to be applicable. A full new legislative procedure became necessary in some of the cases for which no renewal was foreseen. The sunset clause, hoped to be a measure of de-bureaucratization, thus became the cause of additional procedures. However, the sunset clause still constitutes a good tool if there really is only a temporary measure to be taken.

The sunset clause can also be used for parts of legal acts. E.g., the [Canadian Motor Vehicle Safety Act - Regulations amending the Motor Vehicle Safety Regulations](#)<sup>97</sup> contains section specific sunset clauses.

## 9.7. Review clause

Sometimes it is useful to foresee a review of the regulation at a certain point in time or even at regular intervals. An obligation to review set up by the regulator can enter into conflict with the right of initiative of another institution, if, according to law of higher order, only the other institution is authorised to develop drafts. However,

<sup>95</sup> SOR/2014-117 May 16, 2014, P.C. 2014-572 May 15, 2014, Vol. 148, No. 12 — June 4, 2014.

<sup>96</sup> Republic Act No. 10643, published on [July 15, 2014](#).

<sup>97</sup> P.C. 2014-359 April 3, 2014, Vol. 148, No. 9 — April 23, 2014, SOR/2014-82 April 4, 2014.

this is a rather exceptional situation.

Practically speaking, a review clause can be both useful and detrimental. It is useful if a review is necessary and would not take place without the review clause. It is detrimental if the institution in charge of initiating the review would at any rate act within a reasonable space of time. In that case, a stiff time-setting for review can hinder the institution in initiating the review at the most appropriate point in time. The most appropriate point in time may be subject to the maturity of preparatory investigations, experiences made, and developments of the respective sector or of neighbouring sectors or of the law of higher order.

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## 10. Working methods and ethics

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*Achieve results,  
Because this is the natural way.  
Achieve results,  
But not through violence.  
Force is followed by loss of strength.*

Lao Tse

### 10.1. Elaboration methods

The old-fashioned approach of elaborating regulation can be described as follows: The ministry / administration works behind closed doors on a proposal or the draft measure and consults some stakeholders as much as this cannot be avoided.

A more modern approach consists of:

- sharing the basic analysis and ideas,
- describing a range of possible measures,
- consulting the stakeholders extensively by surveys and in open debates,
- letting working groups draft various items, and
- coming up with a proposal or draft measure that does not catch anyone by surprise.

A third approach has not yet been practised yet, but is looming on the horizon: Letting administration staff and stakeholders work on the draft in an open peer-to-peer process<sup>98</sup>. Especially if the open issues to be regulated are extremely numerous or complex, the peer-to-peer process might lead to better results (more aspects covered, a wider range of solutions etc.). This is no surprise as well arranged collective intelligence tends to be superior to the intelligence of a few individuals. On the other hand, the administration would have to make sure that lobbying in the peer-to-peer process does not block the development of good options.

Contrary to what many think, the peer-to-peer method does not reduce the number of options and the “influence” of those formally responsible, but increases them. More people tend to develop more thoughts and more options amongst which the formally responsible service can choose. Peer-to-peer work lessens not the right to decide, but the right to ignore (alternatives).

Identifying the basic strengths of the more open working methods does not mean that the old-fashioned method cannot be the best in some cases. If the administration has good reason to take a certain political line opposing lobby interests, to work behind closed doors is sometimes the only way to defend the political line. Furthermore, it reduces the credibility of the administration’s participatory processes altogether to suggest that a certain question is debatable for the administration whereas, in reality, it is not. Therefore the open methods should only be used to the extent that the administration really is open and can afford to be.

The more open the working method, the more the result will be influenced by the strongest lobbies. Naturally, those on whom legal measures impose a burden will try to avoid them. They will try to influence both the initial legislative process and any implementation afterwards. They often have more resources than the administration and more stable personnel. Therefore it is important to introduce checks and balances, perhaps anticipating third-party review at regular intervals from the start or enforcing publication of results etc. in order to restore some balance.

### 10.2. Negotiating regulation

The author has observed a wide range of attitudes taken by officials when negotiating. The most frequent attitude is to take a position and to defend it, be it alone or be it in an alliance with others. This is the easy game

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<sup>98</sup> More on the peer-to-peer processes to be found on [www.p2pfoundation.net](http://www.p2pfoundation.net); see also the mostly American scientific debate on "E-Rulemaking".

which often leads to a power struggle, not necessarily to the benefit of the common cause. Other officials try to understand the reasons behind a certain view of their interlocutor. They think more in terms of interests. Thinking in terms of interests instead of positions is paramount for finding a consensus. Only on the basis of a good understanding of the interests of all sides can a good or at least acceptable solution be found. Some officials even feel responsible for the negotiation process without being the chair. These officials often have methodological knowledge on process steering and negotiations. These officials are able to intervene when there is a deadlock in the elaboration or negotiation process. They can even prevent problematic situations upstream. They know when more collaborative work forms need to be applied, when a break-out session is necessary or when, on the contrary, more classic streamlining is required to get to a result. They are able to co-steer or even to steer the negotiation process, regardless of who is formally chairing the process.

Sooner or later officials are confronted with difficult situations in which no progress seems to be possible. In such situations, it is helpful to take a step back or to look at the situation from above. The following questions might help you to overcome the deadlock through new ideas. These questions might also be used to establish a controlling process during negotiations even when there is no deadlock:

- What is the issue to be regulated?
- Why is this issue to be regulated?
- What are my major goals?
- How shall my major goals be weighed against one another?
- Who is best placed to regulate the issue? Who is second best placed?
- What major regulation parameters are there?
- Which are the most appropriate incentives?
- What are the stakeholders' preferences with regard to these parameters?
- What are the stakeholders' negotiation positions?
- What are their interests behind the positions?
- By which solutions can these interests (not positions) best be accommodated?
- Which solutions have been found in parallel sectors of the same field or even in other regulatory fields?
- Which solutions could be imported from completely different contexts, e.g. from private business, engineering, or science?

Often the devil is in the detail, for instance in the detailed requirements. If there is a dispute on detailed requirements, it is useful to be familiar with a basic typology of requirements as laid down above (Section 2.3.2). Knowledge of this typology permits the development of new options that might be accepted as a compromise.

Sometimes negotiation deadlocks can be overcome by promising a review process after one to five years. However, such a review process binds important resources and creates uncertainty for stakeholders. In this respect, it is similar to dynamic conditions.

### 10.3. The ethical values as means to find consensus

In courses on negotiation techniques, one learns that talking about interests is more fruitful than talking about positions. In negotiations about regulation, this approach can be complemented by discussing ethical values, especially if the negotiations are stuck. Explicitly expressed ethical values can help to understand the position of others. Ethical values can also become a basis for a good regulatory solution based on mutual understanding and fairness. In the extreme case, discussing ethical values can trigger new solutions, new requirements, and even new measures.

Ethical values can refer to the overall process of developing regulation or to the content of regulation. Ethical values may give new perspectives on the goals or objectives to be pursued, on the requirements to be set up, on the incentives to be used, or on the administrative principles to be applied, e.g. with regard to enforcement.

## 10.4. Creative solution finding

We constantly miss occasions to find better solutions. We do so partly because we are not willing to invest in solution finding and partly because we think that things cannot become better anyway.

The range of possible solutions we find to legislative problems is limited by basic assumptions, be they explicit or implicit. To put aside a basic assumption can help us to find new solutions.

To identify and put aside basic assumptions is one way of finding creative solutions. There are many more ways to find creative solutions:

- Reflect on your issue while imagining that the opposite of a basic assumption was true. If you find a solution with the opposite basic assumption, think about how the opposite basic assumption could become real by measures that you can trigger.
- Put all the elements of your systems on cards and arrange them in a way that best describes your system. Play around with the cards to express a potential alternative system. You do not need to use all of the cards.
- Check what element of your system is not really needed. Arrange the cards without that element.
- Look at the ideal output of the system. Think backwards from the ideal result: what is really needed to get the ideal result? What is the shortest way to this result?
- Look at how things are done in other fields. What could you copy or adapt to your system?
- Look at processes in nature. What could you copy or adapt to your system?
- Talk to managers, scientists or other people with a completely different background. Note their questions and hints, and do not immediately judge them. Though they do not know your system, they might indicate which assumption is questionable or where you could learn from.
- Stretch: how is the issue to be defined on a larger scale and how would it be approached at that scale?
- Squeeze: divide into sub-problems. How else can you approach them?
- List the components, functionalities, mechanisms etc.: Are they needed? Can they be minified?
- How else could functionalities and mechanisms be ensured? What would be the most natural, fluent way of ensuring these functionalities?
- Try to put the components, functionalities and mechanisms to other use.
- Combine the components, functionalities and mechanisms.
- List attributes for components, functionalities and mechanisms: ask how you could change or improve them. Could you cut them into components and find solutions for the components?
- Whichever of the previously listed ways you use: separate the idea finding phase from the idea evaluation. Reserve a second day for the latter. On a different day, you will have a clearer view.

More hints and techniques are to be found in: Michael Michalko, Thinkertoys, Ten Speed Press, Berkeley (California), 1<sup>st</sup> edition 1991.

Another possibility for solution finding consists in involving the stakeholders in a special, creativity fostering setting. Frequently, the joint creative work not only increases acceptance, but also increases the number of options and insights.

However, these methods are not a panacea. They do the job, but they are no guarantee for the ideal solution. Why? Those who operate in a system (the “experts”) are not necessarily those who can best analyse and repair it. And they are not necessarily those who have the most creative potential. Furthermore, the experts need to forget their preconceptions and expertise for the purpose of the idea finding exercise. Not all experts are able or ready to do so. To involve outsiders with a particularly strong analytical capacity for systems and who have a high creative potential is therefore equally important. A combination of the two is ideal.

## 10.5. Finding the optimal path

Once the goal has been identified, some time and energy should be invested in identifying the optimal path towards achieving the goal. The following simple statements might help you to find the best path:

- The shortest path is not necessarily the fastest.
- The fastest path is not necessarily the path which brings along the most sustainable result.
- Neither of these three is necessarily the safest.
- All four might require efforts that go beyond the available energy.
- The steering must be continuously adapted to follow the path chosen, whatever it may be.

Change management knowledge or methodology can help to find a viable path and way of implementation. Change management is dealing with questions of transitions to a goal which is deemed worthy. Regulators are often unaware of the need for conscious change management. Accordingly, many initiatives unnecessarily fail.

## 10.6. Managing regulatory work

The answer to the following questions might influence not only the way of dealing with regulatory issues, but also the decision on what is to be dealt with by regulations and by other means. Conscious reflection and a subsequent choice are especially needed if human resources are limited.

- For whom do we work? In whose interests do we work?
- For whom do we want to work? In whose interests do we want to work?
- How do we balance the different interests?
- What is really the core issue in the sector I have to deal with? How can I best tackle it? What are the other issues? How do all these issues interrelate?
- Do I know the ideal scenario to deal with these issues?
- If not, what is the best way to find out and trigger a process going in the right direction? In which style do I want to steer the process, how narrowly shall it be steered? Do I have the necessary skills in-house? Who else could help me to steer the process?
- If yes, what would the ideal scenario be in five, ten or fifteen years? Which is the time horizon I am mainly interested in?
- What is the easiest way to reach the ideal scenario?
- What is the fastest, what is the safest way?
- Who might oppose it? Why and how?
- How can opponents be convinced?
- What other uncertainties are there?
- What type of steering is needed to get to the ideal scenario? Linear, cybernetic or multi-dimensional and complex steering? Do I have the necessary skills for this type of steering?
- What time frame is needed as a minimum? Does a more generous time frame lead to a better result? What are the consequences of a slower preparation for the addressees of the measure and for the jurisdiction? If more time leads to a better result, does the additional win in quality outweigh the slower entry into application of the measure?
- Provided that resources are limited: What can I achieve together with my colleagues in one year if we work jointly on new regulation? What can we achieve jointly if we work on regulatory measures other than regulation? Where can we achieve most utility? For what kind of measures will we receive how



many staff? (System maintenance and implementation might be less rewarded in terms of staffing than a system renewal whilst not necessarily being less important.)

Sometimes, the answers to these questions depend on the timeframe for which the answer is to be given. The answers may be different in a three-year perspective when compared to a five-year perspective.

## 10.7. Attitudes towards regulatory work

There is a wide variety of attitudes towards regulatory work to be observed. Sometimes officials shift from one attitude to the other or combine two of them. Some examples:

- I develop regulatory measures only if it is advantageous for me or for my unit in terms of visibility;
- I develop regulatory measures if I am asked by my line-managers or if it is in the interest of my line-managers;
- I develop regulatory measures if powerful interest groups ask me to do so;
- I develop regulatory measures if I am completely sure that it is the right step or if it is less risky to take the measure than not to take it;
- I develop regulatory measures if it is the best way to solve the issues in the sector;
- I try to optimise the output I can reach with my staff in order to develop the legal system as well as possible in the years to come;
- I try to optimise the output I can reach with my staff in order to develop the legal system as well as possible in the years to come but also in the longer term.

In these attitudes, we can identify various goals:

- Improve reputation;
- Avoid nuisance from inside the institution - serving those who legitimately represent the institution;
- Avoid nuisance from outside the institution - serving clients;
- Risk avoidance;
- Optimisation of the result for one specific issue;
- Optimisation of the short term overall result for the system;
- Optimisation of the long term overall result for the system.

## 10.8. Ethical considerations in regulatory work

When undertaking regulatory work, it is of the utmost importance to identify the constituency for which one is working. Is it a local constituency, a regional, a nation-state constituency or even a multi-national constituency? Is the constituency the entire population or only a certain part of it? Is the constituency more precisely defined in terms of societal characteristics or economic functions? Once the constituency has been identified, one needs to further define to what extent the defence of the interests of the constituency should prevail over the interests of other people affected by the regulatory work. Defending the interests of citizens of a rich and powerful nation-state in terms of product safety will have effects on the economic chances of operators in poor parts of the world outside this nation-state and the people who depend on these operators for employment. International treaties may exceptionally contain limits to a strong unilateral imposition of rules on operators across the world, but mostly there aren't such limits. At best some basic ethical principles in respect to this are contained in the national constitution. But even in these cases there is room for ethical considerations which can help to fill the loophole in. Ethical considerations should of course be based on an analysis of the impacts of a considered regulatory measure.

Another loophole contained in most legal systems relates to future generations, thus to human beings not yet

born. Research, economic and other activities today may have tremendous effects on future generations; see e.g. the multi-faceted issue of waste or today's research on synthetic biology which can threaten, according to a symposium of the University of Oxford in 2014, the entirety of mankind (whilst there are also undoubtedly benefits thereof). Hardly any legal system provides for protection of those who will be born in the next century, though these human beings do not necessarily merit being protected less than those living today. Hence it is ethically worthwhile to think of the trans-generational effects of what takes place in society and the regulation thereof.

A further topic for ethics is animals. Roughly every week there is new research published on the similarities of processes that take place in certain animals and in human beings, be they related to intelligence or to feelings. There are animals which can express joy after meeting a childhood friend after 30 years, as there are animals which mourn or even bury their mates. Even altruistic behaviour is not limited to mankind. Hence it might well be that, with further research completing the picture, future mankind will regard the lack of protection of the interests of animals as similar to the lack of protection of human beings held in slavery. We may remember that the shift of the majority view as to the ethical correctness of slavery took place only about a hundred years ago. As regulators, do we wish to be regarded, let us say in 50 years, in a similar way as the defenders of slavery in 1900 are regarded by us today?

We have added into the Chapter on Quality Verification (Chapter 11) a few ethical questions that can help to take account of these ethical aspects even if these ethical aspects are not (yet) laid down in the respective constitution.

## 10.9. Temporality of regulatory measures

Some laws survive across thousands of years. The principle „eye for eye, tooth for tooth“, presumably first laid down in the penal code of the ancient empire of Babylon and aimed at limiting vengeance, has been transmitted via the Bible and the Quran to numerous legal systems. It is still a basis of penal law in some jurisdictions today. However, this degree of endurance is rather an exception. Normally, regulation is appropriate in a certain societal context only. The Babylonian principle, though progressive at times of adoption, is now regarded as outdated by most of the jurisdictions which can afford to run prisons. As societies change, it is a question of time as to when a certain piece of regulation becomes inappropriate.

There are two consequences to be drawn from this statement:

- Regulators should provide for updating mechanisms.
  - Regulators should cast regulation in such a way that it can easily be updated – e.g. by a modular approach.
- Another technique for ensuring endurance of regulation is to limit regulation to basic principles<sup>99</sup>. Some of these basic principles, namely those of civil law, can be traced back to Roman times.

Thus there are means to prepare regulation for the future. However, even if we were to respect this advice, we might still bear in mind that everything that is built falls down sooner or later<sup>100</sup>, and so do regulatory systems. Again we might think of Babylon and its famous tower, today only visible by satellite view as mere lines on the ground.

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<sup>99</sup> The French Code Civil, initially also called Code Napoléon, could survive during two centuries in several European states because it is based on essential principles which are not very much subject to changing societal views.

<sup>100</sup> "Time crumbles things; everything grows old under the power of Time and is forgotten through the lapse of Time." (Aristotle)

## 11. Integral quality verification

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*„It is dangerous to be right in matters where established men are wrong.“*  
Voltaire

### 11.1. The need for integral quality verification

Is it already time to think in terms of integral quality verification for regulatory measures? The author fears that the idea will be regarded as sacrilege or at least provoke substantial resistance. However, he thinks that its time has come. He feels this way for different reasons:

- More and more regulation worldwide requires the application of a full quality system from economic operators, which is much more than simple quality verification. It is a question of consistency and credibility to apply the same principles, to whatever extent possible, to one's own activity as well.
- Quality verification as a first step towards quality systems is nowadays used in most of the product- and service-providing industry and also in more and more processes of public authorities. The reasons for this trend are simple: quality verification leads to a better use of resources, less liability risks, a better reputation, and less risk of public criticism. Why shouldn't these reasons apply to regulatory measures?
- Feasibility is no longer a hindrance. The classic negative reaction „Quality verification is not possible for us!“ has been observed in so many other fields but overcome in most of them. With the experience from other societal activities, it is possible today to describe the process of regulating, to name the points which are relevant for the elaboration of regulatory measures and to list the items to be verified at the end of the process.
- Complexity of societal processes increases tremendously. Regulatory measures, if well-conceived, respond to this complexity – and thus become ever more complex themselves! Due to this complexity, mistakes and unconscious omissions become unavoidable. Quality verification (and a systematic approach in the elaboration of regulatory measures as suggested by this handbook) could become a means to reduce the likelihood of these mistakes and omissions. The author remembers many of his course participants saying „If only I had known about this possibility before, when we were casting our measure!“. Some simple quality verification would have helped them.

Aren't impact assessments doing the job of integral quality verification? Impact assessments can only be regarded as a subset of what is called quality verification here. Subject to the design of the impact assessments in the respective jurisdiction, impact assessments go more or less into detail. However, the author has not come across any impact assessment that covers more than one fourth of the topics dealt with in the handbook. Mostly, impact assessment methods limit themselves to much less. Furthermore, impact assessments do not / cannot go far enough into details. It is e.g. usually not the task of impact assessments to verify whether transitional provisions respond to the sector's needs for a smooth transition from the old to the new legal regime.

All this does of course not mean that impact assessments have no merits. Impact assessments can exert certain verification, and often they do so for the most important questions. Historically the concept of impact assessment has the merit of being a very first big step towards quality verification of regulatory measures. But this does not mean that jurisdictions should stay at that level for ever. Evolution is going on, and maybe our views on how regulatory measures should be conceived and controlled should evolve as well.

In some jurisdictions, there are efforts to verify the quality of regulatory measures with regard to particular aspects, e.g. with regard to:

- administrative burden,
- citizen-friendliness,
- business-friendliness,
- rules of legal drafting,
- leaving the utmost liberty to geographic entities / regulating only what is strictly necessary at the level of the Centre. However, all these efforts do not cover more than a fringe of the aspects which need to be borne in mind by the officials selecting and preparing regulatory measures. Accordingly, even all of these efforts together do not reach more than partial quality verification. Integral quality verification would go much further.

## 11.2. Suggested elements for an integral quality verification

It goes without saying that the author, due to his limited knowledge and experience, is not in a position to suggest a model of integral quality verification for any jurisdiction, including those he is relatively familiar with. Setting up quality verification must itself involve many institutions or entities of the respective jurisdiction so that their multiple legitimate perspectives are properly reflected. He simply presents possible elements of basic quality verification in a non-invasive form – simple questions.

The list is incomplete and certainly biased as it is too much influenced by the perspective of one person. However, some institutional readers might, despite these deficiencies, appreciate the list as a start for own reflections. Furthermore, officials who wish to improve their regulatory practice might also find the list to be helpful. To suit the latter, the questions are presented in an order that mirrors as much as possible the structure of the handbook. It goes without saying that the questions could be regrouped in many other ways<sup>101</sup>.

### 11.2.1 Questions regarding all regulatory measures

#### 11.2.1.1 Process (Sections 2.5 and 10.1)

*Has the regulatory measure been subject to a mandatory public consultation?*

*Has the mandatory public consultation provided enough results to identify the needs and the characteristics of the sector?*

*If not, have the necessary further consultations been initiated?*

*Have all the mentioned consultations been appropriately considered?*

*Did the stakeholders have enough occasions to comment and to provide input, and this also with regard to the draft measure?*

*Did the geographic entities have enough occasions to comment and to provide input, and this also with regard to the draft measure?*

*Did the international partners (other jurisdictions and international organisations) have enough occasions to comment and to provide input, and this also with regard to the draft measure?*

*Did other ministries / departments or advisory institutions (e.g. Court of Auditors, Ombudsmen) provide for sufficient input?*

*Has the regulation of other sectors been studied for comparison and inspiration? Has experience from other sectors been appropriately used?*

*Has regulation of other jurisdictions been studied for comparison and inspiration? Has experience from other jurisdictions been appropriately used?*

*If there were different elaboration tracks: have all results of the different elaboration tracks been appropriately integrated? See Section 2.5.1.*

#### 11.2.1.2 Overall architecture (Sections 2.1 to 2.4)

*Have the real needs of the sector been identified?*

*Do(es) the regulatory measure(s) selected fully respond to the identified sector needs?*

*Should the selected measure(s) be complemented by other measures to cover the sector's needs? Check against 2.3.4.1. Check also against information and enforcement needs in Chapter 7.*

*Do(es) the selected measure(s) bring the sector closer and close enough to its ideal state?*

<sup>101</sup> E.g. the questions could be attributed to the following categories: 1. Impacts, efficacy and own policy; 2. Relationship with / consistency with other acts and policies; 3. Internal consistency; 4. Conformity control and enforcement; 5. Other implementation questions; 6. Regulatory policies and drafting rules; 7. Process

*Do(es) the selected measure(s) tackle the issues which had been identified by the sector analysis?*

*Do(es) the selected measure(s) fit with future developments? Check against 2.1.1.1.*

*Will the top five problems of the sector be solved by the measure(s)?*

*Could some of the non-top-five-problems be elegantly solved in addition?*

*Will the top three development potentials for the sector be used?*

*Will the selected measure(s) ensure that the predetermined or set policy goals are reached?*

*Will the measure(s) ensure that the set objectives are reached?*

*Have all appropriate requirements been set? Check against the typology in Section 2.3.2. and against the requirements of similar sectors and of other jurisdictions.*

*Have all appropriate incentives been used? Check against the typology in Section 2.3.3.*

*Is it necessary to ensure that the regulatory measure(s) become(s) known? Have all appropriate information tools been used or foreseen?*

*Given the state of the sector, is it realistic that the citizens, operators and geographic entities can reasonably use or transpose the selected measure(s)?*

*Do(es) the selected measure(s) lead to an optimised use of available resources at the level of the Centre and in geographic entities? Do we reach the best we can with the available resources?*

#### 11.2.1.3 Ethics (Sections 10.8, 3.17)

*Are/is the measure(s) positive / optimised for the constituency?*

*Do(es) the measures strike a fair balance between the interests of those persons (within the constituency) who take profit from it and the interests of those who bear the direct or indirect costs or negative effects?*

*Are/is the measure(s) ethically acceptable with a view of persons not belonging to the constituency?*

*Do(es) the measure(s) strike a fair balance between the positive effects for the constituency and the effects on persons not belonging to the constituency?*

*Are/is the measure(s) ethically acceptable with a view of future generations?*

*Are/is the measure(s) ethically acceptable with a view of animals?*

#### 11.2.1.4 Formal aspects and consistency (only some elements covered in Chapter 2)

*Does the regulatory measure follow the applicable editing policy?*

*Is the regulatory measure correctly structured?*

*Are the sections and subsections correctly numbered?*

*Does the regulatory measure include all necessary references?*

*Are the references correct?*

*Is the terminology of the regulatory measure coherent with the terminology of other regulatory measures and above all with the terminology of the empowering regulation?*

*Is the terminology consistently applied in the regulatory measure, including its annexes?*

*Does the terminology correspond to the common language in the sector?*

*Is the terminology and the syntax understandable for the targeted citizens or operators?*

*Is the regulatory measure altogether understandable for the targeted citizens or operators?*

*Do have citizens and operators a fair chance to fulfil the requirements set by the regulatory measure?*

*Is the regulatory measure fair in terms of predictability (= not too surprising)?*

*Is the regulatory measure fair in terms of equality?*

*Is the average depth / the average level of detail appropriate?*

*Are there important deviations from the average depth / the average level of detail? If so, are they justified?*

*Are the Recitals / the rationale detailed enough?*

*Are the Recitals / the rationale in line with the content?*

*Is the regulatory measure consistent with other, similar measures of the same level? If not, are the deviations justified?*

*Is the regulatory measure consistent with regulatory measures of a higher order (e.g. the Constitution)?*

*Is the regulatory measure compatible with international law?*

*Does the regulatory measure follow the applicable regulatory policies (e.g. on “Better regulation”, “Smart regulation”, “Business friendliness”)?*

### **11.2.2 Questions regarding regulation only**

#### 11.2.2.1 Basic legal choices for regulation (Sections 2.6 to 2.12)

*Does the regulation cover all that it needs to cover? Check against regulation of other sectors, of other jurisdictions, against Section 2.7. and the particular checklists for products and for services at the end of this Section 11.2.*

*Are the subject matter or purpose and the scope of the future regulation rightly defined (=pretending to cover something which is not covered in reality and vice versa)?*

*Are the subject matter or purpose and the scope of the future regulation consistent with one another and with the content of the regulation?*

*Has the right legal basis been chosen? Meaning: Does the legal basis cover the type of regulation to be adopted? Do the goals of the regulation fit with the legal basis? Does the content of the regulation fit with the legal basis?*

*Are overlaps with other regulation reasonably dealt with?*

*Is other regulation meaningfully referred to?*

*Has the right legal instrument (amongst those authorised by the legal basis) been chosen?*

*Mainly for international regulation: has the most appropriate harmonization approach been chosen?*

*Does the regulation have the right degree of density?*

*Is the content of the articles rightly placed in the articles?*

*Is the content of the annexes rightly placed in the annexes?*

*Has the right balance been struck between the various conflicting legislative and constitutional goals?*

*Have the limits for the empowerment of agencies and subordinate bodies been respected?*

#### 11.2.2.2 Risks and performance in requirements and measures (Chapter 3)

*Have the different types of risks been identified and covered by the measure? Check against Sections 3.1 and 3.19.*

*Was it right to establish fixed, stable risk limits or would a risk-benefit analysis be more appropriate?*

*Have basic risk management principles been imposed on operators?*

*Have different types of risks been appropriately valued against one another?*

*Have multi-dimensional impacts been appropriately evaluated?*

*Was it right to apply / not to apply the precautionary principle?*

*Was it right to apply / not to apply a safety margin?*

*Has the proportionality principle (if applicable) been respected?*

*Has adaptation to technical progress been ensured?*

*Was it the right to establish static / dynamic risk and performance requirements?*

*Was it right to establish quantitative / qualitative risk and performance requirements?*

*Was it right to refer / not refer to standards?*

*Should certain standards be referred to in addition?*

*Was it right to refer / not to refer to non-legal documents other than standards?*

*Should certain other non-legal documents be referred to in addition?*

*Have high risk products and processes be appropriately covered?*

*Is a fair balance struck between the interests of those who bear the risks and the interests of those who cause them?*

*Has the right reference time or stage been fixed for assessing whether the requirements are fulfilled?*

### 11.2.2.3 Conformity verification and enforcement (Chapter 7)

*Have operators and citizens been informed of their obligations?*

*Is the regulation precise enough to be enforced?*

*Is the regulation precise as to the verification and enforcement obligations contained therein?*

*Is the verification and supervision of compliance of operators and of citizens foreseen in the regulation:*

- intense enough?*
- targeting the right aspects?*
- executed by the right authorities or by the right private bodies?*
- executed at the right time and the right step of the processes regulated?*
- executed in the right procedure? Check against Section 7.8.*
- provided by the right means?*
- optimised in terms of synergy with other sectors' verification and supervision?*

*Should accredited reference laboratories be used?*

*Does the regulation foresee minimum resource equipment for authorities, be they at the Centre or in the geographic entities?*

*Are the resources necessary for enforcement available in reality in the Centre and in the geographic entities?*

*If not, can they be built up over time? Is there something that can be laid down in the regulation to build them up?*

*Is there a need to build a new agency or shall an existing agency be entrusted with new tasks?*

*If yes, is the necessary budget available?*

*Do the entrusted private bodies possess enough staff, equipment and money to efficiently execute their verification and supervision function?*

*Should the Centre take over the role of enforcement supervisor?*

*Is the verification and supervision of compliance of geographic entities (with regard to verification and enforcement tasks) intense enough?*

*Have alternative enforcement mechanisms (by private persons or by operators) been used or, for good reason, disregarded?*

*Have possibilities for “enhanced enforcement” been used or, for good reason, disregarded? Check against Section 7.12.*

*Should there be reimbursement of verification costs?*

*Has own-brand-labelling been limited to acceptable practices?*

*Have the possibilities of rogue operators been reduced?*

*Have rights for indemnities, administrative sanctions (including confiscation) and penal provisions been introduced or, for good reason, disregarded?*

*Are indemnities, administrative and penal sanctions high enough to deter?*

*Has the responsibility of associated companies been dealt with?*

*Have the special verification and enforcement needs of e-commerce and private imports been dealt with?*

*Have the special verification and enforcement needs of deconstructed products been dealt with?*

*Have the special verification and enforcement needs of services and products originating from zones without state control been dealt with?*

*Are the consequences of non-conformities or negative test results clearly spelled out?*

*Is the regulation clear as to burden, means and degree of proof?*

*Does the regulation provide for all necessary enforcement assistance by other administrations, public and private entities?*

*Is there a need to attribute responsibilities to courts or administrations? Has this need been covered?*

*Does the regulation provide the authorities or entrusted private bodies with the necessary enforcement powers?*

*Is there a need to provide authorities with the right to issue provisional orders to avoid imminent danger?*

#### 11.2.2.4 Other implementation questions (Chapter 8)

*Does the regulation provide enough, but not too much discretionary power?*

*Is the use of vague legal expressions justified / not excessive?*

*Are interpretation guidelines within the regulation or an empowerment for the adoption of interpretation guidelines needed?*

*Are more definitions needed to avoid interpretative questions?*

*Are the existing definitions precise?*

*Are the requirements clear as to the legal persons to whom they apply? What about branches, subsidiaries (daughter companies), mother companies, joint-ventures?*

*Are special rules needed for branches, subsidiaries (daughter companies), mother companies, joint-ventures?*



*Have the necessary means been provided for to ensure the harmonised work of conformity assessment bodies?*

*Have the necessary means been provided for to ensure that the authorities decide in time?*

*Have the necessary means been provided for to ensure that the authorities are strengthened?*

*Have the necessary means been provided for to prevent corruption or other unlawful operations of authorities?*

*Have means for dispute resolution been provided for?*

*Should certain decisions be taken by committees? If yes, have the necessary committees been set up in the regulation or do they exist already? Do the committees have the appropriate means and internal rules?*

*Should certain situations of minor importance be exempted from certain requirements or even from the scope by a “de minimis clause”?*

*Should the possibility of regularisation be offered?*

*Does the regulation contain all the necessary provisions to ensure good cooperation between authorities?*

*Should, for certain items, one authority of the geographic entities coordinate the work of their peers in other geographic entities?*

*Does the regulation contain all the necessary provisions to empower international data-exchange and cooperation?*

*Does the regulation contain all the necessary provisions to ensure confidentiality?*

*Does the regulation contain all the necessary provisions to ensure that verification can take place on the territory of other jurisdictions?*

*Can/should certain foreign certificates or authorisations be recognised as equivalent to domestic ones?*

*Is it clearly stipulated which regulatory measures geographic entities may take in the regulated sector, e.g. to further implement the regulation?*

*Does the regulation contain the necessary provisions to set up the informatics tools needed for its implementation?*

*Is the regulation easy to implement or at least implementable in terms of informatics?*

#### 11.2.2.4 Miscellaneous (Chapter 9)

*Are the transitional provisions sufficient? Check against the questions in Section 9.1.*

*Are the provisions on the validity of decisions, legal acts and certificates based on the so-far applicable law sufficient?*

*Does the regulation contain the necessary provisions of the following types:*

- Repeal provisions;
- Provisions stipulating that other regulations remain unaltered;
- Provisions stipulating that other regulations prevail;
- Provisions stipulating that the new regulation prevails over other regulations;
- Provisions stipulating that no other regulations apply?

*Does the regulation contain what is necessary to determine which acts are authentic?*

*Would it be useful to insert a “separability clause” in case of partial invalidity of the regulation?*

*Would it be useful to insert a sunset clause (limiting the applicability of the regulation in time)?*

*Has a review clause or another updating mechanism been foreseen or, for good reasons, disregarded?*

*Is the regulation easy to update, e.g. by its modular construction?*

### 11.2.3 Questions regarding regulatory acts only

*Can all the content be regulated by a regulatory act (regulation adopted by the administration) or does it fall under the prerogatives of the legislator?*

*Is the scope within the boundaries of the empowering legislation?*

*Are the goals pursued covered by the empowerment contained in the legislation and/or by the legal basis of the first-level empowerment (e.g. in the Constitution)?*

*Are the definitions in line with the definitions used in the empowering act?*

*Are the obligations in line with the obligations contained in the empowering act?*

*Are the obligations covered by the empowerment?*

### 11.2.4 Particular checklist for regulation on products (also partly applicable to materials)

*Check whether you also need to regulate with regard to the following elements:*

- *Product components, replacement parts;*
- *Services used in the production process;*
- *Services with regard to products once they are placed on the market<sup>102</sup>;*
- *Services with the products (offered to final users, consumers etc.);*
- *Long-distance sales (e.g. via Internet), with special focus on salespersons outside the jurisdiction;*
- *Advertisement;*
- *Distribution modalities;*
- *Parallel trade;*
- *Reprocessing;*
- *Manufacturing as an activity;*
- *Professional activities linked to the products and their distribution;*
- *Fees for conformity assessment activities;*
- *Fees for enforcement / market surveillance activities;*
- *Fees for the application of conformity assessment bodies as Conformity Assessment Bodies.*

*Check whether all of the following risks, if relevant, have been covered:*

- *Mechanical risks (e.g. failing of brakes, failing of steering, squeezing mechanisms, cutting mechanisms),*
- *Software failure risks,*
- *Risks of software manipulation,*
- *Risks of electric failure,*
- *Risks linked to electricity,*
- *Risks of incompatibility of devices, connectors, chemical substances etc.*
- *Risks linked to electro-magnetic radiation (risk of interference with devices, risks for ultra-sensitive persons),*
- *Risk of radioactivity,*
- *Risk of other tissue destructing radiation (e.g. by protons or other parts of atoms),*
- *Risk of optical disturbance by beams and other light(s),*
- *Risk of too high or too low temperature,*
- *Risk of fire,*
- *Risk of spreading disease by use of human, animal or synthetic tissues,*
- *Risk of uncontrolled proliferation of living tissues or beings,*

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<sup>102</sup> In some product legislation sectors, manufacturers try to make profit via expensive authorised repair services, blocking competition by cheaper "free" repair service providers. Regulation 168/2013/EU<sup>102</sup> of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles counters this tendency by its Articles 55 to 60. These provisions guarantee access to information and technical documentation for all repair service providers.

- Risks of bio-compatibility of chemicals,
- Risk of too high pressure (e.g. in case of explosion),
- Risk of not performing sufficiently / as intended (e.g. medicine),
- Risk of misunderstanding instructions for use,
- Risk of unintended inappropriate use,
- Risk of intended inappropriate use (“off-label use”).

Check whether the right risk management principles have been applied to each of these risks.

Check whether you need specifically regulate on steps before the final product leaving the manufacturer, e.g. with regard to:

- Risks of research (e.g. the research on synthetic biology might already constitute a risk),
- Development of intermediate products (like synthetic biology tissues intended to be used for various types of final products falling under different legislation),
- Making available of intermediate products (like synthetic biology tissues that could be used for various types of final products falling under different legislation),
- Development of final products (thus not the risk of the final product itself, but the risks of developing final products).

The only sector known by the author for which there is, in some jurisdictions at least, a complete control, from research to final products, is the sector of nuclear research, distribution of nuclear materials and final nuclear products.

#### **11.2.5 Particular checklist for regulation on services (also partly applicable to processes in general)**

Check whether you also need to regulate with regard to the following elements:

- Intermediate services;
- Services used to provide the services;
- Products used to provide the services;
- Remedying deficient services;
- Long-distance services (e.g. via Internet), with special focus on service providers outside the jurisdiction;
- Advertisement;
- Distribution modalities;
- Professional activities linked to the services or linked to the distribution;
- Service providing as a professional activity;
- Fees for conformity assessment activities;
- Fees for enforcement activities;
- Fees for the application of conformity assessment bodies as Conformity Assessment Bodies.

**Final note:** If, during the revision process, substantial amendments have been introduced, it is recommended to apply the checklist a second time in view of these amendments. E.g. the amendments might go beyond the legal empowerment.

### **11.3. A further possible element of quality verification: the analysis of affected interests**

Once the regulatory measures have been conceived, it might be suitable to analyse how the various elements or parts thereof or even particular requirements affect the interests of the targeted population. Such an analysis can be part of an official “impact assessment” or be undertaken separately. The analysis should establish, for each of the elements or parts:

- which interests are affected,
- to what extent the various interests are affected,
- to what extent the affected interests are legitimate and merit being protected,

- whether the improvements reached by the measure(s) justify going against the legitimate interests,
- what can be done to accommodate legitimate interests without disproportionately endangering the improvements.

The analysis might lead to the conclusion that some legitimate interests should be re-formulated as an additional regulatory goal or objective. Such conclusions might invite the officials to re-visit their measures, requirements and incentives in a second step. Once again, we see that a looping-back from quality verification to initial basic steps of planning can increase the overall quality of the regulatory measures.

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## *Annex I: Literature and tools*

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1. "Victorian Guide to Regulation" (elaborated by the Australian province Victoria):  
<http://www.dtf.vic.gov.au/Publications/Victoria-Economy-publications/Victorian-guide-to-regulation>
2. The Australian Government Guide to Regulation  
<https://www.cuttingredtape.gov.au/handbook/australian-government-guide-regulation>
3. OECD: Regulatory Policy and Behavioural Economics (DOI:10.1787/9789264207851-en):  
[http://www.oecd-ilibrary.org/governance/regulatory-policy-and-behavioural-economics\\_9789264207851-en](http://www.oecd-ilibrary.org/governance/regulatory-policy-and-behavioural-economics_9789264207851-en)
4. OECD: International Regulatory Co-operation - Addressing Global Challenges (DOI:10.1787/9789264200463-en):  
[http://www.oecd-ilibrary.org/governance/international-regulatory-co-operation\\_9789264200463-en](http://www.oecd-ilibrary.org/governance/international-regulatory-co-operation_9789264200463-en)
5. Alan IRWIN et al, "Regulatory Science – Towards a sociological Framework", in: Futures, Vol. 29 No. 1 pp 17-33, Elsevier Science Limited, Amsterdam 1997
6. Fiona HAINES, The Paradox of Regulation, Edward Elgar Publishing, Cheltenham (UK) 2012
7. Jacqueline PEEL, Science and Risk Regulation in International Law, Cambridge (UK) 2013
8. Jaap SPIER, Shaping the Law for Global Crises, Eleven International Publishing, The Hague 2012

## *Annex II: Some basics on information systems*

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To ensure that an information system reaches its goal, the architects must ensure a range of conditions and must make conscious choices with regard to a long list of parameters:

1. The architecture of the information system must be clear and simple.
2. It must have a clearly defined purpose.
3. It must be different from other information systems.
4. It must be brought to the attention of the target population.
5. The information system can be embedded into a more comprehensive website or not.
6. It can link to many other websites or not.
7. It can be the destination of links from other websites or not.
8. It can present its own content, copyright free content from other sources or just contain links to sources.
9. It can be comprehensive or selective in its information.
10. It can be mounted as a one-off operation (static after launch) or for continuous operation (dynamic, thus with updates).
11. Updates can be frequent (daily or several times per day), medium frequent (several times per month) or not frequent (once per month or less).
12. It can have one or several layers.
13. It can contain methodical or factual knowledge.
14. Facts can be presented in qualitative or in quantitative terms.
15. Facts can follow the logic of comparison (e.g. comparison of toxicity of substances) or not.
16. It can be managed by an authority or by a private or public body on behalf of the authority.
17. It can be in one or several languages.
18. It can be free of charge or not.

## Annex III: Finding regulation of other jurisdictions

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To find regulation regarding a certain sector in a specific jurisdiction, we recommend proceeding as follows. Go to a search engine and insert the respective keyword(s) (e.g.: car emissions). Furthermore, insert the word “site:” or the expression used by the search engine to indicate that the search shall be limited to certain sites, followed by the domain commonly used by the respective government. Example: “site:infojus.gov.ar” is the search term which allows regulators to find all regulation of Argentina in a targeted way.

For the jurisdictions referred to in this handbook, for Japan and for the U.S., we have listed the respective domains in the chart below.

Argentina	site:infojus.gov.ar
Brazil	for technical regulation: site:inmetro.gov.br; for other regulation: site:senado.gov.br
Canada	site:gazette.gc.ca
European Union (EU)	site:europa.eu
Japan	site:go.jp; in English: site:japaneselawtranslation.go.jp
India	site:indiacode.nic.in
Philippines	site:gov.ph
Senegal	site:gouv.sn
Singapore	site:statutes.agc.gov.sg
Tunesia	site:legislation.tn
United States of America (U.S.)	site:gov or site:agencyabbreviation.gov (e.g.: site:epa.gov)

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## Annex IV: Recommended regulation

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When searching for examples of good regulatory practices, regulators often look to the U.S. and to the EU. This makes sense as both regulatory systems are very highly developed. But regulators should not stop there. Therefore we make in this Annex, and possibly also in the future on a dedicated website<sup>103</sup>, a few more recommendations on other jurisdictions worth being studied.

The technical regulation for products and services established by the Brazilian institute for Metrology INMETRO is generally worth being studied. It has integrated good practices from various other jurisdictions, but improved some of them. It has an elegant structure insofar as all the specific acts refer to a limited number of generic acts of product and service regulation which are modular. Thereby the specific acts do not need to repeat text modules which can be applied across all sectors. Furthermore, this architecture ensures that the specific acts do not contain by accident the minimum necessary to make the regulation work. The generic acts contain a benchmark, e.g. regarding the obligations of economic operators. The application and enforcement is also facilitated because both economic operators and enforcement authorities have to deal with the same core text across all sectors. This saves money both for the economic operators and for the enforcement authorities. The structure permits INMETRO to adopt a high number of specific acts without great effort as the regulatory management is easy. With regard to particular regulatory techniques as well, Brazil's regulation on products and services is also at a top-level worldwide. However, the author cannot assess whether the sector specific requirements are appropriate. The major obstacle for choosing Brazil as a reference is the language. To the knowledge of the author little of the Brazilian regulation is available in English. The major source of information is the website of INMETRO itself which is accessible [here](#). Hopefully, INMETRO will soon render the entirety of its regulation accessible in English.

Besides the technical regulation of Brazil, we can also recommend studying the regulation of Canada and Singapore. So far, we have not come across one single regulation of these jurisdictions that wasn't of good quality with regard to the regulatory techniques used – no statement can be made as to scientific, engineering or other sector specific aspects which do not fall under the expression “regulatory techniques”. As expected these two states tend to use the regulation of various other jurisdictions as a comparison prior to launching their own – influences of various other jurisdictions are perceivable. Therefore, they produce high quality regulation. Contrary to what might be expected, the regulation of the rather small state Singapore is hardly less fine-tuned and sophisticated than that of Canada. However, Singapore tends to give tremendous discretionary power to its authorities and also tends to submit citizens and operators to an extremely tight control. To copy these practices into other jurisdictions would be legally problematic in some cases.

Outside the range of jurisdictions covered by this Handbook, the Japanese regulation ([japaneselawtranslation.go.jp](http://japaneselawtranslation.go.jp)) is highly recommendable. It has reached a degree of solidity hardly reached anywhere else, on account not so much of some German roots, but of the inherently Japanese search for perfection.

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<sup>103</sup> Please contact the author if you wish to be informed on any progress with regard to this project.