

## Table of Contents

1. Scope .....	3
2. Definitions and clarifications .....	5
3. Ban of [sales of] certain goods .....	7
4. Limitation of naturally contained substances .....	7
5. Ban or limitation of additives .....	7
6. Safety features .....	8
7. Packaging .....	8
8. Licensing of operators .....	10
9. Geographic monopolies for traders .....	12
10. Obligations of operators .....	14
11. Structural separation of ACT products in mixed trading outlets .....	17
12. Registration of ACT goods .....	18
13. National ACT (goods) traceability scheme .....	18
14. Incentives linked to traceability scheme .....	20
15. Controlled consumption zones .....	20
16. Prohibition zones .....	21
17. Distribution for on-the-spot consumption .....	22
18. Consumption of tobacco and cannabis in public indoor areas .....	23
19. General use limitations .....	23
20. Advertisement, product placement and representation in media .....	24
21. Sponsorship .....	26
22. Subsidies and lobbying .....	26
23. Ban of products evoking ACT products .....	27
24. Private imports for personal consumption .....	27
25. Private ACT production .....	28
26. Private possession of ACT goods .....	29
27. Monitoring of particularly problematic consumption of ACT goods .....	29
28. Obligations, tasks and powers of the ACT Agency .....	29
29. International cooperation .....	34
30. Intra-state and scientific cooperation .....	35
31. Scientific ACT Committee .....	36
32. Central alert portal and whistle-blowing .....	37
33. Financial incentives .....	38
34. Supervision of the ACT Agency[, the ACT Committee] and the local enforcement authorities .....	38
35. Sanctions .....	39
36. Joint liability and compensation scheme .....	41

37. Legal remedies.....	42
38. Entry into force and application date .....	42
39. Transitional provisions.....	42

Model law component	Rationale and considerations
<p><b>1. Scope</b></p> <p>1.1 This regulation applies to: alcoholic liquids, pure cannabis or cannabis-based goods, and pure tobacco or tobacco-based goods, provided that these are intended or appropriate for human consumption.</p>	<p>It is of course possible to select amongst the three groups of products or to add another one, such as synthetic cannabinoids, other synthetic drugs, or vapour inhalation products. If an extension is chosen, it is recommended to add definitions of consumer units, see below.</p> <p>The “intended <u>or</u> appropriate” ensures that economic operators cannot escape the application of the regulation by simply stating or labelling “This item is not intended for human consumption”.</p>
<p>1.2 This regulation applies also to the artificial cannabinoids and other designed drugs listed in Annex I to this Regulation. Annex I shall be periodically updated by (empowerment for the ACT Agency to update the list e.g. by ordinance).</p>	<p>Artificial cannabinoids are not less harmful than natural cannabis. An industry has emerged that creates ever new artificial cannabinoids in view of escaping the jurisdictions trying to ban the artificial cannabinoids, creating a cat and mouse situation. A ban is thus, if at all, only meaningful where the regulator has the opportunity to react quickly to new artificial products.</p> <p>An alternative strategy consists in banning only those artificial cannabinoids which have turned out to be particularly harmful, as nothing is won if the bans push the industry and consumers to ever less tested artificial cannabinoids.</p> <p>Artificial cannabinoids are only one subcategory of artificially lab-designed drugs that can have a large variety of effects, rendering their joint consumption particularly dangerous.</p>
<p>1.3 This regulation applies also to ... (coca, khat, other local traditional drugs).</p>	<p>We cannot assess the usefulness of covering these drugs. We just point at this possibility, not least because drug policies sometimes have a consistency issue – certain local drugs are often tolerated despite being more harmful than other drugs coming from abroad. For example jurisdictions of advanced economies tolerating permissive alcohol regulatory frameworks.</p>
<p>1.4 This regulation applies also to mushrooms listed in Annex II and extracts</p>	<p>Mushrooms, too, are in some traditional or urban contexts used as drugs. Like for the</p>

thereof. Annex II shall be periodically updated by (empowerment for the ACT Agency to update the list e.g. by ordinance).

1.5 This regulation applies also to herbal goods intended or suitable to be smoked. The rules applicable to tobacco apply to these herbal goods.

(Var. 1) 1.6 This regulation applies also to vapour inhalation products.

(Var. 2) 1.6 Vapour inhalation products are dealt with as tobacco-based products unless they are prescribed by a medical doctor and distributed by pharmacies for persons who have consumed tobacco-based products for more than one year.

1.7 Cannabis-based goods include [notably]: liquid or consistent extracts of the cannabis plant, thus cannabis oil or hashish, and items which contain these extracts or the original cannabis whilst being intended or appropriate for human consumption.

Cannabis-based goods do [notably] not include textiles or textile based items derived from the cannabis plant or other items derived from cannabis which cannot be consumed by humans.

1.8 Tobacco-based goods include [notably]: cigarettes, cigars, cigarillos, tobacco for pipes, tobacco for cigarettes made by the consumers, tobacco intended or appropriate for snifing or chewing.

1.9 This regulation applies finally to all items containing any of the above whilst still being intended or appropriate for human consumption.

1.10 [Alcoholic liquids with less than 1 percent alcohol per volume and cannabis or cannabis-based goods with less than X

artificial cannabinoids, their risk varies widely so that it might be preferable to ban only the particularly risky ones.

Eucalyptus and other plants can also be smoked and are not necessarily less harmful than tobacco.

The current debate on whether it is useful to regulate these products as tobacco or whether they reduce the damage by bringing smokers to use less harmful products is not necessary. Regulators can at the time regulate the positive use of these products as tobacco-replacement and the negative use as drug in its own right, as suggested here.

This wording does not constitute a definition, but a so-called “positive list”. The advantage of the “positive list” is that other products than those listed can still be caught by the term “cannabis-based product”.

Here we suggest a “negative list”. Both types of lists together narrow the range for which questions of interpretations can arise.

This sentence, which also could rightly be placed more above before the first positive list, is useful to avoid that the regulation can be circumvented, e.g. by using tobacco or cannabis as an ingredient in food, placing alcohol into something consistent and thus to be eaten instead of drunk. Of course, it can be debated whether covering slightly alcoholic sweets is really necessary.

It is preferable to not waste administrative resources on products which cannot trigger the typical drug effect.

percent THC are excluded from the application of this regulation.] OR [Alcoholic liquids with less than 1 percent alcohol per volume are excluded from the application of this regulation. The rules for tobacco apply to cannabis or cannabis-based products with less than X percent THC.]

1.11 [Cannabis or cannabis-based products that have obtained a license as pharmaceuticals are exempted from this regulation.]

The idea behind this 2<sup>nd</sup> sentence is: even where cannabis does not cause the typical drug effect, it is still similarly harmful than tobacco.

In an increasing number of jurisdictions certain cannabis-based products or just cannabis is sold for therapeutic purposes, in particular to reduce pain. As the control of distribution is ensured via the pharmacies, it should be considered to exempt therapeutic cannabis products and to subject it to the control as medicine.

## *2. Definitions and clarifications*

“ACT” means alcohol, cannabis and tobacco.

“THC” means tetrahydrocannabinol, the principal psychoactive constituent of cannabis.

“human consumption” means eating, drinking, sniffing, injecting or otherwise inserting into the body or an orifice in a way that permits the transition of substances into the body.

“ACT Agency” means the national administration / authority in charge of supervising the application of this regulation, established ... (e.g. “by virtue of Section 28 of this regulation” or reference to another act that has established the administration / authority).

“Tobacco” means, unless otherwise specified, tobacco leaf, tobacco plant, tobacco seed and parts of these three and anything (including moisture) added to the during manufacturing of tobacco products or processing of the good, and this at any point in the supply chain, from farm to user.

“Vapour inhalation products” means liquids or consistent items intended or appropriate for human inhalation, regardless of whether they use an electronic delivery system or not, but

Adapt “ACT” to “ACTM” if you extend to mushrooms or adapt otherwise if you wish to cover other drugs. The objective here is to have a short abbreviation of the products covered by this regulation that you can easily use all along the following text.

This definition ensures that, e.g., insertion into the mouth in view of extraction of substances is covered as well.

The name needs of course to be adapted if you intend covering less or more items.

The usual term is Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS). However, non-electronic systems (which

do not include items intended to make a certain space smell.

“Goods” or “ACT goods” are items intended or appropriate for human consumption, regardless of whether packed or not, containing alcohol, cannabis or tobacco or derivates of any of these.

“Products” are goods packaged in consumer units.

“Consumer units” are entities between the following limits:

- 0.1 to 1 litre for alcoholic beverages,
- 1 to 3 grams for cannabis,
- 20 to 25 cigarettes, cigars or grams for tobacco,

...

(additions are needed where the regulation covers more than ACT products, e.g. “1 to 5 grams of mushrooms or 0.2 to 1 gram of mushroom extract”, “2 to 10 millilitres of liquids containing nicotine”, 20 to 25 cigarettes, cigars or grams for herbal products for smoking).

“Minimum price per consumer unit” is ... for alcoholic beverages, ... pro cannabis consumer unit, and ... pro tobacco consumer unit.

“Traders” are natural or legal persons selling or intending to sell ACT products to consumers.

“Wholesalers” are natural or legal persons selling or intending to sell ACT goods to other wholesalers or traders and include in the following, unless otherwise specified, importers and manufacturers of ACT products.

“Operators” are manufacturers, importers, traders, wholesalers, and natural or legal persons growing, selling, storing or transporting ACT goods.

“Contractors” are natural or legal persons fulfilling a service for an operator, receiving a service from an operator or supplying items to

operate simply with fire) are not covered by this term, however this alternative could be considered.

To be adapted according to the drugs which are to be covered.

The definition of consumer units facilitates both the formulation of obligations in this regulation and the later application of this regulation. The limits should not be too low, as street selling e.g. of individual cigarettes has turned out to foster tobacco consumption, but evidently also not too high so as to avoid secondary and thus uncontrolled trade. The limits indicated here are examples only.

A higher minimum price is prohibitive. However, too high a minimum price incentivises irregular trade.

<p>or buying items other than ACT goods from an operator.</p>	
<p>“Responsible persons” are natural persons employed under labour law by a wholesaler or trader and designated as responsible for regulatory compliance.</p>	<p>We recommend to add “under labour law” to avoid that external contractors who are not really integrated into the business serve as “responsible persons”.</p>
<p>“Infringement of obligations under this Regulation” includes infringements of obligations laid down in legal acts [of general applicability] adopted in accordance with this regulation by ... (e.g. by the ACT Agency).</p>	
<p><i>3. Ban of [sales of] certain goods</i> The following ACT goods, and thus their growing, manufacturing, possession, trading, transporting or storing, are banned:</p>	<p>One might wonder why to include certain goods in the first place into the scope of this regulation and then to ban them. Without doing so, the goods in question are simply not regulated and thus also not banned. In view of creating a basis for enforcement, it thus can be useful to include certain goods in the scope and then to ban them. Banning a good is evidently easier to enforce than banning the sales of a good. Where appropriate, the ban can also just be issued at the level of products, so that goods which are not products (see definitions) still can circulate.</p>
<p><i>4. Limitation of naturally contained substances</i> 4.1 ACT products may not contain more than X % of ... (alcohol, THC, tar, nicotine, ...) and may not issue more than ... (tar, nicotine, carbon monoxide and other emissions).</p>	<p>Some regulators wish to ban drinks with an extremely high concentration of alcohol, e.g. to prevent alcohol poisoning or public drunkenness or other shocks associated with binge drinking. Equally, it might be regarded as meaningful to limit the concentration of THC in cannabis products to reduce the risk of traffic accidents or of tar in tobacco to reduce the cancer risk, to name but a few examples. However, quite some particular enforcement capacities are needed to verify the concentration.</p>
<p>4.2 The ACT Agency may modify this list by ... (e.g. ordinance).</p>	<p>For jurisdictions which do not have important own scientific capacities, it is recommended to follow the practice of one or several jurisdictions which maintain an advanced scientific apparatus for the assessment of substances.</p>
<p><i>5. Ban or limitation of additives</i> 5.1 ACT products may not contain (Var. 1) any added substances except ... / (Var. 2)</p>	<p>The addition of substances increases in a manifold way the risks of ACT products.</p>

<p>added substances that increase the risk of addiction, and therein in particular ... / (Var. 3) the following substances: ...</p> <p>5.2 The ACT Agency may modify this list by ... (e.g. ordinance).</p> <p>5.3 The following limit values apply to added substances: ...</p> <p>5.4 The ACT Agency may modify this list by ... (e.g. ordinance).</p>	<p>Substances can increase the carcinogenic effects, the psychoactive effect or the risk of addiction. As the knowledge on these substances might quickly evolve, we do not list any substances here, but recommend to follow the scientific discussion and the practice of various jurisdictions with an advanced scientific apparatus or simply the international scientific discussion.</p> <p>Variant 1 is the most cautious one, establishing a positive list of relatively safe additives.</p> <p>One might be tempted to use limit values also to express a ban, as a ban can also be expressed by "0". However, the semi-generic wordings of Variants 1 and 2 can hardly be reproduced by a list of limit values and would look strange in such a list; or otherwise said: the substances captured by the abstract wording risk to be forgotten in a precise list of limit values.</p> <p>Subject to the jurisdiction, all empowerments for modifications of this regulation by the ACT Agency could also be bundled, e.g. towards the end of this regulation.</p>
<p><b>6. Safety features</b></p> <p>Smoke or vapour generating ACT products shall be self-extinguishing, to be tested in accordance with ... (reference e.g. to an industry standard or a methodological guidance document). They shall deliver smoke or vapour at a constant rate and thus with a constant emission of substances.</p> <p>Alcoholic products with more than 15% alcohol shall be protected against opening by children of less than 10 years.</p> <p>Electronic devices intended to be used for the consumption of ACT products / containing ACT products shall fulfil the following requirements: ... (reference to other legislation or industry standards).</p>	<p>The product safety perspective can open the view for additional regulatory content. In particular electronic devices intended to be used for the consumption of ACT products might call for safety requirements. If possible, this regulatory need should be covered by reference to other legislation or industry standards covering electronic and electric risks.</p>
<p><b>7. Packaging</b></p> <p>7.1 Bottles or packages of ACT products intended to be sold to consumers (hereafter referred to as "packaging") shall not be</p>	<p>We repeat here the rationale for establishing "consumer units" and upper and lower limits of these: "The definition of consumer units facilitates both the formulation of obligations</p>

smaller or bigger than the limits of what has been defined as consumer units.

in this regulation and the later application of this regulation. The limits should not be too low, as street selling e.g. of individual cigarettes has turned out to foster tobacco consumption, but evidently also not too high so as to avoid secondary and thus uncontrolled trade."

7.2 Packaging shall contain the following warnings ... (e.g.: "[Excessive] consumption of this product may be bad for human health" or other text explaining the negative effects and risks in descending order of importance). The warning text shall have at least a font size of ... (e.g. 12 pt).

Moreover, the packaging shall contain the following deterring pictures ... (deterring pictures of tumours etc.) with a minimum size of ... (x cm<sup>2</sup> or ¼ of the package).

All the text warnings and deterring pictures shall together occupy at least ... (¼, 1/3, 1/2) of the package surface.

7.3 The packaging shall list with a minimum font size of ... (e.g. 12 pt) the allergens contained, and amongst them namely the cereals containing gluten, eggs, peanuts, soy, milk, tree nuts and derivatives of these allergens.

7.4 The packaging shall contain the following information:

- [All ingredients and substances still present and those used during the manufacturing in a transient way;]
- Name and trademark of the product;
- Name, company name, website, electronic and postal address and place of business of the manufacturer and of the importer;
- Country of origin in the meaning of Law / Regulation / Convention X, including captions such as "Made in X";
- Date of manufacture, batch number and "Best-before" date;
- A scannable electronic code identifying the product down to the batch number;
- The minimum and maximum price applicable to the ACT product;

The warnings are a key element of deterring consumers. The psychology of warnings is a dynamic domain in its own for which we have neither own competence nor feel able to deduce competence from the regulatory examples studied. Hence we can only recommend to investigate what works best at the time of drafting the regulation.

We recommend establishing a minimum space and font size for the key warning messages.

Allergic reactions can be very serious health threats and thus merit, in our view, a dedicated warning space, separated from the less important information listed in the following.

The items listed here have quite different purposes, not all of them having the same importance:

- Mainly giving the possibility to assess risks, but also deterring;
- Traceability in view of authority action;
- Traceability in view of authority action;
- Customs and other laws require often the mentioning of the country of origin;
- Reducing risks, possibility to act against deficient products;
- Possibility to act against deficient products;
- Facilitating the enforcement of the price policy;

- The internet address and contact data of the ACT Agency for the notification of adverse effects and incidents with ACT products, preceded by the words "Please notify adverse effects and incidents to:";
- The internet address and contact data of one or several national institutions helping with ACT product addiction, preceded by the words "For issues related to addiction of ..." (the type of product) "... contact:";
- The internet address and contact data of the ACT Agency for recommendations on consumption of that precise type of product, preceded by the words "Check the recommendations on consumption of ..." (the type of product);
- The recommendation to keep the ACT product out of the reach of children;
- Warnings on any potential side-effects and how to address negative impacts;
- The following symbols which must have the indicated size:



The text means: no selling to minors.

The purpose here is to avoid misleading information or information that increases consumption.

#### 7.5 The packaging may not contain:

- information suggesting that the product is environmental-friendly, harmless, natural, organic, rejuvenating, vitalising, energising, healing or promoting health or providing positive feelings;
- less harmful or otherwise better than other products of the same or another type; and
- logos, brand names, pictures or design elements making the manufacturer and his products recognisable.

#### 8. Licensing of operators

8.1 Only licensed operators are authorised to grow, manufacture, store, move, broker or to

A few jurisdictions extend the licensing to those who store or move ACT goods. We

trade with ACT goods, including seeds or derivate products.

8.2 To obtain a license, operators shall submit the following data:

- i. where the operator is a natural person, information regarding his or her identity, including full name, trade name, business registration number (if any), applicable tax registration numbers (if any) and any other information to allow identification to take place;
- ii. where the operator is a legal person, information regarding its identity, including full legal name, trade name, business registration number, date and place of incorporation, location of corporate headquarters and principal place of business, applicable tax registration numbers, copies of articles of incorporation or equivalent documents, its corporate affiliates, names of its directors and of any designated legal representatives, including any other information to allow identification to take place;
- iii. all electronic communication channels, including websites, email addresses, social media sites;
- iv. precise business location of the manufacturing unit(s), warehouse location and production capacity of the business run by the operator; and
- v. complete identification of the bank accounts intended to be used and other relevant payment details, including data for alternative payment systems.

8.3 To obtain a license, operators or, in case of legal persons, their directors with power of representation, shall fulfil the following conditions:

- Having the nationality of ...;
- Being ... (e.g. 25) years or older;
- Not having committed any criminal offence during the last 10 years;
- Having not infringed fiscal obligations during 10 years;

cannot assess whether this is still proportionate. The same goal can also be reached by prohibiting the outsourcing of storage and transport.

The information required has the following purpose:

- traceability of the natural person and possibilities for enforcement;
- traceability of the legal person and possibilities for enforcement;
- electronic traceability and possibility to enforce with the help of internet service providers;
- facilitating control and enforcement;
- facilitating control and enforcement.

These are reliability requirements.

<ul style="list-style-type: none"> <li>• Not having been listed as deliberately infringing this Regulation in accordance with ... (see the provisions on deliberate infringement in Section 35);</li> <li>• Having undergone a compulsory training for responsible sale offered by the ACT Agency or having nominated a Responsible person who has undergone this training;</li> </ul> <p>... </p>	
<p>8.4 Licenses shall be withdrawn where the initial conditions are no longer fulfilled or turn out not to be fulfilled from the beginning and in case of repeated infringement of various or the same obligation(s) under this Regulation.</p>	<p>We recommend differentiating between the situations in which licenses are mandatorily to be withdrawn and situations in which there should be a discretion and for which less severe measures than withdrawal might be sufficient, see the following.</p>
<p>8.5 Licenses may be subject to conditions, limited in time or be withdrawn in case of a single, but particularly grave infringement of an obligation under this Regulation. Particular gravity [is given] OR [shall be a [rebuttable] presumption] where:</p> <ul style="list-style-type: none"> <li>• minors or other persons meriting particular protection were put at risk, including by selling close to schools or in areas for which there is a ban;</li> <li>• the official trade schemes established by this Regulation were by-passed;</li> <li>• the illegality touches a trade volume of more than ... (limitation by entities or value or both);...</li> </ul>	
<p>8.6 Licenses may be suspended or be subject to conditions for a time up to X months in cases where there is a suspicion of any of the cases mentioned above.</p>	<p>Often it is difficult to ascertain whether a situation is such that a measure is needed. Where there is a suspicion for a particularly grave infringement, it might be justified to suspend or subject the license to conditions.</p>
<p><b>9. Geographic monopolies for traders</b></p> <p>9.1 The district authority shall, in the middle of every third year, auction [in an open, transparent and fair procedure] OR [in accordance with the procedure set out in regulation X] geographically limited monopolies for traders for three-year-periods starting with the beginning of the next calendar years.</p>	<p>Geographic monopolies can be used to generate income for the state or to reduce and control the offer of ACT goods.</p> <p>Where the jurisdiction disposes of a regulation setting out provisions for the auctioning of public licenses, it is recommended to refer to that regulation, either to render that regulation applicable or, if it is by itself applicable, to confirm that applicability.</p>

9.2 The areas for which the monopolies are attributed shall [have more than X and less than Y inhabitants] OR [have a size of X to Y square kilometres]. Monopolies may be attributed to areas with less inhabitants where the population density is below X per square kilometre.

Both the number of inhabitants and the size of the territory are useful parameters to reach an appropriate accessibility whilst also not making it too easy to purchase ACT products and avoiding competition and incorrect practices of operators. If the accessibility is too low, illegal secondary trade becomes more likely.

9.3 The minimum price per monopoly shall be X per inhabitant.

For the establishment of a minimum price, we recommend referring to the number of inhabitants as this is more indicative for the likely revenues than the square kilometres.

9.4 Only licensed traders may participate in the auction.

This ensures reliability.

[9.5 No trader may obtain more than one geographic monopoly / X geographic monopolies.]

This hinders traders to become too powerful. On the other hand, if there is a lack of reliable traders, it might be preferable not use this provision.

9.6 Where the highest trader bidding is not able to pay the price or loses his license, the second or third best bid shall obtain the geographic monopoly for the remaining time of the 3-years-cycle. The price to pay shall be proportionately reduced where the 3-year-cycle has already begun.

This provision is particularly useful for cases of license withdrawal .

9.7 The license fee will be retroactively reduced at the end of the 3-year-period where the ACT consumption has been reduced by 20% or more in comparison to the last 3-year-period for the area of the monopoly and is also 20% below the national average per habitant.

This provision creates an incentive to not boost consumption or even to reduce the consumption.

The entire license fee will be retroactively increased at the end of the 3-year-period by 3% for each % exceeding the average consumption of the last 3-year-period for the area of the monopoly or of the national average per habitant, whatever leads to a higher excess percentage.

It is suggested to increase the license fee more than just proportionally, to create a strong incentive to not encourage consumption.

E.g.:

With a license fee of 20.000.- and a 4% excess,  $20.000 : 100 \times 4 \times 3 = 2.400.-$  are to be paid in addition.

With a license fee of 20.000.- and a 10% excess,  $20.000 : 100 \times 10 \times 3 = 6.000.-$  are to be paid in addition.

Starting from the 11<sup>th</sup> to 20<sup>th</sup> percent exceeding the average consumption, the license fee is increased by 5% for each percent in excess.

Starting from the 21<sup>st</sup> percent of exceeding the average consumption, the license fee is increased by 10% for each percent in excess.

However, the application of these rules shall not lead to more than the doubling/tripling/quadrupling of the initial license fee.

#### *10. Obligations of operators*

Operators shall:

- register themselves, their employees, their contractors and their goods in accordance with this regulation and notify any changes within three working days;
- display proof of their registration and licenses at the entrance of their premises;
- study all information provided by the national ACT Authority;
- maintain rigorous book-keeping control on all incoming and outgoing goods so as to be able to determine their stock at any time;
- protect their stock from robbery and physical deterioration;
- actively participate in the national ACT traceability scheme;
- verify the identity of all suppliers and clients [buying more than the above mentioned consumer units] and document it in the ACT traceability scheme;
- report to the ACT Agency all – by quantity, type or other conditions – suspicious demand for products and suspected non-compliance with this regulation;
- verify that commercial trade partners hold a license in accordance with this

With a license fee of 20.000.- and a 15% excess,  $6.000.- + 20.000 : 100 \times 5 \times 5 = 11.000.-$  are to be paid in addition, the 6.000.- stemming from the previous calculation for the first 10%.

With a license fee of 20.000.- and a 20% excess,  $6.000.- + 20.000 : 100 \times 10 \times 5 = 16.000.-$  are to be paid in addition.

With a license fee of 20.000.- and a 23% excess,  $16.000 + 20.000 : 100 \times 3 \times 10 = 2.400.-$  are to be paid in addition, the 16.000.- stemming from the previous calculation for the first 20%.

One might consider an overall limit to keep the risk for the operator manageable.

This list of obligations is based on what we found in various ACT laws, but was also extended with obligations deemed useful and spotted in very different sectors. If the list is deemed too long, it can of course be shortened.

regulation or, in case of trade partners located abroad, inform the ACT Agency on the commercial contact with this trade partner;

- register data of their trade partners for their own records and [in the goods registration scheme foreseen in Section 12] **OR** [the ACT traceability scheme foreseen in Section 13], whilst these data shall include:
  - i. when the customer is a natural person, information regarding his or her identity, including full name, trade name, business registration number (if any), applicable tax registration numbers (if any) and copy or scanning of his or her official identification;
  - ii. when the customer is a legal person, information regarding its identity, including full name, trade name, business registration number, date and place of incorporation, location of corporate headquarters and principal place of business, applicable tax registration numbers, copies of articles of incorporation or equivalent documents, its corporate affiliates, names of its directors and any designated legal representatives, including the representatives' names and verification of their official identification;
  - iii. a description of the intended use and intended market of sale of the ACT goods;
- (only traders) only buy goods from registered wholesalers and verify the registration of the goods prior to the purchase;
- (only traders) verify by control of the identity card that their customers [looking younger than 30 years old] are not minors **OR** fulfil the minimum age requirement for buying ACT products;
- (only traders) not sell before 10 a.m. and after 6 p.m.;

- (only traders) not sell to persons whom they know do not consume the ACT products themselves;
- (only traders) record customer purchases to enforce regulated product sales limits;
- (only traders) not sell more than one/two/three consumer unit(s) per day to the same person;
- (only traders) not sell to persons who are in an altered state of consciousness or drunk;
- (only traders) inform persons repeatedly in an altered state of consciousness or drunk or showing signs of addiction or consuming ACT products whilst pregnant or in presence of minors on private or public institutions, where to seek help for their repeated state of altered consciousness or perceived addiction;
- [respect the prohibition zones] OR [not sell outside the licensed premises];
- (only traders) not sell unpacked goods;
- (only traders) not sell entities smaller or bigger than the regulated consumer units as defined above;
- respect the authorised price bandwidth and in particular the mandatory minimum price per consumer unit;
- verify that the consumer units are correctly labelled;
- verify that tax and excise obligations have been fulfilled and, if not, fulfil them immediately themselves;
- report to authorities in case of any suspicion on illicit trade, tax or excise or product irregularity, and therein in particular insufficient warning text and pictures on packaging;
- (only traders) place warning text panels with deterring pictures identical to the ones on the packaging next to the ACT products and at a well visible place in their shop, whilst these panels shall have at least the following size ... and characteristics (minimum text, font size, type and size of deterring pictures);
- (only traders) not sell via internet, phone or otherwise at distance or via automatic vending machines;

- verify every six months that all their employees have a clean criminal record and have not been declared to have deliberately infringed this Regulation by the ACT Agency and lay-off employees which do not fulfil these conditions, whilst criminal convictions for negligence only count where they relate to book-keeping, tax and excises and infringements under this Regulation;
- lay-off employees for whom the ACT Agency has stated a deliberate infringement of this Regulation and temporarily suspend the work contract for those whom the ACT Agency has opened an investigation of suspicion of deliberate infringement;
- lay-off employees who do not respect the obligations incumbent on operators;
- inform and train all their staff on these obligations, on the sanctions to be expected in case of non-compliance with these obligations, and on the provisions on whistle-blowing protection set-out in this Regulation. [They shall prove compliance of this provision by sending to the ACT authority the signed declarations of the staff according to which they have been informed and trained about all these obligations;]
- verify that their staff have undergone the training for responsible sale offered by the ACT Agency prior to recruitment and conduct re-training every second year after recruitment;
- establish and implement a self-monitoring plan or quality system ensuring and verifying compliance with these obligations.

#### *11. Structural separation of ACT products in mixed trading outlets*

ACT products in mixed trading outlets shall be kept in a separated area under intense supervision prohibiting the access of minors. This area shall be placed as remotely as possible from the entrance and check-out zone. Where there is a conflict between these

The best control of ACT goods and the lowest temptation for (so-far) non-consumers is achieved where outlets sell only ACT goods. If this is deemed to be too radical or politically not feasible, certain provisions might be set up to reduce the temptation for non-consumers, whilst also

<p>two rules in the implementation in a given outlet, the first rule shall prevail.</p>	<p>ensuring that no minors can access the ACT products.</p>
<p><b>12. Registration of ACT goods</b></p> <p>12.1 Manufacturers and importers shall register ACT goods with the ACT Agency / within the ACT goods database run by the ACT Agency prior to selling these products on the territory of ... (jurisdiction).</p>	<p>The full traceability of ACT goods requires electronic internet-linked tags and a comprehensive traceability scheme, see the next section. It reduces the illegal trade and facilitates the enforcement. But it is cumbersome to achieve such comprehensive traceability. Registration of goods is less cumbersome and provides already an improved basis for enforcement. Moreover, operators can be held accountable when having more goods in their possession than registered.</p>
<p>12.2 The registration shall include in particular the following details:</p> <ul style="list-style-type: none"> <li>• name, address, postal address, email address, internet address and responsible person of the manufacturer and the importer;</li> <li>• name, address, postal address, email address, internet address and contact person of the supplier(s);</li> <li>• name, address, postal address, email address, internet address and contact persons of the wholesalers and other main commercial partners;</li> <li>• description of the product and of its packaging;</li> <li>• chemical substances or materials present or used during manufacturing and their precise quantity;</li> <li>• emissions and their precise quantity;</li> <li>• test reports or statements issued by an approved verification laboratory or research institute confirming the data of the last two indents and confirming the self-extinguishing character of the product;</li> <li>• detailed information on and documentation of any kind of novelty or unusual practice, including relevant test reports issued by laboratories or scientific institutes and effects on toxicity, addictiveness and attractiveness of the novel product.</li> </ul>	<p>This section creates some duplication with elements of the section on obligations of operators. If this section is inserted, the corresponding provisions of Section 10 can be shortened or replaced by a reference to this section.</p>
<p>12.3 The manufacturer or importer shall update the registration with each modification relevant for any of the items above. The previous sub-section applies.</p>	
<p><b>13. National ACT (goods) traceability scheme</b></p> <p>13.1 The ACT Agency shall establish an electronic database hosting the national ACT (goods) traceability scheme. The scheme shall register each entity of ACT goods down</p>	<p>This fully-fledged traceability scheme makes the previous section on registration superfluous. It is a better choice as such to</p>

to the level of consumer units [and individual consumers].

13.2 Each entity of ACT goods entering the territory shall obtain a unique code attributed by the database and an electronic tag corresponding to that unique code. This electronic tag shall be linked to the internet in such a way that the ACT Agency can at any time except during transportation trace the location of the ACT goods.

13.3 In case of division of the entity into smaller entities, the code of the smaller entities shall start with the code of the bigger entity followed by the number of entities into which the bigger entity has been divided followed by a unique code for each of the smaller entities and so on.

13.4 The possession of each entity at any given time shall be attributable to a single natural or legal person [identified via its national registration number]. The identities of the current and previous owners of the goods shall / can be integrated into the goods' code,

13.5 All operators shall be registered at least with regard to the following data:

- i. where the operator is a natural person, information regarding his or her identity, including full name, trade name, business registration number (if any), applicable tax registration numbers (if any) and any other information to allow identification to take place;
- ii. where the operator is a legal person, information regarding its identity, including full legal name, trade name, business registration number, date and place of incorporation, location of corporate headquarters and principal place of business, applicable tax registration numbers, copies of articles of incorporation or equivalent documents, its corporate affiliates, names of its directors and of any designated legal representatives, including any other information to allow identification to take place;

ensure compliance and to reduce substantially illegal trade, but it also much more cumbersome to achieve.

The historic traceability is also helping to prevent illegal practices and to identify products which are deficient and therefore cause a particularly high risk.

This sub-section is not needed where the operators are already registered by virtue of another section and the goods are linked to the operators registered in accordance with that other section.

<ul style="list-style-type: none"> <li>iii. all electronic communication channels, including websites, email addresses, social media sites;</li> <li>iv. precise business location of the manufacturing unit(s), warehouse location and production capacity of the business run by the operator;</li> <li>v. complete identification of the bank accounts intended to be used and other relevant payment details, including data for alternative payment systems.</li> </ul> <p><b>13.6</b> All operators shall register the ACT goods in their possession and acquiring or selling operations including the respective suppliers or customers.</p>	<p>Please check whether there is a redundancy with the provisions on operators' obligations that you have selected.</p>
<p><b>14. Incentives linked to traceability scheme</b></p> <p>14.1 Citizens that commit to not consume ACT products and permitting the transmission of data from traders via the ACT Agency to their health insurance shall receive a reduction of their insurance fee of 3% in the second year and 5% in the following years once they have not purchased any ACT product for one year.</p> <p>14.2 Minors committing to not consumer before their 18<sup>th</sup> birthday and participating in this scheme shall, in addition, receive an allowance of ... for each year they not consumer ACT products</p>	<p>Regulators tend to reflect purely in terms of obligations, whilst the proactive use of incentives can often even better reach the regulatory goal, see Section 4 of the Handbook "How to regulate?".</p> <p>Full traceability down to the level of consumers might be regarded as problematic in terms of protection of privacy and personal data. However, if ever this is not seen as an obstacle, one might well create incentives for not consuming ACT goods on the basis of that given full traceability.</p>
<p><b>15. Controlled consumption zones</b></p> <p>Alt. 1:</p> <p>15.1 Consumption of cannabis goods [and of alcohol] is only permitted in licensed cannabis [and alcohol] clubs.</p> <p>15.2 To obtain a license from the ACT Agency, these clubs shall be duly registered associations with no more than X members. At least three members must have undergone the training for responsible sale offered by the ACT Agency for the specific type of consumption.</p> <p>15.3 Clubs shall ensure safe consumption and safe transport home of persons unable to take part in traffic in a safe way.</p>	<p>Whilst total prohibition is difficult to enforce and often leads to a black market, controlled consumption zones might be at least a good compromise between limiting to the extent possible the consumption whilst avoiding the drift towards a buying black market. We would not be surprised if controlled consumption zones were also extremely efficient in terms of limiting the consumption of ACT goods.</p> <p>We present here two possibilities:</p> <p>Alternative 1 is based on the legislation of Uruguay which established non-commercial Cannabis clubs. This solution ensures a kind of social control, but might not fit in all</p>

<p>15.4 The club is allowed to grow up 2 cannabis plants or store 5 consumer units per member in places specifically protected against burglars. The clubs are subject to the control of the ACT Agency.</p>	<p>contexts. Therefore we present also Alternative 2 which would reach more or less the same goals, but is based on classic business operators. Contrary to normal bar holders, these operators shall have special obligations and establish a control similar to the control offered by Cannabis clubs. This Alternative 2 is also inspired by the Dutch Coffee shops model. In the Netherlands, permanent residents are permitted to consume cannabis in specially licensed cafés/bars called “coffee shops”. Like in Uruguay, access thereto has been limited to permanent residents and persons of the respective nationality, to avoid cannabis tourism.</p>
<p>15.5 The cannabis yields of clubs shall be recorded, with amounts exceeding 5 consumer units per member turned over to the ACT Agency.</p>	
<p>15.6 Only adult persons with permanent residence in ... (jurisdiction) may become members of the clubs. The clubs shall register their members in the database of the ACT Agency. The ACT Agency shall verify that no person is a member of several clubs.</p>	
<p>Alt. 2:</p>	
<p>15.1 Consumption of cannabis goods [and of alcohol] is only permitted in licensed cannabis [and alcohol] bars.</p>	<p>It might be surprising or even shocking for readers from jurisdictions in advanced economies that we recommend regulators to consider the use of the technique “controlled consumption zones” also for alcohol.</p>
<p>15.2 To obtain a license from the ACT Agency, the owner and at least two more staff or, in case of legal persons, at least three staff shall have undergone the training for responsible sale offered by the ACT Agency for the specific type of consumption. One of these trained staff need to be present in the bar at any opening time.</p>	<p>However, we work for jurisdictions around the world, including for those who are much less permissive regarding alcohol. Arabic countries that have established a total ban of alcohol face the usual problem of illegal trade, where controlled consumption zones might constitute an alternative. We also note a trend in terms of regarding alcohol ever more harmful.</p>
<p>15.3 Bars shall ensure safe consumption and safe transport home of persons unable to drive.</p>	<p>Evidently, the technique of controlled consumption zones could also be used for tobacco in a very tobacco-prohibitive approach.</p>
<p>15.4 Only adult persons with permanent residence in ... (jurisdiction) may become clients. Bars shall verify and register the identity of their clients and take, at the entry, a deposit ensuring the possibility to have the client transported home safely.</p>	
<p>15.5 The bars are subject to the control of the ACT Agency, including by undercover agents.</p>	
<p><b>16. Prohibition zones</b></p> <p>16.1 In the following zones and in a perimeter of 50 / 100 / 200 / 500 meters surrounding them, the publicity for, the sales and the consumption of ACT goods is forbidden:</p>	<p>In terms of containment of consumption of ACT goods, controlled consumption zones are certainly amongst the best approaches, see above. However, they will not be politically viable in many jurisdictions. Hence</p>

- zones declared to be non-ACT zones by the owner or the responsible natural or legal person;
- commercial centres;
- kindergartens, schools, and institutions of higher education (including those in the private sector) and students accommodation centres;
- health, day-care, elderly, family, children, educational, vocational, training, sport, recreational, cultural and religious centres;
- sport events;
- public transport facilities, except in zones clearly labelled as ACT zones;
- public transport planes, ships or vehicles including taxis and similar vehicles;
- petrol stations;
- along national roads;
- markets;
- playing grounds;
- shops also selling goods appropriate for children;
- beaches [during holiday seasons]; and
- further public places determined by the ACT Agency.

**16.2** The natural or legal person in charge of the respective place or zone shall:

- display notices indicating that ACT consumption is prohibited in the area;
- supervise and carry out measures to ensure that the prohibition is respected;
- request the offending persons to cease the offence or to leave the area; and
- where the offending person refuses to do so, report to the police / a law enforcement officer and allow s/he to inspect the area.

**17. Distribution for on-the-spot consumption**

17.1 [Street vendors, street vending shops,] clubs, discotheques, cafes, bars and restaurants or similar facilities selling on-the-spot consumption shall always offer at least 10 non-alcoholic choices of beverages at a price 50% lower than the cheapest alcoholic beverage of any volume and the cheapest alcoholic beverage of the same volume.

the question arises how the consumption can be generally curbed with less radical measures and how vulnerable persons and non-smokers can be effectively protected. We list here the different prohibition zones that we have identified in regulation of many jurisdictions worldwide, but of course the list could be added to.

This obligation ensures that price is not an incentive for the consumption of alcohol.

The double reference for the 50% rule ensures that consumers do not have any cost reason to prefer alcoholic to non-alcoholic beverages.

<p>17.2 Selling of alcoholic beverages for on-the-spot consumption [outside restaurants] is limited to beverages with less than 5 / 10 / 15% alcohol by volume.</p>	<p>This rule limits the risk of getting drunk.</p>
<p>17.3 Serving ACT products after 11pm is forbidden.</p>	<p>Limiting the hours of accessibility of alcohol in the evening has not only proven to curb consumption, but also of violence. Similar effects could hence be expected for the use of other drugs influencing the behaviour.</p>
<p>17.4 The obligations listed in Section 10 which are labelled “(only traders)” [and in particular the prohibition of selling of unpackaged goods or incorrectly labelled consumer units] apply.</p>	<p>Of course, these obligations could also be repeated here, and a selection could be made. The part in square brackets is already covered by Section 10, but it might be worthwhile highlighting this ban here in view of the common practice of selling individual pills containing designed drugs. Without clear labelling, the consumer cannot assess at all the effects of the pills and even less so of combinations of pills.</p>
<p><i>18. Consumption of tobacco and cannabis in public indoor areas</i></p> <p>18.1 Smoking of tobacco and cannabis goods [and vapouring] in indoor areas open to the general public is forbidden. [However, clubs, discotheques, cafes, bars and restaurants may reserve and separate by smoke-proof walls and double-doors a zone comprising no more than 1/3 OR 1/4 of the public surface for smokers.] [18.2 This limitation does not apply to facilities whose main purpose is to permit smoking.]</p>	<p>Banning smoking or limiting smoking in restaurants, cafés and bars is a classic tool to curb consumption and to protect non-smokers.</p> <p>Of course, the controlled consumption zones, if any, would need to be added here.</p>
<p><i>19. General use limitations</i></p> <p>19.1 Consumption of ACT products in ad hoc or permanent groups comprising persons under 17 is forbidden.</p> <p>19.2 Consumption of smoked tobacco-based and cannabis products in a way that exposes other persons not consuming these products to secondary smoke in vehicles, buildings or other closed facilities is forbidden.</p>	<p>This rule protects minors.</p> <p>This rule protects non-smokers.</p>
<p>19.3 Consumption of alcohol or cannabis (products) is forbidden when it is planned or not unlikely to be necessary to drive or to operate vehicles, planes, drones, ships, robots or machines. Driving or operating vehicles, planes, ships or machines 12 hours after having consumed alcohol or cannabis</p>	<p>This rule protects the safety of consumers and of others.</p> <p>All the rules of this section are technically simple to enforce, but require a lot of staff on the ground. Still these rules might be useful for deterrence and can be enforced by</p>

<p>(products) is forbidden[, unless the alcohol concentration in the blood stays below 0.05 g/dl.]</p>	<p>agents also in charge of other types of enforcement, e.g. agents ensuring security in highly frequented (party) zones or patrolling police agents.</p>
<p><b>20. Advertisement, product placement and representation in media</b></p> <p>Alt. 1:</p> <p>20.1 Any advertisement for ACT goods with the exception of therapeutic cannabis products is, for all media, including social media and for "influencers", forbidden. Any placement of an identifiable ACT product in media is forbidden. Any "information" provided by operators in media [for the general public] is forbidden.</p> <p><b>OR</b></p> <p>Alt.2:</p> <p>20.1 Any advertisement, including "information" provided to the general public, for ACT goods other than therapeutic cannabis products shall, in all media, including social media and activities of "influencers" scrutinising and recommending products or goods, include:</p> <ul style="list-style-type: none"> <li>i. a well-visible warning informing the public of all the dangers of the respective ACT consumption;</li> <li>ii. a well-visible warning informing the public of the particular dangers of driving and operating machines after consumption of alcohol or cannabis,</li> <li>iii. a well-visible warning informing the public of the danger of the respective ACT consumption when pregnant,</li> <li>iv. a warning that informs the public of the direct link between the respective ACT consumption and fatal cancers, and</li> <li>v. details of a website, to be established and maintained by the ACT agency, providing</li> <li>vi. public health information in relation to the respective ACT consumption.</li> </ul> <p>20.2 Any advertisement for ACT as defined in the previous paragraph shall be limited to the time between 9 p.m. and 4 a.m. and to media with less than 20% audience or readership of minors and subject to the limitations</p>	<p>A strict ban of advertisement and product placement (as indirect advertisement) is preferable to just subjecting advertisement and product placement to certain conditions. But it is not politically viable in all jurisdictions. Hence we provide also some text just to contain the advertisement and product placement practice, see Alternative 2.</p> <p>This rule reduces the likelihood of minors being exposed to advertisement.</p>

applicable to the representation of ACT goods in media with the exception of the following sentence.

20.3 Any placement of advertisement for ACT goods jointly with advertisement for non ACT products is forbidden.

For both alternatives (with different numberings, subject to the alternative):

20.2 or 20.4 Any placement of an ACT brand in advertisement for non-ACT products is forbidden, even where that brand is also used for other products than ACT products.

Any use of promotion agents in relation to consumers is forbidden.

20.3 or 20.5 Any price reduction for ACT goods during certain hours ("happy hours") or on the basis of holding a coupon or personal data or other arbitrary factors is forbidden, and this also for street vendors, street vending shops, clubs, discotheques, cafes, bars and restaurants or similar facilities selling for on-the-spot consumption.

20.4 or 20.6 ACT goods may not be referred to in lotteries, sport events, competitions, or other public events [except where such reference takes place in the context of political or religious position taking].

20.5 or 20.7 Representation of consumption of ACT goods in media in a non-commercial context shall be limited to what is necessary in the specific documentary, artistic or storytelling context. Any presentation of a brand is forbidden. Containers of ACT goods shall be chosen in such a way that shapes which are unique for a certain brand or manufacturer are avoided.

20.6 or 20.8 The following rules shall apply both to advertisement as defined above and the representation of consumption of ACT goods in media in a non-commercial context:

This rule avoids the creation of a positive indirect link between non ACT products and ACT goods.

Certain tobacco companies have promoted their cigarettes by promoting outdoor clothing and shoes with the same brand.

The banned marketing tools generally increase the consumption and hence should be banned. The list of banned marketing tools might merit periodic update and extension, subject to what creative marketing experts invent.

Lotteries, sport events, competitions and other events could be used to indirectly promote ACT goods, hence better ban it. But it might be useful to permit political or religious groups to take a position with regard to the ACT goods.

This aims at reducing the appetite for ACT goods whilst keeping journalistic or artistic freedom.

This prohibits even unconscious product placement and thus cases where it is claimed that the product was not intended to be placed for publicity purposes. Where a shape of a container indicates a single brand or manufacturer, this ban hinders indirect advertisement.

<ul style="list-style-type: none"> <li>• It is forbidden to suggest therapeutic effects, stimulant or sedative effects, higher performance, more wellbeing, liberty, more social or sexual success, more creativity, or higher degrees of awareness linked to the consumption of ACT goods or to present ACT goods as means to solve personal problems.</li> <li>• It is forbidden to show minors consuming or dealing with ACT goods.</li> <li>• It is forbidden to encourage immoderate consumption of alcohol or present abstinence or moderation in a negative light.</li> </ul> <p>[Detailed provisions making these limitations more precise can be laid down by ordinance / regulation adopted by the ACT Agency in accordance with ....]</p>	<p>One of the main reason for the consumption of ACT goods is the positive connotations and presumed effects.</p> <p>This ban helps to avoid that consumption of ACT goods by minors is regarded as normal.</p>
<p><b>21. Sponsorship</b></p> <p>Operators or their organisations may not sponsor any event or activity targetting [the general public,] minors, research of public institutions, research events, political parties, political events, political campaigns, politicians, or organisations operating in the field of politics and the society.</p>	<p>Advertisement also happens via the back-door of sponsorship.</p>
<p><b>22. Subsidies and lobbying</b></p> <p>22.1 No public subsidy or incentive may be granted or granted for the cultivation, production or processing of ACT goods.</p> <p>22.2 Any direct or indirect partnership, any agreement of an obligatory nature for the authorities concluded with the ACT operators and its organisations and with those promoting their interests, is null and void.</p> <p>22.3 All directly or indirectly made efforts of operators or their organisations aiming at influencing politics or decisions of authorities in the field of ACT goods are forbidden.</p> <p>OR</p> <p>22.3 Operators and their organisations shall disclose in the public ACT lobbying register managed by the ACT agency in advance all physical or virtual meetings, encounters and conversations with research institutions, public institutions, political parties, politicians, or organisations operating in the field of</p>	<p>Both the tobacco and alcohol industry use over zealous lobbying techniques, which are often detrimental to public health objectives. We deal with this aspect only in a cursory way in this model law. More measures can be found in the howtoregulate articles on “Countering unfair lobbying” and “Restoring trust: using regulations to protect the impartiality of decisions and research in the public interest”.</p>

<p>politics and the society. These institutions shall do the same. Both sides shall publish in the lobbying register comprehensive minutes of the meetings, encounters or conversations and position papers, letters, or electronic communication.</p>	
<p><b>23. Ban of products evoking ACT products</b></p> <p>23.1 The sale of food, toys, and other products intended for children or adolescents whose designs mimic ACT products is banned.</p> <p>23.2 The sale of clothing [for children] with images of ACT products or with logos or brand names of ACT operators is forbidden.</p> <p>23.3 Games, including online games, referring to ACT products are forbidden.</p>	<p>Examples are: champagne for children, cigarettes made of chocolate.</p>
<p><b>24. Private imports for personal consumption</b></p> <p>24.1 Private import is permitted only when executed personally on the occasion of travel abroad for more than 24/48 hours and only once per week / month.</p>	<p>The first limitation aims at banning private import by parcel, the second aims at banning on purpose or very frequent “travel”, the latter being a sign for the intention to re-sell the ACT goods illegally.</p>
<p>24.2 An adult person may import ACT goods for her or his personal use within the following limits:</p> <ul style="list-style-type: none"> <li>• For alcohol: X litres containing ad maximum Y grams alcohol;</li> <li>• For cannabis: X grams;</li> <li>• For tobacco: X cigarettes or cigarillos, Y cigars or Z grams of tobacco;</li> <li>• For ... : ....</li> </ul>	
<p>24.3 Where the limits are unintentionally exceeded by 50% or less, only the excess amounts shall be confiscated without compensation by the authority stating the infringement. In case of intentional or higher trespassing, the entirety shall be confiscated without compensation.</p>	<p>Of course, the confiscation provisions can be simplified by confiscating the entirety in all cases or just the excess amounts in all cases. However, we wish to show how a more subtle indirect sanctioning system could work.</p>
<p>24.4 Import is subject to following conditions:</p> <ul style="list-style-type: none"> <li>• Passing of the border at an official border control post;</li> <li>• Prior (24h in advance) declaration via internet of one's intention to import these goods;</li> <li>• Oral reference to the private import at the first contact with border control or customs authority agents;</li> </ul>	<p>The list of conditions here is too long and some conditions duplicate slightly. The list offers choices to the users of this model law, therefore please select the conditions that you deem appropriate.</p>

- The traveller seeks as soon as possible after entry the contact with customs authority's agents; and
- The ACT good has been legally acquired and contains all legally necessary marks, warnings, mandatory information, stamps and seals indicating the fulfilment of sales tax and customs duties and of other legal requirements of the country of sale.

Where one of these conditions is not fulfilled, the ACT goods shall be confiscated without compensation.

Here again, we deem it important to state clearly the legal consequence of not complying with the legal conditions, so as to avoid any discretion and bargaining at the border, as such bargaining is prone to corruption.

#### *25. Private ACT production*

Production of ACT goods for own consumption or consumption of family members [of the ascending/descending line] is forbidden OR subject to the following conditions:

- The ground surface used for the cultivation of tobacco or cannabis is limited to 5 or 2 square metres respectively;
- The maximum harvest or stock of tobacco or cannabis per year is 5 or 2 kilograms respectively – yields or stocks going beyond this limit have to be destroyed immediately;
- The maximum stock of wine, cider or beer produced for own consumption is 200 litres;
- The maximum stock of other alcoholic beverages is 30 litres;
- The containers of the ACT goods shall be labelled with the name and the address of the producer and the date and quantity of production or harvest;
- The produced ACT goods, their date of production or harvest and the respective quantities have to be notified to the ACT Agency on the day of production or harvest;
- Stocks have to be notified to the ACT Agency on first day of each month;
- Producers shall provide agents of the ACT Agency at any moment access to their premises, including premises which are not necessarily connected to the production or storage of ACT goods.

Production of home-grown coca, khat, cannabis or alcohol is part of traditional culture in many parts of the world so that a total ban might not be feasible. Moreover, a total ban might be very difficult to enforce. Where a total ban is, for one reason or the other, not pursued, the limits for legal possession (see Section 26) cannot appropriately regulate private production as the harvest yields trespass these limits easily. It might be more appropriate to establish distinct limits e.g. on the basis of 3, 6 or 12 months private consumption rates.

<p><b>26. Private possession of ACT goods</b></p> <p>Possession of ACT goods, including when based on growing plants, is only lawful when respecting the following limits:</p> <ul style="list-style-type: none"> <li>• 200g tobacco, 200 cigarettes or cigarillos, 50 cigars (with 1g tobacco being equivalent to one cigarette or cigarillo and one cigar being equivalent to 4 cigarettes or cigarillos);</li> <li>• 20g cannabis or cannabis products;</li> <li>• 100 litres wine, cider or beer (all combined);</li> <li>• 10 litres of other alcoholic beverages.</li> </ul> <p>Where private persons wish to stock larger quantities of alcoholic beverages, the rules for private production shall apply. A precise inventory shall be communicated every month to the ACT Agency.</p>
--

<p><b>27. Monitoring of particularly problematic consumption of ACT goods</b></p> <p>Professors, teachers, trainers and other persons working for education and training or persons guarding vulnerable persons and employers or superiors shall proactively offer support to the students, children, trainees, vulnerable persons and employees for whom they are responsible and whom they suspect to practice problematic consumption of ACT goods. They shall request the reasons and conditions of such consumption, try to provide remedies in their remit and steer the persons to medical personnel or private or public institutions specialised in ACT consumption.</p>
---

<p><b>28. Obligations, tasks and powers of the ACT Agency</b></p> <p>28.1 An agency is created to manage and oversee the administration of this regulation. The ACT Agency shall:</p> <ul style="list-style-type: none"> <li>• supervise operators, their contractors and other actors potentially infringing this regulation, if needed with the investigative powers attributed to the police <b>OR</b> regulations applicable to the police apply by analogy;</li> <li>• set-up minimum and maximum prices for ACT goods by ... (ordinance, regulation adopted in accordance with ...);</li> <li>• ban or limit the use of substances by modifying the list in Sections 4 and 5 by ... (ordinance, regulation);</li> </ul>
---

Even where a certain ACT good is regarded as illegal in a certain jurisdiction, it might be useful to define a (low) quantity under which the possession of that good is still tolerated, instead of wasting scarce enforcement capacity for minor offences.

This provision aims at social action by the usual social environment to act against problematic consumption of ACT goods.

The reference to the powers of the police and the applicability of respective regulations is an elegant technique to avoid the need for the establishment of own empowerments. Moreover, it assures that the legal terms and their interpretation are quite common-place, thus avoiding legal uncertainty.

However, having never found a list with empowerments which is both precise and

- establish and manage or have managed the ACT goods registration scheme, analyse the data generated by this scheme and provide both the raw data and the analysis to the authorities in charge of taxes, excises and customs; **OR**
- establish and manage or have managed the ACT goods traceability scheme, analyse the data generated by this scheme and provide both the raw data and the analysis to the authorities in charge of taxes, excises and customs;
- levy fees for all procedures it is involved in, including enforcement procedures, by ... (ordinance, regulation adopted in accordance with ...);
- levy contributions to ... (national health insurance, national ACT prevention fund, national ACT compensation scheme) by ... (ordinance, regulation adopted in accordance with ...);
- instruct operators, their contractors and other actors on how to fulfil the obligations of this Regulation correctly;
- develop, for the operators, a prototype self-monitoring plan or quality system ensuring and verifying compliance with all the obligations of operators;
- sanction operators, their contractors and other actors infringing this regulation in accordance with Section 35;
- seize and destroy non-conforming goods or goods for which the origin of production or manufacturing is unknown or uncertain;
- ensure by internal procedures that all staff is independent from interests of operators;
- refuse all financial or other support from private institutions or persons which are directly or indirectly linked to operators, their contractors and subsidiary companies of operators and their contractors;
- refuse instructions from others than the minister for ... and from the Court of Auditors;

without loopholes, we recommend to undertake a careful assessment of the needs for empowerments with the help of Chapter 11 and in particular Sections 11.5 and 15.4 of the Handbook “How to regulate?”. A single empowerment loophole may dramatically hamper the enforcement of regulations.

Below you will find a list of empowerments which we deem to be particularly useful in the given context. If you find, amongst them, empowerments which were not already contained in your domestic empowerments, it is even more strongly recommended to screen the Chapter 11 and in particular Sections 11.5 and 15.4 of the Handbook “How to regulate?” for missed empowerments. Insufficient empowerments is the most frequent and most important deficiency that the Regulatory Institute has found when analysing regulations of the world.

See Section 10 last indent.

The first indent would also fit well here.

- launch information campaigns to inform future and current operators on the obligations set-out in this Regulation;
- offer training courses for operators and their staff;
- launch education and information campaigns for consumers, which may include guidelines for responsible consumption;
- offer a portal for complaints and reports on illegal practices, permitting also anonymous contributions;
- protect persons reporting on illegal practices;
- monitor the effectiveness of this regulation and its application, *inter alia* by surveillance programmes;
- report biannually to the legislature additional possibilities to reduce ACT consumption and and its harmful effects.

28.2 In addition to the powers provided by the analogue application of the ... (police regulation, see above), the ACT Agency shall have the following powers:

- Imposing obligations on operators and third parties to cooperate, without remuneration, with the authority and in particular to permit samples to be taken or provide samples on request, provide information, and to grant access to documentation and premises;
- Arresting persons and imposing financial sanctions in case these obligations are not fulfilled by the third parties;
- Visiting and inspecting offices, factories, warehouses, wholesale establishments, retailing establishments, laboratories, research institutions and other premises in which ACT goods are produced or kept, or where services in relation to these goods are provided;
- Entering and inspecting any vehicle used to transport or hold goods;
- Use undercover agents for investigations;

Anonymous deposits nonetheless permitting bilateral communication are the state-of-the-art.

Whistle-blower protection mechanisms (a universe of its own, see this article).

See above the remarks about (mostly) insufficient empowerments.

- Buying anonymously or via proxy goods in view of assessing their conformity;
- Taking samples of the goods;
- Seizing and taking possession of all goods which are in non-conformity;
- Seizing and taking possession of all documents, data and objects which might serve as means of proof for stating the non-conformity;
- Compelling the attendance of witnesses and the production by third parties of evidence via a subpoena, when there are reasons to believe or evidence for assuming that infringement may have occurred;
- Compelling from any person [potentially / presumably in contact with operators or their contractors] the production or delivery of data, information or documents of any kind, including commercial and on property or other rights related to objects and rights, issuing document search warrants and further measures needed to search and confiscate documents;
- Requesting data from internet or telecommunication service providers;
- Supervising the internet communication or telecommunication (meta-data or even content) in a personalised or generic way;
- Acquiring data and documents from third parties, including against payment or providing advantages;
- Processing data;
- Exchanging data with other authorities, courts, natural or legal persons or other jurisdictions and adopting agreements in this regard;
- Surveillance of persons on the basis of judicial monitoring orders;
- Requesting from internet or telecommunication service provider blocking of certain content;
- Blocking certain internet content by own means;
- Issuing notices of non-compliance and set an appropriate deadline for rectification of the situation;

- Confiscating and destroying goods or means serving to produce illegal products;
- Forbidding the use of premises or establishments for storage of goods or production of products;
- Closing plants and other premises temporarily, in case of suspected massive infringement of this Regulation, and to that end sealing of facilities, confiscating data or objects;
- Closing plants and other premises definitively, in case of proven massive infringement of this Regulation, and to that end sealing of facilities, confiscating or destroying of data or objects;
- Retaining shipments;
- Requesting securities as guarantee for the fulfilment of obligations;
- Confiscating objects, rights or money as means to enforce financial obligation or sanction;
- Confiscating objects, rights or money obtained directly or indirectly from practices infringing this Regulation;
- Delegating enforcement tasks by means of public or private law;
- Obliging local enforcement authorities to fulfil minimum resource requirements;
- Establishing parameters for determining how many full-time equivalents (FTE) are needed for enforcement at the level of local enforcement authorities;
- Cooperating with national or international authorities and scientific institutions and to exchange data, documents and other information on the operators, their contractors and other partners, provided that these authorities and scientific institutions can formally or informally ensure confidential treatment;
- Conducting, or cooperating with persons conducting research, development, tests, demonstrations and studies and publishing this research or test results.

This empowerment is not to be mixed up with the empowerment to confiscate unlawful products in the first series of empowerments.

These two empowerments are again not to be mixed up with the empowerments referred to in the last comment.

## **29. International cooperation**

29.1 The ACT Agency may take the following measures with regard to international organisations and foreign national authorities, under the condition that the same measures of international cooperation are reciprocated:

- Permitting international or foreign national officers to take part in operations of the ACT Agency or local enforcement authorities;
- Disclosing confidential information;
- Establishing joint expert committees and data exchange needed for that purpose;
- Investigating or enforcing on the territory of the other jurisdiction;
- Empowering foreign national authorities to carry out investigations on the territory of the jurisdiction provided that the rule of law and domestic principles of legality will be respected by the foreign national authority;
- Requesting foreign national authorities to enforce on their territory obligations under this Regulation, provided that the rule of law and domestic principles of legality will be respected by the requesting jurisdiction;
- Enforcing or requesting local enforcement authorities to enforce foreign measures provided that the rule of law and basic principles of fairness have been respected by the requesting jurisdiction;
- Permitting foreign national authorities to investigate their cases in your jurisdiction provided that the rule of law and basic principles of fairness have been respected by the other jurisdiction;
- Recognising foreign certificates or approvals on qualification as operator;
- Extending other domestic investigational or enforcement empowerments to cases subject to the law of another jurisdiction; and
- Making agreements on cooperation with regard to all the above and collateral organisational aspects.

There can be mutual assistance between the two jurisdictions based on formal agreements under international public law or based on practical arrangements between administrations. The latter are more flexible and easier to negotiate, but are not legally binding. Nonetheless they can be very useful if both sides voluntarily apply them as if they were binding. To do so, they must have, on both sides, the necessary (unilateral) empowerments. The technique consists in establishing unilateral empowerments to act for the other jurisdiction whilst de facto requesting mutuality.

However, there is a risk in case of power discrepancy between two jurisdictions. Where there are other jurisdictions potentially so powerful to be able to oblige the domestic jurisdiction to act on their behalf without ensuring reciprocity, it might, subject to the case, be wise not to install empowerments for action on behalf of other jurisdictions. Otherwise, the unilateral empowerment serves only the other jurisdiction which has power supremacy.

29.2 Where mutuality is ensured, courts are permitted to provide assistance to foreign courts / jurisdictions, provided that they can ascertain that both have fulfilled the applicable foreign requirements of legality.

This shall include / shall not include:

- Extradition of offenders for offences committed under the law of the other jurisdictions;
- Transfer of witnesses in custody for court procedures in the other jurisdiction; ...

*30. Intra-state and scientific cooperation*

30.1 The following administrations and courts shall, proactively and/or on request, disclose data, documents and other information to the ACT Agency:

- Tax authorities;
- Customs authorities;
- Police authorities;
- Authorities responsible for pharmaceuticals; and
- Courts.

30.2 Courts may postpone the disclosure of data, documents or other information to the end of the respective court procedure(s) in case that the outcome of the procedure might be negatively impacted by the disclosure.

30.3 All state-funded universities or other research or technology institutes shall make their expertise available to the ACT Agency. They shall accept invitations of the ACT Agency to send a competent delegate to meetings or teleconference of the scientific advisory board of the ACT Agency.

30.4 The ACT Agency may invite representatives of foreign institutes and universities and representatives of international organisations to become temporary observers or permanent members of the advisory board.

30.5 Members and observers shall, two weeks before any meeting or teleconference, declare in writing whether they have a potential conflict of interests. The ACT Agency shall decide on the temporary or permanent exclusion of the member or observer with full discretionary power.

Subject to the generic law otherwise applicable, it might be useful or not to oblige certain administrations and courts to cooperate.

Disclosure of data can endanger the finalisation of the court procedures. Hence, the courts should be empowered to postpone the disclosure until the procedures are closed.

30.6 The names and the roles of the members and observers of the advisory board [and their declarations of interests] shall [not] be public.

**31. Scientific ACT Committee**

31.1 The government shall, on proposal of the ACT Agency or of the legislature / after a two-months public call for interest, nominate X members of the Scientific ACT Committee. Members need / do not need to have one of the following nationalities: ...

31.2 [The government shall also nominate the chair of the ACT Committee.] OR [The members shall elect the chair of the ACT Committee.]

31.3 The ACT Agency shall provide the secretariat.

31.4 The ACT Agency shall elaborate the draft rules of procedure which shall become applicable [after approval by the responsible minister] / [adoption by the ACT Committee]. The rules of procedure shall in particular deal with the processing of conflicts of interest.

31.5 The members of the ACT Committee shall obtain a (tax-exempted) daily allowance for each meeting day and X days per year for domestic work. The level daily allowance is Y and shall be annually adapted following the Z index / shall be periodically adapted by decision of the responsible minister.

31.5 The members of the ACT Committee are independent from any instruction. They are obliged to keep confidentiality except in cases where they become aware of undue influences, corruption or falsification of findings. Before alerting the public in these cases, they shall inform the minister in charge unless they have reasons to believe that the minister is involved in the irregularities or that the disclosure would thereby become ineffective.

In the previous section, we have suggested a light, rather informal scientific advisory board. If this is not deemed to be sufficient, a more structured scientific committee could be developed. But evidently the two should not exist in parallel.

Please check whether some provisions displayed for the advisory board should be copied in.

Uneven numbers of members are preferable.

## **32. Central alert portal and whistle-blowing**

32.1 The ACT Agency shall create a central alert portal which permits to upload information on possibly illegal activities anonymously. It shall also provide a hot-line via which any person may inform the ACT Agency orally.

32.2 Employees or other persons working for operators, contractors of operators and staff working for contractors of operators are exempted from their confidentiality obligations under labour or contractual law and any other legal provisions or contracts obliging them to keep information confidential provided that they act in good faith when disclosing information on possible infringement of legal obligations set-out in this Regulation. Good faith is to be presumed where the primary motivation is the disclosure of the infringement of this regulation or a connected law.

32.3 Where the whistle-blowers agree to it, the statement of whistle-blowers shall be recorded in presence of ... (e.g. a judge in charge of instructions). Such statement can be used in all state procedures, including criminal and civil law procedures, even where the whistle-blower "withdraws" it.

32.4 The ACT Agency may compensate whistle-blowers for damage, advise them, and organise the change of identity with the help of the police and its witness protection programme and the authorities ... (in charge of identity documentation).

32.5 Authorities involved in the application of this Section shall keep all information confidential, unless the sharing of information is explicitly foreseen in this or other

In the list of obligations of the ACT Agency, we have inserted two indents about providing the possibility to make – also anonymously - complaints and reports on illegal practices and protecting persons reporting on illegal practices. The section here is a more in-depth-provision on the same items. If readers wish to go ever more into detail, this article is recommended.

Anonymous deposits nonetheless permitting bilateral communication are the state-of-the art, but not easy to implement.

This provision makes the statement of the whistle-blowers admissible even if the whistle-blowers later "withdraw" their statements, e.g. due to pressure or stress.

<p>regulation. The authorities keep / may keep information obtained from a whistle-blower confidential even where there is an obligation to share this information set-up by other regulation. The authorities may not share information obtained from whistle-blowers with other jurisdictions unless the whistle-blower agrees thereto.</p>	<p>An important choice is to be made where there is a conflict of interest due to different pieces of regulation.</p>
<p><b>33. Financial incentives</b></p> <p>The ACT Agency may subsidise within the limits of its budget:</p> <ul style="list-style-type: none"> <li>• The development of best-practice guidance;</li> <li>• Voluntary mutual control or other compliance programmes referring to the legal obligations or the best-practice guidance;</li> <li>• Research permitting to render this regulation more effective;</li> <li>• ACT prevention programmes;....</li> </ul>	<p>In many jurisdictions, a provision like this is not necessary as financial empowerments are only provided by the annual budget.</p>
<p><b>34. Supervision of the ACT Agency[, the ACT Committee] and the local enforcement authorities</b></p> <p>34.1 The work of the ACT Agency[, the ACT Committee] and the local enforcement authorities shall be subject to a review by X (a review body, private or public auditors) every second year. X shall investigate the efficiency and effectiveness, but also possible irregularities. To that end, X shall receive automatic electronic copies of the alerts submitted in accordance with Section 32.</p>	<p>Supervision can e.g. be provided by a Court of Auditors, a legislature committee, a delegated person of high respectability or a governmental instance in charge of supervising the well-functioning of administrations.</p> <p>Supervision seems particularly important in case of ACT as the economy of ACT is likely to be subject to a rather high degree of illegality and thus corruption of state agents.</p>
<p>34.2 X shall have the power to enter all the premises of the ACT Agency and of local enforcement authorities, to request access to all data, documents and other information, to enquire persons and to seize objects. Artificial intelligence may be used to detect irregularities consistent with the respective data collection and privacy legal regimes, administrative law or any other applicable law.</p>	<p>To improve the empirical basis and to avoid the risk that the supervisor remains in the dark, it would be useful to give him/her access to certain, very indicative raw data such as alerts on potential infringements of this Regulation and complaints on the ACT Agency.</p>
<p>34.3 The supervisory role of X shall be clearly communicated on the websites of the ACT Agency and the ACT Committee, jointly with the means of secure communication with X.</p>	<p>This provision creates an incentive for the ACT Agency to work properly and a possibility for third parties to obtain some control of the ACT Agency.</p>

<p>34.4 This same information shall be placed on the infringement alert portal.</p>	<p>There is a certain risk of the ACT Agency not processing correctly complaints and alerts when there is a longstanding relationship with the operator who is said to infringe the law. Informing the reporting person on the supervisory role of X reduces the likelihood of collusion between agents of the ACT Agency and the operator. It also gives a whistle-blower a second chance</p>
<p><b>35. Sanctions</b></p> <p>35.1 Possession of ACT goods by private persons shall be sanctioned as follows: ...</p> <p>35.2 Possession by operators of ACT goods not registered in the ACT traceability scheme shall be sanctioned as follows, regardless of whether the operator is a natural or a legal person: ...</p>	<p>There are evidently many ways to design a system of sanctions with regard to ACT regulation. Hence the provisions should only be regarded as inspiration for the development of own provisions fitting to the respective domestic penal practice.</p>
<p>35.3 The natural persons acting for the operators who were in possession of ACT goods not registered in the ACT traceability scheme shall be sanctioned as follows: ...</p> <p>35.4 In case of deliberate infringement of the obligations set out in this Regulation, the following penal sanctions apply to the natural persons responsible for the infringement, regardless of whether they are employees of operators or contractors or staff of contractors:</p> <ul style="list-style-type: none"> <li>• For infringements of Sections ... up to ... years of imprisonment or a fine of up to triple their annual net salary.</li> <li>• For infringements of Sections ... up to ... years of imprisonment or a fine of up to double their annual net salary.</li> <li>• For infringements of Sections ... up to ... years of imprisonment or a fine of up to their annual net salary.</li> </ul>	<p>We recommend dedicated provisions on illegal possession (35.1 to 35.3) in order to highlight this major legal issue, whilst it would be possible to integrate the illegal possession into the following sub-sections as well.</p> <p>We recommend distinguishing between deliberate and unintentional infringements.</p>
<p>35.5 In case of unintentional non-compliance of obligations [or where the deliberate character of the infringement cannot be proven], the following penal sanctions apply to the natural persons responsible for the infringement, regardless of whether they are employees of operators or contractors or staff of contractors:</p>	<p>The part in square brackets might be necessary or not.</p> <p>We avoid here the term “negligent” which is often understood as implying the violation of a duty of care and therefore renders sanctioning more difficult. However, in some jurisdictions, it would not be appropriate to sideline this duty of care aspect.</p>

- For infringements of Sections ... up to ... years of imprisonment or a fine of up to their annual net salary.
- For infringements of Sections ... up to ... years of imprisonment or a fine of up to 2/3 their annual net salary.
- For infringements of Sections ... up to ... years of imprisonment or a fine of up to 1/3 their annual net salary.

35.6 In addition to or instead of the sanctions listed in 35.1 to 35.5, the ACT Agency may impose the following collateral sanctions against the legal bodies acting as operator or contractor of an operator, when involved in the infringement:

- Administrative sanctions of up to three times their annual budget or turn-over;
- Exclusion from public tenders for up to X years;
- Citation in the public list of law infringing / criminal economic operators for up to X years.

35.7 The ACT Agency may also:

- Publish the names and further data permitting the identification of natural or legal persons who have deliberately infringed this Regulation;
- Confiscate and destroy, as sanction and thus regardless of their illegal character, a proportionate amount of ACT goods, and this in particular where fines are not paid;
- Suspend the licenses of the offender and eliminate him during that time in the register of licensed operators;
- In case of particular grave or repetitive deliberate infringements close the facilities of the operator.

35.8 Sanctions and the collateral measures set out in this section may be extended to subsidiary companies or other legal or natural persons and the staff of all these persons if these legal or natural persons controlled the offending person to such an extent that they were in reality responsible for the offence.

35.9 The ACT Agency may oblige any natural or legal person to cooperate for purposes of enforcement of sanctions and collateral

Some legal bodies acting as operators or contractor of operators are in reality controlled by another legal body, most often a subsidiary company. Some legal bodies create companies as shields or shell companies without assets to pay sanctions. This provision empowers the authorities to counter this situation.

We have, above in Section 28, listed a full range of empowerments serving the enforcement of obligations of this regulation. However, these empowerments do not cover

<p>measures set out in this section, including with regard to the disclosure of confidential information, the hand-over of assets of all forms, the temporary closure of websites, the suspension of services supporting the economic activity of the offending person.</p>	<p>the enforcement of sanctions and their collateral measures. Hence, separate empowerments are needed in order to enforce the sanctions with the help of third persons.</p>
<p><b>36. Joint liability and compensation scheme</b></p> <p>36.1 Operators are, up to ten years after cessation of their activity, jointly liable for damages caused by the consumption of products. These damages include inter alia:</p> <ul style="list-style-type: none"> <li>• damages caused by a consumer who was in an altered state of consciousness due to the consumption of ACT products, unless there is prevailing evidence for non-causality;</li> <li>• death or health damages where there is a prevailing likelihood that they are caused by the consumption of ACT products;</li> <li>• in any case of death or health damages caused by cancer of the lung, the mouth ... after at least three years of consumption of tobacco or smoked cannabis;</li> <li>• in any case of death or health damages caused by cirrhosis of the liver / alcoholic cirrhosis after consumption of X litres of alcoholic beverages / consumption of Y litres of pure alcohol during the last three years [or during three years within the last five years];</li> <li>• in all other cases after five years of consumption;</li> <li>• indirect damages caused [or likely to be caused] by one of the above, including loss of income, including for relatives of a deceased person.</li> </ul>	<p>Liability obligations are often a brutally effective means to deter from damaging economic activities.</p> <p>The main tricky issue and pre-condition for the effectiveness is however the burden of proof. The higher the burden of proof, the less effective. But the lower the burden of proof, the higher is the risk to burden the operators unfairly. Hence, regulators need to make complex trade-off decisions.</p> <p>We present here a variety of formulations to illustrate how the burden of proof can be tackled. They use legal presumptions. These presumptions can be rebuttable or not.</p> <p>The causality likelihood benchmark can be defined in very different ways.</p>
<p>[36.2 Where the causality between consumption and damage is legally presumed according to the above, the operators may rebut the presumption by findings relating to the specific case.]</p>	<p>Here the question arises whether operators shall have the possibility to rebut presumptions.</p>
<p>36.3 The consumption of the ACT products is legally presumed where the consumer has purchased the ACT products (which can be proven by the data of the national ACT products traceability scheme).</p>	<p>The consumption will be difficult to prove as it happens mostly at home or at different places with different witnesses. Hence it might make sense to link a presumption of</p>

<p>36.4 Operators contribute X percent of their turn-over of ACT goods to the national ACT compensation scheme which is managed by the ACT Agency. Claimants may apply to the ACT compensation scheme instead of the operators. The liability of the operators in accordance with the previous section is suspended as long as they have made their respective contributions and the contributions suffice to cover liability claims. Operators may also voluntarily contribute additional funding to the ACT compensation scheme, notably where the funds of the scheme risk to run out. [Regardless of the behaviour of their peers or whether the funds of the ACT compensation scheme suffice, operators are exempted from liability where they have contributed the double / triple of the ordinary contribution for the last 10 years.]</p>	<p>consumption to the fact that ACT products have been purchased.</p> <p>An additional national compensation scheme is preferable to simple liability because it can also work where an individual operator has ceased to exist or is unable to compensate. The relationship between such a scheme and the operators can be designed in many different ways. We present here a model in which the operators remain liable, but only in a subsidiary way, in case the compensation scheme runs out of funds.</p>
<p><i>37. Legal remedies</i> Decisions in accordance with this regulation may be challenged within X months in writing and by [authenticated] electronic email at ... (supervisory administration or court). [Remedies against the decisions of the ... (supervisory administration) shall be addressed at ... (one or several courts).]</p>	<p>Such provisions are evidently not necessary where generic administrative law contains sufficient provisions.</p>
<p><i>38. Entry into force and application date</i> This regulation enters into force as of ... It applies in its entirety as from ... However, Sections ... apply only as from ...</p>	<p>Split application dates can, e.g., be useful to build up the ACT Agency and to get its activities running in a first phase, but to give operators more time to undergo their procedures, to get (their staff) trained and to fulfil their obligations. Evidently, operators should not be requested to do the impossible. If the ACT Agency has not yet established enough training courses, the operators and their staff cannot be expected to be trained.</p>
<p><i>39. Transitional provisions</i> Licenses as operators issued under ... (predecessor act) remain valid until ... OR</p>	<p>The transitional provisions become ever more complex, the more law there was before. E.g., if there were geographic</p>

Operators who have been active at the time of publication of this Regulation dispose of 6 months to undergo the license procedure set out in Section 8.

monopolies before, transitional provisions are also needed in their regard.