



emcdda.europa.eu

Legal Responses to New Psychoactive Substances in Europe

Date 19 February 2009

Author • Auteur B Hughes, T Blidaru

European Legal Database on Drugs
<http://eldd.emcdda.europa.eu/>

Abstract

This paper starts from the premise that, when a new psychoactive substance appears on the licit/illicit market in a country in Europe, legislators need to choose whether to bring it under control of the drug laws, and for public health reasons they may need to do so quickly. A comparative study of the systems and procedures finds that there are a variety of control methods available in the different countries, including the analogue and generic systems, as well as temporary emergency and rapid permanent scheduling procedures. These may be effective immediately, within several days, or needing up to a year to process. A glance at the risk assessment systems that might be used before or during these procedures illustrates an even spread of the possible options across countries, from no system to a full consultation of independent scientists.

1. Introduction	4
------------------------	----------

2. Definitions	5
-----------------------	----------

The Individual Listing System, and associated procedures	5
The Generic System	5
The Analogue System	6
The Risk Assessment Procedure	7

3. National systems and procedures: the legal practice	8
---	----------

Table 1. Summary of estimated durations of legal procedures, and the legal texts produced	18
---	----

4. The Risk Assessment procedure	20
---	-----------

National risk assessment procedures: the practice	20
---	----

5. Findings	24
--------------------	-----------

1. Introduction

“No one shall be held guilty of any criminal offence on account of any act or omission which did not constitute a criminal offence under national or international law at the time when it was committed.”

(European Convention on Human Rights, Art 7(1))¹

Following this ‘principle of legality’ (also known as the *nullem crimen, nulla poena sine lege* principle), controlled psychoactive substances (usually referred to as “drugs”) should be clearly referred to, either individually or in tightly defined groups, by national criminal laws that may apply to them in cases of unauthorised possession or trafficking.

However, such references and definitions can act as a challenge to illicit drug producers and traffickers to adjust a chemical compound to one that is outside the definition of a controlled substance, or to find a new substance, that has similar psychoactive effects. National legislatures will then need to decide if they need to bring this new substance under control – and in cases of immediate risk to public health, they will need to act quickly. Similarly, countries that are parties to the UN treaties or the EU may be obliged to add substances to their lists within a certain deadline, when a decision to control a substance is taken by the UN or by the EU.

In 2004, EMCDDA published a study entitled “Legal Responses to New Synthetic Drugs 2000-2004”. As well as touching on issues relating to new synthetic drugs in the EU Action Plan 2000-2004, the study looked at the formal systems used by Member States to control new synthetic drugs, and also at the legal procedures involved in putting a new substance under control, with estimates of the time that such a procedure might take.

Four years later, this new study updates those latter parts of the previous one. Its scope is broader, as it now addresses: an enlarged EU as well as Norway and Croatia; the legal responses to any sort of new drugs (not just synthetic) in line with the Council Decision 2005/387/JHA on control of new psychoactive substances²; and, briefly, countries’ risk assessments involved during the procedure.

The methods of classification used in these countries are various. For this reason, this study employs a range of working definitions to assist the reader, both with regard to legal systems and procedures, and to risk assessment. These build on the definitions of the previous paper³, even if they have varying degrees of acceptance outside the scope of the study.

As regards the methodology used in conducting the study, the main instruments were questionnaires sent to the ELDD’s Legal Correspondents Network; additionally Early Warning Correspondents contributed with information regarding risk assessment procedures.

¹ The Convention for the Protection of Human Rights and Fundamental Freedoms, Article 7(1), at:
<http://www.echr.coe.int/nr/rdonlyres/d5cc24a7-dc13-4318-b457-5c9014916d7a/0/englishanglais.pdf>

² of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, at:
<http://eldd.emcdda.europa.eu/html.cfm/index5173EN.html?pluginMethod=eldd.showlegalextdetail&id=3301&lang=en&T=2>

³ The *generic system*, the *emergency list* and the *rapid procedure* were addressed (and defined) in the *Legal Responses to New Synthetic Drugs 2000-2004* paper, for the analysis of the different systems in use.

2. Definitions

The Individual Listing System, and associated procedures

Usually, countries name the chemical definitions of controlled substances individually in the national legislation; and all national lists of controlled substances follow the UN Conventions, which may extend the application of the listing to a substance's isomers, esters, ethers and salts, including certain other defined salts⁴. In practice, the addition of a new substance to the list may be made by means of:

- A **standard procedure**, which may be either the only or the most common procedure to be followed in order to control new substances;
- An **emergency procedure**, which is an accelerated procedure to legally control new substances for a limited period of time. If the control is not confirmed during this period by the standard procedure, it will expire. This procedure thus provides for a quick but temporary control measure; or
- A **rapid procedure**, which is an accelerated procedure to legally control new substances. The rapid procedure is different from the emergency procedure in that the control measures are permanent, not expiring after a certain period of time.

In some countries, the individual listing system may also be supplemented by definitions of groups of substances under control, known as **generic** and **analogue** systems. In practice, this means that all substances falling within the legal definition of the group are automatically controlled; consequently, such substances do not need to be listed individually in the applicable legal texts. In this relation, it must be noted that the application of Art. 7(1) ECHR above does not deem it "objectionable that the existing elements of the offence are clarified and adapted to new circumstances which can reasonably be brought under the original conception of the offence"⁵. These systems are defined as follows.

The Generic System

The generic system refers to the inclusion, usually within the list of individual substances under control, of a precise definition of a group of substances; in the context of the current study, this is over and above the isomers, esters, ethers and salts already obliged by the UN Conventions.

⁴ The phrase "including the salts of esters, ethers and isomers whenever the existence of such salts is possible" is found following the list of individual substances in Schedule I of the UN *Single Convention on Narcotic Drugs 1961*, whilst the phrase "including the salts of the isomers as provided above whenever the existence of such salts is possible" follows the list of individual substances in Schedule II of the same Convention, at: http://www.unodc.org/pdf/convention_1961_en.pdf

⁵ *X Ltd and Y v UK* No 8710/79, 28 DR 77 at 81 (1982), quoted in Harris, D.J., O'Boyle, M., and Warbrick, C. (1995), *Law of the European Convention on Human Rights*, p. 277.

One such group-generic definition is by reference to precise compounds which are structurally derived from a specific psychoactive substance. In the UK case of *R v Couzens and Frankel* in 1992, it was specified that "the term 'structurally derived from' does not describe a process, but rather defines certain controlled drugs in terms of their molecular structure"⁶. An example is the definition of:

"any compound (...) structurally derived from fentanyl by modification in any of the following ways, that is to say:

- (i) by replacement of the phenyl portion of the phenethyl group by any heteromonocycle whether or not further substituted in the heterocycle;
- (ii) by substitution in the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halogeno, haloalkyl, amino or nitro groups;
- (iii) by substitution in the aniline ring with alkyl, alkoxy, alkylendioxy, halogeno or haloalkyl groups [...]."⁷

Another description of group-generic substances can occur by illustrating the modifications in the 'parent' molecule without referring to 'structural derivation', as in the following case:

"DMT (dimethyltryptamine) analogues, in which the 3-(2-aminoethyl)indole nucleus has additional radicals, either alone or in combination, attached as follows:

- (a) 1 or 2 alkyl radicals, each with up to 6 carbon atoms, including cyclic radicals, attached to the amino nitrogen atom;
- (b) 1 or 2 methyl groups, or an ethyl group, attached to the carbon atom adjacent to the amino nitrogen atom;
- (c) Any combination of up to 5 alkyl radicals and/or alkoxy radicals (each with up to 6 carbon atoms, including cyclic radicals) and/or halogen radicals, attached to the benzene ring."⁸

The Analogue System

An alternative to the generic system, the analogue system addresses more general aspects of similarity in chemical structure to a 'parent' compound; this aspect might be supplemented by a requirement for similarity in pharmacological activity, attempting a more specific delineation of the analogue system's sphere of control.

One such analogue definition is by reference to any compound deemed to be:

"a substance –
the chemical structure of which is substantially similar to the chemical structure of a controlled substance [in schedule I or II]; [and]
which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the [...] effect [...] of a controlled substance in schedule I or II, or

⁶ Reported in King, L.A. (2003), *The Misuse of Drugs Act. A Guide for Forensic Scientists*, p. 100.

⁷ United Kingdom's *Misuse of Drugs Act 1971*, Schedule 2, Part I

⁸ New Zealand's *Misuse of Drugs Act 1975 no. 116 (as of 01 April 2008)*

with respect to a particular person, which such person represents or intends to have a[n] effect [...] that is substantially similar to or greater than the [...] effect [...] of a controlled substance [in schedule I or II]”⁹.

It is accepted that this particular definition “automatically prohibits a chemical if it is ‘substantially similar in structure’ to an already-prohibited drug, and has a ‘substantially similar chemical effect’ or is ‘represented to have such an effect’.”¹⁰

Another manner of illustrating the analogue system is by exclusive reference to an analogue’s ‘substantially similar chemical structure’ to a controlled compound, with no reference to its effects.¹¹ Or the analogue definition may be interpreted from a legal reference to ‘derivatives’¹².

The Risk Assessment Procedure

For purposes of the current study, the risk assessment of a new psychoactive substance is defined by analogy to the Council Decision 2005/387/JHA, along the following lines:

- An assessment of risks caused by use of, manufacture of, and traffic in a new substance, as well as the potential involvement of organised crime;
- The risks to be assessed include health and social risks, as well as the consequences of possible control measures;
- The assessment is based on the analysis of scientific data and law enforcement information, made available by, e.g. health, social and law enforcement sources (but not necessarily limited to these);
- The assessment may or may not take into account the same factors which warrant the placing of a substance under international control¹³;
- The assessment may be done in accordance with a formalised (legally based) procedure and it may be carried out by a scientific or expert body.

It should be kept in mind that the definitions above are for the purposes of this study, and are not universal. However: it is the functioning mechanism of each system which is considered to be the differentiating criterion of this study, rather than a system’s apparent wording.

⁹ United States’ Federal Analogue Act (1986)

¹⁰ Kau G. (2008), Flashback to the Federal Analog Act of 1986: Mixing Rules and Standards in the Cauldron; University of Pennsylvania Law Review Vol.156 No.4, at <http://www.pennumbra.com/issues/pdfs/156-4/Kau.pdf> , p.1081

¹¹ Canadian Controlled Drugs and Substances Act (1996)

¹² Norway’s Regulation of 30 June 1978 no. 08 Relating to Narcotics etc., §2.

¹³ According to the assessment of a threat to public health comparable to that of the substances listed in the 1961 United Nations Single Convention on Narcotic Drugs or the 1971 United Nations Convention on Psychotropic Substances.

3. National systems and procedures: the legal practice

In this section we describe the systems and legal procedures followed in each country according to the above definitions.

Belgium

The legislation in place provides for the individual listing of substances, in accordance with a standard procedure. This system is founded upon Art. 1 of the Law of 24 February 1921 relating to the traffic in poisons, soporific and narcotic drugs, disinfectants and antiseptics.

The listing procedure is initiated by the Minister of Health and, based on the approval of the Council of Ministers and that of the Council of State, it will be forwarded for signature to the King. Afterwards, the new Royal Decree will be published in the Official Journal.

The duration of the standard procedure mentioned above is of about 1 year.

The Czech Republic

The control over new substances is established by means of the Act No. 167/1998 Coll. (as amended) on dependency-producing substances, with lists of individual substances in the appended tables. The competence for adding new substances rests with the Parliament, in accordance with the power to amend any parliamentary law.

The control procedure is usually started by the Ministry of Health and the amendment proposal is then subjected to the governmental 'tasking process', during which ministries and selected public administration bodies may send comments that must be dealt with before further proceedings. The new draft will be sent for adoption to the government and then to the Parliament's two chambers. Following the Parliament's approval, it should be signed by the President and published in the Collection of Laws.

The length of the procedure is usually about one year.

Denmark

New drugs are controlled by a standard procedure to include their individual chemical definition on the list appended to the Executive Order on Euphoriant Substances. This system is established by means of the Consolidated Act no. 748 of 1 July 2008 on Euphoriant Substances (para. 1, 2).

The Minister for Health and Prevention is thus empowered to lay down regulations to the effect that substances be controlled if they are regarded as (highly) dangerous by reason of their properties – under international decisions or in the opinion of the National Board of Health.

The duration of this procedure is of 2-3 days, from the issuing of the recommendation of the National Board of Health until the respective new Executive Order on Euphoriant Substances, which amends the list of controlled substances, enters into force.

Germany

Germany has an individual listing system, with a standard procedure and an emergency procedure. The former is established by the Betäubungsmittelgesetz's (BtMG – Narcotics Act) section 1(2), the latter is in section 1(3).

The standard listing procedure starts with the submission by the Federal Ministry of Health of a draft Regulation to the Council of Ministers – Bundeskabinett, after consultation with an expert commission. The Council of Ministers decides on the Regulation usually within 2 weeks from submission. The Regulation is then sent to the Bundesrat¹⁴ with a minimum of 6 weeks for examination. Following the Bundesrat's approval, the Regulation is published in the Federal Law Gazette.

Under the emergency procedure, in urgent cases the Federal Ministry of Health decides on a Regulation which needs not be submitted to either the Council of Ministers or the Bundesrat. Following the Minister's decision, the Regulation is published in the Federal Law Gazette. This Regulation, however, expires within 1 year. Within this period, the standard procedure must be followed in order to control the substance permanently.

Excluding the internal preparations and the consultations of the expert commission, the standard legislative procedure takes a minimum of 9 weeks, compared to 1 week in the case of the emergency procedure.

When a substance is controlled at UN level, section 1(4) BtMG stipulates – as in the emergency procedure – that the Ministry of Health needs neither the consent of the Bundesrat, nor does it need to hear any experts, in order to list the substances controlled internationally. This is not applicable in the case of substances controlled by the EU.

Estonia

The control system provides for individual listing via a standard procedure, which is indicated in the Act on Narcotic Drugs and Psychotropic Substances and Precursors thereof, §§ 2(1) and 3¹(1). The control procedure starts with the proposal from the State Agency of Medicines (SAM); it then continues with the drafting of a regulation on the part of the Minister of Social Affairs, to be subjected to comments; the regulation is then signed and published in the State Gazette and will enter into force within 3 days from publishing.

The approximate minimum time needed to control a substance is 1 month and the control measures are permanent.

Ireland

New psychoactive substances are controlled both by individual listing and a generic system. The legal basis establishing these systems is s.2(2) of the Misuse of Drugs Act 1977, combined with subsequent Governmental Declaration Orders.

In practice, a memorandum is drafted and submitted to the relevant Governmental Departments for comments. Following inclusion of the observations and the issue of a Declaration Order, the Minister for Health and Children will send the draft to the Government Cabinet of Ministers. Once approved, the Declaration Order is signed by the Prime Minister. The Declaration Order, together with any related regulations and exemption orders, are then laid before the Houses of the Oireachtas (Lower And Upper

¹⁴ 2nd chamber of Parliament, representing the Länder (federal States.)

Houses) concurrently within 21 sitting days (the statutory time period in relation to the MDA); afterwards, they will be published in the Irish State Gazette.

The procedure can take approximately 6 weeks however it may take longer if delays occur (in drafting SIs or House not in session etc).

The procedure is the same, regardless of the source of the instructions for placing a new substance under control.

Greece

The control system is that of individual listing by means of a standard procedure, founded upon Art. 1(3) of the Law 3459/2006.

The practice starts when the Greek Focal Point informs the Drugs Committee about the misuse of a new substance. The Drug Committee then delivers an opinion, which is sent to the Ministries of Health and Justice. The resulting common decision, in the form of a Joint Ministerial Order, is published in the Official Gazette.

Since the Drugs Committee convenes once per month, the period between the notification on the part of the Focal Point and the classification by the Committee is of 1-2 months.

Spain

The system in place is that of individual listing, by a standard procedure. This is founded upon Art. 2 of Chapter I of the Law 17/1967 on Narcotic Drugs, and on the Final Stipulations (1) of the Royal Decree 2829/1977 on psychotropic substances, as appropriate.

For both narcotics and psychotropic substances, the Ministry of Health and Consumer Affairs initiates the control procedure by preparing a Ministerial Order. The Order is then published in the Spanish Official Journal and it enters into force on the following day.

The entire procedure requires 5-15 days for an Order to come into force.

France

The legislation in place provides for the individual listing of substances, in accordance with a standard procedure. This system is founded upon the Public Health Code (as amended, lastly by the Decree n. 2007-157, of 05/ 02/ 2007), Art. L5132-7 in conjunction with Art. R5132-74 – for the case of narcotics – and in conjunction with Art. R5132-88 for the case of psychotropic substances.

A new psychoactive substance will be added to the respective controlled list at the initiative of the Director General of the French Agency for the Safety of Health Products, following the proposal of the National Narcotic and Psychotropic Substances Board. From the Director General, the proposed draft is submitted to the Ministry of Health and will be passed as a Ministerial Decree, to enter into force upon publication in the Official Journal.

The duration of the above procedure is of minimum 3 months.

Cyprus

New substances are controlled, according to Art. 3 of the Narcotic Drugs and Psychotropic Substances Law of 1977, by the standard procedure to list their individual chemical definition in the tables appended to this law.

The control procedure is started by the Pharmaceutical Services, which draft the required legal text for including a new substance on the controlled lists. The draft will be sent to the governmental Legal Service and consequently forwarded to the Minister of Health. From the Minister, the draft will be brought before the Council of Ministers and, subject to the Council's approval, the new Order will be published in the Government Gazette, thus entering into force upon publication.

The duration of this procedure is usually of 6-12 months.

Latvia

For purposes of criminal law, the law "On the Procedures for the Coming into Force and Application of the Criminal Law" of 24 October 2002 provides an individual listing of the controlled substances and corresponding limit quantities in the appended tables. The wording of this legal text also states that the specified quantities shall apply to "substance derivatives with a similar pharmacological effect", which suggests a supplementary effects-based analogue system, but this phrase has not yet been interpreted in practice in Latvia.

In accordance with the State Administration Law, ss. 16 and 18, the competence for adding a new substance to the controlled lists rests with the responsible Ministry – the Ministry of Health, the Ministry of Welfare, or the Ministry of the Interior, as appropriate. The Ministry's draft for amendment will be submitted to the State Secretaries' meeting, and during the subsequent two weeks ministries and other institutions (including NGOs) must present their opinions. Once agreed, the draft will be submitted to the Committee of the Cabinet of Ministers, and then to the Cabinet of Ministers for approval. It will then be forwarded to the Saeima (the Parliament), which will pass the draft to a responsible commission. The commission will issue an opinion (statement), summarise the results of the voting by the Saeima and draft the text of the law, which should be signed by the President and published in the official gazette.

The duration of the procedure depends on the duration needed for agreements for the involved ministries.

Lithuania

Lithuania has an individual listing system, using a standard procedure, as provided by Arts. 2(1) and 3 of the Law on Control of Narcotic and Psychotropic Substances (1998). The new substance is added to one of three lists to be amended via ministerial Decrees of the Minister of Health.

A new substance will therefore be controlled by order of the Ministry of Health. The proposal for controlling it will be submitted by either the Drug Control Department or the Police Department. The required evaluation concerning whether to control a substance or not will be carried out by the State Medicines Control Agency. Following a positive result of the evaluation, the Agency will prepare the necessary change for the Ministry of Health's order. The order will then be signed by the Minister and published in the official journal. The order will enter into force after publication, which usually takes 1-7 days.

In practice, the duration of the described procedure takes 1-8 months and the control measures are permanent. Nonetheless, it is common for the control procedure to be shorter, about 1-2 months, in cases where the proposal to control a substance originates from the EU/ UN level.

Luxembourg

Luxembourg has an individual listing system, with a standard procedure and a rapid procedure. The standard procedure is founded upon Art. 7 of the Law of 19 February 1973 on the sale of medicinal substances and the control of drug addiction (the main drug law), whilst the rapid procedure is enounced in the Law 12 July 1996 on the reform of the Council of State. The Law of 19 February 1973 outlines the categories of substances to be defined by means of Grand-Ducal Decrees; at the time of writing, 6 such decrees list the substances that are controlled at the national level¹⁵.

In practice, it is usually the case that the Minister of Health (the Ministry of Justice may also be involved) is informed by his/ her respective competent departments or by the Inter-ministerial Group on Drugs (IGD) of the need to bring about a legal change. Consequently, the legal department of the Ministry will be entrusted with the drafting of a project of law or decree. In this process, the advice of the Medical Advisory Board and, under certain circumstances, the advice of the Chamber of Trade – according to a well established custom rather than a legal obligation – is to be asked, together with that of the IGD in case the IGD hasn't taken the role of initiating the procedure. The project of law or decree will then be put on the agenda of the weekly meetings of the Council of Ministers and discussed with the Council of State for their advice; following adoption, it will be sent to the Parliament for vote.

In cases of urgency, the above procedure may be accelerated by the government's not asking for the Council of State's advice. In such circumstances, projects of law or of Grand-Ducal Decrees may be forwarded directly to the Parliament for vote.

In practice, the standard procedure is not used. The rapid procedure is used for almost all cases independently from the level of risk. This is because once the risk assessment concludes that a substance may be harmful enough to put it under control, it gives sufficient reason to control it as fast as possible. Its duration, starting from the competent Ministry and up to the vote in Parliament, is of 1-2 months.

Hungary

At the time of writing, Hungarian legislation is undergoing changes in the field.

The Netherlands

The Netherlands has an individual listing system, with a standard procedure and an emergency procedure, both established in Art. 3a of the Opium Act.

In case of the standard procedure, new substances may be controlled by an Order in Council, which "shall be adopted not earlier than after the passage of 4 weeks since the draft Order had been presented to both Houses of the States General"¹⁶, subject to the draft Order not having been contested within that period.

The emergency procedure provides for the listing of a new substance by means of Ministerial Regulation. The Minister must ensure that, at the time of adoption of the Regulation, the draft of an Order in Council with the same content shall be presented to the Council of Ministers for evaluation. Unless withdrawn

¹⁵ These are: Toxic substances (one Decree) 04/03/74, Psychotropic substances (two Decrees) 20/04/74 and 06/02/97, Narcotics (one Decree) 26/03/74, Precursors (two Decrees) 08/05/93 and 02/02/95. The annexes of these grand-ducal decrees list the substances or the individual chemical names, as appropriate.

¹⁶ Opium Act, Art. 3a(4).

earlier, the Ministerial Regulation shall be effective until its corresponding Order in Council takes effect, but for a period not longer than 1 year following its entry into force.

Whilst the above emergency procedure allows for new substances to be controlled immediately (within 1 week), its effects will expire within 1 year if not confirmed. The standard procedure takes longer, usually 3-6 months, depending on the duration of the procedure in each of the Houses of the States General.

Austria

The control system used in Austria is individual listing by means of a standard procedure, as outlined in the s.2(3) and s.3(2) of the Narcotic Substances Act (SMG) of 1998. The SMG is supplemented by Regulations which list narcotic and psychotropic substances respectively.

The permanent inclusion of substances and preparations in schedules is made by specific orders, signed into Regulations by the Minister of Health. In principle, this can be completed quite quickly. However, any substance under control must be assigned a defined 'limit quantity', which helps to distinguish between serious and other offences. The 'limit quantities' are determined by scientific evaluations and they are set out in additional Regulations by the Minister of Health in collaboration with the Minister of Justice. Control of the substance and legal definition of the limit quantity are in practice synchronised. With the amendments to the SMG coming into force on 1 January 2008 which have simplified the procedure for the establishment of 'limit quantities', the time estimate for putting a new substance under control is 6 months.

Poland

The system for bringing a new substance under control is that of individual listing, by means of the general legislative procedure required for amending any national laws. In cases of urgency a rapid amending procedure might be used.

The standard procedure for controlling a new substance starts with the preparation of a draft by the Ministry of Health's subordinated body in the field: the National Bureau for Drug Prevention, in accordance with Art. 6(3)(6) of the Act of 29 of July 2005. The next step will be that of public administration consultations, after which the text will be submitted to the Council of Ministers. Following the Council's acceptance, the draft law will then be forwarded to the Parliament for adoption. The first chamber (Sejm) will take a decision after 3 readings and will then transmit the draft law to the second chamber, the Senate. Once the Senate have made a decision, the text will be forwarded to the President for signature. The Act would then be published in the National Journal of Laws and usually come into force within 21 days.

In cases of urgency, the procedure may be launched by the Council of Ministers upon proposal of the Ministry of Health. The urgency of the situation will also imply shorter durations for the decisions of the two Parliamentary chambers, as well as for that of the President.

The length of the standard procedure usually amounts to about 9 months. By contrast, the rapid procedure is expected to be shortened by at least 3 months.

Portugal

Portugal has an individual listing system, with a standard procedure. For purposes of criminal law, the applicable provisions are those of the Decree Law 15/93 of 22 January, with lists of individual substances in the appended tables. The competence for adding new substances rests with the Parliament, in accordance with the specific constitutional provisions (art 161(c)).

The control procedure is usually started by one of two agencies of the Ministry of Health, either the IDT (the Institute against Drugs and Drug Addiction) following an EU-level decision, or by the INFARMED (the National Pharmaceutical and Medicines Institute) following an UN-level decision. An amendment proposal might be sent for an inter-ministerial consultation procedure on the part of the Ministry of Health, yet this is not a compulsory step. The new draft will then be submitted for adoption to the Parliament, by a responsible Ministry, on the part of the Government. Following the Parliament's approval, it will be signed by the President and published in the Official Journal, usually entering into force within one day of publication.

The minimum duration of the procedure referred to above is 1-12 months.

Romania

The control system in place is that of individual listing, via a standard procedure. For purposes of criminal law, this is founded on Art. 1(a) of the Law 143/2000 On Combating Illicit Drugs Trafficking and Consumption.

The initiator of the legal procedure may be either the Ministry of Health, or the Ministry of the Interior. In practice, cases of initiation by the Ministry of the Interior are much more frequent since the actual drafting process tends to take place within its National Anti-Drug Agency. The next step will be that of public consultations involving the Ministry of Health (in case of it not having been the legal initiator), the National Medicines Agency, the Physicians College, and possibly other interested bodies. Following public consultations, other Ministries – e.g. the Ministry of Agriculture – may be consulted, whilst the opinion of the Ministry of Justice will be compulsory. The final draft will then be submitted to the Government, to be adopted via an Emergency Ordinance, which will enter into force upon publication in the Official Journal. The Emergency Ordinance will later on need to be confirmed into a Law, yet this does not affect the actual date of its entry into force, nor does it affect its legal consequences.

The duration of the above procedure is approximately 4 months.

Slovenia

The individual listing is the system to be used for controlling new substances, via a standard procedure. This is founded in the Production Of And Trade In Illicit Drugs Act (1999), s. 1, General Provisions, Art. 2. The listing is made in relation to the Decree on the Classification of Illicit Drugs (2000) (Official Gazette No. 49/2000).

The initiator of the classification procedure is the Minister of Health, who makes the proposal for controlling a new substance to the Government, as an amendment to the abovementioned Decree. The Government will then adopt the amendment and, 8 days after its publishing in the Official Gazette, the amendment will enter into force.

The duration of the above procedure is roughly 2 months.

Slovakia

The control over new substances is established by means of the Act No. 139/1998 Coll. of 2 April (as amended) on Narcotic Drugs and Psychotropic Substances and preparations, which lists the individual substances in the appended schedules. The competence for adding new substances rests with the Parliament, in accordance with the power to amend any parliamentary law.

The standard [*national level*] procedure for listing a new substance is usually started with the submission of the draft proposal to comments within the Ministry of Health for up to 10 days. The amendment proposal is then submitted to an online consultations procedure, during which all ministries and selected public administration bodies may send comments (within 2-3 weeks) that must be dealt with before further proceedings. The new draft will be signed by the Minister of Health and then sent for agreement to the government, following which it will require the Parliament's approval. Finally, the President of the Republic should countersign the new Act. This will be published in the Official Journal, usually entering into force within 15 days from publication. The length of this procedure is usually at least 3 months.

In cases of urgency however, an accelerated legal procedure may be followed, which provides for a shortening of the consultation procedure's duration to 7 days. In such cases, the duration of the overall procedure will be of about one month.

The control procedure is identical whether the instruction for control originates in an UN decision or an EU decision.

Sweden

The individual listing is the system to be used for controlling new substances, by means of either a standard or a rapid procedure. This is done in accordance with one of the two acts in the field: according to the Narcotic Drugs Punishment Act (1968:64), the Government may classify substances via the Ordinance on the Control of Narcotic Drugs (1992:1554); and according to the Act on Prohibition of Certain Goods Dangerous to Health (1999:42), it may do so via the Ordinance on the Prohibition of Certain Goods Dangerous to Health (1999:58). This second Act makes it possible to control a substance at an earlier stage. It applies to goods that, "by reason of their innate characteristics, entail a danger to human life or health, or can be used or assumed to be used for the purpose of intoxication or other influence". Compared to the case of narcotic drugs, substances which are regulated by means of this Act are not illegal to use.

The choice between classifying a substance as a narcotic drug/ psychotropic substance or as a "good dangerous to health" is made on a case by case basis, depending on the available information about the substance, its abuse and its industrial use, as has been determined in the risk assessment phase. If, for example, it is deemed that a substance cannot be classified as a narcotic drug or psychotropic substance yet considered necessary to control, then it may be classified as a substance dangerous to health. The competence for classifying a substance nationally thus rests with the Government, following the recommendation of either the National Institute of Public Health or that of the Medical Products Agency. This is done by amending the relevant ordinance.

The duration required for the Government's decision to control a new substance is the same regardless of which of the two ordinances is amended. The preceding evaluation by the competent authority may however last less in the case of a recommendation for classifying a substance as a "good dangerous to health". In practice, cases of fast classification are not very numerous. Subsequently, application of the standard procedure – whereby both national regulations as well as Article 9 of the Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998¹⁷ are followed – results in a classification usually entering into force within 5-6 months from the recommendation for the control of that substance.

In case of urgency – such as significant risk of death or widespread abuse – it is possible for the Government to make the necessary amendment as well as to have that amendment entering into force from one day to the next.

¹⁷ Laying down a procedure for the provision of information in the field of technical standards and regulations.

In cases where a substance is classified as a narcotic drug/ psychotropic substance by a decision at the UN level, its classification will enter into force in Sweden at the same time when this decision will become binding in the international system¹⁸. This direct classification following an international decision does not apply in the case of decisions made at the EU level.

United Kingdom

The system for controlling new substances is the individual listing by means of a standard procedure, supplemented by a generic system, which has proven easy to administer controls of any perceived use of any particular substance. The legal basis establishing this system is s.2 of the Misuse of Drugs Act, combined with subsequent Regulations.

In practice, it is for the Secretary of State for the Home Department (the Home Secretary) to draft an Order for controlling a new substance, only after consultation with or on the recommendation of the Advisory Council on the Misuse of Drugs. The draft will then be submitted for approval of both Houses of the Parliament.

Following the recommendation/ consultation on the part of the Advisory Council, the above procedure usually takes 2-3 months until the new Order has entered into force.

Croatia

For controlling new substances, Art. 2(15) of the Law on Combating Narcotic Drugs Abuse (OG 107/01) establishes an individual listing system, whilst designating the Minister of Health as the authority who is to 'set out' the list.

In cases where the new substance is observed to have appeared on the Croatian market, the procedure starts with the Forensic Laboratory of the Ministry of the Interior, which will transmit its findings to the Ministry. The latter will then inform the Office for Combating Narcotic Drugs Abuse (OCNDA), which will forward the information to the Ministry of Health and Social Welfare. The Ministry will then assemble the commission in charge of risk assessment; and, if the commission's findings deem it necessary – in practice, this should mean that the substance is deemed to pose a serious threat to public health and to have a limited therapeutic value – the Minister of Health will proceed to amend the List of controlled substances.

The above procedure is considered rather fast, taking about 2 months when put in practice. Its legal effects are permanent, unless otherwise decided by the expert commission in charge of risk assessment.

What has come to be regarded as the most commonly used procedure is that of incorporating UN and, more recently, EU level decisions in the national legislation whenever the need might arise. In these cases, risk assessment will no longer be required, whilst the procedure could be initiated by either the Ministry of Health or the OCNDA. Its duration will normally be 0,5-2 months once the UN/ EU decision has reached the Croatian authorities.

¹⁸ As interpreted from the Narcotics Drugs Punishment Act (1968:64), s. 8, which defines the term narcotic drug as: "any medicinal product or goods injurious to health with strongly addictive properties or euphoric effects or goods which can easily be transformed into goods with such properties and which

- i. *on such grounds are subject to control under an international agreement to which Sweden is a party,*
- ii. *or have been declared by the Government to be considered as a narcotic drug."*

Norway

In the Regulation of 30 June 1978 no. 08 Relating to Narcotics etc, §§ 3.1 and 3.2 empower the Norwegian Medicines Agency (NMA) to add controlled substances to the appended Narcotics List. A supplementary analogue system is created by the extension of scope of this Regulation to “derivatives” by §2.

Following a national indication, both a standard as well as what appears to be a rapid procedure are available to add substances to the list. Based on indications from different sources (e.g. the Police, Customs, media), the NMA will send a consultation letter to the relevant authorities, organisations and scientific bodies, and will subsequently take a decision based upon the definitions in the UN Conventions. The amendment to the list will be published in the “Legal Gazette”. In cases of urgency, this procedure may also be completed in the absence of consultations (or with a shorter time for comments).

In addition to the individual listing system, the analogue system provides for control over substances assessed by the NMA to have a similar chemical structure as well as similar effect/s to the scheduled ones. In practice, following risk assessment, a “substance derivative” may be considered to fall within the scope of the Narcotics List without requiring addition to it. Public consultations are not necessary.

The duration of the standard individual listing procedure is of approximately 3 months, whilst the rapid procedure may lead to the listing of a particular substance with immediate effect.

Listing a substance based on an international decision (UN level) requires shorter or no national consultations, as with the rapid procedure. Based on the documentation presented by UN experts, the listing will be published in the “Legal Gazette” and become effective within the period set by the UN Convention.

UN or EU instructions for the control of a new psychoactive substance

Whilst UN level decisions to bring a new psychoactive substance under control must become effective within 180 days¹⁹ of the communication to the Parties, EU Council Decisions to control substances should give a deadline of no later than one year for their implementation²⁰. This means that the national systems and procedures as described above may have a bearing on a State’s ability to implement a decision within the given deadline.

The estimates of durations are summarised in the following table:

¹⁹ At least for psychotropics; Art. 2(7) of the UN *Convention on Psychotropic Substances*, 1971, at: http://www.unodc.org/pdf/convention_1971_en.pdf

²⁰ Art. 9(1) of the EU *Council Decision 2005/387/JHA*.

Table 1. Summary of estimated durations of legal procedures, and the legal texts produced.

(Source: Legal Correspondents Network)

Country	Duration ²¹ of procedure for bringing new substance under control	Legal text produced
BE	About 1 year (standard procedure)	Royal Decree (for controlling new substances)
CZ	Usually about 1 year	Law of Parliament
DK	2-3 days following recommendation of the National Board of Health	Regulation of the Ministry of Health and Prevention
DE	Standard listing: minimum 2 months (excluding preparations)	Standard procedure: Governmental Regulation
	Emergency listing: 1 week (excluding preparations)	Emergency procedure: Regulation of the Federal Ministry of Health
EE	Roughly 1 month	Regulation of the Minister of Social Affairs
IE	Generic system: immediate / implicit control	Governmental Declaration Order
	Standard individual listing: about 1.5 months	
EL	1-2 months (following notification from the NFP)	Joint Ministerial Order of the Ministries of Health and Justice
ES	About 5-15 days for the Order's coming into force	Order of the Ministry of Health and Consumer Affairs
FR	Minimum 3 months	Decree of the Minister of Health
CY	6-12 months	Order of the Council of Ministers
LV	[Neither the analogue system nor the individual listing system's standard procedure have yet been used in practice]	Law amending the "Procedures for the Coming into force and Application of the Criminal Law" of Oct 2002
LT	National decision: 1-8 months	Decree or Order of the Ministry of Health
	If UN/EU decision: 1-2 months	
LU	Standard procedure: not used in practice	Grand-Ducal Decree
	Rapid procedure: 1-2 months	
NL	Standard procedure: 3-6 months	Standard procedure: Order in Council
	Emergency procedure: 1 week (valid for 1 year)	Emergency procedure: Ministerial Regulation
AT	6 months (due to "limit quantities" requirement)	Regulation of the Minister of Health
PL	Standard procedure: Minimum 9 months	Parliamentary Law (amending the Act of 29.07.2005 on counteracting drug addiction)
	Rapid procedure: about 6 months	

²¹ Note that the durations are not strictly comparable as they may or may not take into account risk assessments, or notice periods for the text's entry into force.

Country	Duration ²¹ of procedure for bringing new substance under control	Legal text produced
PT	Minimum duration of procedure: 1-12 months	Parliamentary Law (amending the Decree-Law 15/93 of 22 Jan.)
RO	Approximately 4 months	Governmental Emergency Ordinance
SK	Standard procedure: At least 3 months	Parliamentary Law
	Rapid procedure: about 1 month	
SI	Approximately 2 months	(Governmental) Decree on completion of the Decree on the Classification of Illicit Drugs
SE	Standard procedure: 5-6 months	Governmental amendment to the Ordinance on the Control of Narcotic Drugs; or
	Rapid procedure or international decision: immediate application	Governmental amendment to the Ordinance on the Prohibition of Certain Goods Dangerous to Health
UK	Generic system: immediate/ implicit control	Order in Council made by Her Majesty
	Standard individual listing: 2-3 months after opinion from the Advisory Council on the Misuse of Drugs	
HR	0.5 – 2 months	Ministry of Health's amendment to the List of controlled substances
NO	Analogue system: immediate/ implicit control	Standard procedure: (amending) Regulation of the Norwegian Medicines Agency
	Standard procedure: 3 months	
	Rapid procedure (emergency cases & international decision): immediate effect	

Formatted Table

4. The Risk Assessment procedure

During collection of the information regarding the legal procedures for bringing new substances under national control, one multifarious aspect appeared to be that of the risk assessment procedure(s) as defined earlier. In particular, three aspects of the risk assessment procedure have been considered, where possible:

1. Whether the risk assessment procedure is or is not part of the legal procedure for bringing new substances under control; and if so, whether its basis may be found in a country's main drug law, in some general administrative procedure, or whether it does not have a legal basis;
2. Whether the harm levels detected by the risk assessment will or will not affect the speed of the legal procedure; and
3. Whether the risk assessment is to be performed by experts within the public administration or by independent scientific experts.

National risk assessment procedures: the practice

Belgium: Whilst risk assessment per se is not performed at the national level, various sources (seizures, national EWS and pharmaceutical inspections) contribute to the collection of information to be used during the risk assessment at the European level.

The Czech Republic: Risk assessment is ad-hoc (not legally-based), and non-formalised, which means that there is no link between the results of the risk assessment procedure and the legal procedure for controlling a new substance. Consultations might therefore take place as necessary between public administration experts on the part of the Ministry of Health as well as possible independent scientists from research bodies in the Czech Republic.

Denmark: The risk assessment procedure has its legal basis in the Consolidated Act no. 748 of 1 July 2008 on Euphoriant Substances (para. 1, 2) and it is performed by the National Board of Health assisted by other authorities and scientific experts. In accordance with this legal basis, risk assessment will only be undertaken in cases where a decision to put a certain substance under control has not already been made by the CND or the European Council.

Given the rapidity of the standard listing procedure, the risk assessment's results will not impact the subsequent duration of the legal procedure.

Germany: As part of the standard procedure, an expert commission is consulted, in accordance with the Narcotics Act s.1 para.2. The expert commission examines whether a substance should be put under control and which of the three lists of the Narcotics Act would be appropriate. The meetings of the expert commission take place 2-3 times a year. The experts might need one to several rounds of discussion in order to assess the risks of a particular substance. In urgent cases a decision can be taken by written procedure. Depending on the level of risk and urgency the type of procedure will be chosen: standard or emergency. It is thus possible that the results of an assessment by the expert commission lead to emergency action. Nonetheless, the emergency procedure might also be provoked by information from other sources (in particular the Federal Office of Criminal Investigation – Bundeskriminalamt, BKA). In this

case, the expert commission might not be consulted, as consultation is not obligatory under the emergency procedure.

Estonia: The risk assessment procedure has its legal basis in §3¹(1) of the Act on Narcotic Drugs and Psychotropic Substances and Precursors thereof. It is performed by experts within the public administration – the State Agency of Medicines. In exceptional cases, SAM might ask for the advice of experts from independent scientific bodies.

Ireland: There is no legally-based requirement for risk assessment and consequently no formalised procedure. Nevertheless, the Early Warning and Emerging Trends sub-committee within the National Advisory Committee on Drugs was established to carry out risk assessments, as well as contributing to the collection of information to be used during the risk assessment at the European level. However, to date no instances of risk assessment outside UN/EU-proposed substances were reported. The EWET sub-committee comprises experts within the public administration and independent scientists.

Greece: No risk assessment procedure was reported from Greece.

Spain: There is no legally-based requirement for risk assessment and consequently no formalised procedure; nonetheless, experts within public administration (the National Focal Point) contribute to the collection of information to be used during the risk assessment at the European level.

France: Risk assessment precedes the legal procedure, whilst its legal basis is founded upon Arts. R5132-97 to R5132-116 of the Code of Public Health. These provisions empower the network of Centres on Evaluation and Information on Drug Dependence to collect data and perform harm evaluation, and a technical committee to handle the evaluation of information from the network. All these activities fall under the competence of the National Narcotic and Psychotropic Substances Board, which is subordinated to the French Agency for the Safety of Health Products. However, a possibility of consulting external experts (potentially from independent scientific bodies) is also envisaged. Usually, risk assessment takes an average of 9 months, yet the procedure might be speeded up in cases of urgency, to durations of 3-4 months.

Cyprus: Risk assessment precedes the legal procedure for bringing a new substance under national control rather than being part of it. It is ad-hoc (not legally-based), meaning that there is no formalised link between the results of the risk assessment procedure and the legal procedure for controlling a new substance. The procedure as such is performed by public administration experts within the Pharmaceutical Services and State General Laboratory, to which the National Focal Point adds its input. All these bodies are under the authority of the Ministry of Health.

Latvia: Risk assessment is not a legally-based procedure, whilst it might occur on an ad-hoc basis. During the drafting of the amendment, the minister(s) might ask for an opinion from appropriate public administration experts, as part of the legislative procedure for modifying any legal text.

Lithuania: Risk assessment is part of the legal procedure for bringing new substances under national control, as it is required by the general procedure needed for making any legal changes. It is undertaken by the State Medicines Control Agency, which is an administrative body under the authority of the Ministry of Health. Its results will not affect the duration of the rest of the legal procedure.

Luxembourg: Risk assessment is ad-hoc (not legally-based) and non-formalised, in the sense that it does not involve a standardised procedure. When undertaken, it will be the task of the Inter-ministerial Group on Drugs (IGD) to collect and assess specific information from the several specialised Departments under the coordination of the Ministry of Health. In case there is a risk of great harm, a rapid procedure may be applied.

Hungary: Currently, Hungarian legislation does not provide for a national risk assessment procedure. At the time of writing however, Hungarian legislation is undergoing changes in the field.

The Netherlands: In the case of new substances, 3 procedures of risk assessment are available. These are: fast assessment (should be completed within 24 hours) in cases where a substance presents an acute risk for public health; moderate assessment (should be completed within 10 days) in cases where the risk for public health is not acute, but there will be a risk in the short term; and preventive assessment, a procedure which lasts for several months.

The results of the risk assessment procedure can (and usually do) affect the speed/ urgency of the legislative procedure; scientific proof that a substance is dangerous to the health of the population makes it easier to convince both Houses of the States General of the urgency of the matter.

The actual risk assessment is performed by the Committee for the Risk Assessment of New Drugs, comprising experts from independent scientific bodies and representatives from governmental bodies. The latter are not in fact participating in the actual risk assessment but are involved in the subsequent policy-making.

Austria: As part of the legal procedure for bringing new substances under control, there is no defined procedure for risk assessment that covers all aspects listed in the working definition in this paper. However, there is a simplified form of risk assessment to define the "limit quantities" that are required for distinguishing between serious and other offences, which is performed by an independent scientist. Consulted experts are generally given a time limit of up to 3 months which can be shortened in case of need.

Poland: Risk assessment is not a legally-based procedure, whilst it might occur on an ad-hoc basis. Ministers might ask for a scientific opinion on the part of independent experts or a research institution; this would occur either during the drafting phase or during the inter-ministerial consultations which are part of the legislative procedure. This is not, however, compulsory.

Portugal: Risk assessment is not a legally-based procedure, though it might occur on an ad-hoc basis, should the need arise.

Romania: Risk assessment is part of the general procedure needed for bringing about legal changes, since it falls within the public consultations involving the National Medicines Agency. Consequently, it will be performed by experts within public administration. It has, however, no bearing on the speed of the ensuing legal procedure.

Slovenia: Risk assessment is not part of the legal procedure for bringing new substances under control, yet it might be made available in case of perceived necessity. Consultations would take place on an ad-hoc basis amongst public administration experts within the Ministry of Health.

Slovakia: Risk assessment is part of the general administrative procedure required for adding a new substance to the controlled list. This is a simplified form of risk assessment to evaluate the health risks of the new substance and to determine the relevant schedule for its classification, in the form of an expert opinion. This is performed by the main expert in the field of drug and drug addiction, within the Ministry of Health. Its results will impact upon the subsequent duration of the legal procedure.

Finland: Finnish legislation does not provide for a national risk assessment procedure, since new psychoactive substances are only brought under control following an UN/EU-level decision.

Sweden: In the case of classifying new substances by a national decision, risk assessment might be carried out by either the National Institute of Public Health or, for substances with medical use, by the Medical Products Agency. This is part of the usual procedure needed for bringing about national legal changes, since it falls within the general competences of the agencies. Experts within the public administration will thus evaluate the substance, its use and the dangers associated with it. Following this procedure, the Government Offices (the Ministry of Health and Social Affairs) will estimate the degree of urgency in controlling the new substance, thus choosing between the standard or the rapid listing.

United Kingdom: When adding a new substance as a controlled drug by Order in Council, it is a statutory requirement that the Advisory Council on the Misuse of Drugs (ACMD) be consulted for an assessment of harm, according to s.2 of the Misuse of Drugs Act 1971. The ACMD is a scientific body, established under s.1 of the Misuse of Drugs Act 1971 and charged, amongst others, with "considering any substance which is being or appears to be misused and of which is having or appears to be capable of having harmful effects sufficient to cause a social problem."²² One of its reports can take 6-7 months. The results of the Council's findings are unlikely to affect the speed of the legislative procedure.

Croatia: In cases where substances are not controlled internationally while they are thought to pose a risk to the Croatian society, a multidisciplinary expert group is set up within the Ministry of Health and Social Welfare with the task of completing risk assessment, so the risk assessment procedure is ad-hoc (not legally-based). Its results will not affect the subsequent duration of the legal procedure.

Norway: No matter which of the three control procedures is being considered, risk assessment by experts within the Norwegian Medicines Agency is part of the legislative practice; in fact, for both the rapid listing and the analogue interpretation, risk assessment will represent part of the legislative procedure.

The legal basis is interpreted as stemming from the general powers awarded to the Agency on the basis of the Regulation of 30/06/1978 no. 08 Relating to Narcotics etc – rather than from a formal legal basis. Consequently, the procedure may be considered to be semi-formalised, given its roots in the administrative practice.

²² <http://drugs.homeoffice.gov.uk/drugs-laws/acmd/>

5. Findings

This study illustrates the multitude of systems, procedures and risk assessments that EU Member States, Norway and Croatia have at their disposal for providing legal responses to newly found psychoactive substances. This variety may be considered from different perspectives, as follows.

All the countries presented in the study have the individual listing system in place, whilst two (Ireland and the UK) use the generic system and two (Latvia and Norway) have the analogue system. The analogue system in Norway is interpreted by risk assessment by the National Medicines Agency, the same body responsible for listing new substances individually; this is substantially different from the application of an analogue system such as in the USA (a common law jurisdiction), where the law appears to rely more on the Court to determine “whether a particular chemical is ‘substantially similar’ to another chemical to give content to its standard”²³. The Latvian definition of “substance derivatives with a similar pharmacological effect” has not yet been interpreted in practice.

Regarding the application of the individual listing system, it might be assumed that both the legal basis for the procedure of classification, as well as the nature of the legal text where the new substance will be added for control, would affect the speed of the legal change in each country; a dedicated procedure and changing a list in a decree might imply a faster change than a universal national legislative procedure and a change in the main drug law itself. Concerning the legal basis, in 19 countries²⁴ the classification procedure is explicitly referred to in the main drug control law or its equivalent (in France; the Public Health Code; in Luxembourg; the Law on the reform of the Council of State, which provides for the rapid procedure), whilst in five²⁵ there is a need to use the standard national procedure for amending any primary legislation. However, the proportions are somewhat different when considering the nature of the applicable legal texts: in 14 countries²⁶ newly controlled substances are added to a list annexed to the main drug control law (or, in the case of Spain, one of the two main drug control laws), whilst in 11²⁷ (including the control over narcotics in Spain) they are added to lists established in separate Decrees or Orders.

A further comparison looks not at the formal aspects but at the procedures required for modifications. This is premised on the fact that lists which might be changed simply by the signature of a minister could be altered quicker than lists where either the nature of the text (*e.g.* parliamentary law) or the procedure that it entails requires more steps. As a result, the formal layout of the applicable legal texts appear to only marginally influence the length and intricacy of the legal change, since in order to enter into force:

²³ *Kau supra*, p. 1112.

²⁴ Belgium, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Cyprus, Lithuania, Luxembourg, the Netherlands, Austria, Romania, Slovenia, Sweden, the United Kingdom, Croatia, Norway.

²⁵ The Czech Republic, Latvia, Poland, Portugal, Slovakia.

²⁶ The Czech Republic, Germany, Greece, Spain (for psychotropic substances), Cyprus, Latvia, the Netherlands, Poland, Portugal, Romania, Slovakia, the United Kingdom, Croatia, Norway.

²⁷ Belgium, Denmark, Estonia, Ireland, Spain (for narcotic substances), France, Lithuania, Luxembourg, Austria, Slovenia, Sweden.

- 11 procedures²⁸ require the approval of one Minister or governmental Agency;
- 2 procedures²⁹ require the approval of two Ministers;
- 6 procedures³⁰ require the approval of the government (which may include signature by the Head of State); and
- 13 procedures³¹ require the approval of the parliament (which may include signature by the Head of State).

Following the working definitions of the procedures at the start of this paper, it is interesting to note that of the faster procedures, the two (temporary) emergency procedures (Germany and the Netherlands) lower the level of final approval of the legal text, from Government to one Minister, whilst the (permanent) rapid procedures (Luxembourg, Poland, Slovakia, Sweden, Norway) do not lower the level of approval but shorten the duration of the consultations or omit certain steps. The two emergency procedures remain distinct in that in the Netherlands the standard procedure must be initiated concomitantly with the adoption of the emergency Regulation, which is not so for Germany.

Substances identified by different bodies usually follow identical procedures. In 21 countries³² the source (national, EU, UN) of the instruction to bring a new psychoactive substance under control will be irrelevant to the ensuing legal procedure. However, in three countries, instructions originating from the UN are fast-tracked:

- In Germany, the national legal procedure for controlling substances following UN level decisions will no longer require neither consent of the Bundesrat nor the hearing of experts by the Minister of Health, in order to list the substance (according to section 1(4) BtMG). This is similar to the emergency procedure, only in these cases the listing will be permanent;
- In Norway, listing a substance based on an international decision will require shorter or no national consultations, as with the rapid procedure;
- In Sweden, the classification of a substance as a narcotic or psychotropic by an UN level decision will enter into force nationally at the same time when it will become binding in the international system.

²⁸ Denmark, Germany (emergency procedure), Estonia, Spain, France, Lithuania, the Netherlands (emergency listing), Austria (excluding definition of quantity), Croatia, Norway (standard and rapid listing).

²⁹ Greece, Austria (including definition of quantity).

³⁰ Belgium, Cyprus, Romania, Slovenia, Sweden (both standard and rapid listing).

³¹ The Czech Republic, Germany (standard procedure), Ireland, Latvia, Luxembourg (both standard and rapid procedures), the Netherlands (standard procedure), Poland (both standard and rapid procedures), Portugal, Slovakia (both standard and rapid procedures), the United Kingdom.

³² Belgium, the Czech Republic, Denmark, Estonia, Ireland, Greece, Spain, France, Cyprus, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, the United Kingdom and Croatia.

Durations of the procedures may create problems for the country to implement international decisions by the deadlines normally given. However, often, the country's representatives involved in approving or negotiating that decision at international level can advise to start the process of control at national level even before the international decision is finally taken (and its deadline initiated). In this way, the country is still likely to meet the deadline for international control.

Across the countries studied, there is an even spread of relative importance given to a national risk assessment procedure: six countries³³ do not employ it at the national level – generally due to the reliance on the international or European-level risk assessment – whilst seven countries³⁴ might or could provide for it nationally on an ad-hoc basis, should the case deem it necessary. In seven countries³⁵ risk assessment is part of the general administrative practice to be conducted in accordance with rules of varying degrees of formalism, and in six countries³⁶ it is directly referred to in the main Drug Law or its equivalent.

Of the 20 countries which may or do undertake risk assessment at the national level, its results (the levels of harm that have been detected) will not affect the speed of the legislative procedure in 12 countries³⁷. In four countries (Germany, Luxembourg, Slovakia, Sweden) the levels of risk established by the assessment will determine whether the standard or the emergency/rapid procedure is more appropriate. Another option may be that risk assessment itself will be speedier; in France, Austria and Norway, cases of urgency will lead to a shortened duration for the risk assessment procedure. In the Netherlands, both possibilities are available; not only do the results of the risk assessment affect the speed of the legislative procedure, but also the speed of the risk assessment itself will depend on the perceived level of harm.

When considering the entity in charge of carrying out risk assessment, for 16 countries³⁸ this will be a group of experts within the public administration, either part of a competent ministry (*e.g.* the Ministry of Health), or part of a State or Governmental Agency (*e.g.* State Agency of Medicines, National Board of Health, etc.); six countries³⁹ do or might provide for the possibility of consultations with independent scientists, in case of a perceived need; and in three, the Netherlands, Austria, and the United Kingdom, risk assessment will be performed by scientifically-independent bodies: respectively the Committee for the Risk Assessment of New Drugs, an independent scientist, and the Advisory Council on the Misuse of Drugs.

³³ Belgium, Greece, Spain, Hungary, Portugal, Finland.

³⁴ The Czech Republic, Ireland, Cyprus, Luxembourg, Poland, Slovenia, Croatia.

³⁵ Latvia, Lithuania, Austria, Romania, Slovakia, Sweden, Norway.

³⁶ Denmark, Germany, Estonia, France, the Netherlands, the United Kingdom.

³⁷ The Czech Republic, Denmark, Estonia, Ireland, Cyprus, Latvia, Lithuania, Poland, Romania, Slovenia, the United Kingdom, Croatia.

³⁸ The Czech Republic, Denmark, Germany, Estonia, Ireland, France, Cyprus, Latvia, Lithuania, Luxembourg, Romania, Slovenia, Slovakia, Sweden, Croatia, Norway.

³⁹ The Czech Republic, Denmark, Estonia, Ireland, France, Poland.