COUNCIL OF THE EUROPEAN UNION

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CORDROGUE 30

NOTE

by :	Presidency
to :	Horizontal Working Party on Drugs
No. prev. doc. :	13821/03 CORDROGUE 90
Subject :	Text for a Council decision on information exchange, risk assessment and control of new psychoactive substances

Please find in the annex the text for a Council decision on information exchange, risk assessment and control of new psycoactive substances resulting from the work of the Horizontal Working Party on Drugs on the proposal of the Commission that is in doc. 13821/03 CORDROGUE 90.

	Proposed text as 13821/03 **Proposal for a Council Decision on information exchange, risk assessment and control of new narcotic drugs and new synthetic drugs**	**Proposed revised text or comment** **Proposal for a** Council Decision on information exchange, risk assessment and control **of new psychoactive substances**	
Article 1	This Decision establishes a mechanism for a rapid exchange of information on new narcotic drugs and new synthetic drugs that are being used illicitly or misused. It does not cover information on suspected adverse reactions to be reported under the pharmacovigilance system as established by Title IX of Directive 2001/83/EC of the European Parliament and of the Council. This Decision also provides for an assessment of the risks associated with these new narcotic drugs and new synthetic drugs in order to permit the application of the measures of control on narcotic and psychotropic substances, applicable in the Member States equally to new narcotic drugs or to new synthetic drugs.	This Decision establishes a mechanism for a rapid exchange of information on new psychoactive substances ~~that are being used illicitly or misused~~. It **takes note of** ~~does not cover~~ information on suspected adverse reactions to be reported under the pharmacovigilance system as established by Title IX of Directive 2001/83/EC of the European Parliament and of the Council. This Decision also provides for an assessment of the risks associated with these new psychoactive substances in order to permit the application of the measures of control on narcotic and psychotropic substances, applicable in the Member States equally to new psychoactive substances. *Discussion on this Article parked until May HDG.*	Article 1
Article 2	This decision applies to substances not currently listed in any of the schedules to: a) the 1961 United Nations Single Convention on Narcotic Drugs, that pose a comparable threat to public health as the substances listed in Schedule I or II or IV; and b) the 1971 United Nations Convention on Psychotropic Substances, that pose a comparable threat to public health as the substances listed in Schedule I or II or III or IV; This Decision relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/9010, and Council Directive 92/109/EEC11 provide for a Community regime.	This decision applies to substances not currently listed in any of the schedules to: a) the 1961 United Nations Single Convention on Narcotic Drugs, that may pose a comparable threat to public health as the substances listed in Schedule I or II or IV thereof, and b) the 1971 United Nations Convention on Psychotropic Substances, that may pose a comparable threat to public health as the substances listed in Schedule I or II or III or IV thereof; This Decision relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No. 3677/9010, and **Council Regulation 273/2004** provide for a Community regime.	Article 2
Article 3	For the purpose of this decision the following definitions shall apply: (a)'new narcotic drug': a substance, that has not been scheduled	For the purpose of this decision the following definitions shall apply: a) 'new psychoactive substance': means a new narcotic drug or a new psychotropic drug	Article 3

	under the 1961 United Nations Single Convention on Narcotic Drugs, and that poses a threat to public health comparable to the substances listed in Schedule I, II or IV. b) 'new synthetic drug': a substance that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that poses a threat to public health comparable to the substances listed in Schedule I, II, III or IV; c) 'marketing authorisation': the permission to place on the market of a Member State either a medicinal product for human use as indicated in Title III of Directive 2001/83/EC of the European Parliament and of the Council, or a veterinary medicinal product as indicated in Title III of Directive 2001/82/EC of the European Parliament and of the Council. d) 'United Nations-system': the World Health Organisation (WHO), the Commission on Narcotic Drugs (CND) and/or the Economic and Social Committee (Ecosoc) acting in accordance within their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances. e) 'preparation': a mixture containing either a new narcotic drug or a new synthetic drug.	b)'new narcotic drug': a substance, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs, and that may pose a threat to public health comparable to the substances listed in Schedule I, II or IV. c) 'new psychotropic drug': a substance that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that may pose a threat to public health comparable to the substances listed in Schedule I, II, III or IV; d) 'marketing authorisation': a permission to place a medicinal product on the market, granted by the competent authority of a Member State, as required by Title III of Directive 2001/83/EC (in the case of medicinal products for human use) or Title III of Directive 2001/82/EC (in the case of veterinary medicinal products) or a marketing authorization granted by the European Commission under Article 3 of Council Regulation (EEC) No. 2309\93 (OJ No. L.214, 24.8.93, p1), e) 'United Nations system': the World Health Organisation (WHO), the Commission on Narcotic Drugs (CND) and/or the Economic and Social Committee (Ecosoc) acting in accordance within their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances. f) 'preparation': a mixture containing 'a new psychoactive substance'. **g) 'Reporting Form': *EMCDDA providing text.***	
Article 4.1.	Each Member State shall ensure that its Europol National Unit of the European Police Office ("Europol") and its representative in the Reitox network provide information on the production, traffic and use, including medical use, of new narcotic drugs and of new synthetic drugs and of preparations containing new narcotic drugs or new synthetic drugs, to Europol and the European Monitoring Centre on Drugs and Drug Addiction ("EMCDDA"), taking into account the respective mandates of these two bodies. Europol and the EMCDDA shall collect the information received and communicate this information immediately to each other and to the Europol National Units and the representatives of the Reitox-network of the Member States, the Commission, and to the European Agency for the Evaluation of Medicinal Products ("EMEA").	Each Member State shall ensure that its Europol National Unit of the European Police Office ("Europol") and its representative in the Reitox network provide information on the production, traffic and use, including medical use, of new psychoactive substances and of preparations containing new psychoactive substances, to Europol and the European Monitoring Centre on Drugs and Drug Addiction ("EMCDDA"), taking into account the respective mandates of these two bodies. Europol and the EMCDDA shall collect the information received and communicate this information immediately to each other and to the Europol National Units and the representatives of the Reitox-network of the Member States, the Commission, and to the European Agency for the Evaluation of Medicinal Products ("EMEA").	Article 4.1

Article 4.2.	Europol and the EMCDDA shall supplement the information on a new narcotic drug or a new synthetic drug or on a preparation containing a new narcotic drug or a new synthetic drug obtained from a Member State to the extend that the information available shall entail: (a) a chemical and physical description, including the name under which the new narcotic drug or the new synthetic drug is known, (b) information on the frequency, circumstances and/or quantities in which a new narcotic drug or new synthetic drug is encountered, and information on the means and methods of production of the new narcotic drug or the new synthetic drug, (c) information on the involvement of organised crime in the production or trafficking of the new narcotic drug or the new synthetic drug, (d) a first indication of the risks associated with the new narcotic drug or new synthetic drug, including health and the social risks, (e) information on whether or not the new narcotic drug or the new synthetic drug is currently under assessment, or has been under assessment by the UN-system, (f) the moment of notification of the new narcotic drug or the new synthetic drug to the EMCDDA or to Europol, (g) information on whether or not the new narcotic drug or the new synthetic drug is already subject to control measures at national level in a Member State. (h) As far as possible, information will be made available on: (i) the chemical precursors, (ii) the mode and scope of the established or expected use of the new synthetic drug or the new narcotic drug,	Should Europol and the EMCDDA consider that the information provided by a Member State on a new psychoactive substance does not merit the ~~further collection~~ **communication** of information as described in paragraph (1), they will inform the notifying Member State immediately thereof. Europol and the EMCDDA will justify their decision to the Council within six weeks. However, the Council shall, at the **written** request of at least ~~five~~ **a quarter of the** Member States*, ask Europol and the EMCDDA to produce a Joint Report as defined in Articles 5.1 and 5.2. The Member States shall inform the Council of their desire for a Joint Report as soon as possible, but in any case within six weeks after the receipt of the justification from Europol and the EMCDDA. *** Commission, Europol and EMCDDA entered reservations on this Article.**	Article 4.2

	(iii) other use of the new narcotic drug or new synthetic drug and the extent of such use, the risks associated with this use of the new narcotic drug or new synthetic drug, including the health and the social risks;		
Article 4.3.	The EMEA shall submit to Europol and the EMCDDA supplementary information on whether in the European Union or in any Member State: (a) the new narcotic drug or new synthetic drug has obtained a marketing authorisation; (b) the new narcotic drug or new synthetic drug is in the process of obtaining a marketing authorisation; (c) a provided marketing authorisation has been suspended. Where this supplementary information relates to marketing authorisations granted by Member States, these Member States shall provide this information to the EMEA on request from the EMEA.		
Article 4.4.	Member States are requested to deliver the information referred to under paragraphs (2) and (3) without unnecessary delay.		
Article 4.5.	In case Europol and the EMCDDA consider that the information provided by a Member State on a new narcotic drug or a new synthetic drug would not merit the further collection of information as described in paragraph (1), they will inform the notifying Member State instantly hereof, and the risk assessment procedure referred to in Article 6 will not apply. Europol and the EMCDDA will explain the decision taken in the annual report as referred to in Article 10.		
Article 5	The information collected shall be collated and presented by Europol and the EMCDDA in the form of a Joint Report (hereinafter the "Joint Report"), which shall be submitted directly to the Member States, the EMEA and the Commission 2. The Joint Report shall be submitted no more than thirty working days after the date of reception of information from Member States by Europol or the EMCDDA in accordance with paragraph (1) of Article 4.	Where Europol and the EMCDDA, or the Council, in the circumstances provided for in Article 4.2, consider that the information provided by the Member State on a new psychoactive substance merits the further collection of information, this information shall be collated and presented by Europol and the EMCDDA in the form of a Joint Report (hereinafter the “Joint Report”). This Joint Report shall be submitted to the Council, the EMEA and the Commission.	Article 5.1

		The Joint Report shall entail: (a) a chemical and physical description, including the name under which the new psychoactive substance is known, (b) information on the frequency, circumstances and/or quantities in which a new psychoactive substance is encountered, and information on the means and methods of production of the new psychoactive substance, (c) information on the involvement of organised crime in the production or trafficking of the new psychoactive substance, (d) a first indication of the risks associated with the new psychoactive substance, including the health and social risks, **and on the characteristics of users,** (e) information on whether or not the new substance is currently under assessment, or has been under assessment by the UN-system, (f) the date of notification on the Report**ing** Form of the new psychoactive substance to the EMCDDA or to Europol, (g) information on whether or not the new psychoactive substance is already subject to control measures at national level in a Member State. (h) As far as possible, information will be made available on: (i) the chemical precursors, that are known to have been used for the production of the substance, (ii) the mode and scope of the established or expected use of the new substance, (iii) other use of the new psychoactive substance and the extent of such use, the risks associated with this use of the new psychoactive substance, including the health and social risks.	Article 5.2
		The EMEA shall submit to Europol and the EMCDDA, supplementary information on whether in the European Union or in any Member State: (a) the new psychoactive substance has obtained a marketing authorisation;	Article 5.3

		(b) the new psychoactive substance is the subject of an application for a marketing authorisation; (c) a marketing authorisation that had been granted in respect of the new psychoactive substance has been suspended. Where this supplementary information relates to marketing authorisations granted by Member States, these Member States shall provide this information to the EMEA on request from the EMEA.	
		Member States are requested to provide the information referred to under paragraphs 1and 2 within six weeks from the date of notification on the Report**ing** Form as set out in Article 5.2 (f).	Article 5.4
		The Joint Report shall be submitted no more than four weeks after the date of receipt of the information from Member States by Europol or the EMCDDA in accordance with paragraphs 1 and 2 of Article 5.	Article 5.5
Article 6.1.	The risks, including the health and social risks, caused by the use of, the production of, and traffic in, a new narcotic drug or a new synthetic drug, the involvement of organised crime and possible consequences of prohibition shall be assessed in accordance with the procedure set out in paragraphs 2 to 5, provided that more than half of the Member States have informed the Council in writing to be in favour of such an assessment. The Member States shall inform the Council as soon as possible, but in any case within thirty working days after the date of reception of the Joint Report.	**The Council, taking into account the advice of Europol and the EMCDDA, shall request that t**he risks, including the health and social risks, caused by the use of, the production of, and traffic in, a new psychoactive substance, the involvement of organised crime and possible consequences of control measures shall be assessed in accordance with the procedure set out in paragraphs 2 to 5, provided that at least ~~**five**~~ **a quarter of the** Member States* have informed the Council in writing that they are in favour of such an assessment. The Member States shall inform the Council as soon as possible, but in any case within four weeks after the receipt of the Joint Report. *Commission reservation entered.	Article 6.1
Article 6 2.	As soon as more than half of the Member States have informed the Council in writing to be in favour of a risk-assessment on a new narcotic drug or a new synthetic drug as indicated in paragraph (1), the Council shall alert the EMCDDA and Europol.	As soon as at least ~~**five**~~ **a quarter** of the Member States* have informed the Council in writing that they are in favour of a risk-assessment on a new psychoactive substance as outlined in paragraph (1), the Council shall notify the EMCDDA to this effect. *Commission reservation entered.	Article 6.2
Article 6 3.	In order to carry out the assessment, the EMCDDA shall convene a special meeting under the auspices of its Scientific Committee. In addition, for the purpose of this meeting the Scientific Committee shall be extended with at most five experts, who are specialists in scientific fields not represented, or not sufficiently	In order to carry out the assessment, the EMCDDA shall convene a special meeting under the auspices of its Scientific Committee. In addition, for the purpose of this meeting the Scientific Committee may be extended with at most five experts, to be designated by the Director of the EMCDDA, acting on the advice of the Chairperson of the Scientific Committee, from a panel of experts proposed by Member States and	Article 6.3

	represented, in the Scientific Committee, but whose contribution is necessary for the balanced and adequate assessment of the possible risks, including health and social risks. Furthermore, the Commission, Europol and the EMEA shall be invited to send a maximum of two experts each to this meeting.	approved on a triennial basis by the Management Board of the EMCDDA. Such experts will be in scientific fields not represented, or not sufficiently represented, in the Scientific Committee, but whose contribution is necessary for the balanced and adequate assessment of the possible risks, including health and social risks. Furthermore, the Commission, Europol and the EMEA shall be invited to send a maximum of two experts each to this meeting.	
Article 6 4.	The risk-assessment shall be carried out on the basis of information to be provided to the Committee as described in paragraph 3 (hereinafter "the Committee") by the Member States, the EMCDDA, Europol, the EMEA, taking into account all factors which, according to the 1961 United Nations Single Convention on Narcotic Drugs or the 1971 United Nations Convention on Psychotropic Substances, would warrant the placing of a substance under international control.	The risk-assessment shall be carried out on the basis of information to be provided to the Committee as described in paragraph 3 (hereinafter "the Committee") by the Member States, the EMCDDA, Europol, the EMEA, taking into account all factors which, according to the 1961 United Nations Single Convention on Narcotic Drugs or the 1971 United Nations Convention on Psychotropic Substances, would warrant the placing of a substance under international control.	Article 6.4
Article 6 5.	On completion of the risk-assessment, a report (hereinafter the "Risk-Assessment Report") will be drawn up. The risk-assessment shall consist of an analysis of the scientific information available, and will include possible dissenting scientific opinions held by the members of the Committee. The Risk-Assessment Report shall be submitted to the Commission by the chairman of the Committee within a period of ninety working days, as from the date of the information from the Council to the EMCDDA and Europol referred to in paragraph (2). The Risk-Assessment report shall include: (a) the physical and chemical description of the new narcotic drug or the new synthetic drug and its working, including its medical value, (b) the health risk associated with the new narcotic drug or the new synthetic drug, (c) the social risks associated with the new narcotic drug or the new synthetic drug, (d) information on the level of involvement of organised crime and information on seizures, and production of the new narcotic drug or the new synthetic drug, (e) information on the assessment of the new narcotic drug or the	On completion of the risk-assessment, a report (hereinafter the "Risk-Assessment Report") will be drawn up by the Scientific Committee. The risk assessment shall consist of an analysis of the scientific and law enforcement information available, and will reflect all ~~scientific~~ opinions held by the members of the Committee. The Risk-Assessment Report shall be submitted to the Commission and Council by the chairperson of the Committee, on its behalf, within a period of twelve weeks, from the date of the notification by the Council to the EMCDDA ~~and Europol~~ referred to in paragraph (2). The Risk-Assessment Report shall include: (a) the physical and chemical description of the new psychoactive substance and its mechanisms of action, including its medical value, (b) the health risks associated with the new psychoactive substance, (c) the social risks associated with the new psychoactive substance, (d) information on the level of involvement of organised crime and information on seizures and/or detections by the authorities, and production of the new psychoactive substance, (e) information on any assessment of the new psychoactive substance in the United Nations system,	Article 6.5

	new synthetic drug in the United Nations-system, (f) a description of the control-measures to which the new narcotic drug or the new synthetic drug is submitted in the Member States, when applicable, (g) options for control and the possible consequences of prohibition.	(f) a description of the control-measures that are applicable to the new psychoactive substance in the Member States, when appropriate, (g) options for control and the possible consequences of the control measures, **and** **(h) the chemical precursors that are used for the production of the substance.**	
Article 7 1.	No risk-assessment shall be carried out in case the new narcotic drug or the new synthetic drug concerned is currently under assessment within the United Nations system.	No risk assessment will be carried out in instances where Europol and the EMCDDA have not drawn up a Joint Report. Nor shall a risk assessment be carried out where the new psychoactive substance concerned is at an advanced stage of assessment within the United Nations system, **i.e. once the World Health Organisation expert committee on drug dependence has published its critical review together with a written recommendation, except when there is significant new information relevant in the framework of this Decision.**	Article 7.1
Article 7 2.	In case the new narcotic drug or the new synthetic drug has been under assessment within the United Nations system without the decision having been taken to schedule the new narcotic drug or the new synthetic drug under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances a risk assessment shall only be carried out when there is significant new information relevant in the framework of this Decision.	Where the new psychoactive substance has been under assessment within the United Nations system, without the decision having been taken to schedule the new psychoactive substance under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, a risk assessment shall only be carried out when there is significant new information relevant in the framework of this Decision.	Article 7.2
Article 7 3.	No risk-assessment shall be carried out on a new narcotic drug or a new synthetic drug in case it falls within one of the following categories: (a) The new narcotic drug or the new synthetic drug is an 'authorised medicinal product' which is either a medicinal product intended for human use, that has been granted a marketing authorisation in one or more Member States or in the European Union in accordance with the provisions of Title III of Directive 2001/83/EC12, or a veterinary medicinal product that has been granted a marketing authorisation in one or more Member States or in the European Union in accordance with the provisions of Title III of Directive 2001/82/EC13; or,	No risk-assessment shall be carried out on a new psychoactive substance where it falls within one of the following categories: (a) The new psychoactive substance is a medicinal product which is the subject of a marketing authorisation; or, (b) The new psychoactive substance is a medicinal product which is the subject of an application for a marketing authorisation or, (c) The new psychoactive substance is a medicinal product which is the subject of a marketing authorisation that has been suspended by a competent authority or,	Article 7.3

	(b) The new narcotic drug or the new synthetic drug is a 'medicinal product under review', which is either a medicinal product intended for human use that is under examination in order to be granted a marketing authorisation in one or more Member States or in the European Union in accordance with the provisions of Title III of Directive 2001/83/EC, or a veterinary medicinal product that is under examination in order to be granted a marketing authorisation in one or more Member States or in the European Union in accordance with the provisions of Title III of Directive 2001/82/EC; or, (c) The new narcotic drug or the new synthetic drug is a 'suspended medicinal product', which is either a medicinal product intended for human use for which the marketing authorisation is suspended in one or more Member States or in the European Union, or a veterinary medicinal product for which the marketing authorisation is suspended in one or more Member States or in the European Union; or, (d) The new narcotic drug or the new synthetic drug is an 'exempted medicinal product', which is either a medicinal product for human use, which is exempted from having a marketing authorisation as specified under Article 7 of Directive 2001/83/EC, or a veterinary medicinal product; which is exempted from having a marketing authorisation as specified in Article 8 of Directive 2001/82/EC. In the case the new narcotic drug or the new synthetic drug falls into one of the categories listed under this paragraph, it will be referred to the EMEA for a scientific evaluation of the risks associated with the new narcotic drug or the new synthetic drug and to the Council in order to discuss public health related measures.	Where the new psychoactive substance falls into one of the categories listed under this paragraph, it will be referred to the **Commission who will approach the** EMEA **to take appropriate action.** ~~**.** for a scientific evaluation of the risks associated with the new psychoactive substance with a view to the preparation of a report for the Council in order that it may consider public health related measures.~~ ***Cion to come back re EMEA***.	
Article 8	1. Within thirty working days from the date on which the Risk-Assessment Report has been received, the Commission shall present to the Council an initiative to have the new narcotic drug or new synthetic drug subjected to control measures. If the Commission deems it not necessary to present an initiative to have the new narcotic drug or the new synthetic drug	1. Within six weeks from the date on which the Risk-Assessment Report has been received, the Commission or at least ~~**five**~~ **a quarter of the** Member States shall present to the Council an initiative to have the new psychoactive substance subjected to control measures. If the Commission deems it not necessary to present an initiative to have the new psychoactive substance submitted to control measures, it shall within six weeks from the date on which the Risk-Assessment Report has been	Article 8

	submitted to control measures, it shall within thirty working days from the date on which the Risk-Assessment Report has been received present a report to the Council explaining its views. 2. When the Commission presents the Council with an initiative, the Council shall decide by qualified majority, on the basis of the said initiative and acting in accordance with Article 34 (2) (c) of the Treaty, whether to submit the new narcotic drug or the new synthetic drug to measures of control. 3. The procedure provided for by this Article shall take no longer than ninety working days from the date of reception by the Council of the initiative by the Commission to the date of adoption by the Council of the initiative by the Commission as referred to in paragraph (2).	received, present a report to the Council explaining its views. 2. When the Commission or at least **~~five~~ a quarter of the** Member States present the Council with an initiative, the Council shall decide by qualified majority, on the basis of the said initiative and acting in accordance with Article 34 (2) (c) of the Treaty, whether to submit the new psychoactive substance to control measures. 3. The procedure provided for by this Article shall take, in principle, no longer than 16 weeks from the date of reception by the Council of the initiative by the Commission or at least **~~five~~ a quarter of the** Member States to the date of adoption by the Council of the initiative by the Commission or at least **~~five~~ a quarter of the** Member States as referred to in paragraph (2). ***Commission has entered reservation on this Article.***	
Article 9	1. If the Council decides to submit a new narcotic drug or a new synthetic drug to measures of control, Member States shall take within one year the necessary measures in accordance with their national law to submit: (a) the new synthetic drug to control measures and criminal penalties as provided under their legislation complying with their obligations under the 1971 United Nations Convention on Psychotropic Substances. (b) the new narcotic drug to control measures and criminal penalties as provided under their legislation complying with their obligations under the 1961 United Nations Single Convention on Narcotic Drugs. 2. Member States shall report the measures taken to both the Council and the Commission. 3. Nothing in this Decision shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate once this Member State has identified a new narcotic drug or a new synthetic drug.	1. If the Council decides to submit a new psychoactive substance to measures of control, Member States shall endeavour to take, **as soon as possible but no later than one year** ~~within one year~~**,** the necessary measures in accordance with their national law to submit: (a) the new psychotropic drug to control measures and criminal penalties as provided under their legislation complying with their obligations under the 1971 United Nations Convention on Psychotropic Substances. (b) the new narcotic drug to control measures and criminal penalties as provided under their legislation complying with their obligations under the 1961 United Nations Single Convention on Narcotic Drugs. 2. Member States shall report on the measures taken to both, the Council, and the Commission, as soon as possible after the relevant decision has been taken, **for onward transmission to** the EMCDDA, Europol, the EMEA, and the European Parliament. 3. Nothing in this Decision shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate once a new psychoactive substance has been identified by a Member State. *Need to specify here which schedule regime a substance should be associated with?*	Article 9

Article 10	The EMCDDA and Europol shall report annually to the Council on the operation of this Decision. The report will take into account all aspects relevant to judge the efficacy and achievements of the system created by this Decision.	The EMCDDA and Europol shall report annually to the Council and the European Parliament on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. **~~They~~ The Report** shall, in particular, **~~report on their~~ include** experiences relating to coordination between the system set out in this Decision and the pharmacovigilance system.	Article 10
Article 11	Member States and the EMEA shall secure an appropriate exchange of information between the mechanism set up by means of this Decision and the pharmacovigilance-systems as defined and established under Title VII of Directive 2001/82/EC14 and Title IX of Directive 2001/83/EC15.	Member States and the EMEA shall secure an appropriate exchange of information between the mechanism set up by means of this Decision and the pharmacovigilance-systems as defined and established under Title VII of Directive 2001/82/EC14 and Title IX of Directive 2001/83/EC15. *Bracketed until discussion takes place with EMEA.*	Article 11
Article 12	The Joint Action on New Synthetic Drugs of June 16th 1997 is hereby repealed.	The Joint Action on New Synthetic Drugs of June 16th 1997 is hereby repealed.	Article 12
Article 13	This Decision shall be published in the Official Journal of the European Union. It shall take effect the day following that of its publication. This Decision is addressed to the Member States. Done at Brussels, […]	This Decision shall be published in the Official Journal of the European Union. It shall take effect the day following that of its publication. This Decision is addressed to the Member States. Done at Brussels, […]	Article 13