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REPORT

on the Commission proposal for a Council decision on the information exchange, risk-assessment and the control on new narcotic drugs and new synthetic drugs (COM(2003) 560 – C5-0516/2003 – 2003/0215(CNS))

Committee on Citizens' Freedoms and Rights, Justice and Home Affairs

Rapporteur: Hubert Pirker

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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PROCEDURAL PAGE

By letter of 31 October 2003 the Council consulted Parliament, pursuant to Article 39(1) of the EU Treaty, on the Commission proposal for a Council decision on the information exchange, risk-assessment and the control on new narcotic drugs and new synthetic drugs (COM(2003) 560 – 2003/0215(CNS)).

At the sitting of 5 November 2003 the President of Parliament announced that he had referred the proposal to the Committee on Citizens' Freedoms and Rights, Justice and Home Affairs as the committee responsible and the Committee on the Environment, Public Health and Consumer Policy for its opinion (C5-0516/2003).

The Committee on Citizens' Freedoms and Rights, Justice and Home Affairs appointed Hubert Pirker rapporteur at its meeting of 17 November 2003.

The committee considered the Commission proposal and draft report at its meetings of 17 November 2003, 2 December 2003 and 16 December 2003.

At the last meeting it adopted the draft legislative resolution by 18 votes to 4, with 1 abstention.

The following were present for the vote: Jorge Salvador Hernández Mollar, chairman; Johanna L.A. Boogerd-Quaak, vice-chairwoman; Hubert Pirker, rapporteur; Kathalijne Maria Buitenweg (for Pierre Jonckheer), Felipe Camisón Asensio (for Bernd Posselt pursuant to Rule 153(2)), Marco Cappato (for Maurizio Turco), Charlotte Cederschiöld, Carmen Cerdeira Morterero, Giuseppe Di Lello Finuoli, Jacqueline Foster (for Giuseppe Brienza pursuant to Rule 153(2)), Marie-Thérèse Hermange (for Carlos Coelho), Georg Jarzembowski (for Gérard M.J. Deprez pursuant to Rule 153(2)), Eva Klamt, Alain Krivine (for Ole Krarup), Marjo Matikainen-Kallström (for Timothy Kirkhope), Marcelino Oreja Arburúa, Heide Rühle, Olle Schmidt (for Baroness Ludford), Ole Sørensen (for Bill Newton Dunn), Ulrich Stockmann (for Margot Keßler pursuant to Rule 153(2)), Joke Swiebel, Christian Ulrik von Boetticher and Diana Wallis (for Francesco Rutelli pursuant to Rule 153(2)).

The Committee on the Environment, Public Health and Consumer Policy decided on 27 November 2003 not to deliver an opinion.

The report was tabled on 18 December 2003.

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Commission proposal for a Council decision on the information exchange, risk-assessment and the control on new narcotic drugs and new synthetic drugs (COM(2003) 560 – C5-0516/2003 – 2003/0215(CNS))

(Consultation procedure)

The European Parliament,

– having regard to the Commission proposal to the Council (COM(2003) 560)[1],

– having regard to Articles 29 and 34(2)(c) of the EU Treaty,

– having regard to Article 39(1) of the EU Treaty, pursuant to which the Council consulted Parliament (C5-0516/2003),

– having regard to Rules 106 and 67 of its Rules of Procedure,

– having regard to the report of the Committee on Citizens' Freedoms and Rights, Justice and Home Affairs (A5-0483/2003),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 250(2) of the EC Treaty;

3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;

4. Asks the Council to consult Parliament again if it intends to amend the Commission proposal substantially;

5. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission	Amendments by Parliament
Amendment 1 Article 3(c)	
(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	***Deleted***

[1] Not yet published in OJ.

veterinary medicinal product as indicated in Title III of Directive 2001/82/EC of the European Parliament and of the Council.

Justification

The definition of 'placing on the market' has already been laid down in Article 1 of Council Directive 92/109/EEC of 14 December 1992 on the manufacture and placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

Amendment 2
Article 3(e)

(e) 'preparation': a mixture containing either a new narcotic drug or a new synthetic drug.	***Deleted***

Justification

There is no obvious need for this definition.

Amendment 3
Article 4(2)

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:	***Deleted***
(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,

(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;

Justification

Unnecessary procedural complications should be avoided.

Amendment 4
Article 4(3)

3***. The*** EMEA shall submit to Europol and the EMCDDA supplementary information on whether in the European Union or in any Member State***:***	3. ***Should Europol or the EMCDDA deem it necessary, the*** EMEA shall submit to Europol and the EMCDDA supplementary

	information on whether in the European Union or in any Member State:

Justification

The European Medicines Evaluation Agency should not be compelled to forward information.

Amendment 5
Article 4(4)

4. Member States are requested to deliver the information referred to under paragraphs (2) and (3) without unnecessary delay.	***Deleted***

Justification

The obligation on Member States to cooperate with each other is self-evident.

Amendment 6
Article 4(5)

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.	5. *Should* Europol and the EMCDDA consider that the information provided by a Member State on a new narcotic drug or a new synthetic drug *does* not merit the further collection of information as described in paragraph 1, they *shall immediately* inform the notifying Member State *(deletion) thereof*, and ***the Joint Report*** referred to in Article ***5*** *shall* ***not be drawn up.*** Europol and the EMCDDA *shall justify* the decision taken in the annual report *(deletion)* referred to in Article 10.

Justification

A Joint Report should be a precondition for the carrying-out of a risk-assessment. Accordingly, this should be laid down as the next step in the procedure.

Amendment 7

Article 6(1)

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.	1. ***On the basis of the Joint Report, the Member States shall decide as quickly as possible whether they support a risk-assessment.*** The Member States shall inform the Council as soon as possible, but in any case within thirty working days after the date of *receipt* of the Joint Report.

Justification

Simplification of the procedure.

Amendment 8
Article 6(2)

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.	2. As soon as ***at least one third*** of the Member States have informed the Council in writing *that they are* 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.

Justification

The requirement of a written request from more than half of the Member States constitutes an unjustifiably high hurdle.

Amendment 9
Article 6(5), second subparagraph

The Risk-Assessment report shall include:	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,	(a) the physical and chemical description of the new narcotic drug or the new synthetic drug and its *action*, including its

including its medical value,	medical value,
(b) ***the health risk associated with the new narcotic drug or the new synthetic drug,***	***(b) a description of the control measures to which the new narcotic drug or the new synthetic drug is submitted in the Member States, where applicable,***
(c) ***the social risks associated with the new narcotic drug or the new synthetic drug,***	***(c) information on the assessment of the new narcotic drug or the new synthetic drug in the United Nations system,***
(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,	(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 new synthetic drug in the United Nations-system,	***(e) the health and social risks associated with the new narcotic drug or the new synthetic drug,***
(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,	***(f) options for control and the possible consequences of prohibition.***
(g) options for control and the possible consequences of prohibition.	

Justification

The information to be forwarded should be set out in logical order.

Amendment 10
Article 7(1)

	1. ***No risk-assessment shall be carried out in instances where Europol and the EMCDDA have not drawn up a Joint Report.***
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.	***Nor shall a*** risk-assessment ***(deletion)*** be carried out in ***instances where*** the new narcotic drug or the new synthetic drug concerned is currently under assessment within the United Nations system.

Justification

Simplification of procedure. A Joint Report should be a precondition for the carrying-out of a risk-assessment.

Amendment 11
Article 7(3)

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:	***Deleted***
(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/EC , 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/EC ; or,	
(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.	

Justification

In the instances referred to here, no Joint Report should have been drawn up pursuant to Article 5. Accordingly, there is no need to list the instances (see Amendment 10 which seeks the insertion of a corresponding new sentence in this Article).

Amendment 12
Article 8(1), second paragraph

If the Commission deems it not necessary to present an initiative to have the new narcotic drug or the new synthetic drug 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.	***Deleted***

Justification

Risk-assessment is carried out by the Scientific Committee which consists of experts from Europol, the EMCDDA, the European Medicines Evaluation Agency, the Commission and other experts. Accordingly, it is inappropriate for the Commission to be given any further leeway with

regard to the need for further control measures.

Amendment 13
Article 8(3)

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).	3. The procedure provided for by this Article shall take no longer than ninety working days from the date of *receipt* ***of the Risk-Assessment Report*** by the Commission to the date of adoption by the Council of the initiative by the Commission *(deletion)* referred to in paragraph 2.

Amendment 14
Article 9(1)

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:	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 ***ten months*** the necessary measures in accordance with their national law to submit:

Justification

A period of ten months within which national measures are to be taken is perfectly realistic and feasible.

Amendment 15
Article 9(2)

2. Member States shall report the measures taken to ***both*** the Council and the Commission.	2. Member States shall report the measures taken to ***the European Parliament,*** the Council and the Commission ***immediately after the relevant decision has been taken***.

Amendment 16
Article 10

The EMCDDA and Europol shall report	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.	annually to ***the European Parliament and*** the Council on the operation of this Decision. The report *shall* take into account all aspects *required for an assessment of* the efficacy and achievements of the system created by this Decision.

Amendment 17
Article 10(1a) (new)

	They shall, in particular, report on their experiences relating to coordination between the early-warning system and the pharmacovigilance system.

Justification

There must be a guarantee that information which is essential for the pharmacovigilance system, but which has been erroneously forwarded to the early-warning system, is conveyed to the former without delay.

EXPLANATORY STATEMENT

I. Commission proposal

This Commission proposal seeks to update, strengthen and extend the Joint Action of 16 June 1977 concerning the information exchange, risk-assessment and the control of new synthetic drugs. An external evaluation of the Joint Action has shown that it has proved itself to be an efficient instrument for the rapid exchange of information about synthetic drugs. Accordingly, the Commission is proposing the retention of the basic structure, which consists of three elements:

- an early-warning system for the rapid exchange of all information available on substances notified to Europol and the EMCDDA,

- a risk-assessment by a scientific committee in order to assess the social, health and other risks associated with a notified substance,

- an EU-level procedure whereby notified substances would be subject to control in the Member States.

The changes now proposed involve a reorientation and extension of the scope of the Joint Action. The most significant innovation means that, in future, all new synthetic drugs and narcotic drugs, including those which may be defined as medicinal products, will fall within the scope of the Council Decision.

However, risk-assessment and control remain restricted to a small number of substances in respect of which the Council has taken a decision. Above all, medicinal products and substances already subject to assessment by the United Nations are excluded from those phases.

The reorientation entails the Joint Action operating in the future not only as a rapid-response mechanism but also serving the long-term monitoring of a synthetic substance by means of a continuous exchange of information between the Member States and Europol and the EMCDDA.

II. Your rapporteur's opinion

Your rapporteur basically endorses the reshaping of the Joint Action with a view to combating new synthetic drugs in a more resolute and more efficient manner. In particular, he welcomes the extension of the scope of the Decision to cover new narcotic drugs and the introduction of deadlines for each phase of the procedure.

However, your rapporteur takes the view that the reorientation should concentrate on a ***simplification of the structures involved***. Above all, the proposed exchange of information about the manufacture and consumption of new synthetic drugs should be restricted to the essential steps. Accordingly, your rapporteur has tabled a series of amendments which seek to shorten the exchange of information and the risk-assessment procedures and make them more effective.

Once Europol and the EMCDDA have received relevant information from Europol's national units and the REITOX Network, and after internal coordination, they should take a decision, without any additional intermediate stages, on whether the information received justifies the drawing up of a Joint Report.

The text of the Council Decision should spell out clearly that no Joint Report will be drawn up unless that condition is met. Furthermore, the European Medicines Evaluation Agency should be required to supply information only as and when necessary.

Your rapporteur would like to see the procedure designed in such a way that a Joint Report constitutes the precondition for a risk-assessment. Such risk-assessments are carried out by the Scientific Committee which consists of experts from Europol, the EMCDDA, the European Medicines Evaluation Agency, the Commission and other experts. Given the expertise of the Scientific Committee, your rapporteur deems it inappropriate for the Commission to be given any leeway with regard to the need for control measures.

At the same time, your rapporteur takes the view that a written request from one third of the Member States should be sufficient to have a risk-assessment carried out.

Other amendments seek to guarantee that Parliament is notified about the measures taken by the Member States and about the impact of this Decision. In addition, only those definitions which are really useful should appear in the Decision.

18 December 2003

MINORITY OPINION

pursuant to Rule 161(3) of the Rules of Procedure
Marco Cappato and Maurizio Turco

Instead of governing the phenomena of drugs through appropriate policies and appropriate political decisions, the EU and its Member States prefer to adopt bureaucratic measures such as the one examined in the present report that only contribute to the strengthening of the prohibitionist regime whose results have clearly demonstrated to be a failure. We agree that there should be a mechanism to evaluate the risks associated with new synthetic drugs appearing on the market, but we underline that it is prohibitionism on drugs that pushes for the development of new drugs, since criminal profits are immense and as soon as a certain drug is prohibited, a new one is invented to escape criminal repression. New drugs are consequently put in the market and tested by consumers, that are not informed about the possible damages to their health and interactions with their personal health situation. The mechanism established by the Commission proposal does not break the circle of prohibitionism and, by imposing further criminal measures on acts linked to drugs, it will only give incentives to further production, trafficking and consumption of new and uncontrolled synthetic drugs.