AMENDMENTS 001-021
by the Committee on Civil Liberties, Justice and Home Affairs

Report
Anna Hedh **A7-0153/2013**
Monitoring intra-EU trade in drug precursors

Proposal for a regulation (COM(2012)0548 – C7-0319/2012 – 2012/0261(COD))

Amendment 1

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) A European database on drug precursors should be created to simplify the reporting by Member States with regard to seizures and stopped shipments, to create a European register of operators and users holding a license or a registration which will facilitate verification of the legitimacy of commercial transactions involving scheduled substances, and to enable operators to provide the competent authorities with information about their legal transactions involving scheduled substances.	(10) A European database on drug precursors should be created to simplify the reporting by Member States with regard to seizures and stopped shipments, ***where possible in an aggregated and anonymised manner and in the least intrusive way as regards the processing of personal data, taking into account the principle of data limitation and state of the art of privacy-enhancing technologies,*** to create a European register of operators and users holding a license or a registration which will facilitate verification of the legitimacy of commercial transactions involving scheduled substances, and to enable operators to provide the competent authorities with information about their legal transactions involving scheduled substances.

Justification

To ensure adequate data protection, data on seizures and stopped shipments should, where possible, be reported to the Commission and to the UN should in aggregated and anonymised manner.

Amendment 2

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) Regulation (EC) No 273/2004 envisages the processing of ***data***. ***Such processing*** of data ***may also cover*** personal data which should ***be*** carried out in ***accordance with*** Union ***Law***.	(11) Regulation (EC) No 273/2004 envisages the processing of ***information, including the processing of personal data, for the purposes of enabling the competent authorities to monitor the placing on the market of drug precursors and to prevent the diversion of scheduled substances***. ***The processing of personal data should be carried out in accordance with Union law on data protection and, in particular, with requirements relating to data quality, proportionality, purpose limitation, and rights to information, access, rectification*** of data***, erasure and blocking, organisational and technical measures and international transfers of*** personal data***. Data should be adequate, accurate, relevant and not excessive in relation to the purpose for*** which ***it is collected. It*** should ***not be processed for longer than necessary in relation to the purpose for which it is collected and its accuracy should be regularly reviewed. Processing of data should be carried out under the supervision of the Member States' competent authorities, in particular the public independent authorities designated by the Member States, as regards processing of personal data*** carried out in ***the Member States. It should also be carried out under the supervision of the European Data Protection Supervisor, as regards the processing of personal data carried out by the Commission within the framework of Regulation (EC) No 273/2004. In order to***

enable law enforcement authorities to detect, prevent, investigate or prosecute drug trafficking criminal offences, Member States should be allowed to adopt legislative measures to grant their competent authorities access to personal data processed pursuant to Regulation (EC) No 273/2004 for those purposes and in so far as is necessary, proportionate and subject to adequate safeguards. Since such processing constitutes a restriction of the fundamental right to the protection of personal data, it should be interpreted restrictively and in accordance with the Charter of Fundamental Rights of the European Union ***and the European Convention for the Protection of Human Rights and Fundamental Freedoms. Such processing should only take place on a case-by-case basis and provided that the competent law enforcement authorities have reasonable grounds for believing that it will substantially assist them in preventing, detecting, or investigating drug trafficking criminal offences***.

Justification

This amendment is linked to the change proposed in Art 13b. It is important to specify more in detail the essential elements of the data processing operations that are included in this Regulation. While most data processing will apply to companies or legal persons, in many cases natural persons will be also identifiable. This amendment takes into account recommendations made by the EDPS.

Amendment 3

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) In order to achieve the objectives of Regulation (EC) No 273/2004, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to specify the requirements and conditions for the granting of the licence and registration, for obtaining and	(15) In order to achieve the objectives of Regulation (EC) No 273/2004, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to specify the requirements and conditions for the granting of the licence and registration, for obtaining and

using customer declarations, for the documentation and labelling of mixtures, for provision of information by the operators on transactions involving scheduled substances, for listing operators and users having obtained a licence or registration in the European register and in order to amend the Annexes. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.	using customer declarations, for the documentation and labelling of mixtures, for provision of information by the operators on transactions involving scheduled substances, for listing operators and users having obtained a licence or registration in the European register and in order to amend the Annexes. ***Such delegated acts should also determine categories of personal data which can be processed by Member States and operators pursuant to Regulation (EC) No 273/2004, categories of personal data which can be stored in the European database, the procedures by which data subjects can exercise their rights to information, access, rectification, erasure or blocking of personal data processed in the European database, and the categories of personal data which are to be processed by operators for reporting unusual or suspected transactions***. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, ***and that it seek the opinion of the European Data Protection Supervisor when preparing delegated acts relating to the processing of personal data pursuant to Regulation (EC) No 273/2004.***

Justification

It is important to specify more in detail the essential elements of the data processing operations that are included in this Regulation. While most data processing will apply to companies or legal persons, in many cases natural persons will be also identifiable. This amendment takes into account recommendations made by the EDPS.

Amendment 4

Proposal for a regulation
Article 1 – point 1 – point b
Regulation (EC) No 273/2004
Article 2 – point h

Text proposed by the Commission	*Amendment*
(h) 'user' means any natural or legal person who possesses a scheduled substance and	(h) 'user' means any natural or legal person who ***is not an operator and who*** possesses

is engaged in the processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances.	a scheduled substance and is engaged in the processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances.

Justification

From the opinion of the European Economic and Social Committee.

Amendment 5

Proposal for a regulation
Article 1 – point 2 – point a
Regulation (EC) No 273/2004
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Operators and users shall be required to obtain a licence from the competent authorities before they may possess or place on the market scheduled substances of category 1 of Annex I. Special licences may be granted by the competent authorities to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or armed forces. Such special licences shall only be valid for the use of scheduled substances of category 1 of Annex I within the scope of the official duties of the operators concerned.	2. Operators and users shall be required to obtain a licence from the competent authorities ***of the Member State in which they are domiciled or established*** before they may possess or place on the market scheduled substances of category 1 of Annex I. Special licences may be granted by the competent authorities to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or armed forces. Such special licences shall only be valid for the use of scheduled substances of category 1 of Annex I within the scope of the official duties of the operators concerned.

Justification

Operators should be discouraged from "shopping around" in the EU for the competent authorities with the lightest licensing/registration regime.

Amendment 6

Proposal for a regulation
Article 1 – point 2 – point c
Regulation (EC) No 273/2004
Article 3 – paragraph 6

Text proposed by the Commission	*Amendment*
6. From *[18 months after the date of publication]* operators shall be required to obtain a registration from the competent authorities before placing on the market scheduled substances of category 2 of Annex I. Furthermore, users shall be required to obtain a registration from the competent authorities before possessing scheduled substances of subcategory 2A of Annex I. Special registrations may be granted by competent authorities to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces. Such registrations shall be considered valid only for the use of scheduled substances of category 2 of Annex I within the scope of the official duties of the operators or users concerned.	6. From ...* operators shall be required to obtain a registration from the competent authorities ***of the Member State in which they are domiciled or established*** before placing on the market scheduled substances of category 2 of Annex I. Furthermore, users shall be required to obtain a registration from the competent authorities before possessing scheduled substances of subcategory 2A of Annex I. Special registrations may be granted by competent authorities to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces. Such registrations shall be considered valid only for the use of scheduled substances of category 2 of Annex I within the scope of the official duties of the operators or users concerned.
	_____
	** OJ please insert date: 18 months after the date of entry into force of this Regulation.*

Justification

Operators should be discouraged from "shopping around" in the EU for the competent authorities with the lightest licensing/registration regime.

Amendment 7

Proposal for a regulation
Article 1 – point 2 – point f
Regulation (EC) No 273/2004
Article 3 – paragraph 9

Text proposed by the Commission	*Amendment*
9. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning:	9. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning:
(a) the requirements and conditions for the granting of the licence referred to in paragraph 2;	(a) the requirements and conditions for the granting of the licence referred to in paragraph 2***, and the categories of data,***

	including of personal data, to be provided;
(b) the requirements and conditions for the granting of the registration referred to in paragraph 6**.**	(b) the requirements and conditions for the granting of the registration referred to in paragraph 6 ***and the categories of data, including of personal data, to be provided; and***
(c) the requirements and conditions for listing operators and users having obtained a licence or registration in a European Database on drug precursors referred to in paragraph 8.	(c) the requirements and conditions for listing operators and users having obtained a licence or registration in a European Database on drug precursors referred to in paragraph 8.
	Before developing delegated acts under this paragraph, the Commission shall consult the European Data Protection Supervisor.
	The categories of personal data referred to in points (a) and (b) of the first subparagraph shall not include sensitive data within the meaning of Article 8(1) of Directive 95/46/EC.

Amendment 8

Proposal for a regulation
Article 1 – point 6
Regulation (EC) No 273/2004
Article 8 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for operators to provide information as referred to in paragraph 2.	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for operators to provide information as referred to in paragraph 2***, the categories of personal data to be processed for that purpose, and the safeguards for the processing of that personal data***.
	Before developing delegated acts under this paragraph, the Commission shall consult the European Data Protection Supervisor.

Justification

The categories of personal data which will be processed for this purpose must be specified. Since the proposal does not specify those categories, this should be done by means of delegated acts. This amendment takes account of recommendations of the EDPS.

Amendment 9

Proposal for a regulation
Article 1 – point 6
Regulation (EC) No 273/2004
Article 8 – paragraph 3a (new)

Text proposed by the Commission	*Amendment*
	3a. Operators shall not disclose personal data processed pursuant to this Regulation other than to the competent authorities.

Amendment 10

Proposal for a regulation
Article 1 – point 9
Regulation (EC) No 273/2004
Article 13a – introductory part

Text proposed by the Commission	*Amendment*
The Commission shall ***develop*** a European Database on drug precursors with the following functions:	***Following the adoption of the delegated acts referred to in Article 3(9),*** the Commission shall ***establish*** a European Database on drug precursors with the following functions:

Justification

It is very important first to establish the rules concerning requirements and conditions, including requirements on data protection, before establishing the Database.

Amendment 11

Proposal for a regulation
Article 1 – point 9
Regulation (EC) No 273/2004
Article 13a – point a

Text proposed by the Commission	*Amendment*
(a) facilitating the communication of information pursuant to Article 13(1), its synthesis and analysis on the level of the Union, and the reporting to the International Narcotics Control Board pursuant to Article 13(2);	(a) facilitating the communication of information***, where possible in an aggregated and anonymised manner,*** pursuant to Article 13(1), its synthesis and analysis on the level of the Union, and the reporting to the International Narcotics Control Board pursuant to Article 13(2);

Justification

To ensure adequate data protection, data on seizures and stopped shipments should, where possible, be reported to the Commission and to the UN should in aggregated and anonymised manner.

Amendment 12

Proposal for a regulation
Article 1 – point 9
Regulation (EC) No 273/2004
Article 13a – paragraphs 1a, 1b, 1c and 1d (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission and the competent authorities shall take all necessary measures to ensure the security, confidentiality and accuracy of the information contained in the European Database.
	1b. Information obtained pursuant to this Regulation, including personal data, shall be used in accordance with the applicable law on personal data protection and shall not be retained for longer than necessary for the purposes of this Regulation. Processing of special categories of data referred to in Article 8(1) of Directive 95/46/EC and in Article 10(1) of Regulation (EC) No 45/2001 shall be prohibited.
	1c. A data subject shall be provided with information concerning the purposes of the processing and retention of data, the categories of data processed and retained, the identity of the controller of the data,

	the identity of the recipients of the data, information regarding the right of access, rectification or erasure of the data subject's personal data, the administrative and judicial remedies available and the contact details of the supervisory authority referred to in Article 13b(1). Some or all of that specific information may be withheld only in so far as it would compromise administrative or judicial investigations or procedures, hamper the prevention, investigation, detection or prosecution of criminal offences or jeopardise public or national security.
	1d. The Commission shall make publicly available a comprehensive privacy notice concerning the European Database in accordance with Articles 10 and 11 of Regulation (EC) No 45/2201, in a clear and understandable manner.

Amendment 13

Proposal for a regulation
Article 1 – point 10
Regulation (EC) No 273/2004
Article 13b – paragraph 1

Text proposed by the Commission	*Amendment*
1. The processing of personal data by the competent authorities *in the Member States* shall be carried out in accordance with Directive 95/46/EC and under the supervision of the *public independent* authority of the Member State referred to in Article 28 of *this* Directive.	1. The processing of personal data by the competent authorities shall be carried out in accordance with Directive 95/46/EC and under the supervision of the *supervisory* authority of the Member State *as* referred to in Article 28 of *that* Directive. ***That supervisory authority shall ensure that the rights of data subjects are protected in accordance with Directive 95/46/EC***.

Justification

This amendment clarifies that the data protection authorities shall ensure that the rights of data subjects are protected. The amendment takes into account recommendations made by the EDPS. The wording is similar to existing Community legislation (e.g. provisions in IMI Regulation (EC) No 1024/2012).

Amendment 14

Proposal for a regulation
Article 1 – point 10
Regulation (EC) No 273/2004
Article 13b – paragraph 1a (new)

Text proposed by the Commission	*Amendment*
	1a. Without prejudice to Article 13 of Directive 95/46/EC, personal data obtained or processed pursuant to this Regulation shall solely be used for the purpose of preventing the diversion of scheduled substances.

Justification

In order to ensure adequate data protection it is important to establish the purpose for which personal data under this Regulation will be processed (purpose limitation). At the same time, the possibility currently available under the Data Protection Directive for national competent authorities to use - in duly justified and under national data protection rules - the data provided for the prevention, investigation or prosecution of criminal offences (to discover and dismantle drug trafficking networks) should be preserved.

Amendment 15

Proposal for a regulation
Article 1 – point 10
Regulation (EC) No 273/2004
Article 13b – paragraph 2

Text proposed by the Commission	*Amendment*
2. The processing of personal data by the Commission, including for the purpose of the European Database provided for in Article 13a, shall be carried out in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council and under the supervision of the European Data Protection Supervisor.	2. The processing of personal data by the Commission, including for the purpose of the European Database provided for in Article 13a, shall be carried out in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council and under the supervision of the European Data Protection Supervisor. ***The European Data Protection Supervisor shall ensure that the rights of data subjects relating to the processing in the European Database are protected in accordance with Regulation (EC) No 45/2001***.

Justification

This amendment clarifies that the data protection authorities shall ensure that the rights of data subjects are protected. The amendment takes into account recommendations made by the EDPS. The wording is similar to existing Community legislation (e.g. provisions in IMI Regulation (EC) No 1024/2012).

Amendment 16

Proposal for a regulation
Article 1 – point 10
Regulation (EC) No 273/2004
Article 13b – paragraph 2a (new)

Text proposed by the Commission	*Amendment*
	2a. The public independent authorities of the Member States referred to in paragraph 1 and the European Data Protection Supervisor, each acting within the scope of their competences, shall cooperate actively and shall ensure coordinated supervision of the processing of personal data, including for the purpose of the European Database provided for in Article 13a.

Justification

This amendment aims at ensuring cooperation between the national data protection authorities and the EDPS for the proper monitoring of the processing activities carried out in the framework of the EU Database. The system of coordinated supervision has already been established in several EU legal instruments, namely IMI Regulation, Eurodac, VIS or SIS II.

Amendment 17

Proposal for a regulation
Article 1 – point 10a
Regulation (EC) No 273/2004
Article 13 c (new)

Text proposed by the Commission	*Amendment*
	(10a) The following article is inserted:
	"Article 13c
	Delegated acts
	The Commission shall be empowered to

adopt delegated acts in accordance with Article 15a in respect of the categories of personal data to be processed for the purpose of the European Database, the retention period for personal data processed, the procedures by which data subjects can exercise their rights to access, rectify, erase and, where appropriate, object and block data.

Before developing delegated acts under this Article, the Commission shall consult the European Data Protection Supervisor."

Justification

Data protection law, the various elements of processing personal data, including the exercise of rights by data subjects, must be specified in delegated acts. This amendment takes into account recommendations made by the EDPS.

Amendment 18

Proposal for a regulation
Article 1 – point 11
Regulation (EC) No 273/2004
Article 14 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the standard form for providing the privacy notice referred to in Article 13a.

Justification

Data protection law, the various elements of processing personal data, including the exercise of rights by data subjects, must be specified in delegated acts. This amendment takes into account recommendations made by the EDPS.

Amendment 19

Proposal for a regulation
Article 1 – point 12
Regulation (EC) No 273/2004
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall evaluate the implementation and functioning of this Regulation by [78 months after of the date of entry into force of this amending Regulation]."	***deleted***

Amendment 20

Proposal for a regulation
Article 1 a (new)

Text proposed by the Commission	*Amendment*
	Article 1a
	Review
	By ...*, the Commission shall submit a report to the European Parliament and to the Council on the implementation and functioning of Regulation (EC) No 273/2004, and in particular on the possible need for additional action to monitor and control suspicious transactions with non-scheduled substances.
	_____
	**** OJ please insert date: 66 months after the date of entry into force of this Regulation.***

Amendment 21

Proposal for a regulation
Article 2

Text proposed by the Commission	*Amendment*
This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. ***It shall be consolidated with the Regulation it is amending.*** This Regulation shall be binding in its entirety

and directly applicable in all Member States.