Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2011/0105(COD)
Export and import of hazardous chemicals. Recast Repealing Regulation (EC) No 689/2008 2006/0246(COD) Subject 3.40.01 Chemical industry, fertilizers, plastics 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport) 6.20.02 Export/import control, trade defence, trade barriers 6.20.05 Multilateral and plurilateral economic and trade agreements and relations	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety	S&D JØRGENSEN Dan	08/06/2011
	Committee for opinion	Rapporteur for opinion	Appointed
	INTA International Trade	The committee decided not to give an opinion.	
	ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
	JURI Legal Affairs	PPE LÓPEZ-ISTÚRIZ WHITE Antonio	24/05/2011
Council of the European Union	Council configuration	Meeting	Date
	General Affairs	3180	26/06/2012
	Environment	3139	19/12/2011
European Commission	Commission DG	Commissioner	
	Environment	POTOČNIK Janez	

Key events

05/05/2011	Legislative proposal published	COM(2011)0245	Summary
10/05/2011	Committee referral announced in Parliament, 1st reading		
19/12/2011	Debate in Council	3139	Summary
20/12/2011	Vote in committee, 1st reading		

16/01/2012	Committee report tabled for plenary, 1st reading	A7-0015/2012	Summary
10/05/2012	Results of vote in Parliament		
10/05/2012	Decision by Parliament, 1st reading	T7-0198/2012	Summary
26/06/2012	Act adopted by Council after Parliament's 1st reading		
04/07/2012	Final act signed		
04/07/2012	End of procedure in Parliament		
27/07/2012	Final act published in Official Journal		

Technical information

Procedure reference	2011/0105(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Regulation
	Repealing Regulation (EC) No 689/2008 2006/0246(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 207; Treaty on the Functioning of the EU TFEU 192-p1
Other legal basis	Rules of Procedure EP 159
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/05978

Documentation gateway

Legislative proposal		COM(2011)0245	05/05/2011	EC	Summary
Committee draft report		PE473.949	17/10/2011	EP	
Amendments tabled in committee		PE475.973	18/11/2011	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0015/2012	16/01/2012	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0198/2012	10/05/2012	EP	Summary
Draft final act		00012/2012/LEX	04/06/2012	CSL	
Commission response to text adopted in plenary		SP(2012)488	27/06/2012	EC	
Follow-up document		COM(2018)0596	17/08/2018	EC	Summary
Follow-up document		COM(2018)0697	17/10/2018	EC	Summary
Follow-up document		SWD(2018)0438	17/10/2018	EC	
Follow-up document		COM(2022)0412	13/09/2022	EC	
Follow-up document		SWD(2022)0218	13/09/2022	EC	
Follow-up document		COM(2023)0448	17/07/2023	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2012/649
OJ L 201 27.07.2012, p. 0060 Summary

Final legislative act with provisions for delegated acts

Delegated acts

2015/2867(DEA)	Examination of delegated act
2014/2802(DEA)	Examination of delegated act
2019/2771(DEA)	Examination of delegated act
2020/2658(DEA)	Examination of delegated act
2017/2994(DEA)	Examination of delegated act
2018/2982(DEA)	Examination of delegated act
2022/2550(DEA)	Examination of delegated act
2023/2755(DEA)	Examination of delegated act

Export and import of hazardous chemicals. Recast

PURPOSE: recast of provisions currently in force regarding the import and export of dangerous chemicals.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

BACKGROUND: Regulation (EC) n° 689/2008concerning the export and import of dangerous chemicals implements the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for certain hazardous chemicals and pesticides in international trade.

The Rotterdam Convention was adopted in September 1998. It entered into force on 24 February 2004. Its aim is to promote shared responsibility and co-operative efforts among the Parties in the international trade of dangerous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use.

Regulation (EC) n° 689/2008 go beyond those of the Convention and offer more protection to importing countries since they are addressed to all countries and not just Parties to the Convention. The scope of the Regulation is not limited to chemicals that are banned or severely restricted under the Convention but also covers chemicals that are banned or severely restricted at EU level. In addition the Regulation ensures that all chemicals are appropriately packed and labelled when exported.

It is now necessary to align Regulation (EC) No 689/2008 with Regulation (EC) No 1272/2008on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) 1907/2006.

IMPACT ASSESSMENT: as the overall impact of the review is expected to be limited, it was not considered imperative to carry out an impact assessment. The main effects of the changes can be summarised as follows:

- there will be more clarity, transparency and increased legal certainty for all parties involved in the implementation of the
- Regulation;
- the proposal will not add any additional administrative burden for exporters or the competent authorities involved in the implementation of the Regulation. On the contrary, with respect to exports that are exempted from export notification the proposed amendments will lead to a reduction of administrative burdens;
- some tasks will be transferred from the Commission to the European Chemicals Agency, which is expected to reduce the overall costs and to increase the scientific knowledge available for implementation;
- the current high level of protection of human health and the environment will be maintained.

LEGAL BASIS: in line with the judgment of the Court in case C-178/03 (Commission v Parliament and Council), the proposed Regulation will be based on Article 192(1) (relating to Environmental Protection) of the Treaty on the functioning of the European Union and Article 207 (relating to the Common Commercial Policy).

CONTENT: the proposed new Regulation would essentially maintain all provisions of the current Regulation, including those that go beyond the requirements of the Convention. However, certain technical amendments are deemed necessary to improve the clarity and functioning of the Regulation. The

main changes are as follows:

Definitions: bearing in mind Regulation 1272/2008 and the experience gained from the implementation of Regulation (EC) No 689/2008, the proposal makes certain technical amendments to the operative provisions such as clarify the definitions of a substance, a mixture and an article, and the reference identification number required for exports that are not subject to export notification.?

Explicit consent procedure: in around 30% of the cases to date, despite the efforts made by the designated national authorities (DNAs) of the exporting Member States and the Commission to obtain explicit consent, no response is forthcoming from the importing country, in some cases for many months or even years. As a result, exports cannot proceed, despite the fact that the substances are often not banned or severely restricted in the importing countries. The proposal makes provision for additional conditions that may allow exports to proceed in the absence of a reply from the importing country whilst not lowering the protection afforded to importing countries. It is proposed to allow the export to proceed if there is documentary evidence from official sources showing that the chemical has been imported or used in the last 5 years and no regulatory action has been taken, if, despite all reasonable efforts by the exporter?s DNA, the Agency and the Commission, there is no response from the importing country within 2 months.

Involvement of the European Chemicals Agency: in order to support the Commission in its tasks as a common designated authority foreseen under the Regulation, it is proposed to involve the European Chemicals Agency in certain administrative, technical and scientific tasks necessary for the implementation of the Regulation, in particular regarding the management of the European Database on Export and Import of dangerous chemicals.

Adaptation of provisions to the Lisbon Treaty: in view of the changes introduced by the Lisbon Treaty, it is necessary to clarify provisions relating to the external representation of the European Union and to adapt the provisions concerning comitology. In particular, it should be specified which rules are subject to implementing acts and clarified which conditions apply to the adoption of delegated acts.

FINANCIAL IMPLICATIONS: the proposal is not expected to have important budgetary implications since no new tasks were introduced compared to Regulation (EC) 689/2008. The transfer of certain tasks from the Commission to the European Chemicals Agency is expected to reduce the overall costs of implementation. Further reductions may be achieved in a long-term perspective considering the potential for synergies with other tasks of the Agency. The financing of the tasks carried out by the European Chemicals Agency will be provided in form of a subsidy from the Union budget.

DELEGATED ACTS: the proposal contains certain provisions conferring on the Commission the power to adopt delegated acts in accordance with Article 290 of the TFEU.

Export and import of hazardous chemicals. Recast

The Council took note of a progress report on the proposal for a regulation concerning the export and import of hazardous chemicals.

The aim of the proposal is to replace regulation 689/2008, which implements the Rotterdam Convention on the Prior Informed Consent Procedure (PIC) for certain hazardous chemicals and pesticides in international trade.

The provisions of the regulation go beyond those of the Convention and offer more protection to importing countries since they are addressed to all countries and not just to the Parties to the Convention. The scope of the regulation is not limited to chemicals that are banned or severely restricted under the Convention, but also covers those chemicals at EU level. In addition, the regulation ensures that all chemicals are appropriately packed and labelled when exported.

Export and import of hazardous chemicals. Recast

The Committee on the Environment, Public Health and Food Safety adopted the report by

Dan JØRGENSEN (S&D, DK) on the proposal for a regulation of the European Parliament and of the Council concerning the export and import of dangerous chemicals (recast).

The committee recommends that the European Parliament adopt its position in first reading following the ordinary legislative procedure, taking into account the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission.

According to the Consultative Working Party, the proposal in question does not include any substantive amendments other than those identified as such in the proposal. As regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance.

The committee recommends the following amendments to the proposal :

Preventive approach: Members stress the need to prevent chemicals having any harmful effects on human health and the environment.

Participation of the Union in the Convention: the Commission proposal deletes text stating that it is the Commission and Member States that represents the EU in the Rotterdam Convention. With this deletion it is only the Commission and not Member States that can represent the EU in the Convention. Members consider that this amendment is not justified as the PIC (prior informed consent procedure applicable to certain dangerous chemicals)) regulation is based on both an environmental legal basis and a commercial legal basis. As there is an environmental legal basis, Member States have the right to represent themselves and also to implement the Convention in a stricter way than is required by the EU-legislation.

Members also made certain amendments in order to clarify the Commissions responsibilities.

Tasks of the European Chemicals Agency: as in REACH, ECHA should be responsible for providing assistance and technical guidance and tools for industry and authorities without a legally binding obligation to have a formal agreement of the Commission. Such an obligation would be an excessive burden to ECHA, leading most probably to unnecessary delays in providing these tools and services.

Export notifications forwarded to Parties and other countries: when an exporter is due to export a chemical referred to in paragraph 1 from the Union to a Party or other country for the first time on or after the date on which it becomes subject to this Regulation, the exporter shall notify the designated national authority of the Member State in which he is established, no later than 30 days (rather than 20 working days)

before the export of the chemical is due to take place, unless the exporter has previously given such notification in accordance with Regulation (EC) No 689/2008. Thereafter the exporter shall notify the designated national authority of the first export of such chemical each calendar year no later than 15 days (rather than 20 working days) before the export takes place, unless the exporter has previously given such notification in accordance with Regulation (EC) No 689/2008.

Obligations in relation to exports of chemicals other than export notification requirements: in the case of chemicals listed in Parts 2 or 3 of Annex I, the designated national authority of the exporter may decide that the export may proceed if one of the two following conditions is met:

(1) there is evidence from official sources in the importing Party or other country that the chemical is licensed, registered or authorised; or

(2) for the chemical concerned:

- there is evidence from official sources that it has in the last 5 years been used in or imported into the importing Party or importing other country;
- there is no evidence from official sources of the importing Party or other country having taken regulatory action to ban or severely restrict the chemical in the category for which it is intended to be used; and
- the intended use declared in the export notification is not in a category for which the chemical is listed in Part 2 or 3 of Annex I.

When deciding on the export of chemicals listed in Part 3 of Annex I, the designated national authority in consultation with the Commission assisted by the Agency shall document that it considered the possible impact on human health or the environment of the use of the chemical in the importing Party or other country.

Information regarding chemicals for export: packaging and labelling under the Classification, Labelling and Packaging Regulation depend on classification. As such, all relevant provisions of the CLP Regulation have to apply to the export of chemicals, and not just those on packaging and labelling.

Fees: the Commission shall examine whether it is appropriate for the Agency to charge a fee for the services provided to exporters within three years (rather than five years) of the date of application of the Regulation.

Transitional provisions: under the Classification, Labelling and Packaging Regulation there are transitional arrangements that permit labelling and packaging of mixtures under the old EU system until 1 June 2015. These arrangements should also apply to exports. As that Regulation itself applies only to chemicals placed on the EU market, and not to chemicals for export, Members have clarified that all references to the CLP Regulation in PIC should be read as if the CLP Regulation applied to the exports concerned.

Entry into force: Members propose that the Regulation shall apply as from 1 October 2013 (rather than 1 April 2013). Additional time is needed to give Member States sufficient opportunity to adapt their national enforcement regulations in order to take account of the recast PIC Regulation.

Export and import of hazardous chemicals. Recast

The European Parliament adopted by 563 votes to 16 with 3 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council concerning the export and import of dangerous chemicals (recast) .

Parliament adopted its position in first reading following the ordinary legislative procedure bearing in mind the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission.

The amendments adopted in plenary are the result of a compromise agreement between Parliament and Council. They amend the Commission proposal as follows:

Protection of health and of the environment: the Regulation must contribute to the prevention of harmful effects of chemicals on human health and the environment, particularly with regard to assistance to developing countries and countries with economies in transition to enable those countries to implement the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

Scope: the Regulation shall not apply to chemicals exported for the purpose of research or analysis in quantities that are unlikely to affect human health or the environment and that in any event do not exceed 10 kg from each exporter to each importing country per calendar year. Exporters of the chemicals referred to shall obtain a special reference identification number using the Database on export and import of hazardous chemicals and provide that reference identification number in their export declaration.

Designated national authorities of the Member States: each Member State shall designate the authority or authorities, to carry out the administrative functions required by the Regulation. It shall inform the Commission of such designation within 3 months of entry into force of the Regulation unless that information has been already provided before entry into force of this Regulation, and shall also inform the Commission of any change of designated national authority.

Participation of the Union in the Convention: the amended text stipulates that participation in the Convention shall be a joint responsibility of the Commission and the Member States, in particular as regards technical assistance, the exchange of information and matters relating to dispute settlement, participation in subsidiary bodies and voting.

The Commission shall, in particular, be responsible for the transmission of Union export notifications to Parties and other countries.

Tasks of the European Chemicals Agency: the ECHA will:

- maintain, further develop and regularly update a database on export and import of hazardous chemicals (the Database);
- where appropriate, provide, with the agreement of the Commission and after consultations with Member States , assistance and technical and scientific guidance and tools for the industry in order to ensure the effective application of the Regulation;
- at the request of Member State or Commission experts of the Chemical Review Committee , and within the available resources, provide input in drafting of decision guidance documents referred to in Article 7 of the Convention and other technical documents

related to the implementation of the Convention.

Export notifications forwarded to Parties and other countries: these provisions shall apply regardless of the intended use of the chemical in the importing Party or other country.

When an exporter is due to export a chemical for the first time on or after the date on which it becomes subject to the Regulation, the exporter shall notify the designated national authority of the Member State in which he is established, no later than 35 days before the export of the chemical is due to take place. Thereafter the exporter shall notify that designated national authority of the first export of the chemical each calendar year no later than 35 days before the export takes place. The notifications shall be made available to the Commission and to the Member States by means of the Database.

The designated national authority of the exporter's Member State shall check compliance of the information with Annex II and if the notification is complete forward it to the Agency no later than 25 days before the expected date of export.

The Agency shall, on behalf of the Commission, transmit the notification to the designated national authority of the importing Party or the appropriate authority of the importing other country and take the measures necessary to ensure that they receive that notification no later than 15 days before the first intended export of the chemical and thereafter no later than 15 days before the first export in any subsequent calendar year.

These obligations shall cease when all of the following conditions are fulfilled:

- the chemical has become a chemical subject to the PIC procedure,
- the importing country is a Party to the Convention and has provided the Secretariat with a response in accordance with Article 10(2) of the Convention indicating whether or not it consents to import of the chemical, and
- the Commission has been informed of that response by the Secretariat and has forwarded that information to the Member States and the Agency.

Member States may establish, in a transparent manner, systems obliging exporters to pay an administrative fee for each export notification made and for each request for explicit consent made, corresponding to the costs they incur in carrying out the procedures.

Export notifications received from Parties and other countries: export notifications received by the Agency from the designated national authorities of Parties or the appropriate authorities of other countries concerning the export to the Union of a chemical the manufacture, use, handling, consumption, transport or sale of which is subject to prohibition or severe restriction under that Party's or other country's legislation shall be made available by means of the Database within 15 days of the Agency's receipt of such notification.

Information on export and import of chemicals: at the request of the Commission, assisted by the Agency, or the designated national authority of its Member State, the exporter or importer shall provide any additional information relating to chemicals that is necessary to implement the Regulation.

Obligations in relation to exports of chemicals other than export notification requirements: in the case of chemicals listed in Parts 2 or 3 of Annex I, the designated national authority of the exporter's Member State may, in consultation with the Commission assisted by the Agency, on a case-by-case basis, decide that the export may proceed: (i) if no evidence from official sources of final regulatory action to ban or severely restrict the use of the chemical taken by the importing Party or other country exists and (ii) if, after all reasonable efforts, no response to a request for explicit consent has been received within 60 days and (iii) where one of the following conditions is met:

- there is evidence from official sources in the importing Party or other country that the chemical is licensed, registered or authorised; or
- the intended use declared in the export notification and confirmed in writing by the natural or legal person importing the chemical into a Party or other country, is not in a category for which the chemical is listed in Part 2 or 3 of Annex I, and there is evidence from official sources that the chemical has in the last 5 years been used in or imported into the importing Party or other country concerned.

In the case of chemicals listed in Part 3 of Annex I, an export based on the fulfilment of the condition under point (b) may not proceed if the chemical has been classified in accordance with Regulation (EC) No 1272/2008 as carcinogenic category 1A or 1B, or mutagenic category 1A or 1B, or toxic for reproduction category 1A or 1B or the chemical fulfils the criteria of Annex XIII of the Regulation (EC) No 1907/2006 (REACH) for being persistent, bioaccumulative and toxic or very persistent and very bioaccumulative.

When deciding on the export of chemicals listed in Part 3 of Annex I, the designated national authority of the exporter's Member State shall, in consultation with the Commission assisted by the Agency, consider the possible impact on human health or the environment of the use of the chemical in the importing Party or other country, and submit relevant documentation to the Agency, to be made available by means of the Database.

Information to accompany exported chemicals: chemicals that are intended for export shall be subject to the provisions on packaging and labelling established in, or pursuant to, Regulation (EC) No 1107/2009, Directive 98/8/EC and Regulation (EC) No 1272/2008, or any other relevant Union legislation.

An amendment states that this provision shall apply unless those provisions would conflict with any specific requirements of the importing Parties or other countries.

Obligations of the authorities of the Member States for controlling import and export: the Commission, supported by the Agency, and the Member States shall act in a targeted and coordinated way in monitoring exporters compliance with the Regulation.

A compilation of the information transmitted shall be prepared every two years by the Agency

Monitoring and reporting: Member States and the Agency shall forward information to the Commission every three years concerning the operation of the procedures provided for in the Regulation. The Commission shall adopt an implementing act laying down in advance a common format for reporting. The Commission shall compile a report every three years on the performance of the functions provided for in the Regulation for which it is responsible.

Delegated acts: the Commission shall be empowered to adopt delegated acts concerning the following measures: (i) inclusion of a chemical in

Part 1 or 2 of Annex I and other amendments of Annex I, (ii) inclusion of a chemical that is subject to Part 1 or Part 2 of Annex V; (iii) amendments of Annexes II, III, IV and VI.

Transitional provisions: references in the Regulation to Regulation (EC) No 1272/2008 on classification, labelling and packaging shall be construed in order to avoid any inconsistencies between the timetable of application of that Regulation and this Regulation.

Export and import of hazardous chemicals. Recast

PURPOSE: recast of provisions currently in force regarding the import and export of dangerous chemicals.

LEGISLATIVE ACT: Regulation (EU) n° 649/2012 of the European Parliament and of the Council concerning the export and import of dangerous chemicals.

CONTENT: following an agreement reached with the European Parliament, the Council adopted a Regulation concerning the export and import of dangerous chemicals. This Regulation replaces Regulation (EC) n° 689/2008 and aims to:

- implement the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (the "Convention");
- promote shared responsibility and cooperative efforts in the international movement of hazardous chemicals in order to protect human health and the environment from potential harm;
- contribute to the environmentally sound use of hazardous chemicals.

The objectives set out in the first subparagraph shall be achieved by facilitating the exchange of information concerning the characteristics of hazardous chemicals, by providing for a decision-making process within the Union on their import and export and by disseminating decisions to Parties and other countries as appropriate.

The scope of the Regulation is not limited to chemicals that are banned or severely restricted under the Convention, but also covers those chemicals at EU level. In addition, the Regulation ensures that all chemicals are appropriately packed and labelled when exported.

Participation in the Convention shall be a joint responsibility of the Commission and the Member States, in particular as regards technical assistance, the exchange of information and matters relating to dispute settlement, participation in subsidiary bodies and voting. The Commission will assume, among others, the task of the transmission of Union export notifications to Parties and other countries.

The Member States and the Agency will carry out tasks with regard to the administrative, technical and scientific aspects of the implementation of the Convention through this Regulation, as well as the exchange of information. In addition, the Commission, the Member States and the Agency will cooperate in order to implement the Unions international obligations under the Convention effectively.

ENTRY INTO FORCE: 13/08/2012.

APPLICATION: to apply from 01/03/2014.

DELEGATED ACTS: the Commission can adopt delegated acts to take account of technoogical changes. The power to adopt delegated acts shall be conferred on the Commission for a period of five years from 1 March 2014 (tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension). The European Parliament or the Council can object to delegated acts within a period of two months of notification of that act (this notification can be extended by two months). If the European Parliament or the Council objects, the delegated act will not come into force.

Export and import of hazardous chemicals. Recast

The Commission presents a report on the exercise of the delegation conferred on the Commission pursuant to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals (the PIC Regulation), which implements the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade.

Under the terms of the Regulation, the Commission is required to present a report on the exercise of the delegation conferred on the Commission by the PIC Regulation not later than nine months before the end of the five-year period of the delegation, running from 1 March 2014.

During the period concerned by this report, the Commission adopted three delegated acts in order to amend certain non-essential elements of the PIC Regulation on the basis of Articles 23(4)(a) and 23(4)(b) respectively. The following acts were adopted:

- Commission Delegated Regulation (EU) No 1078/2014: this act was adopted on the basis of Article 23(4)(a) of the PIC Regulation on 28 November 2017 and applies from 1 December 2014. The approach followed in the delegated act to determine which chemicals should be listed in Annex I and in which part they should be listed was subject to discussions and in which part they should be listed was subject to discussions and consultations within the PIC DNA Expert Group consisting of representatives of Member States designated national authorities, the European Chemicals Agency, industry and civil society.
- Commission Delegated Regulation (EU) 2015/2229: this act was adopted on the basis of Article 23(4)(a) of the PIC Regulation on 29 September 2015 and applies from 1 February 2016. Similarly, the PIC DNA Expert Group was consulted on the determination of which chemicals should be listed in Annex I and in which part they should be listed.
- Commission Delegated Regulation (EU) 2018/172: this act was adopted on the bases of Article 23(4)(a) and (b) of the PIC Regulation on 28 November 2017 and applies from 1 April 2018. the PIC DNA Expert Group was consulted not only on which chemicals should be listed in Annex I and in which part they should be listed but also on the listing of certain chemicals in Part 1 of Annex V.

In all three cases, the act was notified to the European Parliament and the Council. In each case, neither the European Parliament nor the Council objected to the delegated acts within the period of two months provided for in Article 26(5) of the PIC Regulation.

The Commission states that it is of the view that the delegated powers conferred by Article 23(4) should be tacitly extended, including those that were not yet exercised, since the need to adapt the PIC Regulation to technical progress in accordance with Articles 23(4)(c), 23(4)(d) and 23(4)(e) can occur at any time in the light of technical and scientific progress.

Export and import of hazardous chemicals. Recast

The Commission presents a summary of the synthesis report on the operation of Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals.

Article 22 of this Regulation (Prior Informed Consent (PIC) Regulation) requires the Commission to report on its activities under the Regulation every three years, and to compile a synthesis report on the performance of the PIC Regulation.

This reporting exercise is the first under this PIC Regulation and covers the implementation since the Regulation became applicable (2014-2016).

Good cooperation

The report demonstrates that the procedures established by Regulation (EU) No 649/2012 operated well and contributed to achieving its objectives. Good cooperation between all stakeholders formed the basis for successful implementation.

The Commission, the Agency and designated national authorities (DNAs) consider the coordination between EU and national institutions effective.

The Agency considered the collaboration with the Commission satisfactory, pointing to a number of areas for improvement, such as the preparation of notifications of FRA, the preparation of meetings, the procedure for updating Annexes.

Higher than expected workload

In general, the Member States met their obligations, although the high workload at the end of each year - caused by the large number of export notifications presented a challenge for some Member States and sometimes led to problems with timeframes.

More specifically, the export notification is the PIC Regulation instrument by which countries exchange information on banned or severely restricted chemicals. During the reporting period, Member States accepted and forwarded 15 771 export notifications to the Agency and rejected 1214. The number of export notifications processed varied significantly between Member States. Three Member States did not process any export notification during the reporting period and five Member States had fewer than 10 notifications. The highest numbers of export notifications were processed by Germany (5196 notifications), France (3358), the United Kingdom (1829), Italy (1321) and Spain (1265). The importing countries that received the highest numbers of export notifications from the Union were Switzerland (1044 notifications), Turkey (984), Russia (890), the USA (754) and China (601).

Explicit consent procedure

The explicit consent procedure, which goes beyond the Convention as a standard procedure for the export of certain chemicals, has led to the high number of 3362 requests for explicit consent sent to importing countries in the reporting period. Experience suggested that those requests presented a challenge for many importing countries, largely because the procedure is rarely used under the Convention and many Parties may not be aware of its existence. This may have resulted in a high number of exports not being allowed to proceed due to unanswered requests for consent. The possibility to apply for a waiver under certain conditions ensured that the number of exports blocked for this reason was kept to a minimum.

Control of the export and import of chemicals subject to the PIC Regulation

Member States must designate authorities, such as customs authorities, to control imports and exports of chemicals listed in Annex I. All Member States have nominated these authorities. Customs are involved in the implementation of the PIC Regulation in all Member States, except Malta and the United Kingdom.

In four countries, the only national enforcement authority (NEA) is the customs administration (Spain, Croatia, Italy and Slovakia).

In almost all Member States, NEAs involved in the enforcement of the PIC Regulation are also involved in the enforcement of other chemicals legislation. Most Member States have also described their applicable penalty system for infringements of the PIC Regulation. DNAs typically described a mix of enforcement measures such as seizure and detention of goods, withdrawal from the market, suspension of activities, etc.

On penalties for infringements, 23 Member States indicated that they impose fines for specific infringements, often with a scale of fines depending on the gravity of the infringement. In seven Member States, a penalty of imprisonment can be imposed for the most serious infringements.

Implementation

The contribution of the Agency to implementation was fully in line with the requirements of the Regulation, and its solid performance was the basis for effective functioning of the relevant procedures. The Commission completed its obligations under the Regulation. Two Commission Delegated Regulations amending Annex I, as well as two Commission Implementing Decisions adopting Union import decisions, were adopted in the reporting period. In addition, the Commission coordinated the contribution of the Union to the international work and represented the Union to the Convention.