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2018/0070 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on persistent organic pollutants (recast)

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Regulation (EC) No 850/2004 of the European Parliament and of the Council¹ ('the POPs Regulation') implements the commitments of the Union under the Stockholm Convention on Persistent Organic Pollutants ('the Stockholm Convention') approved by Council Decision 2006/507/EC² and under the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants ('the POPs Protocol') approved by Council Decision 2004/259/EC³.

The following reasons lead to the proposal to recast the POPs Regulation:

Article 16 of the POPs Regulation states that the comitology committee for general matters of the Regulation has its legal basis in Article 29 of Council Directive 67/548/EEC⁴. However, this Directive was revoked by Article 60 of Regulation (EC) 1272/2008 of the European Parliament and of the Council⁵ with the effect that the comitology committee for the Regulation ceased to exist on 1 June 2015.

As a result of this, and in view of the procedural changes introduced by the Treaty on the Functioning of the European Union (the 'Lisbon Treaty'), it is necessary to adapt the provisions of the POPs Regulation 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.

In order to support the Commission in its tasks foreseen under the POPs Regulation, it is proposed to involve the European Chemicals Agency ("the Agency") in certain administrative, technical and scientific tasks necessary for the implementation of the Regulation. It is also proposed to support the enforcement of the POPs Regulation by Member States by including a coordination role for the Forum for Exchange of Information on Enforcement established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council ('REACH')⁶.

In light of the experience of the functioning of the procedures under the POPs Regulation, it is appropriate to include certain technical amendments to the operative provisions, such as clarifying existing definitions and adding the definitions of manufacturing, use and a closed-system site-limited

¹ Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7.)

² Council Decision 2006/507/EC of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants (OJ L 209, 31.7.2006, p. 1).

³ Council Decision 2004/259/EC of 19 February 2004 concerning the conclusion, on behalf of the European Community, of the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (OJ L 81, 19.3.2004, p. 35).

⁴ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1–98)

⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)

⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)

intermediate. It is also appropriate to update the provisions of the reporting requirements in light of the conclusions reached in the recently adopted Report on Actions to Streamline Environmental Reporting.⁷

As a result of amendments to the Annexes of the Stockholm Convention that were decided at the Conference of the Parties in 2015, it is necessary to update the Annexes of the POPs Regulation in order to comply with the Union's commitments under that Convention.

The proposal contributes to the achievement of priority objective 3 of the 7th Environment Action Programme to 2020: "To safeguard the Union's citizens from environment-related pressures and risks to health and well-being" and also fits under priority objective 4, paragraph 65, which requires that the public has access to clear environmental information at national level. To that end, the proposal makes cross-references to and guarantees consistency with the requirements of Directive 2003/4/EC of the European Parliament and of the Council⁸ and of Directive 2007/2/EC of the European Parliament and of the Council⁹ (the 'INSPIRE Directive').

Furthermore, simplifications of reporting and monitoring processes are pursued, with a focus on automation, lower frequency and relevance of data, in line with the Union's Better Regulation agenda and the findings of the Fitness Check on Environmental Reporting and Monitoring¹⁰. At the same time, this proposal is in line with the Commission's Digital Single Market strategy with provisions to improve citizens' access to information and transparency.

- **Consistency with existing policy provisions in the policy area**

The current Union rules relating to the management of persistent organic pollutants are laid down in the POPs Regulation, as most recently amended by Commission Regulation (EU) 2016/460¹¹. In addition, Union obligations relating to export of persistent organic pollutants are implemented by Regulation (EU) No 649/2012 of the European Parliament and of the Council¹².

- **Consistency with other Union policies**

The proposal is fully in line with existing policies and objectives aimed at protecting human health and the environment globally.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The substantive legal basis is Article 192(1) (relating to Environmental Protection) of the Treaty on the functioning of the European Union, given that the measures agreed under the Stockholm Convention predominantly pursue an environmental objective (i.e. the elimination of persistent organic pollutants).

⁷ COM (2017) 312 available at: http://ec.europa.eu/environment/legal/reporting/pdf/action_plan_env_issues.pdf

⁸ Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26–32)

⁹ Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)

¹⁰ COM (2017) 312 and SWD (2017) 230

¹¹ Commission Regulation (EU) 2016/460 of 30 March 2016 amending Annexes IV and V to Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants (OJ L 80, 31.3.2016, p. 17)

¹² Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)

- **Subsidiarity (for non-exclusive competence)**

The objectives of the proposal cannot be achieved by the Member States because a harmonised approach is needed to ensure that the Union, as a Party to the Stockholm Convention, meets its international obligations.

- **Proportionality**

The proposal complies with the proportionality principle since it does not go beyond what is necessary to achieve its objectives. It concentrates on changes only where they are deemed necessary and appropriate for its proper functioning or where they are necessary due to changes in other legislation.

- **Choice of the instrument**

Given that the existing legislation to be replaced is in the form of a regulation, this is the most appropriate instrument.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

Due to the necessity to undertake the recast and the limited scope of the changes introduced, it was not deemed necessary to carry out an ex-post evaluation of the existing legislation. However, the Commission has recently completed a Fitness Check evaluation on Reporting and Monitoring of environmental legislation and the Report¹³ from this Fitness Check has been examined in order to assess the effectiveness of the reporting obligations laid down in the POPs Regulation. Some adjustments are made in the recast that are considered necessary in line with the actions identified in the Report, including streamlining, simplifying and automatising the reporting/monitoring process and improving the provision of public information.

- **Stakeholder consultations**

Due to the nature of the recast, which introduces only technical amendments to the operative provisions, it was not deemed necessary to carry out a formal consultation of stakeholders.

Relevant stakeholders have been informed within the framework of the meetings of Competent Authorities for the POPs Regulation about the intended modifications. Participants have included stakeholders such as industry and NGOs as well as Member States, all of whom have had an opportunity to give their opinions and to make comments.

- **Collection and use of expertise**

Due to the limited scope of changes proposed in the context of this review, it was not deemed necessary to make extensive use of external expertise. However, the Agency was consulted on some technical issues.

- **Impact assessment**

The current rules set out in the Regulation are generally working well and only minor technical modifications are necessary to facilitate the implementation. The main changes aim to align the POPs

¹³ COM(2017) 312 final- Actions to Streamline Environmental Reporting:
http://ec.europa.eu/environment/legal/reporting/pdf/action_plan_env_issues.pdf

Regulation with the Lisbon Treaty and general chemicals legislation as well as to involve the Agency in the tasks foreseen under the Regulation. 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:

- As a result of the proposed changes, there will be more clarity, transparency and increased legal certainty for all parties involved in the implementation of the Regulation;
- Some tasks will be transferred from the Commission to the 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.

- **Regulatory fitness and simplification**

The proposal does not exempt micro-enterprises and does not include special rules for SMEs since it addresses persistent organic pollutants which are of global concern and, therefore, need to be phased-out by all companies at global level. The proposal does not have any impact on sectoral EU competitiveness or international trade since it implements legally binding obligations under the Stockholm Convention that apply in principle to all Parties to the Convention.

The proposal includes a role for the Agency in receiving, monitoring and exchanging information submitted to it under the provisions of the proposal. As the Agency currently manages other information activities in the framework of EU chemicals legislation, including REACH, CLP and the PIC Regulation, it is considered appropriate to specify a similar role for the Agency in this proposal so as to enhance consistency in regulatory implementation.

- **Fundamental rights**

The unsound management of hazardous substances contributes to overall environmental pollution which may have serious effects on the right to life, the right to the integrity of the person, the right to fair and just working conditions and also the right to environmental protection.

The Stockholm Convention, underpinned by the precautionary principle, entered into force in 2004 to protect human health and the environment from chemicals that persist in the environment for long periods, become widely distributed geographically, accumulate in human and wildlife body tissues, and have adverse effects on human health or the environment.

The POPs Regulation currently implements the provisions of the Convention and the Protocol in the Union. Bearing in mind Principles 14 and 15 of the Rio Declaration on Environment and Development, this Regulation provides measures to minimise, with a view to eliminating where feasible as soon as possible, releases of POPs, and establishes provisions regarding waste consisting of, containing or contaminated by any of those substances.

The proposal will replace the current POPs Regulation while adhering to the commitments made by the Union under the Convention and Protocol.

4. BUDGETARY IMPLICATIONS

The proposal is not expected to have important budgetary implications since no new tasks were introduced compared to the current POPs Regulation. The transfer of certain tasks from the

Commission to the Agency is expected to have no significant impact on the overall costs of implementation. Reductions are expected to be achieved in the medium-term considering the potential for synergies with other existing tasks of the Agency.

The financing of the tasks carried out by the Agency will be provided in form of a subsidy from the Union budget.

5. OTHER ELEMENTS

• Implementation plans and monitoring, evaluation and reporting arrangements

The proposal contains provisions on monitoring of persistent organic pollutants and on reporting on their manufacturing, use and emissions. In addition, it provides for obligations on monitoring the application of the POPs Regulation. It also requires the setting-up and regular review of a plan for implementation of the Stockholm Convention. As this proposal is a recast of an existing Regulation that already contains those elements, it focuses on taking account of the results of the above-mentioned Fitness Check but does not introduce any additional implementation, monitoring or reporting requirements.

• Detailed explanation of the specific provisions of the proposal

The proposed recast Regulation would essentially maintain all provisions of the current POPs Regulation, including those that go beyond the requirements of the Stockholm Convention and the POPs Protocol. However, certain technical amendments are deemed necessary to improve the clarity and functioning of the Regulation. The main changes are as follows:

– Changes and clarifications as regards certain definitions (Article 2)

In order to ensure that the terminology used in this Regulation is clear and reflects the interpretation of terminology used in chemicals legislation in general, the definitions for 'placing on the market', 'article', 'substance', 'waste', 'disposal' and 'recovery' have been amended. The term 'preparation' has been replaced by 'mixture' to reflect the changes in the general chemicals legislation. It has also been deemed appropriate to add definitions for 'manufacturing', 'use' and 'closed-system, site-limited intermediate'.

– Involvement of the European Chemicals Agency (Articles 8, 16 and 17)

A role for the Agency in the implementation of this Regulation has been proposed due to the Agency's expertise and experience with the implementation of general chemicals legislation and international agreements on chemicals, in particular regarding its current involvement in REACH and Regulation (EU) No 649/2012.

It is proposed that the role of the Agency will include its involvement in the technical preparation of dossiers on substances that may be used by the Commission, should it use its discretion to propose one or more such substances to be listed as POPs in the Stockholm Convention. In particular, the Agency will take action where substances are considered to fulfil the criteria in Annex D of the Stockholm Convention.

Substances for which there are uses within the scope of the authorisation requirement of REACH, that are considered to fulfil the criteria in Annex D of the Stockholm Convention and which are identified in accordance with Article 59 of REACH due to their persistence and bioaccumulation should, in general, be subject to the restriction procedure under REACH, unless other regulatory measures are deemed to be more appropriate, with a clear indication that the substance may be submitted to the Convention at a later stage. Where such substances have not been identified in accordance with Article

59 of REACH, they should first be subject to that identification procedure or be subject to assessment by the REACH Member State Committee. The Agency must ensure that the restriction dossier is taken into account when preparing the POP dossier, which shall cover information on all known uses of the substance in the Union and not only those considered under REACH. This will ensure a consistent and efficient implementation of legislation on chemicals in the Union and coherence between the work on a potential POP that is carried out under REACH and the international work that is conducted in support of the Stockholm Convention.

The POP dossier should be made subject to the normal stakeholder consultations undertaken by the Agency. This extended process serves the purpose of obtaining stakeholder information at an early stage and provides the evidence base for the Commission to decide whether to propose the substance as a POP under the Stockholm Convention in a draft Decision pursuant to Article 218(9) of the Lisbon Treaty.

- Inclusion of a role for the Forum for Exchange of Information on Enforcement ('the Forum') established by REACH (Article 8(2)).

The Forum is a network of authorities responsible for the enforcement of REACH, Regulation (EC) No 1272/2008 (CLP) and Regulation (EC) 649/2012 (PIC) in the EU. As a result of the experience it has accrued in relation to those chemical regulations, it is deemed appropriate to propose a role for the Forum in coordinating the enforcement tasks specified in this Regulation.

- Adaptation of provisions in the current POPs Regulation related to the comitology procedures to the procedures of the Lisbon Treaty (Articles 4(3), 7(5), 15, 18)

The provisions in which certain powers are conferred upon the European Commission have been revised in order to reflect the entry into force of the Lisbon Treaty.

- Adaptation of the provisions on reporting and monitoring;

Articles 11 and 13 will be updated by more effective provisions which simplify monitoring. It is foreseen that Member States put in place a data set gathering relevant data under this Regulation, in particular Annex III. Collected spatial data sets require compliance with the INSPIRE Directive. To that end, the support of ECHA is foreseen, whose role will also be to regularly compile and assess the data and provide the Commission with Member State and EU overviews of the Regulation's implementation.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)

2018/0070 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on persistent organic pollutants ~~and amending Directive 79/117/EEC~~ (recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the ~~Treaty establishing the European Community~~ ☒ Treaty on the Functioning of the European Union ☒, and in particular Article ~~175(1)~~ ☒ 192(1) ☒ thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

↓ new

- (1) Regulation (EC) No 850/2004 of the European Parliament and of the Council¹ has been substantially amended several times. Since it is necessary to make further amendments, that Regulation should be recast in the interests of clarity.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
⇒ new

~~(1) This Regulation primarily concerns environmental protection and the protection of human health. The legal basis is therefore Article 175(1) of the Treaty.~~

- (2) The ~~Community~~ ☒ Union ☒ is seriously concerned by the continuous release of persistent organic pollutants ☒ ("POPs") ☒ into the environment. ~~These~~ Those chemical substances are transported across international boundaries far from their sources and they persist in the

¹ Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7).

environment, bioaccumulate through the food web, and pose a risk to human health and the environment. Further measures need therefore to be taken in order to protect human health and the environment against ~~these~~ those pollutants.

- (3) In view of its responsibilities for the protection of the environment, the ~~Community~~ ~~Union~~ ~~signed~~ ~~approved~~ ~~on 24 June 1998~~ ~~19 February 2004~~ ~~the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants², hereinafter ('the Protocol')~~ and ~~approved~~ ~~on 22 May 2004~~ ~~14 October 2004~~ ~~the Stockholm Convention on Persistent Organic Pollutants³, hereinafter ('the Convention')~~.

~~(4) While legislation at Community level relating to persistent organic pollutants has been put in place, its main deficiencies are that there is an absence of, or incomplete legislation on, prohibition of the production and use of any of the currently listed chemicals, that there is no framework to subject additional persistent organic pollutant substances to prohibitions, restrictions or elimination, nor any framework to prevent the production and use of new substances that exhibit persistent organic pollutant characteristics. No emission reduction targets, as such, have been set at Community level and the current release inventories do not cover all sources of persistent organic pollutants.~~

- (4) In order to ensure coherent and effective implementation of the ~~Community's~~ ~~Union's~~ obligations under the Protocol and the Convention, it is necessary to establish a common legal framework, within which to take measures designed in particular to eliminate the ~~production~~ ~~⇒ manufacturing~~ ~~⇒ manufactured~~ ~~⇒ persistent organic pollutants~~ ~~POPs~~ ~~POPs'~~ ~~POPs'~~ characteristics should be taken into consideration in the framework of the relevant ~~Community~~ ~~Union~~ assessment and authorisation schemes.

- (5) ~~Coordination and coherence should be ensured w~~When implementing ~~the provisions of the Convention~~ ~~at Community~~ ~~Union~~ ~~level~~ ~~,~~ it is necessary to ensure coordination and coherence with ~~the provisions of the Rotterdam~~ ~~Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade, which was approved by the Union on 19 December 2002~~ ~~4, Stockholm~~ ~~and~~ ~~of the~~ ~~Basel Conventions~~ ~~on the control of transboundary movements of hazardous wastes and their disposal, which was approved by the Union on 1 February 1993~~ ~~5, and~~ ~~This coordination and coherence should also be maintained~~ ~~when participating in the~~ ~~implementation and further~~ ~~development of the Strategic Approach to International Chemicals Management (SAICM)~~ ~~,~~ adopted by the First International Conference on Chemicals Management in Dubai on 6 February 2006 ~~within the United Nations framework.~~

- (6) Moreover, considering that the provisions of this Regulation are underpinned by the precautionary principle as set forth in the Treaty, and mindful of ~~the precautionary approach to environmental protection as set forth in~~ ~~Principle 15 of the Rio Declaration on Environment and Development and in view of the aim of elimination, where feasible, of the release of persistent organic pollutants~~ ~~POPs~~ ~~into the environment, it is appropriate in~~

² OJ L 81, 19.3.2004, p. 37.

³ OJ L 209, 31.7.2006, p. 3

⁴ OJ L 63, 6.3.2003, p. 29 ~~Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.~~

⁵ OJ L 39, 16.2.1993, p. 3 ~~Convention on the control of transboundary movements of hazardous wastes and their disposal.~~

certain cases to provide for control measures stricter than those under the Protocol and the Convention.

~~(8) In the future, the proposed REACH Regulation could be an appropriate instrument by which to implement the necessary control measures on production, placing on the market and use of the listed substances and the control measures on existing and new chemicals and pesticides exhibiting persistent organic pollutants' characteristics. However, without prejudice to the future REACH Regulation and since it is important to implement these control measures on the listed substances of the Protocol and the Convention as soon as possible, this Regulation should for now implement those measures.~~

(7) In the ~~Community~~ ☒ Union ☒, the placing on the market and use of most of the ~~persistent organic pollutants~~ ☒ POPs ☒ listed in the Protocol or the Convention ~~has~~ ☒ have ☒ already been phased out as a result of the prohibitions laid down in ☒ inter alia, ☒ Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶, Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁷ and Regulation (EU) No 528/2012 of the European Parliament and of the Council⁸ ~~Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances⁹ and Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations¹⁰~~. However, in order to fulfil the ~~Community's~~ ☒ Union's ☒ obligations under the Protocol and the Convention and to minimise the release of ~~persistent organic pollutants~~ ☒ POPs ☒, it is necessary and appropriate also to prohibit the ~~production~~ ☒ manufacturing ☒ of those substances and to restrict exemptions to a minimum so that exemptions only apply where a substance fulfils an essential function in a specific application.

☒ new

(8) For reasons of clarity and consistency with other relevant Union legislation, certain definitions should be specified and terminology should be aligned with that used in Regulation (EC) No 1907/2006 and Directive 2008/98/EC of the European Parliament and of the Council¹¹.

⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

⁷ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

⁸ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

⁹ OJ L 33, 8.2.1979, p. 36. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

¹⁰ OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2004/21/EC (OJ L 57, 25.2.2004, p. 4).

¹¹ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
⇒ new

- (9) Exports of substances covered by the Convention ~~and exports of lindane~~ are regulated by ~~Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals¹²~~ Regulation (EU) No 649/2012 of the European Parliament and of the Council¹³ ⇒ and therefore need not be further addressed in this Regulation ⇐ .
- ~~(11) The production and use of hexachlorocyclohexane (HCH), including lindane, is subject to restrictions under the Protocol but not totally prohibited. That substance is still used in some Member States and therefore it is not possible to prohibit immediately all existing uses. However, in view of the harmful properties of HCH and the possible risks related to its release into the environment, its production and uses should be confined to a minimum and ultimately phased out by the end of 2007 at the latest.~~
- (10) Obsolete or carelessly managed stockpiles of ~~persistent organic pollutants~~ ☒ POPs ☒ may seriously endanger the environment and human health through, for instance, contamination of soil and ground water. It is appropriate, therefore, to ☒ lay down stricter rules concerning the management of such stockpiles compared to those ☒ ~~adopt provisions that go beyond the provisions~~ laid down in the Convention. Stockpiles of prohibited substances should be treated as waste, while stockpiles of substances the ~~production~~ ⇒ manufacturing ⇐ or use of which is still allowed should be notified to the authorities and properly supervised. In particular, existing stockpiles which consist of or contain banned ~~persistent organic pollutants~~ ☒ POPs ☒ should be managed as waste as soon as possible. ~~If other substances are banned in the future, their stocks should also be destroyed without delay and no new stockpiles should be built up. In view of the particular problems of certain new Member States, adequate financial and technical assistance should be provided through existing Community financial instruments, such as the Cohesion and Structural Funds.~~
- (11) In line ~~with the Communication from the Commission on the Community Strategy for Dioxins, Furans and Polychlorinated Biphenyls (PCBs)¹⁴~~, and with the Protocol and the Convention, releases of ~~persistent organic pollutants~~ ☒ POPs ☒ which are unintentional by-products of industrial processes should be identified and reduced as soon as possible with the ultimate aim of elimination, where feasible. Appropriate national action plans, covering all sources and measures, including those provided for under existing ~~Community~~ ☒ Union ☒ legislation, should be ~~drawn up and~~ implemented ☒ and developed ☒ to reduce the ☒ such ☒ releases continuously and cost-effectively ~~as soon as possible~~. To this end, appropriate tools should be developed in the framework of the Convention.
- (12) ~~In line with that Communication,~~ appropriate programmes and mechanisms should be established ☒ or maintained, as appropriate, ☒ to provide adequate monitoring data on the presence of dioxins, furans, ~~and~~ ☒ polychlorinated biphenyls ☒ (PCBs) ⇒ and other relevant

¹² ~~OJ L 63, 6.3.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 775/2004 (OJ L 123, 27.4.2004, p. 27).~~

¹³ Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p. 60).

¹⁴ ~~OJ C 322, 17.11.2001, p. 2.~~

POPs ⇐ in the environment. However, it is necessary to ensure that appropriate tools are available and can be used under economically and technically viable conditions.

- (13) Under the Convention, the ~~persistent organic pollutant~~ ☒ POP ☒ content in waste is to be destroyed or irreversibly transformed into substances that do not exhibit similar characteristics, unless other operations are environmentally preferable. ☒ In order for the Union to comply with its obligations under the Convention, it is necessary to ☒ ~~Since current Community legislation on waste does not~~ lay down specific rules as regards those substances, ~~they should be laid down in this Regulation~~. To ensure a high level of protection, common concentration limits for the substances in waste should be established ~~before 31 December 2005~~ ⇒ , monitored and enforced ⇐ .
- (14) ~~The importance of identifying and separating~~ ☒ It is important to identify and separate ☒ waste consisting of, containing or contaminated by ~~persistent organic pollutants~~ ☒ POPs ☒ at source in order to minimise the spreading of those chemicals into other waste ~~is recognised~~. ~~Council Directive 91/689/EEC of 12 December 1991 on hazardous waste⁴⁵ Directive 2008/98/EC established~~ ☒ establishes ☒ ~~Community~~ ☒ Union ☒ rules on the management of hazardous waste obliging Member States to take the necessary measures to require that establishments and undertakings which dispose of, recover, collect or transport hazardous waste do not mix different categories of hazardous waste or mix hazardous waste with non-hazardous waste.

↓ new

- (15) There is a need to ensure the effective coordination and management of technical and administrative aspects of this Regulation at Union level. The European Chemicals Agency ("the Agency"), established by Regulation (EC) No 1907/2006, has the competence and experience in implementing Union legislation on chemicals and international agreements on chemicals. The Member States and the Agency should, therefore, carry out tasks with regard to the administrative, technical and scientific aspects of the implementation of this Regulation and the exchange of information. The role of the Agency should include the preparation and examination of technical dossiers, including stakeholder consultations, and the drawing up of opinions that may be used by the Commission in considering whether to come forward with a proposal for listing a substance as a POP in the Convention or the Protocol. In addition, the Commission, the Member States and the Agency should cooperate in order to implement the Union's international obligations under the Convention effectively.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
⇒ new

- (16) The Convention provides that each Party is to draw up ⇒ and endeavour to implement, as appropriate, ⇐ a plan for the implementation of its obligations under the Convention. Member States should provide opportunities for public participation in drawing up ⇒ , implementing and updating ⇐ their implementation plans. Since the ~~Community~~ ☒ Union ☒ and the Member States share competence in that regard, implementation plans should be drawn up both at national and ~~Community~~ ☒ Union ☒ level. Cooperation and an exchange of information

¹⁵

OJ L 377, 31.12.1991, p. 20. Directive as amended by Directive 94/31/EC (OJ L 168, 2.7.1994, p. 28).

between the Commission ⇨ , the Agency ⇨ and the authorities of the Member States should be promoted.

⇩ new

- (17) Substances listed in Part A to Annex I or Part A to Annex II to this Regulation should only be allowed to be manufactured and used as closed-system site-limited intermediates if an annotation to that effect is expressly entered in that Annex and if the manufacturer confirms to the Member State concerned that the substance is only manufactured and used under strictly controlled conditions.

⇩ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
⇨ new

- (18) In accordance with the Convention and the Protocol, information on ~~persistent-organic pollutants~~ ⇨ POPs ⇨ should be provided to other Parties ⇨ to those Agreements ⇨ . The exchange of information with third countries not party to those Agreements should also be promoted.
- (19) ⇨ Since ⇨ ~~p~~Public awareness of the hazards that ~~persistent-organic pollutants~~ ⇨ POPs ⇨ pose to the health of present and future generations as well as to the environment, particularly in developing countries, is often lacking, ~~and~~ wide-scale information is ~~therefore~~ needed to increase the level of caution and ~~gain support~~ ⇨ public understanding of the rationale ⇨ for restrictions and bans. In accordance with the Convention, public awareness programmes on ~~these those~~ substances, especially for the most vulnerable groups, as well as training of workers, scientists, educators, technical and managerial personnel should be promoted and facilitated, as appropriate.

⇩ new

- (20) In order to promote the development of a comprehensive chemical exposure and toxicity knowledge base, in line with the General Union Environment Action Programme to 2020 "Living well, within the limits of our planet" (the 7th EAP)¹⁶, the Commission has established the Information Platform for Chemical Monitoring¹⁷. The use of this platform should be encouraged as a means for Member States to comply with their obligations to report chemical occurrence data and to simplify and reduce their reporting obligations.

⇩ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
⇨ new

- (21) Upon request and within available resources, the Commission ⇨ , the Agency ⇨ and the Member States should cooperate in providing appropriate and timely technical assistance designed especially to strengthen the capacity of developing countries and countries with

¹⁶ OJEU L 354, 28.12.2013, p. 171

¹⁷ <https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html> and Commission Staff Working Document SWD(2016) 188 final.

economies in transition to implement the Convention. Technical assistance should include the development and implementation of suitable alternative products, methods and strategies, ~~inter alia, to the use of DDT in disease vector control which, under the Convention, can only be used in accordance with World Health Organisation recommendations and guidelines and~~ to ensure that POPs only continue to be used when locally safe, effective and affordable alternatives are not available to the country in question.

- ~~(22)~~ There should be regular evaluation of the effectiveness of the measures taken to reduce releases of ~~persistent organic pollutants~~ POPs. To that end, Member States should report regularly, in standardised form, to the ~~Commission~~ Agency, in particular as regards release inventories, notified stockpiles and the ~~production~~ manufacturing and placing on the market of restricted substances. ~~The Commission, in cooperation with Member States, should develop a common format for Member States' reports.~~

↓ new

- (23) To address the need for information on implementation and compliance, an alternative system of collecting and making information available should be introduced taking account of the results of the Commission Report on Actions to Streamline Environmental Reporting¹⁸ and its related Fitness Check. In particular, Member States should make accessible all relevant data. This should ensure that the administrative burden on all entities remains as limited as possible. It requires that active dissemination at national level should be done in accordance with Directive 2003/4/EC of the European Parliament and of the Council¹⁹ and Directive 2007/2/EC of the European Parliament and of the Council (INSPIRE)²⁰, to ensure the appropriate infrastructure for public access, reporting and data-sharing between public authorities. In that context, Member States and the Agency should base the specifications for spatial data on the implementing acts adopted under Directive 2007/2/EC.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)

- ~~(24)~~ The Convention and the Protocol provide that Parties thereto may propose ~~other~~ additional substances for international action and consequently additional substances may be listed under those Agreements. ~~In which case~~ such cases, this Regulation should be amended accordingly. ~~Furthermore, it should be possible to modify the existing entries in Annexes to this Regulation, inter alia for the purposes of adapting them to scientific and technical progress.~~

↓ new

- (25) The power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to permit, where appropriate, the manufacture and use of a substance listed in Part A to Annex I or Part A to Annex II to this Regulation as a closed-system site-limited

¹⁸ COM (2017) 312 available at: http://ec.europa.eu/environment/legal/reporting/pdf/action_plan_env_issues.pdf

¹⁹ Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).

²⁰ Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1).

intermediate, to establish concentration limits for a substance for the purposes of Annexes IV and V and to amend the Annexes to this Regulation in order to adapt them to any change to the list of substances set out in the Annexes to the Convention or the Protocol as well as to modify existing entries or provisions in the Annexes to this Regulation in order to adapt them to scientific and technical progress.

- (26) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council should receive all documents at the same time as Member States' experts, and their experts should systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)

- (27) When Annexes to this Regulation are amended to implement any listings of an additional, intentionally produced ~~persistent organic pollutant~~ ☒ POP ☒ in the Protocol or in the Convention, ~~the~~ ☒ the listing ☒ should be included in Annex II, instead of Annex I, only in exceptional cases and when duly justified.

~~(24) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission²⁴~~

↓ new

- (28) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt additional measures relating to waste management and to specify the minimum information to be provided by Member States in monitoring the implementation of this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²².

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
⇒ new

- (29) In order to ensure transparency, impartiality and consistency at the level of enforcement activities, Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive, since non-compliance can result in damage to human health and the environment. ⇒ To ensure consistent and effective enforcement of this Regulation, the Member States should coordinate relevant activities and exchange information

²¹ ~~OJ L 184, 17.7.1999, p. 23.~~

²² Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

in the Forum for Exchange of Information on Enforcement established under Regulation (EC) No 1907/2006. ~~Information on infringements of the provisions of this Regulation should be made public, where appropriate.~~

- (30) Since the objectives of this Regulation, namely to protect the environment and human health from ~~persistent organic pollutants~~ ~~POPs~~ , cannot be sufficiently achieved by the Member States, owing to the transboundary effects of those pollutants, and can therefore be better achieved at ~~Community~~ ~~Union~~ level, the ~~Community~~ ~~Union~~ may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty ~~on the European Union~~ . In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

~~In the light of the above, Directive 79/117/EEC should be amended,~~

HAVE ADOPTED THIS REGULATION

Article 1

~~Objective and scope~~ ~~Subject matter~~

~~1. Taking into account, in particular, the precautionary principle, the objective of~~ ~~†This Regulation is~~ ~~lays down rules, underpinned by the precautionary principle,~~ ~~to protect human health and the environment from persistent organic pollutants~~ ~~POPs~~ by prohibiting, phasing out as soon as possible, or restricting the ~~production~~ ~~⇒ manufacturing~~ , placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants, hereinafter ‘the Convention’, or the ~~1998~~ Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, hereinafter ‘the Protocol’, and by minimising, with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of ~~these~~ ~~those~~ substances.

~~2. Articles 3 and 4 shall not apply to waste consisting of, containing or contaminated by any substance listed in Annexes I or II.~~

Article 2

Definitions

For the purposes of this Regulation:

- (a) ‘placing on the market’ means supplying or making available ~~to third persons against~~ ~~,~~ whether in return for ~~payment or free of charge~~ ~~,~~ to a third party ~~,~~ . Imports into the customs territory of the ~~Community~~ ~~Union~~ shall ~~also~~ be deemed to be ~~placed~~ ~~placing~~ ~~on the market;~~
- (b) ‘article’ means an object composed of one or more substances and/or ~~preparations~~ ~~mixtures~~ which during production is given a ~~specific~~ ~~special~~ shape, surface or design ~~determining~~ which determines ~~its end-use~~ function to a greater ~~extent~~ ~~degree~~ ~~than~~ ~~its chemical composition does;~~

- (c) 'substance' ~~is as defined in Article 2 of Council Directive 67/548/EEC²³~~ ☒ means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition ☒ ;
- (d) ~~'preparation' is as defined in Article 2 of Directive 67/548/EEC~~ ☒ 'mixture' means a mixture or solution composed of two or more substances ☒;

↓ new

- (e) 'manufacturing' means production or extraction of substances in the natural state;
- (f) 'use' means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)

- (ge) 'waste' ☒ means any substance or object which the holder discards or intends or is required to discard ☒ ~~is as defined in Article 1(a) of Council Directive 75/442/EEC²⁴~~;
- (hf) 'disposal' ☒ means any operation which is not recovery even where the operation has as a secondary consequence the reclamation of substances or energy ☒ ~~is as defined in Article 1(e) of Directive 75/442/EEC~~;
- (ig) 'recovery' ☒ means any operation the principal result of which is waste serving a useful purpose by replacing other materials which would otherwise have been used to fulfil a particular function, or waste being prepared to fulfil that function, in the plant or in the wider economy ☒ ~~is as defined in Article 1(f) of Directive 75/442/EEC~~;

↓ new

- (j) 'closed system site-limited intermediate' means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into one or more other substances and where the manufacture of the intermediate and its transformation into one or more other substances take place on the same site under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle.

²³ ~~Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ P 196, 16.8.1967, p. 1). Directive as last amended by Council Regulation (EC) No 807/2003.~~

²⁴ ~~Council Directive 75/442/EEC of 15 July 1975 on waste (OJ L 194, 25.7.1975, p. 39). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).~~

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
⇒ new

Article 3

Control of ~~production~~ ☒ manufacturing ☒, placing on the market and use

1. The ⇒ manufacturing ⇐ ~~production~~, placing on the market and use of substances listed in Annex I, whether on their own, in ~~preparation~~ ☒ mixtures ☒ or as constituents of articles, shall be prohibited.
2. The ~~production~~ ⇒ manufacturing ⇐, placing on the market and use of substances listed in Annex II, whether on their own, in ~~preparation~~ ☒ mixtures ☒ or as constituents of articles, shall be restricted in accordance with the conditions set out in that Annex.
3. Member States and the Commission shall, within the assessment and authorisation schemes for existing and new ~~chemicals and pesticides~~ ☒ substances ☒ under the relevant ~~Community~~ ☒ Union ☒ legislation, take into consideration the criteria set out in paragraph 1 of Annex D to the Convention and take appropriate measures to control existing chemicals and pesticides and prevent the ~~production~~ ⇒ manufacturing ⇐, placing on the market and use of new chemicals and pesticides, which exhibit characteristics of ~~persistent organic pollutants~~ ☒ POPs ☒.

Article 4

Exemptions from control measures

1. Article 3 shall not apply in the case of:
 - (a) a substance used for laboratory-scale research or as a reference standard;
 - (b) a substance occurring as an unintentional trace contaminant in substances, ~~preparations~~ ☒ mixtures ☒ or articles;

↓ new

- (c) waste consisting of, containing or contaminated by any substance listed in Annex I or II.
-

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
⇒ new

2. ⇒ For a substance added to Annex I or II after [date of entry into force of this Regulation], ⇐ Article 3 shall not apply ⇒ for a six months period ⇐ ~~in respect of substances occurring~~ ☒ if that substance occurs ☒ as a constituent of articles produced before or on the date ⇒ that this Regulation becomes applicable to that substance ⇐ ~~of entry into force of this Regulation until six months after the date of its entry into force.~~

Article 3 shall not apply in the case of a substance occurring as a constituent of articles already in use before or on the date ~~of entry into force of this Regulation~~ ⇒ that this Regulation or Regulation (EC) No 850/2004 became applicable to that substance, whichever date came first ⇐.

However, immediately upon becoming aware of articles referred to in the first and second subparagraph, a Member State shall inform the Commission \Rightarrow and the European Chemicals Agency established by Regulation (EC) No 1907/2006 ("the Agency") \Leftarrow accordingly.

Whenever the Commission is so informed or otherwise learns of such articles, it shall, where appropriate, notify the Secretariat of the Convention accordingly without further delay.

3. Where a substance is listed in Part A of Annex I or in Part A of Annex II, a Member State wishing to permit, until the deadline specified in the relevant Annex, the ~~production~~ \Rightarrow manufacturing \Leftarrow and use of that substance as a closed-system site-limited intermediate shall notify accordingly the Secretariat of the Convention.

However, such notification may be made only if the following conditions are satisfied:

(a) an annotation has been entered in the relevant Annex \Rightarrow , by means of a delegated act in accordance with Article 18, \Leftarrow expressly to the effect that such ~~production~~ \Rightarrow manufacturing \Leftarrow and use of that substance may be permitted;

(b) \Rightarrow the manufacturer demonstrates that \Leftarrow the manufacturing process will transform the substance into one or more other substances that do not exhibit the characteristics of a ~~persistent organic pollutant~~ \boxtimes POP \boxtimes ;

~~(c) it is not expected that either humans or the environment will be exposed to any significant quantities of the substance during its production and use, as shown through assessment of that closed system in accordance with Commission Directive 2001/59/EC²⁵;~~

\Downarrow new

(c) the manufacturer confirms that the substance is a closed-system site-limited intermediate within the meaning of Article 2(j).

\Downarrow Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
 \Rightarrow new

The notification shall be communicated also to the other Member States~~;~~ and to the Commission \Rightarrow and the Agency \Leftarrow and shall give details of actual or estimated total ~~production~~ \Rightarrow manufacturing \Leftarrow and use of the substance concerned and the nature of the closed-system site-limited process, specifying the amount of any non-transformed and unintentional trace contamination by any ~~persistent organic pollutant~~ \boxtimes POP \boxtimes starting material in the final product.

\Rightarrow The Commission is empowered to adopt delegated acts in accordance with Article 18 \Leftarrow \boxtimes in order to amend \boxtimes ~~the~~ deadlines \boxtimes in an annotation \boxtimes referred to in the ~~first~~ second subparagraph ~~may be amended~~ in cases where, following a repeat notification from the Member State concerned to the Secretariat of the Convention, express or tacit consent is issued under the Convention for the continued ~~production~~ \Rightarrow manufacturing \Leftarrow and use of the substance for another period.

²⁵ ~~Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 225, 21.8.2001, p. 1).~~

4. Paragraphs 2 and 3 shall not apply to waste consisting of, containing or contaminated by any substance listed in Annexes I or II.

Article 5

Stockpiles

1. The holder of a stockpile, which consists of or contains any substance listed in Annex I or Annex II, for which no use is permitted, shall manage that stockpile as waste and in accordance with Article 7.

2. The holder of a stockpile greater than 50 kg, consisting of or containing any substance listed in Annex I or Annex II, and the use of which is permitted shall provide the competent authority of the Member State in which the stockpile is established with information concerning the nature and size of that stockpile. Such information shall be provided within 12 months of the ☐ date that this Regulation or ☐ entry into force of this Regulation ☒ (EC) No 850/2004 ☒ ☐ became applicable to that substance, whichever date came first for the holder, ☐ and of ☒ relevant ☒ amendments to Annexes I or II and annually thereafter until the deadline specified in Annex I or II for restricted use.

The holder shall manage the stockpile in a safe, efficient and environmentally sound manner.

3. Member States shall monitor the use and management of notified stockpiles.

Article 6

Release reduction, minimisation and elimination

1. Within two years of the date of entry into force of ☐ this Regulation or ☐ this Regulation ☒ (EC) No 850/2004, ☒ ☐ whichever date came first ☐ , Member States shall draw up ~~and maintain release~~ inventories for the substances listed in Annex III ☒ released ☒ into air, water and land in accordance with their obligations under the Convention and the Protocol ☒ and shall subsequently maintain such inventories ☒ .

2. ~~A Member State~~ ☒ States ☒ shall communicate ~~its~~ ☒ their ☒ action ~~plan~~ ☒ plans ☒ on measures to identify, characterise and minimise, with a view to eliminating where feasible as soon as possible, the total releases ☒ of substances listed in Annex III ☒ developed ☒ as recorded in their inventories drawn up ☒ in accordance with ~~its~~ ☒ their ☒ obligations under the Convention, to ~~both~~ the Commission ☐ , the Agency ☐ and ☒ to ☒ the other Member States as part of ~~its~~ ☒ their ☒ national implementation ~~plan~~ ☒ plans ☒ , pursuant to Article 9 ~~8~~.

~~The~~ ☒ Such ☒ action ~~plan~~ ☒ plans ☒ shall include measures to promote the development ☒ of, ☒ and, where ☒ it is considered ☒ ~~deems~~ appropriate, shall require the use of substitute or modified ~~materials, products~~ ☐ substances, mixtures, articles ☐ and processes to prevent the formation and release of ~~the~~ substances listed in Annex III.

3. Member States shall, when considering proposals to construct new facilities or ☒ to ☒ significantly ~~to~~ modify existing facilities using processes that release chemicals listed in Annex III,

~~without prejudice to Council Directive 1996/61/EC²⁶~~; give priority consideration to alternative processes, techniques or practices that have similar usefulness but which avoid the formation and release of substances listed in Annex III ~~☒~~, without prejudice to Directive 2010/75/EU of the European Parliament and of the Council²⁷ ~~☒~~.

Article 7

Waste management

1. Producers and holders of waste shall undertake all reasonable efforts to avoid, where feasible, contamination of this waste with substances listed in Annex IV.

2. Notwithstanding Council Directive 96/59/EC²⁸, waste consisting of, containing or contaminated by any substance listed in Annex IV shall be disposed of or recovered, without undue delay and in accordance with part 1 of Annex V, ~~part 1~~ in such a way as to ensure that the ~~persistent organic pollutant~~ ~~☒~~ POP ~~☒~~ content is destroyed or irreversibly transformed so that the remaining waste and releases do not exhibit the characteristics of ~~persistent organic pollutants~~ ~~☒~~ POPs ~~☒~~.

In carrying out such a disposal or recovery, any substance listed in Annex IV may be isolated from the waste, provided that this substance is subsequently disposed of in accordance with the first subparagraph.

3. Disposal or recovery operations that may lead to recovery, recycling, reclamation or re-use of the substances listed in Annex IV shall be prohibited.

4. By way of derogation from paragraph 2:

↓ 219/2009 Art. 1 and Annex .3(7)
(adapted)

(a) waste containing or contaminated by any substance listed in Annex IV may be otherwise disposed of or recovered in accordance with the relevant ~~Community~~ ~~☒~~ Union ~~☒~~ legislation, provided that the content of the listed substances in the waste is below the concentration limits ~~to be specified in Annex IV. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 17(3). Until such time as concentration limits are established in accordance with such procedure, the competent authority of a Member State may adopt or apply concentration limits or specific technical requirements in respect of the disposal or recovery of waste under this point.~~

²⁶ ~~Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L 257, 10.10.1996, p. 26. Directive as last amended by Regulation (EC) No 1882/2003.~~

²⁷ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

²⁸ Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) (OJ L 243, 24.9.1996, p. 31).

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
→₁ 219/2009 Art. 1 and Annex .3(7)
⇒ new

(b) a Member State or the competent authority designated by that Member State may, in exceptional cases, allow wastes listed in part 2 of Annex V, ~~part 2~~ containing or contaminated by ~~any~~ ☒ a ☒ substance listed in Annex IV up to concentration limits ~~to be specified in part 2 of Annex V, part 2~~ to be otherwise dealt with in accordance with a method listed in part 2 of Annex V, ~~part 2~~ provided that ☒ the following conditions are fulfilled ☒ :

(i) the holder concerned has demonstrated to the satisfaction of the competent authority of the Member State concerned that decontamination of the waste in relation to substances listed in Annex IV was not feasible, and that destruction or irreversible transformation of the ~~persistent organic pollutant~~ ☒ POP ☒ content, performed in accordance with best environmental practice or best available techniques, does not represent the environmentally preferable option and the competent authority has subsequently authorised the alternative operation;

(ii) ~~this~~ ☒ ~~the~~ ☒ operation is in accordance with relevant ~~Community~~ ☒ Union ☒ legislation and ☒ with ☒ the conditions laid down in relevant additional measures referred to in paragraph 6;

(iii) the Member State concerned has informed the other Member States ⇒ , the Agency ⇐ and the Commission of its authorisation and the justification for it.

5.→₁ ⇒ The Commission is empowered to adopt delegated acts in accordance with Article 18 to amend Annex IV and part 2 of Annex V ⇐ ☒ in order to establish ☒ ~~concentration limits in Annex V, part 2 shall be established by the Commission~~ for the purposes of paragraph 4(b) of this Article. ~~Those measures, designed non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 17(3).~~

← Until such time as ~~these~~ those concentration limits are established,

~~(a)~~ the competent authority ☒ of a Member State ☒ may adopt or apply concentration limits or specific technical requirements ~~in respect~~ ☒ for the purposes ☒ of ~~waste being dealt with under~~ paragraph 4(b).

~~(b) where~~ ☒ In respect of ☒ waste ~~is~~ being dealt with under paragraph 4(b), the holders concerned shall provide information on the ~~persistent organic pollutant~~ ☒ POP ☒ content of the waste to the competent authority.

6. The Commission may, where appropriate, and taking into consideration technical developments and relevant international guidelines and decisions and any authorisations granted by a Member State, or ☒ by ☒ the competent authority designated by that Member State in accordance with paragraph 4 and Annex V, adopt ⇒ , by means of implementing acts, ⇐ additional measures relating to the implementation of this Article. ☒ In particular, ☒ ~~the Commission shall~~ ⇒ may ⇐ ~~define a format for the submission of~~ ☒ specify ☒ the information ☒ to be submitted ☒ by Member States in accordance with paragraph 4(b)(iii). Such measures shall be decided in accordance with the ⇒ advisory ⇐ procedure laid down in Article ~~17~~20(2).

~~7. The Commission shall, before 31 December 2009, review the derogations in paragraph 4 in the light of international and technical developments, in particular with regard to their environmental preferability.~~

↓ new

Article 8

Tasks of the Agency

1. The Agency shall, in addition to the tasks allocated to it under Articles 9, 10, 11, 13 and 17, carry out the following tasks:

- (a) provide the designated competent authorities of the Member States, with the agreement of the Commission, with assistance and technical and scientific guidance in order to ensure the effective application of this Regulation;
- (b) upon request, provide the Commission with technical and scientific input and assist it in order to ensure the effective implementation of this Regulation;
- (c) upon request, provide technical and scientific support and input to the Commission for substances that may comply with the criteria for listing in the Convention or the Protocol;
- (d) upon request, provide the Commission with technical and scientific support in the preparation and review of the risk profile and the risk management evaluation of a substance considered under the Stockholm Convention;
- (e) upon request, provide the Commission with technical and scientific support in implementing the Convention, in particular with respect to the POPs Review Committee;
- (f) compile, register, process and make available to the Commission and the competent authorities of the Member States all the information received or available pursuant to Article 4(2) and (3), Article 7(4)(b)(iii), Article 9(2), Article 13(1). The Agency shall make the non-confidential information publicly available on its website and shall facilitate the exchange of that information with relevant information platforms such as those referred to in Article 13(2);
- (g) establish and maintain sections on its website for all matters relating to the implementation of this Regulation.

2. The Forum for Exchange of Information on Enforcement established by Regulation (EC) No 1907/2006 shall be used to coordinate activities of the Member States' authorities responsible for enforcement of this Regulation.

3. The Secretariat of the Agency shall carry out the tasks allocated to the Agency under this Regulation.

Article ~~8~~ 9

Implementation plans

1. When preparing ⇒ and updating ⇐ their national implementation plans, Member States shall, in accordance with their national procedures, give the public early and effective opportunities to participate in this process.
 2. As soon as a Member State has adopted its national implementation plan in accordance with its obligations under the Convention, it shall ⇒ make it publicly available and ⇐ communicate ~~it~~ ⇐ its publication ⇐ both to the Commission ⇒ , the Agency ⇐ and to the other Member States.
 3. When ⇐ Member States are ⇐ preparing ⇒ and updating ⇐ their implementation plans, the Commission ⇒ , supported by the Agency, ⇐ and the Member States shall exchange information on the content, as appropriate.
 4. The Commission ⇒ , supported by the Agency, ⇐ shall, ~~within two years of the entry into force of this Regulation, draw up~~ ⇐ maintain ⇐ a plan for the implementation of ~~Community~~ ⇐ Union ⇐ obligations under the Convention.
- ~~As soon as the Commission has adopted the Community implementation plan, it shall communicate it to the Member States.~~
- ~~The Commission~~ ⇐ and ⇐ shall ⇒ publish, ⇐ review and update ~~the Community implementation~~ that ⇐ plan ⇐ , as appropriate.

Article ~~9~~ 10

Monitoring

The Commission ⇒ , supported by the Agency, ⇐ and the Member States shall establish ⇐ or maintain, as appropriate ⇐ , in close cooperation, appropriate programmes and mechanisms, consistent with the state of the art, for the regular provision of comparable monitoring data on the presence of dioxins, furans and PCBs as identified in Annex III in the environment. When establishing ⇐ or maintaining ⇐ such programmes and mechanisms, due account shall be taken of developments under the Protocol and the Convention.

Article ~~10~~ 11

Information exchange

1. The Commission ⇒ , the Agency ⇐ and the Member States shall facilitate and undertake the exchange within the ~~Community~~ ⇐ Union ⇐ and with third countries of information relevant to the reduction, minimisation or elimination, where feasible, of the ~~production~~ ⇒ manufacturing ⇐ , use and release of ~~persistent organic pollutants~~ ⇐ POPs ⇐ and to alternatives to those substances, specifying the risks and the economic and social costs related to such alternatives.
2. The Commission ⇒ , the Agency ⇐ and ⇐ the ⇐ Member States, as appropriate, shall promote and facilitate with regard to ~~persistent organic pollutants~~ ⇐ POPs ⇐ :

(a) awareness programmes, including relating to their health and environmental effects and their alternatives and on the reduction or elimination of their ~~production~~ ⇒ manufacture ⇐ , use and release, especially for:

(i) policy and decision makers,

(ii) particularly vulnerable groups;

(b) the provision of public information;

(c) training, including workers, scientists, educators and technical and managerial personnel.

3. Without prejudice to Directive 2003/4/EC of the European Parliament and of the Council ~~of 28 January 2003 on public access to environmental information~~²⁹, information ⇒ referred to in paragraphs 1 and 2 ⇐ ~~on health and safety of humans and the environment~~ shall not be regarded as confidential. The Commission ⇒ , the Agency ⇐ and the Member States that exchange ~~other~~ information with a third country shall protect any confidential information ⇒ in accordance with Union law ⇐ ~~as mutually agreed~~.

Article ~~11~~ 12

Technical assistance

In accordance with Articles 12 and 13 of the Convention, the Commission and the Member States shall cooperate in providing appropriate and timely technical and financial assistance to developing countries and countries with economies in transition to assist them, upon request and within available resources and taking into account their particular needs, to develop and strengthen their capacity to fully implement their obligations under the Convention. Such support may also be channelled through non-governmental organisations ⇒ or the Agency ⇐ .

Article ~~12~~ 13

~~Reporting~~ ☒ Monitoring of implementation ☒

⇓ new

1. Without prejudice to Directive 2003/4/EC and Directive 2007/2/EC, Member States shall draw up, publish and keep up-to-date a report containing:

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
⇒ new

(a) ~~1. Member States shall every three years forward to the Commission~~ information on the application of this Regulation, including information on ⇒ enforcement activities, ⇐ infringements and penalties;

~~3. Within three years of the date of entry into force of this Regulation and every three years thereafter Member States shall provide the Commission with:~~

²⁹ Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).

- (a) ~~summary~~ information compiled from the notifications, ~~concerning stockpiles~~, received pursuant to \Rightarrow Article 4(2) and (3), \Leftarrow Article 5(2) \Rightarrow and Article 7(4)(b)(iii) \Leftarrow ;
- (b) ~~summary~~ information compiled from the release inventories drawn up pursuant to Article 6(1);

\Downarrow new

- (d) information on implementation in accordance with the national implementation plans drawn up pursuant to Article 9(2);

\Downarrow Corrigendum, OJ L 229, 29.6.2004, p. 5 (adapted)
 \Rightarrow new

- (e) ~~summary~~ information on the presence of dioxins, furans and PCBs as identified in Annex III in the environment, as compiled pursuant to Article ~~9~~ 10;
- (f) ~~2. Member States shall provide the Commission every year with~~ \boxtimes annual \boxtimes \Rightarrow monitoring and \Leftarrow statistical data on the actual or estimated total ~~production~~ \Rightarrow manufacturing \Leftarrow and placing on the market of any substance listed in Annex I or II \Rightarrow , including relevant indicators, overview maps, reports \Leftarrow .

\Downarrow new

Member States shall give the Commission and the Agency access to the information contained in the reports.

2. Where a Member State shares the information referred to in paragraph 1(e) with the Information Platform for Chemical Monitoring, this shall be indicated by that Member State in its report and the Member State shall be considered to have fulfilled its reporting obligations under that point.

Where the information referred to in paragraph 1(e) is contained in the report of a Member State provided to the Agency, the Agency shall use the Information Platform for Chemical Monitoring for compiling, storing and sharing that information.

\Downarrow Corrigendum, OJ L 229, 29.6.2004, p. 5 (adapted)
 \Rightarrow new

~~4. As regards the data and information to be provided by Member States pursuant to paragraphs 1, 2 and 3, the Commission shall develop in advance a common format in accordance with the procedure referred to in Article 16(2).~~

~~5~~3. Regarding the substances listed in the Convention, the Commission \Rightarrow , supported by the Agency, \Leftarrow shall, at \boxtimes the \boxtimes intervals ~~to be~~ determined by the Conference of the Parties of the Convention, compile a report on the basis of the information provided by the Member States \Rightarrow to the Agency \Leftarrow in accordance with paragraph ~~2~~ 1(f) and communicate it to the Secretariat of the Convention.

~~6. The Commission shall every three years compile a report on the application of this Regulation and shall integrate it with the information already available in the context of the EPER, as established by~~

~~Commission Decision 2000/479/EC³⁰, and CORINAIR Emission Inventory of EMEP (Cooperative Programme for Monitoring and Evaluation of the Long Range Transmission of Air Pollutants in Europe), and with the information provided by the Member States under paragraphs 1, 2 and 3 to form a synthesis report. This report shall include information on the use of derogations as referred to in Article 7(4). It shall forward a summary of the synthesis report to the European Parliament and to the Council and make it available to the public without delay.~~

↓ new

4. The Agency shall compile and publish a Union overview on the basis of the data referred to in paragraphs 1 and 2 that is published or notified by the Member States. The Union overview shall include, as appropriate, indicators for outputs, results and impacts of this Regulation, Union overview maps and Member State reports. The Union overview shall be updated by the Agency at least once every six months or following receipt of a request from the Commission.

5. The Commission may adopt implementing acts further specifying the minimum information to be provided in accordance with paragraph 1, including the definition of indicators, maps and Member State overviews referred to in paragraph 1(f). Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 20(2).

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)

Article ~~13~~ 14

Penalties

Member States shall lay down ~~the~~ rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. ~~The~~ ☒ Where ☒ Member States ☒ have not already done so before the entry into force of this Regulation, they ☒ shall notify those provisions to the Commission one year after entry into force of this Regulation at the latest and shall notify it without delay of any subsequent amendment affecting them.

↓ 219/2009 Art. 1 and Annex .3(7)

Article ~~14~~ 15

Amendment of Annexes

~~1. Whenever a substance is listed in the Convention or the Protocol, the Commission shall, where appropriate, amend Annexes I, II and III accordingly.~~

~~Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 16(3).~~

³⁰ ~~Commission Decision 2000/479/EC of 17 July 2000 on the implementation of a European pollutant emission register (EPER) according to Article 15 of Council Directive 96/61/EC concerning integrated pollution prevention and control (IPPC) (OJ L 192, 28.7.2000, p. 36).~~

~~2. Whenever a substance is listed in the Convention or the Protocol, the Commission shall, where appropriate, amend Annex IV accordingly.~~

~~Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 17(3).~~

~~3. The Commission shall adopt modifications to the existing entries in Annexes I, II and III, including their adaptation to scientific and technical progress.~~

~~Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 16(3).~~

~~4. The Commission shall adopt modifications to the existing entries in Annex IV and modifications to Annex V, including their adaptation to scientific and technical progress.~~

~~Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 17(3).~~

↓ new

The Commission is empowered to adopt delegated acts, in accordance with Article 18, to amend the Annexes to this Regulation in order to adapt them to changes to the list of substances set out in the Annexes to the Convention or the Protocol or to modify existing entries or provisions in the Annexes to this Regulation in order to adapt them to scientific and technical progress.

Article 16

The budget of the Agency

1. For the purposes of this Regulation, the revenues of the Agency shall consist of:

- (a) a subsidy from the Union, entered in the general budget of the Union (Commission Section);
- (b) any voluntary contribution from the Member States.

2. Revenues and expenditure for activities under this Regulation shall be combined with those relating to activities under Regulation (EU) No 649/2012 and shall be reflected in the same section in the Agency's budget. The revenues of the Agency referred to in paragraph 1 shall be used for carrying out its tasks under this Regulation.

Article 17

Formats and software for publication or notification of information

The Agency shall specify formats and software for the publication or notification of data by Member States pursuant to this Regulation and make them available free of charge on its website. In relation to spatial data sets, Member States and the Agency shall design the formats in accordance with the requirements of Directive 2007/2/EC. Member States and other parties subject to this Regulation shall use those formats and software in their data management or data exchange with the Agency.

Article 18

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 4(3), 7(5) and 15 shall be conferred on the Commission for an indeterminate period of time from [...].
3. The delegation of power referred to in Articles 4(3), 7(5) and 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 4(3), 7(5) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of [two months] of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by one month at the initiative of the European Parliament or of the Council.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5
(adapted)
⇒ new

Article ~~15~~ 19

Competent authorities

Each Member State shall designate ~~the~~ ☒ a ☒ competent authority or authorities responsible for the administrative tasks ⇒ and enforcement ⇐ required by this Regulation. It shall inform the Commission of such designation at the latest three months after the entry into force of this Regulation ⇒ , unless it has already done so before the entry into force of this Regulation, and shall also inform the Commission of any change of a designated competent authority ⇐ .

Article ~~16~~ 20

Committee ☒ procedure ⇐ for general matters

1. The Commission shall be assisted by the Committee established by Article ~~29 of Directive 67/548/EEC~~ 133 of Regulation (EC) No 1907/2006 for all matters under this Regulation ~~except for those relating to waste~~.
2. Where reference is made to this paragraph, ~~Articles 5 and 7 of Decision 1999/468/EC~~ ⇒ Article 4 of Regulation (EU) No 182/2011 ⇐ shall apply, ~~having regard to the provisions of Article 8 thereof.~~
~~The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.~~

↓ 219/2009 Art. 1 and Annex .3(7)

~~3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.~~

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5

~~Article 17~~

~~Committee for waste matters~~

~~1. The Commission shall be assisted by the Committee established by Article 18 of Directive 75/442/EEC, for matters relating to waste under this Regulation.~~

~~2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.~~

~~The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.~~

↓ 219/2009 Art. 1 and Annex .3(7)

~~3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.~~

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5

~~Article 18~~

~~Amendments to Directive 79/117/EEC~~

~~In Part B of the Annex to Directive 79/117/EEC, 'Persistent organochlorine compounds', items 1 to 8 shall be deleted.~~

↓ new

Article 21

Repeal

Regulation (EC) No 850/2004 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VII.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 5

Article ~~19~~ 22

Entry into force

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.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

Legislative financial statement ‘Agencies’

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

- 1.1. Title of the proposal/initiative
- 1.2. Policy area(s) concerned in the ABM/ABB structure
- 1.3. Nature of the proposal/initiative
- 1.4. Objective(s)
- 1.5. Grounds for the proposal/initiative
- 1.6. Duration and financial impact
- 1.7. Management mode(s) planned

2. MANAGEMENT MEASURES

- 2.1. Monitoring and reporting rules
- 2.2. Management and control system
- 2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected
- 3.2. Estimated impact on expenditure
 - 3.2.1. *Summary of estimated impact on expenditure*
 - 3.2.2. *Estimated impact on [body]'s appropriations*
 - 3.2.3. *Estimated impact on [body]'s human resources*
 - 3.2.4. *Compatibility with the current multiannual financial framework*
 - 3.2.5. *Third-party contributions*
- 3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council on persistent organic pollutants (recast)

1.2. Policy area(s) concerned in the ABM/ABB structure⁴⁴

Policy area: 07 Environment

Activity: 07 02 : Environmental policy at Union and international level

1.3. Nature of the proposal/initiative

☐ The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action⁴⁵**

☒ The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objective(s)

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

This proposal targets the Commission's general objective:

- General Objective 1: A New Boost for Jobs, Growth and investment;

by ensuring implementation of the Stockholm Convention and in particular its objective to protect human health and the environment from persistent organic pollutants by reducing or eliminating releases from their manufacture and use.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective No 3

To safeguard the Union's citizens from environment-related pressures and risks to health and wellbeing

Specific objective No 6

To increase the Union's effectiveness in addressing international environmental challenges

ABM/ABB activity(ies) concerned

Activity: 07 02 : Environmental policy at Union and international level

⁴⁴

ABM: activity-based management; ABB: activity-based budgeting.

⁴⁵

As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

1.4.3. *Expected result(s) and impact*

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The objective of the proposal is to recast Regulation (EC) No 850/2004 to take into account:

- (1) developments in Union legislation on chemicals, in particular Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008;
- (2) the establishment of the European Chemicals Agency (ECHA) under Regulation (EC) No 1907/2006;
- (3) the establishment of the European Pollutant Release and Transfer Register (E-PRTR) by Regulation (EC) No 166/2006;
- (4) the changes stemming from the Lisbon Treaty;
- (5) the findings of the Fitness Check on Environmental Reporting and Monitoring;
- (6) the experience of practical implementation achieved so far.

The expected results/effects are therefore:

- (1) an increase in coherence with other legislation on chemicals, in particular REACH and CLP, and with obligations and procedures under the Stockholm Convention, e.g. on reporting.
- (2) increased synergies with the implementation of REACH, CLP, Biocides and in particular Regulation (EU) No 649/2012, by transferring administrative, technical and scientific work from the Commission to ECHA. The involvement of ECHA is also expected to harmonise and improve the reporting of Member States and consequently the Union Synthesis Report on implementation of the POPs Regulation.
- (3) some proposed amendments will lead to a reduction of the administrative burden regarding reporting obligations by making better use of existing activities, by facilitating and streamlining the reporting and by harmonising with obligations under the Stockholm Convention.

The proposal will therefore continue to meet the aims of the Stockholm Convention, namely to eliminate the release of persistent organic pollutants from their manufacture and use including from waste in order to protect human health and the environment from potential harm. This is done by prohibiting the manufacturing, placing on the market and use of persistent organic pollutants and by establishing provisions regarding environmentally sound treatment of waste consisting of, containing or contaminated by any of these substances.

1.4.4. *Indicators of results and impact*

Specify the indicators for monitoring implementation of the proposal/initiative.

The proposed regulation, as is the case of the current regulation, aims at eliminating the release of persistent organic pollutants from their manufacture and use including from waste in order to protect human health and the environment from potential harm by prohibiting the manufacturing, placing on the market and use of persistent organic pollutants and by establishing provisions regarding environmentally sound treatment of waste consisting of, containing or contaminated by any of these substances. Indicators for monitoring the implementation of the proposal are therefore:

- the number of persistent organic pollutants listed in the Annex to the Regulation;

- the number of persistent organic pollutants completely phased-out from manufacturing, placing on the market and use as soon as possible after their listing in the Regulation;
- the reduction of the release of persistent of persistent organic pollutants into the environment, including unintentional release;
- the time needed to completely phase-out the manufacturing, placing on the market and use of listed persistent organic pollutants;
- the time needed to bring releases of persistent of persistent organic pollutants into the environment, including unintentional releases, to zero;
- the number of problems encountered in the implementation of the proposed regulation and reported to the network of competent authorities coordinated by the Commission.

These indicators will be summarised in the reporting carried out by the Member States, the ECHA and the Commission.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The main requirements to be met is to align Regulation (EC) No 850/2004, which refers to Directive 67/548/EEC and Directive 75/442/EEC, with Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and Directive 2008/98/EC. In addition, Regulation (EC) No 850/2004 refers to a regulatory committee that does not any more exist and needs to be aligned with the Lisbon Treaty.

In addition the transfer of tasks from the Commission to ECHA ensures a more appropriate setting for providing administrative, scientific and technical support to the implementation. Improvements are in particular expected in the areas of Member States reporting and scientific support for the review of POPs candidates.

1.5.2. Added value of EU involvement

The proposed regulation does not alter any of the objectives set in Regulation (EC) No 850/2004 and hence the added value of EU involvement is identical to that of the current regulation.

Regulation (EC) No 850/2004 implements the responsibilities of the Union under the Stockholm Convention, to which the Union committed itself by ratifying the Convention. At the time of adoption of Regulation (EC) No 850/2004 a Union regulation was considered the most efficient means of meeting those obligations and the experience demonstrates that this is still true.

The proposal foresees the transfer of mainly technical and scientific tasks to the European Chemicals Agency, which would be new tasks for the Agency. Due to the expertise of the Agency in the area of chemicals, industry and Member States are expected to benefit from involving this Union Agency since it will result in better coherence, improved implementation and strengthened enforcement.

1.5.3. *Lessons learned from similar experiences in the past*

The experience gained from the implementation of Regulation (EC) No 850/2004 shows that it is appropriate to include certain technical amendments to the operative provisions such as harmonise and clarify some definitions and streamline certain obligations and to involve the European Chemicals Agency in certain tasks in order to create synergies with other legislation on chemicals and to facilitate obligations on the Member States.

The transfer of tasks from the Commission to ECHA is in particular expected to facilitate and improve Member States reporting and consequently the reporting to be done by the Union. In addition, the scientific support *inter alia* for the review of POPs candidates will ensure better coherence with other areas and higher quality.

The recent transfer of certain administrative, technical and scientific tasks from the Commission to ECHA under Regulation (EU) No 649/2012 on export and import of hazardous chemicals resulted in a number of improvements, in particular a reduction of the workload of industry and Member State authorities, streamlined processes and better compliance.

1.5.4. *Compatibility and possible synergy with other appropriate instruments*

The proposal is fully in line with existing policies and objectives aimed at protecting human health and the environment globally such as those laid down in the 7th Environmental Action Programme.

The proposal ensures better coherence with other legal instruments such as Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EC) No 166/2006.

By placing the scientific and technical work related to the implementation of the proposed regulation at the ECHA, synergies are expected with the implementation work carried out by ECHA on REACH, CLP, Biocides and the PIC Regulation (EU) No 649/2012.

1.6. Duration and financial impact

- ☐ Proposal/initiative of **limited duration**
- ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY
- ☐ Financial impact from YYYY to YYYY

X Proposal/initiative of **unlimited duration**

Implementation with a start-up period from 2018 to 2019,
followed by full-scale operation.

1.7. Management mode(s) planned⁴⁶

X Direct management by the Commission through

- ☐ executive agencies
- ☐ **Shared management** with the Member States

X Indirect management by entrusting budget implementation tasks to:

- ☐ international organisations and their agencies (to be specified);
- ☐ the EIB and the European Investment Fund;
- ☒ X bodies referred to in Articles 208 and 209;
- ☐ public law bodies;
- ☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;
- ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;
- ☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

Comments

[...]

[...]

⁴⁶

Details of management modes and references to the Financial Regulation may be found on the BudgWeb site:
<https://myintracomm.ec.europa.eu/budgweb/EN/man/budgmanag/Pages/budgmanag.aspx>.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

- (1) Member States and the Agency will establish, publish on the internet and update reports concerning the operation of the Regulation, including information on infringements and penalties.
- (2) Member States will make available to the Agency and the Commission statistical data on manufacturing and placing on the market of any substance listed in Annex I or II. In addition, Member States will make available information on release of persistent organic pollutants in the environment.
- (3) The Agency in turn will regularly compile a Union overview report containing indicators for outputs, results and impacts of this Regulation and Union overview maps, as appropriate, for the purpose of publication on the Internet and making available to the public, including the European Parliament and to the Council.

2.2. Management and control system

Risk(s) identified

- The main risks are:
- failure of companies to comply with their obligations;
 - incomplete inventories established by the Member States;
 - insufficient monitoring of the presence of POPs in the environment by the Member States;
 - insufficient control and enforcement systems, e.g. controls carried out by the enforcement authorities of the Member States;
 - failure of ECHA to carry out its tasks.

Control method(s) envisaged

- Multiple management and control systems are in place or will be put in place to ensure the appropriate implementation of the proposed regulation:
- Member States are requested to designate competent authorities responsible for the administrative tasks and enforcement;
 - Member States are requested to establish and update their reports, including on monitoring and enforcement activities carried out in their territories;
 - The technical and scientific coordination of the EU's work is monitored through the meeting of the competent authorities, chaired by the Commission;
 - The day-to-day management of the ECHA tasks fall under the responsibility of the Executive Director, who in turn reports to the ECHA Management Board.
- In addition this financial fiche gives the basis for the subsidy necessary for the ECHA to carry out its tasks.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

The standard measures in place to prevent fraud and irregularities in the Commission apply for the tasks carried out by the Commission under this proposal.

In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1037/1999 apply without restrictions to this Agency.

The Agency has acceded to the Inter-institutional Agreement of May 25, 1999 concerning internal investigations by Olaf and has issued the appropriate provisions applicable to its entire staff.

The decisions concerning funding and the implementing agreements and instruments resulting from them stipulate that the Court of Auditors and Olaf may carry out, if necessary, on-the-spot checks of the recipients of the Agency's funding and the agents responsible for allocating it.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	070205	Diff./Non-diff. ⁴⁷	from EFTA countries ⁴⁸	from candidate countries ⁴⁹	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
2	European Chemicals Agency — Activities in the field of legislation on import and export of dangerous chemicals	Diff.	YES	NO	NO	NO

New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading..... ...]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
[...]	[XX.YY.YY.YY] [...]	[...]	YES/NO	YES/NO	YES/NO	YES/NO

⁴⁷ Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

⁴⁸ EFTA: European Free Trade Association.

⁴⁹ Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	2 – Sustainable Growth: Natural Resources
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DG Environment			Year 2019	Year 2020		Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
Title 1: Staff expenditure (*)	Commitments	(1)	0,100	0,100						
	Payments	(2)	0,100	0,100						
Title 2: Infrastructure and operating expenditure	Commitments	(1a)	0,000	0,000						
	Payments	(2a)	0,000	0,000						
Title 3: Operational expenditure	Commitments	(3a)	0,269	0,163						
	Payments	(3b)	0,269	0,163						
TOTAL appropriations for ECHA(**)	Commitments	=1+1a +3a	0,369	0,263						
	Payments	=2+2a +3b	0,369	0,263						

(*) The average standard allocation, including the costs of 'habillage' as well as taking into account higher living costs in Finland.

(**) To be partially redeployed from the budget lines 07 02 03 (which is part of the LIFE sub-programme for Environment).

Heading of multiannual financial framework	5	‘Administrative expenditure’
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EUR million (to three decimal places)

		Year 2019	Year 2020		Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
DG: Environment									
•									
• Other administrative expenditure									

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EUR million (to three decimal places)

		Year N ⁵⁰	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	0,369	0,263						
	Payments	0,369	0,263						

⁵⁰ Year N is the year in which implementation of the proposal/initiative starts.

3.2.2. Estimated impact on ECHA's appropriations

☐ The proposal/initiative does not require the use of operational appropriations

☒ The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ↓			Year 2019		Year 2020		Year		Year N+3		Enter as many years as necessary to show the duration of the impact (see point 1.6)						TOTAL	
	OUTPUTS																	
	Type 51	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVES No 3 and 6 ⁵² ...																		
IT system for			1	0,2	1	0,1												
Risk profile and risk management evaluation			2	0,01	2	0,01												
Union Synthesis report and MS reports			0	0,039	1	0,033												
Union Implementation Plan			0	0,02	1	0,02												
Subtotal for specific objectives No 3 and 6				0,269		0,163												
SPECIFIC OBJECTIVE No 2 ...																		

⁵¹ Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

⁵² As described in point 1.4.2. 'Specific objective(s)...

- Output																		
Subtotal for specific objective No 2																		
TOTAL COST				0,269		0,163												

Current costs for the scientific and technical work that are covered by the operational budget 2015-2016 amount to about 210.000€ per year and cover service contracts. The transfer to the Agency is expected to create high costs in 2019 for development of new software, which would also be necessary for either alternative approach due to the need to harmonise and improve the reporting of the Member States by creating a database. After this initial phase, operating costs are expected to be stable. An investment is necessary in 2019 in particular for IT investments by the Agency. Once the Agency activities have started in 2019, the overall expenditure of the Agency will be stable while an increase in the workload, in particular the preparation of reports, is expected and will result in a decrease of the "unit cost' per output.

3.2.3. Estimated impact on ECHA's human resources

3.2.3.1. Summary

☐ The proposal/initiative does not require the use of appropriations of an administrative nature

☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year 2019	Year 2020		Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)	TOTAL
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Officials (AD Grades)								
Officials (AST grades)								
Contract staff	1	1						
Temporary staff								
Seconded National Experts								

TOTAL	1	1						
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Estimated impact on the staff (additional FTE) – establishment plan

Function group and grade	Year 2018	Year 2019	Year 2020	Enter as many years as necessary to show the duration of the impact (see point 1.6)
AD16				
AD15				
AD14				
AD13				
AD12				
AD11				
AD10				
AD9				

AD8				
AD7				
AD6				
AD5				
AD Total				
AST11				
AST10				
AST9				
AST8				
AST7				
AST6				
AST5				
AST4				
AST3				
AST2				
AST1				
AST Total				
AST/SC 6				
AST/SC 5				
AST/SC 4				
AST/SC 3				
AST/SC 2				
AST/SC 1				
AST/SC Total				
GRAND TOTAL				

Estimated impact on the staff (additional) – external personnel

Contract agents	Year N	Year N+1	Year N+2	Enter as many years as necessary to show the duration of the impact (see point 1.6)
Function group IV				
Function group III				
Function group II				
Function group I				
Total	1	1		

Seconded National Experts	Year N	Year N+1	Year N+2	Enter as many years as necessary to show the duration of the impact (see point 1.6)
Total				

Please indicate the planned recruitment date and adapt the amount accordingly (if recruitment occurs in July, only 50 % of the average cost is taken into account) and provide further explanations in an annex.

3.2.3.2. Estimated requirements of human resources for the parent DG

- ☐ The proposal/initiative does not require the use of human resources.
- ☐ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

	Year	Year	Year	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
• Establishment plan posts (officials and temporary staff)							
0702 01 01 01 (Headquarters and Commission's Representation Offices)							
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
• External staff (in Full Time Equivalent unit: FTE)⁵³							
XX 01 02 01 (AC, END, INT from the 'global envelope')							
XX 01 02 02 (AC, AL, END, INT and JED in the Delegations)							
XX 01 04 yy⁵⁴	- at Headquarters ⁵⁵						
	- in Delegations						
XX 01 05 02 (AC, END, INT – Indirect research)							
10 01 05 02 (AC, END, INT – Direct research)							
Other budget lines (specify)							
TOTAL							

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

⁵³ AC = Contract Staff; AL = Local Staff; END = Seconded National Expert; INT = agency staff; JED = Junior Experts in Delegations.

⁵⁴ Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

⁵⁵ Mainly for the Structural Funds, the European Agricultural Fund for Rural Development (EAFRD) and the European Fisheries Fund (EFF).

Description of tasks to be carried out:

Officials and temporary staff	DG ENV is responsible for policy development and implementation of the POPs Regulation in the EU, including the adoption of legislation, and for all international obligations stemming from the Convention. DG ENV represents the European Union at Convention level, including the Persistent Organic Pollutants Review Committee, and does the international negotiations work.
External staff	

Description of the calculation of cost for FTE units should be included in the Annex V, section 3.

3.2.4. *Compatibility with the current multiannual financial framework*

☒ The proposal/initiative is compatible with the current multiannual financial framework.

☐ The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

[...]

☐ The proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework⁵⁶.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

[...]

3.2.5. *Third-party contributions*

X - The proposal/initiative does not provide for co-financing by third parties.

The proposal/initiative provides for the co-financing estimated below:

EUR million (to three decimal places)

	Year N	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

⁵⁶

See Articles 11 and 17 of Council Regulation (EU, Euratom) No 1311/2013 laying down the multiannual financial framework for the years 2014-2020.

3.3. Estimated impact on revenue

☒ The proposal/initiative has no financial impact on revenue.

☐ The proposal/initiative has the following financial impact:

- ☐ on own resources
- ☐ on miscellaneous revenue

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative ⁵⁷						
		Year N	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
Article								

For miscellaneous ‘assigned’ revenue, specify the budget expenditure line(s) affected.

[...]

Specify the method for calculating the impact on revenue.

[...]

⁵⁷

As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25 % for collection costs.

