

Basic information

2011/0429(COD)

COD - Ordinary legislative procedure (ex-codecision procedure)
Directive

Water policy: priority substances

Amending Directive 2000/60/EC [1997/0067\(COD\)](#)
Amending Directive 2008/105/EC [2006/0129\(COD\)](#)

Subject

3.10.06 Crop products in general, floriculture
3.15.01 Fish stocks, conservation of fishery resources
3.40.01 Chemical industry, fertilizers, plastics
3.70.04 Water control and management, pollution of waterways, water pollution
3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport)

Procedure completed

Key players

European
Parliament

Committee responsible

ENVI

Environment, Public Health and Food Safety

Rapporteur

[SEEBER Richard \(PPE\)](#)

Appointed

13/03/2012

Shadow rapporteur

[ARSENIS Kriton \(S&D\)](#)

[KRAHMER Holger \(ALDE\)](#)

[SCHLYTER Carl \(Verts/ALE\)](#)

[GIRLING Julie \(ECR\)](#)

[WILS Sabine \(GUE/NGL\)](#)

[ROSSI Oreste \(EFD\)](#)

Committee for opinion

ITRE

Industry, Research and Energy

Rapporteur for opinion

The committee decided not to give an opinion.

Appointed

AGRI

Agriculture and Rural Development

The committee decided not to give an opinion.

PECH

Fisheries

The committee decided not to give an opinion.

Council of the European Union	Council configuration	Meetings	Date
	Environment	3173	2012-06-11
European Commission	Commission DG	Commissioner	
	Environment	POTOČNIK Janez	
European Economic and Social Committee			
European Committee of the Regions			

Key events			
Date	Event	Reference	Summary
31/01/2012	Legislative proposal published	COM(2011)0876 	Summary
14/02/2012	Committee referral announced in Parliament, 1st reading		
11/06/2012	Debate in Council		Summary
28/11/2012	Vote in committee, 1st reading		
04/12/2012	Committee report tabled for plenary, 1st reading	A7-0397/2012	Summary
01/07/2013	Debate in Parliament		
02/07/2013	Decision by Parliament, 1st reading	T7-0298/2013	Summary
02/07/2013	Results of vote in Parliament		
22/07/2013	Act adopted by Council after Parliament's 1st reading		
12/08/2013	Final act signed		
12/08/2013	End of procedure in Parliament		
24/08/2013	Final act published in Official Journal		

Technical information	
Procedure reference	2011/0429(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Amending Directive 2000/60/EC 1997/0067(COD) Amending Directive 2008/105/EC 2006/0129(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 192-p1
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/08744

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE492.914	17/07/2012	
Amendments tabled in committee		PE500.412	08/11/2012	
Amendments tabled in committee		PE496.330	14/11/2012	
Amendments tabled in committee		PE496.465	14/11/2012	
Amendments tabled in committee		PE500.615	27/11/2012	
Committee report tabled for plenary, 1st reading/single reading		A7-0397/2012	04/12/2012	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0298/2013	02/07/2013	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00021/2013/LEX	12/08/2013	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2011)0876 	31/01/2012	Summary
Document attached to the procedure	SEC(2011)1546 	31/01/2012	
Document attached to the procedure	SEC(2011)1547 	31/01/2012	
Commission response to text adopted in plenary	SP(2013)625	24/09/2013	

National parliaments

Document type	Parliament/Chamber	Reference	Date	Summary
Contribution	PT_PARLIAMENT	COM(2011)0876	26/03/2012	
Contribution	AT_BUNDESRAT	COM(2011)0876	11/04/2012	
Contribution	PL_SENATE	COM(2011)0876	12/04/2012	
Contribution	ES_PARLIAMENT	COM(2011)0876	19/04/2012	
Contribution	UK_HOUSE-OF-LORDS	COM(2011)0876	10/05/2012	
Contribution	BG_PARLIAMENT	COM(2011)0876	11/07/2012	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1307/2012	23/05/2012	

Additional information		
Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act
<p>Directive 2013/0039 OJ L 226 24.08.2013, p. 0001</p> <p style="text-align: right;">Summary</p>

Water policy: priority substances

2011/0429(COD) - 04/12/2012 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Richard SEEBER (EPP, AT) on the proposal for a directive of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy.

The committee recommends that Parliament adopt its position in first reading following the ordinary legislative procedure, and amend the Commission proposal. The main amendments are as follows:

New priority substances: the report recalls that the proposal adds 15 chemicals to the list of 33 pollutants that are monitored and controlled in EU surface waters, including industrial chemicals, biocides, plant protection products and, **for the first time, three pharmaceutical substances**. These are 17alpha-ethinylestradiol, 17beta-estradiol and Diclofenac.

The substances have been selected on the basis of scientific evidence that they may pose a significant risk. Whilst all 15 substances are retained in the priority substances list, the committee **deletes Environmental Quality Standards (EQS) for the 3 pharmaceutical substances**. The Commission shall **propose EQS for these substances by 27 December 2016**.

Members note that pollution with pharmaceutical residues is an emerging environmental problem. Current evaluation and control of the risk of medicinal products to the aquatic environment do not provide adequate attention to Union environmental objectives. An ongoing Commission study on the risks of environmental effects of medicinal products aims to provide an analysis of the relevance of the current legislative framework protecting the environment and human health via the aquatic environment, and finally the identification of possible measures to better address the problem.

Specific provisions for pharmaceutical substances: pursuant to Directive 2000/60/EC, the Commission shall, within two years, **draw up a strategy against pollution of water by pharmaceutical substances**. The strategy shall include: (i) proposals enabling, to the extent necessary, the environmental impacts of medicines to be taken into account more effectively in the procedure for placing medicinal products on the market (Directive 2001/83/EC, Directive 2011/83/EU, Regulation (EC) No 726/2004); (ii) an assessment of the risks associated with the presence of medicines in aquatic environments and proposals to reduce them; (iii) information with which to calculate the cost-effectiveness ratio of the measures proposed.

Watch list: the watch list shall contain no more than 25 substances or groups of substances, which shall be selected in accordance with a transparent technical procedure and relevant objective criteria. The Commission must take into account in its selection the results of **robust risk assessment** based on widely accepted, validated analytical methods and scientific data from state-of-the-art studies.

Member States shall monitor each substance in the watch list at selected representative monitoring stations over at least a **12-month period** commencing within six months of its inclusion in the watch list.

The Commission shall be empowered to adopt **delegated acts concerning the drawing up of the watch list**, the inclusion and removal of substances from the watch list and laying down technical specifications for the monitoring of the substances in the watch list. The watch list shall be valid for a maximum of four years from the date of its adoption, or until a new list is drawn up by the Commission if this happens before the end of the four-year period.

Monitoring stations: the committee stated that each Member State shall select at least one monitoring station, plus one station per, on average, 30 000 km² geographical area, plus one station per, on average, 5 million inhabitants (the Commission having proposed at least one station per, on average, 15000 km² geographical area, with a minimum of one per Member State.)

Ubiquitous persistent, bioaccumulative and toxic substances: Member States must monitor these at least once every three years in order to provide sufficient data for a long-term trend analysis.

Separate presentation of new priority substances: as regards the presentation of chemical status in accordance Directive 2000/60/EC, for the purposes of the first update of the programmes of measures and of the river basin management plans, **Member States should be allowed to present separately the impact on chemical status of new priority substances and of existing substances with updated EQS**, so that the introduction of new requirements is not mistakenly perceived as a deterioration of the chemical status of surface waters. In addition to the obligatory map covering all substances, two additional maps, one covering only new substances and existing substances with updated EQS and one covering other substances, could be provided.

Coherence with river basin management plans: the committee notes that the newly identified priority substances and their EQS, and the updated EQS for existing priority substances set out in the Directive, should be taken into account in the programmes of measures and river basin management plans when they are next updated in accordance with the deadlines set out, respectively, in Article 11(8) and Article 13(7) of Directive 2000/60/EC. For good chemical status, the EQS should be met by the end of the corresponding six-year river basin management plan cycle, without prejudice to provisions for extending the deadline for meeting good chemical status or achieving less stringent environmental objectives for specific bodies of water.

Website: it is important that timely and proper information on the status of European surface waters and on the achievements of the strategies against chemical pollution is made available to the general public. A single website providing information on the river basin management plans and their reviews and updates should be made available in each Member State.

Water policy: priority substances

2011/0429(COD) - 02/07/2013 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 646 votes to 51, with 14 abstentions a legislative resolution on the proposal for a Directive of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy.

Parliament adopted its position at first reading under the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise negotiated between the European Parliament and the Council. They amend the proposal as follows:

Environmental quality standards (EQS): the amended text provides that the revised EQS for existing priority substances should be taken into account for the first time in river basin management plans covering the **period 2015 to 2021**. The newly identified priority substances and their EQS should be taken into account in the establishment of supplementary monitoring programmes and in preliminary programmes of measures to be submitted **by the end of 2018**.

With the aim of achieving good surface water chemical status, the revised EQS for existing priority substances should be met **by the end of 2021** and the EQS for newly identified priority substances **by the end of 2027**.

Technical guidelines on monitoring strategies and analytical methods for substances, including sampling and monitoring of biota, shall be developed, to the extent possible, by 22 December 2014, as part of the existing implementation process of Directive 2000/60/EC.

Specific provisions for pharmaceutical substances: the new legislation recognises the risk of contamination of water and soil by pharmaceutical residues. Pursuant to Directive 2000/60/EC, the Commission shall, within two years, draw up a **strategy** against pollution of water by pharmaceutical substances. Among other things, this will include proposals enabling, to the extent necessary, the environmental impacts of medicines to be taken into account more effectively in the procedure for placing medicinal products on the market. The Commission will propose measures to be taken at Union and/or Member States level, as appropriate, to address the possible environmental impacts of pharmaceutical substances on the environment.

Watch lists: the first watch list established by the Commission shall contain a maximum of **10 substances or groups of substances** and shall indicate the monitoring matrices and the possible methods of analysis not entailing excessive costs for each substance.

Diclofenac (CAS 15307-79-6), **17-beta-estradiol (E2)** (CAS 50-28-2) and **17-alpha-ethinylestradiol (EE2)** (CAS 57-63-6) shall be included in the first watch list, in order to gather monitoring data for the purpose of facilitating the determination of appropriate measures to address the risk posed by those substances.

Once adopted, the first watch list shall be **updated every two years**. The duration of a continuous watch list monitoring period **for any individual substance** shall not exceed **four years**.

For the first watch list, the monitoring period shall commence within six months of the establishment of the watch list. For each substance included in subsequent lists, Member States shall commence monitoring within six months of its inclusion in the list.

Monitoring stations: the amended text stipulates that each Member State shall select **at least one monitoring station**, plus one station if it has more than one million inhabitants, plus the number of stations equal to its geographical area in km² divided by 60 000 (rounded to the nearest integer), plus the number of stations equal to its population divided by five million.

Maps presenting the chemical status of water with respect to certain substances: in the river basin management plans, Member States may provide **additional maps** that present the chemical status information for one or more of the following substances **separately** from the information for the rest of the substances identified in Part A of Annex I to this Directive: (i) substances behaving like ubiquitous PBTs; (ii) newly identified substances; and (iii) substances for which revised, stricter EQS are established.

Coordination: the text provides for the exploration of potential synergies with a view to identifying possible areas where data gathered through implementation of Directive 2000/60/EC can be used to support REACH and other relevant substance evaluation procedures.

Public awareness: environmental information on the status of Union surface waters and on the achievements of strategies against chemical pollution is made available to the public in a timely manner. With a view to strengthening access and transparency, a **central portal** providing information on the river basin management plans and their reviews and updates should be accessible to the public electronically in each Member State.

In order to improve the information basis for future identification of priority substances, in particular as regards emerging pollutants, **implementing powers** should be conferred on the Commission in respect of the establishment and updating of a watch list.

Review: the Commission shall review the adopted list of priority substances **at the latest four years after the date of entry into force** of this Directive and at least every six years thereafter, and come forward with proposals as appropriate.

Water policy: priority substances

2011/0429(COD) - 12/08/2013 - Final act

PURPOSE: to achieve good surface water chemical status by laying down EQS for priority substances and certain other pollutants,

LEGISLATIVE ACT: Directive 2013/39/EU of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy

CONTENT: this new Directive amends two existing Directives, namely:

- Directive 2000/60/EC establishing a framework for Community action in the field of water policy lays down a strategy against the pollution of water. That strategy involves the identification of priority substances amongst those that pose a significant risk to, or via, the aquatic environment at Union level.
- Directive 2008/105/EC on environmental quality standards in the field of water policy which lays down environmental quality standards (EQS), for priority substances mentioned above.

The main amendments made by the new Directive are as follows:

New substances for priority action in the field of water policy: the Directive adds **12 new substances** to the current list of 33 priority substances in Annex X of the Water Framework Directive.

The Commission will report on the outcome of the regular review of Annex X to Directive 2000/60/EC It shall accompany the report, where appropriate, with legislative proposals to amend Annex X including, in particular, proposals to identify new priority substances or priority hazardous substances or to identify certain priority substances as priority hazardous substances and to set corresponding EQS for surface water, sediment or biota, as appropriate.

Environmental quality standards (EQS): the EQS for some of the existing substances are revised and updated in line with the latest scientific and technical knowledge concerning risks to, or via, the aquatic environment.

The revised EQS for **existing priority substances** must be taken into account for the first time in river basin management plans from 22 December 2015 with the aim of achieving good surface water chemical status in relation to those substances by 22 December 2021.

The **newly identified priority substances** and their EQS should be taken into account in the establishment of supplementary monitoring programmes and in preliminary programmes of measures to be submitted by the end of **2018**, with the aim of achieving good surface water chemical status in relation to those substances by 22 December **2027**.

Watch list: the Directive provides that the Commission will establish a list of substances for which Union-wide monitoring data are to be gathered for the purpose of supporting future prioritisation exercises (watch list.)

The first watch list will be established by 14 September 2014 and will contain 10 substances, inter alia, three pharmaceutical substances (Diclofenac, 17-beta-estradiol (E2) and 17-alpha-ethinylestradiol (EE2).

The watch list must be **updated every 2 years**. The duration of a continuous watch list monitoring period for any individual substance shall not exceed four years.

Special provisions for pharmaceutical substances: the Commission shall, as far as possible within two years from 13 September 2013 develop a **strategic approach** to pollution of water by pharmaceutical substances. That strategic approach shall, where appropriate, include proposals enabling the environmental impacts of medicines to be taken into account more effectively in the procedure for placing medicinal products on the market.

Monitoring stations: Member States must monitor each substance in the watch list at selected representative monitoring stations over at least a 12-month period.

Each Member State shall select at least one monitoring station, plus one station if it has more than one million inhabitants, plus the number of stations equal to its geographical area in km² divided by 60000 (rounded to the nearest integer), plus the number of stations equal to its population divided by five million (rounded to the nearest integer). The frequency of monitoring shall be no less than once per year.

ENTRY INTO FORCE: 25/08/2013

TRANSPOSITION: 14/09/2015.

DELEGATED ACTS: the Commission may adopt delegated acts in respect of the updating of the methods for applying the EQS laid down in the Directive. The power to adopt delegated acts is conferred on the Commission for a period of six years from 13 September 2013. The European Parliament or Council may object to a delegated act within a period of two months from the date of notification (this period may be extended by two months). If either Parliament or council express objections, the delegated act will not enter into force.

Water policy: priority substances

2011/0429(COD) - 31/01/2012 - Legislative proposal

PURPOSE: to amend Directives 2000/60/EC and 2008/105/EC to add 15 chemicals to the current list of 33 priority substances.

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

BACKGROUND: this Commission proposal concerns the review of the list of priority substances (PS) in the field of water policy, i.e. the chemicals identified among those presenting a significant risk to or via the aquatic environment at EU level which are listed in Annex X to the Water Framework Directive (WFD) 2000/60/EC. The revision takes place following the review of priority substances required by both the WFD and the Environmental Quality Standards Directive (EQSD) 2008/105/EC. In the course of reviewing the priority substances list, improvements in the functioning of the EQSD were identified, as well as a mechanism for improving the identification of additional priority substances in future reviews.

IMPACT ASSESSMENT: technical work on the review of the PS list began in 2007 and was supported by an extensive consultation with experts from the Commission services, Member States, stakeholders and the Scientific Committee on Health and Environmental Risks (SCHER). As the technical work was in its final stages in 2010, work on the impact assessment began with the commencement of a study by the consultancy Entec.

The Impact Assessment Board discussed the Impact Assessment report at its meeting on 22 June 2011. The comments made were addressed in the accompanying Impact Assessment report.

LEGAL BASIS: Article 192(1) of the Treaty on the Functioning of the EU.

CONTENT: the proposal is limited to the identification of priority substances and to establishing EQS at EU level. The main amendments are as follows:

Amendments to Annex X of the WFD: the updated Annex X includes the newly proposed priority substances and identifies two existing priority substances as priority hazardous substances.

The new list is comprised of the following:

- Plant protection product substances: Aclonifen, Bifenox, Cypermethrin, Dicofol, Heptachlor, Quinoxifen
- Substances used in biocidal products: Cybutryne, Dichlorvos, Terbutryn
- Industrial chemicals: Perfluorooctane sulfonic acid (PFOS), Hexabromocyclododecane (HBCDD)
- Combustion by-products: Dioxin and Dioxin-Like PCBs
- Pharmaceutical substances: 17 alpha-ethinyloestradiol (EE2), 17 beta-estradiol (E2), Diclofenac.

Amendments to EQSD: the main amendments are as follows:

New Annex for priority substances and biota: Part A of Annex I is replaced by Annex II to this Directive. The latter introduces the newly proposed priority substances, amends the EQS for some of the existing priority substances and introduces a column for biota standards. This latter column includes the three biota standards that were already established by EQSD as well as biota standards for some other existing priority substances and some new priority substances. Listing the biota standards in Annex I of the EQSD simplifies presentation and improves clarity.

Matrix: a definition of "matrix" is introduced i.e. the environmental compartment to which the EQS apply and in which the concentrations of priority substances and priority hazard substances are therefore to be monitored: usually water, sediment or biota (fish unless otherwise stated).

The text is amended to make it coherent with the new structure of Part A of Annex I (in particular with the inclusion of biota standards in the Annex), and to amend the obligations of Member States as regards the selection of the matrix for monitoring. A default monitoring matrix is specified for each substance, on the basis of its intrinsic properties. The existing flexibility for Member States to choose an alternative matrix is retained, but it is now conditional on the fulfilment of the minimum analytical performance criteria in Article 4 of Commission Directive 2009/90/EC11.

Notification: the notification obligations set out in the EQSD are integrated into the reporting of the river basin management plans under the WFD.

Comitology: the comitology mandate to amend paragraph 3 of Part B of Annex I is aligned to the new delegated powers under Article 290 of the Treaty.

Furthermore, changes are made to the text to align it with Regulation (EU) No 182/2011 on Commission implementing powers.

PBT substances: persistent, bioaccumulative and toxic substances (PBTs) and other substances that behave like PBTs may be found for decades in the aquatic environment at levels posing a significant risk, even if extensive measures to reduce or eliminate emissions have already been taken. A new provision is inserted that makes specific provision for substances behaving as ubiquitous persistent, bioaccumulative and toxic substances.

Watch list: a new provision is inserted to establish a watch list for the targeted collection of monitoring data to support future reviews of the priority substances list.

BUDGETARY IMPLICATIONS: the proposal contains no budgetary implications.

Water policy: priority substances

2011/0429(COD) - 11/06/2012

The Council was informed by the Presidency about the **state of play** of the the proposal for a directive on environmental quality standards in the field of water policy (priority substances).

This proposal concerns the review of the list of priority substances (PS) in the field of water policy, i.e. the chemicals identified among those presenting a significant risk to or via the aquatic environment at EU level which are listed in Annex X to the Water Framework Directive (WFD). The list is to be revised following the review of priority substances required by both the WFD (Directive 2006/60/EC) and the Environmental Quality Standards Directive (EQSD) (Directive 2008/105/EC).

Discussions in the Council preparatory bodies are ongoing. The main outstanding issues concern the list of Priority Substances (PS) and Priority Hazardous Substances (PHS), the measures laid down in the WFD related to ubiquitous, persistent, bioaccumulative and toxic substances (u-PBT) and the new watch-list mechanism.