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COMMISSION IMPLEMENTING DECISION (EU) 2025/439

of 28 February 2025

establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council

(notified under document C(2025) 1244)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council ([1]), and in particular Article 8b(5), first subparagraph, thereof,

Whereas:

(1) Article 8b(1) of Directive 2008/105/EC provides for the establishment of a watch list of substances for which Union-wide monitoring data are to be gathered for the purpose of supporting future prioritisation exercises in accordance with Article 16(2) of Directive 2000/60/EC of the European Parliament and of the Council ([2]). The first such watch list was to include an indication of the monitoring matrices and possible methods of analysis not entailing excessive costs for each substance.

(2) The substances in the watch list are to be selected from amongst those for which the information available indicates that they may pose a significant risk, at Union level, to or via the aquatic environment, but for which monitoring data are insufficient to come to a conclusion on the actual risk posed. Highly toxic substances, used in many Member States and discharged to the aquatic environment but not or rarely monitored, are to be considered for inclusion in the watch list. That selection process is to take into account information as itemised in Article 8b(1), points (a) to (e), of Directive 2008/105/EC, giving particular consideration to emerging pollutants.

(3) The monitoring of the substances in the watch list should generate high-quality data on their concentrations in the aquatic environment, fit for the purpose of supporting, in a separate review exercise pursuant to Article 16(4) of Directive 2000/60/EC, the risk assessments that underpin the identification of priority substances. In that review, substances found to pose a significant risk are to be considered for inclusion in the priority substances list. An environmental quality standard is then also to be set which Member States have to meet. The proposal of a substance for inclusion in the priority substances list is subject to an impact assessment.

(4) Pursuant to Article 8b(2) of Directive 2008/105/EC, the Commission is to update the watch list every two years. When updating the list, the Commission is to remove any substance for which a risk-based assessment as referred to in Article 16(2) of Directive 2000/60/EC can be concluded without additional monitoring data.

([1]) OJ L 348, 24.12.2008, p. 84, ELI: http://data.europa.eu/eli/dir/2008/105/oj.
([2]) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

(5) The first watch list of substances was set out in Commission Implementing Decision (EU) 2015/495 ([3]) and contained ten substances or groups of substances, together with an indication of the monitoring matrix, possible analytical methods not entailing excessive costs, and maximum acceptable method detection limits. The watch list was updated in 2018, 2020 and 2022 as set out in Commission Implementing Decisions (EU) 2018/840 ([4]), (EU) 2020/1161 ([5]) and (EU) 2022/1307 ([6]).

(6) Pursuant to Article 8b(2) of Directive 2008/105/EC, the duration of a continuous watch list monitoring period for any individual substance is not to exceed four years. Therefore the watch-list monitoring obligation for the six substances or groups of substances that had been on the list since 2020, namely sulfamethoxazole, trimethoprim, venlafaxine and its metabolite O-desmethylvenlafaxine, the group of ten azole compounds (the pharmaceuticals clotrimazole, fluconazole and miconazole and the pesticides imazalil, ipconazole, metconazole, penconazole, prochloraz, tebuconazole and tetraconazole) and the fungicides famoxadone and dimoxystrobin, ceased in 2024. The monitoring data obtained will be considered in the context of the prioritisation exercise referred to in Article 16(2) of Directive 2000/60/EC.

(7) The data obtained since 2022 for azoxystrobin, which was in the same group as dimoxystrobin, are sufficient to show that it poses a risk in a few Member States, and is therefore to be addressed accordingly, that is as a pollutant of national concern, which is to be monitored in those Member States where it continues to pose a risk, pursuant to the provision for 'other pollutants' in point 1.3.4 of Annex V to Directive 2000/60/EC. As regards diflufenican, the data obtained since 2022 indicate that it poses a Union-wide risk and is therefore a potential candidate for inclusion in the priority substances list. In the meantime, it is appropriate for Member States to monitor it as if it were a pollutant of national concern. Both azoxystrobin and diflufenican should be removed from the watch list.

(8) On the basis of the monitoring data obtained for the other five substances or groups of substances monitored since 2022, namely fipronil, clindamycin, ofloxacin, metformin and its metabolite guanylurea, and a group of three sunscreen agents (butyl methoxydibenzoylmethane, also known as avobenzone; octocrylene; and benzophenone-3, also known as oxybenzone), the Commission concluded that insufficient high-quality monitoring data had been obtained to assess the risk posed by them, and that, therefore, those substances or groups of substances should remain on the watch list.

(9) During 2023, the Commission gathered data on a range of other substances that could be included in the watch list. It took into account the different types of relevant information referred to in Article 8b(1) of Directive 2008/105/EC, and consulted experts from Member States and stakeholder groups. Substances for which doubt exists about their toxicity, or for which the sensitivity, reliability or comparability of the available monitoring methods are not adequate, should not be included in the watch list. The sunscreen agent 2-ethylhexyl salicylate, also known as octisalate, the industrial antioxidant substance N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine (6PPD) and its degradation product 6PPD-quinone, the insecticide and anthelmintic abamectin, a group of azole antifungal substances (bromuconazole, climbazole, cyazofamid, difenoconazole, epoxiconazole, itraconazole, ketoconazole, mefentrifluconazole, propiconazole, triticonazole), the insecticide etoxazole, the antidepressants fluoxetine and

([3]) Commission Implementing Decision (EU) 2015/495 of 20 March 2015 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council (OJ L 78, 24.3.2015, p. 40, ELI: http://data.europa.eu/eli/dec_impl/2015/495/oj).

([4]) Commission Implementing Decision (EU) 2018/840 of 5 June 2018 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council and repealing Commission Implementing Decision (EU) 2015/495 (OJ L 141, 7.6.2018, p. 9, ELI: http://data.europa.eu/eli/dec_impl/2018/840/oj).

([5]) Commission Implementing Decision (EU) 2020/1161 of 4 August 2020 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council (OJ L 257, 6.8.2020, p. 32, ELI: http://data.europa.eu/eli/dec_impl/2020/1161/oj).

([6]) Commission Implementing Decision (EU) 2022/1307 of 22 July 2022 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council, and repealing Commission Implementing Decision (EU) 2020/1161 (OJ L 197, 22.7.2022, p. 117, ELI: http://data.europa.eu/eli/dec_impl/2022/1307/oj).

propranolol, and the antibiotics oxytetracycline and tetracycline were identified as suitable candidates. The inclusion of the pharmaceuticals is consistent with the EU Strategic Approach to Pharmaceuticals in the Environment ([7]), and the inclusion of the two antibiotics is also consistent with the European One Health Action Plan against Antimicrobial Resistance (AMR) ([8]), which supports the use of the watch list to 'improve knowledge of the occurrence and spread of antimicrobials in the environment'.

(10) Pursuant to Article 8b(1) of Directive 2008/105/EC, the Commission identified possible methods of analysis for the proposed substances. For all the retained and newly added substances, the method quantification limit should be, for each substance, including each individual substance in a group, at least as low as the substance-specific predicted no-effect concentration in the relevant matrix.

(11) Metformin and its metabolite guanylurea are grouped because of their potentially additive effects; they can and should continue to be analysed together. Octisalate is grouped with the three retained sunscreen agents because they have the same mode of action and could have additive effects; they can and should be analysed together.

(12) 6PPD and 6PPD-quinone are expected to occur together and they can and should be analysed together.

(13) The azole substances are grouped because they have the same mode of action and could also have additive effects; they can and should be analysed together.

(14) The two tetracycline class antibiotics could have additive effects; they can and should be analysed together.

(15) The analytical methods specified in the watch list are not considered to entail excessive costs. If new information leads in the future to a decrease in the predicted no-effect concentration for any of the newly added substances, the maximum acceptable method quantification limit for those substances may have to be lowered as long as they remain on the list.

(16) Article 8b of Directive 2008/105/EC specifies, among other things, the conditions and modalities for the monitoring of the substances included in the watch list and for the reporting of the monitoring results by the Member States. It specifies in particular that, in selecting the representative monitoring stations, the monitoring frequency and the timing for each substance, Member States are to take into account the use patterns and possible occurrence of the substance. Even though the minimum monitoring frequency is once per year, Member States should consider, for all the substances, a monitoring frequency of at least twice per year to take account of their fluctuating usage, to ensure that data of sufficiently high quality are collected, and that the watch-list mechanism can thus provide properly effective support to subsequent risk–assessment processes.

(17) To ensure comparability of results from different Member States, all substances should be monitored in whole water samples.

(18) For reasons of legal clarity, the Annex to Implementing Decision (EU) 2022/1307 should be replaced in its entirety. Implementing Decision (EU) 2022/1307 should therefore be repealed.

(19) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 21(1) of Directive 2000/60/EC,

([7]) Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, European Union Strategic Approach to Pharmaceuticals in the Environment, COM(2019) 128 final, 11 March 2019.

([8]) Communication from the Commission to the Council and the European Parliament A European One Health Action Plan against Antimicrobial Resistance (AMR), COM(2017) 339 final, 29 June 2017.

HAS ADOPTED THIS DECISION:

Article 1

The watch list of substances for Union-wide monitoring referred to in Article 8b of Directive 2008/105/EC is set out in the Annex to this Decision.

Article 2

Implementing Decision (EU) 2022/1307 is repealed.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 28 February 2025.

For the Commission
Jessika ROSWALL
Member of the Commission

ANNEX

Watch list of substances for Union-wide monitoring as set out in Article 8b of Directive 2008/105/EC

Name of substance/group of substances	Chemical Abstracts Service (CAS) number	European Community (EC) number (1)	Indicative analytical method (2), (3)	Maximum acceptable method quantification limit (ng/l)
Fipronil	120068-37-3	424-610-5	SPE-HPLC-MS/MS	0,77
Clindamycin	18323-44-9	242-209-1	SPE-LC-MS/MS	44
Ofloxacin	82419-36-1	680-263-1	SPE-UHPLC-MS/MS	26
Metformin and Guanylurea (4)	657-24-9 141-83-3	211-517-8 205-504-6	SPE-LC-MS/MS	156 000 100 000
Sunscreen agents (5) Butyl methoxydibenzoyl-methane Octocrylene Benzophenone-3 Octisalate (2-ethylhexyl salicylate)	70356-09-1 6197-30-4 131-57-7 118-60-5	274-581-6 228-250-8 205-031-5 204-263-4	SPE-LC-ESI-MS/MS	3 000 266 670 168
N-1,3-Dimethylbutyl-N'-phenyl-p-phenylenediamine (6PPD) and 6PPD-quinone (6)	793-24-8 2754428-18-5	212-344-0 893-269-6	SPE-LC-MS/MS	370
Abamectin (7) Avermectin B1a and Avermectin B1b	71751-41-2 65195-55-3 65195-56-4	265-610-3 265-611-9	SPE-LC-MS/MS	1
Azole compounds (8) Bromuconazole Climbazole Cyazofamid Difenoconazole Epoxiconazole Itraconazole Ketoconazole Mefentrifluconazole Propiconazole Triticonazole	116255-48-2 38083-17-9 120116-88-3 119446-68-3 133855-98-8 84625-61-6 65277-42-1 1417782-03-6 60207-90-1 131983-72-7	408-060-3 253-775-4 601-671-8 601-613-1 406-850-2 617-596-9 265-667-4 822-682-6 262-104-4 603-543-7	SPE-LC-MS/MS	15 110 130 360 180 8 50 1 600 1 000 1 000
Etoxazole	153233-91-1	604-891-2	SPE-GC-MS/MS	0,4

Name of substance/group of substances	Chemical Abstracts Service (CAS) number	European Community (EC) number (1)	Indicative analytical method (2), (3)	Maximum acceptable method quantification limit (ng/l)
Fluoxetine	54910-89-3	611-209-7	SPE-LC-QTOF-HRMS	12
Propranolol	525-66-6	208-378-0	SPE-LC-MS/MS	20
Oxytetracycline and Tetracycline (9)	79-57-2 60-54-8	201-212-8 200-481-9	SPE-LC-MS/MS	500 90

(1) Not available for all substances
(2) All substances shall be monitored in whole water samples.
(3) Extraction methods:
SPE – solid-phase extraction
Analytical methods:
HPLC-MS/MS– High-performance liquid chromatography (tandem) triple quadrupole mass spectrometry
LC-MS/MS – Liquid chromatography (tandem) triple quadrupole mass spectrometry
LC-ESI-MS/MS – Liquid chromatography (tandem) triple quadrupole mass spectrometry with positive electrospray ionisation
LC-QTOF-HRMS – Liquid chromatography quadrupole time-of-flight high-resolution mass spectrometry
UHPLC-MS/MS – Ultra-high-performance liquid chromatography (tandem) triple quadrupole mass spectrometry
(4) Metformin and guanylurea shall be analysed together in the same samples but reported as individual concentrations.
(5) The sunscreen agents shall be analysed together in the same samples but reported as individual concentrations.
(6) 6PPD and 6PPD-quinone shall be analysed together in the same samples but reported as individual concentrations
(7) The two major components of abamectin (B1a and B1b) shall be analysed together in the same samples and reported as a sum concentration.
(8) The azole compounds shall be analysed together in the same samples but reported as individual concentrations.
(9) Oxytetracycline and tetracycline shall be analysed together in the same samples but reported as individual concentrations.