DECISIONS

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

(notified under document C(2022) 5098)

(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, should be considered for inclusion in the watch list. That selection process should 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 according 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 should be considered for inclusion in the priority substances list. An environmental quality standard would then also be set which Member States would have to meet. The proposal of a substance for inclusion in the priority substances list would be subject to an impact assessment.

(4) 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.

([1]) OJ L 348, 24.12.2008, p. 84.

([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).

([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).

(5) According 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.

(6) The watch list was updated in 2018 as set out in Commission Implementing Decision (EU) 2018/840 ([4]) by the removal of five substances and the addition of three, such that the list contained eight substances or groups of substances.

(7) The watch list was further updated in 2020 as set out in Commission Implementing Decision (EU) 2020/1161 ([5]) by the removal of five substances or groups of substances and the addition of six, such that the list contained nine substances or groups of substances.

(8) According to Article 8b(2) of Directive 2008/105/EC, the duration of a continuous watch list monitoring period for any individual substance shall not exceed four years. Therefore the watch-list monitoring obligation for the three substances or groups of substances that had been on the list since 2018, namely metaflumizone, amoxicillin and ciprofloxacin, ceased in 2022. 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.

(9) On the basis of the monitoring data obtained for the other six substances or groups of substances 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, the Commission concluded that insufficient high-quality monitoring data had been obtained, and that, therefore, those substances or groups of substances should remain on the watch list.

(10) During 2021, 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 fungicide azoxystrobin, the herbicide diflufenican, the insecticide and veterinary pharmaceutical fipronil, the antibiotics clindamycin and ofloxacin, the human pharmaceutical 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) were identified as suitable candidates. The addition of the pharmaceuticals is consistent with the EU Strategic Approach to Pharmaceuticals in the Environment ([6]), and the inclusion of the two antibiotics is also consistent with the European One Health Action Plan against Antimicrobial Resistance (AMR) ([7]), which supports the use of the watch list to 'improve knowledge of the occurrence and spread of antimicrobials in the environment'.

(11) In accordance with Article 8b(1) of Directive 2008/105/EC, the Commission identified possible methods of analysis for the proposed substances. For the substances retained on the list, the method detection 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. For the 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.

([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).

([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).

([6]) 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).

([7]) 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).

(12) Sulfamethoxazole and trimethoprim are commonly, but not always, used in combination because of their claimed synergistic effects; they can and should continue to be analysed together even though they are not grouped together in the list. Venlafaxine and its metabolite are grouped because of their potentially additive effects; they can and should continue to be analysed together. The azole substances are grouped because they have the same mode of action and could also have additive effects; they can and should also continue to be analysed together.

(13) Azoxystrobin is included alongside dimoxystrobin because it has the same mode of action; these substances can and should be analysed together. Metformin and its metabolite could have additive effects; they can and should be analysed together. The three sunscreen agents are grouped because they have the same mode of action and could have additive effects, they too can and should be analysed together.

(14) 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.

(15) Article 8b of Directive 2008/105/EC specifies, inter alia, 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.

(16) For comparability, all substances should be monitored in whole water samples.

(17) For reasons of legal clarity, the Annex to Implementing Decision (EU) 2020/1161 should be replaced in its entirety. Implementing Decision (EU) 2020/1161 should therefore be repealed.

(18) 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.

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) 2020/1161 is repealed.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 22 July 2022.

For the Commission
Virginijus SINKEVIČIUS
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	CAS number (1)	EU number (2)	Indicative analytical method (3), (4)	Maximum acceptable method detection or quantification limit (ng/l)
Sulfamethoxazole (5)	723-46-6	211-963-3	SPE-LC-MS-MS	100 (11)
Trimethoprim (5)	738-70-5	212-006-2	SPE-LC-MS-MS	100 (11)
Venlafaxine and O-desmethylvenlafaxine (6)	93413-69-5 93413-62-8	618-944-2 700-516-2	SPE-LC-MS-MS	6 (11)
Azole compounds (7)			SPE-LC-MS-MS	
Clotrimazole	23593-75-1	245-764-8		20 (11)
Fluconazole	86386-73-4	627-806-0		250 (11)
Imazalil	35554-44-0	252-615-0		800 (11)
Ipconazole	125225-28-7	603-038-1		44 (11)
Metconazole	125116-23-6	603-031-3		29 (11)
Miconazole	22916-47-8	245-324-5		200 (11)
Penconazole	66246-88-6	266-275-6		1 700 (11)
Prochloraz	67747-09-5	266-994-5		161 (11)
Tebuconazole	107534-96-3	403-640-2		240 (11)
Tetraconazole	112281-77-3	407-760-6		1 900 (11)
Dimoxystrobin Azoxystrobin (8)	149961-52-4 131860-33-8	604-712-8 603-524-3	SPE-LC-MS-MS	32 (11) 200 (12)
Famoxadone	131807-57-3	603-520-1	SPE-LC-MS-MS	8,5 (11)
Diflufenican	83164-33-4	617-446-2	SPE-LC-MS-MS	10 (12)
Fipronil	120068-37-3	424-610-5	SPE-HPLC-MS-MS	0,77 (12)
Clindamycin	18323-44-9	242-209-1	SPE-LC-MS-MS	44 (12)
Ofloxacin	82419-36-1	680-263-1	SPE-UPLC-MS-MS	26 (12)
Metformin and Guanylurea (9)	657-24-9 141-83-3	211-517-8 205-504-6	SPE-LC-MS-MS	156 000 (12) 100 000 (12)
Sunscreen agents (10)				
Butyl methoxydibenzoyl-methane	70356-09-1	274-581-6	SPE-LC-MS-MS/ESI	3 000 (12)
Octocrylene	6197-30-4	228-250-8		266 (12)
Benzophenone-3	131-57-7	205-031-5		670 (12)

(1) Chemical Abstracts Service
(2) European Union number – not available for all substances
(3) To ensure comparability of results from different Member States, all substances shall be monitored in whole water samples.
(4)
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-MS-MS/ESI – Liquid chromatography (tandem) triple quadrupole mass spectrometry with positive electrospray ionisation
UPLC-MS-MS – Ultra-performance liquid chromatography (tandem) triple quadrupole mass spectrometry
(5) Sulfamethoxazole and trimethoprim, although not grouped, shall be analysed together in the same samples but reported as individual concentrations.
(6) Venlafaxine and O-desmethylvenlafaxine shall be analysed together in the same samples but reported as individual concentrations.
(7) The azole compounds shall be analysed together in the same samples but reported as individual concentrations.
(8) Dimoxystrobin and azoxystrobin shall be analysed together in the same samples but reported as individual concentrations.
(9) Metformin and guanylurea shall be analysed together in the same samples but reported as individual concentrations.
(10) The sunscreen agents shall be analysed together in the same samples but reported as individual concentrations.
(11) Maximum acceptable detection limit
(12) Maximum acceptable quantification limit