

# DECISIONS

## 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**

*(notified under document number C(2020) 5205)*

**(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 <sup>(1)</sup>, and in particular the first subparagraph of Article 8b(5) 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 <sup>(2)</sup>. 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 points (a) to (e) of Article 8b(1) 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 <sup>(3)</sup> 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.
- (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.

<sup>(1)</sup> OJ L 348, 24.12.2008, p. 84.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

- (6) The watch list was updated in 2018 as set out in Commission Implementing Decision (EU) 2018/840 <sup>(4)</sup> by the removal of five substances and the addition of three, such that the list contained eight substances or groups of substances.
- (7) 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 five substances or groups of substances that had been on the list since 2015, namely 17-alpha-ethinylestradiol (EE2), 17-beta-estradiol (E2) and estrone (E1), the group of macrolide antibiotics, methiocarb, and the group of neonicotinoids, ceased in 2019. 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.
- (8) On the basis of the monitoring data obtained for the other three substances, namely metaflumizone, amoxicillin and ciprofloxacin, since 2018, the Commission concluded that insufficient high-quality monitoring data had been obtained, and that, therefore, those substances should remain on the watch list.
- (9) During 2019, 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 sulfonamide antibiotic sulfamethoxazole and the diaminopyrimidine antibiotic trimethoprim, the antidepressant venlafaxine and its metabolite O-desmethylvenlafaxine, a group of threeazole pharmaceuticals (clotrimazole, fluconazole and miconazole) and sevenazole pesticides (imazalil, ipconazole, metconazole, penconazole, prochloraz, tebuconazole, tetraconazole), and the fungicides famoxadone and dimoxystrobin were identified as suitable candidates. The inclusion of the various pharmaceuticals is consistent with the EU Strategic Approach to Pharmaceuticals in the Environment <sup>(5)</sup>, and the inclusion of the two antibiotics is also consistent with the European One Health Action Plan against Antimicrobial Resistance (AMR) <sup>(6)</sup>, which supports the use of the watch list to 'improve knowledge of the occurrence and spread of antimicrobials in the environment'.
- (10) In accordance with Article 8b(1) of Directive 2008/105/EC, the Commission identified possible methods of analysis for the proposed substances. 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.
- (11) Sulfamethoxazole and trimethoprim are commonly, but not always, used in combination because of their claimed synergistic effects; they can and should 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 be analysed together. Theazole substances are grouped because they have the same mode of action and could also have additive effects, despite their emissions coming from a range of sources and likely fluctuating over time; they can and should also be analysed together. The two fungicides, whose emissions are also likely to fluctuate, may but need not be analysed together.
- (12) 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 specific substances, the maximum acceptable method detection limit may have to be lowered as long as those substances remain on the list.
- (13) For comparability, all substances should be monitored in whole water samples.
- (14) For reasons of legal clarity, the Annex to Implementing Decision (EU) 2018/840 should be replaced in its entirety. Implementing Decision (EU) 2018/840 should therefore be repealed.
- (15) 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,

<sup>(4)</sup> 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).

<sup>(5)</sup> 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).

<sup>(6)</sup> 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).

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) 2018/840 is repealed.

*Article 3*

This Decision is addressed to the Member States.

Done at Brussels, 4 August 2020.

*For the Commission*  
Virginijus SINKEVIČIUS  
*Member of the Commission*

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## 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 <sup>(1)</sup>	EU number <sup>(2)</sup>	Indicative analytical method <sup>(3)</sup> <sup>(4)</sup>	Maximum acceptable method detection limit (ng/l)
Metaflumizone	139968-49-3	604-167-6	LLE-LC-MS-MS or SPE-LC-MS-MS	65
Amoxicillin	26787-78-0	248-003-8	SPE-LC-MS-MS	78
Ciprofloxacin	85721-33-1	617-751-0	SPE-LC-MS-MS	89
Sulfamethoxazole <sup>(5)</sup>	723-46-6	211-963-3	SPE-LC-MS-MS	100
Trimethoprim <sup>(5)</sup>	738-70-5	212-006-2	SPE-LC-MS-MS	100
Venlafaxine and O-desmethylvenlafaxine <sup>(6)</sup>	93413-69-5 93413-62-8	618-944-2 700-516-2	SPE-LC-MS-MS	6
<i>Azole compounds</i> <sup>(7)</sup>			SPE-LC-MS-MS	
Clotrimazole	23593-75-1	245-764-8		20
Fluconazole	86386-73-4	627-806-0		250
Imazalil	35554-44-0	252-615-0		800
Ipconazole	125225-28-7	603-038-1		44
Metconazole	125116-23-6	603-031-3		29
Miconazole	22916-47-8	245-324-5		200
Penconazole	66246-88-6	266-275-6		1 700
Prochloraz	67747-09-5	266-994-5		161
Tebuconazole	107534-96-3	403-640-2		240
Tetraconazole	112281-77-3	407-760-6		1 900
Dimoxystrobin	149961-52-4	604-712-8	SPE-LC-MS-MS	32
Famoxadone	131807-57-3	603-520-1	SPE-LC-MS-MS	8,5

<sup>(1)</sup> Chemical Abstracts Service.

<sup>(2)</sup> European Union number.

<sup>(3)</sup> To ensure comparability of results from different Member States, all substances shall be monitored in whole water samples.

<sup>(4)</sup> Extraction methods:

LLE – liquid liquid extraction

SPE – solid-phase extraction

Analytical methods:

LC-MS-MS – Liquid chromatography (tandem) triple quadrupole mass spectrometry.

<sup>(5)</sup> Sulfamethoxazole and trimethoprim shall be analysed together in the same samples but reported as individual concentrations.

<sup>(6)</sup> Venlafaxine and O-desmethylvenlafaxine shall be analysed together in the same samples but reported as individual concentrations.

<sup>(7)</sup> The azole compounds shall be analysed together in the same samples but reported as individual concentrations.