

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***(notified under document C(2018) 3362)*

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) 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) 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.
- (3) 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.
- (4) 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.
- (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.
- (6) 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.

⁽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).

- (7) During 2017, the Commission analysed the data from the first year of monitoring of the substances in the first watch list. On the basis of that analysis, the Commission concluded that sufficient high-quality monitoring data are available for the substances tri-allate, oxadiazon, 2,6-ditert-butyl-4-methylphenol and diclofenac, and that, therefore, those substances should be removed from the watch list.
- (8) As referred to in Implementing Decision (EU) 2015/495, it would be appropriate to monitor the substance 2-ethylhexyl-4-methoxycinnamate in sediment. However, most monitoring data gathered are for water and the limited amount of sediment data reported are not enough to carry out a conclusive analysis for that monitoring matrix. To ensure that the monitoring data gathered for that substance fully reflect the risk that it poses, the Commission will further investigate whether Member States could monitor it in sediment in a reliable and comparable manner. In the meantime, that substance should be removed from the watch list.
- (9) For the macrolide antibiotic azithromycin and for two of the neonicotinoids, namely imidacloprid and thiamethoxam, additional high-quality monitoring data are still needed to support the targeted risk-based assessment as referred to in Article 16(2) of Directive 2000/60/EC. Therefore those substances should be retained in the watch list. Macrolide antibiotics and neonicotinoids were included as groups in the first watch list to account for the fact that substances with the same mode of action could have additive effects. This argument also justifies keeping the two groups in the watch list, despite the fact that sufficient high-quality monitoring data are available for some of the individual substances in those groups (the macrolide antibiotics clarithromycin and erythromycin, and the neonicotinoids acetamiprid, clothianidin and thiacloprid).
- (10) During 2017, the Commission also 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 insecticide metaflumizone, and the antibiotics amoxicillin and ciprofloxacin, were identified as suitable candidates. The inclusion of amoxicillin and ciprofloxacin is consistent with the European One Health Action Plan against Antimicrobial Resistance (AMR) ⁽¹⁾, 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. The method detection limit should be, for each substance, at least as low as the substance-specific predicted no-effect concentration in the relevant matrix.
- (12) While reviewing the first watch list, the Commission identified new ecotoxicological information for the macrolide antibiotics clarithromycin and azithromycin, for methiocarb, and for the neonicotinoids imidacloprid, thiacloprid and thiamethoxam, which led it to revise the predicted no-effect concentrations for those substances. The maximum acceptable method detection limits set out in the watch list for those substances and groups of substances should be updated accordingly.
- (13) The analytical methods indicated 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.
- (14) For comparability, all substances should be monitored in whole water samples.
- (15) Implementing Decision (EU) 2015/495 should be repealed.
- (16) 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,

⁽¹⁾ 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) 2015/495 is repealed.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 5 June 2018.

For the Commission
Karmenu VELLA
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 limit (ng/l)
17-Alpha-ethinylestradiol (EE2)	57-63-6	200-342-2	Large-volume SPE - LC-MS-MS	0,035
17-Beta-estradiol (E2), Estrone (E1)	50-28-2, 53-16-7	200-023-8	SPE - LC-MS-MS	0,4
Macrolide antibiotics ⁽⁵⁾			SPE - LC-MS-MS	19
Methiocarb	2032-65-7	217-991-2	SPE - LC-MS-MS or GC-MS	2
Neonicotinoids ⁽⁶⁾			SPE - LC-MS-MS	8,3
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

⁽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:

LLE — liquid liquid extraction

SPE — solid-phase extraction

Analytical methods:

GC-MS — Gas chromatography-mass spectrometry

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

⁽⁵⁾ Erythromycin (CAS number 114-07-8, EU number 204-040-1), Clarithromycin (CAS number 81103-11-9), Azithromycin (CAS number 83905-01-5, EU number 617-500-5)

⁽⁶⁾ Imidacloprid (CAS number 105827-78-9/ 138261-41-3, EU number 428-040-8), Thiacloprid (CAS number 111988-49-9), Thiamethoxam (CAS number 153719-23-4, EU number 428-650-4), Clothianidin (CAS number 210880-92-5, EU number 433-460-1), Acetamiprid (CAS number 135410-20-7/160430-64-8)