1 October 2025

Joint Non-paper on the implementation of the revised Urban Waste Water Treatment Directive 2024/3019/EU by Austria, Belgium, Estonia, Finland, Germany, Luxemburg, Netherlands and Sweden

The Need for EU-wide Standardised Requirements as part of the Implementation of Articles 9 and 10 UWWTD 2024/3019

The implementation of the extended producer responsibility (EPR) under the Urban Waste Water Treatment Directive (UWWTD) into national legislation requires a common approach on the requirements with regard to Articles 9 and 10 UWWTD in all Member States. Otherwise, there is a risk that producers will be judged by different standards or that anti-competitive relocation movements with negative impacts for the goals of water protection as well as for pharmaceutical supply will occur within the EU-market. Early action is needed at EU-level before implementation of a national system to avoid unintended effects.

Against this background, DE also welcomes the general intention of the non-paper recently submitted by FRA, which aims to reduce unclear implementation issues of the EPR through further harmonisation at EU level and to achieve overall simplification and streamlining. In particular, DE shares the view that potential negative effects on the industries affected by the EPR and on the supply of pharmaceuticals must be avoided. However, DE does not consider the specific proposal to create a positive list to be the appropriate approach. The creation of a positive list entails considerable challenges and uncertainties. At the same time, there is a risk of even greater cost accumulation for a smaller number of pharmaceuticals or their manufacturers. The need remains for a well-founded and comprehensible allocation of contributions to wastewater pollution with micropollutants.

An important starting point for the necessary EU-wide uniform regulation on the extended producer responsibility system are the results of the updated study announced by the Commission. Germany also expects a comprehensible review and presentation on the impact of the industrial sectors. Regarding this updated study, the Commission is requested to provide information on additional surveys conducted for the study and to provide an interim report.

At this stage, it is important and useful to consider the following points:

I. Implementing acts required to implement Art. 9 and 10 UWWTD

Art. 9 (5) UWWTD empowers the Commission to adopt implementing acts to establish detailed criteria on the uniform application of the condition laid down in paragraph 2, point (b) to specify categories of products and their biodegradability or hazardousness (**rapid biodegradability** of substances or no generated micropollutants in wastewater at the end of their life). Due to consideration with regard to the national implementation process we have the following suggestions on this:

1. The deadline of the implementing act of Art. 9 (5) sentence 2 UWWTD is the 31 December 2027. This is clearly too late for the implementation process of Member States, which includes, among others, the registration of relevant producers, who place any of the products listed in Annex III on the market. Therefore, we ask the COM to forward **the deadline of the implementing act to 2026**. This ensures that Member States can fulfil their national implementation obligations in time. In addition, it allows Member States to align their implementation and avoid unnecessary individual decisions on exemptions in accordance with Art. 9 para. 2 UWWTD (‘one substance - one assessment’). Also, MS might have to adjust their legislation again to the implementing act.

2. The implementing act should also include the following:
   a) a list of substances and product groups for which an exemption from the EPR is granted; the exemption rules must be uniform. And it is worth considering general exemptions for natural substances such as vitamins, proteins, and peptides, as such substances are also exempted from an environmental risk assessment in the authorisation process of medicinal products. Thus, it should be clarified (in the implementing act?) whether and to what extent inorganic substances fall under the EPR.
   b) a pragmatic definition of criteria for substances considered as rapidly biodegradable and which criteria apply to prove that a substance does not leave any micropollutants in wastewater at the end of its life.
   c) There should be clear rules for substances/products on data requirements and a process that defines how to deal with data gaps. The implementing act should also consider the assessment of hazardousness within the meaning of the information obligation under Art. 9 (3) a) (ii) UWWTD and the assessment under Art. 9 (3) c) UWWTD (see also II.);
   d) A proposal how to proceed with environment relevant data submitted with an application for a medicinal product, checked and validated by an authority. The Commission is requested to provide potential ways for the use of these data, e.g. information such as biodegradability or hazardousness of pharmaceuticals.

II. Need for further provisions for a uniform EU enforcement of the EPR

With respect to the uniform EU enforcement, we have additional comments:

1) It needs to be clarified whether or not an **extension of the catalogue of substances** by single Member States (see Annex III UWWTD) beyond pharmaceuticals and cosmetic residues should require an EU-wide harmonised decision and may not be carried out individually by the Member States.
2) According to Article 9 (2) a) of the UWWTD, producers can apply for an exemption if the quantity of substances in the products they place on the Union market is less than one tonne per year. The Commission is requested to identify low-cost and legally secure options for a uniform EU-wide implementation of the requirements, also taking into account comparable provisions already existing in EU legislation and to check this exemption in case the producers ask for such an exemption. Both, Art. 10 (6) no. 2 UWWTD (exchange of information) and Art. 10 para. 7 UWWTD (list of requests for exemptions) may serve as starting points for this system. The planned EU 'common data platform'[1] could also be used for this purpose.
3) In order to ensure an effective enforcement in the EU, a **uniform assessment of the hazardousness of substances** is also required beyond the clarification of the biodegradability exemption (see I above). This means that standardised assessment criteria should be provided (possibly in an EU guideline - following Art. 10 (6) UWWTD) including a harmonised and coordinated approach at EU level to avoid different and duplicative assessments by Member States. This central assessment also contributes to the 'One Substance - One Assessment' approach pursued by the Commission with the support of the EP and Council.
4) A common approach for Art. 9 (3) c) shall follow a simple model. A simplified model could be that the hazardousness is based on few categories only (e.g. categories "high – medium – low", meaning not a linear approach for hazardousness).

[1] Proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals; https://data.consilium.europa.eu/doc/document/ST-10883-2025-ADD-1/en/pdf

5) The **use of data from the intended program for the environmental assessment of legacy products** in accordance with the current draft of EU pharmaceuticals legislation[2] (Article 23) or from the active substance monographs (Article 24) has to be ensured.
6) A clarification for the pharmaceutical and cosmetics sector regarding the meaning of the term 'producer' (e.g. for the pharmaceutical sector the producer as a permit-holder for a pharmaceutical product, the distributor or the pharmacy?). It is also important to have a uniform interpretation and application of the term '**placing on the market'** within the meaning of Art. 2 (26) UWWTD (specification of „first making available of a product on the market of a Member State"). With regard to this aspect, it has to be clarified which responsibilities and payment obligations for the import/export exist within the EU (see also Art. 10 para. 4 UWWTD).

As the deadlines for the implementation of the EPR are very demanding, the Commission should clarify as soon as possible which further specifications/regulations can be expected and indicated a release date. Member States need this essential information to set up their EPR enforcement systems.

[2] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC; COM(2023) 192 final