# **Assessment of the EU Legality of the UWWTD**

The UWWTD justifies the imposition of EPR obligations on producers of human medicines on the EU polluter pays principle and the need to incentivize producers to develop greener (pharmaceutical) products. In particular, Article 1 of the Directive states that “[the UWWTD] also lays down rules on […] the implementation of the polluter pay principle,” and Recital 20 further explains that:

“[i]n order to cover [the additional costs of quaternary treatment] and in accordance with the polluter pays principle expressed in Article 191(2) of the [TFEU]), it is essential that the producers placing on the Union market products containing substances which, at the end of their life, are found as micropollutants in urban wastewaters (‘micropollutant substances’) take responsibility for the additional treatment required to remove those substances, generated in the context of their professional activities. A system of extended producer responsibility is the most appropriate means to achieve this, as it would limit the financial impact on the taxpayer and water tariff, while providing an incentive to develop greener products” (emphasis added).

Recital 21 also claims that the EPR obligations on producers of human medicines are proportionate on the grounds that “[a]ccording to the available data, the potential increase of costs of the products or the potential reduction of the profit margins of the industries placing the products on the Union market due to the application of the extended producer responsibility would be marginal at EU level and would not endanger the affordability, availability and accessibility to these products on the EU market.”

However, despite the UWWTD’s claim, there are strong arguments to claim that the Directive violates the EU principles of polluter pays, proportionality, and non-discrimination. As explained further below, this is because the EPR obligations will require producers of human medicines to pay for significantly more than their products’ contribution of micropollutants to wastewater pollution, it will be difficult for producers to substitute their human medicines for greener products, the EPR obligations may risk the access of patients to medicines, and the Directive imposes costly obligations on producers of human medicines and cosmetic products and not to other important contributors of micropollutants to wastewaters.

## **The UWWTD Violates the EU Polluter Pays Principle**

There are strong arguments to claim that the EPR obligations that the UWWTD imposes on producers of human medicines violate the EU polluter pays principle because they will require such producers to pay significantly more than the costs of the quaternary treatment of the micropollutants in wastewaters that result from their products, and the obligations do not take into account the contribution to micropollutants of other product sectors.

The polluter pays principle is a basic principle of EU environmental law. Article 191(2) of the TFEU states that “Union policy on the environment […] shall be based on the […] principles that […] the polluter should pay” (emphasis added).[[1]](#footnote-2) As explained by the European Court of Auditors, the application of the polluter pays principle means that “polluters bear the costs of their pollution including the cost of measures taken to prevent, control and remedy pollution and the costs it imposes on society” (emphasis added).[[2]](#footnote-3)

The Court of Justice of the European Union (“CJEU”) has repeatedly emphasized that the polluter pays principle requires making sure that polluters pay for the costs of their pollution, and not more. For example, it has held that “in accordance with the ‘polluter pays’ principle [an obligation] is imposed on operators only because of their contribution to the creation of pollution.”[[3]](#footnote-4)

In *Standley and Others,* the CJEU also held that authorities must not make polluters “take on burdensfor the elimination of pollution to which they have not contributed.”[[4]](#footnote-5) Authorities must “take into account other sources of pollution” and “are not to impose […] costs of eliminating pollution that are unnecessary.”[[5]](#footnote-6)

By making producers of human medicines (and cosmetic products) pay for “at least 80% of the full costs” of the quaternary treatment of wastewaters, the UWWTD violates the polluter pays principle as it makes producers of human medicines pay for significantly more than the elimination of micropollutants to which they contribute, without taking into account the sources of micropollutants from other categories of producers and adequately distributing the burden among covered producers. We provide further details.

### **The UWWTD Ignores the Contribution of Other Sectors to Micropollutants in Wastewater**

The UWWTD fails to properly distribute the burden of removing micropollutants. While the UWWTD and the Impact Assessment and Feasibility Study that accompanied the Commission’s legislative proposal partially acknowledge the contribution to micropollutants in wastewaters of other industrial sectors, the Directive imposes the obligation to pay at least 80% of the costs of quaternary treatment only on producers of human medicines and cosmetic products.

Recital 20 of the Directive justifies the imposition of the EPR obligations on producers of human medicines and cosmetic products on grounds that “[p]harmaceuticals and cosmetic residues currently represent the main sources of micropollutants found in urban wastewater requiring an additional treatment (quaternary treatment).” However, the Recital also acknowledges that other product groups may contribute to micropollutants in wastewater as it states that “[b]ased on the results of the urban wastewater monitoring and the most recent scientific data, the Commission should regularly evaluate whether other industrial sectors should be included in the Extended Producer Responsibility system.” Moreover, Recital 28 also acknowledges the contribution of other industrial sectors to micropollutants in wastewaters as it states that “[u]rban wastewater treatment plants also receive non-domestic wastewater, including industrial wastewater, which can contain a range of pollutants […] such as […] micropollutants […] This nondomestic wastewater may come from industries, or commercial establishments, or hospitals and other medical facilities, etc.” (emphasis added). Despite this, the UWWTD imposes the EPR obligations only on producers of human medicines and cosmetic products.

This sole focus on human medicines and cosmetic products without a proper assessment of the impact of other sectors was already evident in the Commission’s Impact Assessment and the Feasibility Study that the Commission contracted to prepare its assessment. As demonstrated by a report prepared by the consultancy Ramboll, the Feasibility Study and Commission’s Impact Assessment focused mostly on studies conducted on micropollutants resulting from human medicines without much consideration for other studies that would have also highlighted the significant impact of other product sectors, such as biocides, pesticides and house cleaning products.[[6]](#footnote-7) In effect, chapter 2.2 of the Feasibility Study acknowledged that its “study specifications already identified pharmaceuticals for human use as one of the sectors to be covered by this study,”[[7]](#footnote-8) and that “[t]he study defines the approach to identify a second sector (to start with) that would also contribute to the EPR scheme.”[[8]](#footnote-9)

Thus, the Commission’s assessment focused on the micropollutants of the human medicines and cosmetics sectors without taking in account other studies that explained the contribution of other product sectors to micropollutants in wastewater,[[9]](#footnote-10) thus failing to comply with the polluter pays principle.

In fact, the Feasibility Study recognized that focusing only on two sectors was not optimal.[[10]](#footnote-11) The study acknowledged that in defining the scope of the EPR, rather than a selection of covered sectors, a “selection of substances, if based on objective criteria that relate to the contribution to the cost of the fourth treatment (biodegradability), improves the application of the [polluter pays principle]. A selection of substances fosters substitution and could reduce the administrative burden while improving the reliability of declarations by focusing the scope on key contributors only” (emphasis added).[[11]](#footnote-12)

### **The UWWTD Requires Producers of Human Medicines to Pay for More than the Costs of the Quaternary Treatment of the Micropollutants from their Products**

Moreover, by requiring producers of human medicines and cosmetic products to pay at least 80% of the costs of quaternary treatment, the UWWTD requires these producers to pay significantly more than the costs of the quaternary treatment to remove the micropollutants resulting from their own products. This approach is not in accordance with the polluter pays principle because it is scientifically unjustified and disproportionate.

First, it is very likely that the Impact Assessment and Feasibility Study overestimated the contribution of human medicines to micropollutants in wastewaters. The Impact Assessment and Feasibility Study failed to take into account that, as recognized by the European Medicines Agency, many human medicines are metabolized in the human body,[[12]](#footnote-13) and are biodegradable or are removed from wastewaters by absorption to sewage sludge.

Article 9(2) of the UWWTD does require Member States to exonerate producers from their EPR obligation if they market products with substances that are rapidly biodegradable in wastewaters or that do not generate micropollutants in wastewater. However, this is only with respect to individual producers and not for the entire sector of producers of human medicines. The UWWTD requires producers of human medicines (and cosmetic products) as a group to pay up to 80% of the costs of the quaternary treatment, even if a scientific assessment would have shown that many of their products are biodegradable or do not result in micropollutants.

Second, not only the Commission’s Impact Assessment and Feasibility Study failed to assess the micropollutants contribution of other sectors and overestimated that of human medicines, but the UWWTD also imposes on producers of human medicines (and cosmetic products) a higher share of the costs of the quaternary treatment than their actual contribution to micropollutants in the Impact Assessment. In line with the Feasibility Study,[[13]](#footnote-14) the Commission’s Impact Assessment claimed that “pharmaceuticals represent 59% of input quantities to wastewater treatment plants (14% for PCPs [*i.e.*, cosmetic products]), 48% of the toxic chronic load (17% for PCPs) and 66% of the total toxic load PNEC […] (26% for PCPs).”[[14]](#footnote-15) These figures indicate that human medicines and cosmetic products contribute less than 80% of the pollution of micropollutants to wastewaters. Yet, the UWWTD requires producers of such products to pay at least 80% of the costs of quaternary treatment of all micropollutants. The UWWTD, Commission’s Impact Assessment and Feasibility Study provide no adequate and evidence-based justification for this decision.

### **The UWWTD Requires Individual Producers to Pay Significantly More than the Contribution to Micropollutants of their Individual Products**

The UWWTD has an even more disproportionate impact on “individual” producers of human medicines that are covered by the EPR obligations. As a result of the UWWTD’s exoneration provisions, the Directive imposes on individual producers that are not exonerated costs that are significantly beyond their contribution to the pollution.

As explained above, the UWWTD requires producers of human medicines and cosmetics to pay for at least 80% of the costs of the quaternary treatment to remove all micropollutants. However, in practice, the individual producers of medicinal products that are required to pay for the costs of quaternary treatment will pay significantly more than 80% of the costs. This is because Article 9(2) of the Directive requires Member States to exonerate producers on the basis of the volume of the substances in their products (below one ton per year) and the rapid biodegradability or non-generation of micropollutants of such substances.

Thus, contrary to the polluter pays principle, those producers that are left to pay in the scheme do not only pay for the costs of removing their own pollution but of all pollution, including that of exonerated products and producers, even if they are not responsible for it.

### **The UWWTD’s EPR Obligations on Producers of Human Medicines Are Not in Accordance with Other EU EPR Schemes**

The UWWTD’s obligation on producers of human medicines to pay for the quaternary treatment of wastewaters beyond their contribution to micro-pollution also constitutes a significant departure from the approach followed by the regimes of other EU EPR legislations, such as those of the WEEE Directive, the Packaging and Packaging Waste Directive (“PPWD”),[[15]](#footnote-16) or the Sustainable Batteries Regulation (“SBR”).[[16]](#footnote-17) While these legislations may vary on whether they impose strict individual or collective responsibility on producers, they are all based on the premise that producers should pay for the waste take-back, treatment and recycling of their own products and not that of others.

In particular, these different EPRs do not require producers to pay for the waste take-back of products marketed by others. For example, when the WEEE Directive excludes from its EPR obligations “large-scale stationary industrial tools,” it does not require producers of all other electronical and electronic equipment that are covered by the scheme to pay for the waste take-back, treatment and recycling of waste from large-scale stationary industrial tools. To the contrary, the WEEE Directive makes clear that “[e]ach producer shall be responsible for financing the operations referred to in paragraph 1 relating to the waste from his own products” (emphasis added).[[17]](#footnote-18) Similarly, the SBR establishes the general principle that “[p]roducers should have extended producer responsibility for the management of their batteries at the end-of-life” (emphasis added).[[18]](#footnote-19) In the same line, the Waste Framework Directive states that “Member States shall take the necessary measures to ensure that the financial contributions paid by the producer of the product to comply with its extended producer responsibility obligations cover […] costs for the products that the producer puts on the market in the Member State concerned” (emphasis added).[[19]](#footnote-20) Directive (EU) 2019/904 on the Reduction of the Impact of Certain Plastic Products on the Environment (“SUPD”) follows a similar approach as it requires producers that place on the market single-use plastic products listed in Part E of its Annex to cover the waste-back costs of “those products.”[[20]](#footnote-21)

## **The UWWTD Violates the EU Principle of Proportionality**

Article 5(4) of the Treaty on European Union (“TEU”) requires that EU measures, such as the UWWTD, comply with the principle of proportionality.[[21]](#footnote-22) The CJEU has repeatedly held that to be proportionate, EU measures must: (i) be appropriate for attaining the legitimate objectives pursued by the legislation at issue;[[22]](#footnote-23) (ii) not go beyond what is necessary to achieve them; and (iii) not impose an excessive burden on the individual in relation to the objective to be achieved.[[23]](#footnote-24)

The UWWTD’s EPR obligation on producers of human medicines violates the EU principle of proportionality because it: (i) as explained above, imposes financial obligations on producers of human medicines that go beyond these products’ contribution to micropollutants; (ii) is not appropriate to achieve the substitution of medicinal products that result in micropollutants in wastewater; and (iii) imposes such burden on human medicines that it may risk the access of patients to medicines. As explained in the Estonian Statement on the proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast) of October 12, 2023:

“[t]he clear added value of EPR in case of pharmaceuticals has not been confirmed by the feasibility study (carried out as part of the Commission’s impact assessment), as the effect of EPR on behavioral change would be very limited. On one hand, EPR is unlikely to significantly incentivise the substitution of pharmaceutical active ingredients in short- to medium-term, considering their specific innovation cycles. On the other hand, patients would not have the option to decrease their consumption of a medically indicated medicinal product or switch to another product. In this respect, ethical aspects are not sufficiently considered, as additional costs would have to be borne by patients, putting a disproportionate and unfair burden on population groups in a vulnerable situation due to their health condition” (emphasis added).[[24]](#footnote-25)

### **The UWWTD’s EPR Obligation on Producers of Human Medicines is Not Appropriate to Achieve the Substitution of Medicinal Products for Greener Products**

Contrary to what Recital 20 of the UWWTD claims, the EPR obligation that the Directive imposes on producers of human medicines will not encourage the development of greener products. As the Commission’s own Feasibility Study acknowledges, the UWWTD’s “EPR is unlikely to significantly incentivize the substitution of pharmaceuticals, considering their specific innovation cycles and the priority of therapeutical activity in identifying eligible substances. […] The added value of EPR in this regard is unclear.”[[25]](#footnote-26)

The Feasibility Study further explains that the EPR is not likely to result in substitution in the pharmaceutical sector because such sector is “mainly focused on the efficiency and cost-effectiveness of treatments. Moreover, the time required for research and innovation is generally several years (5.5 years on average), and the number of substances to be tested before making the final selection is significant (between 5,000 to 10,000 medicinal candidates for a selection of 10 to 20 final candidates). Finally, the sector has a complex value chain.”[[26]](#footnote-27) The Study adds that the EPR system “is unlikely to significantly incentivise the substitution of pharmaceuticals in short- to medium-term, considering their specific innovation cycles and the priority of therapeutical activity in identifying eligible substances.”[[27]](#footnote-28)

Furthermore, the Feasibility Study and the Commission’s Impact Assessment do not provide any evidence that there are alternatives available to replace the APIs that result in micropollutants in wastewaters without compromising patient safety and efficacy. In effect, as shown by the chemical assessment of pharmaceutical ingredients by the European Chemicals Agency under the REACH Regulation and other EU chemicals legislation, the identification and development of alternative ingredients for human medicines is a long hit-and-miss process that will typically take more than a decade and it is also subject to stringent requirements and long market authorization deadlines under the EU Human Medicines Code.[[28]](#footnote-29)

Thus, the EPR obligation on producers of human medicines is not an appropriate mechanism to incentivize producers to substitute their substances and products that generate micropollutant residues in urban wastewater.

### **The UWWTD Imposes an Excessive Burden on Individual Producers of Human Medicines**

The Directive’s EPR obligations impose on producers of human medicines a burden that is excessive in relation to its claimed objectives, *i.e.*, make polluters pay and incentivize the substitution of human medicines, as it fails to consider the social contribution of human medicines and puts at risk their affordability and accessibility and the EU’s strategic pharmaceutical supply chain autonomy.

As explained above, the EPR obligation will require individual producers of human medicines to pay significantly more than in proportion to their products’ contribution to micropollutants in wastewaters. In addition, as the costs will fall only on those producers of human medicines that are not exonerated under Article 9(2), they will have a significant impact on the costs of at least some human medicines. Thus, contrary to what Recital 21 of the Directive claims,[[29]](#footnote-30) the UWWTD is very likely to impose disproportionate costs on specific producers of human medicines, and it will thus jeopardize the affordability and accessibility of their products.

In particular, the Feasibility Study and Impact Assessment underestimated the impact of the EPR obligations on particular human medicines. The Feasibility Study states that “if passed on consumers through a price increase, the EPR costs could induce a relative price increase of 0.09 to 2.34% of individual expenditure in the pharmaceutical sector.”[[30]](#footnote-31) It also explains that if the costs are not passed on consumers, the obligations will result in an increase of costs of 0,6% for the production of human medicines and cosmetic products and a 0,7% average decrease of profit margin.

However, these assessments fail to take into account that the costs will not be allocated evenly among all producers of human medicines that may result in micropollutants. For those producers of human medicines whose products are not exonerated under Article 9(2) of the Directive, it is more likely that the added average product costs could increase by 2.8 to 4.9% and decreased average profit margin could be 3.2 to 5.7%.

Thus, despite the claims of Recital 21 of the UWWTD that the EPR obligation will not endanger the affordability and availability of human medicines, there is a significant risk it will do exactly that at least with respect to some products. This risk is even recognized by Article 10 of the UWWTD as it requires the Commission to ensure an exchange of information on such risks among Member States. In effect, the excessive burden that the UWWTD’s EPR obligations impose on producers of human medicines contradicts the basic principle of the EU that it should not impeded the access to medicinal products or their affordability and availability, as reflected in Article 168(1) of the TFEU.[[31]](#footnote-32)

The importance that the EU gives to the social contribution of human medicines also highlights how the UWWTD imposes an excessive burden on producers of human medicines. For example, in its recent Communication “Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals”, the Commission makes clear that “in the case of medicinal products for human […] use, […], the strategic autonomy of the Union and availability of substances used in the manufacturing of products for health applications must be given due priority;” and that “[f]or uses that are essential for society [such as human medicines], the concept [of essential uses] can give companies certainty that substances otherwise targeted for phase-out can continue to be used to fulfil societal needs, until alternatives are available” (emphasis added).[[32]](#footnote-33) Similarly, the Communication on the European Union Strategic Approach to Pharmaceuticals in the Environment, which is mentioned in Recital 18 of the UWWTD, states that “actions to address the risk [from pharmaceutical residues in the environment] do not jeopardise access to safe and effective pharmaceutical treatments for human patients and animals.”[[33]](#footnote-34)

## **The UWWTD Violates the EU Principle of Non-Discrimination**

The UWWTD’s EPR obligations also violate the EU principle of non-discrimination because they make producers of human medicines and cosmetic products pay for at least 80% of the quaternary treatment of all micropollutants in wastewaters without considering the contribution of other products to such pollution.

The principle of equal treatment or non-discrimination is enshrined in Articles 20 and 21 of the EU Charter of Fundamental Rights.[[34]](#footnote-35) The CJEU has explained that this principle “requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.”[[35]](#footnote-36) A difference in treatment is only deemed justified if “it is based on an objective and reasonable criterion, meaning it is related to a legitimate aim pursued by the legislation in question, and if that difference is proportionate to the aim pursued by the treatment in question.”[[36]](#footnote-37)

The UWWTD violates the principle of non-discrimination because it makes producers of human medicines and cosmetic products pay for at least 80% of the costs of the quaternary treatment of all micropollutants while it exonerates other producers without sufficiently assessing the justification to do so.

First, as explained above, the Commission’s Feasibility Study, Impact Assessment and legislative proposal failed to consider in any detail the impact of other producers to micro-pollution in wastewaters. In particular, the Feasibility Study focused mostly on the contribution of human medicines and failed to take into consideration studies that would have also highlighted the contribution to pollution of other sectors. Thus, the EU legislator never provided a reasonable, evidence-based justification to treat differently producers of human medicines and cosmetic products by making them pay and excluding producers of other products, such as pesticides, food products, house cleaning products.

Second, while arguably the EU legislator may be entitled to first regulate some categories of products, or those products that are shown to contribute more to micro-pollution, such approach is still discriminatory to the extent that it will make producers of human medicines pay for significantly more than their contribution to pollution.

Thus, by making producers of human medicines pay for the pollution of other sectors without providing an objective justification, the UWWTD discriminates against producers of human medicines. The fact that Recital 21 states that the potential increase of costs of the products or the potential reduction of the profit margins “would not endanger the affordability, availability and accessibility to these products on the EU market” is not an objective or sufficient reason to explain the discrimination. This is even more the case given that this statement is not correct, as shown above.

1. Article 191(2) of the TFEU. [↑](#footnote-ref-2)
2. European Court of Auditors, Special Report The Polluter Pays Principle: Inconsistent application across EU environmental policies and actions, 2021, p. 4, accessible [here](https://www.eca.europa.eu/Lists/ECADocuments/SR21_12/SR_polluter_pays_principle_EN.pdf). [↑](#footnote-ref-3)
3. Judgment of 9 March 2010, *ERG and Others*, C-378/08, ECLI:EU:C:2010:126, para. 57. [↑](#footnote-ref-4)
4. Judgment of 29 April 1999, C-293/97, *Standley and Others*, ECLI:EU:C:1999:215, para. 51 ; see also Judgment of 25 February 2010, *Pontina Ambiente*, C-172/08, ECLI:EU:C:2010:87, para. 38. [↑](#footnote-ref-5)
5. Judgment of 29 April 1999, C-293/97, *Standley and Others*, ECLI:EU:C:1999:215, para. 52. [↑](#footnote-ref-6)
6. Ramboll, Micropollutants in Urban Wastewater: Critical review of the Impact Assessment accompanying the proposed recast of the EU Urban Wastewater Treatment Directive (UWWTD) ("Ramboll Study"), April 2023, p. 9. [↑](#footnote-ref-7)
7. Feasibility Study, p. 12. [↑](#footnote-ref-8)
8. Feasibility Study, p. 12 [↑](#footnote-ref-9)
9. Finckh *et al*., "*A risk based assessment approach for chemical mixtures from wastewater treatment plant effluents*”, 2023, accessible [here](https://www.sciencedirect.com/science/article/pii/S016041202200160X?via%3Dihub); Küster & Adler, “*Pharmaceuticals in the environment: scientific evidence of risks and its regulation*”, 2014, accessible [here](https://royalsocietypublishing.org/doi/10.1098/rstb.2013.0587); Gunnarsson *et al*., “*Pharmacology beyond the patient – The environmental risks of human drugs*”, 2019, accessible [here](https://www.sciencedirect.com/science/article/pii/S0160412019309493). [↑](#footnote-ref-10)
10. Feasibility Study, p. 54, Table 12. [↑](#footnote-ref-11)
11. Feasibility Study, p. 55. [↑](#footnote-ref-12)
12. European Medicines Agency, Guidelines on the environmental risk assessment of medicinal products for human use, 15 February 2024, accessible [here](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-environmental-risk-assessment-medicinal-products-human-use-revision-1_en.pdf). [↑](#footnote-ref-13)
13. Feasibility Study, p. 88. [↑](#footnote-ref-14)
14. European Commission, Impact Assessment Accompanying the Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast), 26.10.2022, COM(2022) 541 final, p. 57 and following, accessible [here](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022SC0541). [↑](#footnote-ref-15)
15. European Parliament and Council Directive 94/62/EC on packaging and packaging waste, OJ L 365, 31.12.1994, p. 10, accessible [here](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01994L0062-20180704). [↑](#footnote-ref-16)
16. Regulation (EU) 2023/1542 of the European Parliament and of the Council concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC, OJ L 191, 28.07.2023, p. 1, accessible [here](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02023R1542-20230728). [↑](#footnote-ref-17)
17. Article 12(3) of Directive 2012/19/EU of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE), OJ L 197, 24.07.2012, p. 38, accessible [here](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012L0019-20240408). [↑](#footnote-ref-18)
18. Recital 101 of Regulation (EU) 2023/1542 of the European Parliament and of the Council concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC, OJ L 191, 28.07.2023, p. 1, accessible [here](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02023R1542-20230728). [↑](#footnote-ref-19)
19. Article 8a(4)(a) of Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives, OJ L 312, 22.11.2008, p. 3, accessible [here](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008L0098-20240218). [↑](#footnote-ref-20)
20. Article 8 (2) of Directive (EU) 2019/904 of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment, OJ L 155, 12.06.2019, p. 1, accessible [here](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0904). [↑](#footnote-ref-21)
21. Article 5(4) of the TEU states that “[u]nder the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties”. [↑](#footnote-ref-22)
22. Judgment of 10 January 2006, *IATA and ELFAA*, C‑344/04, EU:C:2006:10, paragraph 79: “The principle of proportionality, which is one of the general principles of Community law, requires that measures implemented through Community provisions should be appropriate for attaining the objective pursued and must not go beyond what is necessary to achieve it.” [↑](#footnote-ref-23)
23. Judgment of 8 June 2010, *Vodafone and Others,* C-58/08, ECLI:EU:C:2010:321, paragraph 51 to 53; Judgment of 12 July 2001, *Jippes*, C-189/01, ECLI:EU:C:2001:420, paragraph 81; Judgment of 13 November 1990, *The Queen / Ministry of Agriculture, Fisheries and Food, ex parte FEDESA and Others*, C-331/88, ECLI:EU:C:1990:391, para. 13; Judgment of 7 September 2006, *Spain v Council*, C-558/07, ECLI:EU:C:2006:521, para. 95 and following. [↑](#footnote-ref-24)
24. Statement by Estonia on the proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast), 12.10. 2023, p. 2, accessible [here](https://data.consilium.europa.eu/doc/document/ST-13857-2023-ADD-1/en/pdf). [↑](#footnote-ref-25)
25. Feasibility Study, p. 106. [↑](#footnote-ref-26)
26. Feasibility Study, p. 102. [↑](#footnote-ref-27)
27. Feasibility Study, p. 112. [↑](#footnote-ref-28)
28. Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67, accessible [here](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02001L0083-20220101). [↑](#footnote-ref-29)
29. Recital 21 of the UWWTD states that “the available data, the potential increase of costs of the products or the potential reduction of the profit margins of the industries placing the products on the Union market due to the application of the extended producer responsibility would be marginal at EU level and would not endanger the affordability, availability and accessibility to these products on the EU market.” [↑](#footnote-ref-30)
30. Feasibility Study, p. 137. [↑](#footnote-ref-31)
31. Article 168(1) of the TFEU states that “a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.” [↑](#footnote-ref-32)
32. Communication from the Commission, Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals, 22.04.2024, C(2024) 1995 final, p. 2, accessible [here](https://environment.ec.europa.eu/document/download/fb27e67a-c275-4c47-b570-b3c07f0135e0_en?filename=C_2024_1995_F1_COMMUNICATION_FROM_COMMISSION_EN_V4_P1_3329609.PDF). [↑](#footnote-ref-33)
33. 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, 11.03.2019, COM(2019) 128 final, p. 6, accessible [here](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019DC0128). [↑](#footnote-ref-34)
34. Judgment of 14 September 2010, *Akzo Nobel Chemicals and Akcros Chemicals v Commission*, C-550/07 P, ECLI:EU:C:2010:512, paras. 54. [↑](#footnote-ref-35)
35. Judgment of 8 July 2010, *Afton Chemical*, C-343/09, ECLI:EU:2010:419, para. 74; Judgment of 7 July 2009, *S.P.C.M. and Others*, C-558/07, ECLI:EU:C:2009:430, para. 74; Judgment of 14 December 2004, *Swedish Match*, C-210/03, ECLI:EU:2004:802, para. 70; Judgment of 9 September 2004, *Spain v Commission*, C-304/01, ECLI:EU:2004:495, para. 31; Judgment of 12 November 2014*, Guardian Industries and Guardian Europe v Commission*, C-580/12 P, ECLI:EU:2014:2363, para. 51; Judgment of 14 September 2010, *Akzo Nobel Chemicals and Akcros Chemicals v Commission*, C-550/07 P, ECLI:EU:C:2010:512, paras. 54-55; Judgment of 3 May 2007, *Advocaten voor de Wereld*, C-303/05, ECLI:EU:C:2007:261, para. 56; Judgment of 16 December 2008, *Arcelor Atlantique and Lorraine v Others*, C-127/07, ECLI:EU:C:2008:728, para. 23; Judgment of 26 October 2006, *Koninklijke Coöperatie Cosun*, C-248/04, ECLI:EU:C:2006,666, para. 72. [↑](#footnote-ref-36)
36. Judgment of 17 October 2013, *Schaible*, C-101/12, ECLI:EU:C:2013:661, para. 77; Judgment of 16 December 2008, *Arcelor Atlantique and Lorraine v Others*, C-127/07, ECLI:EU:C:2008:728, para. 47. [↑](#footnote-ref-37)