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ARTICLE

Precautiously Circular: Perspectives on the Application of the Precautionary Principle in European Union Waste and Chemicals Regulation

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Abstract

Both the waste regulation and chemicals regulation of the European Union are based on the precautionary principle. The main objective of the chemicals regulation is to protect human health and the environment from the risk caused by hazardous chemicals. The modern waste regulation aims, among other things, at fostering the recovery of waste. These material circulation aims have been recently emphasised by introducing the ambitious circular economy objectives. Many of the waste streams contain hazardous substances that may pose risks to human health and the environment. This article examines the role of the precautionary principle in the circular economy. We argue that sustainable material circulation can only be achieved through a case-by-case application of the precautionary principle, but this also requires participatory discourse in which competing arguments, beliefs and values are openly discussed.

Keywords: chemicals regulation; circular economy; material circulation; precautionary principle; waste regulation

I. Introduction

"Circular economy" has quickly become a term that everyone following European Union (EU) politics or environmental discourse recognises. The circular economy can be defined as an industrial system in which the value of products, materials and resources is maintained in the economy for as long as possible, waste generation is minimised and value-creation mechanisms are therefore decoupled from the consumption of finite resources.[1] According to the European Commission, the scaling up of the circular economy will make a "decisive contribution" to achieving climate neutrality by 2050, and decoupling economic growth from resource use and has the potential to increase the gross domestic product of the EU by an additional 0.5% by 2030 and create around 700,000 new jobs. The aim set by the Commission is to double the use of circular materials in the EU by 2030.[2]

[1] Commission, "Closing the Loop – An EU Action Plan for the Circular Economy" (Communication) COM (2015) 614 final, 2; Ellen MacArthur Foundation, "Growth Within: A Circular Economy Vision for a Competitive Europe" (2015), 37 <https://ellenmacarthurfoundation.org/growth-within-a-circular-economy-vision-for-a-competitive-europe> (last accessed 6 April 2022).

[2] Commission, "A New Circular Economy Action Plan for a cleaner and More Competitive Europe" (Communication) COM (2020) 98 final, 2.

The circular economy can be fostered by removing regulatory barriers that hinder the reuse, recycling and other recovery of secondary raw materials.[3] In parallel, it is necessary to protect humans and the environment from harmful exposure to the hazardous substances that those secondary raw materials and objects may contain. The regulatory mechanisms that require the waste treatment operator to obtain information on the chemical composition of the recovered material or object and pose restrictions on hazardous substances are crucial in achieving chemicals and product legislation that ensures a high level of protection of human health and the environment. Balancing the material circulation objectives and safety objectives is the main dilemma of the precautionary regulation of material circulation. Too cautious regulation of the safety aspects may hamper the achievement of the environmental benefits of the circular economy, whilst too permissive regulation of recovery may cause irreversible damage to human health or the environment. The regulation of material circulation also entails situations where different risks must be balanced and where trade-offs between risks may be necessary.

The risk–risk trade-off approach as originally introduced by Graham and Wiener[4] has been strongly criticised by many authors.[5] However, there are situations in the regulation of chemicals where the precautious regulation of risks necessarily and inevitably also requires consideration of the countervailing risks, as in some occasions the elimination of one risk may lead to another risk. This is obvious in, for example, "regrettable substitution", which means that banned substances will be substituted with less studied and possibly more harmful substances.[6]

The precautionary principle is the cornerstone of EU risk regulation. According to the precautionary principle, decision-makers may – and should – adopt *precautionary measures* to protect human health and the environment even if the *scientific evidence* about the risk *is not certain*. In other words, *precautious restriction mechanisms* should be applied in order to protect people and the environment from the *uncertain risks* posed by hazardous chemicals.

In this article, we examine the role of the precautionary principle in balancing the material circulation objectives and safety objectives in EU waste and chemicals regulation. In Section II, we discuss the role of scientific uncertainty in the precautious regulation of risks, in particular chemical risks. In Section III, we examine the role of the precautionary principle in the EU waste and chemicals legislation and the related case law, and we set out a proposal for the classification of the risk problems of the circular economy.

We conclude in Section IV that the objectives of waste and chemicals regulation that are in tension and the competing uncertainties of case-by-case decision-making related to material circulation form a dilemma facing the precautious circular economy that can be solved only by balancing the risks and benefits and reconciling the various objectives

[3] Secondary raw materials in a circular economy refer to materials that can be recovered and injected back into the economy as new raw materials, thus increasing the security of supply; see Commission, supra, note 1, p 11.

[4] JD Graham, JB Wiener, "Confronting Risk Tradeoffs" in JD Graham and JB Wiener (eds), *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment* (Cambridge, MA, Harvard University Press 1995) pp 2–3. Decision-makers need to evaluate the likelihood and severity of the countervailing risks as compared to the target risk. In the long term, additional options to reduce both target risk and avoid countervailing risks may exist and should be sought out.

[5] See, eg, SF Hansen, M Krayer von Krauss and JA Tickner, "The Precautionary Principle and Risk–Risk Tradeoffs" (2008) 11(4) Journal of Risk Research 423; SF Hansen and JA Tickner, "Putting Risk–Risk Tradeoffs in Perspective: A Response to Graham and Wiener" (2008) 11(4) Journal of Risk Research 475; JA Tickner and C Raffensperger: "The American View on the Precautionary Principle" in T O'Riordan, J Cameron and A Jordan (eds), *Reinterpreting the Precautionary Principle* (London, Cameron May 2001) pp 200–201; P Sandin et al., "Five Charges Against the Precautionary Principle" (2002) 5(4) Journal of Risk Research 287.

[6] An example is replacement of bisphenol A with bisphenol S; see A Maertens, E Golden and T Hartung, "Avoiding Regrettable Substitutions: Green Toxicology for Sustainable Chemistry" (2021) 9 ACS Sustainable Chemistry and Engineering 7749, 7754. The authors stated that although bisphenol S has lower oestrogen receptor binding, it binds with higher affinity to other receptors.

through an analysis that gives appropriate weight to different types of risk problems and associated uncertainties.

II. Application of the precautionary principle to chemical risks

As set out in the settled case law of the European Court of Justice (ECJ), the precautionary principle justifies the adoption of restrictive measures "[w]here it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise".[7] Scientific information can be unclear (imprecise) if there is an epistemic debate ongoing in science (ie competing models or basic assumptions are adopted in different disciplines).[8] Insufficiency may occur if the disciplines involved in the assessment are not developed enough to explain the cause–effect relationship.[9] Scientific uncertainty thus exists if it is difficult to specify a set of possible consequences of certain actions or if it is difficult to establish an accurate prediction model.[10]

Decision-making on the regulation of hazardous substances often involves a genuine lack of knowledge on potential harmful effects due to missing, inadequate or incomplete data (epistemic uncertainty).[11] Most obviously, this is the case when a new chemical substance is placed on the market: a precautious approach is needed until the necessary toxicological and ecotoxicological studies are performed in order to know more about the properties of that substance. Following such studies, the hazardous properties of certain substance can be determined to a certain extent, within the limits of current knowledge, by performing tests the costs of which are proportionate to the aims pursued. However, whether or not the exposure to the hazardous substance in question is such that it leads to adverse effects in human health or the environment is always and inevitably uncertain, at least to some extent. Moreover, there may be uncertainty as regards the fate of a certain substance in the human body or the environment. Such hazardous substances may be

[7] Case C-192/01 *Commission* v *Denmark* [2003] EU:C:2003:492, para 52. De Sadeleer points out that it is not entirely clear what the EU courts mean by referring to insufficiency, inconclusiveness and imprecision, and that therefore the factors triggering precautionary action are still open to debate; N de Sadeleer, "The Precautionary Principle and Management of Uncertainties in EU Law on Chemicals" (Jean Monnet Working Paper Series – Environment and Internal Market, 1/2019, 10) <https://tradevenvironment.eu/index.php/2019/11/21/working-paper-2019-1/> (last accessed 31 May 2022).

[8] Von Schomberg uses long-term effects of genetically modified organisms as an example: biotechnologists usually refer to the practice of conventional plant breeding as a basis for risk predictions, whereas ecologists refer to experience based on the introduction of particular species into new environments; see R von Schomberg, "The Precautionary Principle: Its Use within Hard and Soft Law" (2012) 2 European Journal of Risk Regulation 147, 151. There are thus contradictory views amongst scientists. Other illustrative examples of imprecision include data unavailability (which is related to ignorance), information gaps, measurement errors, indeterminacy and ambiguity; see N de Sadeleer, "The Precautionary Principle in EC Health and Environmental Law" (2006) 12(2) European Law Journal 139, 156.

[9] De Sadeleer, supra, note 8, 156. Heselhaus has opined in 2010 that, for instance, the novel characteristics of nanomaterials call for a specific field of nanotoxicology; see S Heselhaus, "Nanomaterials and the Precautionary Principle in the EU" (2010) 33 Journal of Consumer Policy 91, 102.

[10] T Aven, "On Different Types of Uncertainties in the Context of the Precautionary Principle" (2011) 31(10) Risk Analysis 1515, 1522.

[11] O Renn and ED Elliot, "Chemicals" in JB Wiener, MD Rogers, JK Hammit and PH Sand (eds), *The Reality of Precaution. Comparing Risk Regulation in the United States and Europe* (Washington, DC, RFF Press 2011) pp 246–248; R Cooney, "A Long and Winding Road? Precaution from Principle to Practice in Biodiversity Conservation" in E Fisher, J Jones and R von Schomberg (eds), *Implementing the Precautionary Principle. Perspectives and Prospects* (Cheltenham, Edward Elgar Publishing 2006) p 229.

transformed in the human body or the environment, and the combined effects of different substances are generally not known and may be impossible or very costly to clarify.

In the case of epistemic uncertainty, normative qualifiers come into play while invoking the precautionary principle, as the uncertainties involved are precisely related to the impossibility of assigning a degree of likelihood.[12] It may therefore be better to relate the normative qualifiers to the quality of available information. This relates to the triggering factor of "inconclusiveness" identified by the ECJ. Heselhaus notes that "conclusiveness asks for a broad approach, taking into account whatever might affect the quality of investigations and not setting unpredictable variables aside".[13] This is not determined by the amount or degree of uncertainty but relates to what type of information is known or should be known and of which one is ignorant. Von Schomberg opines that the qualifier "reasonable grounds for concern", expressed in the communication of the Commission on the precautionary principle,[14] relates in fact to a judgment on the quality of the available information.[15]

Furthermore, a risk assessment describes scientific uncertainties and specifies probabilities but does not normally consider values or expected utilities. Because it could be based on assumptions that may turn out to be wrong or not adequately reflecting all aspects of concern, there is always a need for risk evaluation. It should be recognised that there is a leap between the analytical frameworks and decision-making that can never be removed by improved analytical methods.[16]

In many regulatory scenarios, including the regulation of many hazardous substances, whether the uncertainties are scientific or not is not really the point.[17] Aven opines that a broader "cautionary principle" has been the main perspective adopted, although not one specifically referred to, for handling such risk.[18] Aven and Renn have defined the cautionary principle as follows:

> If the consequences of an activity could be serious and subject to uncertainties, then cautionary measures should be taken or the activity should not be carried out.[19]

The cautionary principle applies for all types of uncertainties and ambiguities, whether they are scientific or not.[20] If the activity considered is associated with the possibility of severe negative consequences, regulatory measures are justified to avoid or limit these consequences, even if they are not yet sufficiently known to science or accurately quantified using any formalised method. De Sadeleer contends that precaution is a testament to a new relationship with science in which science is consulted less for the knowledge that it has to offer than for the doubts and concerns that it is in a position to raise.[21] However, for

[12] Von Schomberg, supra, note 8, p 152.

[13] Heselhaus, supra, note 9, p 102.

[14] Commission, "Communication from the Commission on the Precautionary Principle" (Communication) COM (2000) 1 final, 9.

[15] Von Schomberg, supra, note 8, p 152.

[16] T Aven, "On How to Deal with Deep Uncertainties in a Risk Assessment and Management Context" (2013) 33(12) Risk Analysis 2082, 2087, 2090.

[17] T Aven, "The Cautionary Principle in Risk Management: Foundation and Practical Use" (2019) 191 Reliability Engineering and System Safety 106585.

[18] ibid.

[19] T Aven and O Renn, "Improving Government Policy on Risk: Eight Key Principles" (2018) 176 Reliability Engineering and System Safety 230, 236.

[20] ibid, p 237.

[21] De Sadeleer, supra, note 8, p 159. His view is that, for example, in the case of delayed pollution, feedback from experience is too slow and the (pre)cautionary principle must be applied without having to use weak proof to seek to demonstrate the likelihood of ecological damage; see N de Sadeleer, "The Effect of Uncertainty on the Threshold Levels to Which the Precautionary Principle Appears to Be Subject" in *Environmental Risk*, vol. II (Farnham, Ashgate 2004) p 468.

some specific situations, it may be important to clarify that the uncertainties are scientific.[22] For example, in the approval of new products, understanding scientific uncertainties is important to ensure appropriate qualification processes are enacted. Clarifying the distinction is also relevant when more knowledge and science can reduce the scientific uncertainties and consequently better distinguish between discussions about uncertainties and discussions about values.

It must also be understood that the (pre)cautionary principle is not an autonomous transplantable rule but is shaped by the surrounding legal and socio-political culture, and that variations in formulations and interpretations arise from this context.[23]

III. (Pre)cautious regulation of the chemical hazards and risks of secondary raw materials

1. The precautionary principle in the EU waste and chemicals legislation and case law

The precautionary principle is codified in Article 191 of the Treaty on the Functioning of the European Union (TFEU) as one of the guiding principles of the environmental policy of the EU. The precautionary principle is also explicitly mentioned as an underpinning principle of the regulatory regimes or specific obligations in many sector-specific regulations and directives. Among others, the Waste Framework Directive (2008/98/EC; WFD)[24] and the REACH Regulation ((EC) No 1907/2006; REACH),[25] which are the two focal pieces of legislation in the regulation of material circulation and hazardous chemicals, are based on the precautionary principle.

Article 1(3) of REACH provides that:

> This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

Moreover, according to recital 9 of REACH, the reason underlying the commencement of the regulatory reform of the European chemicals regulation that eventually led to the adoption of REACH was "the need to do more to protect public health and the environment in accordance with the precautionary principle". The preamble of REACH also emphasises the importance of the precautionary principle in the regulation of Substances of Very High Concern (SVHCs).[26] According to recital 69 of REACH, SVHCs should, "having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment", and be subject to careful attention "in accordance with the precautionary principle".

[22] Aven, supra, note 17, p 5.

[23] E Fisher, "Precaution, Precaution Everywhere: Developing a 'Common Understanding' of the Precautionary Principle in the European Community" (2002) 9(1) Maastricht Journal of European and Comparative 7, 8, 15–16, 19.

[24] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, [2008] OJ L 312/3.

[25] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Establishing a European Chemicals Agency, Amending Directive 1999/45/EC and Repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, [2006] OJ L 396/1.

[26] SVHCs are substances that have certain carcinogenicity, mutagenicity or toxic for reproduction classification; they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative or pose equivalent levels of concern to human health or the environment, such as endocrine disruptors (Art 57 REACH).

In WFD, the precautionary principle is particularly mentioned in the context of the waste hierarchy set out in Article 4. The principal aim is to reduce the amount of waste generated by fostering resource efficiency. If waste, however, is generated, it should be prepared for reuse, recycled or otherwise recovered. Waste should be disposed of (ie landfilled or incinerated without energy recovery) only if none of the abovementioned options can be applied. Article 4(2) of WFD requires Member States to apply the waste hierarchy by taking into account "the general environmental protection principles of precaution and sustainability".

Furthermore, the preamble of WFD describes the more generic role of the precautionary principle as the underlying guideline in the implementation of waste policies. Pursuant to recital 30 of WFD, it is necessary to set general environmental objectives for the management of the waste in the EU "[i]n order to implement the precautionary principle and the principle of preventive action enshrined in Article [191] (2) [TFEU]", and that "[b]y virtue of those principles" the EU and its Member States are required to eliminate the recognised risks that such waste brings about. Thus, the recovery objectives of WFD and the prevention of the harms caused by the hazardous substances that the recovered materials contain are both based on the precautionary principle.

REACH is independent of the legislation on waste, and wastes are excluded from the scope of REACH.[27] However, REACH sets out specific rules for materials that are defined under WFD as by-products and for former wastes that have ceased to be wastes (end-of-waste; EoW). The provisions of REACH may guide the application of the respective provisions of WFD. The ECJ has, for example, stated that the compliance of the material with the REACH provisions may be relevant for determining whether EoW has occurred.[28] However, in the big picture, the tensions between the recovery objectives of WFD and the safety objectives of the chemicals regulation are much more complicated. Whilst WFD aims at achieving environmental benefits by fostering the reuse and recycling of materials, the restriction mechanisms of the chemicals regulation protect human health and the environment from the harmful chemical substances that the recovered materials may contain. The transition to a circular economy requires a radically new kind of reconciliation of these objectives.[29]

In accordance with the precautionary principle, the authorities should restrict the use of any secondary raw material that contains a hazardous substance that *may* pose a real harm to human health or the environment. However, as held several times by both the ECJ and the General Court (GC), such restrictive measures cannot be applied to "purely hypothetical risks".[30] As is well illustrated by the *Solvay* case, this does not prevent the application of restrictive measures in cases where the existence of a potential risk is not yet confirmed but the application of the precautionary principle also cannot lead to the requirement to prove the lack of any such risk.[31]

[27] See Art 2(2) of the REACH Regulation and Case C-358/11, *Lapin luonnonsuojelupiiri* [2013] EU:C:2013:142, para 28.

[28] See *Lapin luonnonsuojelupiiri,* supra, note 27, paras 60–64, according to which the fact that the respective use is exempted from the applicable REACH restriction provision may indicate that a waste has ceased to be waste. See also C-399/17, *Commission v Czech Republic* [2019], EU:C:2019:200, para 73, according to which existing registration as a chemical substance under REACH may also be considered as one factor in the EoW assessment. On the interaction between the provisions of REACH and WFD, see also J Alaranta and T Turunen, "Drawing a Line between European Waste and Chemicals Regulation" (2017) 26(2) Review of European, Comparative & International Environmental Law 163.

[29] C Bodar et al., "Risk Management of Hazardous Substances in a Circular Economy" (2018) 212 Journal of Environmental Management 108, 109.

[30] Case T-13/99, *Pfizer* [2002] EU:T:2002:209, para 143; Case T-229/04, *Sweden* v *Commission* [2007] EU:T:2007:217, para 147; Case C-41/02, *Commission* v *Netherlands* [2004] EU:C:2004:762, para 52; Case C-236/01, *Monsanto Agricoltura* [2003] EU:C:2003:431, para 106; *Commission* v *Denmark*, supra, note 7, para 49; Case C-24/00, *Commission* v *France* [2004] EU:C:2004:70, para 56.

[31] Case T-392/02, *Solvay* [2003] EU:T:2003:277, paras 129–35.

On the other hand, the authorities are required to ensure that any preventative measures are based on as thorough a scientific risk assessment as possible, as the lack of such assessment could lead to the adoption of "arbitrary measures which cannot be rendered legitimate by the precautionary principle".[32] In the regulation of (hazardous) chemical substances, which are subject to comprehensive risk assessment, this forms a direct link between the precautionary principle and the procedural requirements. The authority must ensure that it complies with the relevant procedural requirements and that its conclusion is based on careful and impartial examination of all of the relevant facts of the individual case in question.[33]

Ultimately, it is for the competent public authority to examine on a case-by-case basis what is the level of unacceptable risk that triggers the precautionary measures. In a veterinary drug case, such as *Pfizer*, the authority performing such an examination may take account of, for example, the severity, extent, persistence, reversibility and possibility of delayed effects of the any potential adverse effects that the actualisation of the respective risk would entail.[34] Therefore, the more severe the potential harmful effects in question, the less evidence is needed regarding the probability of the actualisation of the suspected risk to apply the precautious restrictive measures.

In addition, the authorisation of chemical substances for specific uses, such as plant production products, is based on the precautionary principle. Therefore, when authorising a plant production product, the absence of harmful effects cannot be presumed, and the burden of proof on the conformity with the applicable criteria lies with the applicant for the authorisation.[35]

On those premises, the precautionary principle has been applied by the ECJ and the GC in a variety of cases concerning restrictive measures for hazardous chemical substances. The application of the precautionary principle has led to:

- Strict application of the exemptions of the restrictions set out for the hazardous substances in electrical and electronic equipment;[36]
- The requirement for the Commission to reject an application of an active substance of plant protection products in a case where a risk to human health could not be excluded[37] and an application for an active substance that could have endocrine-disrupting properties even in the absence of guidelines for assessing such properties;[38]
- Accepting strict national restrictions for a fuel additive even in the absence of comprehensive risk assessment;[39] and
- Allowing the identification of substances such as an SVHC under REACH even with the existence of uncertainties as regards the determination of the safe level of exposure to that substance.[40]

[32] *Pfizer*, supra, note 30, para 162; Case T-456/11, *International Cadmium Association and Others* [2013] EU:T:2013:594, para 52.

[33] Case C-691/15 P, *Commission* v *Bilbaína de Alquitranes and Others* [2017] EU:C:2017:882, para 35. See also de Sadeleer, supra, note 7, 25.

[34] *Pfizer*, supra, note 30, para 153.

[35] Case C-616/17, *Blaise and Others* [2019] EU:C:2019:800, paras 78–80.

[36] Joined Cases C-14/06 and C-295/06, *European Parliament and Denmark* v *Commission* [2008] EU:C:2008:176, para 75.

[37] *Sweden* v *Commission*, supra, note 30, para 224.

[38] Case C-77/09, *Gowan* [2010] EU:C:2010:803, para 83.

[39] Case C-343/09, *Afton* [2010] EU:C:2010:419, para 69.

[40] Case T-207/18, *PlasticsEurope* [2020] EU:T:2020:623, paras 223–229. For more on the case law concerning the precautionary principle in the regulation of chemicals, see also de Sadeleer, supra, note 7.

In the application of the waste regulation, the precautionary principle has resulted in a non-restrictive interpretation of the concept of waste.[41] The ECJ has pointed out several times that in recovering production residues, special precaution must be taken as regards the potentially hazardous nature of their composition.[42] The precautionary principle has been relied on in recent case law concerning waste management. In particular, the precautionary principle played an important role in the ECJ's reasoning in *Verlezza*, which concerned the conditions under which a waste must be classified as hazardous, and *Prato Nevoso*, which concerned the conditions for EoW.

The classification of waste as hazardous in accordance with Annex III of WFD is a crucial dimension of waste management under WFD, as wastes classified as hazardous must be treated in specialised facilities that are subject to a specific permit procedure. In *Verlezza*, the ECJ considered that in accordance with the precautionary principle the starting point is that the classification of waste as hazardous is required only where, following as complete an assessment of the risks as possible, there is objective evidence that such classification is required.[43] However, the starting point for such assessment depends to a large extent on what is known about the composition of the waste batch in question. When applying the provisions on hazardous waste classification, the Member State must strike a balance between the precautionary principle on the one hand and technical feasibility and economic viability on the other. Therefore, the waste holders may confine themselves to ascertaining the substances that may reasonably be found in the waste in question and assess the hazardous properties of the waste based on that information. If it is impossible to determine the presence of hazardous substances but doubt regarding the hazardous properties of the waste remains, the waste must be classified as hazardous.[44]

In *Prato Nevoso*,[45] the ECJ applied the precautionary principle in the context of EoW; that is, as regards the conditions under which a waste may cease to be waste. The dispute concerned the use of residual vegetable oils in a power plant to replace methane. One of the conditions for EoW set out in Article 6(1) of WFD is the absence of adverse environmental or human health impacts of the substance or object in question. The role of the precautionary principle and the need to balance different environmental impacts were explicitly considered in the ruling. The ECJ held that the Member State could, taking into account the precautionary principle, decide not to authorise the combustion of vegetable oil, as the risks of that use to human health and the environment "are potentially higher than those associated with the use of such oils to produce biodiesel".[46] Moreover, in accordance with the precautionary principle, the Member State was required to refrain from confirming the EoW status of the vegetable oil if it had not been demonstrated that the combustion of vegetable oil was devoid of adverse impacts on the environment and human health.[47]

Verlezza, *Prato Nevoso* and other recent judgments related to the precautionary principle can be seen as new, more restrictive readings of the precautionary principle that have led to a stricter application of environmental provisions.[48] The application of the precautionary

[41] Joined Cases C-418/97 and C-419/97, *ARCO Chemie* [2000] EU:C:2000:318, para 40; Case C-399/17, *Commission* v *Czech Republic* [2019] EU:C:2019:200, para 59; Case C-624/17, *Tronex* [2019] EU:C:2019:564, para 18; Case C-629/19, *Sappi Austria* [2020] EU:C:2020:824, para 48.

[42] *ARCO Chemie*, supra, note 41, para 87; Case C-9/00, *Palin Granit* [2002] EU:C:2002:232, para 43; Case C-113/12, *Brady and Others* [2013] EU:C:2013:627, para 41.

[43] Joined Cases C-487/17 to C-489/17, *Verlezza and Others* [2019] EU:C:2019:270, para 48.

[44] ibid, paras 59–62.

[45] Case C-212/18, *Prato Nevoso* [2019] EU:C:2019:898.

[46] ibid, paras 52, 56–57.

[47] Ibid, paras 58–59. It is, however, important to note that, according to other recent case law of the ECJ, hazardous waste may also cease to be waste, see *Lapin luonnonsuojelupiiri*, supra, note 27, para 60.

[48] C Sobotta, "Recent Applications of the Precautionary Principle in the Jurisprudence of the CJEU – A New Yardstick in EU Environmental Decision Making?" (2021) 21 ERA Forum 723, 727–35.

principle also depends on the subject matter of the case in question.[49] Therefore, the strict approach of the precautionary principle may not be applied in all subject matters. The precautionary principle should be applied differently, for example, in such water and nature conservation cases where the effects of the planned activity are very difficult to predict and in the regulation of the well-known health risks of certain hazardous substances.[50]

In addition, as Sobotta points out, many decisions actually involve a choice where there are scientific doubts about the harmfulness of all options, including the do-nothing option. In such cases, the strict application of the precautionary principle is impossible, as some of the uncertain options must inevitably be chosen.[51]

This is where the trade-offs of the circular economy are inevitably brought into the decision-making. In fact, most of the decision-making in the circular economy with complex, uncertain and ambiguous risk problems – including situations like those of *Verlezza* and *Prato Nevoso* – is subject to such competing uncertainties. Recovering materials that may contain hazardous substances may pose uncertain risks to human health or the environment, but harm to the environment may also result from treating the magnitude of wastes through hazardous waste treatment procedures for safety's sake or from obtaining other fuels when the waste-based fuel cannot be used as intended. In cases such as the latter, attention must also be paid to the environmental benefits of the different uses: it may be better for the environment to use recovered vegetable oils as raw materials of biofuels instead of combusting them as such. The requirement for a "high level of protection" set out in Article 191(2) TFEU in combination with the precautionary regulatory frameworks force risk managers to seek "transformable" standards that respect the chosen level of protection in order to make the necessary normative conclusions concerning the adverse effects of the issues at stake, and they also force them to evaluate whether future developments would not allow us to design policies that retrospectively define current practices as insufficient.[52]

Balancing the chemical safety and circular economy objectives may lead, for example, to the need to exempt secondary materials from certain restriction rules of the chemicals legislation.[53] Setting the same stringent limit value for a hazardous substance in both virgin and recycled materials does not necessarily lead to the most sustainable outcome. This has been recognised in the Chemicals Strategy for Sustainability, which states the following:

> As a principle, the same limit value for hazardous substances should apply for virgin and recycled material. However, there may be exceptional circumstances where a derogation to this principle may be necessary. This would be under the condition that the use of the recycled material is limited to clearly defined applications where there is no negative impact on consumer health and the environment, and where the use of recycled material compared to virgin material is justified on the basis of a case-by-case analysis.[54]

[49] C-343/09, *Afton*, Opinion of Advocate General Kokott [2010] EU:C:2010:258, paras 66–74.

[50] De Sadeleer, supra, note 7, 6.

[51] Sobotta, supra, note 48, 734.

[52] The chosen level of protection changes over time while scientific knowledge grows and cultural values change, which results in precautionary regulation always being based on standards that remain open for discussion concerning the societal acceptability of particular emissions or products; see von Schomberg, supra, note 8, pp 153–154. Von Schomberg also explains that there seems to be an institutional preference to compare alternatives with current practice. He raises the point that current practice should not be taken as the default norm in terms of sustainability requirements.

[53] J Alaranta and T Turunen, "How to Reach a Safe Circular Economy? – Perspectives on Reconciling the Waste, Product and Chemicals Regulation" (2021) 33 Journal of Environmental Law 113, 124–25.

[54] Commission, "Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment" (Communication) COM (2020) 667 final, 6.

Such recovery exemptions are applied, for example, in some of the restrictions provisions under REACH. According to those provisions, polyvinyl chloride (PVC) with up to 0.1% by weight of cadmium can be recovered, whereas the generally applicable concentration limit for cadmium in plastics is 0.01%.[55] Similarly, the applicable REACH restrictions provision allows certain reuses of wood treated with currently otherwise banned copper–chromium–arsenic (CCA) solution.[56] On the other hand, in situations where the chemical risk is specifically related to the contamination of secondary raw materials, safe material circulation may require the application of more stringent hazardous substances concentration limits to secondary raw materials than to virgin raw materials. An example of this is the recently adopted REACH restriction on rubber granules and mulches that are usually manufactured from recycled tyres and used as infill material in synthetic turf pitches or on playgrounds. REACH now limits the concentration of polycyclic aromatic hydrocarbons (PAHs) of those materials to 20 mg/kg, whilst other mixtures can be placed on the market if they contain up 100 mg/kg or even 1,000 mg/kg of the same PAHs.[57]

The case of rubber granules and mulches illustrates clearly the need to reconcile the objectives of minimising chemical risks and maximising material circulation. The adoption of the restriction followed the conclusion of the European Chemicals Agency (ECHA) that the generally applicable PAH concentration limits were not sufficient to adequately control the human health risks posed by the rubber granules and mulches used in loose form on playgrounds and synthetic turf pitches.[58] On the other hand, the ECHA considered that the costs of a more stringent option – setting the concentration limit value to 6.5 mg/kg – would exceed its (greater) health benefits (eg because of societal costs and increased greenhouse gas emissions).[59] In some cases, it may also be appropriate to apply different concentration limits to the same secondary raw material in its different uses.[60]

The need to reconcile the competing uncertainties and objectives that are in tension is the dilemma facing the precautious circular economy, representing a crucial difference from the context of "classical" risk management issues, under which standards can usually be predefined.[61] This can only be solved through careful case-by-case decision-making in which due attention is paid also to the inevitable trade-offs. It should go beyond

[55] REACH, Annex XVII, entry 23. It should be noted here that the requirements for recycled plastics may vary between different sectors. For example, Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, [2011] OJ L 12/1 and Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 OJ L 243/3 set out strict requirements for the technical quality and purity of substances (Arts 8–12 of Regulation (EU) No 10/2011) as well as for recycling processes (Arts 3–4, 17–19 of Regulation (EU) No 2022/1616). Cadmium is not permitted to migrate from food contact materials (Annex II of Regulation (EU) No 10/2011).

[56] REACH, Annex XVII, entry 19. This provision was at stake in *Lapin luonnonsuojelupiiri* in which the ECJ examined, for example, whether the condition on the absence of repeated skin contact was fulfilled when the CCA-treated wood was reused as underlay of duckboards in a hiking track in Finnish Lapland, *Lapin luonnonsuojelupiiri*, supra, note 27, para 51.

[57] REACH, Annex XVII, entries 50 and 28.

[58] European Chemicals Agency, "Opinion on an Annex XV dossier proposing a restriction on Polycyclic-aromatic hydrocarbons" (2019), 8 <https://echa.europa.eu/documents/10162/53688823-bf28-7db7-b9eb-9807773b2109> (last accessed 30 May 2022).

[59] ibid, 51, 76.

[60] See, eg, the recent proposal for amending the EU Regulation on persistent organic pollutants that discussed as one option the possibility of setting a lower dioxins and furans limit value for untreated wastes such as sludges applied directly on land than for other secondary raw materials, Proposal for a regulation of the European Parliament and of the Council amending Annexes IV and V to Regulation (EU) 2019/1021 of the European Parliament and of the Council on persistent organic pollutants, COM (2021) 656 final, 6.

[61] Von Schomberg, supra, note 8, pp 153–54.

policymaking focused on legislative action and should involve the communication and collaboration of all relevant actors. Guidance for such decision-making can be sought from the classification of the risk problems, as discussed in Section III.2. Precautionary frameworks facilitate deliberation at the science/policy/society interfaces, moving from a science-centred debate on the probability of risks towards a science-informed debate on uncertainties and plausible adverse effects.[62]

2. *Classification of the risk problems of the circular economy*

Application of the precautionary principle involves deliberation on a range of normative dimensions.[63] "Normative" refers here, as described by von Schomberg, to all of the prescriptive statements or value judgments in contrast to factual scientific statements. Deliberation at different levels creates an ideal-type description of all relevant, mutually informing deliberation activities in relation to the precautionary principle.[64]

An essential normative political choice is the determination of the chosen level of protection (eg regarding the environment or human health).[65] This is hardly ever defined in quantitative terms, and in cases of significant scientific uncertainty such quantification is not feasible. In addition, the level of protection may need to be redefined in the light of the acquisition of new knowledge. De Sadeleer has argued that the precautionary principle must be seen as part of a dynamic and not a static process, and that decisions taken under the precautionary principle should be understood as open to review in the light of new scientific evidence.[66]

Risk problems should be distinguished from risk itself because they also include diverse values regarding how to deal with a specific risk. The distinction between the concepts of risk and the risk problem is well illustrated by the nuclear energy example of the Aven and Renn: the risk that nuclear energy poses is well-known and scarcely contested. However, the related risk problem is characterised by the different views of people on how to deal with this nuclear risk.[67] The classification of risk problems is based on their features (characterisation, perception and/or handling).[68] We base our classification in this paper on the classification of risk problems into "simple", "complex", "uncertain" and "ambiguous" presented by Aven and Renn,[69] with the addition of a class of "purely hypothetical risks" (Table 1). It is important to note that the case law excludes from the scope of the principle of proportionality only purely hypothetical risks.[70] All uncertain risks are hypothetical to some extent. Therefore, the concept of "purely hypothetical risk" must be interpreted restrictively, as otherwise it would exclude a considerable amount of genuine risks.

[62] ibid, p 156.

[63] R von Schomberg, "The Precautionary Principle and Its Normative Challenges" in E Fisher, J Jones and R von Schomberg (eds), *Implementing the Precautionary Principle. Perspectives and Prospects* (Cheltenham, Edward Elgar Publishing 2006) p 19; von Schomberg, supra, note 8, pp 147–49.

[64] Von Schomberg, supra, note 63, p 22.

[65] ibid, pp 24–25.

[66] N de Sadeleer, "The Precautionary Principle in EU Law" (2010) 5 Aansprakelijkheid Verzekering En Schade 173–74, 184.

[67] T Aven and O Renn, "Some Foundational Issues Related to Risk Governance and Different Types of Risks" (2020) 23(9) Journal of Risk Research 1121, 1122.

[68] ibid, p 1124. It is essential to distinguish between characterisations of hazards and risks on the on hand and characterisations of risk problems on the other; see ibid, p 1122.

[69] ibid, pp 1124–25.

[70] See, supra, note 30.

Table 1. Classification of risk problems and example cases related to material circulation.[71]

Risk problem class	Description	Main risk management strategies	Example
Simple	"Objective" probabilities available	Use of statistical analysis and traditional risk assessments Risk management by defining thresholds on the basis of a chosen level of protection	Intrinsic hazard properties of a substance or a waste as a basis for regulatory requirements, see *PlasticsEurope*[72] or *Verlezza and Others*[73]
Complex	Difficult to accurately predict the performance of the system considered based on the functions of its individual components	Broad risk characterisations highlighting knowledge aspects and uncertainties Weight given to cautionary/ precautionary/ robustness/resilience approaches and measures	Risks and benefits of recycling a plastic material that contains a Substances of Very High Concern, see *ClientEarth*[74]
Uncertain	(1) A potential for extreme consequences (2) Large uncertainties concerning the nature and extent of any consequences	Broad risk characterisations highlighting knowledge aspects and uncertainties Weight given to cautionary/precautionary/ robustness/resilience approaches and measures	Potential traces of hazardous substances that a mechanically treated municipal waste may contain and the related requirements to ascertain the composition of such waste, see *Verlezza and Others*[75]
Ambiguous	(1) A potential for extreme consequences (2) Different values related to the risks (consequences, uncertainties)	Participatory discourse, in which competing arguments, beliefs and values are openly discussed	End-of-waste of a sewage sludge that may contain hazardous substances, see *Tallinna Vesi*[76]
Purely hypothetical	Risks that have not been scientifically confirmed cannot be accepted	Invocation of precautionary principle is not justified	Repeated skin contact of a hiker with the hazardous substances that the underlay of duckboards on a wetland contains, see *Lapin luonnonsuojelupiiri*[77]

In the case of simple risk problems, the occurrence of events and their consequences can be predicted quite accurately. In the chemicals regulation, the mere intrinsic hazard property of a substance can be a sufficient ground for triggering regulatory actions. As is well illustrated in *PlasticsEurope*, a hazard property that makes a substance "capable" of having an adverse effect on human health or the environment can, for instance, lead to including it in the REACH Candidate List of SVHCs and making it subject to the related immediate regulatory requirements.[78] Similarly, a waste that is found to be hazardous

[71] Sources: von Schomberg, supra, note 63; Aven and Renn, supra, note 67.
[72] T-636/17, *PlasticsEurope* v *European Chemicals Agency (ECHA)* [2019] EU:T:2019:639.
[73] Supra, note 43.
[74] C-458/19 P, *ClientEarth* [2021] EU:C:2021:802.
[75] Supra, note 43.
[76] Case C-60/18, *Tallinna Vesi* [2019] EU:C:2019:264.
[77] Supra, note 27.
[78] *PlasticsEurope*, supra, note 72, paras 95–98.

according to the conditions set out in WFD becomes subject to specific requirements concerning traceability, packaging and labelling and the ban on mixing that waste with any other waste, and it must be treated in specifically designated hazardous waste treatment facilities.[79]

The risk of repeated skin contact of a hiker with the hazardous substances that the recycled telecommunication pole underlay of duckboards on a wetland contains, as examined in *Lapin luonnonsuojelupiiri*, is an example of a purely hypothetical risk.[80] The ECJ found that if those poles are merely used as an underlay for those duckboards without being part of the surface crossed under normal conditions by users, repeated skin contact with the treated wood would appear unlikely. As the referring court concluded in its final judgment, such exposure could occur only if the hiker was barefoot and intentionally stepped on the underlay of these duckboards.[81]

The precautionary principle also is not applied in the case of simple risk problems, where the level of protection is defined and the risk can be quantified so that the policymakers can respond with a normal risk management approach (eg by setting thresholds). The necessary measures can be adopted without invoking the precautionary principle because there is a consolidated scientific basis concerning the adverse effects in question. The interventions are thus preventative.

A risk problem is complex if it is difficult to accurately predict the performance of the system as a whole based on knowledge of the specific functions and states of its individual components.[82] There may be many intervening variables between a trigger and its effects. In the recent EU case law related to material circulation, such dimensions can be found in the *ClientEarth* case. In that case, ClientEarth contested the decision by which the Commission had authorised the use of recycled PVC containing bis(2-ethylhexyl) phthalate (DEHP), which is subject to an authorisation requirement under REACH due to its reproductive toxicity and endocrine-disrupting properties. Both authorising and prohibiting the use of secondary plastic materials containing such a hazardous substance have different consequences that interconnect; thus, the overall outcome as regards the related risks is difficult to predict. Under the REACH authorisation procedure, this complexity is assessed in an analysis of the available alternatives and via a socio-economic analysis. Under Article 60(4) of REACH, the Commission may grant authorisation if the socio-economic benefits outweigh the risk to human health or the environment arising from the use of the respective substance and if there are no suitable alternative substances or technologies. In *ClientEarth*, the GC and subsequently the ECJ held that, contrary to the applicant's arguments, the Commission's authorisation decision was based on sufficient examination of the available alternatives and the socio-economic benefits and risks of the use of the recycled PVC.[83]

If it is difficult to accurately predict the occurrence of events or their consequences, a risk problem is uncertain. In *Verlezza and Others*, which is our example in this category, the ECJ examined the conditions for classifying wastes as hazardous under WFD. The case concerned mechanically treated municipal waste, which, under WFD, has a hazardous waste mirror code. As Advocate General (AG) Sánchez-Bordona points out, such waste may contain hazardous substances originating, for example, from batteries that have been disposed

[79] *Verlezza and Others*, supra, note 43, para 38.

[80] *Lapin luonnonsuojelupiiri*, supra, note 27, para 51. Under the applicable REACH restriction, CCA-treated wood such as that used for the telecommunication poles in this case can be reused in certain applications; see supra, note 56.

[81] Finnish Supreme Administrative Court, judgment of 4 June 2013, KHO:2013:102, point 2.4.4.

[82] Aven and Renn, supra, note 67, pp 1124–25.

[83] T-108/17, *ClientEarth* v *Commission* [2019] EU:T:2019:215, paras 195–203, 247–48; *ClientEarth*, supra, note 74, paras 63–65.

of incorrectly.[84] The uncertainty related to the potential hazardous properties of such waste may therefore be large, and at the same time the consequences of the presence of hazardous substances to human health or the environment could be extreme. In such a situation, the precautionary principle requires that the uncertainty is narrowed down by acquiring such further information as is technically feasible and economically viable. The waste holder must determine the composition of the waste and ascertain the hazardous substances that may reasonably be found in that waste.[85] However, if it remains impossible to determine whether the waste contains hazardous substances or has hazardous properties, the (pre)cautious approach requires that the hazardousness is presumed and the waste is classified as hazardous.[86]

Different views on the relevance, meaning and implications of the basis for the decision-making or on the values to be protected and priorities to be established result in interpretative or normative ambiguity, respectively.[87] Ambiguity is usually the result of complexity and uncertainty, so ambiguous risk problems also have features of these categories, and the boundary between the categories is not precise.[88] With regards to interpretative ambiguity, knowledge available can be viewed as justified beliefs, which are founded on data, information, analysis, argumentation or testing (evidence) but may never be conclusive, resulting in ambiguity. A key issue to consider is whether the knowledge and lack of knowledge have been properly addressed. The solidness (eg compliance with all rules and assumptions, limitations or constraints introduced) of the assessments behind the knowledge, as well as the degree to which the results obtained are reliable and valid, should be considered in decision-making.[89] Poor solidness, reliability and/or validity may lead to different understandings of what the risk characterisation expresses.

Normative ambiguity extends beyond the scientific domain. Whether a risk problem that is characterised with high uncertainty deserves attention depends on the values at stake: the potential for serious consequences and different views on how to handle them. Normative ambiguity does not reflect features related to knowledge but concerns how one values these features. The differences in values are influenced by several factors, including the geographical dispersion of potential damage, the temporal extension of potential damage, its reversibility, the latency period between the initial event and the actual impact (delayed effect) and the potential for the mobilisation of individuals and affected groups.[90]

Tallinna Vesi concerned the recognition of the EoW status of biologically treated sewage sludge and the Member States' margin of discretion in a case-by-case application of the EoW criteria. There were no EoW criteria at the EU or national level. Tallinna Vesi AS wished to market the treated (anaerobic digestion, drying, aerobic digestion) sludge as a greening soil.[91] The main legal question was whether and under what conditions Member State authorities are obliged to adopt case-by-case EoW decisions. The ECJ ruled that a Member State is not obliged to recognise EoW status on a case-by-case basis and that Article 6(4) of WFD does not allow a waste holder to demand the recognition of EoW status by the competent authority or by a court of the Member State.[92]

[84] Joined Cases C-487/17 to C-489/17, *Verlezza and Others*, Opinion of Advocate General Sánchez-Bordona [2018] EU:C:2018:915, para 38.

[85] *Verlezza and Others*, supra, note 43, paras 54 and 59.

[86] ibid, paras 60–62.

[87] Aven and Renn, supra, note 67, pp 1124–25.

[88] ibid, p 1129.

[89] ibid, pp 1126–27. "Reliability" refers to the appropriateness of the measuring instrument (such as methods, procedures and experts), while "validity" refers to the success in measuring the given target.

[90] ibid, pp 1130–31.

[91] *Tallinna Vesi*, supra, note 76, paras 10–11.

[92] ibid, para 31.

The cases *Tallinna Vesi* and *Prato Nevoso* underlined that the safety of secondary raw materials is at the heart of the circular economy. The ECJ stated in *Tallinna Vesi* that "the recovery of sewage sludge entails certain risks for the environment and human health, in particular those linked to the presence of hazardous substances", and that a Member State may refrain from recognising EoW status or from laying down standards that would lead to EoW status.[93] However, the Member State must ensure that such a measure does not amount to an obstacle to the attainment of the objectives of WFD, such as encouraging the application of the waste hierarchy or enabling the development of a circular economy.[94] Therefore, the Member States may have grounds for refraining from recognising the EoW status of certain wastes, but they cannot apply such a policy as a rule to all wastes. The duty of the Member States to ensure that EoW is applied was introduced in Article 6(1) in the 2018 amendment of WFD.[95] However, for the sake of legal certainty and proper functioning of the internal market, the preference should be given to adopting EU-wide EoW criteria for specific waste streams.[96]

The ECJ also recalled that fulfilling the EoW criteria set out in Article 6(1) of WFD cannot in itself directly establish that certain wastes or waste categories must no longer be regarded as such.[97] This was also stated in *Prato Nevoso*, in which the ECJ underlined that "the fact that the competent national authority finds that, provided that certain criteria are met, a given waste loses the status of waste for a certain use does not imply that it ceases to be waste when used for other purposes".[98] The ECJ stated that Member States have a wide margin of discretion as regards the establishment of appropriate procedural arrangements and the substantive examination of compliance with the conditions for EoW status, involving complex technical and scientific assessments by the competent national authorities.[99]

These two cases also highlight clearly the uncertainties related to decision-making in ambiguous risk problems. For example, sludge originating from a municipal wastewater treatment plant, such as in our example case *Tallinna Vesi*, typically contains residues of hazardous substances, such as persistent industrial chemicals, pesticides and pharmaceuticals, from various industrial and domestic sources. The World Health Organization (WHO) has indicated that there are potential negative health implications of the use or sewage sludge in agriculture, including a wide range of direct health end points, such as typhoid, dysentery and diarrhoeal diseases, as well as direct or indirect changes in soil or water quality.[100] Inappropriate reuse

[93] ibid, para 28.

[94] ibid, para 27. In her opinion, AG Kokott pointed out that there may be some waste that, after taking account of all relevant factors and the most recent state of scientific and technical knowledge, has beyond any reasonable doubt undergone a recovery operation enabling it to be made usable without endangering human health or harming the environment. In such a case, the discretion by the Member State would be more limited; C-60/18, *Tallinna Vesi*, Opinion of Advocate General Kokott [2018] EU:C:2018:969, paras 52–53.

[95] Alaranta and Turunen, supra, note 53, pp 132–34.

[96] Such as the EoW criteria for iron, steel and aluminium scrap as set out in Council Regulation (EU) No 333/2011 of 31 March 2011 establishing criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council [2011] OJ L94/2.

[97] *Tallinna Vesi*, supra, note 76, para 29.

[98] *Prato Nevoso*, supra, note 45, para 50.

[99] ibid, para 36.

[100] World Health Organization (WHO), "Circular Economy and Health: Opportunities and Risks" (2018), 26 <https://apps.who.int/iris/handle/10665/342218> (last accessed 29 April 2022). In the EU, Council Directive of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture, [1986] OJ L 181/6 sets out concentration limits for heavy metals in soil to which sludge is applied and concentration limits for heavy metals in sludge, as well as the maximum annual quantities of such heavy metals that may be introduced into soil intended for agriculture (Arts 4–5). The Directive does not consider other possible hazardous substances, such as pharmaceuticals. The Commission stated in its new Circular Economy Action Plan that it will consider reviewing Directive 86/278/EEC, supra, note 2, 12. The Commission launched in 2020 a public consultation to assess the effectiveness, efficiency, relevance, coherence and EU added value of the Directive, the results of which will inform the Commission on the need to revise the Directive; see Commission, "Sewage Sludge" <https://ec.europa.eu/environment/topics/waste-and-recycling/sewage-sludge_en> (last accessed 27 May 2022).

practices may, for example, contaminate surface and groundwater sources that are used for the production of drinking water, as well as spread antimicrobial agents and potentially toxic metals in the environment, increasing the risk of the development of antimicrobial resistance.[101] The risk level depends on, for example, how the sludge is treated and how it is used on the soil.[102] In wastewater treatment systems, monitoring of many of these substances is limited or lacking.[103] In addition, the lack of comprehensive toxicological data regarding the potential impacts on human health and the environment results in interpretative ambiguity. Such uncertainty may be related to hazard identification (whether a certain substance is hazardous[104] or is a direct or indirect hazard[105]), the existence of the substance in a secondary material, the fate of the substance in the environment in a specific use[106] and the actual risk to human health and the environment.[107] These uncertainties may result from complexity or a lack of knowledge regarding the underlying phenomena or processes, giving rise to interpretative ambiguity,[108] but they may also lead to the balancing of different values (normative ambiguity) and environmental impacts.[109]

IV. Balancing the risks and benefits of material circulation

Material flows in the circular economy should not cause adverse impacts on human health and the environment, and the climate and other environmental benefits pursued by the circular economy should never lead to compromises as regards the protection of human health and the environment from chemical risks.

Therefore, the complex web of uncertainties surrounding the circular economy calls for precautious regulation of hazardous substances. One could argue that, in accordance with the precautionary principle, waste holders should obtain complete information on the composition of these wastes and that all secondary (raw) materials containing hazardous substances should be phased out. However, such an approach would significantly hamper the achievement of the objectives of the circular economy and might also lead to the actualisation of countervailing risks caused by the management of hazardous waste.

[101] WHO, supra, note 100, p 45. Fertilising materials, such as treated sewage sludge, will add toxic metals to existing levels of such in soil, and these metals then accumulate in the environment. There is evidence that the presence of potentially toxic metals is a driver of the development of AMR in exposed bacteria, but the dose and time exposure most likely to cause this effect is not known; see Norwegian Scientific Committee for Food Safety (VKM), "The Link between Antimicrobial Resistance and the Content of Potentially Toxic Metals in Soil and Fertilising Products" (2017), 6–7 <https://vkm.no/download/18.723f25015f11706398734fe/1513852492815/The%20link%20between%20antimicrobial%20resistance%20and%20the%20content%20of%20potentially%20toxic%20metals%20in%20soil%20and%20fertilising%20products.pdf> (last accessed 29 April 2022).

[102] WHO, supra, note 100, p 45.

[103] ibid, p 46.

[104] For example, toxic metals have several modes of action, including protein dysfunction, production of reactive oxygen species and genotoxicity; see VKM, supra, note 101, pp 21–24.

[105] For example, antimicrobial-resistant pathogenic bacteria resulting as a direct outcome from exposure to potentially toxic metals is a direct hazard, whereas an indirect hazard arises through resistance forming in a non-pathogenic bacterium that can subsequently act a source of resistance after horizontal gene transfer into a pathogenic bacterium; ibid, p 20.

[106] In the case of potentially toxic metals, one should consider the fate of metals, metal-resistant bacteria and metal-resistance genes; see ibid.

[107] More research is needed on, eg, how increased levels of toxic metals influence the complex global processes of resistance gene dynamics; see ibid, pp 32, 34. The VKM report stated that although present levels in agricultural soils may still be low, the long-term horizon of toxic metals in the environment indicates the importance of applying the precautionary principle to minimise environmental enrichment.

[108] Aven and Renn, supra, note 67, p 1130.

[109] Aven and Renn opine that there are nearly always different views on how much weight to give to uncertainties, relative to potential benefits, in (political) decision-making processes, and that the priorities and risk attitudes differ; see ibid.

In a wider perspective, the disposal of useful materials would require obtaining more virgin materials, which again would pose other risks to human health and the environment.[110] Therefore, decision-making in the circular economy era is very often made in a situation where all of the choices are subject to uncertain risk.

The transition to a more circular economy results in tensions between the waste and chemicals regulation: the new circularity provisions of the waste legislation aim at maximising the recovery of materials, whilst the provisions of the regulation on hazardous wastes and chemicals aim at removing circulation materials that contain substances that may pose a risk to human health or the environment. In other words, the safety objectives of the (hazardous) waste and chemicals legislation represent factors that limit the maximisation of material circulation.

Allowing the uncontrolled circulation of all secondary raw materials would lead to irreparable harm to human health and the environment, whilst prohibiting the recycling and recovery of all materials that may contain hazardous substances would hamper the environmental objectives of the circular economy. Recognising and reconciling the objectives of the chemicals and waste regulation that are in tension is the prerequisite for achieving a sustainable circular economy.

For this balancing there is no one-size-fits-all solution that could be applied to all secondary raw materials that may contain hazardous substances. Achieving a safe and sustainable material circulation requires a toolbox of various measures that must be applied on a case-by-case basis. This may imply, for example, exempting certain secondary materials from the REACH restrictions but setting more stringent concentration limits for some other hazardous substances in secondary raw materials than in virgin raw materials, or applying different thresholds in different secondary uses.

The first step for such case-by-case decision-making should always be a proper identification of the risk problems that are at stake. The dilemma of the precautious circular economy can be solved only by balancing these risks and benefits and by reconciling the different objectives through an analysis that also gives appropriate weight to different types of risk problems and their associated uncertainties. The complex web of uncertainties of the material circulation inevitably requires a case-by-case application of the precautionary principle, but eventually the related ambiguities can only be addressed in participatory discourse, in which competing arguments, beliefs and values are openly discussed.

Disclaimer. All opinions and mistakes are the authors' own and cannot be attributed to the institutions they represent. Some parts of the text are loosely based on Miettinen's dissertation (M Miettinen, "Regulating Uncertainty in Risk Governance of Nanomaterials and Pharmaceutical Pollutants" (Joensuu, University of Eastern Finland 2022)).

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[110] It is important to note that Art 191(1) TFEU sets both the protection of human health and the environment and the prudent and rational utilisation of natural resources as objectives of the EU's environmental policy and does not set any priority order for these objectives.

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