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CASE ANNOTATION

The Law Is Elastic but Does Not Bend: A Literal Interpretation of European Union Chemical Legislation Could Leave Health and the Environment Unprotected

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Case C-458/19 P, ClientEarth v European Commission, ECLI:EU:C:2021:802

Appeal – Action for annulment – Commission Implementing Decision C(2016) 3549 final – Authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) – Regulation (EC) No 1907/2006 – Articles 60 and 62 – Regulation (EC) No 1367/2006 – Request for internal review – Commission Decision C(2016) 8454 final – Rejection of the request (official headnote)

Article 60(4) of 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, OJ L 396, 30.12.2006, pp 1–849 (EN)

Abstract

This piece addresses Case C-458/19 P before the Court of Justice of the European Union (CJEU) concerning a substance of long-term exposure, namely bis(2-ethylhexyl) phthalate (DEHP). The case concerned the interplay of two complex procedures of European chemical law, namely: the procedure for authorising the use of a substance listed in Annex XIV of Regulation (EC) No 1907/2006 (REACH Regulation); and the procedure for listing a substance in Annex XIV of the REACH Regulation on the basis of its intrinsic properties as a substance of very high concern for the risks it poses, or may pose, to human and environmental health. The significance of this judgment is that it provides a better understanding of how Article 60(4) of the REACH Regulation is interpreted in an analogous manner in relation to other provisions of the same Regulation. Whether DEHP is a question of reproductive toxicity (Article 57(c) of the REACH Regulation) or endocrine-disrupting properties (Article 57(f) of the REACH Regulation), this judgment offers insights into the limits of the CJEU's willingness and/or ability to use a teleological approach to interpret legislation in this area. Furthermore, this work supports the possibility of applying the principle of intergenerational equity to issues related to long-term exposure such as this one.

Keywords: Authorisation procedure; bis(2-ethylhexyl) phthalate (DEHP); endocrine-disrupting properties; intergenerational equity; long-term exposure

I. Introduction

One of the main concerns of European Union (EU) policy relates to substances of very high concern (SVHCs), which may have adverse effects on human and environmental health in cases of long-term exposure. In view of these risks, the EU has an authorisation procedure in place for the use of substances listed in Annex XIV of Regulation (EC) No 1907/2006 (hereinafter "the REACH Regulation"),[1] which aims to progressively reduce the use of these substances and replace them with less hazardous substances to ensure a high level of health protection, as laid down both in EU primary[2] and secondary legislation.[3]

This piece addresses Case C-458/19 P before the Court of Justice of the EU (CJEU), involving a substance of long-term exposure, namely bis(2-ethylhexyl) phthalate, known by its acronym DEHP. The case has reached the end of its judicial process with the CJEU's ruling upon appeal, which concerned the interaction of two complex European chemical law procedures,[4] namely: (1) the procedure for the authorisation of the use of a substance listed in Annex XIV of the REACH Regulation because of its toxic properties for reproduction; and (2) the procedure for the listing of the same substance in Annex XIV of the REACH Regulation because of its intrinsic properties as an endocrine disruptor. Both properties make this substance a SVHC for the risks it poses, or may pose, to human and environmental health.

Below, this piece provides an overview of the facts surrounding the case, before exploring the CJEU judgment. Although the appeal has been dismissed in its entirety, this case is interesting because it facilitates an enriched understanding of how case law interprets Article 60(4) of the REACH Regulation according to its wording and in connection with other provisions of the same Regulation. In other words, this judgment provides insights into the limits of the CJEU's willingness and/or ability to employ a teleological approach to legislative interpretation in this field. After setting out the legal comments on this case, I consider the temporal dimension of issues relating to toxic substances, such as endocrine disruptors, and the possibility of applying the principle of intergenerational equity. I believe that the application of this principle would have allowed for greater consideration of environmental and health protection. Finally, I conclude that the consequences of long-term exposure to substances such as DEHP for future generations should be adequately considered.

II. Facts

Phthalates form a family of synthetic chemicals with a broad variety of uses, spanning from consumer to industrial goods. There are several types of phthalates, and they are commonly used as softeners to make plastics, such as polyvinyl chloride (PVC), more flexible and long-lasting. Because of their widespread use, phthalates are found virtually everywhere in the natural environment. Although not all phthalates have been fully studied, there is evidence that some are harmful to health, as they can, for example, interfere with the human hormonal system. Due to their associated risk of

[1] 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, OJ L 396, 30.12.2006, pp 1–849 (EN).

[2] Ie, in the Lisbon Treaty, specifically in TFEU (Art 114(3)), TEU (Art 3(3)) and Charter of Fundamental Rights (Arts 35 and 37).

[3] Ie, supra, note 1, see Art 1(1) and Recitals 1, 3 and 7.

[4] Case C-458/19 P, *ClientEarth v European Commission* [2021], Opinion of Advocate General Kokott, p 10. ECLI:EU:C:2021:145 <https://curia.europa.eu/juris/document/document.jsf?text=&docid=238180&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=18008453> (last accessed 5 December 2022).

causing adverse health effects, the use of certain phthalates has already been regulated in the EU.[5]

The case at hand involves the European Commission's (hereinafter "the Commission") authorisation for the use[6] of one of these phthalates, namely DEHP. This plasticiser[7] was most widely used in the 1990s, being added to a number of PVC building materials (eg in PVC flooring). As to further examples of its use, DEHP could be found in perfumes and flexible PVC products including shower curtains, garden hoses and diapers.[8] In the food sector, DEHP is present in food contact materials such as those used in food packaging and storage.[9]

The usage of DEHP is currently restricted in all toys and childcare articles[10] and banned in cosmetic products,[11] as it has been considered toxic to reproduction[12] since 2011.[13] Furthermore, the use of DEHP is subject to authorisation, which shall be granted by the Commission as the competent authority on this matter following the provisions laid down in Article 60(2) of the REACH Regulation.

The present case addresses DEHP from the perspective of two distinct legal procedures, although both refer to the same legal instrument and are to be brought before the same body, which is the Commission. On the one hand, the case includes the authorisation procedure because of DEHP's reproductive-toxic properties. On the other hand, it also includes the procedure for the inclusion of DEHP in the list of substances subject to authorisation contained in Annex XIV of the REACH Regulation due to its endocrine-disrupting properties. The controversy therefore revolves around the chronological interaction of these two administrative procedures and whether this interaction implies an obligation for the Commission to take the latter into account when deciding on the former.

[5] European Chemicals Agency's website, retrieved from <https://echa.europa.eu/hot-topics/phthalates> (last accessed 2 December 2022); M Monti, M Fasano, L Palandri and E Righi, "A review of European and international phthalates regulation: focus on daily use products" (2022) 32(Suppl 3) European Journal of Public Health ckac131.226.

[6] The concept of "use" in the context of the REACH Regulation is understood as: "any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation" (Art 3(24) REACH Regulation).

[7] "Bis(2-ethylhexyl) phthalate" yielded about 22,500 search results in the Google Patents Database, which demonstrates the activity around and the importance of this chemical; see <https://www.google.com/search?q=%22Bis(2-ethylhexyl)+phthalate%22&tbm=pts> (last accessed 18 December 2022).

[8] Di(2-ethylhexyl) phthalate (DEHP), Glossary (European Commission website) <https://ec.europa.eu/health/scientific_committees/opinions_layman/en/phthalates-school-supplies/glossary/def/dehp-di-2-ethylhexyl-phthalate.htm> (last accessed 3 December 2022).

[9] "Substance Infocard" of DEHP (European Chemicals Agency website) <https://echa.europa.eu/de/substance-information/-/substanceinfo/100.003.829> (last accessed 4 December 2022).

[10] "Childcare articles" are understood as any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children, according to Annex XVII 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 <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1669985397139&uri=CELEX%3A02006R1907-20221217> (last accessed 4 December 2022). DEHP can be found as the substance with CAS number identification 117-81-7, accordingly to ECHA's official website <https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/10536> (last accessed 4 December 2022).

[11] DEHP is currently the substance listed as number 677, under CAS number identification 117-81-7, in Annex II of Regulation (EC) No 1223/2009, of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20221217> (last accessed 5 December 2022), known as the Cosmetic Products Regulation.

[12] DEHP is currently the substance listed as number 4 in Annex XIV of the REACH Regulation, being considered both toxic for reproduction (category 1B) as well as a substance with endocrine-disrupting properties for human health and the environment, under Art 57(f) REACH Regulation.

[13] Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation No 1907/2006 (OJ 2011, L 44, p 2).

In 2013, a consortium of three waste-recycling companies submitted a joint application for authorisation to place DEHP on the market for two use cases[14] specified in their application. This application was submitted under Article 62 of the REACH Regulation, initiating the authorisation procedure required to place this chemical on the market despite its reproductive-toxic properties (Article 57(c) REACH Regulation).

In 2016, three years after the registration of the authorisation application, the Commission finalised the procedure through the authorisation decision.[15] In 2014 and, hence, within the authorisation procedure's timeframe, a second administrative procedure was initiated. This second parallel procedure concerned the listing of DEHP in Annex XIV of the REACH Regulation and was based on the grounds of the substance's endocrine-disrupting properties (Article 57(f) REACH Regulation).

It should be noted at this point that at the time of the application for authorisation for the use of DEHP (2013), this substance was already listed in Annex XIV of the REACH Regulation because of its reproductive-toxic properties. For this reason, an obligation to request authorisation for the production, marketing and use of DEHP existed.

These companies' application for authorisation was based on Article 60(2) of the REACH Regulation. This article requires applicants to demonstrate in their chemical safety report that they have the risk under control (ie "risk to human health or the environment arising from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled"). However, the authorisation decision granted by the Commission, in accordance with the opinions issued by the Committee for Risk Assessment and the Committee for Socio-Economic Analysis (hereinafter "ECHA Committees"), is based on Article 60(4) REACH Regulation. Article 60(4) applies subsidiarily when authorisation cannot be granted based on Article 60(2) REACH Regulation. Put differently, the ECHA Committees concluded that authorisation could not be granted based on Article 60(2) since it had not been proven that the health risks to workers, concerning the two requested uses of DEHP, were safely controlled by the applicant companies regarding DEHP's reproductive-toxic properties.[16]

Instead, after a socio-economic analysis, the ECHA Committees considered it appropriate to grant authorisation on the basis of Article 60(4) REACH Regulation, which establishes that "an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies". Additionally, this analysis shall take into account several elements[17] listed in the same provision, as well as the opinions issued respectively by the ECHA Committees.

[14] Those uses are described by the applicants as "the formulation of recycled soft polyvinyl chloride (PVC) containing DEHP in compounds and dry-blends" and "the industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles" (supra, note 4, Case C-458/19 P, *ClientEarth v European Commission*, ECLI:EU:C:2021:802, para 12).

[15] Implementing Decision C(2016) 3549 final, the "authorisation decision".

[16] ECHA/RAC/SEAC Opinion N° AFA-O-0000004151-87-17/D (p 3) <https://echa.europa.eu/documents/10162/8d9ee7ac-19cf-4b1a-ab1c-d8026b614d7a> (last accessed 1 December 2022).

[17] Several elements listed in Art 60(4) of the REACH Regulation, namely: (1) the risk posed by the uses of the substance; (2) the socio-economic benefits; (3) the analysis of the alternatives submitted or any substitution plan submitted; and (4) available information on the risks to human health or the environment of any alternative substances or technologies.

Against this authorisation decision, ClientEarth[18] filed a request before the Commission for an internal review of the authorisation decision[19] in 2016, pursuant to Article 9(3) of the Aarhus Convention.[20] Interestingly, the legal grounds on which the request for internal review were based are not reproduced in the CJEU judgment.[21] Despite the fact that there does not appear to be a legal obligation to reproduce them in the judgment in application of Article 87 of the Rules of Procedure of the Court of Justice,[22] there is no doubt that their reproduction in the judgment of the CJEU is fundamental to understanding the whole process, starting with the parties' request for a preliminary administrative ruling.[23]

Although the Commission denied the review as unfounded (hereinafter "review decision"),[24] ClientEarth initiated the judicial process by filing an appeal before the General Court of the EU in 2017 requesting the annulment of both the review decision and the authorisation decision. Nevertheless, in 2019, the General Court dismissed by judgment[25] ClientEarth's appeal against the review decision in its entirety as inadmissible and, in any event, unfounded. ClientEarth then appealed before the CJEU to issue a ruling on the case.

In its "pleas in law", ClientEarth asked the CJEU to rule on the following issues: (1) to set aside the judgment of the General Court; and (2.a) refer the case back to the General Court for re-examination; or (2.b) as a subsidiary plea, declare the action for annulment as admissible and well-founded and, consequently, annul the review decision; and (3) impose costs on the Commission. By contrast, the Commission and ECHA contended that the CJEU should dismiss the appeal and order the appellant to pay the costs.

[18] ClientEarth is a non-profit organisation whose objective is environmental protection. Among its priorities, ClientEarth aims to take action towards a "safer use of chemicals across the EU". Its website can be found at the following link: <https://www.clientearth.org/what-we-do/priorities/chemical-pollution/> (last accessed 3 December 2022). The non-governmental organisation is entitled to request internal review on the basis of Art 10(1) of Regulation 1367/2006 establishing the requirements for the request for internal review of administrative acts: "Any non-governmental organisation which meets the criteria set out in Article 11 is entitled to request an internal review to the Community institution or body that has adopted an administrative act under environmental law or, in case of an alleged administrative omission, should have adopted such an act ...." Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies. OJ L 264, 25.9.2006, pp 13–19 (EN), permanent European Legislation Identifier: <http://data.europa.eu/eli/reg/2006/1367/oj> (last accessed 5 December 2022).

[19] The Commission may be asked to conduct an internal review of authorisation decisions per Art 10 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32006R1367> (last accessed 5 December 2022).

[20] Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, signed at Aarhus (Denmark) on 25 June 1998 and approved on behalf of the European Community by Council Decision 2005/370/EC of 17 February 2005(OJ 2005 L 124, p 1).

[21] Supra, note 4, Case C-458/19 P, *ClientEarth v European Commission*, ECLI:EU:C:2021:802, para 21.

[22] Art 87(l) of the Rules of Procedure of the Court of Justice provides that the judgment of the CJEU shall contain "a summary of the facts". Whilst the mention of the request for internal review is indeed included in judgment C-458/19 P, this does not mention the grounds to which the request for internal review referred. Rules of Procedure of the Court of Justice OJ L 265, 29.9.2012, pp 1–42 (EN), permanent European Legislation Identifier: <https://eur-lex.europa.eu/eli/proc_rules/2012/929/oj> (last accessed 20 December 2022).

[23] Nevertheless, one can find some of the grounds for internal review scattered throughout the General Court Judgment of 4 April 2019, *ClientEarth v Commission* (T-108/17, EU:T:2019:215) (eg in paras 41 and 48).

[24] Decision C(2016) 8454 final, the "review decision".

[25] Supra, note 23.

III. Judgment

Although ClientEarth based its appeal on seven grounds, the core question was whether other intrinsic risks of the substance should be considered in the framework of the socio-economic balance besides the one risk for which the obligation to apply for authorisation for the use of the substance in question arises.

In this particular case, the only risk taken into consideration by the authorities was the reproductive-toxic properties of DEHP. However, in the timeframe between the application for authorisation and the decision granting the authorisation, another parallel administrative procedure began[26] whereby it was requested that DEHP be listed in Annex XIV of the REACH Regulation not only for its reproductive-toxic properties (Article 57(c) REACH Regulation, which were already listed), but also for its alleged[27] endocrine-disrupting properties (Article 57(f) REACH Regulation).

The administrative procedure by which a substance becomes part of Annex XIV of the REACH Regulation requires three procedural phases.[28] The substance in question is included in the candidate list once the first phase of the procedure is concluded. However, it is only when the second phase of the procedure is completed that the substance can be included in Annex XIV due to its intrinsic properties evaluated during the procedure. Once Annex XIV has been updated and published in the *Official Journal of the EU*, it becomes mandatory to apply for authorisation for use of the substance through the third phase of the procedure. In this phase, the individual operators must demonstrate that they have the chemical risks that may arise from these substances under control or, if they cannot do this, they must demonstrate that the benefits outweigh the risks and, therefore, their authorisation can be granted based on a socio-economic analysis. This happened in the present case, with the inconvenience that DEHP was *only* listed in Annex XIV for its reproductive-toxic properties both at the time when the authorisation was requested and at the time when it was granted, and even at the time when the judicial proceeding of the CJEU was finalised. Among the numerous updates to Annex XIV, it is in the update dated 8 January 2022 – notably after the CJEU judgment – that DEHP is *also* included for its endocrine-disrupting properties.[29]

Different legal perspectives exist concerning the issue at hand. Some consider that the reproductive-toxic and endocrine-disrupting properties of DEHP should both have been taken into account in the ECHA Committees' opinions and, consequently, in the Commission's authorisation decision. This argument has been substantiated in various ways by ClientEarth and the Advocate General.[30]

[26] According to Advocate General Kokott (see supra, note 4), on 26 August 2014 Denmark filed a dossier identifying DEHP as a SVHC due to its endocrine-disrupting properties in the environment (para 19).

[27] Alleged at that time. DEHP is now considered to have endocrine-disrupting properties and has been added to Annex XIV since 8 January 2022 (shortly after the CJEU ruling on this case).

[28] The three phases of the procedure are the following: at the request of the Commission, (1) the ECHA or a Member State identifies the substance as a SVHC, according to Art 57 of the REACH Regulation; at the end of this first phase of the procedure, the substance is included in the candidate list when there is unanimity and, if not, it is referred to the Commission, but in no case does the procedure end here, as two further phases remain; (2) the substance is recommended for inclusion in Annex XIV; and (3) it is included in Annex XIV. (European Chemicals Agency website) <https://echa.europa.eu/en/regulations/reach/authorisation/recommendation-for-inclusion-in-the-authorisation-list> (last accessed 5 December 2022).

[29] DEHP is now included in Annex XIV due to its endocrine-disrupting properties since the update of the REACH Regulation in the *Official Journal of the European Union* published on 8 January 2022 (see supra, notes 1 and 27).

[30] Advocate General Kokott (see supra, note 4) opines that the socio-economic benefits of the use of DEHP depend not only on its advantages, but also on its disadvantages, such as the environmental and health risks associated with it, since such risks are also socio-economic factors. This has been elaborated by Advocate General Kokott as follows: "If they result in damage to the environment or health, they represent a burden on society and give rise to economic costs. The risks, therefore, diminish socio-economic benefits and, accordingly, must be taken

The appellant, ClientEarth, supported this ground of appeal on several legal grounds, of which the following are worth highlighting: firstly, on the risk assessment, ClientEarth claimed that the General Court had made a literal interpretation of Article 60(4) of the REACH Regulation instead of taking into account the context and objective pursued by the legislator.

In this regard, the CJEU disagrees and responds that Article 60(4) must be understood to imply that the risk assessment must be based solely on the intrinsic properties already included in Annex XIV. Although it cannot be deduced from the literal wording of Article 60(4), an extrapolation of the terms used in the wording of Articles 60(2) and 62(4) allows such an understanding.

Secondly, as regards the documentation to be considered, ClientEarth states that the General Court had articulated that the Commission is obliged to examine *ex officio* all of the information available to it at the time of the decision, without limiting itself to the information provided by the applicants. Thus, the Commission should have considered the documentation relating to the identification of DEHP as a substance with endocrine-disrupting properties. The latter was likely not contained in the documentation provided by the applicants but was available to the Commission since it is also the competent authority for deciding on the administrative procedure for a substance to be included in Annex XIV of the REACH Regulation. In this regard, the CJEU makes no reference to whether the Commission shall be limited to consider solely the documentation provided by the applicants, but rather disagrees with ClientEarth and provides an answer to this point explaining that the mere inclusion of a substance in the candidate list of Article 59(1) of the REACH Regulation does not mean that the substance will necessarily be definitively included in the Annex XIV list, as there is a specific administrative procedure for this purpose that may or may not lead to such inclusion.

As to the remaining grounds of appeal, these are all equally rejected in the CJEU judgment. The appeal is therefore dismissed in its entirety. Many of the grounds of appeal were based on assertions that indicate that the appellant probably did not understand what the General Court had expressed in its judgment. Hence, the CJEU finds them either unfounded or inoperative.

However, the fifth and seventh grounds, both relating to Article 60(4), should be highlighted. The CJEU seems to indicate that, had it argued otherwise, the grounds could have succeeded, or at least the CJEU could have analysed other interesting aspects. In the fifth ground of appeal, regarding the chemical safety report, the CJEU recalls that "the General Court stated, in paragraph 131 of the judgment under appeal, that the existence of uncertainties or deficiencies in that report could raise the question of whether, on the basis of the facts and evidence available to the Commission, the authorisation was capable of being granted under Article 60(4) of the REACH Regulation". Nevertheless, the appellant did not raise this point in any of the appeals.[31]

Relating to the seventh ground concerning the precautionary principle as regards Article 60(4) of the REACH Regulation, the appellant submits that the General Court infringed the precautionary principle and misinterpreted its previous claim. ClientEarth claims that it had not argued that the precautionary principle obliges the Commission to refuse authorisation in the event that the requirements of Article 60(4) are met, but rather that the principle should guide the institution's assessment in the application of that

into account in assessing whether benefits outweigh the risk justifying the authorisation requirement" (para 55). Hence, in her opinion, the authorisation decision of DEHP would be vitiated by deficiencies, as she considers it to be based on an incomplete balancing exercise. For this reason, she suggested the CJEU set aside the judgment of the General Court and annul the review decision, as requested by ClientEarth on its appeal's *petitum*.

[31] Supra, note 4, Case C-458/19 P, *ClientEarth v European Commission*, ECLI:EU:C:2021:802, para 113.

provision. In response, the CJEU agrees with the General Court, stating that "Article 60(4) of the REACH Regulation is the expression of the need to take into account that principle [ie the precautionary principle] and the principle of proportionality where one of the conditions laid down in Article 60(2) of that regulation is not satisfied, in the present case, the condition concerning evidence of control of the risk posed to human health or the environment by the use of the substance at issue". Furthermore, the CJEU adds that "it cannot validly be argued that the precautionary principle precludes an authorisation being granted under Article 60(4) of the REACH Regulation on the sole ground that there is no proof of control of the risk, without calling into question the validity of that provision, which allows authorisation to be granted in such a situation".[32] However, the validity of Article 60(4) was not pointed out by the appellant, but rather the way in which it should be applied.

IV. Comments

The relevance of this judgment is that it provides a better understanding of how Article 60(4) of the REACH Regulation is legally interpreted with respect to other provisions of the same Regulation, namely Articles 60(2), 62(4)(d) and 59, in an analogous manner. This is regardless of whether the case concerns reproductive-toxic properties (Article 57(c) REACH Regulation) or endocrine-disrupting properties (Article 57(f) REACH Regulation). This decision is also of particular interest because it unveils the limits of the CJEU's willingness or ability to employ a teleological approach to legislative interpretation in this area, as discussed below.

However, it cannot be said that this judgment offers major findings concerning the review procedure, as neither the decision of the General Court nor the one of the Commission has been contradicted. The opportunity seems to have been missed to request from the CJEU whether it really applied Article 60(4) of the REACH Regulation in a subsidiary way for the granting of authorisation in a case where there were uncertainties or deficiencies in the chemical safety report required by Article 60(2). Indeed, it is quite different not to have the chemical safety under control or not to submit the required information under the pre-established requirements, which, arguably, could have been alleged as a formal defect in the application.

There was also an opportunity to ask the CJEU about the validity of the same Article 60(4) insofar as it allows the authorisation to be granted even without demonstrating that chemical safety is under control. The appellant could have asked whether this is contrary to the validity of the provision, as well as with the precautionary principle as stated in Article 1(3) of the REACH Regulation,[33] which provides that REACH Regulation provisions are underpinned by this principle. This therefore opens up the question of whether the REACH Regulation could be employing seemingly contradictory reasoning in its construction, which would have been an interesting issue to consider and, potentially, a perspective that the applicants could have explored further.

That said, the CJEU's decision is not surprising, as it is in line with the principles of legal certainty and legitimate expectations.[34] Based on a legalistic reading of the regulation that

[32] ibid, para 139.

[33] Art 1(3) of the REACH Regulation establishes that "[t]his 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."

[34] "... the principle of legal certainty, which requires that legal rules be clear and precise, and aims to ensure that situations and legal relationships governed by Community law remain foreseeable. ... [T]he principle of the protection of legitimate expectations may be invoked as against Community rules only to the extent that the Community itself has previously created a situation which can give rise to a legitimate expectation." Case C-63/93, *Duff and Others v Minister for Agriculture and Food*, para 20. Judgment of the Court of 15

was in place at the time of submitting the application for authorisation, it is understandable that substances not yet listed in Annex XIV are not included in the risk assessment and socio-economic balance. For the purpose of comparison, the substance that has been identified and added to the candidate list must follow the procedure all the way to the end in order to determine whether it is finally considered a SVHC or not, in the same way that a person suspected of a crime is only considered guilty if proven by judgment, which comes at the end of the respective process.

Yet, it is obvious that further consideration of chemicals such as DEHP, not only for their reproductive-toxic properties but also for their endocrine-disrupting properties and their respective inclusion in Annex XIV, will allow a more comprehensive screening of these substances. Thus, a higher level of protection could be achieved, presumably by avoiding long-term exposure that may have adverse effects on future generations.

Therefore, although the CJEU's decision was to be expected under the principles of legal certainty and legitimate expectations, this decision is based on a legalistic, or literal, reading of the REACH Regulation and not on notions of fairness. Perhaps the CJEU *should* have concluded that authorisation must be rejected (as opposed to what they *could* conclude under the law in force). This highlights the contrast that often exists between the theoretical and the practical level – the inconsistency of laws that create a regulatory framework that does not always conform to reality, particularly in cases such as the one at hand, where scientific research plays a fundamental role, leading to continuous changes in knowledge. It is clear from the analysis of this case that if DEHP had been included in Annex XIV *before* the date of the authorisation decision, its endocrine-disrupting properties would have been taken into account in both the risk assessment and the socio-economic balance. It remains uncertain what the outcome of this counterfactual authorisation procedure would have been, but assuming it had been rejected, the reason for rejection would have been in the interest of better protection of human health and the environment.

This leads us to reflect on several aspects: this judgment highlights the limits of the CJEU's willingness or possibility to apply a teleological approach to legislative interpretation in this area,[35] as well as it arguing for the inability of the law to adjust, or adapt, to social changes (in this case, to new scientific discoveries). Indeed, while science had already *identified* this chemical as having endocrine-disrupting properties, the law had not yet *recognised* it as such. Thus, once again, legal formalism and the lengthy administrative procedures usually entail a chronological mismatch that distances justice from the state of the art in science. Hence, one may reflect on the time dimension in the risk analysis concerning the identification and recognition of substances with endocrine-disrupting properties and their inclusion in Annex XIV of the REACH Regulation. Currently, there are only seven substances listed in this Annex for endocrine-disrupting properties according to Article 57(f).[36] By contrast, scientific sources claim that there are more than 1,000 chemical substances reported to have endocrine-disrupting properties.[37]

February 1996. European Court Reports 1996 Page I-00569 <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61993CJ0063:en:HTML> (last accessed 20 December 2022).

[35] A teleological interpretation in this area would be meaningful in relation to what the legislator expressed in Recital 9 of the REACH Regulation of the initial legal act: "the need to do more to protect public health and the environment in accordance with the precautionary principle" <http://data.europa.eu/eli/reg/2006/1907/2022-12-17> (last accessed 20 December 2022).

[36] Supra, note 1. Update of the REACH Regulation as of 17 December 2022.

[37] According to TT Schug, AF Johnson, LS Birnbaum, T Colborn, LJ Guillette Jr, DP Crews et al, "Minireview: Endocrine Disruptors: Past Lessons and Future Directions" (2016) 30(8) Molecular Endocrinology 833–47.

Aware of this issue, the EU proposes in its Chemicals Strategy[38] to risk assess substances to be identified as endocrine disrupters on a group-by-group basis instead of, as is done presently, on a substance-by-substance basis. This should speed up the process of identification and inclusion of a substance in Annex XIV,[39] although it remains to be seen whether this will be sufficiently rapid and fit for purpose.

Beyond the judicial process, one can note that in their application for authorisation[40] the applicants requested permission to use PVC coming from a recycling process and to transform it into other PVC products. It is worth noting that, among the reasons given in their socio-economic analysis, the applicants claimed that if authorisation was not granted, the companies involved in the PVC recycling process would eventually cease to operate due to a lack of customers and declining demand for PVC. In other words, after the recycling process, PVC is separated and could be taken out of circulation instead of re-entering the market. Despite the consensus around the idea of circularity,[41] it may, as a side effect, support reintroducing substances into the market for which warnings have already been issued regarding their potential adverse effects. Hence, one can arguably consider such a substance reintroduction to be an undesirable risk[42] considering the intrinsic properties mentioned both in Article 57(c) and (f) of the REACH Regulation.

Given, among others, these undesirable risks from reintroduced substances, one could consider this judgment of the CJEU as a lost opportunity for obtaining a judicial pronouncement in relation to the principle of intergenerational equity, which would have been an interesting consideration given the significance of this principle and its rare presence in the EU legal arena. The concept of intergenerational equity asserts that humans hold planet Earth in common with other species, with other people and with past, present and future generations; this consequently encompasses a concept of fairness between generations in the right to use and the obligation to preserve the environment and its natural resources.[43]

[38] The EU's chemicals strategy for sustainability towards a toxic-free environment COM/2020/667 final, Annex. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN> (last accessed 20 December 2022).

[39] Under the title "Providing a comprehensive and transparent knowledge base on chemicals", this strategy states: "Proposals to revise requirements for registration in REACH to ensure: the identification of substances with critical hazard properties, including effects on the nervous and immune systems, the move towards grouping approaches, the registration of a sub-set of polymers, information on the overall environmental footprint of chemicals, the obligation of chemical safety reports for substances between 1–10 tonnes" (see ibid).

[40] Based on the public information available to us via the official ECHA website <https://echa.europa.eu/documents/10162/21d44ab1-9845-4265-b448-4f010fb0c956> (last accessed 14 December 2022).

[41] Chemicals as well as waste and recycling are two of the top policy areas of the EU's new Circular Economy Action Plan (CEAP). Related strategies are, for instance, the Chemicals strategy and the Plastics strategy. Find more information at <https://environment.ec.europa.eu/strategy/circular-economy-action-plan_en> (last accessed 14 December 2022).

[42] On this note, please see: J Alaranta and M Miettinen, "Precautiously Circular: Perspectives on the Application of the Precautionary Principle in European Union Waste and Chemicals Regulation" (2023) 14(1) European Journal of Risk Regulation 14–30.

[43] Oxford Public International Law (http://opil.ouplaw.com). © Oxford University Press 2021. Intergenerational equity, Max Plank Encyclopedias of International Law <~https://opil.ouplaw.com/display/10.1093/law:epil/9780199231690/law-9780199231690-e1421#:~:text=1%20The%20principle%20of%20intergenerational,other%20generations%2C%20past%20and%20future> (last accessed 13 January 2023); E Brown Weiss, "In Fairness to Future Generations and Sustainable Development" (1992) 8(1) American University International Law Review 19–26.

1. Principle of intergenerational equity

The legal basis of the principle of intergenerational equity is to be found in several international environmental legal pieces, such as the Rio Declaration[44] (1992), Principle 3; the United Nations Framework Convention on Climate Change,[45] Article 3(1); and the Aarhus Convention, Preamble and Article 1; the last two being legally binding in the EU, as it is a Party of those sources of international law and a supporter of the Rio Declaration.[46] National and European courts can act to reinforce the international legal order as implementers of international law in their respective legal orders.[47] The CJEU ruled accordingly in Case C-363/18,[48] establishing that the EU is obliged to contribute "to the strict observance and development of international law" based on Article 3(5) TEU.[49] However, Bogojević[50] illustrates that the high-profile environmental lawsuits seen in other parts of the world,[51] in which minors take action against governments' climate failures on the basis of their own human rights and the rights of future generations, were largely absent in the EU by 2020. "As such, these cases are often framed as actions about intergenerational equity and our responsibilities towards future generations."[52] Arguably, this was the case in a German Constitutional Court ruling from 2021.[53] Despite its slow

[44] United Nations Conference on Environment and Development (UNCED), held in Rio de Janeiro in 1992, is commonly known as the Rio Declaration, which establishes twenty-seven non-binding principles, among which Principle 3 establishes "the right to development must be fulfilled so as to equitably meet developmental and environmental needs of present and future generations".

[45] United Nations Framework Convention on Climate Change (UNFCCC), <https://unfccc.int/resource/docs/convkp/conveng.pdf>, of which the EU is Party <https://unfccc.int/process/parties-non-party-stakeholders/parties-convention-and-observer-states> (last accessed 14 December 2022).

[46] "The European Union is a strong supporter of the Declaration at the 1992 United Nations Earth Summit in Rio de Janeiro", as stated by the EU itself on the Communication from the Commission to the Council and the European Parliament – Draft Declaration on Guiding Principles for Sustainable Development /* COM/2005/0218 final */ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX%3A52005DC0218> (last accessed 14 December 2022).

[47] K Purnhagen, J Van Zeben, C Ahlborn and P Oosterveer, "Beyond Food Safety – EU Food Information Standards as a Facilitator of Political Consumerism and International Law Enforcement Mechanism", Wageningen Working Paper Law 2020/01, p 25. DOI: 10.13140/RG.2.2.23221.42721p.

[48] Case C-363/18, *Organisation juive européenne and Vignoble Psagot Ltd v Ministre de l'Économie et des Finances*, para 48. ECLI identifier: ECLI:EU:C:2019:954 <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62018CJ0363> (last accessed 20 December 2022).

[49] This establishes that: "In its relations with the wider world, the Union shall uphold and promote its values and interests and contribute to the protection of its citizens. It shall contribute to peace, security, the sustainable development of the Earth, solidarity and mutual respect among peoples ..., as well as to the strict observance and the development of international law ...."

[50] S Bogojević, "Human rights of minors and future generations: Global trends and EU environmental law particularities" (2020) 29(2) RECEIL: Review of European, Comparative & International Environmental Law 191–200.

[51] As this author cites in its article (see ibid), there have been some cases referring to the rights of future generations in several countries, namely: Philippines (no. 1, *Minors Oposa v Secretary of the Department of Environmental and Natural Resources*, Case No 33 ILM 173), Colombia (no. 2, PA Acosta Alvarado and D Rivas-Ramírez, "A Milestone in Environmental and Future Generations' Rights Protection: Recent Legal Developments before the Colombian Supreme Court" (2018) 30 Journal of Environmental Law 519, 521), the USA (no. 4, United States Court of Appeals for the Ninth Circuit, D.C. No 6:15-cv-01517-AA, *Juliana et al. v the United States of America et al.*), Kenya (no. 13, *Moffat Kamau & others v Aelous Kenya Limited & others*, Constitutional Petition No 13 of 2015 [2016] Eklr) and the Netherlands (no. 13, *The State of the Netherlands v Stichting Urgenda* (2019), ECLI:NL:HR:2019:2007).

[52] Bogojević, supra, note 50, p 192.

[53] BVerfG, Order of the First Senate (Federal Constitutional Court of Germany) of 24 March 2021 – Cases 1 BvR 2656/18 – 1 BvR 78/20 – 1 BvR 96/20 – and 1 BvR 288/20, paras 1–270 <http://www.bverfg.de/e/rs20210324_1bvr265618en.html> (last accessed 13 May 2023).

pace, this trend of rights-based environmental litigation alleging that institutions have failed to protect the human rights of children and future generations is slowly emerging at the EU level as well.[54]

An explicit mention of "future generations" can also be found in EU law, namely the Charter of Fundamental Rights of the European Union.[55] More precisely, the sixth paragraph of this Charter's Preamble indicates "responsibilities and duties with regard to other persons, to the human community and to *future generations*".[56] Although the Preamble is not legally binding, it expresses the legislator's will and guides the application of the articles that follow it. In this regard, it should be noted that Article 35 states that "a high level of human health protection shall be ensured", while Article 37 furthermore demands "[a] high level of environmental protection ... in accordance with the principle of sustainable development". In addition, Article 3(3) TEU establishes that "[the Union] shall work for the sustainable development of Europe ... aiming at ... a high level of protection and improvement of the quality of the environment ... and shall promote solidarity between generations". If one considers these legal clauses in connection with Article 60(4)(a) and (d) of the REACH Regulation concerning the consideration of risks to human health and the environment within the socio-economic analysis, it is applicable that appropriate consideration should be given to the consequences for future generations due to long-term exposure to substances such as DEHP. As described above, the interests of future generations have so far been addressed in purely environmental cases. However, I believe that this might be extended to many cases of long-term exposure to toxic substances such as SVHC, like endocrine disruptors, or persistent organic pollutants (POPs).

At this point, it is worth mentioning that there is a doctrine developed in 1989 by Brown Weiss[57] that creates a possible normative framework for the application of the concept of "intergenerational equity" and the protection of "future generations". However, some scholars[58] have pointed out that "[t]here appears to be a conscious or unconscious distancing [by the EU] from, or even rejection of, the doctrine of IGE [intergenerational equity] as developed by Brown Weiss". Whether or not the aforementioned doctrine applies, it seems clear that EU public authorities have an obligation to protect the interests of future generations as an inalienable requirement for achieving the long-term objective of sustainable development that informs EU law as a whole.[59] Sustainable development is understood as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs".[60] In its application within the

[54] Bogojević, supra, note 50, p 195. This author points to the Carvalho case (Case T-330/18, *Carvalho v EP and Council of the EU*) as an example in the EU. In this case, at para 24, the applicants refer to the action for damages resulting from the emission of greenhouse gases. Reference is made to damage that is both present and *future* and consists of damage to living conditions: <https://curia.europa.eu/juris/liste.jsf?num=T-330/18> (last accessed 25 April 2023).

[55] Supra, note 2. Note that this Charter is included in the so-called EU Constitution, the Lisbon Treaty, together with the TEU and the TFEU. Hence, this legislation is at the top of the normative pyramid, giving these dispositions priority over other rules.

[56] Emphasis added.

[57] E Brown Weiss, *In Fairness to Future Generations: International Law, Common Patrimony, and Intergenerational Equity* (Tokyo, United Nations University 1989). As elaborated by LM Collins, "Environmental Rights for the Future Generations? Intergenerational Equity in the EU" (2007) 16(3) RECIEL: Review of European Community & International Environmental Law 326.

[58] Collins, supra, note 57.

[59] Sustainable development officially became one of the long-term objectives of the EU under Art 3(3) TEU. See supra, note 2.

[60] This concept of sustainable development is commonly understood as given in *Our Common Future* (World Commission on Environmental and Development 1987), known as the "Brundtland Report".

EU, it "seeks to reconcile economic development with the protection of social and environmental balance".[61]

From the above, one can infer the legislator's will in primary law. In addition, secondary law seems to be accordingly aligned[62]; for instance, see the 7th Environment Action Programme to 2020[63] and, even more explicitly and recently, the 8th Environmental Action Programme to 2030[64] (although the latter was adopted after the CJEU's judgment that concerns this work). These programmes articulate plans and set targets for a decade or even thirty years into the future. For example, the aforementioned 8th Environmental Action Programme sets in Article 2(1) "the long-term priority objective that by 2050 at the latest, people live well, within the planetary boundaries in a well-being economy where nothing is wasted .... A healthy environment underpins the well-being of all people ... and other environmental risks. The Union sets the pace for ensuring the prosperity of present and future generations globally, guided by intergenerational responsibility." This target represents a very short timescale in terms of environmental protection. Therefore, some authors[65] arguments are to be considered valid when they point out that, even with the numerous EU actions in favour of human and environmental health, the EU tends to follow short-term horizons and to have limited overall efficacy, since the general trend is one of continuous environmental damage.

V. Conclusion

In conclusion, in the present case, there was a missed opportunity to obtain a ruling from the CJEU on the matter of intergenerational equity. In this respect, and considering the elaborated scientific and legal contexts, the EU's important and multi-faceted work to protect health and the environment appears to be insufficient, at least for the time being, to achieve fully sustainable development. This calls for further work towards the protection of the environment as well as health, which are both recognised as fundamental rights,[66] from long-term exposure to substances such as DEHP. It is important to bear in mind that, when talking about toxic properties, these include their possible associated

[61] According to the official glossary of the EU <https://eur-lex.europa.eu/EN/legal-content/glossary/sustainable-development.html> (last accessed 14 December 2022).

[62] Although intergenerational solidarity is mentioned mainly in relation to the issue of ageing in the EU. Some references are the following: Decision No 940/2011/EU of the European Parliament and of the Council of 14 September 2011 on the European Year for Active Ageing and Solidarity between Generations (2012) (OJ 2011 L 246, p 5); GREEN PAPER ON AGEING Fostering solidarity and responsibility between generations COM/2021/50 final <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0050&qid=1682440381822>; or Commission Regulation (EC) No 16/2004 of 6 January 2004 implementing Regulation (EC) No 1177/2003 of the European Parliament and of the Council concerning Community statistics on income and living conditions (EU-SILC) as regards the list of target secondary variables relating to the "intergenerational transmission of poverty", OJ L 4, 8.1.2004, pp 3–6 (EN), permanent European Legislation Identifier <http://data.europa.eu/eli/reg/2004/16/oj> (last accessed 25 April 2023).

[63] Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 "Living well, within the limits of our planet" Text with EEA relevance OJ L 354, 28.12.2013, pp 171–200 (EN), permanent European Legislation Identifier <http://data.europa.eu/eli/dec/2013/1386/oj> (last accessed 14 December 2022).

[64] Decision (EU) 2022/591 of the European Parliament and of the Council of 6 April 2022 on a General Union Environment Action Programme to 2030 PE/83/2021/REV/1 OJ L 114, 12.4.2022, pp 22–36 (EN), permanent European Legislation Identifier <http://data.europa.eu/eli/dec/2022/591/oj> (last accessed 14 December 2022).

[65] Collins, supra, note 57, pp 329–31.

[66] Eg Arts 35 and 27 Charter of Fundamental Rights of the European Union.

negative health effects, which can be as harmful as cancer or infertility, and which may have an effect not only on current but also on future generations.[67]

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[67] In the 1970s, many pregnant women were exposed to a substance called diethylstilboestrol (DES), and "it was more than 20 years later that many of the daughters of women needlessly prescribed DES were diagnosed with vaginal cancer, an unusual cancer, especially in young women. Today, we know that even the granddaughters of the women involved have a higher risk of this disease." B Demeneix, *Toxic Cocktail* (Oxford, Oxford University Press 2017) p 1.

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