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Clarifications from the Court of Justice of the EU on the identification of "substances of very high concern" under REACH

Some industries have been particularly active in their use of the Court of Justice of the EU (the Court) against the inclusion of new substances or new properties in the candidate list.[1] However, it is worth noting that all court cases brought to annul a decision from the European Chemical Agency (ECHA) on the basis of Article 57 of the REACH Regulation have failed so far.

It emerges from this case law that the Court recognises **a broad power to ECHA and Member States to identify substances of very high concern (SVHC)** under Article 57 and especially 57(f).[2] The Court still exercises a thorough control of the legality of the decisions and scrutinises in particular the way the supporting evidence is relied upon and the scientific reasoning explained in the support documents. But overall, this case law provides key clarifications that support Member States and ECHA by categorically rejecting many of the industry's arguments that, if upheld, would have made the identification of SVHCs an excessively heavy procedure for them.

1. The identification of a SVHC depends on its hazardous properties, not its use

→ No, the competent authority does not have any obligation to take into account information on the use of the substance when identifying a SVHC

The Court clarified, unequivocally, that "inclusion of a substance in the candidate list of substances are **carried out solely on account of the intrinsic properties** of a substance and not on account of the use of that substance".[3] It is only in the context of Article 57(f), when interpreting the concept of "concern", that the Court stated that Article 57(f) *does not prohibit* the taking into account of data other than those relating to the hazards arising from the intrinsic properties of the substance.[4]

The Court made clear that, even when applying Article 57(f) where the notion of "concern" is relevant, "ECHA has a discretion but is **not obliged** to take into account information other than concerning intrinsic properties".[5]

For example, the permitted migration limit of a substance set under the food contact material regulation, is **a factor** which ECHA **can** take into account for the purposes of identifying a SVHC under Article 57(f). However, **it does not have to**. In other words, if ECHA does not take into

[1] See list of cases on ECHA's website: https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/transparency/cases-where-echa-is-a-party/candidate-list
[2] T-636/17 para. 58-59
[3] T-185/17 para. 75, referring to C-650/15P (emphasis added); see also C-324/15P para. 25
[4] T-185/17 para. 76-78, referring to C-650/15P (emphasis added) interpreting C-324/15P para. 34, 40-44
[5] T-185/17 para. 79, referring to C-650/15P; see also para. 41, 67 of T-636/17

account the permitted migration limit in its assessment of the equivalent level of concern, this cannot justify the annulment of its decision to identify the SVHC.[6]

→ Yes, a substance used as an intermediate can be identified as a SVHC

A substance **used** as an *on-site isolated intermediate* or as a *transported isolated intermediate* is not exempted from all the provisions of Title VII in application of Article 2(8)(b). It **does not escape the identification procedure of SVHC**.[7]

The Court has affirmed that intermediates are submitted to the identification procedure because of the standalone objectives of the candidate list, which is the establishment of information sharing obligations in respect of the SVHC within the supply chain and with consumers – which would be undermined if intermediates were not covered.[8]

→ Only the capacity to cause adverse effects matters under Article 57(f), not the probability of it happening

The concept of “risk” is a function of the “probability” that using the substance will have an adverse effect while the concept of “hazard” asks whether a substance is “capable” of having adverse effects.[9] The Court made clear that the assessment of the intrinsic properties of the substance under Article 57(f) is not an assessment of the risks arising from the practical use of a substance or exposure to it, but rather an assessment of the hazards of that substance.[10] **It is not required to establish the probable nature of the serious effects** on health or the environment, **only that the effects are “possible”**.[11]

2. The burden of proving an ‘equivalent level of concern’ is not heavy

The fact that Article 57(f) contains the additional condition of “equivalent level of concern” is sometimes perceived as one more hurdle that is resource consuming to overcome. However, the Court has given very clear indications of the contrary.

The Court has not created a strict test (such as an exhaustive list of criteria to meet) to verify whether the condition has been fulfilled. The Court has done the exact opposite by considering that it considers the condition to be fulfilled if information is brought on a wide array of non-exhaustive and non-cumulative criteria such as:[12]

- Effects on health: type of these effects, irreversibility, delay in the manifestation of the effects[13]

[6] T-636/17 para. 121
[7] T-636/17 para. 191-200 and T-185/17 para. 44-57 referring to C-650/15P
[8] T-185/17 para. 52, 64
[9] T-636/17 para. 97-98
[10] T636/17 para. 96
[11] T-636/17 para. 101
[12] As France did and acknowledged by the General Court in T-636/17 para. 43; also in case T-135/13 para. 101 (not covered by the appeal in C-324/15)
[13] See C-324/15P para. 36-39

- Impact on quality of life[14]
- Societal concern[15], or consequences of those effects for society.[16] This is important as it shows that the factors that may be taken into account go beyond the potential physical impact.
- The difficulty of adequately assessing the risks posed by the substance when it is impossible to determine with the necessary certainty a ‘derived no effect level’[17]

This approach signals to ECHA and the Member States that it is the seriousness of the concern that matters, and the appreciation of what is serious is not limited to a pre-defined set of factors. It depends on the context, and ECHA and Member States are recognised a broad discretion in identifying what a serious concern is.

So far, the Court has validated the demonstration of an equivalent level of concern for two endocrine disruptors (DEHP[18] and BPA[19]), and sensitizers[20] under Article 57(f) in a way that shows that the establishment of an equivalent level of concern is not a hurdle.

On a side note, concerning the best way to structure the support document to pass the control of the Court, the structure of the support document of France in the identification of BPA as an endocrine disruptor under Article 57(f) should be used as a blue print or template.[21] Indeed, the support document needs to mirror the wording of article 57(f), and include both demonstrations, separately that:

(i) The substance **can have serious effects** on human health or the environment; **and**
(ii) **Those effects give rise to an equivalent level of concern** to those of other substances referred to in Article 57(a) to (e).[22]

3. The Court recognises the need for studies from different sources and the discretion to integrate them to a specific assessment

→ No, a ‘non-guideline’ study is not automatically ‘unreliable’

The Court had the opportunity to rule on this issue in a case where competent authority had assessed the reliability of the studies using the Klimisch scoring system. The Court stated, without ambiguity:

> “there is nothing in the Klimisch scoring system to indicate that all ‘non-guideline’ studies should receive a ‘3 = not reliable’ rating. In fact, the ‘2 = reliable with restriction’ rating can be given precisely to studies for which the documented test parameters do not fully

[14] T-636/17 para. 43
[15] T-636/17 para. 43
[16] C-324/15 P para. 38
[17] T-636/17 para. 121 ; C-324/15 P para. 39
[18] T-115/15 and C-419/17 P
[19] T-636/17, in particular para. 113 (pending appeal C-876/19 P)
[20] C-324/15 P and C-323/15 P
[21] However, it would be unreasonable to wait to gather the same amount of evidence/studies as France gathered on BPA to propose the identification of other substances as SVHC since BPA is one of the most studied substances in the world.
[22] As explained by the General Court in T-636/17 para. 41-43 applied to an endocrine disruptor

> comply with a specific guideline. Consequently, in contrast to what the applicant suggests, the mere fact that an expert’s report is described as a ‘non-guideline’ study does not imply that that study is not reliable”.[23]

This does not mean that the Klimisch scoring system is the only rating system public authorities can rely on. It just shows that it is the coherence between the system of selection/ranking announced and the ways in which studies are actually selected/ranked that matters.

The argument that non-guideline studies (i.e. not following OECD guidelines) are not reliable, seems to be raised often by industry in public consultation comments. This argument has, however, as the Court confirmed, no legal nor factual basis. There is no legal reason to exclude non-OECD studies independent from vested interests, which is logical as there is no scientific reason to do so. This is also clear from the ECHA Guidance on Information Requirements and Chemical Safety Assessment.[24] It is also worth consulting the Q&A document made by OECD itself that confirms this fact.[25]

→ Yes, ECHA can consider a study ‘instructive’ even if EFSA or SCOEL considered it ‘unreliable’

In the appreciation of the reliability of a given study, the Court gives a significant importance to the specific purpose of this process. Generally, regulatory bodies and scientific committees other than ECHA, including EFSA and SCOEL, do not have the same duties as ECHA and draw up their scientific opinions for purposes other than those envisaged by ECHA.[26] A study considers not reliable by one may therefore be legally considered as reliable for another.

In particular, the Court made clear that since the spheres of activity and duties of ECHA and EFSA are different, the findings of one of those agencies with regard to the reliability of a study do not necessarily call into question the findings of the other agency with regard to the same study.[27] This is because EFSA’s examination of the data in the context of its mission such as the one under the food contact material regulation, is very different in scope and nature to determining whether the substance was a substance of very high concern under Article 57(f).[28]

→ No, ECHA does not have the obligation to wait for the results of ongoing studies to list a SVHC

The principle of legal certainty does not require that an EU institution await the conclusion of a specific scientific study before taking a decision on the substance it concerns.[29] As the Court

[23] T-115/15 para. 185
[24] Chapter R.4.2. p.3, available at : https://echa.europa.eu/documents/10162/13643/information_requirements_r4_en.pdf/d6395ad2-1596-4708-ba86-0136686d205e
[25] See question 19 of OECD Q&A: http://www.oecd.org/chemicalsafety/testing/General-Questions-and-Answers-Concerning-OECD-Principles-of-GLP.pdf
[26] T-636/17 para. 72
[27] T-636/17 para. 65, 83
[28] T-636/17 para. 62
[29] T-636/17 para. 163

raised: “If ECHA had to wait the completion of all the studies conducted on a certain substance, no substance could ever be identified as being of very high concern, which would be contrary to the main objective of that regulation, which is to ensure a high level of protection of human health and the environment”.[30]

The Court also helpfully clarified that a decision to wait for the conclusion of a study in the context of an “evaluation” under Article 46 could not create a “legitimate expectation” in the context of the SVHC identification.[31]

While it is true that ECHA may create a “legitimate expectation” that it will do or not do something, which if breached can lead to the annulment of the decision, the level of evidence for this argument to succeed is very high. Indeed, such argument may only succeed if the applicant can prove it received **specific, unconditional and consistent assurances** from ECHA or other reliable sources that the expected event would undoubtedly happen.[32] The Court refused to recognised that any “legitimate expectations” were breached in the context of Article 57 in the two cases where such argument were raised.[33]

4. ECHA has the power to supplement existing entries in the candidate list with new grounds within the meaning of Article 57

Even if a substance is already on the candidate list for a given reason/hazardous property falling under Article 57, the Court confirmed that ECHA has the power to add to the entry of this substance in the Candidate list other hazardous properties falling into the criteria of Article 57.[34]

[30] T-636/17 para. 170
[31] T-636/17 para. 169
[32] T-636/17 para. 166; C-419/17P para. 67-75
[33] T-636/17 para. 167, C-419/17P, para. 74 T-115/15 para.137-139
[34] T-636/17 para. 177-184, interpreting C-323/15P para. 24-26; C-419/17 para. 34-38, interpreting C-323/15P para. 24

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Contacts:

Dr. Apolline Roger
Law and Policy Advisor,
Chemicals Project Lead
aroger@clientearth.org

Alice Bernard
Lawyer (Juriste),
Chemicals Project
abernard@clientearth.org