POSITION PAPER

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ESIG Position Paper

Application of REACH Article 57(f)

The European Solvents Industry Group (ESIG), a Cefic sector group, serving as the common umbrella for the Hydrocarbon Solvents Producers Association (HSPA) and the Oxygenated Solvents Producers Association (OSPA), supports the objectives of REACH in ensuring a high level of protection for human health and the environment, including the identification and appropriate management of Substances of Very High Concern (SVHCs)[1]. That said, the application of Article 57(f), the Equivalent Level of Concern route, must remain clear, consistent, transparent and proportionate.

1. Summary

ESIG recognises the importance of maintaining a robust, credible and consistent SVHC framework, which is key to ensure both regulatory effectiveness and stakeholder confidence. At the same time, we consider that the application of Article 57(f), Equivalent Level of Concern (ELoC), must remain clear, consistent, transparent and proportionate.

Using the n-hexane case as an important precedent, this paper highlights the need for a separate, case-by-case ELoC assessment, transparent scientific reasoning, and a clear distinction between intrinsic hazard-based SVHC identification and considerations relating to risk management, instrument choice and added regulatory value.

The n-hexane case is of particular importance, as ECHA has communicated it as the first neurotoxic STOT-RE 1 (neurotoxicity) ELoC case under Article 57(f).

The Annex XV dossier submitted by Slovenia in August 2025 outlines substantial methodological shortcomings which have not been sufficiently addressed nor justified during the comments revision process. Without binding minimum standards, there is a risk that Article 57(f) becomes, in practice, a hazard-based shortcut – at the expense of legal certainty, consistency and proportionality.

[1] There is a list of abbreviations available at the end of the document.

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Key asks:

- Full transparency on the scientific reasoning, including how severity, permanence, reversibility, thresholds and uncertainty were assessed and weighted.
- Clear explanation of the added regulatory value of Candidate Listing, in particular for authorisation, value-chain communication or another defined regulatory objective.
- Separate assessment of downstream risk-management options.

2. Introduction: relevance of the n-hexane case

n-hexane (EC 203-777-6, CAS 110-54-3) was identified as an SVHC under Article 57(f) of REACH and added to the Candidate List with effect from 4 February 2026. ECHA explicitly refers to the case as a "first neurotoxic case of Equivalent Level of Concern (ELoC)"[2], and consultation materials describe it as "unprecedented"[3].

This decision has potentially far-reaching consequences:

- It sets a standard of reasoning for future application of Article 57(f).
- It highlights the ambiguity with the application of the criteria underpinning Article 57(f), weakening the credibility of the Article itself.
- It also impacts other substances, including unknown or variable composition or biological origin (UVCB) substances and mixtures containing n-hexane.

The n-hexane listing risks having detrimental effects on the competitiveness of the European industry, with imported materials from outside the EU containing n-hexane at safe levels being more cost-effectively produced than in Europe.

[2] https://echa.europa.eu/-/echa-s-member-state-committee-december-meeting-highlights

[3] Mitsui Chemicals Inc Company, Japan, n-hexane RCOM document, page 50; https://echa.europa.eu/documents/10162/9c49de65-bd78-154a-05fa-b95839cc64a0)

3. Legal standard under Article 57(f)

Article 57(f) of REACH does not appear as a purely "hazard track", but rather as a provision with its own criteria; those criteria justify an "Equivalent Level of Concern". The European Court of Justice, when examining Article 57(f), clarified that two cumulative conditions trigger its application: first, that it is probable that the substances concerned have serious effects on human health or the environment, and second, that those effects 'give rise to an equivalent level of concern to those of [CMR, PBT or vPvB substances]'. In other words, the identification of a substance as being of very high concern must be rejected if either of those conditions is not met[4].

A CLP classification can be a starting point, but it does not replace the need for a standalone ELoC justification. Otherwise, Article 57(f) would be reduced to a hazard-based shortcut, which would seem inconsistent with the wording and purpose of the provision.

SVHC listing on grounds of Article 57(f) REACH ("equivalence of concern") should not be based only on hazards – a more holistic assessment considering e.g. human exposure reflecting the risk management measures in force must be included.

4. Significance of the n-hexane SVHC dossier

4.1 A hazard shortcut

It is to be noted that ECHA-affiliated authors have recently published an article[5] listing more than 100 neurotoxic or suspected neurotoxic substances based on CLP harmonised classification, which was referred to during the 92nd Member State Committee (MSC) meeting[6]. The concern is not the number of potentially relevant substances as such, but the risk that Article 57(f) be applied without a sufficiently documented analysis and justification for ELoC.

Importantly, a substantiated ELoC justification is one of the two mandatory conditions for identifying a substance as an SVHC under Article 57(f). Therefore, each Article 57(f) case should include a separate, transparent and well-documented ELoC assessment, clearly explaining why the

[4] Judgement of 15 March 2017, Hitachi Chemical Europe GmbH, C-324-15 P, ECLI:EU:C:2017:208, para. 26

[5] A reference list of neurotoxicants based on CLP harmonised classifications (Kai Craenen, Panagiotis Kosiaras, Kati Hellsten); A reference list of neurotoxicants based on CLP harmonised classifications - ScienceDirect

[6] Minutes of the 92nd Meeting of the Member State Committee (MSC-92), 9-11 December 2025, Item 8.2 (link)

properties of the substance give rise to an equivalent level of concern comparable to Article 57(a)–(e).

If the ELoC justification is not clearly separated from the hazard finding, this may lead to generalisations, i.e. neurotoxicity ⇒ ELoC, undermining the specificity of Article 57(f).

To improve transparency on the decision taken, in Article 57(f) cases, ECHA and MSC should present the ELoC conclusion answering separately the two conditions "serious effects" and "equivalent level of concern" and how they were weighted.

4.2 Realism and reversibility of the ELoC assessment

The Slovenian Annex XV dossier supports the ELoC argument based on, first, the severity of neurotoxic effects, second, delay/progression, third, long recovery times and fourth, societal concern. At the same time, the dossier itself indicates that mild to moderate cases typically recover fully and that even severe cases can show improvement.

Where ELoC is justified on the basis of severity, delayed progression or long recovery, the dossier should set out, in a verifiable manner:

- How seriousness, duration, reversibility, permanence and recovery were assessed and weighted.
- Whether threshold or dose-response considerations and uncertainties were adequately addressed.
- Why the intrinsic effects are genuinely comparable to the level of concern represented by Article 57(a)–(e).
- Whether the evidence underpinning the intrinsic hazard reflects effects of sufficient seriousness and concern, rather than effects arising only under exceptional or poorly documented circumstances.

The justification should disclose which realistic EU use/exposure scenarios were relevant and how reversibility/recovery, and, potentially, misuse was considered in the ELoC context.

4.3 Value of transparency with stakeholders during the Article 57(f) process

The BAuA RMOA[7] Document suggests that n-hexane may pose an unacceptable risk to consumers, yet the basis for this conclusion was not made publicly available to stakeholders during the consultation period.

In our view, a rational science-based review of the relevant Derived No-Effect Level (DNEL) and Risk Characterization Ratio (RCR) calculations should be made available to stakeholders, the impacted value chain and in particular to those suppliers who are responsible for the manufacturing and safe use of those substances before conclusions are formalised.

4.4 Proportionality and choice of instrument

N-hexane is already addressed under existing regulatory instruments, including harmonised GHS/CLP classification as STOT-RE 1 (neurotoxicity), established occupational exposure limits or worker-protection instruments, and standardised risk-management measures in the supply chain. Against this background, an Article 57(f) identification should explain which additional concern remains unresolved beyond the existing regulatory instruments and risk management measures. The added regulatory value of Candidate Listing should also be clearly explained, including whether it is intended to support authorisation, strengthen communication through the value chain, or serve another defined regulatory objective.

Candidate Listing may have significant practical implications for supply chains and market availability, as downstream users and customers may seek to substitute listed substances irrespective of actual exposure levels or the availability of effective risk-management measures. These practical impacts should therefore be taken into account when assessing the proportionality and overall regulatory benefits of Candidate Listing in comparison with other available regulatory instruments.

Regarding proportionality, the case law of the European Court of Justice indicates that, where no harmonised EU occupational exposure limits or equivalent EU measures exist to address a specific risk, additional regulatory intervention may be justified. From this consideration it is possible to infer that, where workplace exposure limits and related risk-management measures already provide an appropriate framework to control the risk, any further regulatory measure should be

[7] BAuA - *Risk Management Option Analysis (RMOA) – Conclusion Document: n-Hexane in consumer products* (Germany, 20 Aug 2024)

carefully assessed to avoid unnecessary duplication and to ensure that it is proportionate. This is the case, for instance, when OELs are set[8].

4.5 Co-exposure

Co-exposure is already handled in exposure assessment via various guides, practices, and regulation (e.g. TRGS 900, CAD 98/24/EC, ACGIH, HSE, HCSC) since many years. Co-exposure has been presented in the n-hexane Annex XV dossier[9] as an unaccounted-for uncertainty when, in reality, it is a recognized and routinely managed element of workplace exposure assessment. A hazard arising from co-exposure can only support an Article 57(f) argument if evidence shows that current regulatory systems are unable to identify and control those mixed exposures.

5. Conclusion and key asks

5.1 Clarity on the application of Article 57(f)

The application of Article 57(f) should be based on minimum requirements:

- Clear “serious effects”justification.
- Explicit ELoC justification, explaining why the concern is equivalent to criteria listed in Article 57(a)–(e).
- A transparent weight-of-evidence assessment should form the core Article 57(f) ELoC test, focusing on elements such as severity, seriousness, duration, permanence or reversibility, threshold or dose-response considerations, uncertainty and comparability of concerns with Article 57(a)–(e) including consideration of exposure, existing controls and proportionality. should be addressed separately under risk management, instrument choice and added regulatory value.
- Clarity on the weight of each underpinning the Article 57(f) conclusion.

[8] Judgement of 25 September 2015, VECCO and Others v Commission, T-360/13, ECLI:EU:T:2015:695, paragraph 40.

[9] Annex XV report, Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACh article 57.

5.2 Transparency in the decision-making process

The decision-making process should clearly document how Article 57(f) criteria were applied, how the evidence was weighted, and why the final ELoC conclusion was reached. This is necessary to ensure verifiability, legal certainty and predictability for future Article 57(f) cases.

5.3 Added regulatory value of Candidate Listing

Listing SVHC on the candidate list should only be pursued where its added regulatory value is clearly demonstrated and proportionate in comparison with other available regulatory instruments.

5.4 Priority for targeted measures where risks are use-specific

Where risks are use-specific[10], authorities should separately assess whether targeted measures, such as Annex XVII restrictions, would be more appropriate and proportionate follow-up measures than broader action following Candidate Listing.

5.5 Further development of the REACH framework

It should be evaluated whether the ELoC concept should be further clarified in the context of a future development of REACH, to increase legal certainty and predictability for Article 57(f) cases.

Thank you for the consideration of the above and ESIG is available for responding to questions.

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About Cefic	About ESIG
Cefic, the European Chemical Industry Council, is the forum of large, medium and small chemical companies across Europe, accounting for 1.2 million jobs and 13% of world chemicals production. On behalf of its members, Cefic's experts share industry insights and trends, and offer views and input to the EU agenda. Cefic also provides members with services, like guidance and trainings on regulatory and technical	ESIG is a joint activity of the European manufacturers of hydrocarbon and oxygenated solvents. Our primary objective is to equip our members with the necessary advice and guidance to ensure compliance with the most up-to-date legislation. Simultaneously, we encourage our members to share ESIG's insights and recommendations with all stakeholders involved in the use or handling of their solvent products. Our

[10] Use-specific risks should not include unintended uses such as glue sniffing.

matters, while also contributing to the advancement of scientific knowledge	overarching goal is to establish industry positioning and ensure that the regulatory framework pertaining to the manufacturing, storage, distribution, and usage of these solvents is rooted in sound science and best practices.

6. Abbreviations and explanatory notes

BAuA – Bundesanstalt für Arbeitsschutz und Arbeitsmedizin.

CAS number – Chemical Abstracts Service Registry Number, a unique identifier for chemical substances.

Cefic – European Chemical Industry Council – the Brussels-based association of the European chemical industry, representing its interests towards EU institutions, authorities and other stakeholders.

CLP – Classification, Labelling and Packaging Regulation.

CMR – Carcinogenic, Mutagenic or Toxic to Reproduction.

DNEL – Derived No-Effect Level.

ECHA – European Chemicals Agency.

EC number – European Community number, a European identifier for chemical substances.

ELoC – Equivalent Level of Concern.

ESIG – European Solvents Industry Group.

GHS – Globally Harmonized System of Classification and Labelling of Chemicals.

HSPA – Hydrocarbon Solvents Producers Association, representing 7 hydrocarbon solvent producers: DHC Solvents, ExxonMobil, HELLENiQ Petroleum, Moeve Chemicals, Sasol, Shell and TotalEnergies Fluids

MSC – Member State Committee.

OEL – Occupational Exposure Limit.

OSPA – Oxygenated Solvents Producers Association, representing 17 oxygenated solvent producers: Arkema, BASF, Borealis, Clariant, Dow, Eastman, ExxonMobil, Ineos Acetyl, Ineos Oxide & Solvents, Ineos Phenol, Lambiotte, LyondellBasell, Moeve Chemicals, Sasol, Seqens, Shell and Versalis.

RCOM – Response to Comments.

RCR – Risk Characterization Ratio.

RMOA – Risk Management Option Analysis.

STOT-RE – Specific Target Organ Toxicity – Repeated Exposure.

SVHC – Substance of Very High Concern.

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