



REACH dossier consistency for improved hazard and risk assessment

ECHA Enforcement Forum
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Concawe

Structured update of joint submissions for >140 petroleum substances

Concawe is the scientific division of the European Fuel Manufacturers Association and amongst other activities, manages the joint submissions for over 140 petroleum substances supporting over 4000 registrations.

The dossiers for each of these substances are updated annually and submitted by lead registrants. This update is a structured approach that incorporates new hazard and exposure information while maintaining alignment with changes in the REACH regulation and ECHA guidance, ECHA technical completeness check requirements and IUCLID versions

This is possible because of the year round Concawe activities

- Collection of registrant data e.g. new uses, SIP, Classification and labelling permutations
- Development of guidance documents to support dossier update
- SIEF Team to actively respond to registrant questions and inform of latest relevant developments
- Review of revisions to the REACH Regulation and ECHA advice/guidance
- Active engagement with ECHA on all matters related to ongoing Evaluation of petroleum substances
- Ongoing study management and development of future Evaluation strategy

Misalignment of lead & co-registrant dossiers

- Annual Concawe dossier updates are made available to all registrants
- While Concawe actively encourages all registrants to update their dossier, submission of updated dossiers is entirely dependent on registrants action
- While the ECHA dissemination website indicates that registration dossiers of Concawe petroleum substances are regularly updated (>65% of active registrations last submitted since 2018), there is a growing discrepancy between the annually updated LR dossiers and those of co-registrants that have not updated.
- This leads to a consistency gap, with inconsistent information within the joint submission regarding supported uses and substance identity
- Amongst these older dossiers are those belonging to legal entities that no longer exist yet continue to appear as active registrants

Consequences of dossier inconsistency (I)

Uses and Uses Advised Against (IUCLID Section 3)

Specific uses advised against were introduced in Concawe dossiers in 2017 after careful consideration of available information to ensure safe use conditions for some professional and consumer non-fuel uses where exposure could not be sufficiently limited by Risk Management Measures

These uses advised against in the lead registrant dossier still appear as registered uses in co-registrant dossiers (seen in the ECHA dissemination website)

While own assessments (registrants prepare CSR for own use not in LR dossier) are possible, non supported uses may remain because dossiers have not been updated since the introduction of uses advised against

The risk is that uses in member dossiers, that are not found in the LR dossier, are also not supported by a CSA & exposure scenario. This could represent an unacceptable risk or could be a “phantom risk”

In order to maintain regulatory focus on addressing uses of the actual risk to human health and the environment, it is important that the joint submission is coherent.

Uses advised against	HFO	KEROSINE	AKI	NAPHTHA Ld. 1,6 benzene	OtherGO Carbocyclic	SRGO
03b - Use in Coatings: Professional	X	X		X		X
03c - Uses in Coatings: Consumer		X				
04b - Use in Cleaning Agents: Professional		X		X		X
04c - Use in Cleaning Agents: Consumer		X		X		
06b - Lubricants: Professional (low environmental release)		X			X	X
06c - Lubricants: Professional (high environmental release)		X			X	X
06d - Lubricants: Consumer (low environmental release)		X				
06e - Lubricants: Consumer (high environmental release)		X				
07b - Metal working fluids / rolling oils: Professional		X				X
10b - Use as binders and release agents: Professional		X				X
11a - Use in Agrochemicals: Professional		X				
11b - Use in Agrochemicals: Consumer		X				
13b - Functional Fluids: Professional					X	X
15 - Road and construction applications: Professional	X	X				X
16 - Other Consumer Uses ⁴						X
18b - Explosives manufacture & use: Professional		X	X			X

⁴ Use name in Chesar assessments “ Uses in cosmetics/personal care products, perfumes and fragrances”

Consequences of dossier inconsistency (II)

Substance Identity Information (IUCLID sections 1.2 and 1.4)

- Substance Identity Profiles were introduced in Concawe dossiers in 2017 in order to help registrants determine the correct substance to register by checking details of their substance's source, manufacturing process and composition using analytical data obtained by industry standard methods
- For dossiers not updated since 2016, and for those with inadequate analytical data the certainty that the registered substance is described by the joint submission is diminished in the absence of SIP, particularly for UVCB substances
- The risk is that registrants of older dossiers may not be covered by the SIP, and their products may fall outside the scope covered by test materials and read-across justifications.

Addressing dossier inconsistencies

Regulatory assessments must be based on accurate and up to date information. This can be achieved by:

- An ECHA database that reflects reality e.g. removing dormant dossiers
- Differentiation e.g. taking into account only the most recently updated dossiers
- Basing regulatory assessments on LR dossier only

Removing dormant dossiers may be facilitated by cleaning up the ECHA database to remove registrations from legal entities which no longer exist

- e.g. Petroplus which ceased to exist 10 years ago and is still in REACH IT.
- Work together with national authorities to provide to ECHA proof of insolvency.

Upgrade the ECHA database IT system to align with the real world

- e.g. Confirmation of registrant needed when certain parameters are absent or infrequently updated.



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**Thank you for
your attention**