Input Consultation

November 2019

The Hydrocarbon Solvents Producers Association (HSPA)would like to submit the following comments to the stakeholder consultation launched as part of the "Study for the review of the list of restricted substances and to assess a new exemption request under Directive 2011/65/EU (RoHS 2) – Pack 15"

Our comments focus on the inclusion of:

112-40-3	Dodecane
544-76-3	Hexadecane
629-59-4	Tetradecane
90622-58-5	Alkanes, C11-15, iso-

Our comments also refer partially to four substances hereunder. Solvents registrations under REACH use EC numbers that might link to those CAS numbers which however describe boarder aromatics – if those refer to solvents the aromatic content (benzene)e is <0.1ppm

64742-46-7	*Distillates (petroleum), hydrotreated middle*
64742-80-9	*Distillates (petroleum), hydrodesulfurized middle*
64742-95-6	*Solvent naphtha (petroleum), light arom.*
64771-72-8	*Paraffins (petroleum), normal C5-20*

For us to provide you with a constructive input, we would like to have some clarification on the methodology and especially on the ranking you have used. This would help us better understand how our substances ended up in the list of restricted substances.

Due to the complexity of regulatory processes, the information you are using in your methodology comes obviously from diverse sources, which are not always based on sound-science, the guiding principle in any EU regulatory process. For instance, the fact that a Member State includes a substance in the Community rolling action plan (CoRAP) only means that a concern is suspected and hence the substance will be evaluated. It is not necessarily based on additional scientific evidences and the outcome remains uncertain. We also believe that the SIN list should not be used for regulatory purposes.

As a result, we think that what you define as a "hazard" in the reference document is not clear and, in some instances. The grouping activity seems to be based on two difference methodologies: the tables for 1/3 (Group I, II and III) on the Classification, Labelling and Packaging (CLP) classification, the remaining categories on "potential hazard". Thus, it is not entirely clear which criteria it is based on. We believe that any hazardous category or group should in the first place be a recognized hazard class under CLP. In addition, you end up with strange results in terms of 'numbers' such as that suspected carcinogenic, mutagenic, or toxic for reproduction (CMR2) substance being of a lesser hazard than aquatic or aspiration toxicity 1 (see also remark 4). Please be aware that some hazard classes are purely phys-chem hazards (aspiration hazard).

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It raises further questions that we would like you to answer:

1. According to the element of Scientific Evaluation, there should be a thorough assessment of the substances BEFORE the precautionary principle is evoked, clearly expressing the uncertainties in the data base. This means that each substance should have been thoroughly reviewed and uncertainties clearly expressed to justify its inclusion in a particular list. For example, how can n-alkanes (Dodecane, tetradecane, hexadecane) end up in the list when these substances are easily metabolized and eliminated from the body with no indication that it is hazardous? The same applies to C5-C20 iso-alkanes? Is there a transparent assessment of how these substances have been evaluated and why the precautionary principle has been applied?
2. Page 43 Read across: In our view, to be aligned with REACH and ECHA high standards of read across, grouping of substances should follow ECHA's actual assessment (approval/ rejection) of groupings submitted by industry. How can there be consistency with REACH if two divergent approaches of substances' "grouping" are used especially given the fact that the hazard assessment is done based on the same available data (existing or to be submitted to ECHA). If the same groupings are not used, hazard assessments will not be in synchronized with REACH. Will Ökoinstitut derive its own substance groupings and check against those used in REACH? Who will evaluate whether the read-across complies with the ECHA high standards that are expected from the industry?
3. Page 15, weight of evidence: can you please provide us with the methodology used for weight of evidence (WoE)? This should be transparent as there are different methodologies used for WoE. See for example Memorandum of SCENIHR of 2012 "Weighing evidence and expression of uncertainty". This is an essential aspect of demonstrating that the information available is uncertain which leads to applying the precautionary principle. If this assessment cannot be justified in a transparent manner, how can it be disclosed?
4. Hazard groups: in our view, the approach used based on "CLP" hazard classes does not entirely reflect the complexity of these chemicals. For instance, aspiration toxicity and carcinogens category 1 should not belong to the same group I. CLP uses hazard classes and not "numeric groups". Thus, the fact that aspiration hazard has a category I, does not mean that it should put at the same level as carcinogen category 1. The first is based on ACUTE swallowing of a fluid with a low viscosity that explicitly leads to chemical pneumonitis, whereas Carcinogens category 1 is based on chronic exposures in a multi stage process. Although both could have category 1 in the label, the number has a totally different dimension to the hazard. In the context of the use of hazardous substances in electrical and electronic equipment (EEE), how can aspiration hazard be considered as causing as much concern as a proven human carcinogen category 1?
5. Hazard category:
    a. Endocrine disruption is NOT a hazard under CLP. Because Endocrine disruption is not an endpoint, it should be evaluated on the basis of risk and not hazard. The hazard is either reproductive or developmental toxicant.
    b. The listing of substances does not seem very transparent. Aa proper documentation on how each substance was ranked should be made available for commenting.
    c. Table 1-4 indicate four groups: could you explain on what basis is the substance "only suspected" to be in category IV? The list we reviewed with alkanes has V categories. For example, n-alkanes appear in Hazard Group V. How did they end up there and do you have the documentation that justifies it?

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We would be grateful if you could provide us with an answer, which would enable us to submit a constructive and useful input to the consultation.

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About HSPA
The Hydrocarbon Solvents Producer Association represents the EU Manufacturer of these substances.
Cepsa, DHC Solvents, Haltermann Carless, ExxonMobil, Neste, Hellenic, Sasol, Shell, Total Fluides.