MINISTERIO
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SUBDIRECCIÓN GENERAL DE
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LABORAL

FINAL DOCUMENT e-Consultation: Harmonized approach to consider a co-formulant as a substance of concern (*SoC*) based on its workplace exposure limits

19th April 2021

On 28th July ES submitted an e-consultation with the aim to find a harmonized approach to determine **when should a co-formulant with an established Occupational exposure limit value be considered as a *substance of concern* (SoC) in accordance with criterion number 5**[i] and therefore a quantitative exposure assessment should be performed, and the co-formulant has to be listed on point 2: Qualitative and quantitative information on the composition of the biocidal product.

A coformulant can be a substance of concern for multiple reasons. This document only intends to clarify **how to assess candidates to SoC according to criterion number 5**, and does not imply that a given coformulant could not be considered a soc for reasons other than the presence of an IOELV. **It is therefore outside the scope of this document to evaluate any other criteria to consider a coformulant as a substance of concern.**

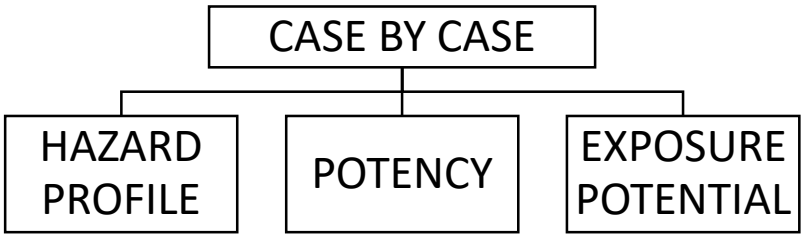
LEGAL BACKGROUND

A SoC is a co-formulant contained in a biocidal product that meets at least one of the conditions specified in Art 3(f) of the Regulation 528/2012 (BPR).

The document *CA-Nov14-Doc.5.11 - SoC guidance_final.doc* [currently included in the BPR guidance, Volume III Human Health - Assessment & Evaluation (Parts B+C) - Annex A - version 4, Dec.2017, henceforth referred as the guideline] provides additional information on SoC triggering criteria. In addition to the three clearly defined conditions (three indents) specified in Article 3(f) of the BPR, the five criteria listed in the BPR guidance should be taken into account when identifying co-formulants present in a biocidal product as SoC[ii].

- *Criterion (5): Substances for which **there are Community workplace exposure limits**. A generic concentration cut-off value (for their presence in a product) applicable to all such substances cannot be specified. This should be determined on a **case-by-case basis depending on the hazard profile, potency and exposure potential of the substance**.*

Annex I: Step wise approach to handle a candidate to soc by IOELV (Criterion number 5)



The guideline also states that *SoCs meeting criterion (5) – This criterion identifies substances for which there are* ***European Indicative Occupational Exposure Limit Values (henceforth, IOELVs)****. The requirements of band C* (i.e. quantitative assessment) *should apply to these SoCs.*

POINTS OF DISCUSSION

1. **Taking into account that a SoC should be identified before any risk assessment is performed, does any co-formulant with an IOELV automatically become a SoC**?

It was acknowledged that the criterion **number 5** of the guideline establishes that only those substances for which the EU OEL constitutes an actual risk derived from THE HAZARD, POTENCY AND THE EXPOSURE should be considered a SoC. In addition, and in support of this rationale, it has been pointed out that if having an IOELV automatically means that a co-formulant is a SoC, this will close the door for Simplified Authorisations with such Annex I biocidal actives.

CONCLUSION: This e-consultation concludes that the existence of an IOELV does not convert a co-formulant into a substance of concern. The decision tree included in the Annex I must be followed. Conclusion was reached by consensus

2. **How could we prevent to overlook the existence of a potential SoC by IOELV in future regulatory actions whenever post-authorisation changes imply a change on the HAZARD, POTENCY AND EXPOSURE POTENTIAL?**

It was agreed to list the potential candidates to SoC by IOELVs in the confidential annex.
Consequently, in the event that the candidate does not trigger the SoC consideration by IOELV the information to be considered for future regulatory actions, (e.g. authorization amendments including new uses) will be readily available to the eCA. Union OEL values of CAS xxxxxxxx must be indicated in the confidential Annex and in section 8.1 of the SDS.

CONLCUSION: This e-consultation concludes that Union OEL values of CAS xxxxxxxx must be indicated in the confidential Annex of the PAR and in section 8.1 of the SDS. Conclusion was reached by consensus

3. **Should national occupational exposure limits be considered?**

Only IOELVs should be taken into consideration. This conclusion is supported by the following facts:

- National OELs are not harmonized nor comparable among the Member States
- In the frame of a MR-S, having to consider national levels of each concerned member state potentially leads to a tremendous workload for the ref-MS involved in this MR-S procedure.
- Considering national OELs would lead to a potential problematic situation when leading with UA-APPs

However, in the event that one Member State desires to consider national occupational limits at a national level, this approach includes a description of STOP at step 1 to address this concern (See Annex). **This however, should not have an impact on the PAR nor the SPC.**

Regarding the **BOELV** (binding occupational exposure limit values), these limits are only referred to carcinogenic and/or mutagenic substances and therefore already contemplated by other SoC triggering criteria. The guideline specifically mentions IOELV so, even if no specifically excluded generally we consider unnecessary to address this limits on this document.

CONCLUSION: This e-consultation concludes that ONLY IOELVS should be taken into account even if MS are entitled to take actions at a national level to address any national OEL concern. Conclusion was reached by consensus

4. Are IOELVs relevant for general public?

Different views were expressed during the discussion:

REASONS SUPPORTING THAT IOELVS ARE IRRELEVANT FOR GENERAL PUBLIC	**REASONS SUPPORTING THAT IOELVS ARE RELEVANT FOR GENERAL PUBLIC**
1. The risk of increasing even more the workload with the additional burden arising from **having to derive values to evaluate if one of them may or may not be relevant for general public outweighs any potential threat (NOT covered by other criteria, which is quite unlikely) posed by these values**. **2.** Realistic worst case scenarios should be kept in mind as well as how IOELVs are set (8h/day, 5days/week for 40 years). Occupational exposure limits are maximum acceptable air concentrations that are used as reference parameters for the protection of workers from overexposure to chemical substances	1. The guideline even if misleading could be indicated that a case by case decision is needed in any case. *If a risk assessment for members of the general public is also required,* ***it should be considered whether the IOELV is appropriate for such use or whether it should be lowered by the application of an assessment factor to take account of vulnerable groups.*** *For SoCs for which IOELVs have not been set or are not appropriate (e.g. for non-professional users),* ***the existence of other possible reference values should be explored.*** 2. There may be a need to take into account the hazard or basis for the

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by inhalation. OELVs are generally established in relation to a reference period of a typical 8-hour working day, i.e. as 8-hour time weighted average (TWA) exposure limits. Further, they are generally set on the basis of a nominal 40-hour working week and for a working lifetime of 40 years (48 weeks/year; 5 days/week; i.e. 9600 days or 76,800 hours). **3.** In order to derivate this values (if IOELV are not to be directly used), the authorities start from a default value and apply several factors to calculate, for example, the DNEL. Such values are obtained by taking into consideration other factors, such as the **measurement techniques available at the workplace, and socio-economic factors of the sector**, irrelevant for general public. Using DNEL values would imply an additional overwork and are not representative. **This is too conservative.** 4. Occupational data is already considered for the purposes of determining whether a substance and/or mixture entails a physical, health or environmental hazard according to the CLP requirements. And therefore, already used to conclude whether a substance is classified as dangerous according to CLP and considered SoC according to Article 3(f) of the BPR. 5. Even if the wording of the guidance is conflicting, the guidance could be indicating that IOELVs are not relevant and simply referring the need to explore other values is covered by incidents other than criterion number five, and only IF an assessment is required: "***IF*** *a risk assessment for members of the general public is also required, it should be*	derivation of a worker limit for the general public. This could be achieved either by using the IOELV (only when the basis of this value can also be used for general public) or if necessary other relevant values (e.g. DNELs) can be used. 3. The principles laid down for active substance evaluation could be extended to SoC. The BPR Guidance on HH specifically mentioned that for active substance assessment when an EU IOEL exists the basis for the IOEL can be considered during the derivation of a reference value for a.s. 4. In future RAC is going to derive the OELs and that there is a new ECHA guidance published (Appendix to R.8; Guidance for preparing a scientific report for health based exposure limits at the workplace, August 2019), which describes transparently the methodology behind limit value derivation.

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considered whether the IOELV is appropriate for such use or whether it should be lowered by the application of an assessment factor to take account of vulnerable groups. For SoCs for which IOELVs ***have not been set or are not appropriate (e.g. for non-professional users),*** *the existence of other possible reference values should be explored****".***	

CONCLUSION: This e-consultation concludes that IOELVs are **not** relevant for general public. However, in the event that this discussion is pursued in the WG and different conclusions arise from that discussion, the member state who initiated this e-consultation will update this conclusion.

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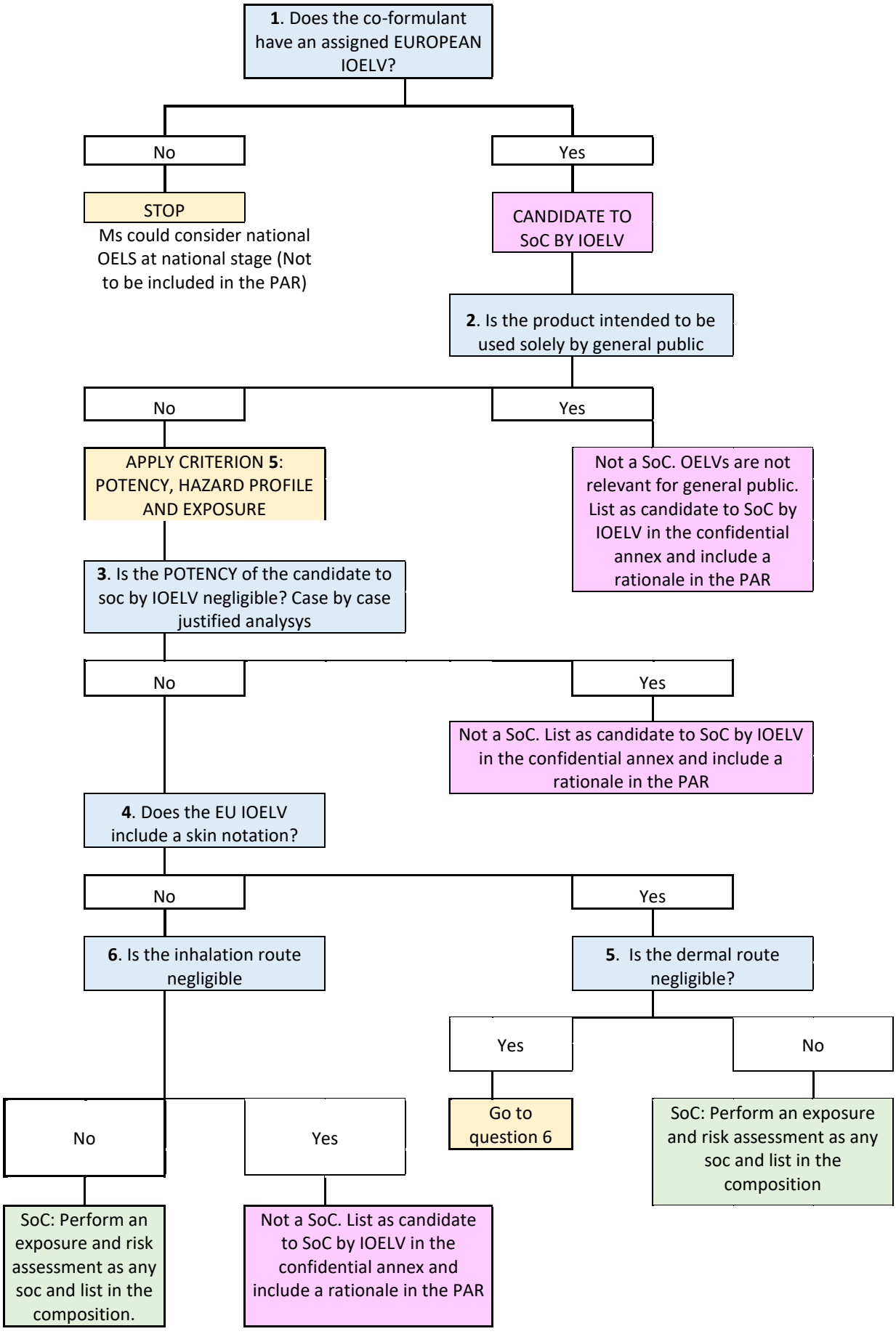

[i] A co-formulant can be considered a soc for different reasons. This paper only intends to provide a harmonized approach on when a co-formulant with an IOELV should be considered a SoC. This should be understood without prejudice to any other criteria met by a given co-formulant that would meet the SoC definition for other reasons.

[ii] On a minor note, the legal background of the document has been modified as consequence of one comment received.