



Sent by email to ENV-CARACAL@ec.europa.eu and GROW-CARACAL@ec.europa.eu on 29 August 2019

Follow-up 30th meeting of CARACAL

Comments on document CA/56/2019: Updates of REACH Annexes related to data requirements for endocrine disruptors

CHEM Trust welcomes the opportunity to provide comments on the proposed update of the REACH Annexes for inclusion of data requirements on endocrine disruption which was presented at the CARACAL meeting of 1st July 2019.

CHEM Trust welcomes this initiative; the update of the REACH Annexes as regards endocrine disruption is extremely important for the identification of endocrine disrupting chemical substances and has been in great demand for a very long time.

CHEM Trust acknowledges that the discussion of new data requirements for endocrine disrupting properties is part of a process that may take some time, however, the OECD updates as regards endocrine endpoints of test methods already implemented into the REACH regulation should immediately be implemented in the REACH regulation without any further delay.

CHEM Trust would be happy to participate actively to the process and be part of the subgroup.

General comments

- The proposed approach seems in general sensible.
- It is very positive that the Commission refers to the extensive work done by OECD on identification of endocrine disruptors, e.g. development of test guidelines, ED Conceptual framework and Guidance Document 150, and the intention to integrate that into the REACH Annexes.
- We find it important to integrate expertise from both toxicology and ecotoxicology in the work in one unique sub-group for improved mutual discussion and use of test results.
- We find it also important to reflect and include future developments as regards ED identification into the work by consulting experts working on ED test methods development from the EU-funded projects within the EURION cluster.
- The timeline for the process is worrying especially given the already long delay in updating the REACH annexes. It should be stressed that the actions laid down by the 7th EAP aiming at protection of human health and environment towards exposure to endocrine disruptors have been neglected by the Commission for several years and it is now high time to take swift action.
- The inclusion of an impact assessment seems unnecessary as regulation of endocrine disruptors is already a part of REACH, and as this update process only includes technical updates of the annexes for specification of compulsory information based on the state of the science.

Specific comments

The proposed process and approach

Even though we find the general approach proposed by the Commission sensible, we are concerned about the timeline for the work. It is stated that more comprehensive changes should be addressed on a mid/long term basis, however, without any specification.

There is a need for further specification of the updates, with clear description of objectives, deliveries and specific timelines.

In particular, is it important to ensure that the process of drafting guidance documents (action 2) does not become an obstacle for the updates (under action 1) to come into force.

Further, we are concerned about the reference to the outcome of the ED fitness check and the consequences for the update process. It is not clear how the outcome of the ED fitness check is expected to impact the update process; relevant conclusions in support of the update of REACH annexes should of course be included in the update work, but the outcome and time of completion of the ED fitness check should not be a reason for postponing the update process.

The OECD updates as regards endocrine endpoints of test methods already implemented into the REACH regulation can immediately be implemented into the REACH regulation. In line with this, it seems high time to ensure that an automatic update of REACH implemented OECD test guidelines or other documents takes place immediately after the endorsement of these by the OECD.

We find it very positive that the Commission refers to the extensive OECD work on endocrine disruptors identification and assessment, i.e. the OECD conceptual framework and the OECD GD 150. Integration of this work will both ensure international coherence, support the technical part of the work and speed up the REACH work. However, the focus of the OECD GD 150 is primarily on the EATS modalities (oestrogen, androgen, thyroid, steroidogenesis) and therefore, it is important that the work also consider how to embrace identification of ED substances with non-EATS ED modalities.

Updates of Annexes VII to X

In principle we agree with the proposed actions for updating Annexes VII to X. However, we would like to point at some important issues in relation to the tiered approach as regards endocrine disruptors:

In line with the Annexes VII to X, we in principle acknowledge that a tiered approach should also be developed for explicit information and specific tests on ED to be conform to the REACH principles. However, the many uncertainties related to the identification and effects of endocrine disruptors should also be acknowledged when updating the annexes, e.g. that EDCs - equivalent to chemicals with PBT/vPvB properties - has the potential to lead to serious and irreversible effects in current and future generations. Further, several endocrine disruptors have been shown to cause serious effects in very low doses and far below the doses normally used in standard testing and further, to display non-monotonic dose responses without evidence of thresholds below which no effects occur. Another problem is that adequate test methods for identification of many endocrine disrupting properties are also lacking or under development.

In the light of this where a tiered approach based on quantities may be questionable - and for animal welfare reasons - we find that the use of existing information should be improved and rethought. QSARs and in vitro batteries for identification of EDCs should be compulsory parts of the REACH standard information requirements and introduced already at the lowest tonnage level as well as use of information from academic publications and mutual reference to available knowledge from human health and environment and vice versa and should be standard procedure for deciding upon the further information and testing requirements.

In order to ensure quality and transparency the standard information requirements should include specifications for information retrieval, acceptable QSAR tools and relevant in vitro test/test batteries, and it may also be relevant to specify/consider the qualifications needed for the assessors of the information.

The use of QSARs and in vitro tests should be conducted to elucidate whether there are alerts for ED properties which require further testing.

If concern is raised about ED effects or ED mode of action based on either QSARs or in vitro tests already at the lowest tonnage level, this should lead to direct requirements of definitive tests, e.g. the extended one-generation reproductive toxicity study or the fish sexual development test. For more details as regards test methods and testing strategy, we refer to the report: "Information/testing strategy for identification of substances with endocrine disrupting properties" published by the Danish Centre on Endocrine Disruptors in 2013.

Even though triggers may seem sensible, we find that default requirements for each tier is preferable to avoid endless scientific discussions about relevance of the trigger.

It should, however, be emphasised that there is still a lack of adequate test methods available to identify chemicals endocrine disrupting properties as latest pointed out by Demeneix and Slama¹ and in the Commission Communication: towards a comprehensive European Union framework on endocrine disruptors². This should be reflected when establishing the ED standard information requirements.

Further, under the regulation on medical devices which comprises very sensitive uses endocrine disruptors are identified by reference to REACH and this aspect also underlines the importance of a precautionary approach when establishing ED standard information requirements. The standard information requirements may also be relevant in relation to future updates of other regulations on consumer products as regards endocrine disruptors, e.g. on toys, cosmetics and food contact materials. Measures should be taken so substances will not be considered as safe solely due to lack of relevant test methods. The standard information requirements should be prepared for the future and be able to include future updates of test methods, new test methods as well as new findings from e.g. the EU funded research projects on new testing and screening methods (EURION-cluster) so all ED modalities and all potential ED endpoints are well covered.

As already pointed at, existing REACH test methods must be updated with the latest revisions from the OECD and as regards the extended one-generation reproductive toxicity study, the DNT and the DIT cohorts should be compulsory.

Annexes VII to X is related to the registration of substances. However, it should also be considered whether the information requirements also are relevant as part of the dossier evaluation process.

With these initial comments, we look forward to actively participating in the further work. We do hope that this needed and important ED work will go fast and be efficient in order to improve the protection of human health and the environment. It is really worrying that we are still exposed daily to thousands of chemicals that have not at all been tested or evaluated for their potential endocrine disrupting effects.

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¹ Endocrine Disruptors: from Scientific Evidence to Human Health Protection. Petitions. Policy Department for Citizens' Rights and Constitutional Affairs, Directorate General for Internal Policies of the Union. PE 608.866 – March 2019.

² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. COM(2018) 734 final. 7.11.2018.