



Consultation Response November 2019

Response to EFSA public consultation on

“Cumulative dietary risk characterisation of pesticides that have chronic effects on the thyroid” and

“Cumulative dietary risk characterisation of pesticides that have acute effects on the nervous system”

<https://www.efsa.europa.eu/en/press/news/public-consultation-cumulative-risk-assessment-pesticides>

General comments

“Cumulative dietary risk characterisation of pesticides that have chronic effects on the thyroid”

CHEM Trust acknowledges the extensive work EFSA has carried out to address the cumulative effects of exposure to various pesticides on certain endpoints. In our view this is a very important area which deserves more urgent attention from risk assessors and policymakers (<https://chemtrust.org/tag/mixtures/>).

We welcome the approach to use common assessment groups and the concept of dose addition. We appreciate the approach used for allocation of substances to the common assessment groups which is based on their common specific effects as this is the approach that most realistically reflects the actual cumulative risk.

We have, however, some **general comments** as regards the whole approach for assessing and concluding on the cumulative risks for chronic effects on the thyroid. In particular we question the final conclusion “taking account of the available data and the uncertainties involved, it is concluded that cumulative exposure to pesticides that have chronic effects on the thyroid does not exceed the threshold for regulatory consideration established by risk managers”, or in other words – the cumulative exposure to pesticides that have chronic effects on the thyroid is considered as safe.

We are aware that this conclusion is based on the available data and uncertainty analyses as described by the term of references. We note that the risk characterisation is based on very sophisticated exposure modelling and assessment, however, the same advanced level is not at all the case when it comes to the hazard assessment. As also stated by the authors there are several limitations in the available knowledge and data that affect the assessment. These uncertainties should be properly reflected by the hazard characterisation.

CHEM Trust would like to point out some important limitations of the cumulative risk characterisation. For the allocation to the Common Assessment Groups and assessment of

cumulative risks, only data from official documents produced for the EU-approval of the active substance has been used. This was supplemented by assessment reports from recognised international bodies, but information from the open scientific literature is not included in the assessment. This weakness in the assessment becomes even more significant because:

- many substances have not been tested with guidelines that require measurements of thyroid hormone levels and this may result in underestimation of the amount of substances that may affect the thyroid hormonal system. The complex functioning of the thyroid hormone system and the adverse effects caused by disruption of the system seems not to be adequately addressed by the assessment, and in particular the lack of including thyroid-mediated impaired neurodevelopment constitutes a crucial deficiency of the whole assessment
- the most sensitive and important endpoints, including exposure during sensitive windows of development, as well as estimation of exposure of pregnant women have not been adequately covered by the assessment
- effects associated with non-monotonic dose-response relationships (NMDR) were not considered even though the occurrence of NMDR's is very likely in the careful study of dose-response curves for thyroid disrupting chemicals, and this often includes the occurrence of adverse effects at very low doses
- many assumptions have been included and several decisions have been taken which may add to the level of uncertainty (CAG's may be incomplete, NOAEL setting uncertain, adjustment of MOETs) and bias the uncertainty assessment in a more favourable direction.

Following from this the overall conclusion of the cumulative dietary risk characterisation seems overly firm and biased, also in the light that estimates for MOET's for toddlers are very close to 100. It could easily be misinterpreted in the way that cumulative exposure to pesticides is considered safe and with no risks of causing thyroid effects which is not based on the scientific evidence.

We therefore recommend changing the final conclusion and providing cautionary language which describes the limitations of the database as well as the fact that the assessment does not include thyroid-mediated impaired neurodevelopment. This serious lack of knowledge should be highlighted and properly reflected by the conclusion and it should be considered whether a judgement about whether a threshold for regulatory consideration is exceeded is reasonable based on the current database and uncertainties.

General comments

“Cumulative dietary risk characterisation of pesticides that have acute effects on the nervous system”

CHEM Trust acknowledges the extensive work EFSA has carried out to address the cumulative effects of exposure to various pesticides on certain endpoints. In our view this is a very important area which deserves more urgent attention from risk assessors and policymakers (<https://chemtrust.org/tag/mixtures/>).

We welcome the approach to use common assessment groups and the concept of dose addition. We appreciate the approach used for allocation of substances to the common assessment groups which is based on their common specific effects as this is the approach that most realistically reflect the actual cumulative risk.

We have, however, some **general comments** as regards the whole approach for assessing and concluding on the cumulative risks for acute effects on the nervous system. In particular we question the final conclusion “taking account of the available data and the uncertainties involved, it is concluded that cumulative exposure to pesticides that have acute effects on the nervous system does not exceed the threshold for regulatory consideration established by risk managers” or in other words – the cumulative exposure to pesticides that have acute effects on the nervous system is considered as safe.

We are aware that this conclusion is based on the available data and uncertainty analyses as described by the term of references. We note that the risk characterisation is based on very sophisticated exposure modelling and assessment, however, the same advanced level is not at all the case when it comes to the hazard assessment. As also stated by the authors there are several limitations in the available knowledge and data that affect the assessment. These uncertainties should be properly reflected by the hazard characterisation.

CHEM Trust would like to point out that many assumptions have been included and several decisions have been taken which may add to the level of uncertainty and bias the uncertainty assessment in a more favourable direction. In particular, we are concerned about the estimated MOET’s for toddlers and children which are below 100 for several populations and which then are adjusted to a level which consequently will not lead to regulatory considerations.

We find the overall conclusion of the cumulative dietary risk characterisation biased and overly firm also in the light that estimates for MOET’s for toddlers are uncertain and may be below 100. It could easily be misinterpreted in the way that cumulative exposure to pesticides is considered safe and with no risks of causing effects on the nervous system which is not based on scientific evidence. We therefore recommend changing the final conclusion and providing cautionary language which highlights the limitations of the database as well as the fact that the assessment does not include neurodevelopmental toxicity. This lack of knowledge should be highlighted and properly reflected by the conclusion and it should be considered whether a judgement about whether a threshold for regulatory consideration is exceeded is reasonable based on the current database and uncertainties.

CHEM Trust is very concerned about the effects on nervous system in vulnerable populations as summarised in our CHEM Trust report ‘No Brainer: The impacts of chemicals on children’s

brain development: a cause for concern and a need for action (<https://chemtrust.org/brain/>) where we summarised the state of the science regarding the concerns about the human health exposure to substances which can impact on brain development.

Therefore, we agree with the following recommendation made in the report, namely:

- Develop a testing and assessment methodology covering developmental neurotoxicity of pesticides, and, if appropriate, to establish CAGs and perform CRAs in this area and
- draw up a new CAG for developmental neurotoxicity (DNT) and further perform CRA to assess the 1 combined impact of organophosphates, pyrethroids and other insecticides with DNT potential on infant, toddler and children populations