CHEMTrust
Protecting humans and wildlife from harmful chemicals

Consultation Response

CHEM Trust's response to the UK Health and Safety Executive consultation on "*Regulation (EC) No 1107/2009: Proposed Criteria For The Determination Of Endocrine Disrupting Properties*"

September 2016

Introduction

CHEM Trust would like to thank the HSE for the opportunity to comment on the European Commission's proposals on setting criteria for identifying pesticides with endocrine disrupting properties as specified under the Plant Protection Products Directive.

CHEM Trust has already submitted comments to the Commission's consultation on these criteria, in which we are very critical of the Commission's proposal, for details see:

- http://www.chemtrust.org.uk/edc-criteria-consultation/

In particular, the Commission's proposal requires an extremely high burden of proof to identify a chemical as an EDC. This makes it very likely that human health and the environment will be harmed before regulatory action is taken, which is in opposition to the precautionary principle that the EU is bound to apply.

The requirement for "known adverse effects relevant to humans" makes this a much more demanding definition in comparison to how, for example, carcinogens (chemicals that cause cancer) are identified. In the case of carcinogens (and also mutagens and reprotoxic compounds) European laws trigger legal action when effects are "known and presumed" to cause adverse effects – not just when it is 'known'.

Context

There is growing concern globally that exposure to chemicals with endocrine disrupting properties are likely to be contributing to the increase in hormone related cancers (of the breast, testicular and prostate), reduced sperm counts, birth defects in the genitals of baby boys, effects on the developing brain, and other endocrine related diseases. Moreover, there are many reports of disrupted hormone related effects in wildlife. A recent report from the World Health Organisation underlines many of the concerns (WHO & UNEP,2013).

It is likely that it is not one substance which is contributing to these effects, but rather a combination effect due to exposures in pregnancy or during critical life phases. However,

CHEM Trust
34b York Way
London
N1 9AB, UK
www.chemtrust.org.uk
askchemtrust@chemtrust.org.uk
Twitter: @CHEMTrust

UK Registered Charity No. 1118182
Company number: 5933897

risk assessment as currently undertaken does not consider cumulative exposure from, for example, consumer products, cosmetics and pesticides.

It is always difficult to prove beyond doubt that certain chemicals are causing certain effects in a population, particularly when diseases are multifactorial and exposures vary and many substances may be involved. Furthermore, getting epidemiological proof of causation is hampered because many of the disorders linked to endocrine disruption do not manifest until later life, and exposures during the in-utero phase are largely unknown. Nevertheless, the disease increase cannot be due to genetics alone because genes in a population do not change that quickly. Moreover, as similar effects are seen in some wildlife species, then although lifestyle factors will be important, it is clear that they are not the only factor. This highlights that it is time for Governments to take action to try to eliminate exposure to endocrine disrupting chemicals where possible.

Comments on the Commission's proposal

CHEM Trust is very concerned that the current proposal will not effectively reduce exposure to EDCs.

Our concerns focus in two areas, the definition itself (with associated text on research to be used), and proposed changes to the text of the PPP.

1) The definition

CHEM Trust considers that the barrier for proof has been set far too high, and will result in very few EDCs actually being identified as such. We would suggest changing the Commission's proposed text shown in quotation marks in black below with the text in red and deleting the parts shown crossed out.

- 2.1 "It is known or presumed to cause an adverse effect in mammalian animals ~~relevant for human health~~ which is a change in the morphology, physiology growth, development , reproduction….."

The requirement for a substance to be known to cause an adverse effect relevant for human health is too high, and not in line with the EU approach to regulate mainly based on animal evidence. The word presumed must be added to allow in future the move to non-animal test methods which are sufficiently advanced to allow presumption of the effect in mammals /humans.

The proposed criteria deal with the issue of human relevance in point 3.3 (C) where it is noted that "where there is information demonstrating that the adverse effects are clearly not relevant for humans the substance should not be considered a human endocrine disruptor". Therefore the words relevant for human health should be deleted in the para 2.1 above as shown.

Moreover, the democratically agreed legal text needs to be reflected in the criteria and the legal text states '***may cause adverse effect***.' This highlights that the word **presumed** is a necessary addition.

Another important change that is needed in the proposed criteria is in para 2.(3) where again the necessary change is shown in red.

- "the adverse effect relevant for human health is considered to be a consequence of the endocrine mode of action."

CHEM Trust would agree that there needs to be a plausible link between the adverse effects and the endocrine mode of action, but getting actual proof of the mode of action is notoriously difficult. It took decades to elucidate the mechanism by which smoking caused lung cancer, and similarly there has been much debate on the precise mechanism by which TBT causes imposex in mollusc. The legal text needs to allow for expert judgement, and moreover should not facilitate vexatious and un-helpful legal challenges from industry who

could delay legislative action on the grounds that there is not enough proof that the adverse effect seen is caused by an underlying endocrine disruption mechanism. That said, there must be sufficient grounds for experts to consider that it is a consequence of the endocrine mode of action.

Other issues that need to be addressed in the proposal are that all data should be assessed, including a review of the scientific literature. It is not acceptable in applying a weight of evidence determination to restrict the determination to internationally agreed guideline studies. Moreover, the study protocols listed in the framework setting out the data requirements should be carefully considered if they have been carried out according to the most recent test protocols, but much less weight should be placed on tests carried out using old protocols. This is because it needs to be acknowledged and reflected in the text that test methods carried out to old protocols are not adequate to identify endocrine disruption. (eg. the old 2 generation reproductive toxicity test is not adequate to pick up certain EDCs).

With regard to the criteria to identify EDs relevant for wildlife, CHEM Trust would suggest the following changes. Again, less emphasis should be placed on internationally agreed guidelines, which are certainly important, but should not preclude consideration of all relevant data. Moreover, we consider that all information should inform the determination, including the mammalian/human data as of course there are mammals in the environment. In particular, the section below needs changing as shown.

- "3.(a)i Both positive and negative results shall be considered together in a single weight of evidence determination, taking into account all information available from different ~~discriminating between~~ taxonomic groups…" This is because the words discriminating between suggests that data on ED properties in each species would be looked at in isolation, but it would be far better for the information available in one species to inform the interpretation of the data that is available in another species.

Identification of an ED relevant for the environment must be able to be based on laboratory studies and also there must be a reasonable presumption of when effects seen in laboratory studies will lead to population level effects. Therefore we suggest the following changes.

- "3.(a)ii. The weight of evidence should consider the relevance of the study designs for relevance of the adverse effects at the population level and for the evaluation of mechanistic information. Generally, ~~from field studies shall have precedence over other data. Nevertheless positive~~ results from well-conducted laboratory studies shall be considered but field studies shall also be taken into account, if available ~~even in the case of lack of positive results in field studies.~~

These changes are required because a lot of damage would occur if conclusive evidence based on field studies were required, but of course, where they are available, field studies should be looked at and given due weight.

- "3(a)iii. The adverse consequences on reproduction and growth/development, as these are the effects most likely to impact on populations. Any relevant effect seen in such studies should be presumed to have population level effects. ~~Adequate, reliable and representative higher tier experimental studies and/or results from reliable population models shall be considered where available for assessing the relevance of the adverse effect at the population level.~~

This change is needed because it would not be acceptable to wait for modelling results to confirm that the chemical has a population level effect. There needs to be a reasonable assumption of which effects will be liable to affect a population. For example, if a chemical affects sperm in fish and fewer fish contribute to the next generation, that population may not be impacted at first, but it will have less adaptability to deal with future stresses due to reduced genetic diversity.

2) Proposed changes to the PPP text

In CHEM Trust's view the Commission has overstepped its legal mandate in its proposed changes to the democratically agreed legislative text; this is backed by a legal analysis commissioned by Client Earth[1].

There are two relevant changes proposed, one on the level of evidence required (as discussed above) and the other on the requirement for negligible exposure, both of which should be reversed:

- "3. An active substance, safener or synergist shall only be approved if it is not identified as having endocrine disrupting properties that may cause adverse effects on target organisms according to the criteria specified above, unless ~~the risk from~~ exposure of the non-target organisms to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use, is negligible."

The proposal to change the text to allow approval of an ED pesticide if it gives rise to negligible risk rather than the previously worded well-defined negligible exposure is unacceptable. We oppose this change because although 'negligible risk' sounds to be something that is safe, risk assessment does not take into account cumulative exposures from all sources, and furthermore it relies on very detailed knowledge of exposures and whether or not a substance has a threshold for effects. Given the difficulty in determining thresholds for effects, and the potential for non-monotonic dose response curves, we consider that risk assessment for EDCs may be unreliable and is certainly untenable if conducted as presently undertaken on a single substance.

Costs and benefits

CHEM Trust is very concerned that the HSE seems to want to focus on the costs to industry and agriculture and ignore the public health benefits.

It needs to be recognised that industry in the past has tended to try and inflate the costs of regulation (CHEM SEC, 2015). Moreover, it needs to be recognised that any regulation will stimulate innovation and allow market access for companies designing safer substances. The UK needs to rise to this challenge and put public health to the fore.

There have been many costings of the likely savings that would accrue to health services if EDCs were adequately regulated. These include Bellanger et al., 2014; Hauser et al., 2014; HEAL, 2014; Legler et al., 2014; TemaNord, ISSN 0908-6692, 2014; Trasande et al., 2014; Rijk et al., 2016. The available studies have various approaches, are looking at various ED chemicals and related health effects including various types of costs. However, it is pertinent to note that for the EU the costs of the health effects may be over €100 billion per year.

CHEM Trust is also concerned that the UK may want to hold on to its original position that potency should be considered in determining which substances should be regulated as having endocrine disrupting properties. This is despite the fact that a consensus of scientists who are experts in the field have stressed that potency is not relevant to the identification of a substance with ED properties (see BfR,2016).

[1] http://www.documents.clientearth.org/library/download-info/summary-of-analysis-of-european-commission-proposals-and-legal-requirements-concerning-the-determination-of-scientific-criteria-to-identify-endocrine-disruptive-properties-of-active-substances/

References

Bellanger et al., 2014. *Neurobehavioral Deficits, Diseases and Associated Costs of Exposure to Endocrine Disrupting Chemicals in the European Union*. Journal of Clinical Endocrinology and Metabolism.

CHEM SEC, 2015. *Cry Wolf.*
See http://chemsec.org/publication/chemicals-business/cry-wolf-2015/

Hauser et al., 2014. *Male Reproductive Disorders, Diseases, and Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union*. Journal of Clinical Endocrinology and Metabolism.

HEAL, 2014. *Health costs in the European Union, how much is related to EDCs*?

Legler et al., 2014. *Obesity, Diabetes and Associated Costs of Exposure to Endocrine Disrupting Chemicals in the European Union*. Journal of Clinical Endocrinology and Metabolism.

RIJK et al., 2016. See http://www.uu.nl/sites/default/files/rijk_et_al_2016_-_report_iras_-_health_cost_associated_with_edcs_3.pdf

Trassande L et al, 2015. *Estimating burden and disease costs of exposure to endocrine-disrupting chemicals in the European Union*. J Clin Endocrinol Metab.

WHO & UNEP, 2013. *State of the science of endocrine disrupting chemicals* – 2012
See http://www.who.int/ceh/publications/endocrine/en/.

Gwynne Lyons, Policy Director CHEM Trust 12th September 2016

Gwynne.lyons@chemtrust.org.uk