



Comments on Draft technical guidance on the interpretation of points 3.6.3 to 3.6.5 and 3.8.2 of Annex II to regulation (EC) No 1107/2009, in particular regarding the assessment of negligible exposure to an active substance in a plant protection product under realistic conditions of use (Version May 2015)

24th July 2015

General comments

Thank you for the opportunity to provide comments on this important matter. We support the need for a guidance document and appreciate DG Sante's efforts in the discussions.

However, we believe that the current draft falls very short of adequately reflecting the legal text of the PPPR. We are very concerned that the clear intention of EU legislators to drive replacement of the most hazardous pesticides is undermined by the current approach (as outlined in the guidance and reflected in the presentation given at the Stakeholder meeting on 25th of June 2015).

In our view it is clearly not in line with the legal text to interpret the "negligible exposure" provision mainly by prohibiting the non-professional use, applying a "stricter" risk assessment with additional safety factor applied and recommending risk mitigation measures. The proposed approach in this guidance document seems to make the exception to the rule by introducing more risk-based considerations instead of strictly limiting use scenarios.

The text in Annex II is very clear and stringent ("closed systems" or "excluding contacts with humans"). In particular, the requirement of the legal text is not the same as "reducing exposure as much as possible" which should be part of any good agricultural practice and therefore apply to ALL pesticides.

The legal text specifies that a pesticide which is a category 1a or 1b carcinogen or reproductive toxicant or which has ED properties relevant for humans is not to be approved for use *"unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in*

closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.”

By stipulating ‘**that is...**’ the intent is clear, and it means that the product can only be used in closed systems or conditions where human contact is excluded. The text does not specify ‘such as’ which would signal that other uses not specified in the legal text (albeit which lead to similar exposure) could be envisaged.

Overall the principle of the legal text is NOT to tolerate the exposure to humans to CMR/PBT/POP/EDC pesticides, except in very exceptional and therefore few cases (see proposals in “Specific comments” below).

Last but not least, the chapter on the non-target organisms in the environment is still missing. In our view this needs to be developed before granting any authorization to a pesticide with carcinogenic, reprotoxic or endocrine disrupting properties.

SPECIFIC COMMENTS

Chapter, Lines	Comments
Chapter 2, lines 68 - 75	This paragraph does not reflect a correct interpretation of the legal text . By stipulating ‘ that is... ’ the intent is clear, and it means that the product can only be used in closed systems or when human contact is excluded. We suggest to reword or take out.
Chapter 2.1, Figure 1	A clarification on the link between the derogation provisions to article 4.7 and Annex II, 3.6.3/6.4/6.5 is needed.
Chapter 2.2 Line 159-175	<p>The interpretation of “closed system” as “<i>Equipment and procedures designed to reduce as far as technically possible the escape (...)</i>” (line 173) is not acceptable.</p> <p>Even though the technical conditions to achieve a closed system may be burdensome it is clear that it means the <u>pesticide application in a closed system</u> and it does not mean the application <i>via</i> a closed system (spray container) into the „open environment”. However, the current guidance document would still allow this.</p> <p>Existing definitions for closed systems should be used as starting points. See for example this worker’s protection provision for handling hazardous substances such as carcinogens in closed systems: http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/pdf/TRGS-500.pdf?__blob=publicationFile&v=3</p>

	<p>It is true that a “closed system’ is never 100% closed but the guidance should make a better effort in defining those rare use scenarios which come close to fulfilling these strict conditions for excluding contact with humans. One example could be high-tech sealed greenhouse system with specific conditions that need to be fulfilled for operation and maintenance purposes.</p> <p>Furthermore this section illustrates the importance of including the environmental exposure into the considerations of what “closed system” means.</p>
Chapter 2.2 Line 180-196	<p>We disagree with this paragraph which seems to suggest that negligible exposure is defined in the legal text only for dietary exposure. This is not the case, because the legal text clearly states that negligible exposure in this case means closed systems or other conditions excluding contact with humans. Humans would, of course, include operators, bystanders/residents and workers via all relevant routes of exposure (dermal, inhalation and oral).</p> <p>This means the scope of closed systems or other conditions excluding contacts with humans should be much more set out and quite limited.</p>
Chapter 2.2 Line 178-179	<p>The guidance document states: “For risk assessment purposes ‘negligible’ can be considered to be a level so small that it does not appreciably add to the risk and can safely be ignored”</p> <p>This transition from “negligible exposure” to “negligible risk” is not covered by the legal text of the PPPR.</p>
Chapter 3.2.1 Line 259	<p>We agree that consumer use should never be authorized for hazardous substances with CMR, PBT/POP and EDC properties.</p>
Chapter 3.2.2 Line 269-272	<p>It seems out of place to refer to “natural background levels in the environment” for pesticides which are mostly synthetic compounds. The implications of these sentences are unclear.</p>
Chapter 3.2.2 Line 276-278	<p>We disagree with the approach to conduct a risk assessment for the non-dietary exposures and merely add a safety factor (which has not yet been decided on, as we understand).</p> <p>The procedure for investigating if indeed a case for granting an authorization based on negligible exposure can be made should only be carried out in exceptional cases.</p>
Chapter 4 Line 293	<p>The guidance should not be adopted without the currently missing part on “non-target organisms in the environment”. Environment must include all agricultural areas, forest and garden, parks – being all part of the „open environmental system“.</p>

Chapter 5 Line 308-311	It is not logic to consider the dietary route first, as this is the exposure taking place last. The law places the emphasis of “negligible exposure” during application (closed system/other condition) and therefore the direct contact for workers, residents by-standers should probably be the first consideration to take. The dietary route should be more considered as a safety net to ensure that also the general population is protected.
Chapter 5 Line 324	<p>“These measures will contribute to ensure that human exposure is at the lowest level that can be achieved based on the available technologies”</p> <p>We disagree with this general statement. In our view this guidance document is insufficient to ensure a minimization of exposure. It merely lays out a few steps for exposure <u>reductions</u>, which should anyway be included in good plant protection practice. Suggesting a (stricter) risk assessment approach instead of implementing conditions for closed system/other conditions excluding contact with humans as foreseen in the legal text will undermine a high level of protection.</p>
Chapter 6 328, Annex	<p>In our view the Annex should be deleted as it only lists professional use risk reduction mitigation measures to reduce exposures, but this belongs in every “best practice guide” for pesticide use in general. We therefore suggest to replace this Annex with a list of use scenarios which could potentially qualify as a “closed system/other conditions (...).”</p> <p>For example, we could envisage a scheme where a pesticide with low persistence was formulated robotically in a closed system sealed greenhouse. We would foresee use of high concern substances to be limited to only these exceptional cases when more specific exposure verification should also take place. Such exposure verification should always be based on real data and a commitment to continuous monitoring of potential emissions to ensure the “negligible exposure condition” is fulfilled over time.</p>

For comments or questions please contact:

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