Pesticide Action Network Europe

Brussels
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Comments on Commission's DG SANTE "technical guidance on the interpretation of points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, in particular regarding the assessment of negligible exposure to an active substance in a PPP under realistic conditions of use".

Pesticide Action Network Europe (PAN Europe).

Thank you for your invitation to comment on the draft guidance document on negligible exposure currently under development by DG SANTE, pesticide unit 3. After reading the document and participating in the AG on the specific issue PAN Europe would like you to take the following points into consideration during the final development of the guidance:

1) **Incomplete document.** The document as it is, is incomplete, as the evaluation of what is "negligible exposure" for non-target organisms and bees has not been developed at all. Thus, any decisions taken at this stage may jeopardize the health of non-target species and their populations.

Annex II, paragraphs 3.8.2 and 3.8.3 of PPPR 1107/2009 specifically require that an active substance (AS) "shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms **unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.**" … and further in relation to honeybees "**unless it will result in a negligible exposure of honeybees**". Humans may use mitigation measures during operational application of pesticides to minimise their exposure. This is impossible for non-target organisms that are directly exposed to these chemicals in their natural environment.

The importance of protecting the environment from the use of harmful PPP for non-target species is highlighted in the PPPR by articles 4 (2b, 3e) but also by articles 21 (1) and 44 (1), where the approval of a pesticide may be withdrawn if the objectives of 2000/60/EC (Water framework directive- WFD) are not fulfilled. WFD aims to restore the currently deteriorating aquatic ecosystems and achieve a good ecological and chemical status for European surface and groundwater. The environmental quality standards directive (EQS) 2008/105/EC includes for example cholrpyrifos, setting a

level of 0.03 µg/L (i.e. 30 ng/L), a very low concentration level, which must be taken into account when examining negligible exposure for non-target organisms for this pesticide. More authorised pesticides are foreseen to be added in EQS, which urges to evaluate the effects of pesticides on aquatic organisms before accepting a negligible exposure guidance document based on effects on humans. Aquatic organisms are very sensitive to pesticides exposure, especially during the larval stage, with a direct impact on species population. As recognised by WFD, aquatic ecosystems are deteriorating and we need to act to restore their ecological status. A recent scientific study on 4000 rivers and lakes across Europe found that organic chemicals were likely to exert chronic toxicity in aquatic organisms in 42% of the sites and acute lethal toxicity in 14%[1]. For the latter, the study shows that pesticides were responsible for 81-97% of acute lethal toxicity in aquatic organism (fish, invertebrates, larvae). All these must be taken into consideration before defining negligible exposure for non-target organisms.

Thus, particularly in the case of EDCs, exposure must be proven *negligible* both for humans and non-target organisms and this document, as it is, does not provide information on how to achieve this.

2) **Evaluation of ED pesticides is a priority**. The document intends to finalise the definition of negligible exposure and include substances in the candidates for substitution without having the final criteria for EDC substances. In the document the COM doesn't explain how it will do this. Will the interim criteria be used instead? These criteria do not specifically identify endocrine disruptors and must be updated. What will be the process when EDC criteria are produced and new test methods with specific endpoints for EDCs are fully incorporated in the legislation?

3) **The document uses risk assessment instead of a hazard-based approach**. PPPR sets "cut-off" criteria to accelerate the process of the assessment of pesticides with the underlined scope to protect human health and the environment. Points 3.6.3/3.6.4/3.6.5 for humans and points 3.8.2 & 3.8.3 for non-target organisms, aim to skip this prolonged process of assessment of pesticides and "secure" human and environmental health by directly banning these very harmful chemicals. This means that if an AS/S/SN falls under these points the pesticide will not be authorised (unless article 4 (7) applies) and must be removed from the market. With this working document the COM is proposing to continue this time-consuming and expensive RA process, even for chemicals that fall under these "hazard" categories, with the overall aim to identify "safety" limits and define how these limits can be achieved without banning these harmful pesticides. Thus, the COM appears to refuse to accelerate the process of removing hazardous chemicals from the market, which was the underlying aim of the regulation. Transitioning to the use of less harmful substances in

[1] E Malaj, C Peter, M Grote, R Kühne, CP Mondy, P Usseglio-Polaterag, W Bracka, and RB Schäfer (2014). Organic chemicals jeopardize the health of freshwater ecosystems on the continental scale. PNAS, **111**:9549-9554

agriculture and more sustainable practices is a priority in EU and is clearly addressed by the Sustainable Use Directive 2009/128/EC.

4) **Closed systems**. The definition of "closed systems" (lines 173-175) is weak and may be misinterpreted by applicants. A closed system is one in which no substances are either added or lost from it. Although there might be some release into the environment, the closest definition to "a closed system" in which pesticides may be used in agriculture is a "greenhouse". Following the definition in Article 3 (27) "*greenhouse' means a walk-in, static,* ***closed place*** *of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and* ***prevents release of plant protection products into the environment***." In the guidance document the COM defines a closed system as "*equipment and procedures designed to reduce as far as technically possible the escape of an active substance, safener or synergist into the environment either during or after the use of the plant protection product*". The wording seems incorrect because a closed system that reduces as far as technically possible the release of an AS/S/SN into the environment but doesn't prevent it **sufficiently** cannot be called "closed". Furthermore, although several examples are given in lines 159-172 before the definition, the document doesn't give clear examples of what examples would fall under the given "closed systems" definition. Further, there is an EFSA guidance document on "clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments" which specifically evaluates the emissions of what could be called a closed system in PPPR 1107/2009. According to the document, even greenhouses and walk-in tunnels (the only ones assessed as a guidance) have to be developed further with regard to groundwater and surface water leakages in order to fulfil the regulation.

5) **Negligible exposure** (lines 176-179). PAN Europe agrees that according to the dictionary negligible exposure is not equal to zero, but- as mentioned in the guidance document- according to the Oxford English Dictionary, is a quantity "so small or unimportant as to be not worth considering; insignificant". However, when transferring this definition to pesticides, the COM uses the term "a level so small that it does not appreciable add to the risk and can safely be ignored" interpreting "negligible exposure" as "negligible risk". "Negligible risk" is included in article 4(2) of the Biocide Products Regulation BPR 528/2012 and was deliberately excluded from PPPR. This is actually one of the regulatory decision options of the roadmap[2] on EDCs, where Option B specifically proposes to amend the PPPR to introduce the exemption of the ban when "negligible risk" rather than "negligible exposure" can be demonstrated. Introducing "negligible risk" its against the mandate of the pesticide regulation.

[2] Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf

Further, COM contradicts the science behind carcinogenic 1A, reprotoxic 1A, carcinogenic 1B and endocrine disruptors with no thresholds, assuming that small concentrations may be safe. In non-threshold hazardous chemicals, event the smallest concentration can be considered significant to cause adverse effects. PAN Europe proposes to refuse authorisation to all substances with no threshold (including EDCs for which a threshold hasn't been proven when exposure takes place during the very early life stages of development for humans or other organisms).

6) **Non-dietary exposure** (lines 247-250). Here the guidance document proposes that by using risk mitigation measures, exposure to humans can be reduced as much as technically possible. As mentioned before "as much as technically possible" does not equal negligible, when the exposure is not reduced sufficiently. Further, this shouldn't be applied to pesticides with no thresholds. As mentioned in point (1), the fact that exposure should also be negligible to non-target organisms and bees, has been totally neglected. The legislation aims to reduce exposure to negligible levels both for humans and non-target organisms.

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