Pesticide Action Network Europe

DG SANTE's decisions on endocrines and pesticides.

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To: Mr. Vytenis Andriukaitis
European Commissioner for Health and Consumer Policy
European Commission
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Concerning : The policy of your DG on the (interim) criteria for endocrine disrupting pesticides.

Dear Commissioner Andriukaitis,
It must be no news for you to hear that the incidences of endocrine-related diseases such as breast and prostate cancer keep on rising in all EU member states[1]. You will also be aware that many pesticides are linked to endocrine adverse effects. Just to mention an example for only one endocrine target: 69 of the EU approved pesticides cause a decrease of thyroid hormone levels; a further 56 cause an increase of relative thyroid weight[2]. Given the urgency to act, it is a surprise to us that your DG did not propose to put an end to the market access of endocrine disrupting pesticides yet. Regulation 1107/2009 has been in place for 6 years now and we are very disappointed about the implementation by your DG, not only on endocrine disrupting pesticides but on other issues as well. Nothing has changed so far to start banning harmful pesticides and to start introducing sustainable practices (IPM, integrated pest management) while the use of pesticides is increasing in most member states and the number of approved pesticides has more than doubled since 2009.
We ask for your intervention and for a radical change of policy.

We currently observe a lack of spirit to fight for SANTE's mission to improve health and the environment and for a proper implementation of Regulation 1107/2009. It is not only the failure to present criteria for endocrine disruption and the pointless impact assessment on endocrines with a range of options which are not in line with the Regulation, it is also the apparent reluctance to follow the rules and the automatic reflex of your DG to develop derogations, loopholes and backdoors to the rules. We therefore need your support to get your DG on the right track for the following topics:

1. Pesticides which are subject to the new "hazard" ("cut-off") procedure in Regulation 1107/2009, such as a classification R1B (like **Amitrole, Flumioxazin, Linuron**) or PBT (like **Esfenvalerate, Bifenthrin**) should be banned with the highest possible urgency. These pesticides have horrible adverse effects, cause

[1] Philipa Mladovski et al. Health in the European Union, European Observatory on Health systems and policy, 2009, Ed. WHO, at http://www.euro.who.int/pubrequest.
[2] http://www.efsa.europa.eu/en/consultationsclosed/call/130717

harm to people and the environment every day and should never have been allowed on the market in the first place. We urge you to instruct your DG to immediately ban these pesticides.

2. Pesticides which are part of the interim criteria for endocrine disruption beyond doubt such as the classification C2+R2 (like **Flupyrsulfuron, Isoproturon, Pymetrozin, Flutianil**, a new substance even!) should be banned or not-approved without delay ("shall " in the pesticide legislation). Food Authority EFSA indicated for all of them a "critical area of concern", meaning that no safe use is identified and an approval is therefore legally impossible.

3. Also for the pesticides which are part of the interim-criteria based on a classification R2 + being toxic for endocrine organs (like **Azibenzolar-S-methyl, Thifensulfuron-methyl, Bentazon**) a non-approval is necessary. We think it is unlawful to approve these pesticides and ask for "confirmatory data" in case the assessment of toxic effects on the endocrine organs is not finalised. In these cases the precautionary principle should prevail and the pesticide should be taken from the market till the required information has been assessed. The "confirmatory data" loophole that is used by your DG as a standard procedure is a violation of the precautionary principle and gives the advantage of the doubt to the commercial parties and not to people and the environment as it should.

4. We really dislike the never-ending row of derogations and bypasses of the rules that are developed in pesticide decision-taking by your DG[3,4,5], and kept on being developed. While the text on "negligible exposure" in Reg. 1107/2009 is quite clear *(the product is used in closed systems or in other conditions excluding contact with humans),* your DG feels the need to develop derogations in a draft guideline that ends up equating full field pesticide spraying conditions with "closed systems" and allows substantial exposure of residents, bystanders and of the non-target organisms in the environment. This is a type of implementation that is totally opposite to the rules. We ask you to forget about this guideline and simply apply the legal text on "closed systems" and "excluding contacts with humans" in your decisions without using loopholes.

5. Your DG stopped evaluating pesticides after their first (legal) 10-years approval period and started granting extra years of market access for almost all pesticides. This is the so-called "prolongation", a new system which is not mentioned in Reg. 1107/2009 at all. We think there is no legal basis for these prolongations and we especially oppose these prolongations for those pesticides that are part of the "cut-off" procedure in 1107/2009. Art.4.1 is very clear and states: *"The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied".* It is hard to understand why your DG did not make this easy assessment before considering a "prolongation" or at the moment of the submission of the dossier. Now very

[3] PAN report Resubmission
[4] PAN report 120-day derogation
[5] PAN-report on Metam

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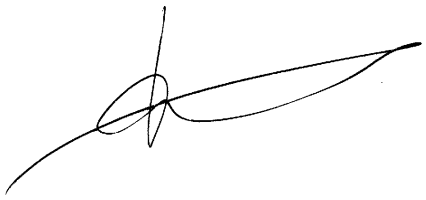
harmful pesticides like **Glufosinate, Flumioxazin, Linuron, Pymetrozine**, all R1B, remain on the market for an additional time, allowing harm to be done. We ask you to stop this prolongation-policy, at least for the classified pesticides.

6. Pesticides are not tested for their endocrine disrupting effects. Food Authority EFSA relies mainly on the decades-old industry chronic studies on reproduction and cancer. Studies which have a questionable reliability given the conflict of interest of industry. The use of independent academic studies would be welcome but despite the obligation in Reg. 1107/2009 to do so, in almost all cases these studies "are missed and dismissed"[6]. And since the OECD framework for endocrine testing is available and even included in the EU data requirements, we do not understand why your DG doesn't oblige applicants for ALL currently approved pesticides to do these studies now. Without a reliable scientific basis and tests for all endocrine systems, it will be hard to do a proper assessment and decisions might be taken arbitrarily. We hope you will oblige testing for all currently approved pesticides and rule that studies shall be delivered by 2018.

7. Regarding the environment it is absolute shame that your DG is not implementing the rules of Annex II, 3.82[7]. It is clear that your DG (given the draft guideline on "negligible") will allow full field spraying conditions for pesticides which are classified R1B and for pesticides that are part of the interim criteria for endocrines. This will ensure that 3.8.2 is violated because the non-target organisms will be exposed at non-negligible levels, given the fact that your DG abandoned the rules on "closed systems" and substituted them by traditional risk assessment. Biodiversity is going down now for decades, the link with pesticides is clear and proven[8], and still the environment is 'forgotten' by your DG. We ask you to immediately start assessing endocrine disrupting effects for the environment in any decision taken from now on and protect our precious natural environment.

We hope for your support for a radical U-turn of the policy of your DG,
Sincerely yours,



H. Muilerman.

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[6] PAN E report Missed and Dismissed

[7] An active substance, safener or synergist 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.

[8] Flavia Geiger et al., Persistent negative effects of pesticides on biodiversity and biological control potential on European farmland, Basic and Applied Ecology 11 (2010) 97–105

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