Decision on the approval of the herbicide Amitrole.

Brussels, 15-07-2104.

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To: Mr. Tonio Borg
European Commissioner for Health and Consumer Policy
European Commission
B-1049 Brussels.

Concerning : Your proposal to the Standing Committee regarding the pesticide Amitrole.

Dear Commissioner Borg,

Pesticide Action Network Europe is very much interested in the proposal you will send to the Standing Committee on the potential (re)approval) of the pesticide Amitrole. Amitrole is likely the first pesticide that is subject to the so called 'interim' criteria for endocrine disrupting pesticides (Annex II, 3.6.5) and we would be very keen to know if you are going to respect this provision of Regulation 1107/2009. We hope you will clarify your position to us.

The EFSA peer review (http://www.efsa.europa.eu/en/efsajournal/pub/3742.htm) even concludes that the classification of the herbicide Amitrole should be changed based on the evidence -demonstrated in the industry-sponsored studies- of severe harm done by Amitrole to the offspring. The current R2 should be changed to the more strict R1B-classification according to EFSA and this automatically rules out any further approval discussion on Amitrole since Annex II, 3.6.4 excludes pesticides with an R1B from approval.

We therefore would like to encourage you to propose a full ban on Amitrole without any essential uses or other types of derogations. Most EU Member States already do not authorise Amitrole anymore and this is a clear indication that good alternatives are present for the main use in orchards, grapes and olives.

We would like to make two additional remarks.

The EFSA peer-review concludes that thyroid tumours found in mice are of little relevance for humans based on differences in mode of action. We have consulted active endocrinologists and they state that this assumption by EFSA is not based on current science. The EFSA assumption is likely based on the language used in the RAR (Revised Assessment Report, http://dar.efsa.europa.eu/dar-web/provision) on Amitrole, possibly suggested by the applicant and accepted by the Rapporteur France. Differences in Iodine uptake and differences in follicle size in the thyroid, as claimed in the RAR,

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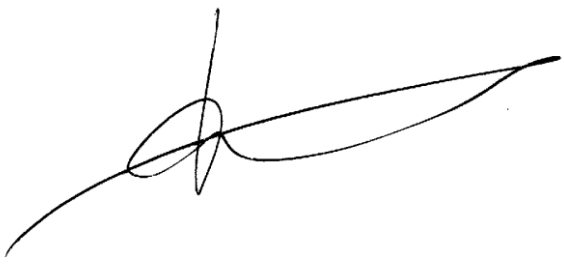
however have no relevance for the thyroid system which is highly conserved during evolution and there are many more similarities than differences in both,
1) Uptake and organification of iodide by the thyroid gland, and
2) General physiology of the hypothalamus/pituitary/thyroid (HPT) axis.

The 'human relevance' argument is used many times in pesticide risk assessment and we have strong doubts if it used a scientific way. Industry and industry-linked scientists put a lot of effort in getting their ideas accepted in independent bodies like IPCS and EFSA. Opinions therefore need to be updated and revised as a matter of urgency. This 'human relevance' element is far from unimportant. It is also part of the criteria for endocrine disrupting pesticides and should be based on solid science. We therefore ask you to mandate EFSA to take a closer look at 'human relevance' and instruct them to do this in a working group with members exclusively being active endocrinologists to make sure current science is used as a basis. Experts with industry-links and industry-specific interests should be excluded.

Another point we like to mention is the obligation of Regulation 1107/2009 to take independent peer-reviewed literature into account. We easily found 25 independent studies with adverse effects of Amitrole in the search-machines PUBMED and ScienceDirect, several of them at low dose. The RAR however takes no single independent academic study into account at all. This approach by the applicant of Amitrole and apparently accepted by the Rapporteur MS undermines the rules and creates mistrust in European institutions. We would like to encourage you to start a discussion in the Standing Committee about the necessity to respect accepted rules such as on collecting independent literature and better monitor yourself the duties of the Rapporteur. We are currently doing a survey on respecting the rules on independent literature and will send you the outcome soon. While we are happy to do this to demonstrate lack of implementation by EU Member States, we feel it is your duty to control and enforce the implementation of Brussels rules.

We hope for your support,
Sincerely yours,



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