Pesticides Action Network Europe
Rue de la Pepiniere 1
1000 Brussels

Brussels 1st December 2015

Dear Members of the Standing Committee on Plants, Animals, Food and Feed,

I am writing to you, on the behalf of Pesticides Action Network Europe, in relation to the re-approval of glyphosate-based pesticides for another 10 years in the European Union. The re-approval of glyphosate is of concern, since hundreds of studies available in the academic scientific literature report different types of toxicity following exposure to glyphosate or glyphosate-based products in humans, laboratory animals and wildlife[1].

The International Agency for Research on Cancer (IARC) of the World Health Organisation (WHO), classified glyphosate as a "probable human carcinogen", following a thorough analysis performed by 17 independent experts from 11 countries using publicly available studies[2,3]. This conclusion was reached due to "limited evidence of carcinogenicity in humans" and "sufficient evidence" in experimental animals. Furthermore, the experts took into consideration the strong evidence of genotoxicty and oxidative stress in humans and laboratory animals following exposure to glyphosate-pesticides and its metabolites.

In the EU, according to regulation (EC) No 1272/2008, this evidence should lead to a classification of glyphosate as "presumed human carcinogen" (category 1B) due "*evidence from animal experiments for which there is sufficient (1) evidence to demonstrate animal carcinogenicity*" and also due to "*limited evidence of carcinogenicity in humans*" (Annex II 3.6.2). Such classification should result in the ban of glyphosate in Europe since the authorization of pesticides that are classified as carcinogens category 1B cannot be approved (Regulation 1107/2009; Annex II, 3.6.3).

However, unlike IARC/WHO, the European health risk assessment prepared by the o, and the peer-review of European Food Safety Authority (EFSA) concluded that "glyphosate is unlikely to pose a carcinogenic hazard to humans"[4]. This divergence in the classification was possible because EFSA, similar to RMS, dismissed epidemiological studies showing carcinogenicity in humans, overlooked tumour data from experimental animals and disregarded all data on genotoxicty. Overall, EFSA and BfR dismissed from their evaluation all studies showing effects of glyphosate-based pesticides, because the risk assessment protocol (data requirements) is designed to study the effects of the active ingredient rather than the whole pesticide product.

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1 http://www.i-sis.org.uk/pdf/Glyphosate_research_papers_compiled_by_Dr_Alex_Vasquez_and_Dr_Eva_Sirinathsinghji.pdf
2 http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf
3 http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf
4 http://www.efsa.europa.eu/en/press/news/151112

The purpose of Regulation 1107/2009 concerning the placing of plant protection products on the market, is "*to ensure a high level of protection of both human and animal health and the environment*" (Article 4.3) and is "*underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment*" (Article 1.4). Thus, not only the risk assessment has to be performed in the most rigorous and "precautionary" manner, but all studies indicating adverse effects on human or animal health have to be taken into consideration, including the ones on the effects of the whole pesticide product. The evaluation of BfR acting as RMS and EFSA, has failed to fulfil those tasks.

Dismissing evidence of carcinogenicity following exposure to the pesticide product rather than just the active compound because is not in the "data requirements", is unacceptable, dangerous and against the principles of the pesticide regulation to protect humans and the environment from dangerous chemicals. Also, assuming that malignant tumour data from animal experiments are "incidental" and not treatment-related, when independent scientific studies indicate the opposite is a highly dangerous misinterpretation and should be corrected immediately.

Scientists around the world have reacted to this conclusion, accusing either RMS or EFSA for its "flawed" assessment. We particularly want to bring your attention to the following reviews:

- 96 independent academic and governmental scientists from 25 countries sent an Open letter[5] to the Health Commissioner to express their concerns on EFSA's classification. The letter highlights the major scientific flaws committed by EFSA (and also BfR) that made this classification possible.
- The three critique analyses of senior toxicologist Dr. Peter Clausing, on (1) the re-approval assessment report performed by BfR[6], (2) on BfR's addendum following IARC's publication that compares the two assessments[7], and (3) on EFSA's opinion[8]. The three reports highlight in detail the major flaws that lead both EFSA and RMS to the wrong conclusion.
- The Independent Scientists Manifesto on Glyphosate, signed by 524 scientists so far, calling to ban the use of glyphosate-based herbicides, to protect human and environmental health[9]. The manifesto stresses out that carcinogenicity is not the only adverse effect observed following glyphosate exposure.

Considering that risk assessment is performed to protect human health and the environment we urge you to react, revise the assessment performed by EFSA and BfR and prevent the re-authorization of this dangerous chemical in the EU for another 10 years.

On the behalf of PAN Europe,

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[5] http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-offener-brief.pdf

[6] https://blog.campact.de/wp-content/uploads/2015/09/Glyphosat-Studie_final.pdf

[7] http://www.pan-germany.org/download/PAN_Germany_Addendum_analysis_09112015.pdf

[8] http://www.pan-germany.org/download/Analysis_EFSA-Conclusion_151201.pdf

[9] http://www.i-sis.org.uk/Independent_Scientists_Manifesto_on_Glyphosate.php - form

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