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Institut für unabhängige Folgenabschätzung in der Biotechnologie

LOBBY CONTROL

Commissioner Vytenis Andriukaitis
European Commission Directorate-General
for Health and Food Safety
Rue de la Loi / Wetstraat 200
1049 Brussels
Belgium

Subject: Approval process for pesticides

Dear Commissioner Andriukaitis

On 12 November, the European Food Safety Authority EFSA finally concluded that glyphosate is "probably not carcinogenic" and recommended it for re-approval. We are presently not concerned with criticising the actual decision, but rather the decision-making process itself. One element of our criticism was brought to your attention by our online petition demanding that the BfR report should be published in September. At this point, we would like to raise several points that illustrate why we think the process was not transparent and shaped by conflicts of interest. Most of our points do not only refer to the glyphosate authorisation process, but are, in our view, problems inherent in the EU pesticide approval process in general:

1. First of all, the applicants seeking approval for a pesticide are the ones to choose the country that compiles the assessment report. Naturally, the applicants will choose a country sympathetic to their request: Germany has the biggest chemical industry in Europe – and it also compiled the first glyphosate assessment report.
2. The dossier submitted by the applicants was to a large extend based upon studies carried out or sponsored by the producers themselves. It was, in fact, carried out according to the pesticide legislation, which we see as problematic, since this can lead to bias in preparing and assessing the data.
3. These studies and the raw data from the tests were kept secret due to commercial confidentiality agreements. This appears to be the case in many other approval processes. Thus, it is impossible for independent scientists to assess the data.
4. Independent studies were not taken into account as a priority. The risk assessment was not based on sufficiently defined criteria such as peer-reviewed and fully referenced publications.
5. Since the public consultation in 2014, the BfR Renewal Assessment Report on glyphosate has no longer been publically accessible. Only the applicants had the opportunity to see the report. They were even allowed to add additional research results to the report. This kind of unbalanced access is unacceptable. Nobody apart from the glyphosate producers knew exactly which research results had been used and the impact they had had on the final version. Thus, stakeholders who had participated in the consultation process were unable to check if their arguments had been taken into account or not.
6. An analysis carried out by Friends if the Earth Germany has also criticised the close relationship between industry and members of the relevant German authorities responsible for the report.[1] The same has been said in many other cases about the relationship between industry and EFSA.

1 Bund für Umwelt und Naturschutz Deutschland (Friends of the Earth Germany): Note "Mangelhaft": Das Zulassungsverfahren für Glyphosat. Berlin, september 2015, available online: http://www.bund.net/fileadmin/bundnet/pdfs/gentechnik/150928_bund_gentechnik_glyphosat_zulassung_studie.pdf

In pesticide approval processes, the EFSA and the responsible member state make crucial decisions on our health and our environment. We call upon you to reassess the whole approval process for pesticides in order to make it more transparent and credible for EU citizens. Here are some suggestions for this reassessment:

- The EU Commission itself, not the applicants, should choose the country that conducts the assessment on the basis of transparent criteria.
- The regulatory studies for (re-)approval of a certain substance must be conducted by independent academic institutions, not by the producers themselves. Funding for this should be provided by an independent fund, financed by the producers.
- All studies taken into account in a dossier must be made public and therefore verifiable. The regulatory studies assess the risk which a certain substance poses for human health and the environment. The public's right to know in the case of glyphosate should be prioritised over commercial interests.
- The pesticide regulation 1107/2009, which rules that independent studies (i.e. science financially independent of private interests) must now be taken into account and properly implemented when the EU is assessing and considering approval for a pesticide.[2]
- A lot more needs to be done in terms of transparency of the authorisation process. The risk assessment report must be open to the public long before the EFSA draws its conclusion in order to allow for review by independent academics.
- Information on experts and authorities involved in the assessment has to be publicly available. The public should have access to the names and CVs/professional background of all experts who participate in the decision-making process, including all previous or current co-operations with industry or organisations funded by/close to industry. The European Medicines Agency may serve as an example in this respect.[3]

The Commission has postponed its decision on glyphosate until summer 2016. We believe that it should use this time and make sure that all risks have been thoroughly assessed before glyphosate is allowed to be used for the next ten years. This should be done in an open and transparent process, taking into account the many critics regarding the BfR report.

I look forward to hearing from you

Yours sincerely

Nina Katzemich
LobbyControl

Christoph Then
Testbiotech

2Pesticide Action Network Europe: Missed and Dismissed. Pesticide Regulaters ignore the legal obligation to use independent science for deriving safe exposure levels. Brussels, september 2014, available online http://www.pan-europe.info/old/Resources/Reports/PANE%20-%202014%20-%20Missed%20and%20dismissed.pdf

3 http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000105.jsp&mid=WC0b01ac0580028c32