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Your response to the open letter written to the newspaper *taz.die tageszeitung*

Ladies and Gentlemen,

Many thanks for your letter of 24 February 2017 and your detailed debate with my points of criticism on the report “Behörden unter Druck (Authorities Under Pressure)” of 30 December 2016.

I acknowledge that you describe several of your own statements in the article as “imprecise” and “somewhat exaggerated” and welcome your suggestions for more careful formulation in several cases. We agree that a scientific political consultation that is intended to form the basis of administrative and political decisions of great magnitude may in no way be arbitrary and must satisfy specific scientific principles.

Our goal as an independent institute for consumer health protection is to deliver the best possible scientific evidence as the basis for political decisions. In the case of foods and feeds, as well as the safety of products and chemicals, the authorities ordered the reorganisation of consumer health protection in Germany 15 years ago in the aftermath of the BSE crisis. The federal government of the time stipulated that the identification, assessment and communication of risks should be independent of administrative and political actions and free from their influence. In this way, an independent authority based solely on the principles of science was to be given the opportunity to speak openly about risk estimations and communicate them publicly for the protection of consumers, even if they proved to be uncomfortable. The principle of independence is the central characteristic here:

This principle protects the risk assessment for the benefit of consumers from particular interests of all kinds. This applies to the possible influence by political parties and elected representatives and by trade and industry associations, as well as by socio-political interest groups such as NGOs and citizens' initiatives. In the field of risk assessment, scientific work means to carry out an evaluation on the basis of adequate data, to make it public and in principle comprehensible and refutable for everyone. Science does not claim to be infallible, but it does claim, on the basis of generally recognised principles, to present reliable evaluation results, the conclusions of which can be validated by third parties, and to express them in a way that pays no heed as to whether or not the scientific assessment is politically or socially acceptable.

It is a necessary prerequisite of social discourse to put findings and facts in different contexts, thus arriving at divergent conclusions and arguments. It goes without saying that different interests are involved, but I hope we can agree that this social discourse has to be based on verifiable findings. Unfortunately, the article in *taz* which triggered our correspondence did not take this into account (see Item 1 of the enclosure).

Precisely because we know that, based on different role perceptions, the social and scientific discourses often go separate ways, one of our most important tasks is to ensure that this dialogue is not discontinued, so that the general population and political decision makers are provided with a solid basis for making decisions on topics relevant to consumers.

To deepen our discussion even further, I would like to make the following proposal to you: We are currently in the process of reappointing the members of the BfR committees and would of course also welcome applications from experts from civil society.[1] The application process is open, with the only criterion for appointment to the committees being the provision of evidence of scientific expertise in the appropriate specialised field. I would be pleased to receive applications from within your circle.

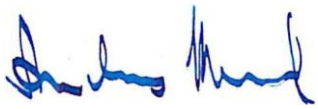
We are enclosing our detailed reply to points 1 to 8 of your letter as an annex to this letter.

In line with our transparency policy, we propose to publish this letter on the BfR website along with your letter of 24.02.2017 in order to make the discourse available to a wider public.

[1] You will find more information on the application procedure here:
http://www.bfr.bund.de/de/presseinformation/2017 /08/externe sachverstaendige fuer neubesetzung der bfr kommissionen gesucht-200058 .html.

Please let us know if you agree to the publication of your letter.

Yours sincerely,



Andreas Hensel

Annex
- Replies from the BfR to the points raised in the letter of 24.02.2017

This text version is a translation of the original German text which is the only legally binding version.

Annex

Replies from the BfR to the points raised in the letter of 24.02.2017:

Point (1):
You concede that the statement in your article is abbreviated and that the reference to the re-approval of the active substance is actually inaccurate in its form. The manufacturers could not, as was asserted in your article, choose the member state for the retesting of the active substance glyphosate. In line with the provisions of Art. 18 of Regulation (EC) No 1107/2009, the Commission prepares a work programme for the re-approval of active substances. In this regard, your statement is not abbreviated, it is wrong.

Point (2):
You say that you merely describe what actions the industry takes in a pesticide authorisation procedure and how the manufacturers make the pre-selection of the scientific studies. In my opinion, an important piece of information on EU legislation is missing here, which I already described in my letter of 30 January 2017, but you make no mention of it. The manufacturers must submit updated versions of all legally required documentation in accordance with regulations (EC) Nos 283/2013 and 284/2013. It is explicitly listed in the introductions to the annexes to these regulations that the information to be presented must satisfy the following requirements among others: “All information concerning the possible damaging effects of the active substance, its metabolites and contaminants on human and animal health or on groundwater must be contained”. The studies are in no way selected at random but rather in line with clear, legally prescribed rules. The term “pre-selection” suggests that it is at the discretion of the applicant which studies are selected for presentation. Where the scientific literature is concerned, it is pointed out that the applicants must process and report on the results of their literature research in compliance with the “GUIDANCE OF EFSA - Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009” (EFSA Journal 2011;9(2):2092).

Point (3):
You write that German authorities are regarded as friendly to industry and quote in your letter “numerous interviews and extensive research” as the basis for this statement. For me as a scientist, this is an assertion that cannot be backed up and a purely subjective estimation. In the remainder of the article you do not refer to “interviews and research” but rather to the legal European process and the alleged fact that the manufacturers of pesticides can decide by themselves in which EU country the test is to take place where the re-approval of glyphosate is to be carried out. That is not correct, as explained in Point 1.

Point (4):
The BfR and the European Food Safety Authority included all of the findings and available data and information in line with the current state of science and technology. In addition to the studies submitted by the applicants, this includes all other studies available to the BfR, including those not conducted in line with GLP, and all available scientific publications. The “independent studies” to which you refer are an integral part of the risk assessment and there is no focus on manufacturers’ studies.

Point (5):
Transparency is necessary on all levels of risk assessment. As you correctly point out, we already implement our transparency promise within the framework of European legislation and jurisdiction.

Point (6):
Even after you named the source for the assertion in your letter, I cannot follow your statement that no “independent study” was ever classified as a reliable key study in the BfR glyphosate risk assessment. The BfR conducts scientific assessments with the inclusion of all available data and information (see the answer to Point 4). In doing so, the studies are evaluated with regard to their scientific acceptance and relevance for each concrete assessment issue. A categorisation of studies as “key studies” is not made.

Point (7):
As outlined above, the only institution in the world to date to come to the conclusion that there is “sufficient evidence” that glyphosate is carcinogenic in animals bases its hazard estimation on publications about studies which were funded by industry. The argument that data which comes from industry and is not publicly accessible leads to the result “no risk” while data which is available to experts and the general public leads to the result “probably carcinogenic” is therefore incorrect. Moreover, the BfR has never given the assurance that the “hazard estimation of the WHO cancer agency is insignificant”, as you claim. On the contrary, the BfR explicitly made a scientific check of the IARC monograph on behalf of the federal government. Written evidence of this can be found at:
http://www.bfr.bund.de/cm/343/bfr-prueft-monographie-der-internationalen-agentur-fuer-krebsforschung-iarc-zu-glyphosat-divergenzverfahren-innerhalb-der-who-noch-nicht-aufgehoben.pdf

The idea that reference to the results of other scientifically renowned institutions could foster mistrust in the BfR communication is, in my view, unfounded. It goes without saying that the general public has the right to know which scientists worldwide have arrived at which conclusions.

I was astonished to read your assertion that the BfR presentation was misleading. The categorisation of a substance as “carcinogenic” would preclude its approval. The BfR and EFSA have clearly communicated on several occasions that, in compliance with the criteria of the valid legislation governing pesticides, as well as the current level of available knowledge, the categorisation of glyphosate as carcinogenic is not necessary: (http://www.efsa.europa.eu/de/efsajournal/pub/4302). Along with the experts of the member states, the BfR and EFSA have not been able to derive any “sufficient evidence” from experiments with animals. There is divergence here with the IARC: (http://www.bfr.bund.de/de/fragen_und_antworten_zur_unterschiedlichen_einschaetzung_der_krebserzeugenden_wirkung_von_glyphosat_durch_bfr_und_iarc-195575.html). This result was last confirmed by the ECHA RAC:

http://www.bfr.bund.de/cm/343/echa-klassifiziert-glyphosat-als-nicht-krebserregend-nicht-mutagen-und-nicht-reproduktionstoxisch.pdf

Of course there should be reports and discussion about differences in scientific assessments. Scientific debate is essential and an intrinsic component of the scientific system. The challenge lies in assessing scientific studies independently, transparently and with assured quality, because politics and administration need sound advice in order to reach knowledge-based decisions.

Point (8):
You criticise a lack of sensitivity on the part of the BfR when dealing with conflicts of interest. I cannot accept this either, since all declarations of interest are published in the internet and are queried at the meetings – as can be read in the published minutes.

I would also like to emphasise here once again that the BfR committees do not conduct or give their consent to any risk assessments. The BfR performs its legal risk assessment tasks independently of the BfR committees and vice-versa. Risk assessments are conducted solely by our staff members. The BfR committees have no influence of any kind on the decision processes at the BfR and usually convene twice a year for a meeting. Conversely, though, it cannot be concluded from this circumstance that the BfR committees would then necessarily be “superfluous” (just because they do not have the influence that you claim they have). They provide scientific advice and assure the external quality control of the work conducted by the BfR, and they help us to identify additional research requirements and to further develop scientific research concepts.

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