By The Institute of Science in Society Science Society Sustainability http://wwwby http://www.i-sis.org.uk/Scandal_of_Glyphosate_Reassessment_in_Europe.php

Press Release

EU rapporteur state Germany recommends re-approval with daily intake increased by 67 %; its re-assessment was carried out by Monsanto and a consortium of chemical companies in Europe based almost entirely on studies from industry; it should be rejected outright ***Dr Nancy Swanson***
and
Dr Mae Wan Ho

Preposterous verdict of “acceptable” risks for glyphosate

Germany, acting as the European Union rapporteur member state (RMS) submitted their glyphosate renewal assessment report (RAR) to the European Food Safety Authority (EFSA) in January 2014, recommending re-approval of glyphosate for use in Europe with increase in the acceptable daily intake (ADI) from 0.3 to 0.5 mg per kg body weight per day [1].

The overall findings of the RAR are that glyphosate poses no unacceptable risks. Glyphosate is not metabolized or accumulated in the body, not genotoxic, not carcinogenic, not endocrine disrupting, and not considered persistent or bioaccumulative; it has no reproductive toxicity, no toxic effects on hormone-producing or hormone-dependent organs, and no unacceptable effect on bees. Therefore any risks are within acceptable standards. The only risks noted were that

glyphosate is a severe eye irritant and is persistent in soil.

Issues that could not be finalized in the assessment were: relevance of impurities, effects on microorganisms, effects on non-targeted plants, and indirect effects on biodiversity - non-targeted organisms, particularly birds.

The Proposed Decision at the end of Vol. 1 is completely blacked out.

Scandalous conclusion amid overwhelming evidence of toxicities

How did they arrive at such a preposterous conclusion when the evidence for glyphosate herbicides toxicity has accumulated worldwide to such an extent that a number of countries are already banning its use? Denmark took the lead to ban the herbicide back in 2003 [2] The Dutch Parliament banned it in April 2014 for non-commercial use [3], to take effect by the end of 2015; France is set to follow. Brazil, one of the largest growers of glyphosate-tolerant genetically modified (GM) crops has now filed a law suit by Federal Prosecutors to ban glyphosate along with 8 other dangerous pesticides [4]. El Salvador imposed a complete ban in February 2013, linking glyphosate herbicides to an epidemic of chronic kidney disease that has struck the region [5]. Sri Lanka's scientists have provided evidence for glyphosate accumulation in the body especially in the presence of hard water. Its ability to capture and retain arsenic and nephrotoxic metals enables it to act as a carrier to deliver the toxins to the kidney [6] (see [7] Sri Lanka Partially Bans Glyphosate for Deadly Kidney Disease Epidemic
,
SiS
62). The Sri Lankan government initially instituted a ban, but reneged under pressure from industry [8].

Glyphosate has also been linked to many other health problems including cancers (see [9] Glyphosate and Cancer
,
SiS 62
), infertility (see [10]
Glyphosate/Roundup & Human Male Infertility
,
SiS
62), along with neurotoxicity, reproductive problems, birth defects, genotoxicity, and other human health problems as well as ecotoxicity (see [11]
Ban GMOs Now
, special ISIS report), and many have considered a world-wide ban long overdue.

A severely restrictive electronic-only and biased comment process

EFSA had put the RAR on their website for public consultation, which ended 11 May 2014. The response was electronic only on a rigid template with predetermined categories of answers, and severe limitations on space. Neither e-mail, nor ordinary mail was accepted. Commenters had to sign an agreement to have their comments deleted if deemed unsuitable. Thus, all comments relating to Roundup were ignored, even though Roundup is the most widely used glyphosate herbicide in Europe. The consultation was strictly limited to pure glyphosate. Dr Brian John of GM-Free Cymru lodged a complaint with the European Ombudsman saying that EFSA had no right to impose those conditions, accusing the process of being [12] “biased, and heavily weighted towards those who want to see glyphosate continue in use” and “entirely unfit for purpose.”

The entire process of risk assessment was also completely non-transparent.

Who were the authors of the risk assessment report?

The German Federal Institute for Risk Assessment (BfR-- Bundesinstitut für Risikobewertung) is responsible for the RAR. There is no information on authorship anywhere within the 15 documents totalling 3 744 pages [13]. Between April and June of 2014, the BfR was contacted and asked on four separate occasions to provide information on who authored the report and which committee at BfR was responsible for the report. To date, they have not responded.

The BfR Committee for Pesticides and Their Residues (CPTR), which might be expected to be responsible for preparing the RAR, has 3 out of 12 of its 2014 members and 4 out of its 16 2011-2013 members from either BASF or Bayer CropScience [14, 15]. This serious conflict of interest in a regulatory agency is not restricted to BfR, it is endemic to the EU regulatory agency.

EFSA has a history of conflicts of interest. The Corporate Europe Observatory report ' Unhappy Meal'
published in October 2013 [16], revealed that some 59 % of EFSA's scientific panel members still had direct or indirect links to companies whose activities fell under EFSA’s remit. As a result the European Parliament voted in April 2014 for a resolution to ban scientists with ties to the agriculture and food industries from working at the agency, and has given EFSA two years to clean up its act [17].

But the conflict of interest is even more blatant than anyone could have imagined. It is Monsanto and a consortium of European chemical companies that performed the risk assessment for the re-approval of glyphosate.

Monsanto & a consortium of European chemical companies did the risk assessment

The BfR stated in its press release [18]: “Apart from the BfR, other institutes involved in the new assessment of glyphosate were the Federal Environment Agency, the Julius Kühn Institute and the Federal Office of Consumer Protection and Food Safety, the latter as risk management authority.” That was designed to add undue respectability and gravitas to the risk assessment.

But BfR and its federal agency partners did not actually review the published toxicology studies. Instead they relied on a summary provided to them by the Glyphosate Task Force (GTF) [19]. And the GTF consists of Monsanto and a consortium of chemical companies all over Europe, including Syngenta UK and Dow Italy, with an odd one from Taiwan thrown in for good measure (see pp. 9-13 of Vol. 1 of the RAR [13]). Although the BfR added comments here and there, all the assessments of the toxicological studies were from the GTF. Hence Monsanto and other companies who stood to gain from selling glyphosate herbicides were given free rein to pronounce glyphosate effectively even safer than before, hence the increase in ADI.

Let us be clear: even the industry’s studies found toxic effects for acute (single dose), subchronic (short-term) and chronic (long-term) exposures at some dosage . The way the game is played is to vary the dose and find the maximum dose where no adverse effects are observed (NOAL). Then divide that by 100 to obtain the ADI and declare the substance “safe”. The chemical industries
already know
that glyphosate is toxic and can cause a host of physical problems.

Selective ‘expert’ rejection of counter-evidence

The GTF used a scheme devised by H.J. Klimisch and other scientists working for BASF in 1997 to assess the reliability of toxicological studies [20]. The method aims to classify toxicological data into one of four categories: reliable without restriction, reliable with restrictions, not reliable, and not assignable. However, the assignment is weighted toward industry studies and is heavily dependent on the judgment of the human toxicologists involved. It can certainly not overcome human bias.

Consequently, the rapporteur member state (RMS) has accepted, without question, virtually all of the unpublished reports given to them by the chemical companies. Much of the information is blacked out (author, report title, laboratory) but the sponsoring company is named (Monsanto, Syngenta etc.) and the reports are referred to by a number.

When the industry toxicology reports were in conflict with each other, they chose to sanction the ones that reported less toxic responses, relegating others to “supplementary” status. When the toxic effects were significant compared to their own controls, they used illicit “historical controls” instead to make them appear less significant.

Of the published reports, with the exception of genotoxicity, they only used those that tested for glyphosate alone. The glyphosate was “supplied by Monsanto at 99% purity.” That, despite the fact that the public has been using nothing but formulations, especially Roundup!

The GTF took all of the peer-reviewed studies and proceeded to find excuses to throw out the ones that didn’t agree with the already-accepted industry studies. First they threw out all studies that used the actual product (Roundup, Rodeo, Lasso etc.) because the active ingredient percentage is not the same from product to product and the surfactants used vary from product to product so the results cannot be compared and are thus inconclusive. They threw out any studies where they deemed that the dosage was unreasonably high, compared to their “safe” levels, although their own toxicology studies showed the same results at the higher dosages. They threw out any that they decided were inapplicable to mammals (frog embryos, insect larvae etc.) or that were administered in a non-natural way (injection). They took issue with how many rats/mice/dogs/guinea pigs were or were not used and how things were or were not measured or reported.

For human studies, the GTF argued that the dose/response could not be determined; the toxic effect could not be traced to glyphosate alone, the application rates were unreasonable for Europe, or there were reporting deficiencies of some sort.

For more details see a synopsis of the toxicology section of the RAR prepared by Nancy Swanson [21].

To conclude

The entire process of risk assessment for re-approval was flawed and corrupt to the core. It is rife with conflict of interest, non-transparent and heavily biased towards unpublished, non-peer reviewed studies from industry. The RAR is worse than useless, and should be rejected outright. All available evidence including studies on commercial formulations of glyphosate herbicides should be seriously considered in any risk assessment, and by a truly independent, unbiased panel free from any conflict of interest.

We thank Rosemary Mason for providing crucial information and discussion in preparing this report.

References

1. Announcement of RAR finalized on BfR website: http://www.bfr.bund.de/en/the_bfr_has_finalised_its_draft_report_for_the_re_evaluation_of_glyphosate-188632.html

2. Glyphosate, Wikibooks, 17 March 2013, http://en.wikibooks.org/wiki/Horticulture/Glyphosate

3. “Dutch Parliament bans Roundup, France and Brazil to follow”, The Healthy Home Economist, 12 April 2014, http://www.thehealthyhomeeconomist.com/roundup-banned-netherlands-france-brazil-likely-soon-follow/

4. Brazil’s Federal Public Prosecutor Requests Total Ban of Glyphosate Herbicides. SustainablePulse.com, accessed 26th March 2o14. http://sustainablepulse.com/2014/03/26/brazils-federal-public-prosecutor-requests-total-ban-glyphosate-herbicides/#.UzL_A_l_vTE

5. El Salvador Government Bans Roundup over Deadly Kidney Disease. Sustainablepulse.com, accessed 27th February 2014 http://sustainablepulse.com/2013/09/19/el-salvador-government-bans-roundup-over-deadly-kidney-disease/#.Uw94kfl_uSo

6. Jayasumana C, Gunatilake S, Senanayake P. Glyphosate, hard water and nephrotoxic metals: are they the culprits behind the epidemic of chronic kidney disease of unknown etiology in Sri Lanka? *International Journal of Environmental Research and Public Health* 2014, *11*, 2125-2147; doi:10.3390/ijerph110202125

7. Sirinathsinghji E. Sri Lanka partially bans glyphosate for deadly kidney disease epidemic. Science in Society 62
, 18-21, 2014.

8. “Sri Lanka lifts ban on sale of glyphosate”, Sustainable Pulse, 13 May 2014, http://sustainablepulse.com/2014/05/13/sri-lanka-lifts-ban-sale-glyphosate/#.U7p8znnjjIU

9. Ho MW. Glyphosate and Cancer. Science in Society, to appear. 2014

10. Ho MW. Glyphosate/Roundup and Human Male Infertility. Science in Society, to appear.

11. Ho MW and Sirinathsinghji E. *Ban GMOs*Now, ISIS, 2013, http://www.i-sis.org.uk/Ban_GMOs_Now.php

12. “EFSA’s public consultation on glyphosate is “entire unfit for purpose””, GM-Free Cymru, 23 May 2014, http://www.gmfreecymru.org/news/Press_Notice23May2014.html

13. Renewal Assessment Report on glyphosate (2014). Vol. 1. Report & proposed decision, 174 pages. Report and Proposed Decision. (Summary); Vol. 2 Annex A. List of tests & studies, 251 pages; Vol. 3 Annex B.1. Identity, 12 pages. (Molecular structure and description); Vol. 3 Annex B.2. Physical & chemical properties, 41 pages; Vol. 3 Annex B.3. Data on application and further information, 30 pages. (Application rate, storage & handling); Vol. 3 Annex B.4. Proposals for the classification and labelling, 3 pages; Vol. 3 Annex B.5. Methods of analysis, 103 pages. (Analytical methods for determination of active substance, impurities and residues); Vol. 3 Annex B.6.1. Toxicology and metabolism, 947 pages. (Animal and human toxicology); Vol. 3 Annex B.7. Residue data. 965 pages. (Crop residues); Vol. 3 Annex B.8. Environmental fate and behaviour, 361 pages; Vol. 3 Annex B.8 (Appendix). Evaluation of open literature

regarding environmental fate and behaviour, 323 pages; Vol. 3 Annex B.9. Ecotoxicology, 314 pages; (Non-targeted plants, birds, fish and other creatures); Vol. 3 Annex B.9 (Appendix). Evaluation of peer-reviewed literature on ecotoxicology, 201 pages; List of endpoints, 77 pages; List of information, tests and studies which are considered as relied upon by the RMS for evaluation, 143 pages. (This document has been taken down from the website after 11 May, but one of us has kept a copy.)

14. 2014 members of BfR Committee for Pesticides and Their Residues. http://www.bfr.bund.de/en/members_of_bfr_committee_for_pesticides_and_their_residues-189322.html

15. 2011-13 members of BfR Committee for Pesticides and Their Residues. http://www.bfr.bund.de/en/members_of_bfr_committee_for_pesticides_and_their_residues-53534.html

16. “Unhappy meal. The European Food Safety Authority’s independence problem”, Corporate Europe Observatory, 23 October 2013, http://corporateeurope.org/efsa/2013/10/unhappy-meal-european-food-safety-authoritys-independence-problem

17. “The European Parliament demans stricter regulation of conflicts of interest at EU’s food safety authority”, Corporate Europe Observatory, 3 April 2014, http://www.corporateeurope.org/pressreleases/2014/04/european-parliament-demands-stricter-regulation-conflicts-interest-eus-food

18. Glyphosate: no more poisonous than previously assumed, although a critical view should be taken of certain co-formulants, BfR website: http://www.bfr.bund.de/en/press_information/2014/03/glyphosate__no_more_poisonous_than_previously_assumed__although_a_critical_view_should_be_taken_of_certain_co_formulants-188898.html

19. Glyphosate facts. Transparency on safety aspects and use of glyphosate-containing herbicides in Europe, accessed 7 July 2014, http://www.glyphosate.eu/

20. Klimisch score. Wikipedia, 19 August 2012, http://en.wikipedia.org/wiki/Klimisch_score

21. Swanson N. Glyphosate re-assessment in Europe is corrupt, 8 July 2014, https://www.academia.edu/7595699/Glyphosate_re-assessment_in_Europe_is_corrupt_Toxicology