

German Glyphosate Reassessment is fraudulent: reply to the CMO for Scotland 30/07/2014

In a Press Release in March 2014, The President of the German Federal Institute of Risk Assessment (BfR), Prof Dr Dr Andreas Hensel, on the basis of evaluation of 150 new studies and an additional 900 studies from the scientific journals, was quoted as having said on behalf of BfR: *These new studies do not suggest that glyphosate has carcinogenic or embryo-damaging properties or that it is toxic to reproduction in test animals. The data do not warrant any significant changes in the limit values of the active ingredient...*¹

The BfR legal department claims that the reassessment was solely done by BfR staff members

On 15/07/2014 Herr König, on behalf of the BfR Justizariat (Legal Department), wrote to Dr Nancy Swanson with regard to her request for information (06/04/2014) about the Renewal Assessment Report (RAR) on glyphosate. Herr König said that the work on the RAR on glyphosate was “solely done by the BfR staff members of department no. 6, who are civil servant employees.”

This was not what independent scientists from the Institute of Science in Society discovered

This seems to contradict the findings of Dr Nancy Swanson and Dr Mae Wan Ho of the Institute of Science in Society (I-SIS) after detailed examination of the 15-volume, 3,744 page RAR.²

“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...

Consequently, the rapporteur member state (RMS) has accepted, without question, virtually all of the unpublished reports given to them by the chemical companies.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...

Conclusion: *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.*

The President of the BfR said that glyphosate did not affect humans and animals

In the second part of the Press Release the President went on to say: *Worldwide, glyphosate is one of the most common active ingredients in pesticides used to prevent unwanted plant growth in plant cultivation or to accelerate the ripening process of crops (desiccation). Glyphosate inhibits an enzyme which is essential for the biosynthesis of certain amino acids. This enzyme is not found in animals and humans. The statement by BfR is incorrect: glyphosate poisons humans in the same way as it poisons plants. Humans and animals have exactly the same pathway as in plants; mammals can only absorb nutrients via the bacteria in their gut; the gut microbiome. The gut microbiome is the collective genome of organisms inhabiting our body.*³

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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

² http://www.i-sis.org.uk/Scandal_of_Glyphosate_Reassessment_in_Europe.php

³ <http://www.nature.com/nature/journal/v500/n7464/abs/nature12506.html>

This lie (which must have been promoted by Monsanto since Prof Jonathan Jones of the Sainsbury Laboratory first told me in 2011) has been perpetuated by the GM industry and their supporters

In 2010, in a document on glyphosate uses in Europe, Monsanto describes it as “environmentally benign” ...“has an excellent safety profile to operators, the public and the environment”...“uses to benefit mankind and the environment.”⁴ Glyphosate has been used by many farmers in the UK for desiccation (drying) of crops since about 2004 hence we are all exposed to glyphosate residues in our staple, non-organic foods⁵ (and in beer and whisky since 2007) .

The 2002 German reassessment of glyphosate must have been done by the pesticides industry

We have to assume that the BfR assessment in 2002 was done by industry as well. The link used by a Monsanto scientist in the US to prove that glyphosate did not bio-accumulate was to the European Assessment 2002.⁶ By excluding many independent studies, in 2014 they still appear to be attempting to convince the public that residues do not accumulate in humans and animals.

Delays by the European Commission and EFSA

Could that be linked to the fact that the reassessment due in 2012 was delayed after a 52-page document from Earth Open Source⁷ was sent to former European Commissioner John Dalli?⁸ Roundup® and Birth defects: Is the public being kept in the dark? “The EU Commission dismissed these findings, based on a rebuttal provided by the German Federal Office for Consumer Protection and Food Safety, BVL. BVL cited unpublished industry studies to back its claim that glyphosate was safe...However, shortly after the Commission was notified of the latest research showing that glyphosate and Roundup cause birth defects, it quietly passed a directive delaying the review of glyphosate and 38 other dangerous pesticides until 2015.”

In addition in 2012, Dr Graciela Gomez, an Argentinian lawyer, came to Europe to petition European Commissioner Dalli on behalf of rural communities in Argentina against glyphosate, which was causing birth defects and cancers.

The European Commission and EFSA appear to have delayed it even further.

On 24/07/2014 I had an apology from the Chief Attorney to EFSA, Mr Dirk Detken, for not having replied to my email of December 13 2013 Subject: Corporate Espionage: The Séralini Affair and Beyond.⁹ The Chief Attorney stated that: “The publication of the EFSA conclusion completing this procedure is anticipated to take place by May-June 2015.”

UK Parliament Meeting Brings ‘Dangers’ of Roundup® into Public Focus. This meeting of world experts on glyphosate held on June 18 2014¹⁰ was not reported by the UK mainstream Media

The All-Party Parliamentary Group (APPG) on Agroecology, Chaired by the Countess of Mar, met in the Houses of Parliament in London on June 18, 2014 to discuss the possible harm caused by the world’s most popular herbicide – Roundup®.

In what was one of the most comprehensive meetings ever held in Europe on Glyphosate and Roundup, experts from around the World gathered in London to share their expertise with the media, members of a number of UK political parties, NGO representatives and members of the public.

⁴ <http://www.monsanto.com/products/Documents/glyphosate-background-materials/Agronomic%20benefits%20of%20glyphosate%20in%20Europe.pdf>

⁵ <http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/PRiF/about-PRiF>

⁶ http://ec.europa.eu/food/plant/protection/evaluation/existactive/list1_glyphosate_en.pdf

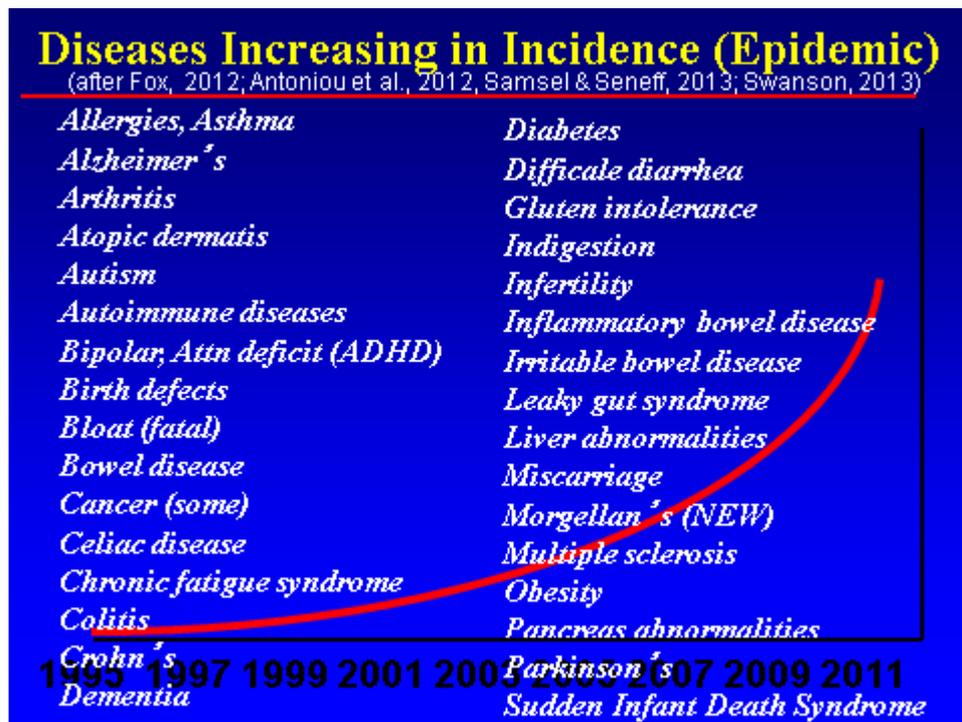
⁷ <http://www.earthopensource.org/files/pdfs/Roundup-and-birth-defects/RoundupandBirthDefectsv5.pdf>

⁸ John Dalli, the former European Health and Consumers Commissioner, was forced to resign in October 2012 after allegedly being involved in a bribery scandal.

⁹ <https://independent.academia.edu/RosemaryMason>

¹⁰ http://sustainablepulse.com/2014/07/02/uk-parliamentary-meeting-brings-dangers-roundup-public-focus/#.U7TvD-j_hzl

The World Health Organisation and the Chief Medical Officer for England, Professor Dame Sally Davies both declared that antibiotic-resistant diseases pose an apocalyptic threat to humans. The CMO placed the blame on vets, farmers and GPs for over-use of antibiotics. In 2013 the CMO told Parliament that this issue should be added to the national risk register of civil emergencies. When I informed her that glyphosate was an antibiotic, she replied that this was up to the pesticide regulators to decide. I wrote to inform Prof Mark Woolhouse, Professor of Infectious Disease Epidemiology at the University of Edinburgh and Dr Jeremy Farrar, Director of the Wellcome Trust when they published an article in Nature on 29/04/2014 about the Intergovernmental Panel on Antimicrobial Resistance.¹⁹ An Editorial in the same journal states:²⁰ *"If the threat of antibiotic resistance is to be managed, existing drugs must be marshalled more effectively and new medicines must get to the market fast...Public education – both to restrict the waste of antibiotics and to build support for measures to restrict unnecessary use – is vital... There is no equivalent of Big Oil of Big Tobacco in this debate to delay and obfuscate."*
My intervention must have been very unwelcome and as yet I have had no reply.
 With Monsanto's chemical (antibiotic, antiprotozoal and chelator of minerals) glyphosate, which is sold around the world by all the pesticide companies, the day of the apocalypse is getting closer.²¹



Dr Huber's second slide shows diseases which have increased in incidence since 1995, correlated with the red line, which represents the increasing use of glyphosate in the US

The Cancer Research UK (CRUK) website shows similar graphs from 1975 (when glyphosate was introduced) for thyroid cancer,²² breast cancer,²³ prostate cancer,²⁴ malignant melanoma,²⁵ liver

¹⁹ <http://www.nature.com/news/policy-an-intergovernmental-panel-on-antimicrobial-resistance-1.15275>

²⁰ <http://www.nature.com/news/a-three-step-plan-for-antibiotics-1.15291>

²¹ http://www.naturalnews.com/044879_MERS_pandemic_Saudi_Arabia_drug-resistant_superbugs.html

²² <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/thyroid/incidence/>

²³ <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/breast/incidence/#trends>

²⁴ <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/prostate/incidence/uk-prostate-cancer-incidence-statistics#trends>

²⁵ <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/skin/incidence/uk-skin-cancer-incidence-statistics#trends>

cancer,²⁶ myeloma,²⁷ and anal cancer.²⁸ Michael Pragnell MA MBA was the founder of Syngenta and CEO of Syngenta AG based in Switzerland (from its public listing in 2000 to the end of 2007). He was appointed a Trustee of CRUK in March 2010 and Chairman in November 2010. CRUK is donating money (£450 million/year) to the Government's Strategy for UK Life Sciences²⁹ and AstraZeneca (Syngenta's parent company) is providing 22 compounds to academic research to develop medicines.

“Any change in policy made by the Scottish Government has to be based on evidence from recognized sources such as peer- reviewed journals and based on accredited research findings or observations” (letter from Dr Aileen Keel CBE, Acting CMO for Scotland 14/07/2014)

There are many of these studies (1,050 were reviewed by BfR). However, a large number of them were excluded by BfR (i.e. GTF) in favour of their own unpublished (and data-protected) studies.

How did the Rapporteur Member State (RMS), Germany and EFSA recommend re-approval?

The German RMS has excluded papers on the following topics:

- Evidence of diseases in humans and animals in South America associated with GMO agriculture and Monsanto's Roundup® Ready Soy; (reproductive problems, birth defects, DNA changes and cancers).³⁰ A report of the many types of birth defects in regions of Argentina has also been excluded.³¹



A baby with a neural tube defect; this is a meningo-myelocele. More extensive defects can occur. Hospital de Posadas, Misiones, Argentina. Photograph by kind permission of Dr Graciela Gomez.

- The original paper from Prof Andrès Carrasco's Embryology Department in Buenos Aires which described teratogenic effects (neural tube defects) in frog and chick embryos exposed

²⁶ <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/liver/incidence/#trends>

²⁷ <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/myeloma/incidence/#trends>

²⁸ <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/anal-cancer/Incidence/#Trends>

²⁹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/32457/11-1429-strategy-for-uk-life-sciences

³⁰ Lopez, S.L. *et al* GMO Pesticides Used in South American GMO-Based Agriculture: A Review of Their Effects on Humans and Animal Models. In *Advances in Molecular Toxicology*, Vol. 6, 201 published by Elsevier: ISSN 1872-0854.

³¹ <http://www.ncbi.nlm.nih.gov/pubmed/21132229> [Births prevalence of 27 selected congenital anomalies in 7 geographic regions of Argentina]. Campaña H et al. High frequencies regional analysis showed the following significant results: PAM: severe hypospadias; CEN: spina bifida, microtia, cleft lip with cleft palate, polycystic kidney, postaxial polydactyly and Down syndrome; CUY: postaxial polydactyly; NOA: omphalocele, gastroschisis, cleft lip without cleft palate, cleft lip with cleft palate, anorectal atresia/stenosis, indeterminate sex, preaxial polydactyly and pectoral agenesis; PAT: cleft lip without cleft palate.

to low dose glyphosate was considered.³² But this is what the RMS said about it: “*Not reliable. Non-guideline study that is not sufficiently described for assessment. Inadequate positive and negative control experiments. Not relevant. Irrelevant routes of exposure and inappropriately high doses. Test system not adequate for human risk assessment.*” (It was interesting to note that the BfR had included a letter by them criticising the publication.) However, a Medical Enquiry has at last been announced in Argentina into the effects on human health of glyphosate in GMO systems of agriculture. The problems were investigated on BBC Radio 4.³³ Prof Andr s Carrasco, who had been a member of Conicet, the Argentinian Scientific Committee, had continually challenged Monsanto and the pesticide regulators. He would have been a key witness. However, he died on May 10th 2014 at the age of 67, in the period between his giving evidence to Linda Pressly and when the BBC Radio 4 programme was broadcast on May 14th. These are Roundup® Ready GMO crops that the British Government is trying to force upon an unwilling British public.

- Other papers with evidence of Roundup® and birth defects in humans.³⁴ In Teratogenic effects of glyphosate-based herbicide: divergence of Regulatory Decisions from Scientific Evidence.³⁵ Prof Michael Antoniou (from the Department of Genetics at King’s College London) with a multinational team had managed to obtain a copy of the German DAR. They pointed out that evidence of teratogenicity had been found, but the German and EU authorities minimized these findings in their assessment and set a potentially unsafe acceptable daily intake (ADI) level for glyphosate.
- Any papers in which glyphosate or AMPA was detected in human urine; e.g. samples in Germany³⁶ and in the whole of Europe.³⁷ This means that Monsanto can maintain the claim of no accumulation, which they did in the 2002 EU reassessment. Moms Across America commissioned independent studies and found glyphosate in breast milk, urine and water.³⁸
- Prof Monika Kr ger’s (Leipzig Veterinary Laboratory) findings of glyphosate in animals³⁹ and humans, in sick animals and humans (Dairy cows in Germany had botulism⁴⁰) and dairy cows in Denmark⁴¹ which had evidence of liver and kidney dysfunction and increased lipid profile marker cholesterol as well as glyphosate in their urine. Watch this video of a German farmer whose cows had glyphosate in their urine and faeces and died from botulism.⁴² In a mega dairy in Wales 70 cows died from botulism in May 2014.

³² Paganelli, A. *et al.* Glyphosate-Based Herbicides Produce Teratogenic Effects on Vertebrates by Impairing Retinoic Acid Signaling *Chem. Res. Toxicol.*, 2010, 23 (10), 1586–1595. DOI: 10.1021/tx1001749

³³ <http://pubs.acs.org/doi/abs/10.1021/tx1001749>

³⁴ <http://www.bbc.co.uk/programmes/b042ldz0>

³⁵ <http://www.earthopensource.org/files/pdfs/Roundup-and-birth-defects/RoundupandBirthDefectsv5.pdf>

³⁶ Antoniou, M. *et al.* Teratogenic Effects of Glyphosate-Based Herbicides: Divergence of Regulatory Decisions from Scientific Evidence *J Environ Anal Toxicol* 2012, S:4 <http://dx.doi.org/10.4172/2161-0525.S4-006>

³⁷ A study has shown the presence of glyphosate in human urine in urban populations in Germany.

<http://www.ithaka-journal.net/herbizide-im-urin?lang=e>

³⁸ <http://www.foeeurope.org/weed-killer-glyphosate-found-human-urine-across-Europe-130613>

³⁹ http://www.momsacrossamerica.com/glyphosate_testing_results

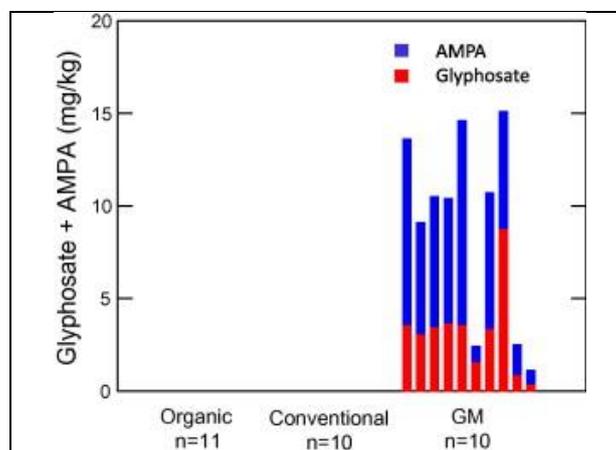
⁴⁰ Kr ger, M. *et al.* Glyphosate suppresses the antagonistic effect of *Enterococcus* spp. on *Clostridium botulinum*. *Anaerobe* 2013, Feb 6.

⁴¹ <http://www.ncbi.nlm.nih.gov/pubmed/22200452> Kr ger M *et al.* Visceral botulism at dairy farms in Schleswig Holstein, Germany: prevalence of *Clostridium botulinum* in feces of cows, in animal feeds, in feces of the farmers, and in house dust.

⁴² Glyphosate in urine of cows in Denmark; metabolic changes in blood parameters including increased lipid profile marker cholesterol <http://dx.doi.org/10.4172/2161-0525.1000186> This is the first study showing the extent of the exposure to glyphosate of Danish dairy cattle and its impact on different blood parameters.

⁴³ http://www.youtube.com/watch?v=iVjLtG3tn_E

- A combined study between researchers in the US and Australia from Carman & Vlieger⁴³ was a long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet. GM-fed females had on average a 25% heavier uterus than non-GM-fed females, a possible indicator of disease that requires further investigation. Also, the level of severe inflammation in stomachs was markedly higher in pigs fed on the GM diet.
- Prof Thomas Bøhn's paper from Norway which found that GM soya is not 'substantially equivalent' to non-GM was ignored.⁴⁴ This paper describes the nutrient and elemental composition, including residues of herbicides and pesticides, of 31 soy bean batches from Iowa, USA. In a commentary on the paper Bøhn wrote: "Extreme Levels" of Roundup® in Food Became the Industry Norm:⁴⁵ *"Roundup® Ready GM-soy accumulates residues of glyphosate and aminomethylphosphonic acid (AMPA) and GM soy also differs markedly in nutritional composition compared with soybeans from other agricultural practices. Organic soybean samples also showed a more healthy nutritional profile (e.g. higher in protein and lower in saturated fatty acids) than both industrial conventional and GM soybeans. Lack of data on pesticide residues in major crop plants is a serious gap of knowledge with potential consequences for human and animal health. How is the public to trust a risk assessment system that has overlooked the most obvious risk factor for herbicide tolerant GM crops, i.e. high residue levels of herbicides, for nearly 20 years? If it has been due to lack of understanding, it would be bad. If it is the result of the producer's power to influence the risk assessment system, it would be worse."*



From: Compositional differences in soybeans (Organic, Conventional and GM.) from Iowa, USA. Diagram by kind permission of Professor Thomas Bøhn, Genøk, Centre for Biosafety, Norway.

- Laboratory studies which showed that Formulated Roundup® affects cell cycle regulation⁴⁶ and activates DNA-Response checkpoint.⁴⁷

⁴³ <http://www.organic-systems.org/journal/81/8106.pdf>

⁴⁴ <http://www.sciencedirect.com/science/article/pii/S0308814613019201> Compositional differences in soybeans on the market: glyphosate accumulates in Roundup Ready GM soybeans.

⁴⁵ <http://www.independentsciencenews.org/news/how-extreme-levels-of-roundup-in-food-became-the-industry-norm/>

⁴⁶ Marc, J., Mulner-Lorillon, O., Bellé, R. Glyphosate-based pesticides affect cell cycle regulation.

<http://www.ncbi.nlm.nih.gov/pubmed/15182708>

⁴⁷ Marc, J., Bellé, R. Formulated Glyphosate Activates the DNA-Response Checkpoint of the Cell Cycle Leading to the Prevention of G2/M Transition Toxicological Sciences 2004, 82 (2): 436-442.

<http://toxsci.oxfordjournals.org/content/82/2/436.full.pdf>

- All papers involving testing of formulated chemicals (e.g. Roundup®). These contain commercially secret ingredients that help the chemicals penetrate the plant. These have been shown to be far more toxic than glyphosate alone.⁴⁸
- Samsel & Seneff's two papers^{49, 50} were notably absent. I have a copy of a letter sent by Lord de Mauley and the CRD to Lord Hylton which says: *"The review paper by Samsel and Seneff referred to by Dr Mason suggests possible links between exposure to glyphosate and a wide range of human diseases. CRD notes that many of the proposed associations between glyphosate and human disease seem hypothetical rather than being based on convincing evidence to support cause and effect."* Nevertheless the CRD had agreed to submit this paper to Germany, the Rapporteur Member State for glyphosate for its review of the chemical.
- In 2012, Séralini's team performed 24 month feeding studies in rats (GM Roundup® Ready maize, also with Roundup® separately) instead of Monsanto and EFSA's 90 days. Séralini's team found disturbances of liver and kidney function. Tumours started to grow in males at 4 months (mostly renal) and females (mostly mammary) and there was evidence of endocrine disruption. (Endocrine disruption had already been reported with glyphosate.) This 12-minute YouTube made by Séralini's team over the 2-year period of testing in rats.⁵¹ Fourteen months after publication and following the appointment of a Monsanto Scientist to the *Journal of Food and Chemical Toxicology* (FCT), the paper was withdrawn.

Brief summary of BfR evaluation of peer-reviewed literature regarding ecotoxicity (RAR Vol 3 Annex B9): Most ecotoxicity papers appear to have been discounted or dismissed

Aquatic organisms: Summary page 64. *"It was not possible to distinguish between the effects of the technical glyphosate and the surface active substance added to the commercial formulation."*

Aquatic vertebrates: Summary page 68. *"No report of statistical power of test glyphosate: most on commercial formulations."*

Effects on amphibians: Summary page 95. *"Does not resemble the lead formulation for EU assessment of renewal approval of glyphosate as an active substance."*

Terrestrial arthropods including bees: Summary page 113 *"Summary of relevant literature in 31 publications: none of the publications acceptable for risk assessment."*

Effects on earthworms: Page 123. Twenty one publications submitted. Summary of relevant literature in earthworms: *"Herbicide application did not directly affect movement or reproduction. The outcome of risk assessment did not change."*

Effects on soil non-target micro-organisms; Page 143. *"No negative effects at the moment, but should be included in future risk assessments."*

Glyphosate detected in the organs of 38 piglets with birth defects⁵²

Glyphosate was detected in all organs of one-day-old malformed Danish piglets (N=38). This paper was presented at the Symposium on Glyphosate held in Beijing in July 2014.

⁴⁸ A further independent paper published in December 2013 showed that: "Roundup® was by far the most toxic among the herbicides and insecticides tested. Most importantly, 8 formulations out of 9 were several hundred times more toxic than their active principle. <http://www.hindawi.com/journals/bmri/aip/179691/>

⁴⁹ Glyphosate's Suppression of Cytochrome P450 Enzymes and Amino Acid Biosynthesis by the Gut Microbiome: Pathways to Modern Diseases. <http://www.mdpi.com/1099-4300/15/4/1416>

⁵⁰ Glyphosate, pathways to modern diseases II: Celiac sprue and gluten intolerance.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3945755/>

⁵¹ http://www.youtube.com/watch?v=Njd0RugGjAg&feature=player_embedded

⁵² <http://omicsonline.org/open-access/detection-of-glyphosate-in-malformed-piglets-2161-0525.1000230.pdf>

The researchers note, "Further investigations are urgently needed to prove or exclude the role of glyphosate in malformations in piglets and other animals."

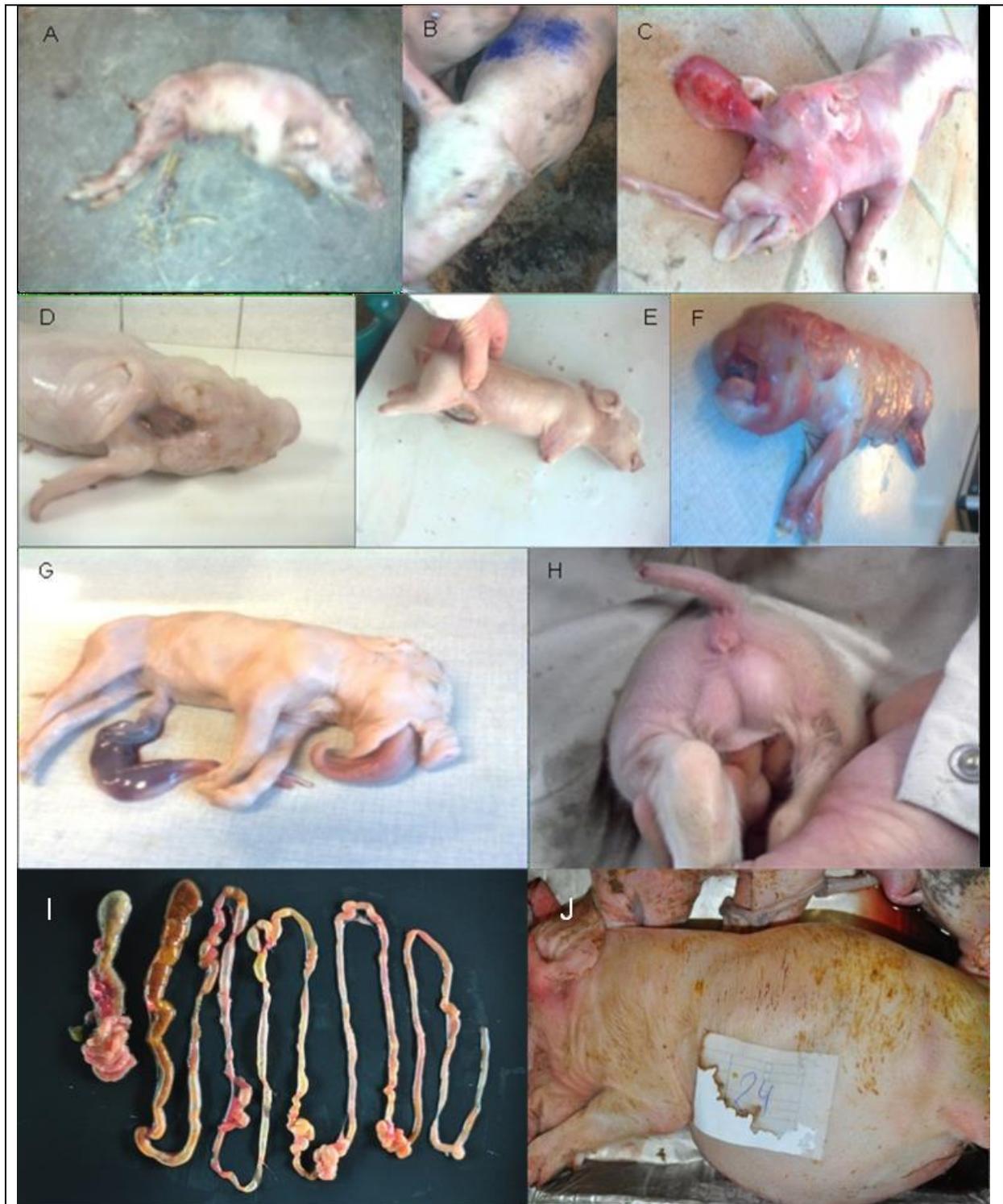


Figure 1: Selected pictures of malformed Danish piglets. A: spinal deformation, B: ear is not formed, C: cranial deformation, D: cranium hole in head, E: piglets born alive having short legs and one eye not developed, F: one large eye, an elephant trunk with bone in it, G: elephant tongue, H: female piglet with testes, I: fore gut and hind gut of the piglet with swollen belly are not connected, J: malformed piglet with swollen belly. Photos by kind permission of Ib Borup Pedersen.

Rosemary Mason MB ChB FRCA on behalf of global citizens 30/07/2014