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Monsanto Knew of Glyphosate (Roundup)-Cancer Link 35 Years Ago

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According to evidence unearthed from the archives of the EPA (Environmental Protection Agency) in the United States, it has been established that Monsanto was fully aware of the potential of glyphosate to cause cancer in mammals as long ago as 1981.

Recently the WHO's International Agency for Research on Cancer (IARC) issued a statement in which glyphosate (the main component of Roundup herbicide) was classified as "probably carcinogenic" to humans and as "sufficiently demonstrated" for genotoxicity in animals (1). This announcement of a change to toxicity class 2A was given vast coverage in the global media, causing Monsanto to move immediately into damage limitation mode. The corporation demanded the retraction of the report, although it has not yet been published! Predictably, there was more fury from the industry-led Glyphosate Task Force (2). This Task Force also sponsored a "rebuttal" review article (3) from a team of writers with strong links with the biotechnology industry; but because of the clear bias demonstrated in this paper (which suggests that glyphosate has no carcinogenic potential in humans) it is best ignored until it has been carefully scrutinized by independent researchers (4).

With Monsanto continuing to protest that glyphosate and Roundup are effectively harmless (5) if used according to instructions, in spite of accumulating evidence to the contrary, we undertook a search through Environmental Protection Agency (EPA) records with a view to finding out what was known about glyphosate at the time of its initial registration. This followed up earlier investigations by Sustainable Pulse which highlighted a sudden change in the EPA view on toxicity in 1991. What was discovered was very revealing. There were many animal experiments (using rats, mice and dogs) designed to test the acute and chronic toxicity of glyphosate in the period 1978-1986, conducted by laboratories such as Bio/dynamics Inc for Monsanto and submitted for EPA consideration. Two of these reports relate to a three-generation reproduction study in rats (6) (7), and another is called "A Lifetime Feeding Study Of Glyphosate In Rats" (8); but like all the other older studies they were and still are treated as Trade Secrets and cannot be freely accessed for independent scrutiny. That in itself is suggestive that the studies contain data which Monsanto still does not wish to be examined by experts in the toxicology field. It is also deeply worrying that EPA acceded to the routine Monsanto requests for secrecy on the flimsiest of pretexts.

However, archived and accessible EPA Memos from the early 1980's do give some indications as to what the rat studies contain (9). Although the studies predate the adoption of international test guidelines and GLP standards they suggest that there was significant damage to the kidneys of the rats in the 3-generational study — the incidence of tubular dilation in the kidney was higher in every treated group of rats when compared to controls. Tubular dilation and nephrosis was also accompanied by interstitial fibrosis in all test groups

and in some of the lumens the researchers found amorphous material and cellular debris. Less than a third of the control rats showed signs of tubular dilation. In the rat study results, the changes in the bladder mucosa are significant because metabolites, concentrated by the kidneys, have led to hyperplasia that could be considered as a very early and necessary step in tumour initiation. EPA was worried in 1981 that these indications were sinister, and at first declined to issue a NOEL (no observed adverse effect level) — it asked for further information and additional research. In its 1982 Addendum, Monsanto presented evidence that minimised the effects and confused the data — and on that basis EPA accepted that glyphosate was unlikely to be dangerous. But Monsanto knew that scrutiny of the data in the studies would potentially threaten its commercial ambitions, and so it asked for the research documents concerned to be withheld and treated as Trade Secrets. So there was no effective independent scrutiny. Monsanto and EPA connived in keeping these documents away from unbiased expert assessment, in spite of the evidence of harm. (It is clear that EPA was thinking about carcinogenic effects — it knew in 1981 that glyphosate caused tumorigenic growth and kidney disease but dismissed the finding as "a mystery" in order to set the NOEL for the chemical and bring it to market.)

In the rat studies, the glyphosate doses fed to the test groups were 1/100 of those used in a later mouse study (9). It is unclear why these very small doses were decided upon by Monsanto and accepted by EPA, since there must be a suspicion that the studies were manipulated or designed to avoid signs of organ damage. In its 1986 Memo, EPA remarked on the very low doses, and said that no dose tested was anywhere near the "maximally tolerated dose." Then the Oncogenicity Peer Review Committee said: "At doses close to an MTD, tumours might have been induced." A repeat rat study was asked for. However, BioDynamics (which conducted the research for Monsanto) used data from three unrelated studies, which they conducted in house, as historical controls to create "experimental noise" and to diminish the importance of the results obtained by experiment.

In a 1983 mouse study conducted by Bio/dynamics Inc for Monsanto (10), there was a slight increase in the incidence of renal tubular adenomas (benign tumours) in males at the highest dose tested. Malignant tumours were found in the higher dose group. However, "it was the judgment of two reviewing pathologists that the renal tumors were not treatment-related". Other effects included centrilobular hypertrophy and necrosis of hepatocytes, chronic interstitial nephritis, and proximal tubule epithelial cell basophilia and hypertrophy in females. The EPA committee determined there was a "weak oncogenic response" — so evidence was suggestive of early malignancy. The EPA Science Advisory Panel was asked for advice, and they said the data were equivocal and called for further studies in mice and rats. A further report was delivered in 1985. Part of the reason for this dithering was the prevalent but false EPA belief that all physiological effects had to be dose-related: namely, the higher the dose, the greater the effect.

Even though pre-cancerous conditions were imperfectly understood 35 years ago, and cortical adenomas in kidney were not thought dangerous at the time, the evidence from the Memos is that Monsanto, BioDynamics Inc and the EPA Committees involved were fully aware, probably before 1981, of the carcinogenic potential of glyphosate when fed to mammals. In the Memos there are references to many more "secret" animal experiments and data reviews, which simply served to confuse the regulators with additional conflicting data. Thus EPA publicly accepted the safety assurances of the Monsanto Chief of Product Safety, Robert W. Street, and the status of the product was confirmed for use in the field (11). But behind the scenes, according to a later EPA memo (in 1991), its own experts knew

before 1985 that glyphosate causes pancreatic, thyroid and kidney tumors.

On the EPA website (last updated 31.10.2014) reference is made to five Monsanto studies of 1980 – 1985, and it is noteworthy that these studies have not been made public in the light of current knowledge about malignant tumours and pre-cancerous conditions (12). Neither have they been revisited or reinterpreted by Monsanto and EPA, although one 1981 rat study and one 1983 mouse study are mentioned in the recent review by Greim et al (2015) (3). Following the conclusion that glyphosate was "not classifiable as to human carcinogenicity" nothing in the EPA advice about this chemical has changed since 1990. Given the recent assessment by the WHO Panel, and given the flood of scientific papers relating to health damage associated with glyphosate (13) the EPA attitude smacks of complacency and even incompetence.

Speaking for GM-Free Cymru, Dr Brian John says: "The evidence shows that by 1981 both Monsanto and the EPA were aware of malignant tumours and pre-cancerous conditions in the test animals which were fed small doses of glyphosate in the secret feeding experiments. Although concerns were expressed at the time by EPA committees, these concerns were later suppressed under the weight of conflicting evidence brought forward by Monsanto, some of it involving the inappropriate use of historical control data of dubious quality. None of these studies is available for independent examination (14). That is a scandal in itself. There has been a protracted and cynical cover-up in this matter (15). Glyphosate is a "probable human carcinogen", as now confirmed by the WHO Working Group, and no matter what protestations may now come from Monsanto and the EPA, they have been fully aware of its potential to cause cancer for at least 35 years. If they had acted in a precautionary fashion back then, instead of turning a blind eye to scientific malpractice (16), glyphosate would never have been licensed, and thousands of lives might have been saved."

Retired Academic Pathologist Dr Stanley Ewen says: "Glyphosate has been implicated in human carcinogenesis by IARC and it is remarkable that, as early as 1981, glyphosate was noted to be associated with pre neoplastic changes in experimental mice. This finding was never revealed by the regulatory process and one might therefore expect to see human malignancy increasing on the record in the ensuing years. John Little (personal communication) has demonstrated an unexpected and alarming 56% upsurge in malignancy in England in those under 65 in the past 10 years. Presumably British urinary excretion of glyphosate is similar to the documented urine levels in Germany, and therefore everyone is at risk. The effect of glyphosate on endocrine tissue such as breast and prostate, or even placenta, is disruptive at least and an increased incidence of endocrine neoplasia is likely to be seen in National Statistics. The Glyphosate Task Force denies the involvement of glyphosate in human malignancy despite their knowledge of many reports of lymphomas and pituitary adenomas in experimental animals dosed with glyphosate. On the other hand, Prof. Don Huber at a recent meeting in the Palace of Westminster, has warned of severe consequences if rampant glyphosate consumption is not reined in. I feel sure that the suppression of the experimental results of 1981 has enhanced the global risk of malignancy."

Toxico-pathologist Professor Vyvyan Howard says: ""The drive towards transparency in the testing of pharmaceuticals is gathering pace with legislation in the EU, USA and Canada being developed. All trials for licensed drugs will likely have to become available in the public domain. In my opinion the case with agrochemicals should be no different. At least

with pharmaceuticals exposure is voluntary and under informed consent. There are several biomonitoring studies which demonstrate that there is widespread exposure of human populations to glyphosate, presumably without informed consent. Given the clear level of mistrust over the licensing of this herbicide and the emerging epidemiological evidence of its negative effects there can, in my opinion, be no case whatsoever for keeping the toxicological studies, used to justify licencing, a secret. They should be put in the public domain."

Research scientist Dr Anthony Samsel says: "Monsanto's Trade Secret studies of glyphosate show significant incidence of cell tumors of the testes and tumorigenic growth in multiple organs and tissues. They also show significant interstitial fibrosis of the kidney including effects in particular to the Pituitary gland, mammary glands, liver, and skin. Glyphosate has significant effects to the lungs indicative of chronic respiratory disease. Glyphosate has an inverse dose response relationship, and it appears that its effects are highly pH dependent. Both Monsanto and the EPA knew of the deleterious effects of this chemical in 1980 at the conclusion of their multiple long-term assessments, but the EPA hid the results of their findings as "trade secrets." Monsanto has been lying and covering up the truth about glyphosate's harmful effects on public health and the environment for decades. The increases in multiple chronic diseases, seen since its introduction into the food supply, continue to rise in step with its use. Monsanto's Roundup glyphosate based herbicides have a ubiquitous presence as residues in the food supply directly associated with its crop use. Nations must stand together against Monsanto and other chemical companies who continue to destroy the biosphere. We are all part of that biosphere and we are all connected. What affects one affects us all."

Notes

(1) Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate (2015)
Kathryn Z Guyton, Dana Loomis, Yann Grosse, Fatiha El Ghissassi, Lamia Benbrahim-Tallaa, Neela Guha, Chiara Scoccianti, Heidi Mattock, Kurt Straif, on behalf of the International Agency for Research on Cancer Monograph Working Group, IARC, Lyon, France
Lancet Oncol 2015. Published Online March 20, 2015 http://dx.doi.org/10.1016/S1470-2045(15)70134-8
International Agency for Research on Cancer 16 Volume 112: Some organophosphate insecticides and herbicides: tetrachlorvinphos, parathion, malathion, diazinon and glyphosate. IARC Working Group. Lyon; 3–10 March 2015. IARC Monogr Eval Carcinog Risk Chem Hum (in press).

(2) Monsanto seeks retraction for report linking herbicide to cancer
By Carey Gillam, Reuters
http://www.reuters.com/article/2015/03/24/us-monsanto-herbicide-idUSKBN0MK2GF20150324
The response by the pesticide industry association, the Glyphosate Task Force, is here:
http://www.wmcactionnews5.com/story/28574811/statement-of-the-gtf-on-the-recent-iarc-decision-concerning-glyphosate

(3) Helmut Greim, David Saltmiras, Volker Mostert, and Christian Strupp (2015) REVIEW ARTICLE: Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies. Crit Rev Toxicol, 2015; Early Online: 1–24 DOI: 10.3109/10408444.2014.1003423

(4) Not only is this paper written by authors who have strong industry links, but the 14 carcinogenicity studies assessed are carefully selected industry studies which have not been peer-

reviewed and published in mainstream scientific journals. All of the studies were conducted for clients (like Monsanto) who would have experienced gigantic commercial repercussions if anything "inconvenient" had been reported upon, with glyphosate already in use across the world. Therefore the possibility of fraud and data manipulation cannot be ruled out. The 14 studies are all secret, and cannot be examined by independent toxicology experts. The fact that the review article in question reproduces (as online supplementary material) a series of tables and data sets is immaterial, since the data are useless in the absence of clear explanations of the laboratory protocols and practices of the research teams involved.

(5) http://www.monsanto.com/glyphosate/pages/is-glyphosate-safe.aspx

(6) "A Three-Generation Reproduction Study in Rats with Glyphosate" (Final Report; Bio/dynamics Project No. 77-2063; March 31, 1981) — submitted by Monsanto to EPA

(7) "Addendum to Pathology Report for a Three-Generation Reproduction Study in Rats with Glyphosate. R.D. #374; Special Report MSL-1724; July 6, 1982″ EPA Registration No 524-308, Action Code 401. Accession No 247793. CASWELL#661A" — submitted by Monsanto to EPA

(8) "A Lifetime Feeding Study Of Glyphosate In Rats" (Report by GR Lankas and GK Hogan from Bio/dynamics for Monsanto. Project #77-2062, 1981: MRID 00093879) — submitted by Monsanto to EPA
and Addendum Report #77-2063

(9) Archived EPA memos from 1982 and 1986:
http://www.epa.gov/pesticides/chemicalsearch/chemical/foia/cleared-reviews/reviews/103601/103601-135.pdf
http://www.epa.gov/pesticides/chemicalsearch/chemical/foia/cleared-reviews/reviews/103601/103601-210.pdf
The 1991 EPA Memo is accessible via:
http://sustainablepulse.com/2015/03/26/who-glyphosate-report-ends-thirty-year-cancer-cover-up/#.VSVPZ2Z3bJk

(10) Knezevich, AL and Hogan, GK (1983) "A Chronic Feeding study of Glyphosate (Roundup Technical) in Mice". Project No 77-2061. Bio/dynamics Inc for Monsanto. Accession No #251007-251014 — document not available but cited in EPA 1986 Memo.
Follow-up study: McConnel, R. "A chronic feeding study of glyphosate (Roundup technical) in mice: pathology report on additional kidney sections". Unpublished project no. 77-2061A, 1985, submitted to EPA by BioDynamics, Inc.

(11) Glyphosate was first registered for use by the United States Environmental Protection Agency (U.S. EPA) in 1974, and after various reviews reregistration was completed in 1993.
Glyphosate (CASRN 1071-83-6)
Classification — D (not classifiable as to human carcinogenicity)
Basis — Inadequate evidence for oncogenicity in animals. Glyphosate was originally classified as C, possible human carcinogen, on the basis of increased incidence of renal tumors in mice. Following independent review of the slides the classification was changed to D on the basis of a lack of statistical significance and uncertainty as to a treatment-related effect.
http://www.epa.gov/iris/subst/0057.htm
http://sustainablepulse.com/2015/03/26/who-glyphosate-report-ends-thirty-year-cancer-cover-up/
npic.orst.edu/factsheets/glyphotech.pdf

(12) Monsanto Company. 1981a. MRID No. 0081674, 00105995. Available from EPA. Write to FOI, EPA, Washington, DC 20460.
Monsanto Company. 1981b. MRID No. 00093879. Available from EPA. Write to FOI, EPA, Washington, DC 20460.
Monsanto Company. 1985. MRID No. 00153374. Available from EPA. Write to FOI, EPA, Washington, DC 20460.
Monsanto Company. 1980a. MRID No. 00046362. Available from EPA. Write to FOI, EPA, Washington, DC 20460.
Monsanto Company. 1980b. MRID No. 00046363. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

(13) http://www.i-sis.org.uk/Scandal_of_Glyphosate_Reassessment_in_Europe.php
http://permaculturenews.org/2012/11/01/why-glyphosate-should-be-banned-a-review-of-its-hazards-to-health-and-the-environment/
Key studies showing toxic effects of glyphosate and Roundup. Ch 4 in GMO Myths and Truths
http://earthopensource.org/earth-open-source-reports/gmo-myths-and-truths-2nd-edition/
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
http://www.earthopensource.org/files/pdfs/Roundup-and-birth-defects/RoundupandBirthDefectsv5.pdf

(14) That having been said, Monsanto has allowed access to selected later reports to selected researchers (Greim et al, 2015). It is still uncertain whether these selected reports are available in full, for detailed independent scrutiny — even though there can now be no possible justification for "trade secret" designation, following the lapse of the US glyphosate patent in 2000.

(15) http://sustainablepulse.com/2015/03/26/who-glyphosate-report-ends-thirty-year-cancer-cover-up/
In 1985 the carcinogenic potential of glyphosate was first considered by an EPA panel, called the Toxicology Branch Ad Hoc Committee. The Committee then classified glyphosate as a Class C Carcinogen on the basis of its carcinogenic potential. This classification was changed by the EPA in 1991 to a Class E category on the basis of "evidence of non-carcinogenicity for humans". Mysteriously this change in glyphosate's classification occurred during the same period that Monsanto was developing its first Roundup-Ready (glyphosate-resistant) GM Crops. Not for the first time, commercial considerations were allowed to trump public health concerns.
The EPA scale of cancer-forming potential of substances:
Group A: Carcinogenic to humans
Group B: Likely to be carcinogenic to humans
Group C: Suggestive evidence of carcinogenic potential
Group D: Inadequate information to assess carcinogenic potential
Group E: Not likely to be carcinogenic to humans

(16) Wikipedia 2012: Internal EPA Memos Document Fraud
1983 EPA Scientist on EPA's public stance: "Our viewpoint is one of protecting the public health when we see suspicious data." Unfortunately, EPA has not taken that conservative viewpoint in its assessment of glyphosate's cancer causing potential."
"There are no studies available to NCAP evaluating the carcinogenicity of Roundup or other glyphosate-containing products. Without such tests, the carcinogenicity of glyphosate-containing products is unknown."

"Tests done on glyphosate to meet registration requirements have been associated with fraudulent practices."
"Countless deaths of rats & mice are not reported."
"Data tables have been fabricated"
"There is a routine falsification of data"

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