How Monsanto suppressed Professor Andrès Carrasco's research on teratogenicity of glyphosate-based herbicides

US EPA Glyphosate Issue Paper: Evaluation of Carcinogenic Potential[1]
Page 158 Carrasco, A. E. (2011). "Reply to the Letter to the Editor Regarding Our Article (Paganelli et al., 2010)." *Chem. Res. Toxicol.* 24(5): 610-613. The original article was not disclosed because the Glyphosate Task Force Renewal Assessment Report (RAR) in Europe had already rejected it.

Prof Andrès Carrasco and his team in Buenos Aires showed that glyphosate-based herbicides caused malformations in amphibian and chicken embryos
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[2]
Reports of neural defects and craniofacial malformations from regions where glyphosate-based herbicides (GBH) are used led them to undertake an embryological approach to explore the effects of low doses of glyphosate in development. Treated embryos were highly abnormal with marked alterations in cephalic and neural crest development and shortening of the anterior-posterior (A-P) axis. It was shown that the effects were due to the glyphosate itself, rather than the additive.

When carrying out the Renewal Assessment Report (RAR) for glyphosate, why did the European GTF exclude most papers from Latin America that reported birth defects and cancers associated with glyphosate: and why did they dismiss papers that showed teratogenicity?
In the RAR for glyphosate a total of 18 peer-reviewed publications showing reproductive toxicity were ranked 3 – not reliable. The RAR commented on the study by *Paganelli et al.* [3] It was very revealing. Whoever reviewed it wanted it deleted, regardless of content.
This was the classic study from Professor Andrès Carrasco in the University of Buenos Aires that showed embryological evidence in frogs and chicks, of what was happening to human embryos in the Crop-sprayed towns of Argentina.
RAR Report: "The study reported endocrine disruption but was deemed "*not reliable*". The RAR commented: *"Non-Guideline study that is not sufficiently described for assessment - Inadequate positive and negative control experiments. Irrelevant routes of exposure and inappropriately high doses. Test system not adequate for human risk assessment"* [Volume 3 Annex B.6.1, p 669]. Furthermore, *"multiple high-quality toxicity studies and expert review panels consistently agree glyphosate is not a teratogen or reproductive toxicant. The author's justification for this research is flawed, providing no valid basis, other than an opinion, of an increase in the rate of birth defects in Argentina. Direct injection of frog embryos and through chick egg shells do not reflect real world exposure scenarios to either environmental species or humans."* [4] There were several papers on the increasing rate of birth defects in South America where GM Roundup Ready crops are grown; but the European Glyphosate Task Force had excluded all of them.

GMO Pesticides Used in South American GMO-Based Agriculture: A Review of Their Effects on Humans and Animal Models [5]

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[1] https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094
[2] http://www.ncbi.nlm.nih.gov/pubmed/20695457
[3] 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 http://pubs.acs.org/doi/abs/10.1021/tx1001749
[4] http://www.i-sis.org.uk/Scandal_of_Glyphosate_Reassessment_in_Europe.php
[5] 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 http://www.sciencedirect.com/science/article/pii/B9780444593894000021

Genetically-Engineered Corn and Roundup®-Ready Soya were introduced into the rural towns of Argentina and Paraguay in 1996. The devastation of human and animal health and biodiversity is described in this chapter: *"In South America, the incorporation of genetically modified organisms (GMO) engineered to be resistant to pesticides changed the agricultural model into one dependent on the massive use of agrochemicals. Different pesticides are used in response to the demands of the global consuming market to control weeds, herbivorous arthropods, and crop diseases. Here, we review their effects on humans and animal models, in terms of genotoxicity, teratogenicity, and cell damage. We also stress the importance of biomarkers for medical surveillance of populations at risk.*

Cancer and detrimental reproductive effects in an Argentine agricultural community environmentally exposed to glyphosate[6]

"*Over the last 20 years, industrial agriculture in Argentina has expanded by almost 50 %, taking over regions intended for other productions, for family farming, and most of all, forests. More and more children are born with defects in these areas, especially if the first months of pregnancy coincide with the time of spraying. Down's syndrome, spina bifida, myelo-meningocele (neural tube defect), congenital heart disease, etc. are diagnosed more frequently in those areas; in some towns and during some years, at triple the normal rates, and directly linked to increased pesticide applications around the towns... Neural tube defects are among the most common developmental birth defects observed, which is consistent with lab studies and farm observations…The model of agricultural production foisted on Argentina by international biotechnology companies has led to 858 % increase in the amount of pesticides used per year, resulting in a massive environmental and health impact in the region. Glyphosate is the most commonly used toxic agrochemical in Argentina, comprising 64 % of total sales, and 200 million litres of glyphosate were applied during the last crop season… The clinical manifestations that physicians working in the crop-sprayed towns find in patients are consistent with the results of scientific research on the effects of various pesticides including glyphosate on experimental animals. Laboratory research by our Scientists show how glyphosate acts on embryonic development to produce birth defects, and how this poison damages DNA molecules in the cell nucleus, promoting mutant cell lines that will cause cancer if they cannot be eliminated by the individual."*

Fig 1 shows: The rise in birth defects correlates with the rise in cultivation of GM glyphosate-tolerant soybeans in Chaco, Argentina. Birth defects per 10 000 live births increased from approx. 15/10,000 live births in 1997 to approx. 82/10,000 live births in 2008.

They produced evidence of *in vitro* genotoxicity of an environmental metabolite of glyphosate (AMPA) in humans as assessed by the Comet assay and cytogenetic tests.

Birth defects in seven regions of Argentina

A report of the many types of birth defects in seven geographical areas of Argentina[7] was excluded from the BfR glyphosate re-assessment (it was in Spanish, but with an English abstract). A sample of 21,844 new born with birth defects was selected, ascertained from 855,220 births, between 1994 and 2007, in 59 hospitals belonging to the ECLAMC network.

Extracts: "*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*." [Metropolitana (MET); Pampa (PAM); Centro (CEN); Cuyo (CUY); Noroeste (NOA); Nordeste (NEA) and Patagonia (PAT)].

Drastic action was taken to stop the public presentation of Carrasco's paper in La Leonesa

[6] http://www.amsi.ge/jbpc/31515/15-3-abs-2.htm

[7] http://www.ncbi.nlm.nih.gov/pubmed/21132229 [Births prevalence of 27 selected congenital anomalies in 7 geographic regions of Argentina]. Campaña H

Monsanto must have been sufficiently worried about the damaging nature of this research that showed glyphosate to be a teratogen (and a carcinogen) that someone stopped the presentation of this paper to the residents of Crop-Sprayed Towns of Argentina. Many of these rural residents had experienced birth defects and cancers that had been ignored by local health officials. On 7th August 2010 Professor Andrès Carrasco, lead embryologist at the University, Buenos Aires Medical School and the Argentinean National Research Council, came to give a talk about his research to community activists and residents gathered in La Leonesa. His research showed that Roundup, an agrochemical used on genetically modified soy and rice in Argentina, causes birth defects in animal embryos at levels far below those frequently used in agricultural spraying. A delegation of public officials and residents from the nearby community of Resistencia also came to La Leonesa to hear the talk.[8] *"But it never took place. As the delegation walked towards the school where the talk was to be held, it was attacked by a violent mob of approximately 100 people. Three people were seriously injured. Carrasco and a colleague shut themselves in a car and were surrounded by people beating the vehicle for two hours. Witnesses believe that a local rice producer and officials had organised the attack to protect agribusiness interests. As the police seemed reluctant to intervene, Amnesty International subsequently called for an investigation."* [9]
The Amnesty International investigation established that: "*One person has since suffered from lower body paralysis after being hit on his spine, and another is undergoing neurological examinations after receiving blows to the head. The former provincial Sub-Secretary of Human Rights, Marcelo Salgado, was struck in the face and left unconscious. Members of the community were injured and a journalist's camera equipment was damaged*.

Prof Andrès Carrasco's death occurred on May 10th 2014
A Medical Enquiry had been announced in Argentina into the effects on human health of glyphosate in GMO systems of agriculture in 2014. The problems were investigated on BBC Radio 4.[10] Prof Andrès Carrasco, who had been a member of Conicet, the National Scientific and Technical Research Council – Argentina, had continually challenged Monsanto and the pesticide regulators. **He would have been a key witness**. However, he died suddenly 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.

Monsanto on trial in France for Roundup causing serious malformations 14/06/2018
Glyphosate: For the first time in France, the parents of a child born with serious malformations are suing Monsanto in court. "*A moral duty to act*", according to these parents who hope, through their struggle, to prevent other tragedies from happening.[11]
William Bourdon was one of the lawyers, who testified at the International Monsanto Tribunal. He is an expert on Freedom of Information and Transnational Corporations,[12] He said: "*Monsanto is a caricature of what a multinational corporation is able to do. In the name of extreme profit and greed, globally it organises in a sophisticated manner, directly or not, serious violations of freedom of information and freedom of scientific research. I explained to the judges that this aggressive approach featuring conflicts of interest and corruption of public decision making in order to turn it to your advantage, is the only consequence of the global monopoly strategy set up by Monsanto. Global monopoly necessarily comes with disinformation and concealment, since Monsanto is obsessed with*

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8 http://www.theecologist.org/blogs_and_comments/commentators/other_comments/686959/revealed_the_glyphosate_research_the_gm_soy_lobby_doesnt_want_you_to_read.html
9 http://www.amnesty.org/en/library/asset/AMR13/005/2010/en/303e9ee6-9138-405f-97fc-ed58965b76d0/amr130052010en.html
10 http://www.bbc.co.uk/programmes/b042ldz0
11 https://www.la-croix.com/France/Justice/Glyphosate-famille-contre-Monsanto-2018-06-14-1200947226
12 https://vimeo.com/217296721

keeping its impunity and un-liability, despite all scandals regarding its marketed products (deadly products) which features appeared to be the opposite of what was advertised. ***It is a great global lie organised to benefit Monsanto."***

In 2017, The Monsanto Papers, a collection of documents released in the US in a collective action by farmers suffering from cancers, showed that Monsanto, now acquired by the German firm Bayer, knew from 1999 the mutagenicity of glyphosate, but concealed it.

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

Julieta, who died aged 7 months from multiple abnormalities in 2010 Bandera Santiago del Estero Photograph by kind permission of Dr Graciela Gomez

Monsanto's Mission Statement for its projects in Latin America (2012 website)
"*Monsanto is committed to helping improve lives – especially the lives of farmers in small rural communities around the world*." Pablo Vaquero, Monsanto Latin America South corporate affairs director, said: "*Today, we are helping to change the lives of many individuals in remote and forgotten communities where opportunities are scarce. We are convinced that by helping with training and education, as a company, we are able to add value to people and their communities.*" *'Projects have been implemented in 14 provinces in Argentina (Buenos Aires, Santa Fe, Córdoba, La Pampa, San Luis, Santiago del Estero, Entre Ríos, Corrientes, Formosa, Misiones, Salta, Tucumán, Jujuy and Chaco) and one in the Republic of Paraguay. Many farmers and people know about Monsanto Company because of the Roundup® Ready trait, which is a trait that gives in-plant tolerance to Roundup® agricultural herbicides. The trait was introduced to the market in 1996 and brought a whole new element to farmers. In 1996, farmers could now plant soybeans, spray the*

soybeans with Roundup®, and poof- the weeds were gone and the soybeans were still as healthy as they were before they sprayed the field'.

The European Monitoring of Congenital Anomalies 2017: increases in certain anomalies [13]
The increasing trends in the pan-Europe analysis were identified for the following subgroups: Ventricular Septal Defect (VSD); Atrial Septal Defect (ASD); Tricuspid atresia and stenosis; Hypoplastic right heart; Multicystic renal dysplasia; Congenital hydronephrosis; Club foot – talipes equinovarus; Laterality Anomalies.
The data for East Midlands and South Yorkshire have been excluded because they are a year behind in their reports. Therefore, only Northern England, Thames Valley, South West England, UK Wessex and UK Wales have been analysed.
Clusters: Skeletal dysplasias in Wales (18 cases observed versus seven expected).
The registries involved will continue to monitor these anomalies.
Eight types of congenital anomaly have increased in Europe between 2006 and 2015.

Massive amounts of pesticides have been sprayed on UK crops
People have been exposed to increasing amounts of Roundup in their food (Roundup sprayed by UK farmers went from 226,762 kg in 1990 to 2,240,408 kg in 2016, a 10-fold increase in 16 years because of Roundup-resistant weeds. The same happened in Argentina). Other pesticides were used by farmers in the UK. At the RSM Conference on pesticides safety the Soil Association presented alarming figures. [14] Under FOI request Fera Science (previously a government agency, now privatized) provided figures that showed that the number of active ingredients applied to wheat had risen **12-fold** from 1.7 in 1974 to 20.7 in 2014; that those applied to potatoes had risen **5.8** times from 5.3 in 1975 to 30.8 in 2014; that those applied to onions and leeks had risen **18-fold** from 5.3 in 1975 to 30.8 in 2014. Pesticides are tested individually but no one tests the cocktail of pesticides to which humans and the environment are exposed.

However, the extent of usage of glyphosate on 'amenity' land is 'unknown' or not recorded
The Chemicals Regulation Directorate commissioned a Report *Determining the Usage and Usage Patterns of Amenity Pesticides Across the UK*, from Risk & Policy Analysts in association with Britt Vegetation Management.[15] It was published in February 2011.
The customers for Contractors were: all local authorities across the UK; transport organisations (including the Highways Agency, Network Rail, British Waterways and airport management companies); Ministry of Defence; sports and leisure clubs and facilities (including golf clubs, football clubs, cricket clubs, rugby clubs, bowling greens, leisure centres); conservation bodies (including the National Trust, local Wildlife Trusts, the RSPB, Natural England, National Park Authorities, Countryside Council for Wales, Scottish Natural Heritage and the Environment and Heritage Service Northern Ireland); industrial premises, factories and utility companies; and contracted third parties.
The surface types considered were: amenity grass; sports turf; amenity woodland including tree and shrub beds; riparian and aquatic areas; roads; and other hard surfaces, including gravel/ballast surfaces, pavements and kerbs.

Rosemary Mason 18 June 2018

[13] https://ec.europa.eu/jrc/en/publication/european-monitoring-congenital-anomalies-jrc-eurocat-report-statistical-monitoring-congenital
[14] https://www.soilassociation.org/news/2017/november/rapid-increase-in-pesticide-use-and-new-evidence-of-health-impacts-of-very-low-doses/
[15] Amenity_Pesticide_Report_Final Feb 2011.pdf