

# « The Guardians of reason »

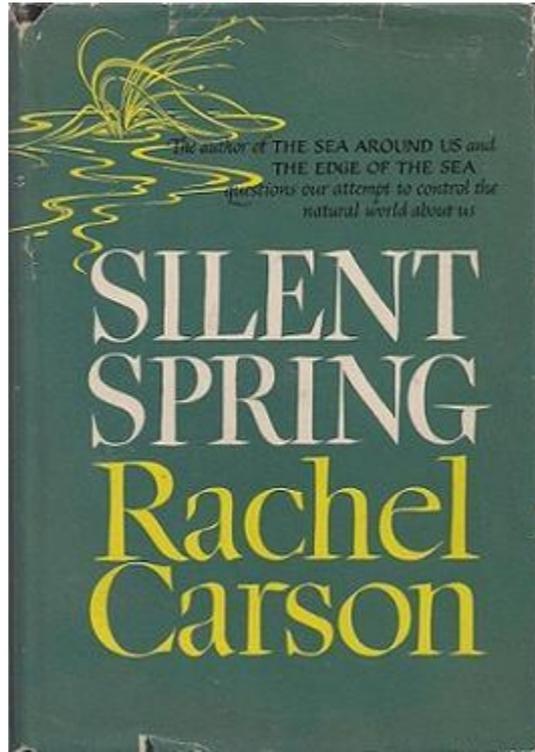
***Deny, avoid, and circumvent  
the scientific evidence  
on pesticides  
& other chemicals***

Stéphane Foucart (*Le Monde*)

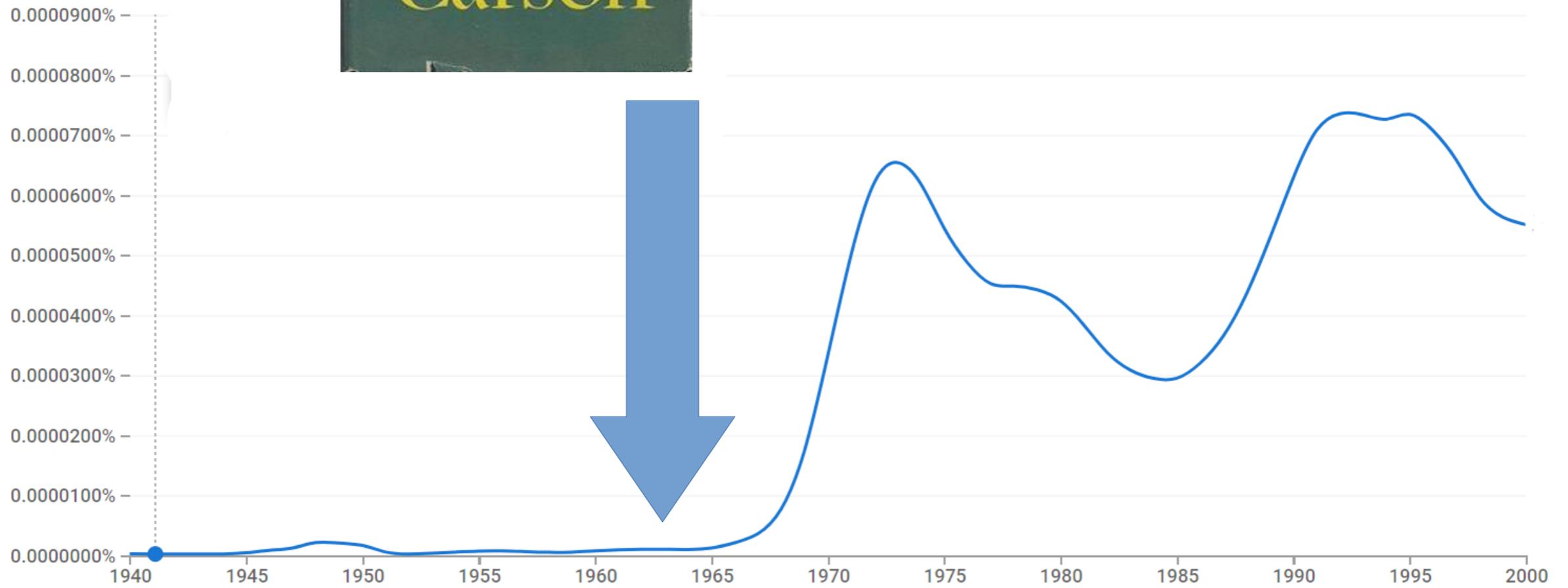
Brussels, 5 octobre 2022

*Silent Spring* 60th anniversary





**« Protect the environment »**  
written English, 1940-2000  
(Google NGram)



# Back in 1993

actions."

"However, without a major, concentrated effort to expose the scientific weaknesses of the EPA case, without an effort to build considerable reasonable doubt about that case -- particularly among consumers -- then virtually all other efforts including the effort to achieve a more balanced approach by OSHA, will be significantly diminished in effectiveness. This is the toughest challenge of all, the one against which the clock is ticking the fastest and the one that should

Strategy (lifted from page two of attached document number one, "ETS Media Strategy")

"The growing perceptions about and animosity toward EPA, as an agency that is at least misguided and aggressive, at worst corrupt and controlled by environmental terrorists, offer one of the few avenues for inroads. Of particular importance are the scare tactics and the scientific laxity of the risk assessment process, the economic and social harm of over-regulation and the out-of-control

**"The credibility of EPA is defeatable, but not on the basis of ETS alone. It must be a part of a larger mosaic that concentrates all of the EPA's enemies against it at one time."**

While this strategy represents a specific approach to media (please read document one, ETS Media Strategy) it also provides a strategic

From: Thomas Borelli

Subject: GEP review

I reviewed the criteria. It's not a bad place to start by it lacks teeth and as written it does not have enough meat to help us on ETS. However setting up our own standards is a good project for us and our consultant's program. It would be good offensive strategy for our consultant's to be out there trying to fix epidemiology instead of being critical all the time. I will send you a copy of the Carlo survey on epi standards as a possible starting point.

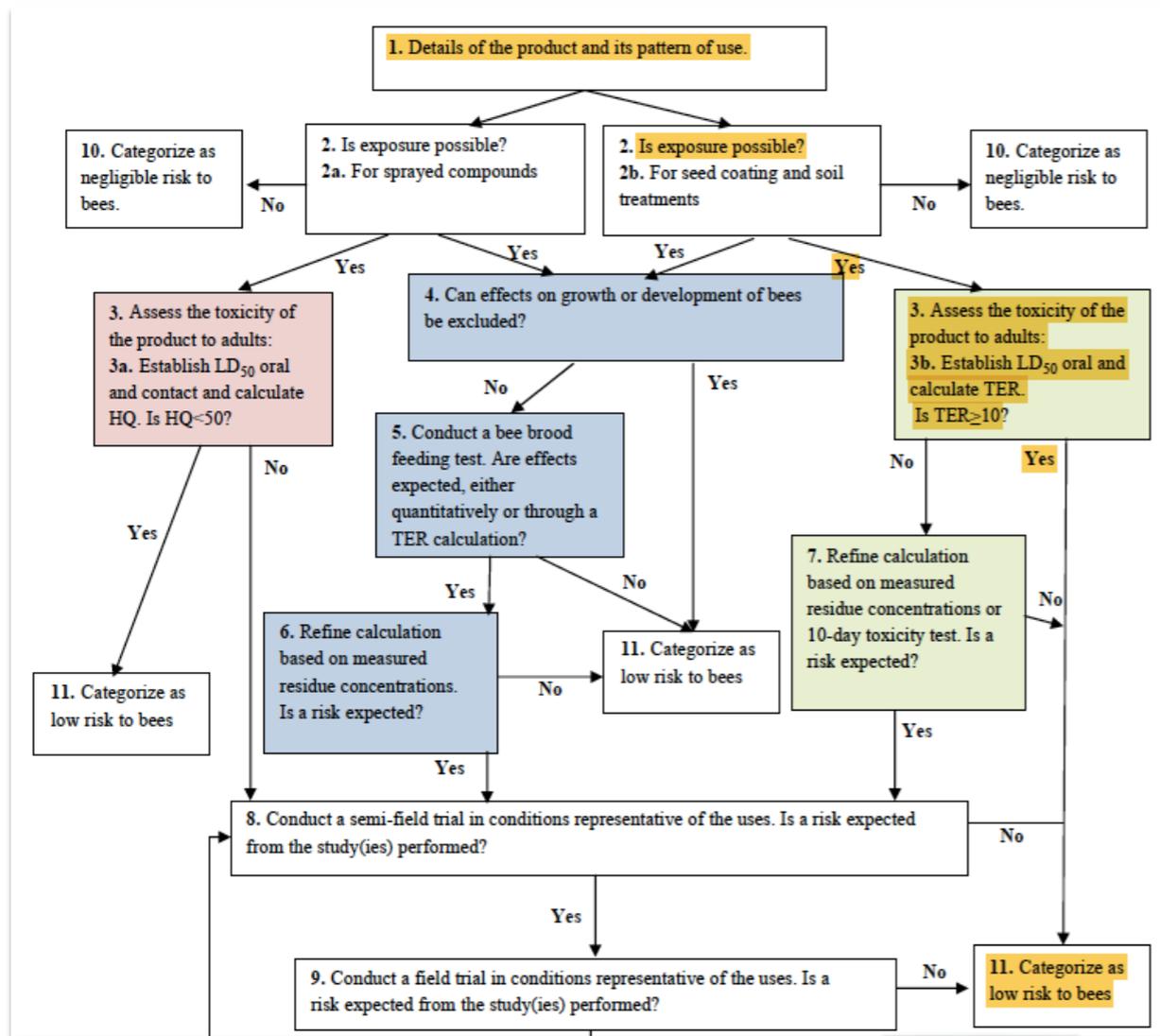
Regards

2025477107 0

# Standards & « good practices »

- . « **Good Epidemiology Practices** » promoted by Big Tobacco in 1994 (confusing the size of the effect and the strength of the evidence) failed to convince epidemiologists.
- . For pesticides & chemicals, regulatory agencies (EPA) & health authorities (EFSA) require « **Good Laboratory Practices** » (aka GLP) studies from the industrial firms seeking the approval of their product.
- . Introduced in the US in the **1970s**, these GLPs safety testings are designed to ensure the quality of the studies (reliability, reproducibility, proper reporting of the data...).
- . Additionally, those GLP studies must follow **guidelines** established by intergovernmental organization such as OECD or EPPO. Always for the better ?

# Standards & « good practices »

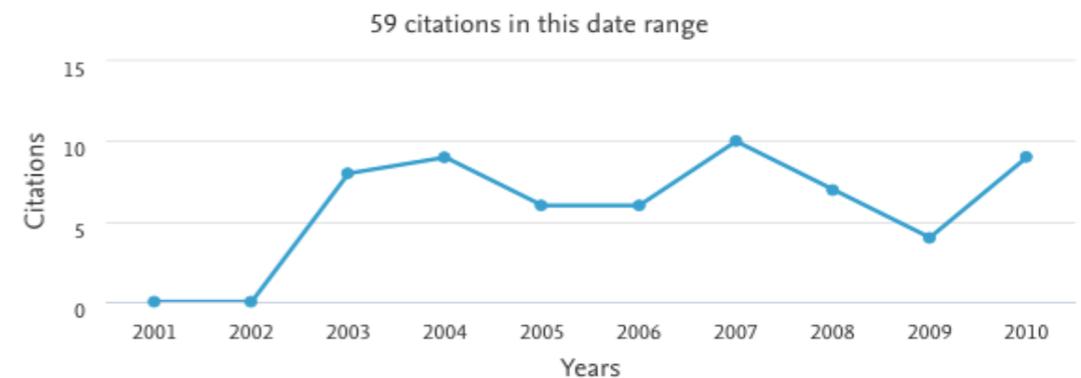


## DISCREPANCY BETWEEN ACUTE AND CHRONIC TOXICITY INDUCED BY IMIDACLOPRID AND ITS METABOLITES IN *APIS MELLIFERA*

SÉVERINE SUCHAIL, DAVID GUEZ, and LUC P. BELZUNCES\*  
INRA, Laboratoire de Toxicologie Environnementale, UMR INRA-UAPV Ecologie des Invertébrés, Site Agroparc,  
84914 Avignon Cedex 9, France

(Received 3 August 2000; Accepted 19 March 2001)

**Abstract**—Imidacloprid is a systemic nitroguanidine insecticide that belongs to the neonicotinoid family. As an agonist of the acetylcholine receptor, it attacks the insect nervous system and is extremely effective against various sucking and mining pests. Oral acute and chronic toxicity of imidacloprid and its main metabolites (5-hydroxyimidacloprid, 4,5-dihydroxyimidacloprid, desnitroimidacloprid, 6-chloronicotinic acid, olefin, and urea derivative) were investigated in *Apis mellifera*. Acute intoxication by imidacloprid or its metabolites resulted in the rapid appearance of neurotoxicity symptoms, such as hyperresponsiveness, hyperactivity, and trembling and led to hyporesponsiveness and hypoactivity. For acute toxicity tests, bees were treated with doses of toxic compounds ranging from 1 to 1,000 ng/bee (10–10,000 µg/kg). Acute toxicity (LD50) values of imidacloprid were about 60 ng/bee (600 µg/kg) at 48 h and about 40 ng/bee (400 µg/kg) at 72 and 96 h. Out of the six imidacloprid metabolites tested, only two (5-hydroxyimidacloprid and olefin) exhibited a toxicity close to that of imidacloprid. Olefin LD50 values were lower than those of imidacloprid. The 5-hydroxyimidacloprid showed a lower toxicity than imidacloprid with a LD50 four to six times higher than that of imidacloprid. Urea also appeared as a compound of nonnegligible toxicity by eliciting close to 40% mortality at 1,000 ng/bee (10,000 µg/kg). However, no significant toxicity was observed with 4,5-dihydroxyimidacloprid, 6-chloronicotinic acid, and desnitroimidacloprid in the range of doses tested. To test chronic toxicity, worker bees were fed sucrose solutions containing 0.1, 1, and 10 µg/L of imidacloprid and its metabolites for 10 d. Fifty percent mortality was reached at approximately 8 d. Hence, considering that sucrose syrup was consumed at the mean rate of 12 µl/d and per bee, after an 8-d period the cumulated doses were approximately 0.01, 0.1, and 1 ng/bee (0.1, 1, and 10 µg/kg). Thus, all tested compounds were toxic at doses 30 to 3,000 (olefin), 60 to 6,000 (imidacloprid), 200 to 20,000 (5-OH-imidacloprid), and >1,000 to 100,000 (remaining metabolites) times lower than those required to produce the same effect in acute intoxication studies. For all products tested, bee mortality was induced only 72 h after the onset of intoxication.



. Risk assessment scheme established in 2010 by the EPPO to take into account systemic pesticides (**no !**), updated by the work done by the International Consortium on Plant-Bee Relationship (**ICPBR**, a group which was mainly gathering agrochemical scientists).

« Environmental risk assessment scheme for plant protection products », EPPO Bulletin, 2010 & Suchail et al., 2001

# Guideline EPPPO 170 (2010)

Size of a test  
field  
vs.  
Size of the  
foraging area



# Glyphosate : science or GLPs ?

**2015** Glyphosate is “**probably** carcinogenic to humans”, w/ « strong evidence of genotoxicity ».

– International Agency for Research on Cancer (IARC)

**2015** « **Unlikely** to pose a carcinogenic hazard »

– European Food Safety Authority (EFSA)

**2016** « **Not likely** to be carcinogenic to humans at doses relevant for human health risk assessment »

– Environmental Protection Agency (EPA)

**2017** « **Not classified** as a carcinogen », no genotoxicity

– European Chemical Agency (EChA)

# Glyphosate : science or GLPs ?

. **4 meta-analysis/pooled epidemiological studies** show an association between glyphosate use & Non Hodgkin Lymphoma (NHL) : Schinasi & Leon (2014), Chang & Delzell (2016), Zhang et al. (2019), Leon et al. (2019).

. **90+ academic scientists** (epidemiologists, toxicologists and biologists) sided w/ the IARC, in a paper showing « serious flaws » in EFSA's report (Portier et al., *Journal of Epidemiology and Community Health*, 2017).

. Pr Lianne Sheppard (university of Washington), a member of the EPA Scientific Advisory Panel (!) found « **multiple and clear inconsistencies between the EPA's guidelines for Carcinogenic Risk Assessment and its approach in its glyphosate review** » (*Forbes*, Feb. 20, 2020)

# Glyphosate : science or GLPs ?

- . **Genotoxicity** is a key point : if the regulators can be convinced that glyphosate is not genotoxic, equivocal results on carcinogenicity (on humans or laboratory animals) can be discarded.
- . GLP studies do not show genotoxicity, but academic studies do so. Here is the **hiatus** : 70 % of all published academic papers on glyphosate genotoxicity find some, and only 1 % of unpublished industrial GLP studies submitted to EPA (Benbrook, 2020).
- . Same for **reprotoxicity** : some published academic studies find problems.
- . Solution : publish in the scientific literature **independant review articles** that always conclude that everything is OK. But HOW ? **Ghostwriting** is an option.

**From:** SALTMIRAS, DAVID A (AG/1000) [REDACTED]  
**Sent:** Monday, January 28, 2013 7:19 AM  
**To:** [REDACTED]@genetoxconsulting.co.uk'; [REDACTED]@q.com'  
**Subject:** Re: Adding Author

Then no need to bother the editor. The paper is Kier and Kirkland.

Thanks for your patience,

David

REVIEW ARTICLE

## Review of genotoxicity studies of glyphosate and glyphosate-based formulations

Larry D. Kier<sup>1</sup> and David J. Kirkland<sup>2</sup>

<sup>1</sup>Private Consultant, Buena Vista, CO, USA and <sup>2</sup>Kirkland Consulting, Tadcaster, UK

For the overall plausibility paper that we discussed with John (where he gave the butadiene example), I'm still having a little trouble wrapping my mind around that. If we went full-bore, involving experts from all the major areas (Epi, Tox, Genetox, MOA, Exposure - not sure who we'd get), we could be pushing \$250K or maybe even more. A less expensive/more palatable approach might be to involve experts only for the areas of contention, epidemiology and possibly MOA (depending on what comes out of the IARC meeting), and we ghost-write the Exposure Tox & Genetox sections. An option would be to add Greim and Kier or Kirkland to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000.

## Safety Evaluation and Risk Assessment of the Herbicide Roundup<sup>1</sup> and Its Active Ingredient, Glyphosate, for Humans

Gary M. Williams,\* Robert Kroes,† and Ian C. Munro‡<sup>2</sup>

\*Department of Pathology, New York Medical College, Valhalla, New York 10595; †RITOX, Universiteit Utrecht, P.O. Box 80176, NL-3508 TD Utrecht Yalelaan 2, The Netherlands; and ‡Cantox Health Sciences International, 2233 Argentia Road, Suite 308, Mississauga, Ontario L5N 2X7, Canada

**From:** FARMER, DONNA R [AG/1000]  
**Sent:** Thursday, November 18, 2010 1:50 PM  
**To:** 'John DeSesso'  
**Subject:** First half

John,

Attached is the first 46 pages.

I added a section in genotox from the Gasnier study...see a attached a critique we did that I took that from. Am working on a section for gasiner in the mechanistic section. Also we cut and pasted in

**Developmental and Reproductive Outcomes in Humans and Animals after  
Glyphosate Exposure:  
A Critical Analysis of the Available Literature**

Amy Lavin Williams<sup>1,2</sup>  
Rebecca E. Watson<sup>1,3</sup>  
~~Donna R. Farmer<sup>4</sup>~~  
John M. DeSesso<sup>1,2,5,6</sup>

<sup>1</sup>Noblis  
Falls Church, VA

<sup>2</sup>Exponent, Inc.  
Menlo Park, CA

<sup>3</sup>SNBL USA  
Everett, WA

<sup>4</sup>The Monsanto Company  
~~St. Louis, Missouri~~

*Journal of Toxicology and Environmental Health, Part B*, 15:39–96, 2012  
Copyright © Taylor & Francis Group, LLC  
ISSN: 1093-7404 print / 1521-6950 online  
DOI: 10.1080/10937404.2012.632361



**DEVELOPMENTAL AND REPRODUCTIVE OUTCOMES IN HUMANS AND ANIMALS  
AFTER GLYPHOSATE EXPOSURE: A CRITICAL ANALYSIS**

Amy Lavin Williams<sup>1</sup>, Rebecca E. Watson<sup>2</sup>, John M. DeSesso<sup>1,3</sup>

<sup>1</sup>Exponent, Inc, Alexandria, Virginia, USA

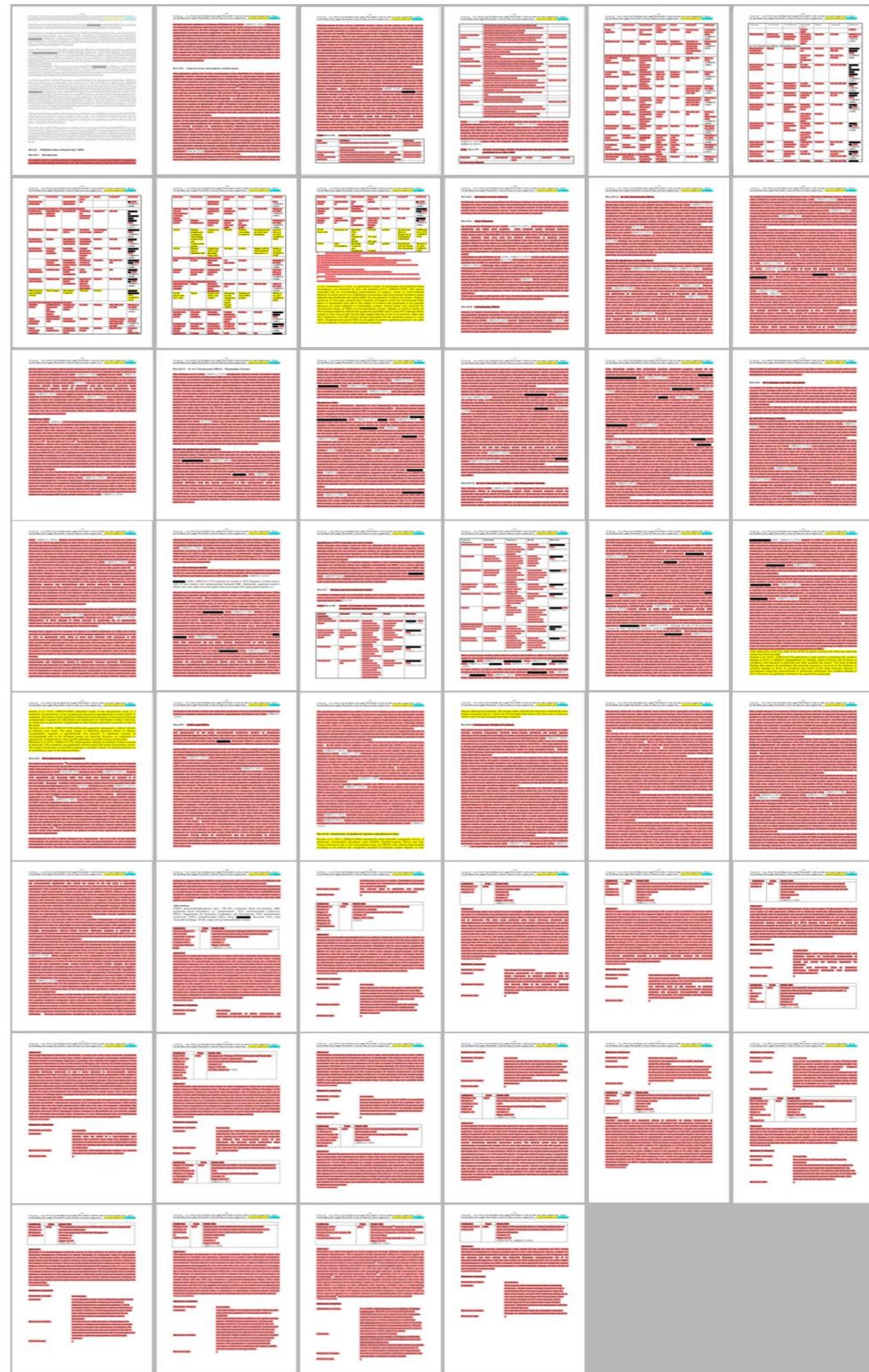
<sup>2</sup>SNBL USA, Everett, Washington, USA

<sup>3</sup>Georgetown University School of Medicine, Washington, DC, USA

# From ghostwriting to plagiarism

. **2017** the genotox chapter Renewal Assessment Report (RAR, basis of EFSA expertise) prepared by Germany, is a **copy-paste** from the dossier submitted by the industry (Global 2000). All academic studies finding genotox are considered « unreliable », after applying the **Klimisch (who?)** criteria (Global 2000, 2017).

. **2021** the new RAR was prepared by four member states. But among the **7188 academic studies** assembled in the RAR, **only 3 % are considered « relevant »**, and **0,4 % « reliable »** (Generations futures, 2021).



# **Comments from the public** **consultation on the 2021** **European expertise**

« (...) the studies showing that glyphosate has genotoxic effects are more important in terms of quality and quantity than those suggesting an absence of effect. A genotoxic effect of glyphosate is consistent with the induction of oxidative stress, observed in different species and cell systems, sometimes at exposure doses consistent with those encountered in the environment. »

– INSERM

# **Comments from the public** **consultation on the 2021** **Renewal Assessment Report**

« INSERM concluded on a moderate presumption of a link between occupational exposure to glyphosate and increased risk of non-Hodgkin lymphoma (NHL) for farmers or other employment categories (...) Our conclusion based on epidemiological studies is supported by experimental toxicology studies as glyphosate shows prooxidant and genotoxic effects. »

– INSERM

# **Why does the discrepancy between regulatory & academic science matter ?**

- . It makes possible to authorize dangerous pesticides & chemical to enter the market.
- . Risk assessment for regulatory purposes is often confused with the outcome of a scientific consensus.
- . After years of climate denialism, there is a sort of « climate-change-scientific-consensus » effect within the medias, science communicators, policymakers... Once fooled, these people are now looking for a « scientific consensus » on any other topics.

# **Non-monotonic effects : a scientific consensus incompatible w/ risk assessment**

- . Some chemicals w/ endocrine disrupting properties can trigger larger effects at very low doses of exposures, than at higher doses.
- . In 2012, Vandenberg et al. found 800+ academic studies suggesting such non-monotonic dose-response curves (NMDRCs).
- . All over the world, reg. Agencies & health authorities denied the very existence of such effects.

# The case of BPA

**Table 1.** Biased outcome due to source of funding in low-dose *in vivo* BPA research as of December 2004.

Source of funding	All studies		CD-SD rat studies		All studies except CD-SD rats	
	Harm	No harm	Harm	No harm	Harm	No harm
Government	94 (90.4)	10 (9.6)	0 (0%)	6 (100)	94 (96)	4 (4)
Chemical corporations	0 (0)	11 (100)	0 (0%)	3 (100)	0 (0)	8 (100)

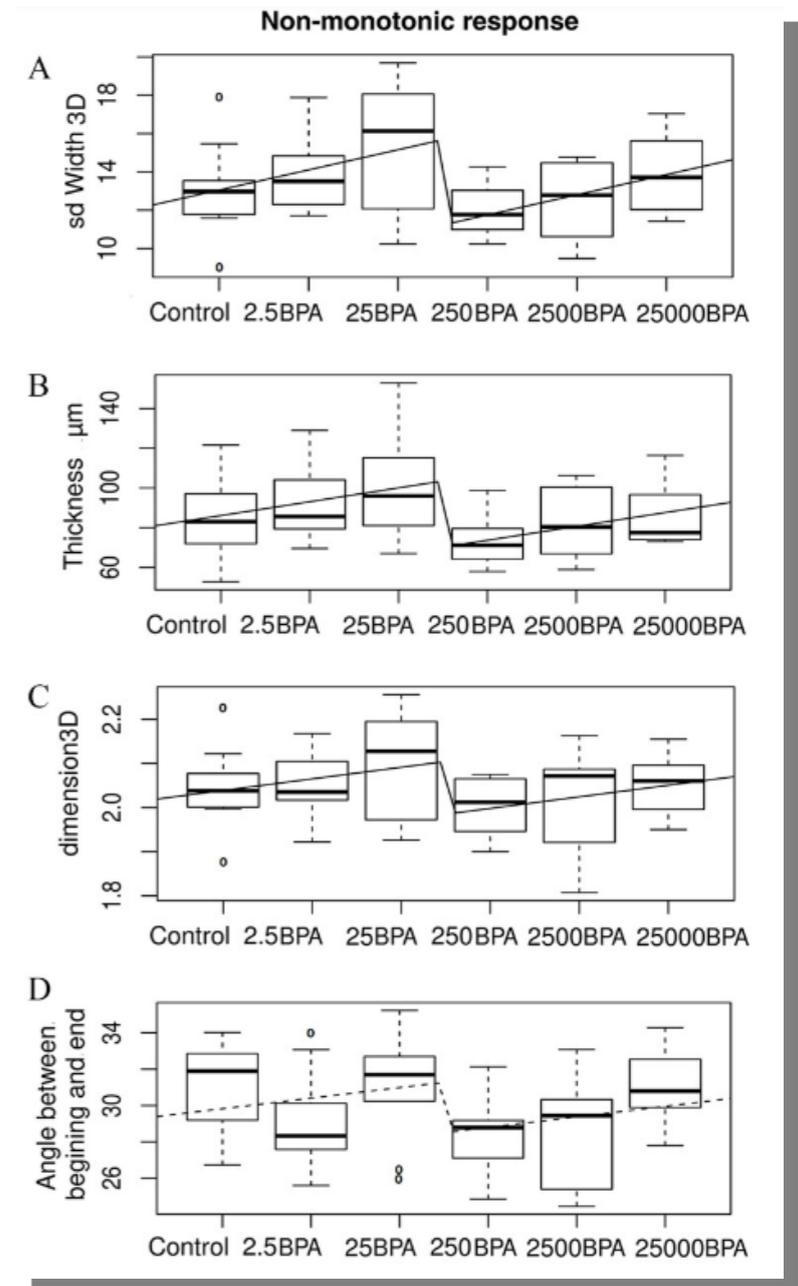
Values shown are no. (%).

EFSA : BPA Tolerable daily intake

from 50  $\mu\text{g}/\text{kg}/\text{day}$  (2010)

to 4  $\mu\text{g}/\text{kg}/\text{day}$  (2015)

to 0,04  $\text{ng}/\text{kg}/\text{day}$  (2021 proposal)

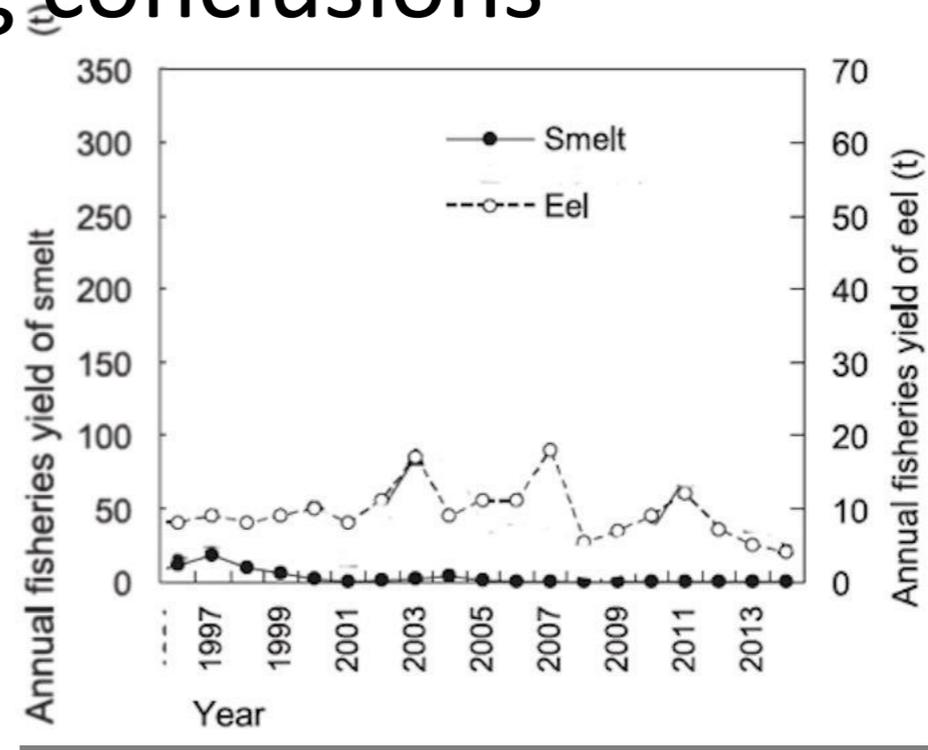
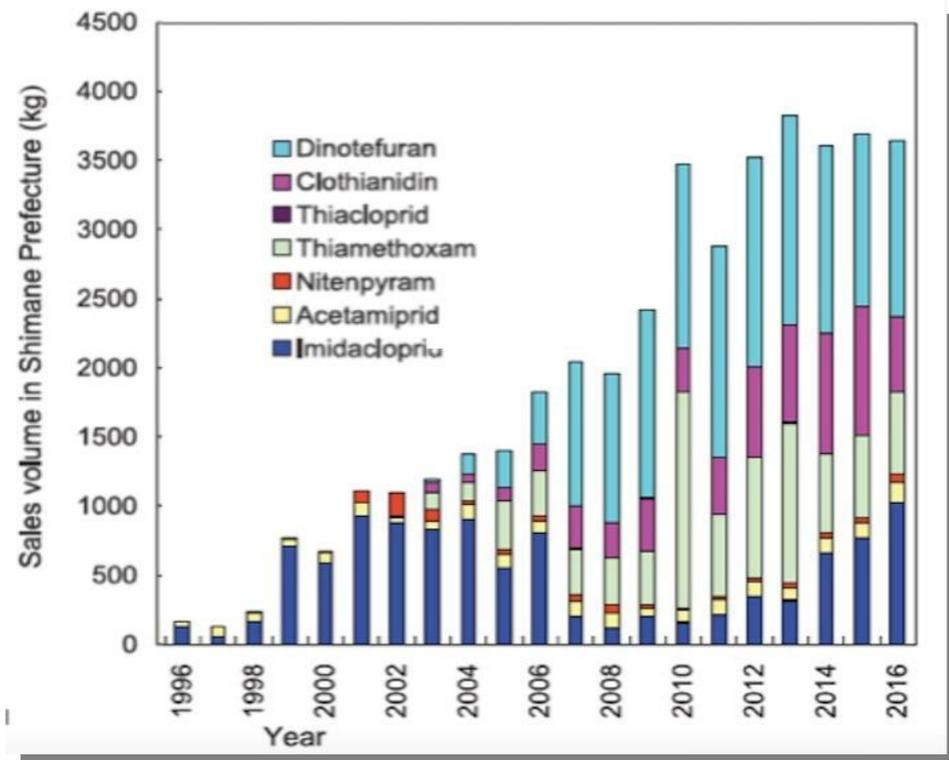


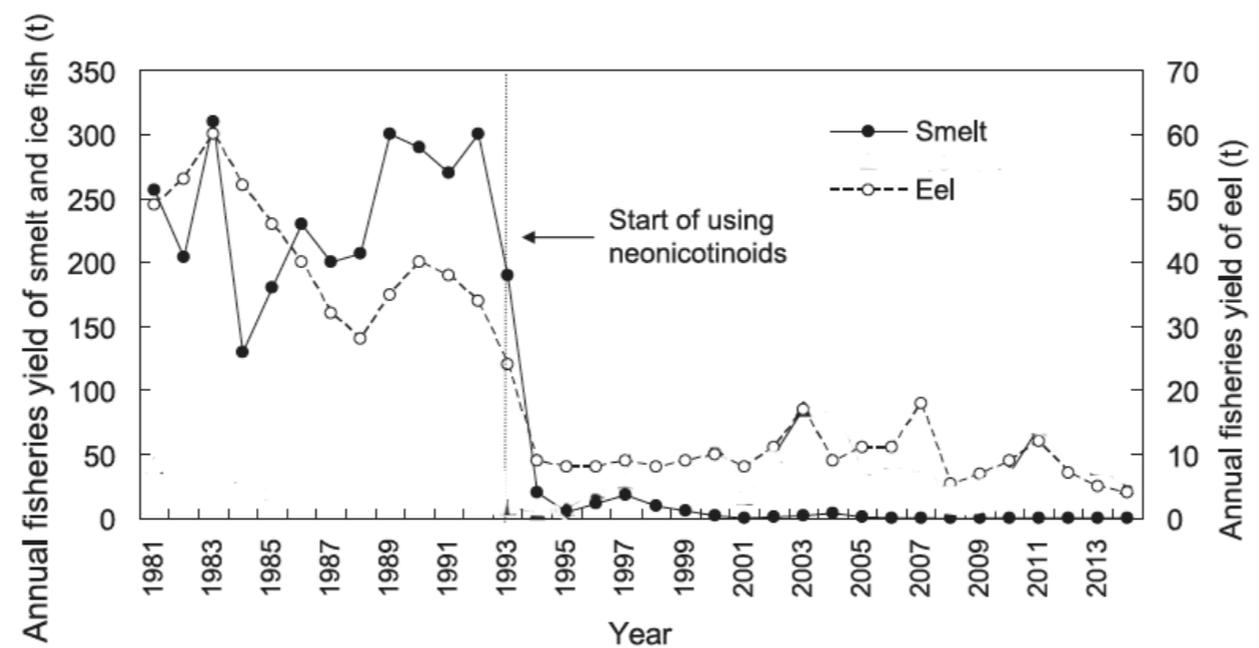
Vom Saal & Hugues,  
2005

Montevil et al., 2020

# Pervasive chemicals and new baselines

- . In most situations, it is difficult to fully assess the effects of pesticides.
- . Trying to find a dose-effect after a chemical has been released >> misleading conclusions





**Fig. 3. Annual yield (tons) of smelt, ice fish, and eel in Lake Shinji from 1981 to 2014.** The vertical dashed line indicates when neonicotinoid use began in the watershed of the lake.

