



The EU Glyphosate assessment and the “Monsanto Papers”

**When industry’s ‘sound science’
meets
peer review**

Martin Pigeon, Corporate Europe Observatory



CORPORATE EUROPE OBSERVATORY

Exposing the power of corporate lobbying in the EU

- we work on specific policy issues (energy, economy and finance, environment, food & agriculture, international trade...) and on lobbying regulation. We have worked on EFSA's independence and transparency policy since 2009-2010.
 - 100% independent funding
(no public subsidies, no links to corporate funding, all funding sources [disclosed](#) since 2006)
- 15 staff, more or less half in Brussels, the rest in other EU countries – Germany, Netherlands, Spain, UK, Denmark

CEO is also a supporter of the Stop Glyphosate European Citizens Initiative (I am personally a member of the organising Committee), the fastest ECI ever, which was just successfully registered by the European Commission. I will come back to our demands in my conclusions.

“Rooted in Science”

A recent
Monsanto PR
campaign
invokes
illustrious
scientific
figures.

Here, Galileo.

#RootedInScience

“And yet it moves.”

Galileo Galilei

MONSANTO



Monsanto and “sound science”: science for policy-making...

MONSANTO 

Innovations

Products

Company

- Advocating for sound public policy on issues relating to agriculture

“Specifically, we advocate for supportive policies, regulation and laws that are based on the principles of sound science.”

Monsanto, like many companies and stakeholders, advocates our position on various topics before governments. Specifically, we advocate for supportive policies, regulation and laws that are based on the principles of sound science. Academic experts who share our science-based views sometimes advocate in support of the same policies. We occasionally share our opinions in similar public forums, and Monsanto employees and academic researchers sometimes share the stage at events. In every case, we thoroughly follow local laws and conduct routine audits to ensure our efforts are transparent, appropriate and legal.

PS: “sound science” is an expression with a bit of [history](#).

...and keeping democracy at bay

MONSANTO



29 August 2017

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Dear Conference of Presidents,

I am writing to you in response to your letter of invitation to Monsanto CEO Hugh Grant to attend a European Parliament joint public hearing on "The Monsanto papers and Glyphosate" on 11 October 2017. While it is always a privilege to be invited to address members of the European Parliament, it is with regret that neither Mr Grant nor Monsanto will be in a position to attend.

Having carefully considered your invitation, we do not feel that the discussion as proposed is an appropriate forum to consider these issues. That being said, we refute the allegations recently made by anti-agriculture pressure groups that Monsanto unduly influenced scientific research on the safety of glyphosate. Science is always a collaborative process. Monsanto's participation in the various scientific literature reviews recently noted in the media was entirely appropriate and fully disclosed in the acknowledgements sections of the papers, and the papers themselves were the subject of rigorous peer review prior to publication.

Further, the recent media attention focuses solely on literature review papers and not on the underlying Good Laboratory Practice (GLP) regulatory studies that support the registration of glyphosate. Thus, to quote the European Commission in its answer to a Parliamentary Question on 9th August 2017, "both ECHA¹ and EFSA² confirmed that the information contained in the 'Monsanto papers' concerning some scientific reviews, even if true, would not have had an impact on their overall assessment of glyphosate. Scientific reviews have limited weight in the agencies' overall assessment, as EU experts had access to the raw data and produced their own conclusions on the original studies."

We note in your invitation that "the purpose of the hearing is to discuss the credibility of scientific studies behind both the decision of US regulatory agencies to authorize RoundupTM, as well as conclusions of the EU risk assessment agencies on the issue of Glyphosate." With respect, it is not the role of the European Parliament to question the credibility of the scientific output of either the independent EU agencies or those in third countries.

We have observed with increasing alarm the politicisation of the EU procedure on the renewal of glyphosate – a procedure which should be strictly scientific but which in many respects has been hijacked by populism. Indeed, a recent statement by ECHA highlighted this concern: "ECHA is concerned of an attempt to publicly malign the integrity of EU institutions mandated to ensure safe use of chemical substances in the EU."³

Monsanto's refusal of the European Parliament's invitation to this hearing

"With respect, it is not the role of the European Parliament to question the credibility of the scientific output of either the independent EU agencies or those in third countries."

We have observed with increasing alarm the politicisation of the EU procedure on the renewal of glyphosate – a procedure which should be strictly scientific..."

¹ https://echa.europa.eu/documents/10162/22431146/echa_statement_regarding_assessment_of_glyphosate_en.pdf/2d4acba1-37e1-46cf-7fe5-77811768b75

² <https://www.efsa.europa.eu/sites/default/files/170523-efsa-statement-glyphosate.pdf>

“Science” vs. democracy, again

Agribusiness industries react very angrily to Juncker's proposal to publish national governments' votes in comitology. The secrecy of these votes is a key component of the EU's democratic deficit



Joint Statement:

The EU must not change the comitology system to the detriment of innovation and the single market

13 February 2017

We, European Associations representing a wide number of economic sectors affected directly or indirectly by comitology rules, consider that science-based decisions must be central to comitology to allow for legal and regulatory certainty in the EU.

Therefore, we urge the EU Commission:

- to ensure proper and efficient implementation of existing EU legislation on comitology and improve legal certainty and predictability thus increasing the confidence of economic sectors in the EU system and allowing a better functioning of the single market and access of economic operators all along the chains to innovative products;
- to keep science-based decision-making as a fundamental aspect of the areas ruled by comitology;
- to consider the impact that moving away from a science-based system would have on research, innovation and investment in Europe;

“We... consider that science-based decisions must be central to comitology to allow for legal and regulatory certainty in the EU”.

Studies possibly or probably ghostwritten by Monsanto in EFSA's assessment?

- Wallace et al. 2000: quoted 36 times in EFSA's RAR., full endorsement of the study
- Kier & Kirkland 2013: quoted 6 times in EFSA's RAR, full endorsement of the study
- Greim 2015: quoted once, not used

“Sound science” = “Our Science”

Message

From: HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
Sent: 4/10/2001 6:09:25 PM
To: JACOBS, ERIK [AG/5040] [erik.jacobs@monsanto.com]; MARTENS, MARK A [AG/5040] [mark.a.martens@monsanto.com]; MCKENNA, RUTH M [AG/5040] [ruth.m.mckenna@monsanto.com]; VAN BOSSUYT, ALFRED [AG/5035] [alfred.van.bossuyt@monsanto.com]
Subject: RE: Propachlor sample request

All,

Please don't do anything until we discuss this. Data generated by academics has always been a major concern for us in the defense of our products.

“Data generated by academics has always been a major concern for us in the defense of our products.”

SWOT ANALYSIS

STRENGTHS

- Willingness to fund further research and position as responsible industry
- Sound production base in Europe and network of contacts

WEAKNESSES

- Scientific evidence showing endocrine disrupting properties of plastics
- Availability of good alternatives?
- Reputation management vs. political and NGO forces
- ED strategy in DG ENVI

OPPORTUNITIES

- Plastics properties for applications which alternatives do not have?
- Scientific research that can show different results on endocrine disruptors
- Difficult scientific discussion
- Definition of ED criteria left DG ENVI for DG SANCO

THREATS

- Big political pressure from Member States (France, Sweden and Denmark most vocal) and European Parliament
- Issue is highly political leading to high probability of EU action
- Consumer organizations and environmentalists' pressure which could lead to lower demand and business reputation management issues
- Campaigning scientists

So... what about
glyphosate-
based herbicides
such as
Roundup?

How have the
EU authorities
dealt with them?



THE ULTIMATE KILLING MACHINE



Now Roundup® Attack™ with iQ Inside™ is a weed's worst nightmare.
No weed is safe, even the toughest, hard to kill weeds.

Incorporating a unique weed targeting technology called iQ, Roundup® Attack™ with iQ Inside™ is not only more powerful, it's smarter. With a new patented penetrator that gets into weeds more efficiently, the kill is faster and more effective. You also have more tank mix options for greater flexibility and spraying can continue closer to rain than ever before.

Trust your killer instinct and insist on new Roundup Attack with iQ Inside.



Get connected: roundupattack.com.au



Roundup is a registered trademark of Monsanto Technologies LLC used under license by Nufarm Australia Limited. Attack and with iQ Inside are trademarks of Nufarm Australia Limited.

Lobbying is a relationship.

Monsanto's intrigues would not be as effective if the EU had a credible, independent and transparent system in place to assess the toxicity of pesticides (and other products).

Unfortunately, that is not the case, and this is really what the pesticides industry doesn't want you to understand (typical arguments they use: "we have the safest food in the world", "keep trusting science", etc.).

The many flaws in the EU's Pesticides Assessment System

1. EFSA does not have the financial & legal means of its mission.

- No access to samples of the products discussed (only literature reviews),
- Hardly any budget to perform or commission research themselves,
- Hardly any budget to pay external experts (= too many have COIs),
- Impossible to publish most of the underlying evidence behind their decisions (industry's property).

Of course EFSA defend themselves and say they're doing a great job (which of course they sometimes do) and that we should trust them. Understandable and desirable, but not credible in the long run.

EU agencies rely on the data and evaluations industry sends them, sometimes to an absurd degree (cf. recent “copy-paste” scandal).

Little incentives to attract the best scientists (industry studies cannot be quoted = no publication possible in the scientific literature).

The “copy-pasting” scandal: a lot of it boils down to a lack of capacity at agencies. But not all of it.

“Due to the large number of submitted toxicological studies, the RMS [BfR] was not able to report the original studies in detail and an alternative approach was taken instead. The study descriptions and assessments as provided by GTF were amended by deletion of redundant parts (such as the so-called “executive summaries”) and new enumeration of tables.

Obvious errors were corrected. Each new study was commented by the RMS. These remarks are clearly distinguished from the original submission by a caption, are always written in italics and may be found on the bottom of the individual study summaries.”

B.6 Toxicology and metabolism

General introduction and explanation of the approach taken by RMS

This health evaluation of glyphosate is based on the following sources:

- *Toxicological and ADME studies that were submitted by the GTF for this re-evaluation.*
- *Toxicological studies and ADME studies that had been reported in the previous DAR (1998, ASB2010-10302) already and, thus, were part of previous EU evaluation. However, they were subject to re-assessment by the RMS according to current quality standards and were used only when regarded as acceptable or at least supplementary. In very few cases, NOAELs/LOAELs were revised. Unacceptable (old or new) studies were usually deleted with justifications given in the respective sections of Volume 3. In exceptional cases, such studies are still mentioned, i.e., if they were formerly taken into consideration for, e.g., ADI setting.*
- *Scientific publications and other relevant information that were submitted either by the GTF or by third parties or of which the RMS was aware before. It must be emphasised that a large part of the publications was on formulations different from the representative one and, thus, is of limited value for the toxicological evaluation of the active ingredient. With rather few exceptions in the areas of genotoxicity and human data, mainly scientific literature published since 2000 was assessed.*

Due to the large number of submitted toxicological studies, the RMS was not able to report the original studies in detail and an alternative approach was taken instead. The study descriptions and assessments as provided by GTF were amended by deletion of redundant parts (such as the so-called “executive summaries”) and new enumeration of tables. Obvious errors were corrected. Each new study was commented by the RMS. These remarks are clearly distinguished from the original submission by a caption, are always written in italics and may be found on the bottom of the individual study summaries.

Description by the BfR of how it simply edited industry’s assessment of glyphosate toxicity instead of writing its own

| EFSA's Renewal Assessment report | Glyphosate Task Force - May 2012 - Glyphosate & Salts of Glyphosate |
|---|---|
| B.6.4.8.11 Genotoxicity Weight of Evidence | Annex II, Document M, Section 3 Point 5: Toxicological and toxicokinetic studies 10. Genotoxicity Weight of Evidence |
| “Overall, the weight of evidence of the studies considered in the earlier review as well as the studies considered in this review indicates that glyphosate and GBFs are not genotoxic in the two general endpoint categories most directly relevant to heritable mutagenesis, gene mutation and chromosome effects.” | “Overall, the weight of evidence of the studies considered in the earlier review as well as the studies considered in this review indicates that glyphosate and GBFs are not genotoxic in the two general endpoint categories most directly relevant to heritable mutagenesis, gene mutation and chromosome effects.” |
| B.6.5.3 Published data on carcinogenicity (released since 2000) - Epidemiology studies | Annex II, Document M, Section 3 Point 5: Toxicological and toxicokinetic studies 3. Literature Review of Carcinogenicity Publications |
| “A number of epidemiology studies over the last decade have focused on pesticide exposure and associated health outcomes. Publications vary in the specificity of their conclusions regarding pesticides in general, classes of pesticides and in some cases individual insecticides, herbicides or fungicides. While some of these publications specifically mention glyphosate, few draw tenable associations with any specific cancer outcome.” | “A number of epidemiology studies over the last decade have focused on pesticide exposure and associated health outcomes. Publications vary in the specificity of their conclusions regarding pesticides in general, classes of pesticides and in some cases individual insecticides, herbicides or fungicides. While some of these publications specifically mention glyphosate, few draw tenable associations with any specific cancer outcome.” |
| B.6.6.12 Published data (released since 2000) Epidemiology Glyphosate DART/ED Publications | 1. Literature Review of Developmental and Reproductive Toxicity (DART) and Endocrine Disruption (ED) Publications |
| “Several epidemiology studies in which glyphosate exposure was considered have evaluated the following range of reproductive outcomes; miscarriage, fecundity, pre-term delivery, gestational diabetes mellitus, birth weights, congenital malformations, neural tube defects, attention-deficit disorder / attention-deficit hyperactive disorder (ADD/ADHD). In most instances, glyphosate and reproductive outcomes lack a statistically significant positive association” | “Several epidemiology studies in which glyphosate exposure was considered have evaluated the following range of reproductive outcomes; miscarriage, fecundity, pre-term delivery, gestational diabetes mellitus, birth weights, congenital malformations, neural tube defects, attention-deficit disorder / attention-deficit hyperactive disorder (ADD/ADHD). In most instances, glyphosate and reproductive outcomes lack a statistically significant positive association” |

Agencies' (and European Commission's) explanations so far: it is not a scandal because we do it all the time

- BfR: “When the applicants cite studies correctly or interpret these studies correctly from a scientific and methodological perspective in their corresponding summaries, the European assessment authorities have in the past had no cause to rewrite these statements in the numerous authorisation and approval procedures for plant protection products, chemicals and medicines.”
- EFSA: “To be clear, the process for the EU assessment of glyphosate was carried out properly, transparently, and in the same way as the assessment of all other pesticides involving EFSA...”

plagiarism expert Stefan Weber [concluded](#) it was a case of “significant scientific misconduct” and that the BfR “obviously did not conduct its own assessment of the cited studies”.

The many flaws in the EU's Pesticides Assessment System

2. Secrecy of the Data

The studies given the most weight by EU regulators are not peer-reviewed studies but industry-funded, confidential “guideline studies” (because they are performed along regulatory toxicology standards). These are provided by industry and never published in the scientific literature. **No transparency, no peer review!**

The high cost of these studies is a high entry barrier on the pesticides market, which drives concentration and favours large corporations. Furthermore, this cost is used as an argument by industry to prevent publication.

It took a year, and exceptional political circumstances, for the European Commission and EFSA to partly disclose the raw data of these confidential industry studies on glyphosate.

At CEO we introduced an access to documents request in December 2015, for six studies EFSA had referred to as “key”. MEPs from the Greens/FFA group filed a similar request (but for all undisclosed studies) in March 2016. The documents only reached us in October 2016.

EFSA and the European Commission faced strong pushback from industry when they were considering to publish.



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██████████
Public Access to Document Team
Legal and Regulatory Unit
European Food Safety Authority
Via Carlo Magno, 1A
I-43126 Parma

Brussels, 4th February 2016

Dear ██████████,

Re: Request for access to documents

In response to your email letter dated 22 January 2016 concerning receipt of a third party request for access to one of our studies on Glyphosate in EFSA's possession, namely,

██████████ A chronic feeding study of glyphosate (Roundup technical) in mice 77-2061 (BDN-77-420) TOX9552381 (the "Study").

Monsanto hereby formally objects to the disclosure of the entirety of the Study.

That EFSA decided to nevertheless send us the documents is important and must be acknowledged (EFSA has clearly understood how important data transparency is to enable scientific scrutiny – but they cannot go against EU law either).



European Food Safety Authority

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Home News Glyphosate: EFSA to share raw data

29 September 2016

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Glyphosate: EFSA to share raw data



EFSA is to release the raw data used in the recent EU safety evaluation of glyphosate, as part of its commitment to open risk assessment.

The information will be shared with a group of MEPs following a public access to document request. When combined with the detailed [background documents](#) already published on EFSA's website, the information will be sufficient to enable a third-party scientist to scrutinise the evaluation of glyphosate that was carried out by EFSA and



Nevertheless...

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- the documents were image pdfs: it was impossible to machine-search them, or import the data in any other software. Huge amount of human labour needed! Did the agencies really look at them?
- numerous, important sections of the documents were redacted by EFSA for legal reasons, including even the summary, methodology and conclusions.
- anyone publishing it could be sued by industry for it.

Having access to the studies' raw data enabled C. Portier to re-analyse some of them and find results that industry had failed to report, and the BfR and EFSA to identify. **EU experts would have failed to identify more than a third of all statistically significant cancer findings in the rodent carcinogenicity studies they reviewed.**




The many flaws in the EU's Pesticides Assessment System

3. Only “active substances” are assessed at the EU level. The real-world formulations are only checked superficially at the national level, with no long-term toxicity studies.

A lot of the independent scientific literature, which deals with real world conditions and products, was deemed irrelevant/“second grade” evidence by the GTF and this approach was followed by EU regulators.

Monsanto executive in an email: “you cannot say that Roundup is not a carcinogen – we have not done the necessary testing on the formulation to make that statement... The testing on the formulations are not anywhere near the level of the active ingredient.”




The terms glyphosate and Roundup cannot be used interchangeably nor can you use "Roundup" for all glyphosate-based herbicides any more. For example you cannot say that Roundup is not a carcinogen...we have not done the necessary

Confidential - Produced Subject to Protective Order

MONGLY00922458

testing on the formulation to make that statement. The testing on the formulations are not anywhere near the level of the active ingredient. We can make that statement about glyphosate and can infer that there is no reason to believe that Roundup would cause cancer.

List of studies
required by the
BfR in
application of
the EU
legislation on
formulations



In addition, BfR assesses the following effects of the plant protection product submitted for authorisation:

- Acute toxicity (oral, dermal, inhalation)
- Irritation of skin and eyes, skin sensitisation
- Dermal absorption (uptake through the skin)

If necessary, further assessments may be carried out regarding the combination effects of plant protection product ingredients.

The many flaws in the EU's Pesticides Assessment System

4. As a rule, and for the purpose of checking that no “trade secret” is left in the documents being published, industry can access EFSA's final conclusions two weeks ahead of their publication, giving them two weeks of extra lobby pressure if they need to.

The many flaws in the EU's Pesticides Assessment System

5. The EU system is meant to be articulated on the strict separation between risk assessment (science-based) and risk management (non-scientific considerations are taken into account for a final decision). But there are (anonymous!) representatives of national governments involved in the EFSA “peer review”...



The process has few guarantees against risks of political interference in the “science-based” part...

The J. Rowlands/EPA case

Jess Rowlands, a US expert exposed in the "Monsanto Papers" in a probable collusion with Monsanto ("we all know Jess", as one Monsanto executive said in an email), intervened in EFSA's glyphosate assessment, providing information which comforted EFSA in its decision to discard the conclusions of a study showing significant cancer results in mice exposed to glyphosate (Kumar 2001).

Following the revelation, EFSA told the press and civil society that it had double-checked Rowlands' information.

But when requested by CEO to disclose documents showing it had actually performed these double-checks, EFSA had nothing to show...

The many flaws in the EU's Pesticides Assessment System

6. Last elephant in the room:

“The current assumption underlying pesticide regulation – that chemicals that pass a battery of tests in the laboratory or in field trials are environmentally benign when they are used at industrial scales – is false”

I. Boyd (scientific adviser to the UK's Department of Environment, Food and Rural Affairs - DEFRA)

A. Milner (DEFRA)



The screenshot shows the top of a Science journal article page. The header is dark with the word "Science" in large white font, followed by navigation links: "Home", "News", "Journals", and "Topics". Below the header, the article title "Toward pesticidovigilance" is prominently displayed. To the left of the title are social media sharing icons for Facebook, Twitter, and Google+, each with a "0" below it. Above the title, the text "SHARE" is in red, "PERSPECTIVE" is in red, and "BRIDGE - MEDICINES AND PESTICIDES" is in a smaller, lighter font. Below the title, the authors "Alice M. Milner¹, Ian L. Boyd²" are listed, followed by a link "+ See all authors and affiliations". At the bottom, the publication details are given: "Science 22 Sep 2017; Vol. 357, Issue 6357, pp. 1232-1234" and the DOI "DOI: 10.1126/science.aan2683".

Science Home News Journals Topics

SHARE PERSPECTIVE BRIDGE - MEDICINES AND PESTICIDES

Toward pesticidovigilance

Alice M. Milner¹, Ian L. Boyd²
+ See all authors and affiliations

Science 22 Sep 2017;
Vol. 357, Issue 6357, pp. 1232-1234
DOI: 10.1126/science.aan2683

PS: Monsanto's core business: monocropping made easier

This is a "green desert" in
Argentina: endless
Roundup-tolerant soy
monocropping.

The most destructive form
of agriculture ever invented
for biodiversity and rural
communities.

But scale of use is not part
of the EU's environmental
assessment scope.



Beware: there are also very positive points in the EU's 2009 Pesticides Regulation, which need to be defended against the pesticides industry's permanent attempts to destroy them

The “cut-off criteria” in the 2009 Pesticides Regulation: probably the 8 paragraphs the pesticides industry hates the most in the whole EU legislation



3.6. Impact on human health

- 3.6.1. Where relevant, an ADI, AOEL and ARID shall be established. When establishing such values an appropriate safety margin of at least 100 shall be ensured taking into account the type and severity of effects and the vulnerability of specific groups of the population. When the critical effect is judged of particular significance, such as developmental neurotoxic or immunotoxic effects, an increased margin of safety shall be considered, and applied if necessary.
- 3.6.2. An active substance, safener or synergist shall only be approved if, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as mutagen category 1A or 1B.
- 3.6.3. An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.
- 3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.
- 3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

By 14 December 2013, the Commission shall present to the Standing Committee on the Food Chain and Animal Health a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.

In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.

Remarks on ECHA's assessment

To differ from EFSA's opinion (to which it had participated), ECHA would have needed to :

- Be ready to go to war with EFSA publicly whereas it had already contributed to EFSA's opinion
- Contradict the preparatory document written for the agency by Germany's BfR (it really is a scandal that the agency having drafted all the EU assessments on glyphosate refused to attend this hearing)

Could it do it at all?

The “Stop Glyphosate” European Citizens Initiative: our demands

Ban glyphosate-based herbicides, exposure to which has been linked to cancer in humans, and has led to ecosystems degradation;

Ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry;

Set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future. This must be accompanied by support measures for farmers.

What about farmers?

- Right now, farmers (farm workers) relying on glyphosate are facing an impossible dilemma: keep using it and risking cancer, or stop using it and risking economic losses.
- Why should they face the competition of non-EU farmers using farming practices that are a public health and environmental disaster?
- They cannot get out of this alone and need support measures, in the form of trade protections and technical support.

Is the EU ready to do this? The very last market intervention mechanisms, sugar quotas, have just been dismantled and the EC keeps pushing to sign CETA and other FTAs...

Suggestions for a way out

- Non-chemical alternatives to glyphosate for weeds management are already there but they will always be more complex – and more expensive – than the ‘napalm agriculture’ enabled by the industrial use of broad-spectrum herbicides.
- Broaden the discussion to other policy areas: water, climate, air quality... Munich, Paris and New York’s water systems have already helped farmers for a very long time now (Paris more recently) to not use polluting chemicals (synthetic pesticides & fertilisers...) and an excessive number of animals. Why? Because they have done the math: **it is cheaper for public water authorities to help farmers not polluting than paying for the clean-up.**
- Prevention is usually cheaper, and healthier, than cure... But there is less money to be made out of it for large companies.