

# **Malfunction**

**in the European Approval System**

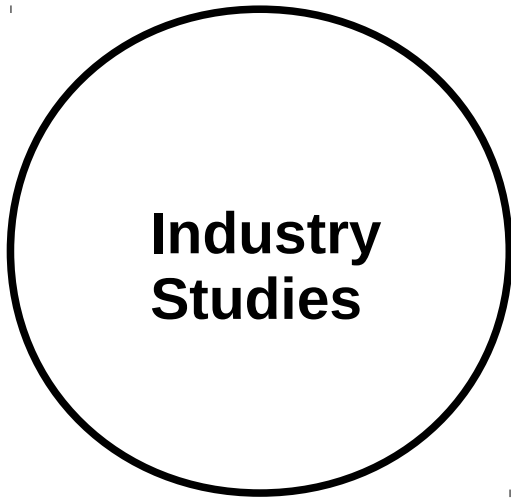
Glyphosate as a prime example

*Brussels, October 17th 2017*

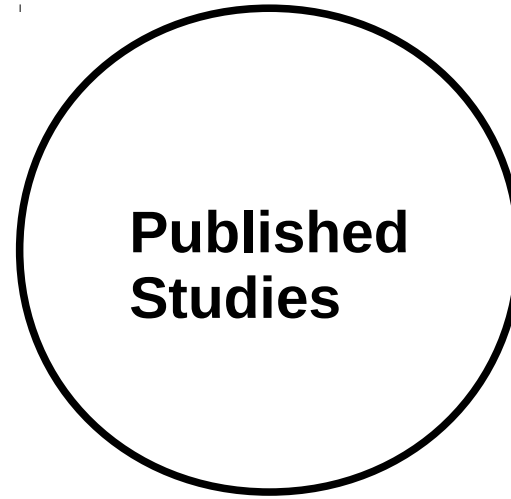
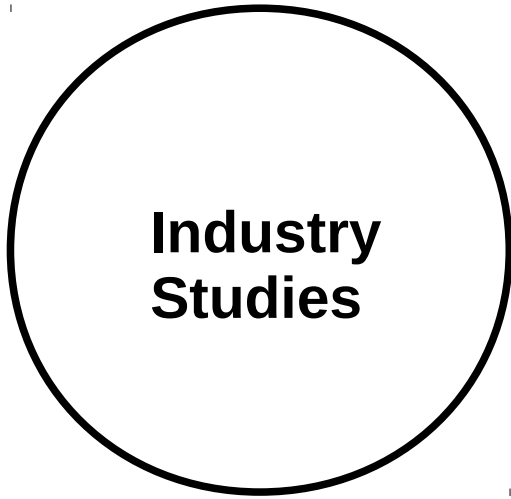
*„There have been a lot of allegations of plagiarism and of copy paste by people that do not understand the process.“*

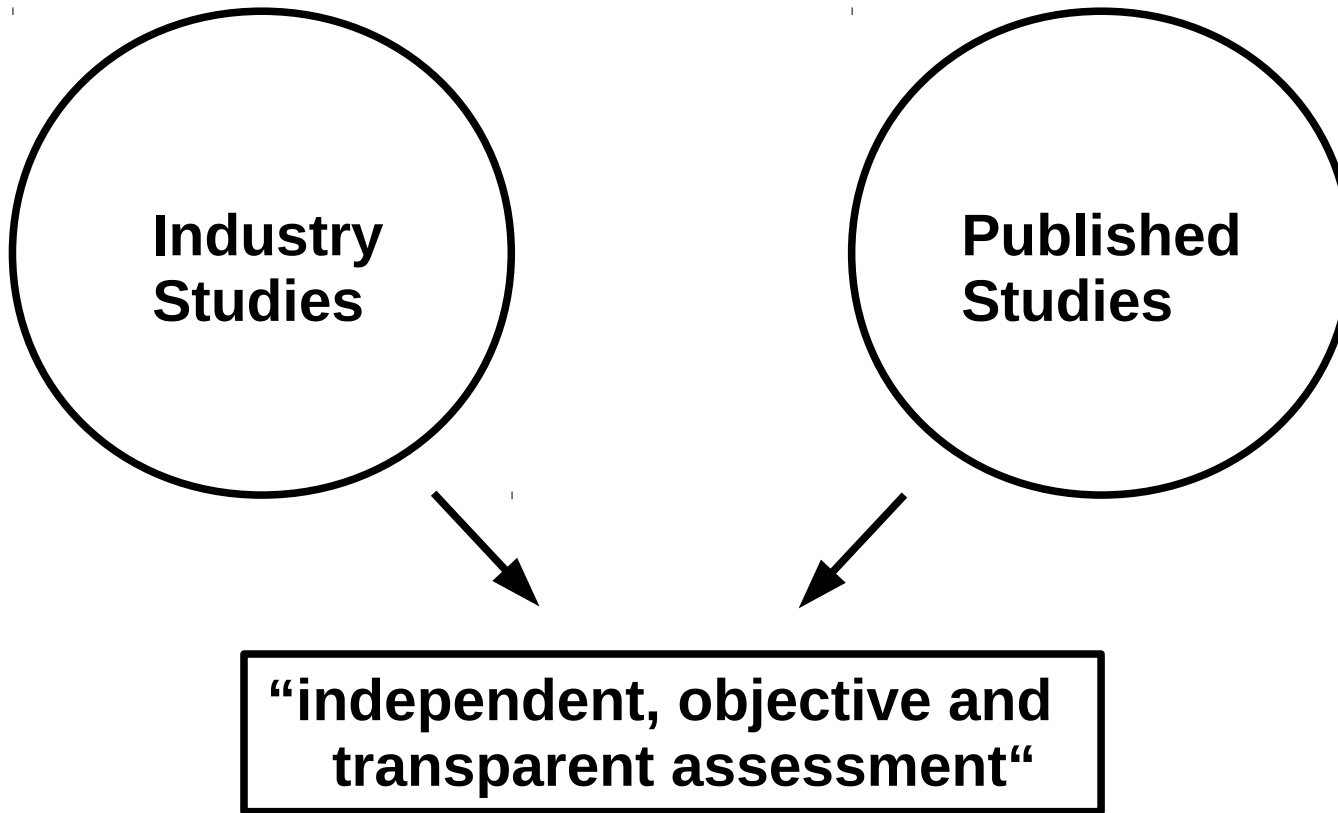
Jose Tarazona (EFSA), Oct. 11th 2017, European Parliament





**Industry  
Studies**

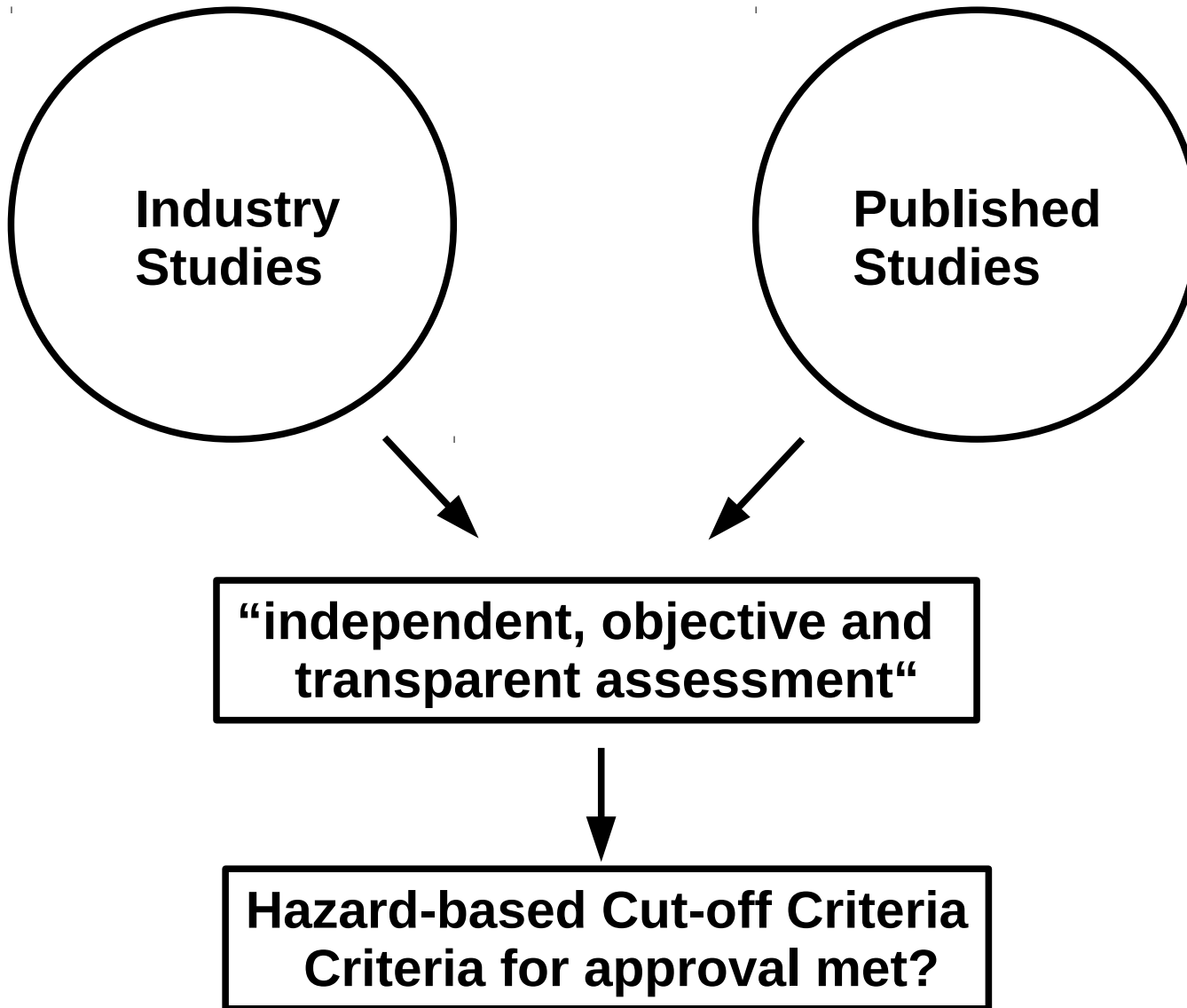


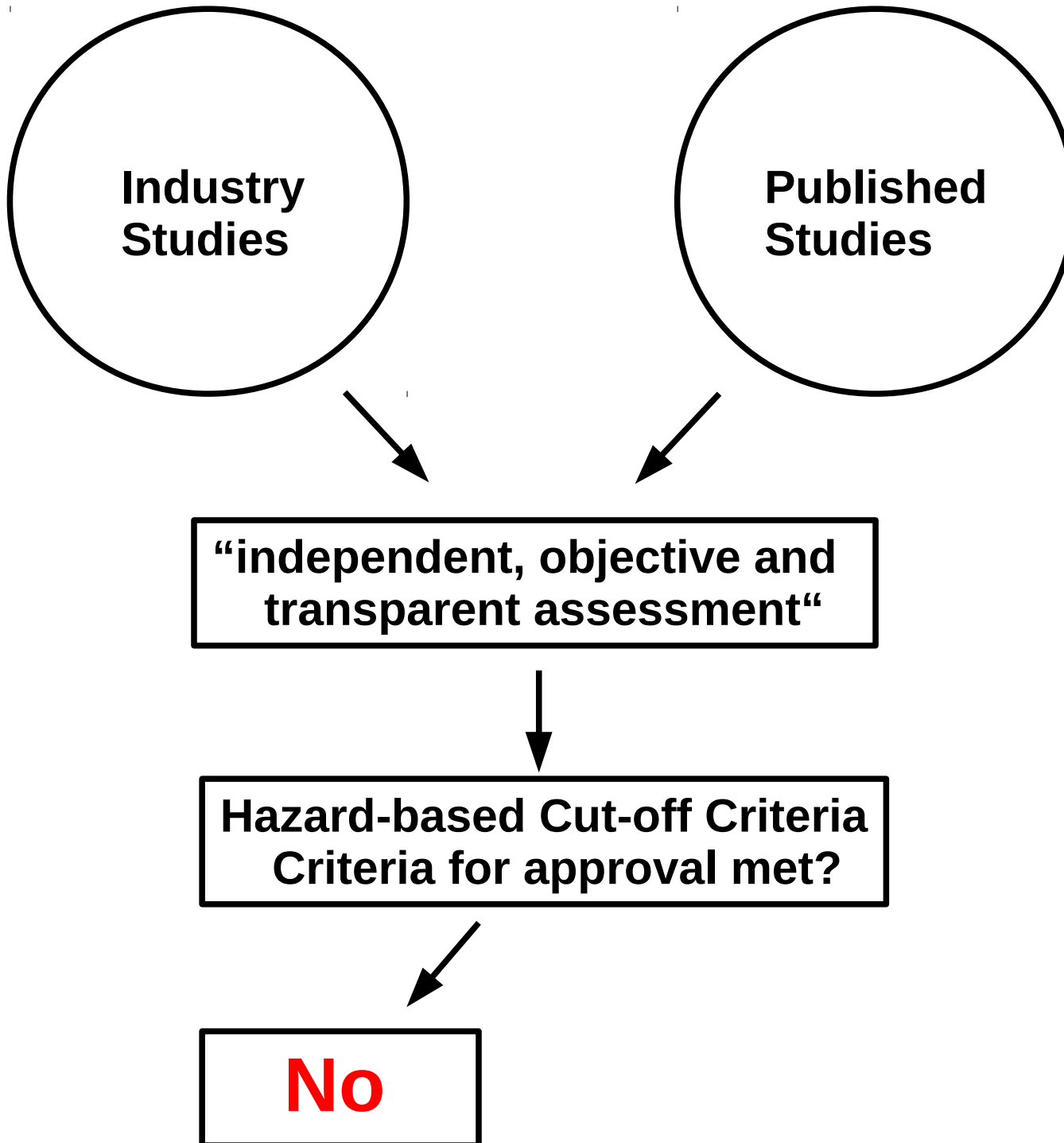


**Industry  
Studies**

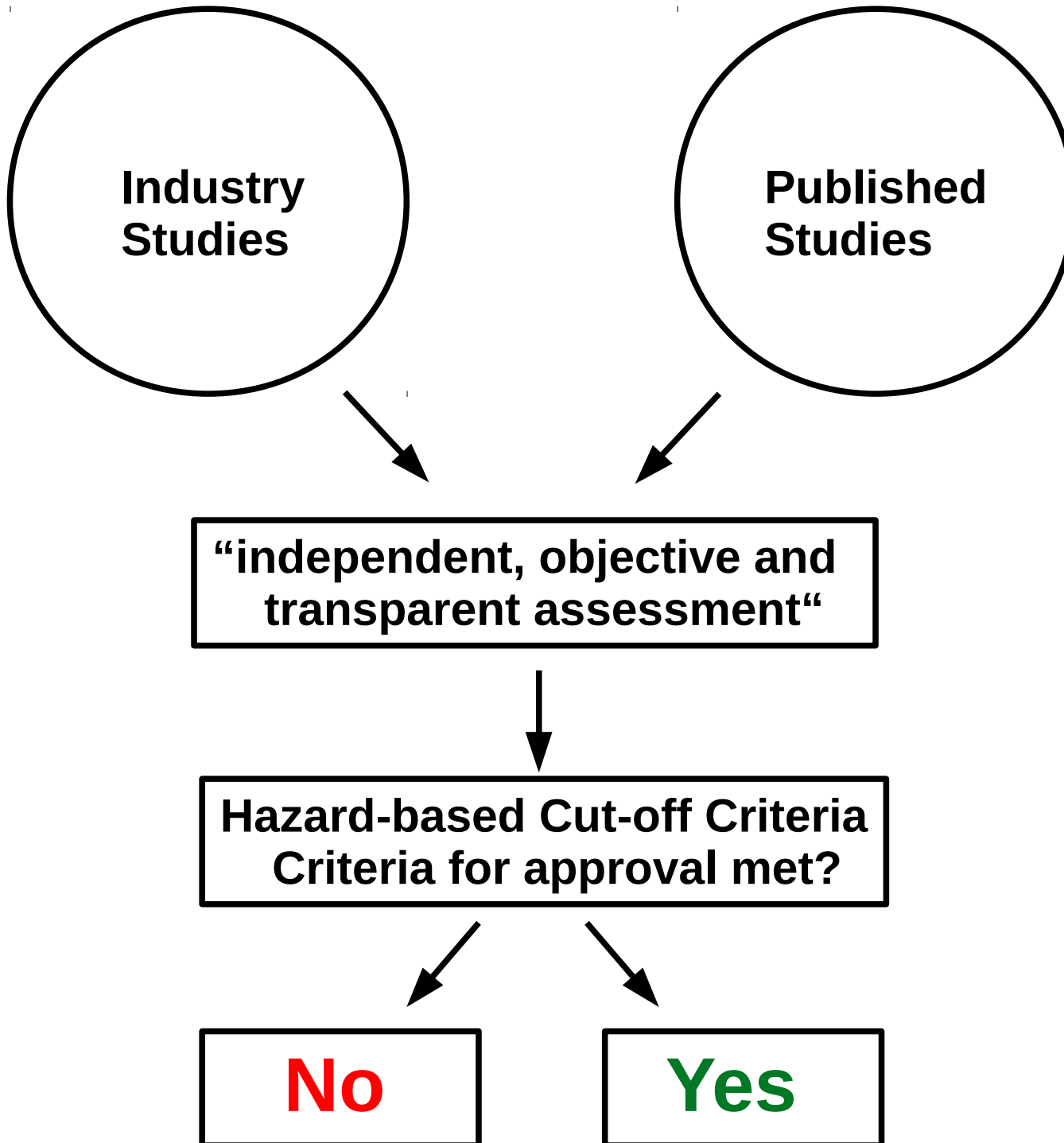
**Published  
Studies**

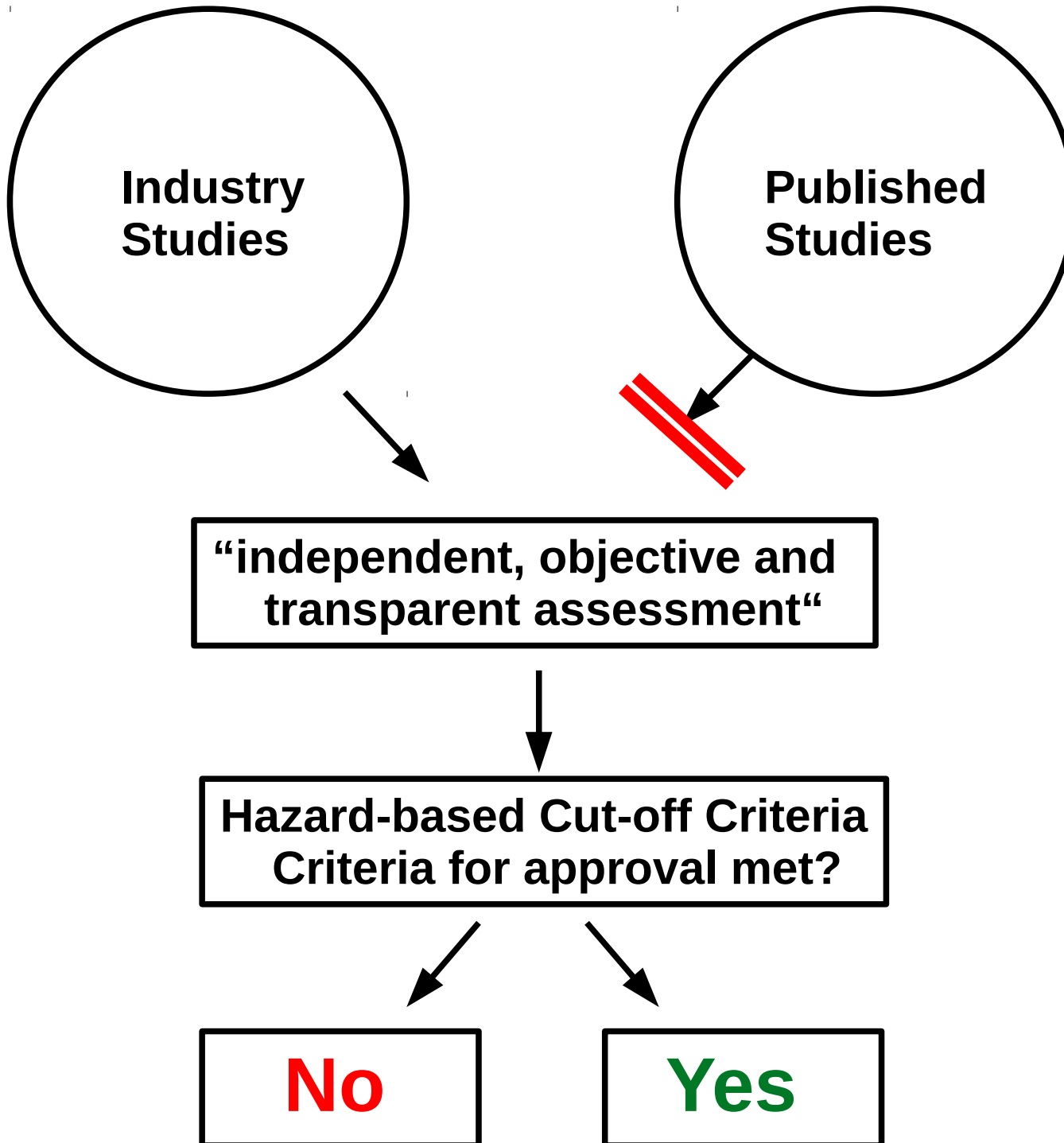
**“independent, objective and  
transparent assessment“**

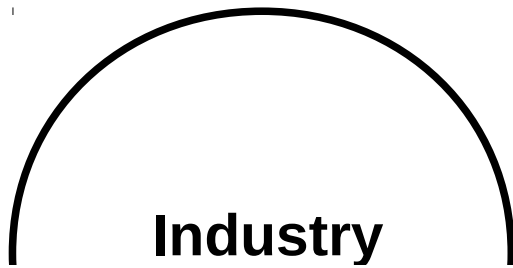












**Industry**



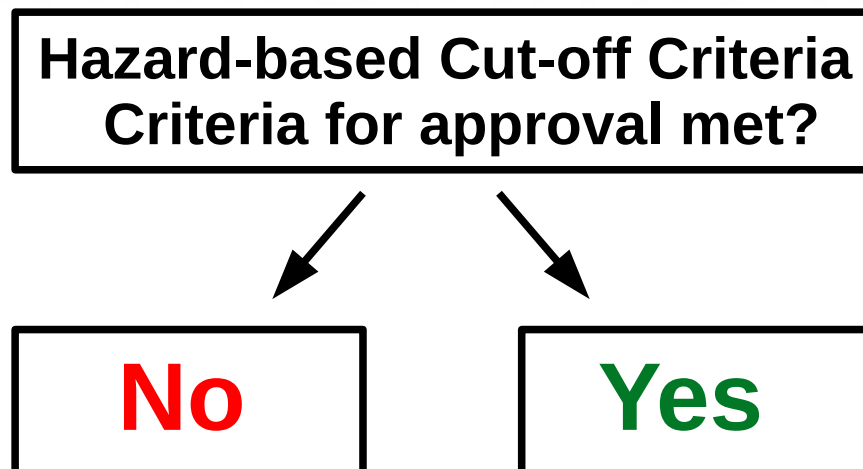
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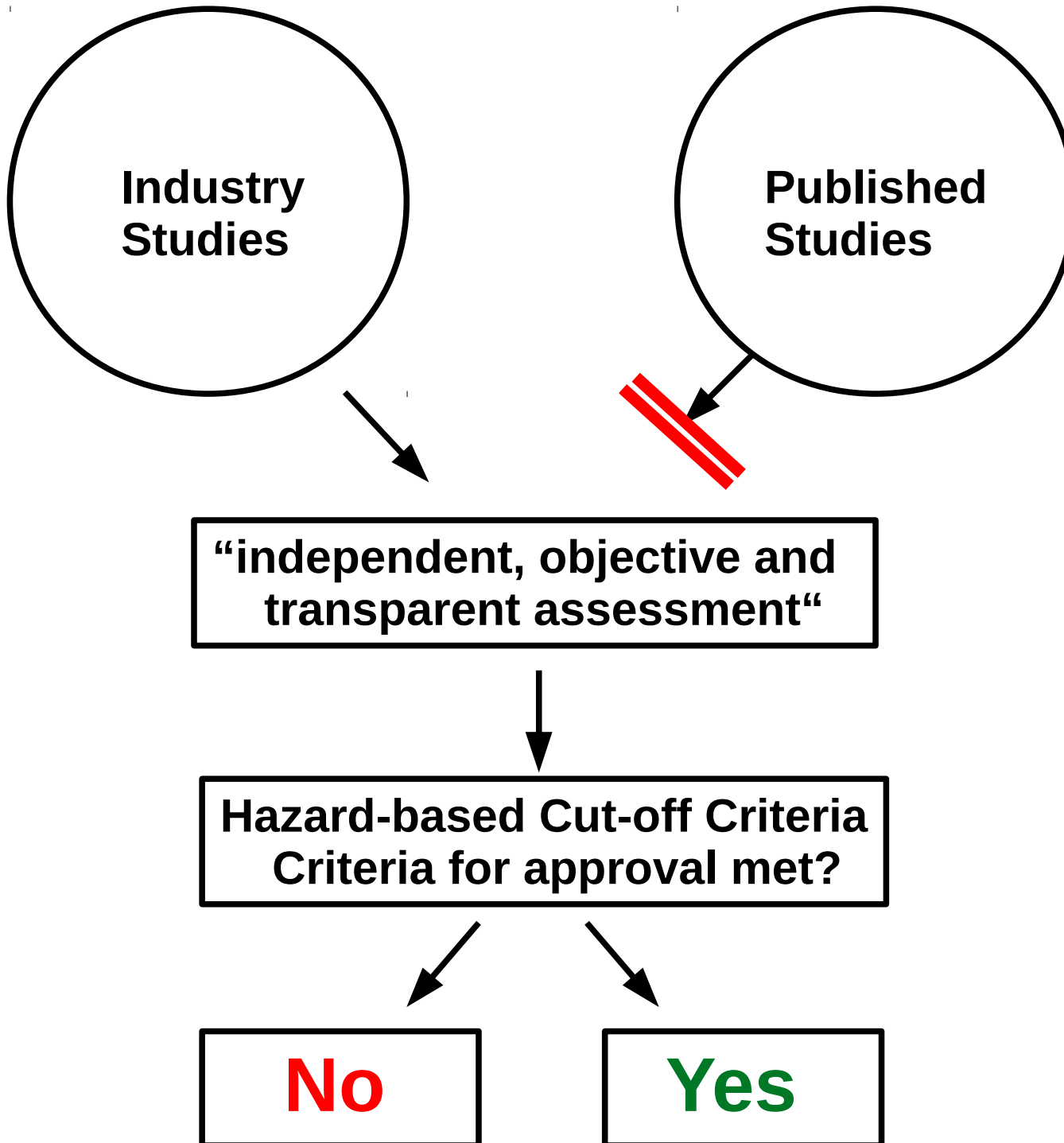
### **Conclusion by the Notifiers**

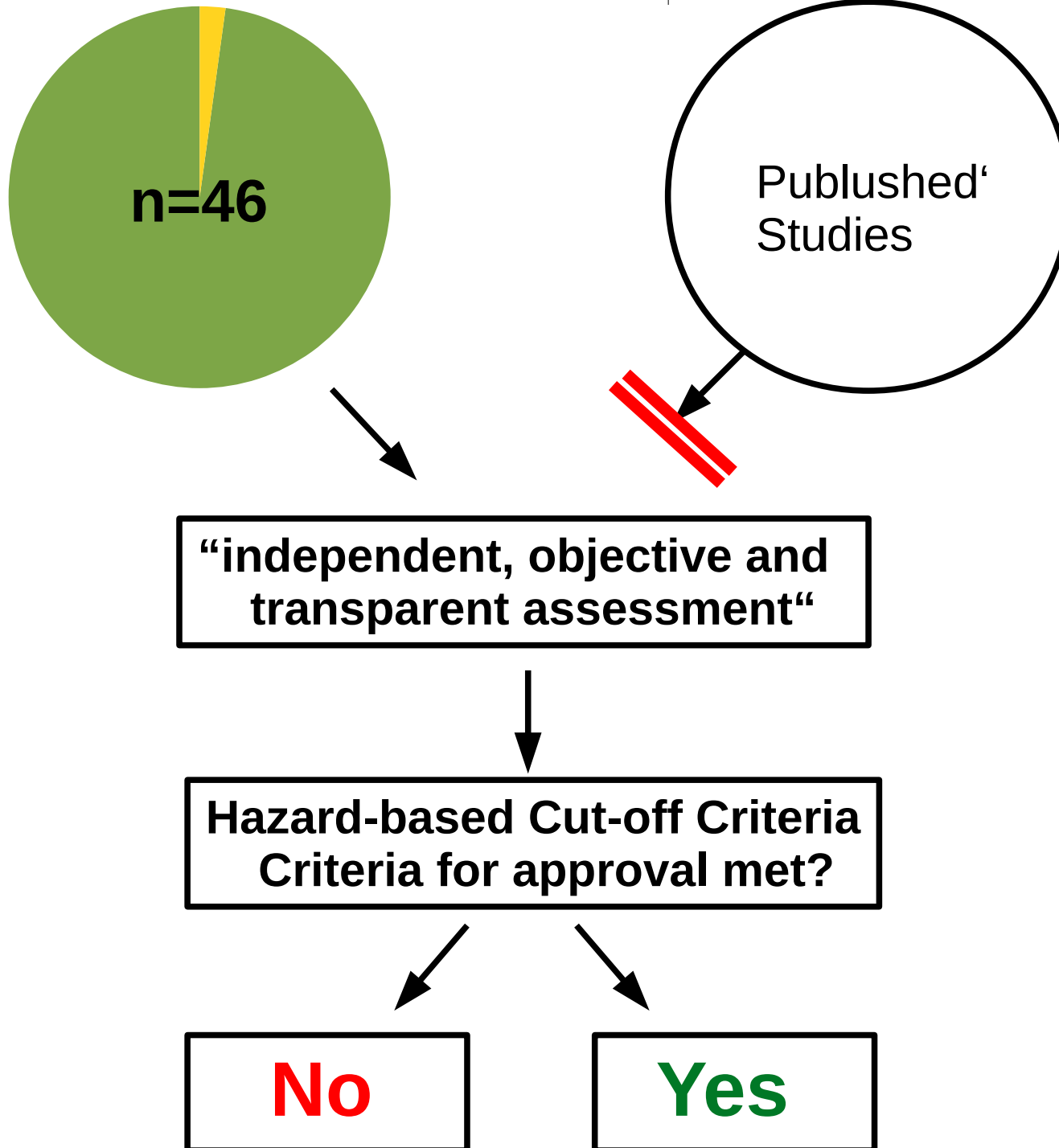
Based on the mild toxic effects on body weight gain and the increased organ weights without histopathological changes the NOAEL in rats after chronic exposure to Glyphosate technical for 24 month is 25,000 ppm (corresponding to 1290 mg/kg bw/day for males and 1740 mg/kg bw/day for females). It is concluded that Glyphosate technical is not carcinogenic in rats.

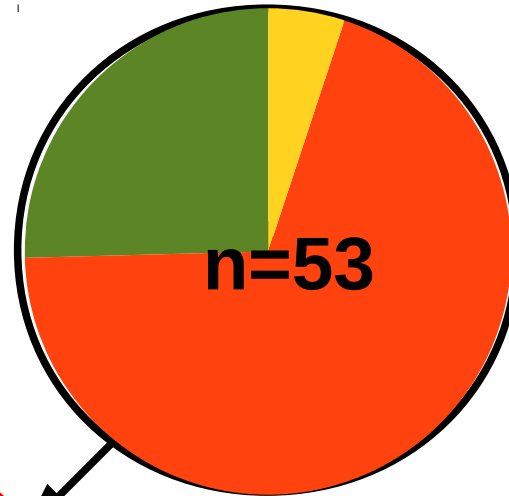
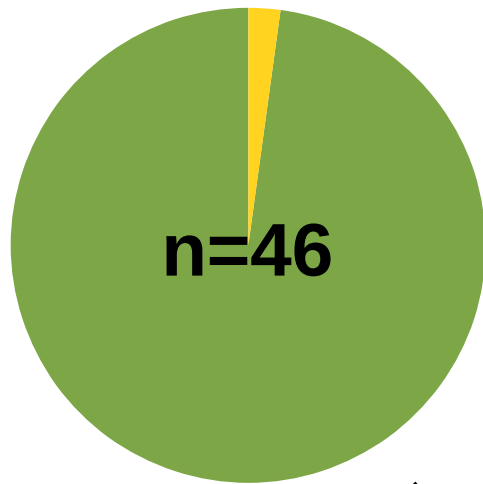
### **RMS comment:**

*This study is not acceptable because no core information on the test substance such as batch number or purity was given and, thus, it is not clear what was in fact tested. Even if this data would be available, the study might be considered at best supplementary because of its many additional deficiencies. [...]*







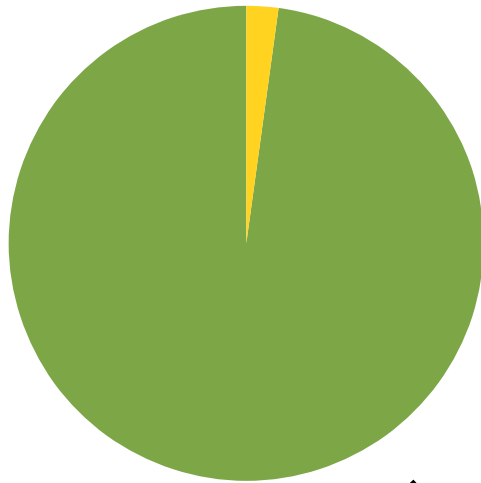


“independent, objective and transparent assessment”

Hazard-based Cut-off Criteria  
Criteria for approval met?

No

Yes



**“independent, objective and transparent assessment”**



**Hazard-based Cut-off Criteria  
Criteria for approval met?**



**No**

**Yes**

BfR's Assessment report, *chapter: B.6.4.8 Published data (released since 2000)*



- Red (94 %): Copy-pasted from GTF's dossier
- Yellow (4%): Studies that have been submitted later than the dossier
- White (2 %): (Reference-) Numbers for studies and headlines



„All in all, the writers of the report must be accused of significant scientific misconduct and of fulfilling all the definitional criteria of text plagiarism in the sense of conscious deception about the true authorship.“

Expert Opinion, Doz. Dr. Stefan Weber

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#### **4. Literature Review of Genotoxicity Publications**

**The following genotoxicity literature review was conducted by an expert in the field of genotoxicology. Relevant OECD Tier II-like summaries and Klimisch ratings (Klimisch, 1997), as described in introduction of the overall literature review, follow this genotoxicity literature review.**

***Review of Genotoxicity of Glyphosate and Glyphosate Based Formulations,*  
**Larry D. Kier, PhD, Genotoxicology Consultant, Buena Vista, CO****

#### ***Abbreviations***

AMPA, aminomethylphosphonic acid ; CB MN, cytokinesis block micronucleus;  
GBF, glyphosate based formulation; i.p., intraperitoneal ; NCE, normochromatic  
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# Industry's Dossier

## “3. Literature Review of Carcinogenicity Publications“

### KLIMISCH EVALUATION

**1. Reliability of study:**

**Not reliable**

**Comment:** Study prone to selection and recall bias. No evidence of relevant glyphosate exposures. Medical history was assessed, but not reported.

**2. Relevance of study:**

**Not relevant** (Exposure to multiple chemicals and though glyphosate exposure data were convincing (7/1145 subjects) and statistically non-significant positive associations reported.)

**3. Klimisch code:**

**3**

### Response 3 – Monsanto Review by John Acquavella, PhD and Donna Farmer, PhD

#### Executive Summary

Hardell and Eriksson conducted a case control study to look for associations between reported pesticide use and non-Hodgkin's lymphoma (NHL). The study included 404 NHL cases and 741 controls. The measure of association in this study was the odds ratio (OR), a statistic that estimates of the ratio of disease rates (in this case NHL rates) for exposed and unexposed populations.

The authors reported statistically significant associations for NHL with: reported use of any herbicide (OR

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# BfR's Assessment Report

## "B.6.5.3 Published data on carcinogenicity (released since 2000)"

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#### Additional comments:

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„In the incriminating passages the reader has no doubt that the BfR is describing its own literature research – including presenting its methodology – and giving its own judgments, while in reality these are the judgments either of the ‘Glyphosate Task Force’ or of Dr Kier.“

Expert Opinion, Doz. Dr. Stefan Weber



**Thank you for your attention!**