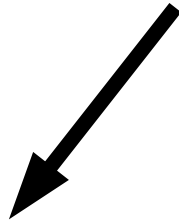


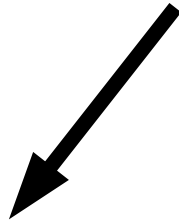
Glyphosate and Cancer Buying Science

Glyphosate and Cancer Buying Science

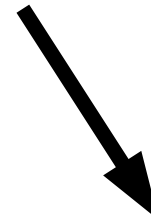


Quality ?

Glyphosate and Cancer Buying Science

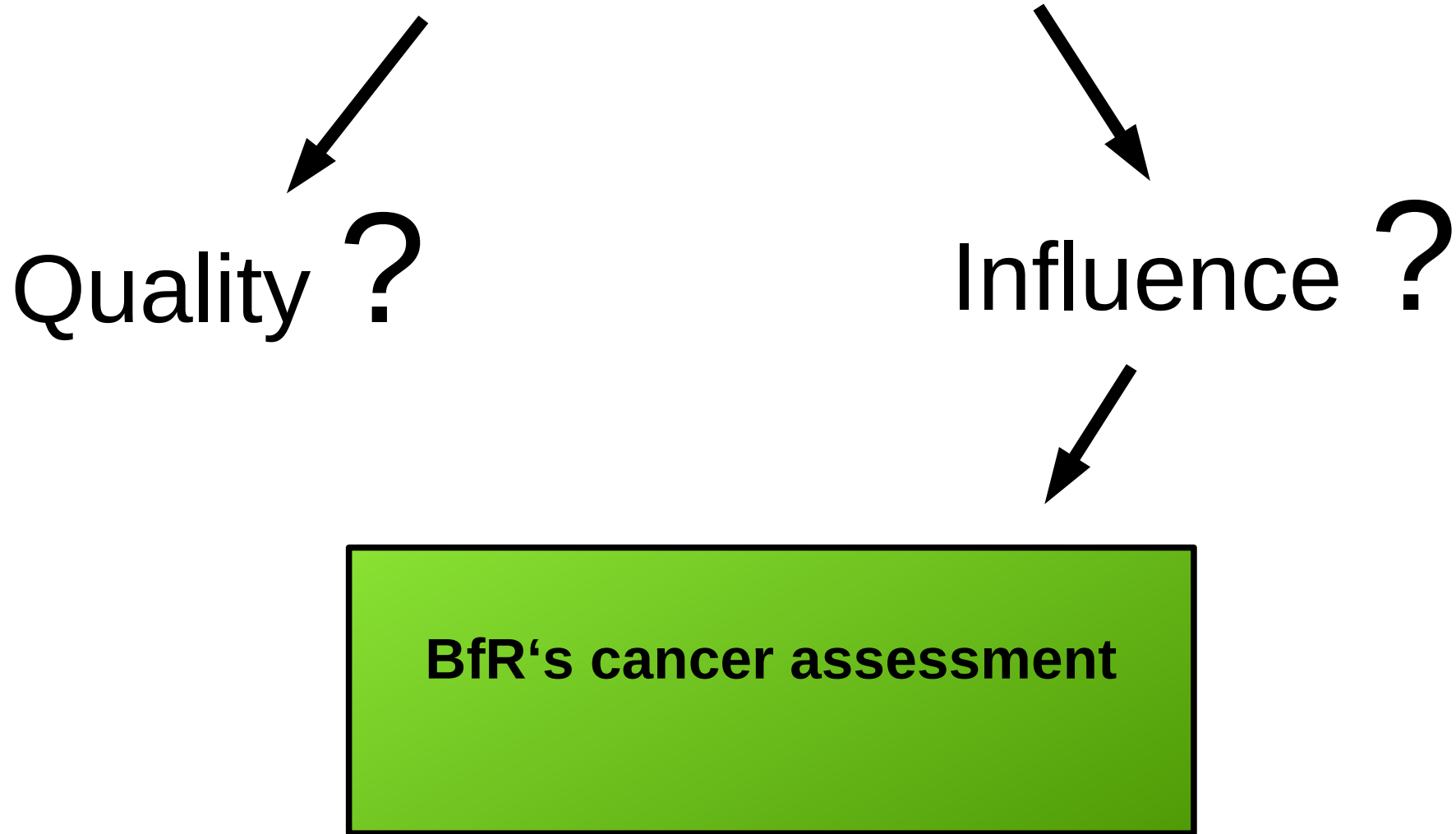


Quality ?



Influence ?

Glyphosate and Cancer Buying Science



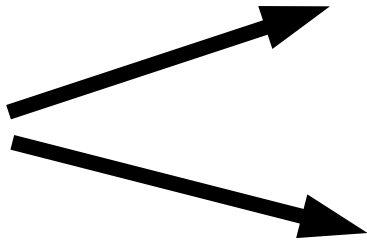
**BfR's cancer
Assessment
on glyphosate**

**BfR's cancer
Assessment
on glyphosate**



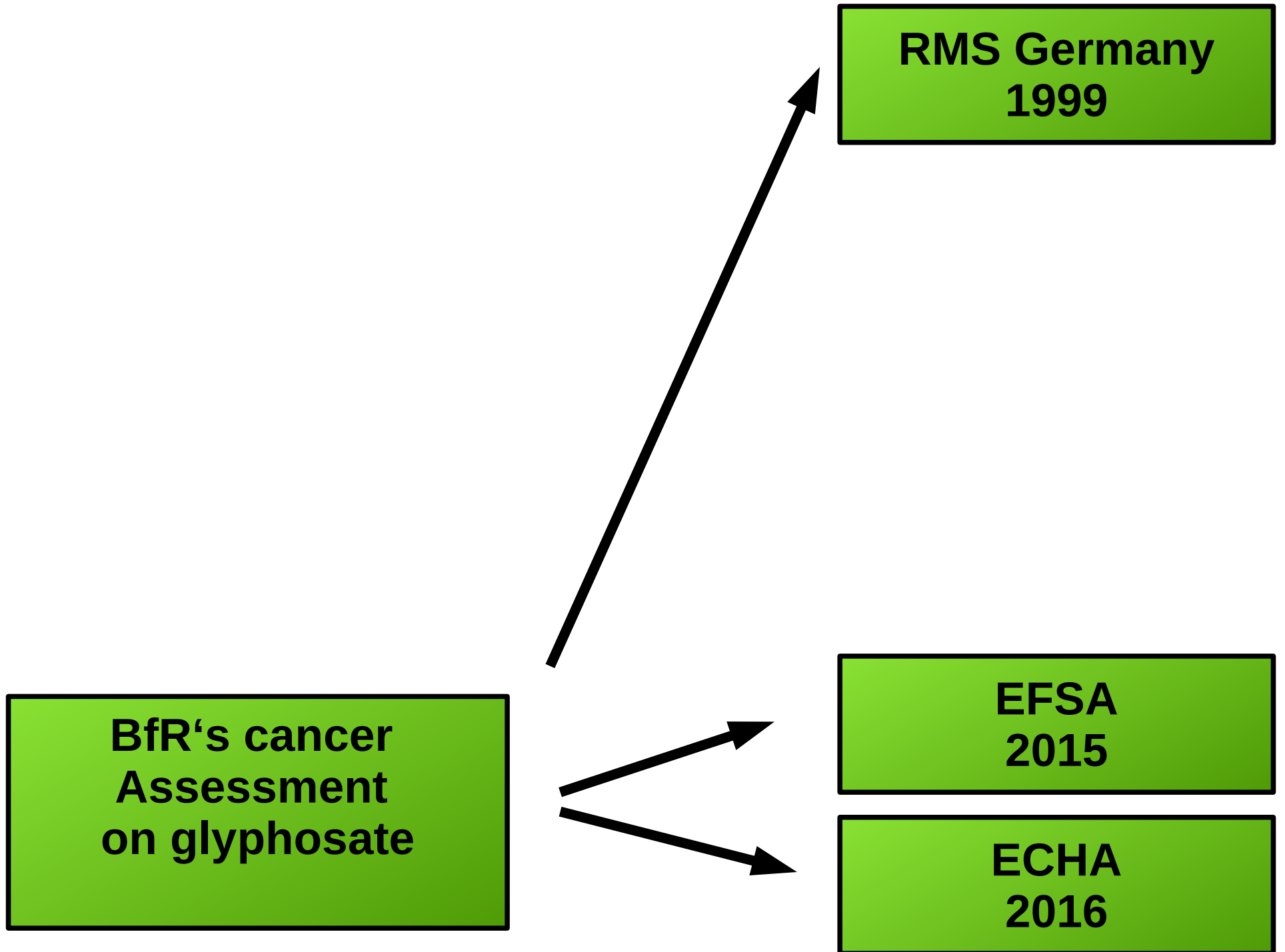
**EFSA
2015**

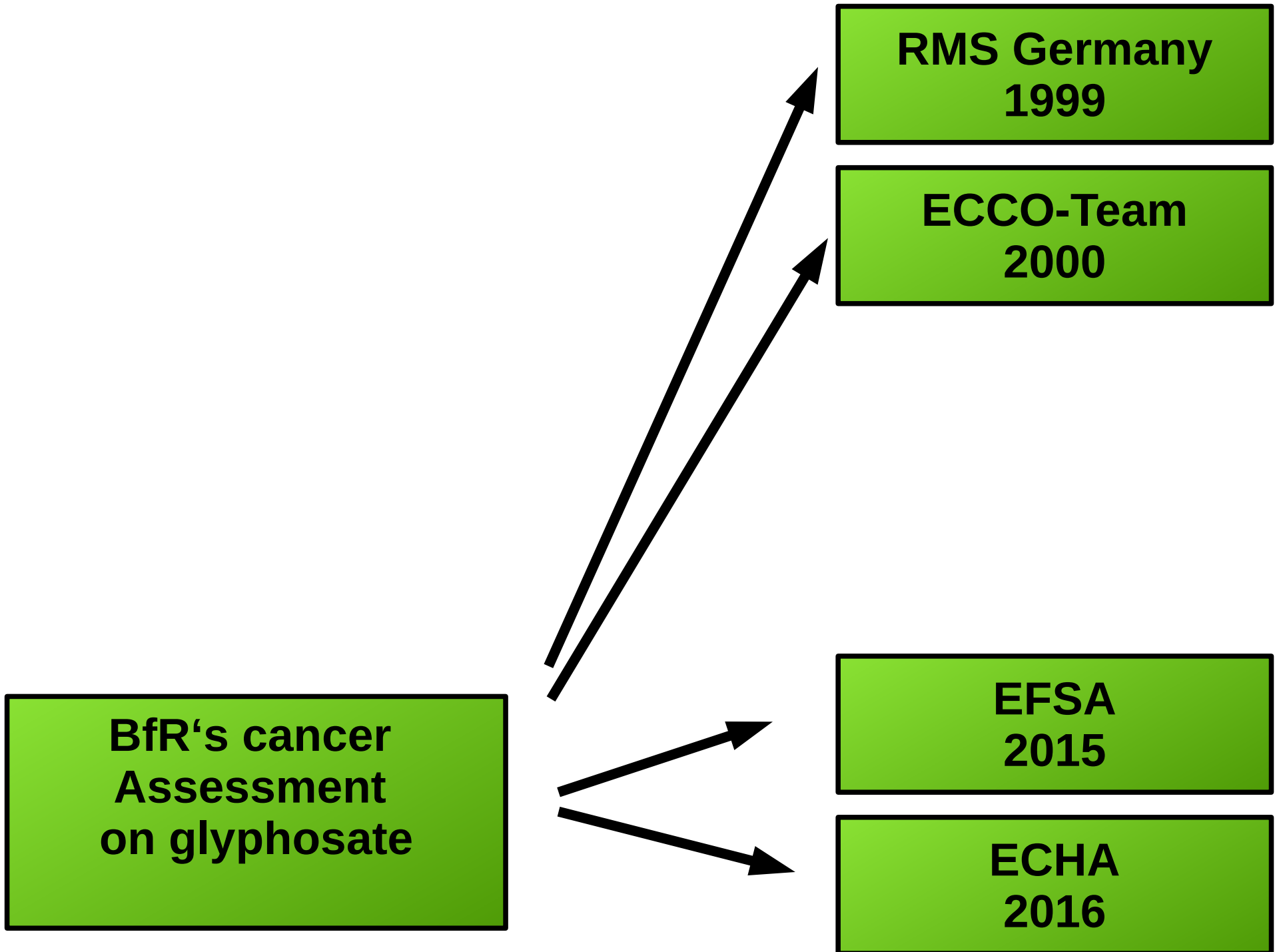
**BfR's cancer
Assessment
on glyphosate**

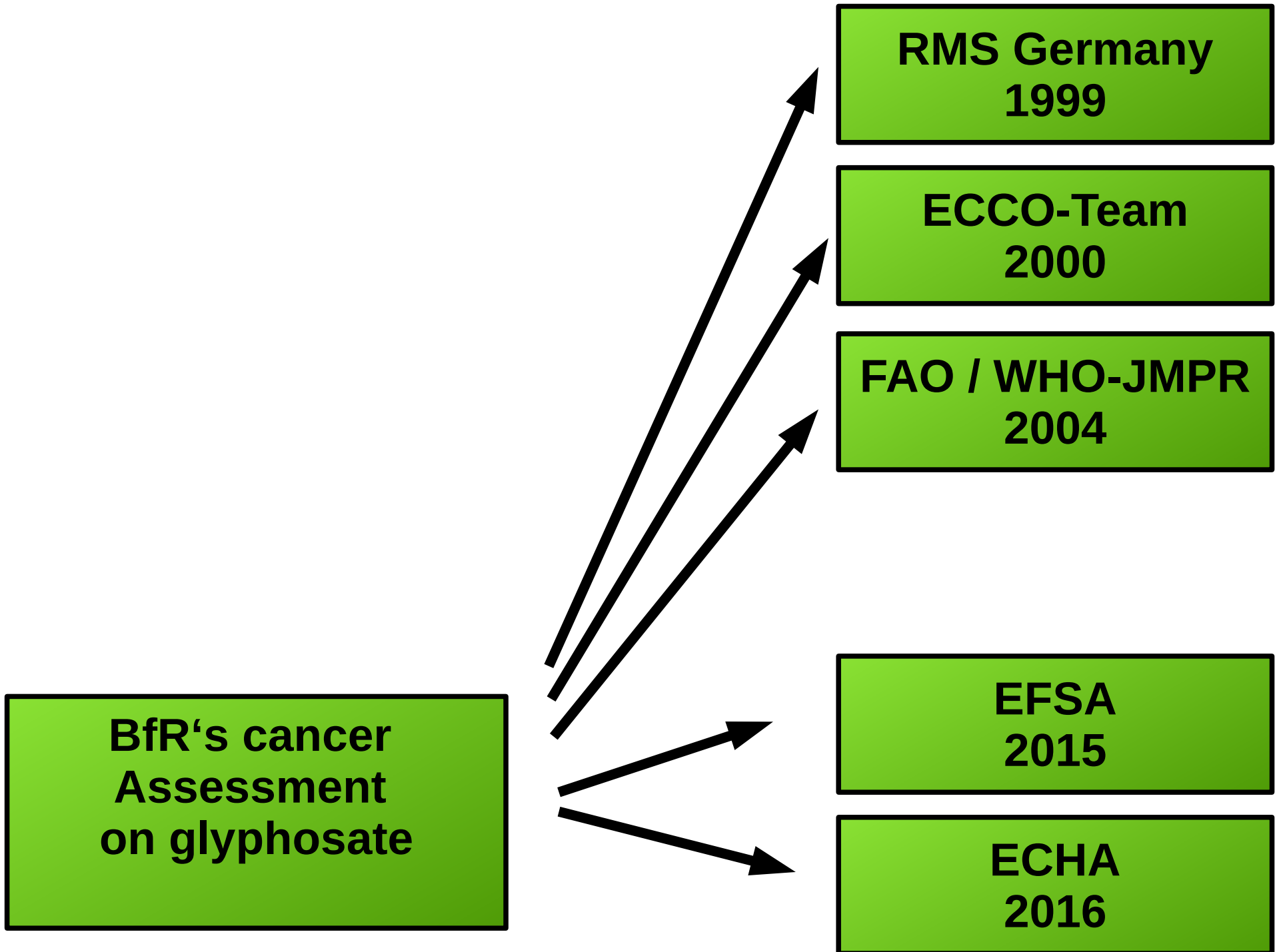


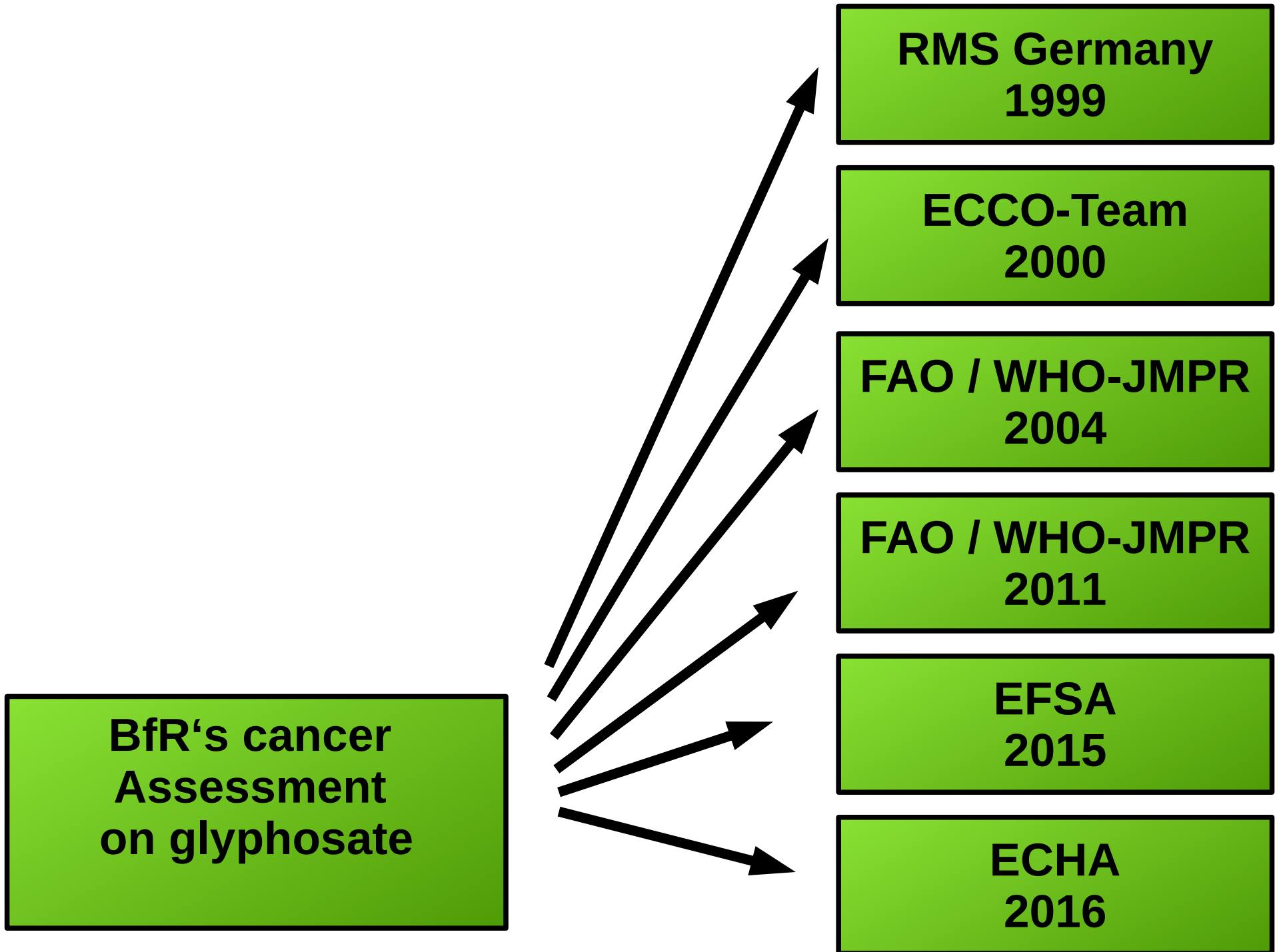
**EFSA
2015**

**ECHA
2016**



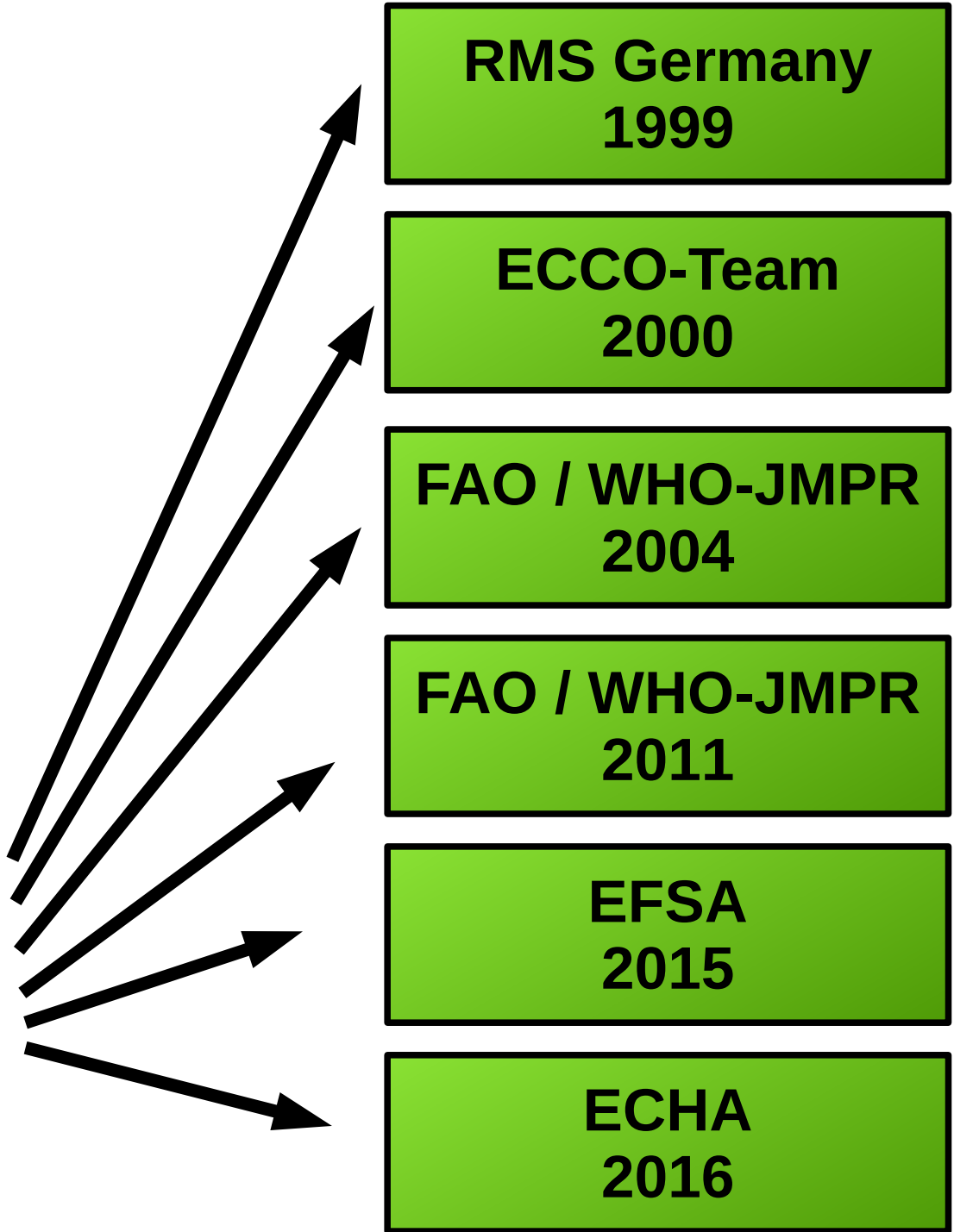


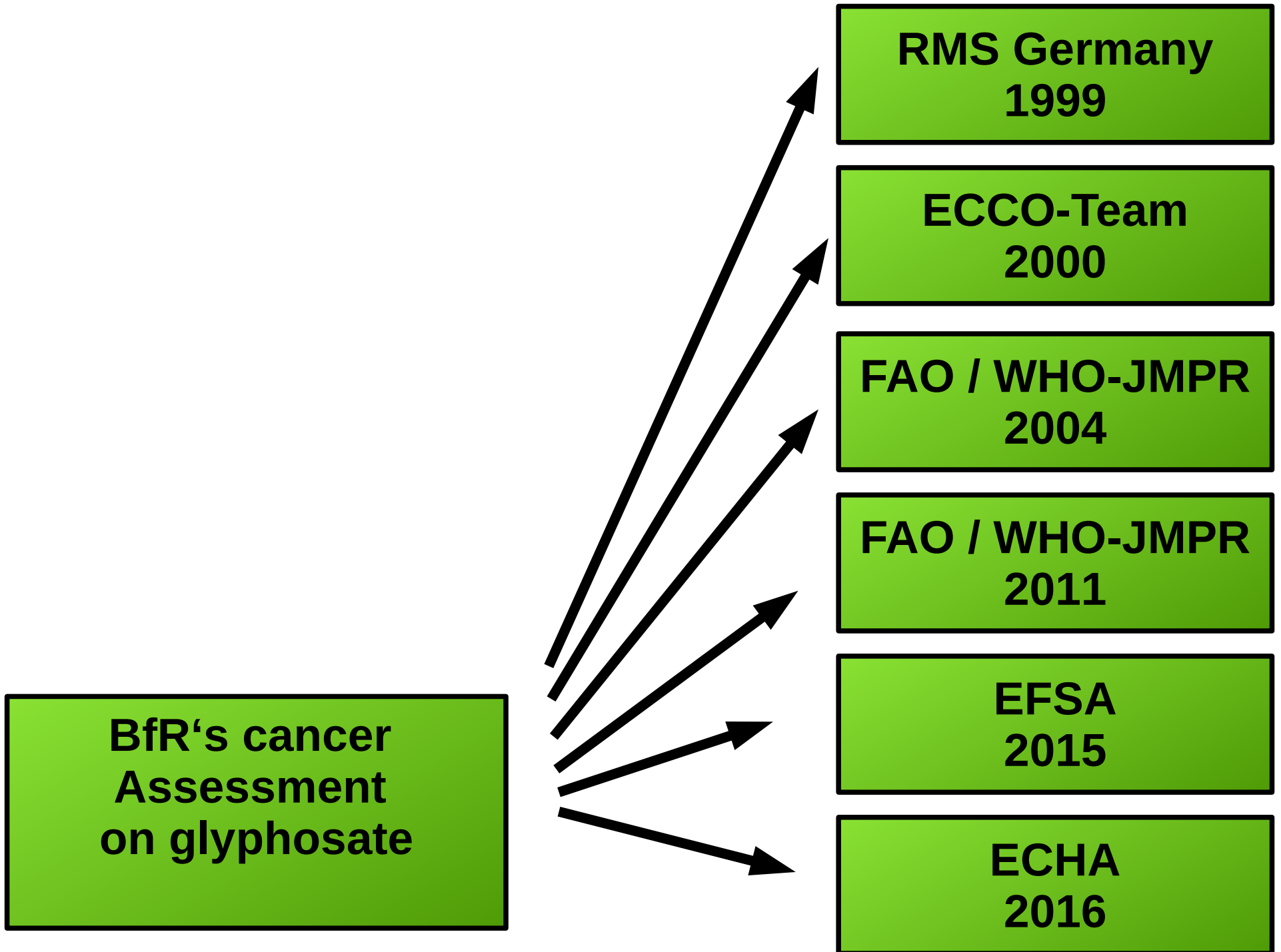


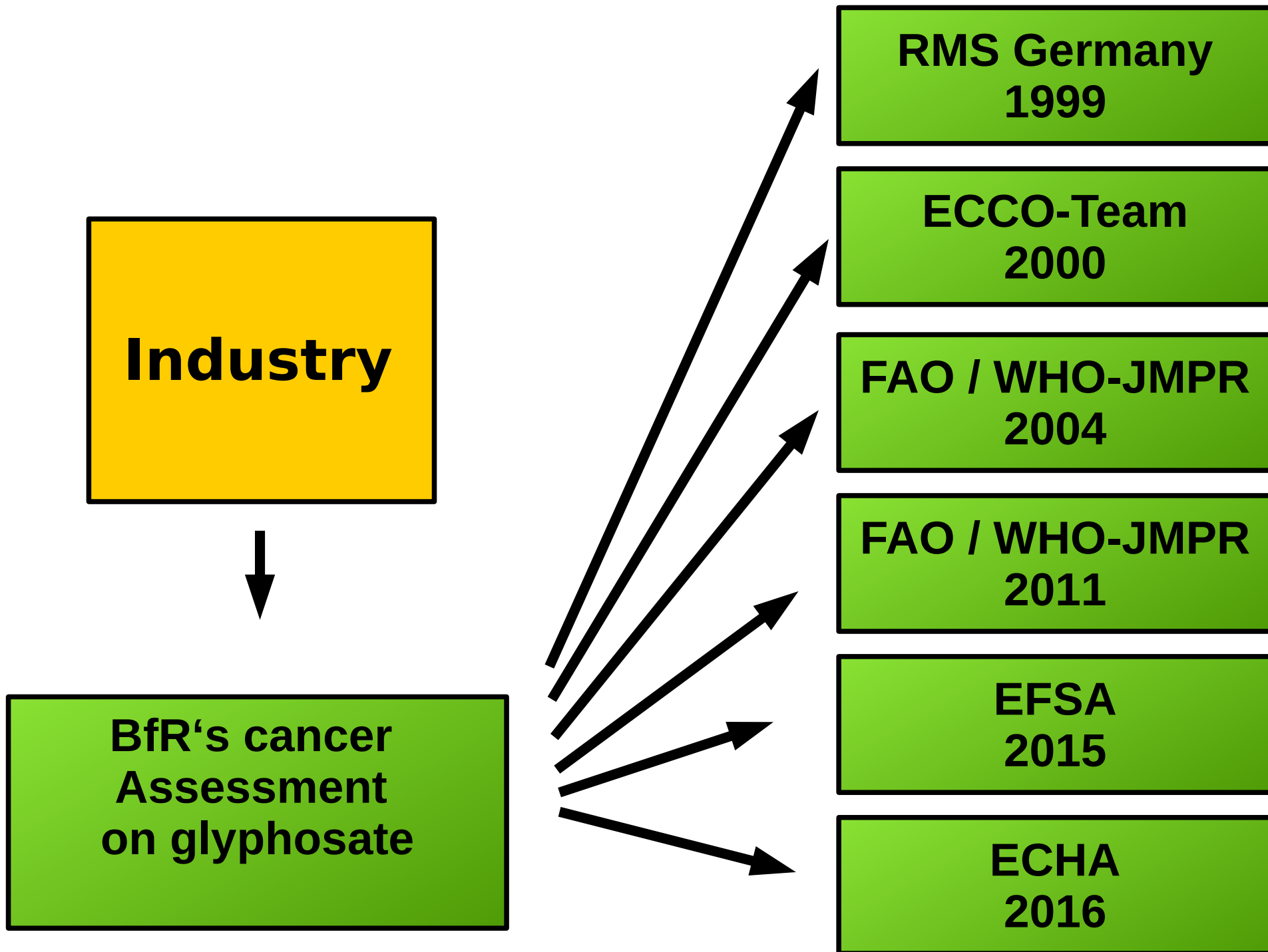


Revolving Doors ?

**BfR's cancer
Assessment
on glyphosate**

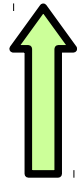






**BfR's cancer assessment
(May 2012 – March 2015)**

**BfR's cancer assessment
(May 2012 – March 2015)**



**Unpublished
regulatory
studies**

**BfR's cancer assessment
(May 2012 – March 2015)**



**Unpublished
regulatory
studies**



**Published
Monsanto-
sponsored
review articles**

**BfR's cancer assessment
(May 2012 – March 2015)**



**Unpublished
regulatory
studies**

**Published
academic
studies**



**Published
Monsanto-
sponsored
review articles**

**BfR's cancer assessment
(May 2012 – March 2015)**



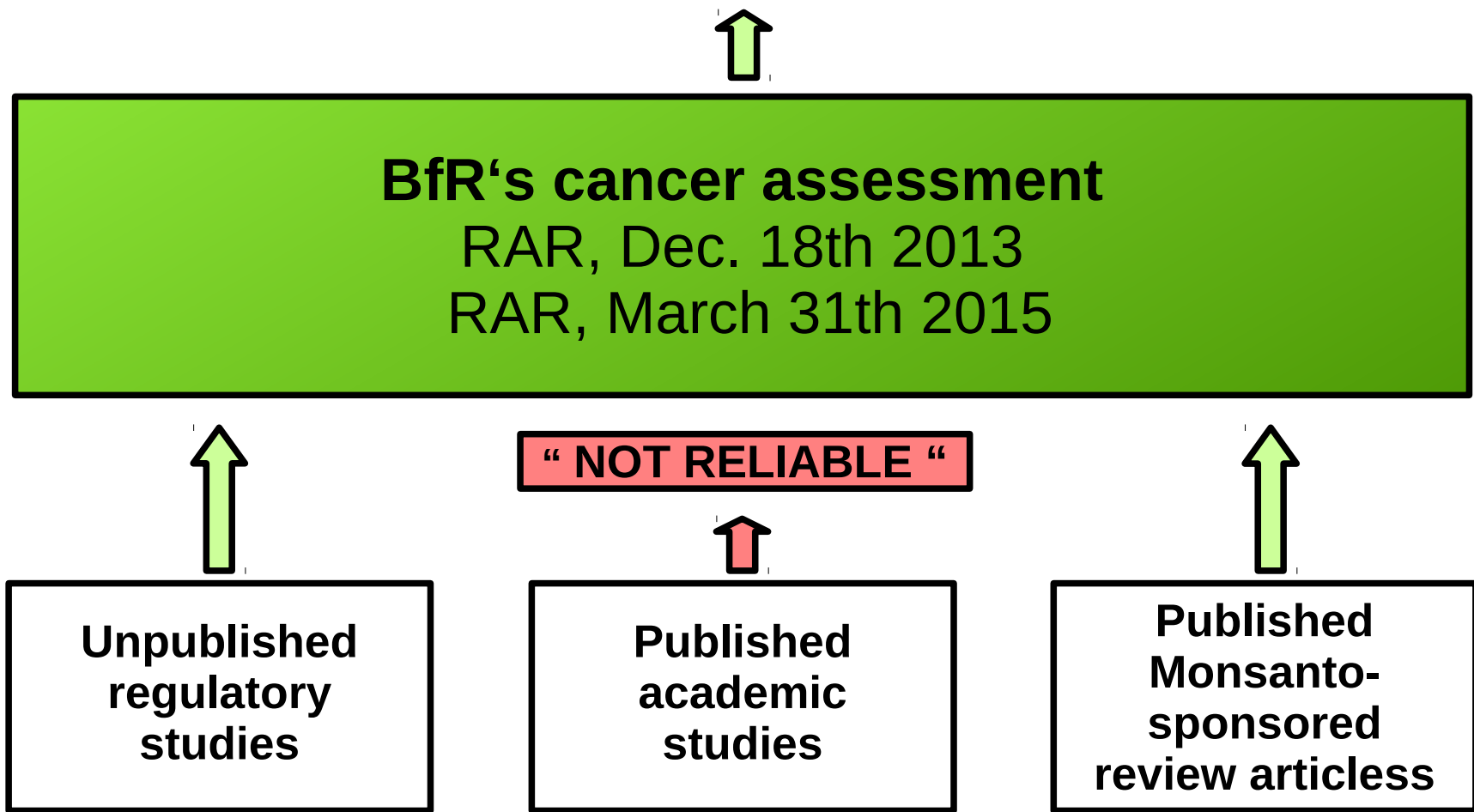
“ NOT RELIABLE “



**Unpublished
regulatory
studies**

**Published
academic
studies**

**Published
Monsanto-
sponsored
review articles**

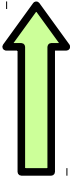


No evidence of carcinogenicity in humans



BfR's cancer assessment
RAR, Dec. 18th 2013
RAR, March 31th 2015

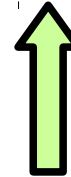
“ NOT RELIABLE “



**Unpublished
regulatory
studies**



**Published
academic
studies**



**Published
Monsanto-
sponsored
review articles**

No evidence of carcinogenicity in humans

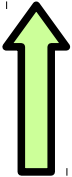
No evidence of carcinogenicity animals



BfR's cancer assessment

RAR, Dec. 18th 2013

RAR, March 31th 2015



Unpublished
regulatory
studies

“ NOT RELIABLE “



Published
academic
studies

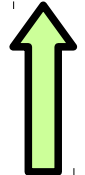


Published
Monsanto-
sponsored
review articles

No evidence of carcinogenicity in humans
No evidence of carcinogenicity animals
No evidence of genotoxicity



BfR's cancer assessment
RAR, Dec. 18th 2013
RAR, March 31th 2015

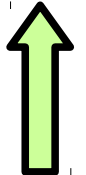


Unpublished
regulatory
studies

“ NOT RELIABLE “



Published
academic
studies



Published
Monsanto-
sponsored
review articles

IARC's cancer assessment

IARC's cancer assessment



**Published
academic
studies**

IARC's cancer assessment



**Published
academic
studies**

Lack of Transparency



**Published
Monsanto-
sponsored
review articles**

IARC's cancer assessment

Lack of Transparency



Unpublished
regulatory
studies



Published
academic
studies

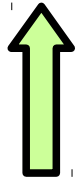
Lack of Transparency



Published
Monsanto-
sponsored
review articles

IARC's cancer assessment

Lack of Transparency



Unpublished
regulatory
studies

4



Published
academic
studies

Lack of Transparency



Published
Monsanto-
sponsored
review articles

Limited evidence of carcinogenicity in humans



IARC's cancer assessment:
Glyphosate is a probable human carcinogen

Lack of Transparency



Unpublished
regulatory
studies

4



Published
academic
studies

Lack of Transparency



Published
Monsanto-
sponsored
review articles

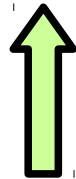
Limited evidence of carcinogenicity in humans

Sufficient evidence of carcinogenicity animals



IARC's cancer assessment:
Glyphosate is a probable human carcinogen

Lack of Transparency



Unpublished
regulatory
studies

4



Published
academic
studies

Lack of Transparency



Published
Monsanto-
sponsored
review articles

Limited evidence of carcinogenicity in humans

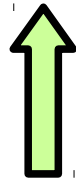
Sufficient evidence of carcinogenicity animals

Strong evidence of genotoxicity



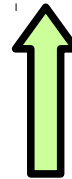
IARC's cancer assessment:
Glyphosate is a probable human carcinogen

Lack of Transparency



Unpublished
regulatory
studies

4



Published
academic
studies

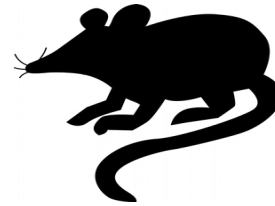
Lack of Transparency



Published
Monsanto-
sponsored
review articles

The Strength of Evidence according to IARC

**Sufficient
(strong)
evidence**



**Limited
Evidence**



**Inadequate
evidence**

**Evidence
of lack of
carcinogenicity**

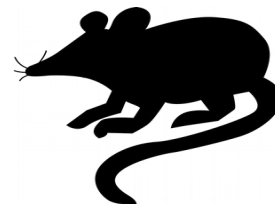
The Strength of Evidence according to BfR (January 2014)

**Sufficient
(strong)
evidence**

**Limited
Evidence**

**Inadequate
evidence**

**Evidence
of lack of
carcinogenicity**



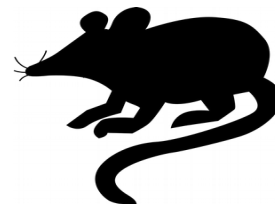
The Strength of Evidence according to BfR (January 2014)

**Sufficient
(strong)
evidence**

**Limited
Evidence**

**Inadequate
evidence**

**Evidence
of lack of
carcinogenicity**



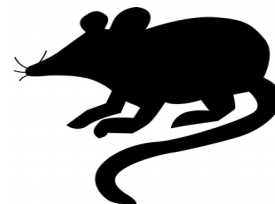
The Strength of Evidence according to BfR (January 2014)

**Sufficient
(strong)
evidence**

**Limited
Evidence**

**Inadequate
evidence**

**Evidence
of lack of
carcinogenicity**



1. How published studies were dismissed:

Evaluation of the human evidence by IARC



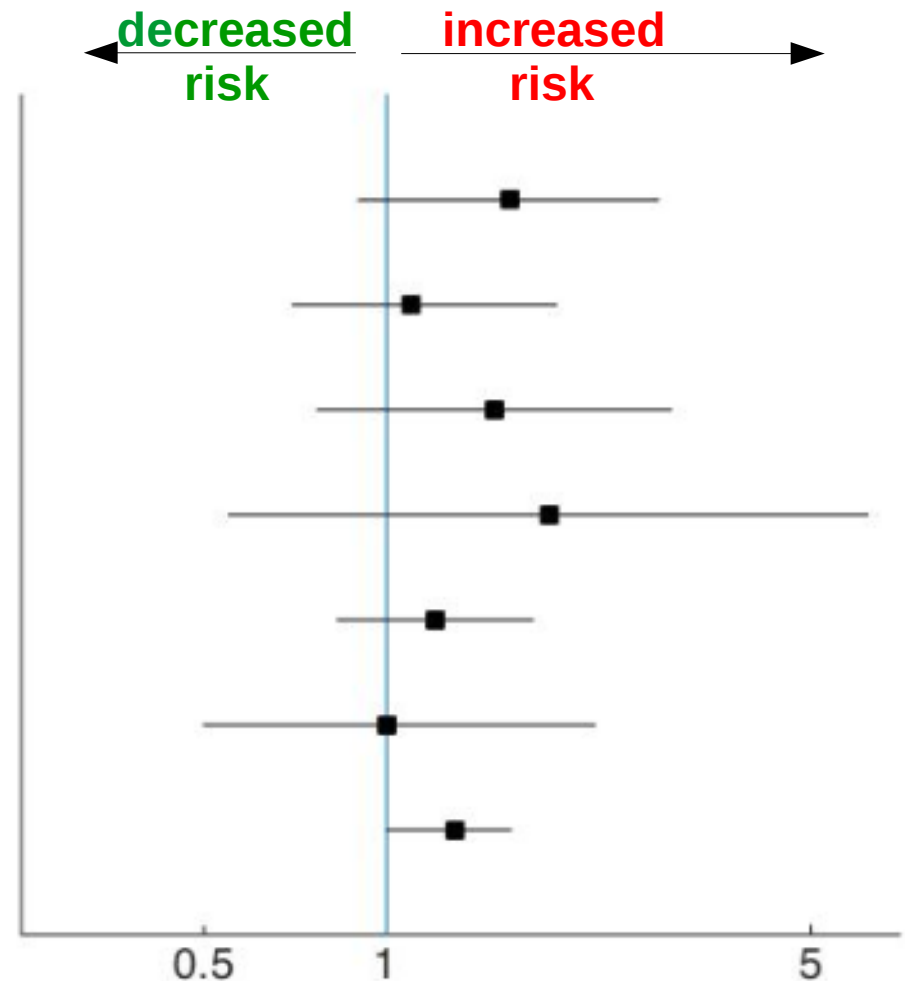
Epidemiological Studies on Glyphosate & Cancer	Increase of Risk for Non-Hodgkin-Lymphoma	Confidence Interval $p < 0,05$
De Roos et al. 2003	1,6	0,9 - 2,8
De Roos et al. 2005*	1,1	0,9 - 1,3
Eriksson et al. 2008	1,51	0.77 - 2.94
Hardell et al. 2002	1,85	0.55 - 6.20
McDuffie et al. 2001	1,2	0,83 - 1,74
Orsi et al. 2008	1,0	0,5 - 2,2
Meta-Analysis Shinasi & Leon	1,5	1,1 - 2,3

1. How published studies were dismissed:

Evaluation of the human evidence by IARC



Epidemiological Studies on Glyphosate & Cancer	Increase of Risk for Non-Hodgkin-Lymphoma	Confidence Interval $p < 0,05$
De Roos et al. 2003	1,6	0,9 - 2,8
De Roos et al. 2005*	1,1	0,9 - 1,3
Eriksson et al. 2008	1,51	0.77 - 2.94
Hardell et al. 2002	1,85	0.55 - 6.20
McDuffie et al. 2001	1,2	0,83 - 1,74
Orsi et al. 2008	1,0	0,5 - 2,2
Meta-Analysis Shinasi & Leon	1,5	1,1 - 2,3

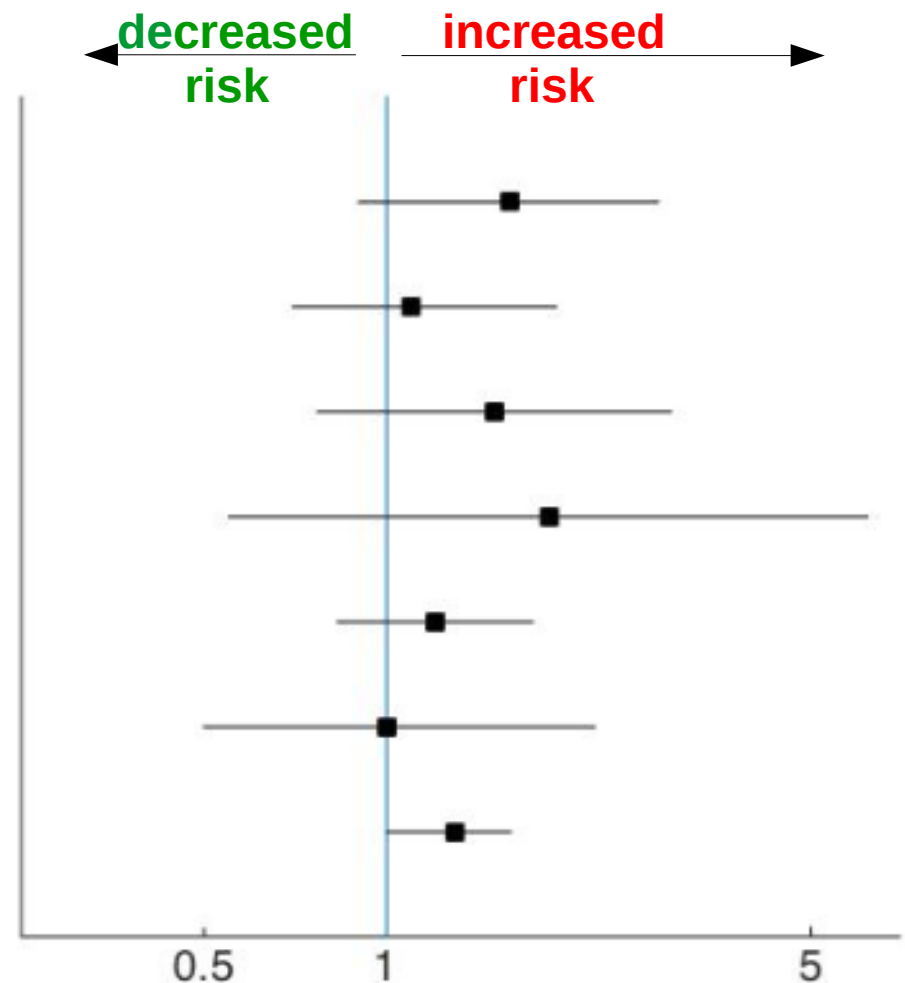


1. How published studies were dismissed:

Evaluation by the BfR (**before IARC**)



Epidemiological Studies on Glyphosate & Cancer	Increase of Risk for Non-Hodgkin-Lymphoma	Confidence Interval $p < 0,05$
De Roos et al. 2003	1,6	0,9 - 2,8
De Roos et al. 2005*	1,1	0,9 - 1,3
Eriksson et al. 2008	1,51	0.77 - 2.94
Hardell et al. 2002	1,85	0.55 - 6.20
McDuffie et al. 2001	1,2	0,83 - 1,74
Orsi et al. 2008	1,0	0,5 - 2,2
Meta-Analysis Shinasi & Leon	1,5	1,1 - 2,3

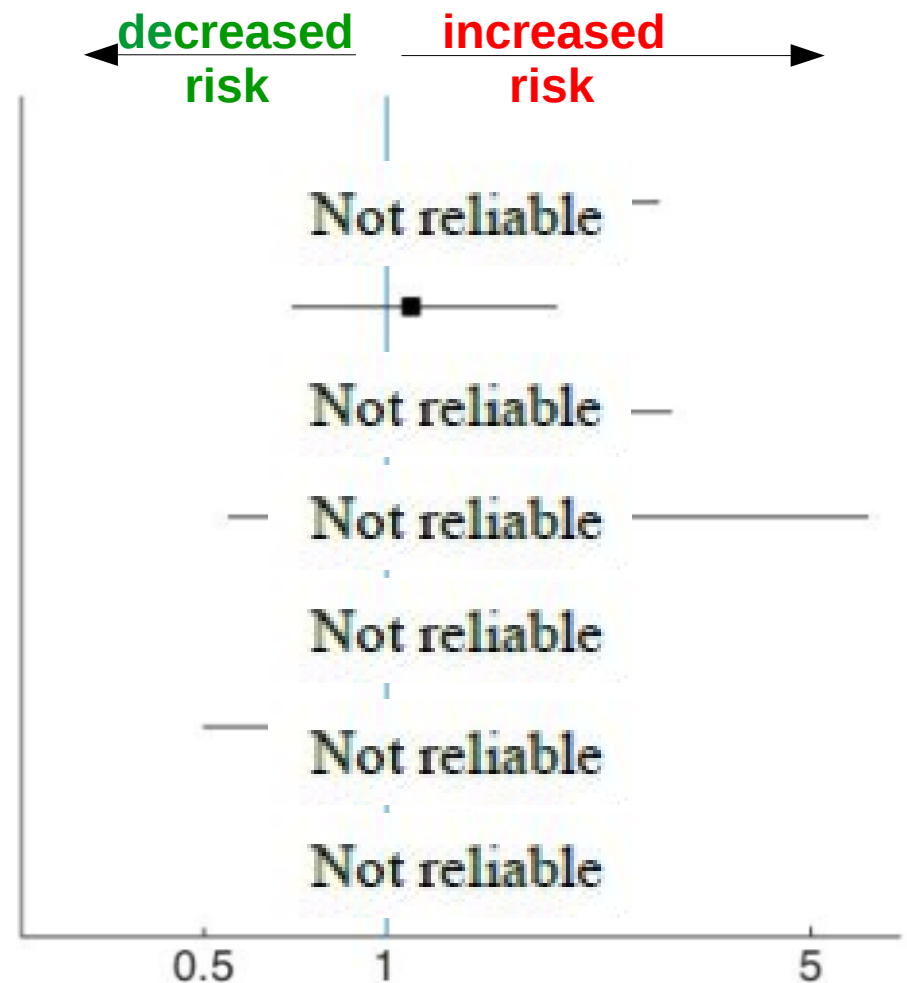


1. How published studies were dismissed:

Evaluation by the BfR (**before IARC**)



Epidemiological Studies on Glyphosate & Cancer	Increase of Risk for Non-Hodgkin-Lymphoma	Confidence Interval p<0,05
De Roos et al. 2003	Not reliable	2,8
De Roos et al. 2005*	1,1	0,9 - 1,3
Eriksson et al. 2008	Not reliable	2.94
Hardell et al. 2002	Not reliable	6.20
McDuffie et al. 2001	Not reliable	1,74
Orsi et al. 2008	Not reliable	2,2
Meta-Analysis Shinasi & Leon	Not reliable	2,3



1. How published studies were dismissed:

Evaluation by the BfR (**before IARC**)



Case-Control Study by Hardell et al. 2002

Klimisch evaluation

Reliability of study:

Not reliable

Comment:

This publication combines the results of two previous studies by the authors on HNL (Hardell and Eriksson, 1999, ASB2012-11838) and HCL (Nordström, et al., 1998, TOX1999-687). No information about exposure duration, exposure concentration, as well as medical history, lifestyle factors (e.g. smoker, use of prescribed drugs etc). Study documentation is insufficient for assessment.

Relevance of study:

Not relevant (Due to reliability of data set drawn from Hardell and Eriksson, 1999, ASB2012-11838)

Klimisch code:

3

1. How published studies were dismissed:

Evaluation by the BfR (**before IARC**)



Case-Control Study by Hardell et al. 2002

Klimisch evaluation

Reliability of study:

Not reliable

Comment:

This publication combines the results of two previous studies by the authors on HNL (Hardell and Eriksson, 1999, ASB2012-11838) and HCL (Nordström, et al., 1998, TOX1999-687). No information about exposure duration, exposure concentration, as well as medical history, lifestyle factors (e.g. smoker, use of prescribed drugs etc). Study documentation is insufficient for assessment.

Relevance of study:

Not relevant (Due to reliability of data set drawn from Hardell and Eriksson, 1999, ASB2012-11838)

Klimisch code:

3



1. How published studies were dismissed:

Evaluation by the BfR (**before IARC**)

“...without a doubt that all the data claimed by the BfR to be missing had actually been ascertained according to scientific epidemiological methodology.”

Professor Eberhard Greiser
Public Hearing, Deutscher Bundestag 28.09.2015



1. How published studies were dismissed:

Evaluation by the BfR (**before IARC**)

"This approach [...] represents a deliberate falsification of study content, presumably with the intention of qualifying the studies as scientifically inferior."

Professor Eberhard Greiser
Public Hearing, Deutscher Bundestag 28.09.2015

1. How published studies were dismissed:

Evaluation by the BfR (**after IARC**)



**Sufficient
(strong)
evidence**

**Limited
Evidence**

**Inadequate
evidence**

**Evidence
of lack of
carcinogenicity**



1. How published studies were dismissed:

Evaluation by the BfR (**after IARC**)



**Sufficient
(strong)
evidence**

"[BfR].. agrees with IARC that the other IARC categories are not suitable for the classification of the evidence from studies in humans."

**Limited
Evidence**



**Inadequate
evidence**

**Evidence
of lack of
carcinogenicity**

1. How published studies were dismissed:

Evaluation by the BfR (**after IARC**)



**Sufficient
(strong)
evidence**

"[BfR].. agrees with IARC that the other IARC categories are not suitable for the classification of the evidence from studies in humans."

**Limited
Evidence**

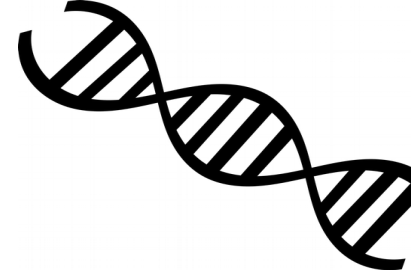
"However, [BfR] adopts **a more cautious** view since no consistent positive association was observed...."

**Inadequate
evidence**

**Evidence
of lack of
carcinogenicity**

1. **Has BfR been inappropriately influenced?**

The Genotox Hole

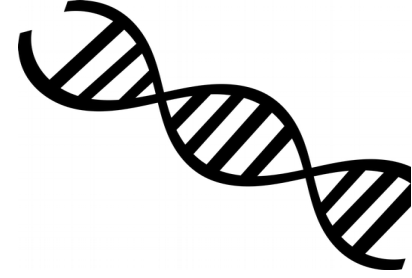


1. Has BfR been inappropriately influenced?

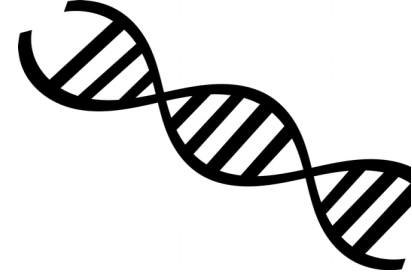
The Genotox Hole

"no hazard classification of glyphosate for mutagenicity is warranted....."

CLH-report („ECHA-proposal“)



1. Has BfR been inappropriately influenced?



The Genotox Hole

"no hazard classification of glyphosate for mutagenicity is warranted....."

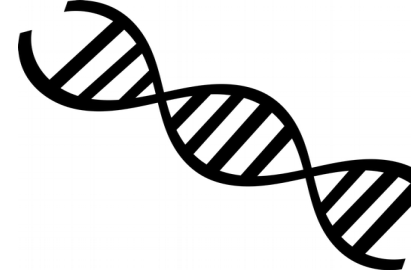
because of the..

".....negative results in the majority of the *in vitro* and *in vivo* mutagenicity tests..[...]"

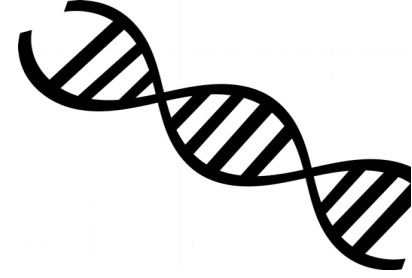
CLH-report („ECHA-proposal“)

1. Has BfR been inappropriately influenced?

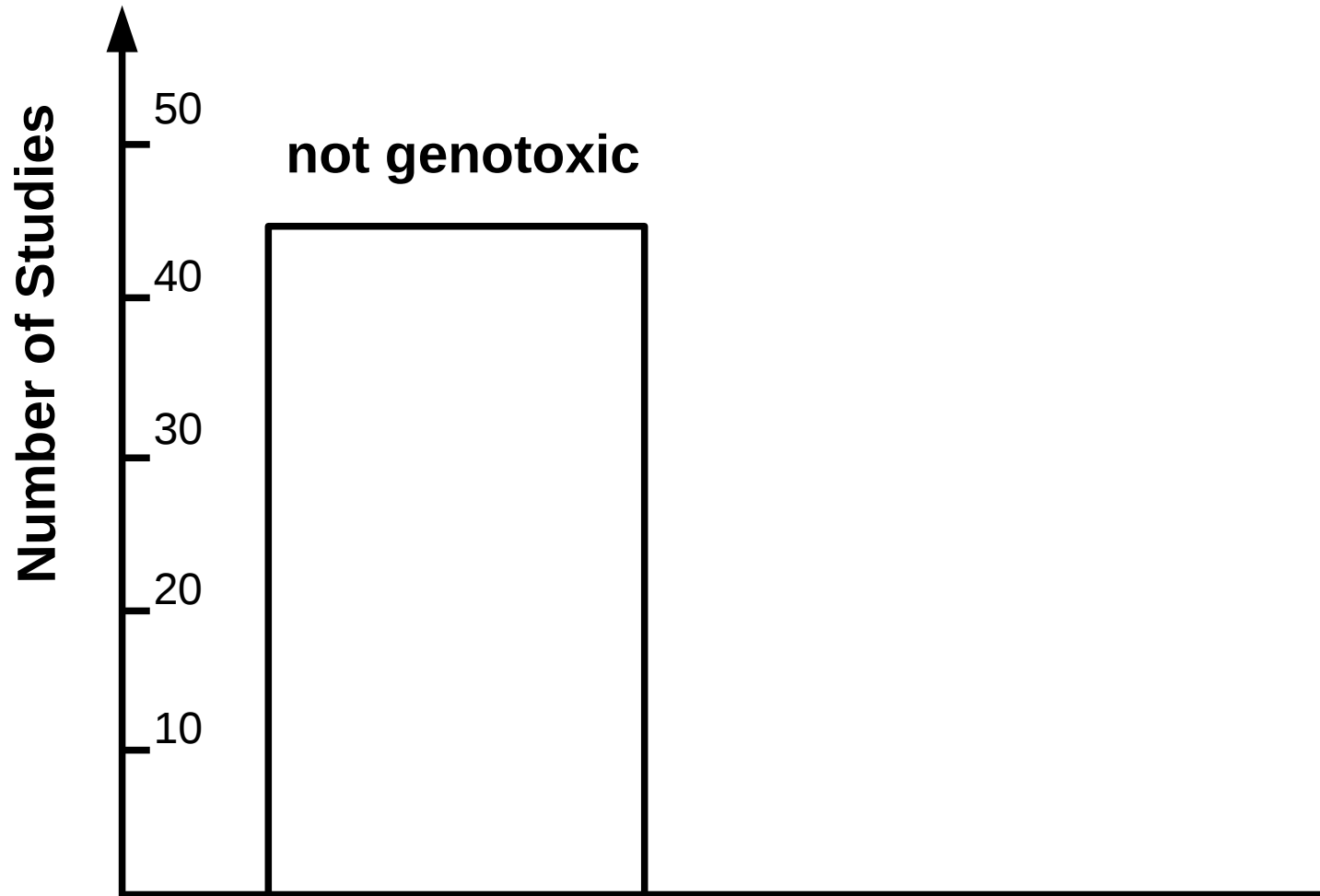
The Genotox Hole



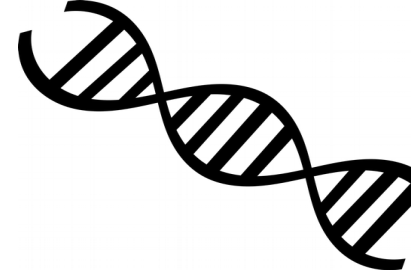
1. Has BfR been inappropriately influenced?



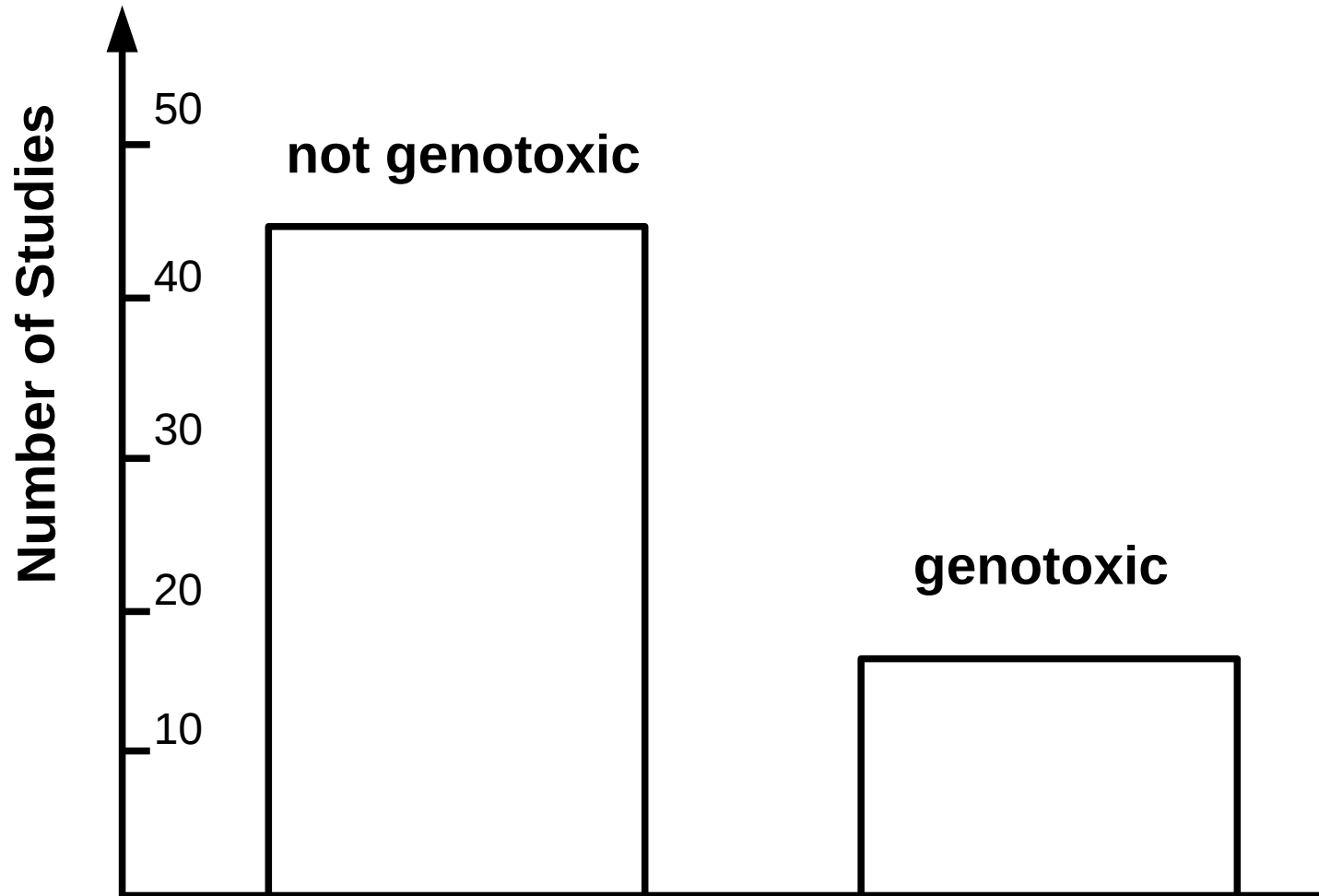
The Genotox Hole



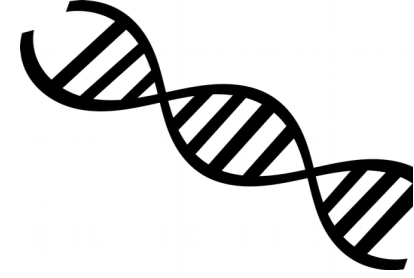
1. Has BfR been inappropriately influenced?



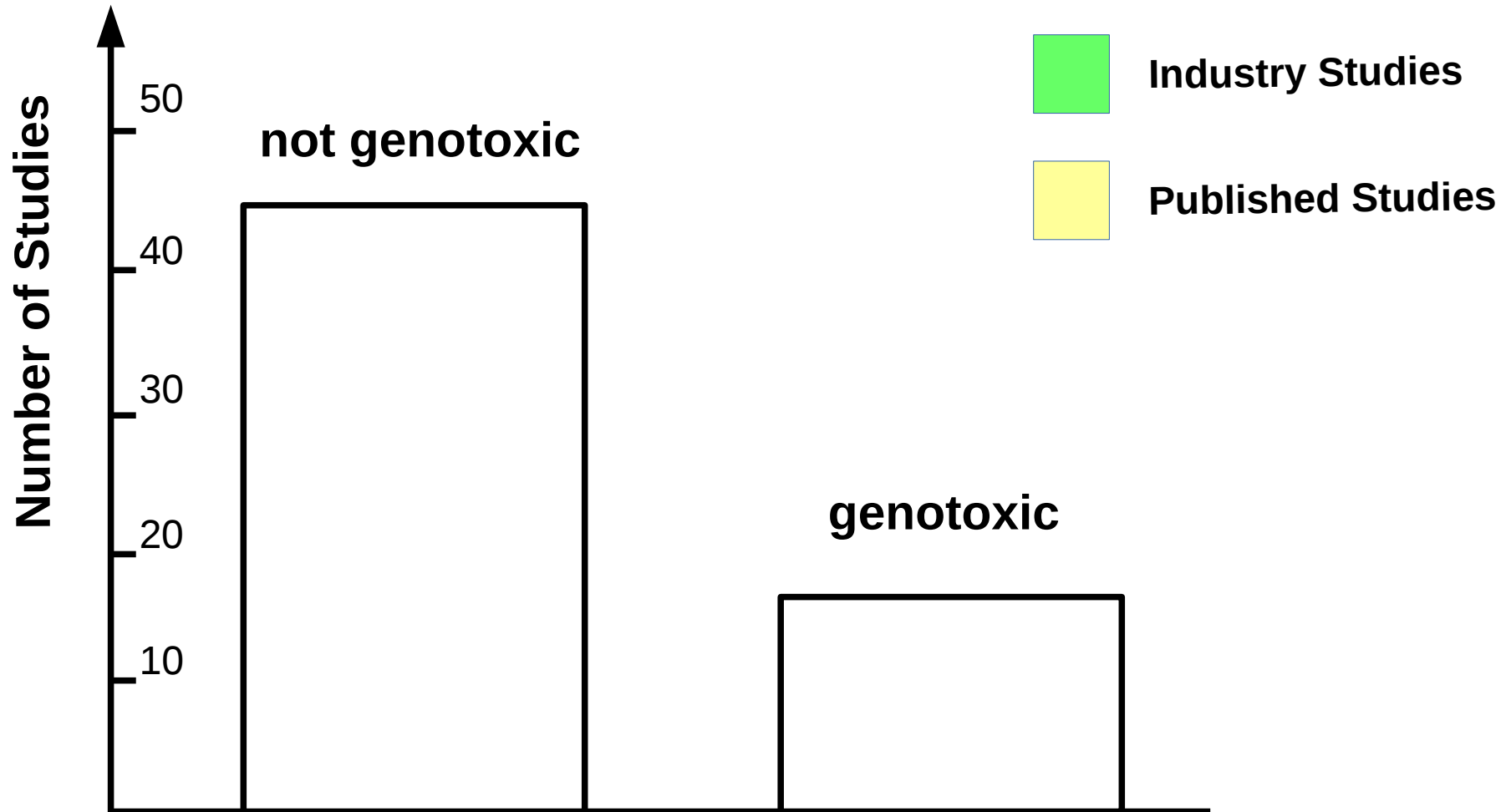
The Genotox Hole



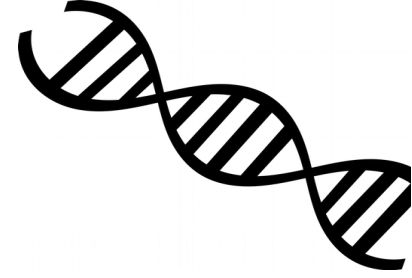
1. Has BfR been inappropriately influenced?



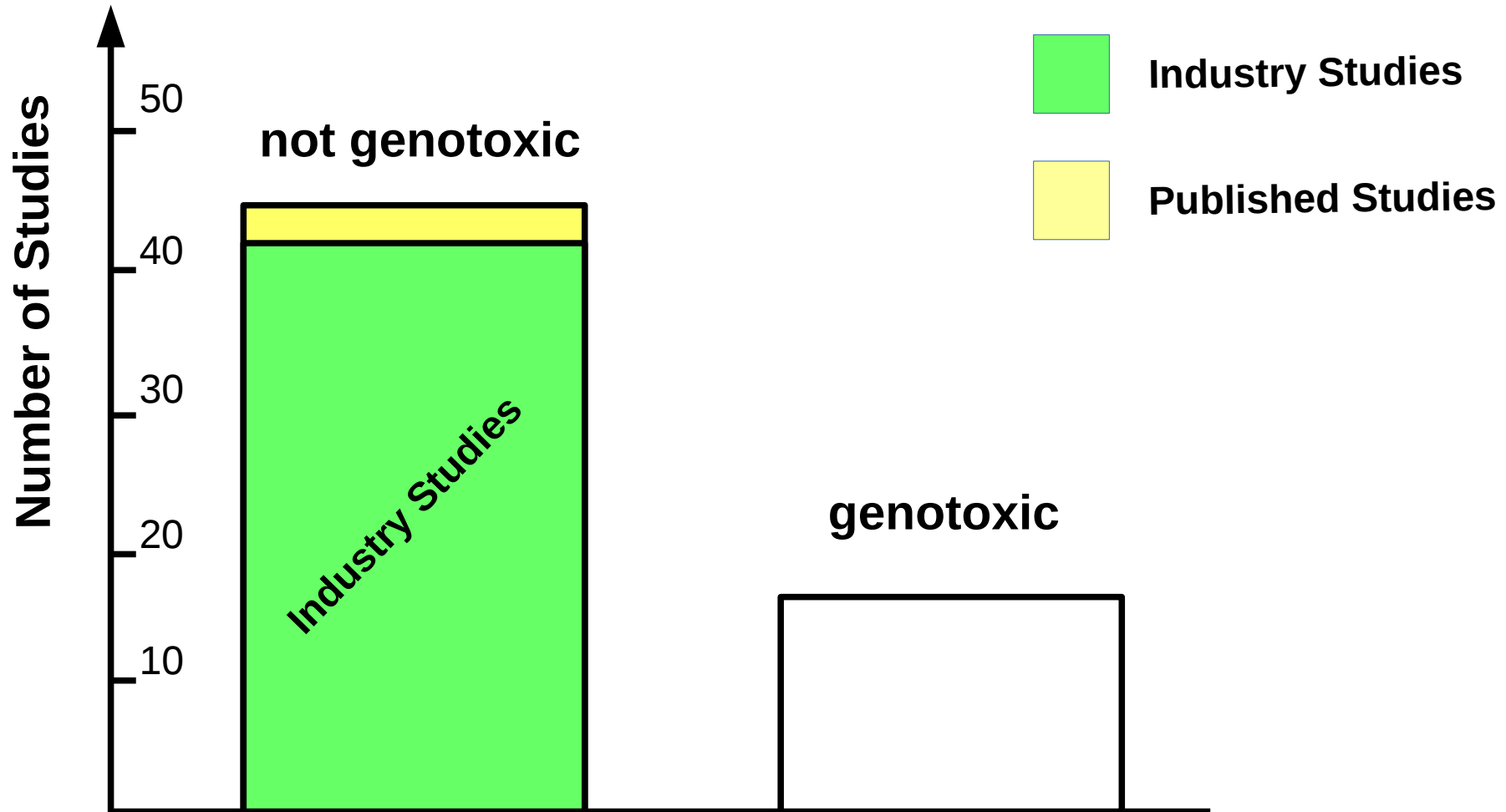
The Genotox Hole



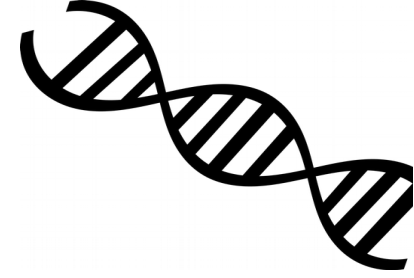
1. Has BfR been inappropriately influenced?



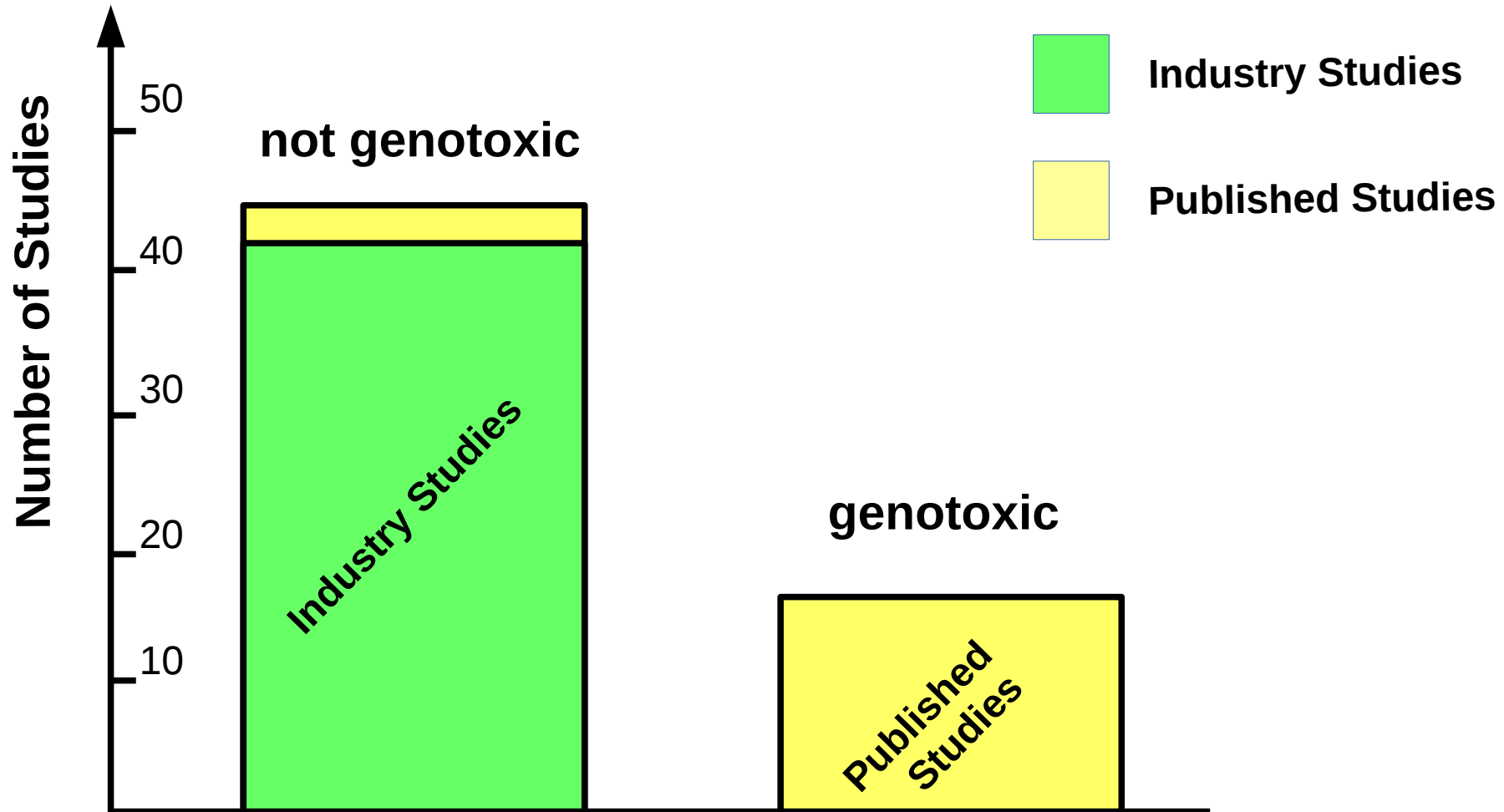
The Genotox Hole



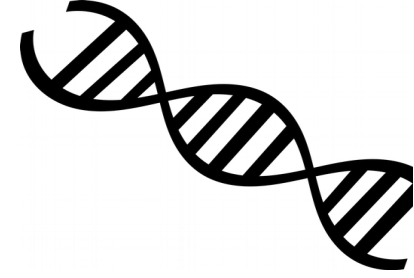
1. Has BfR been inappropriately influenced?



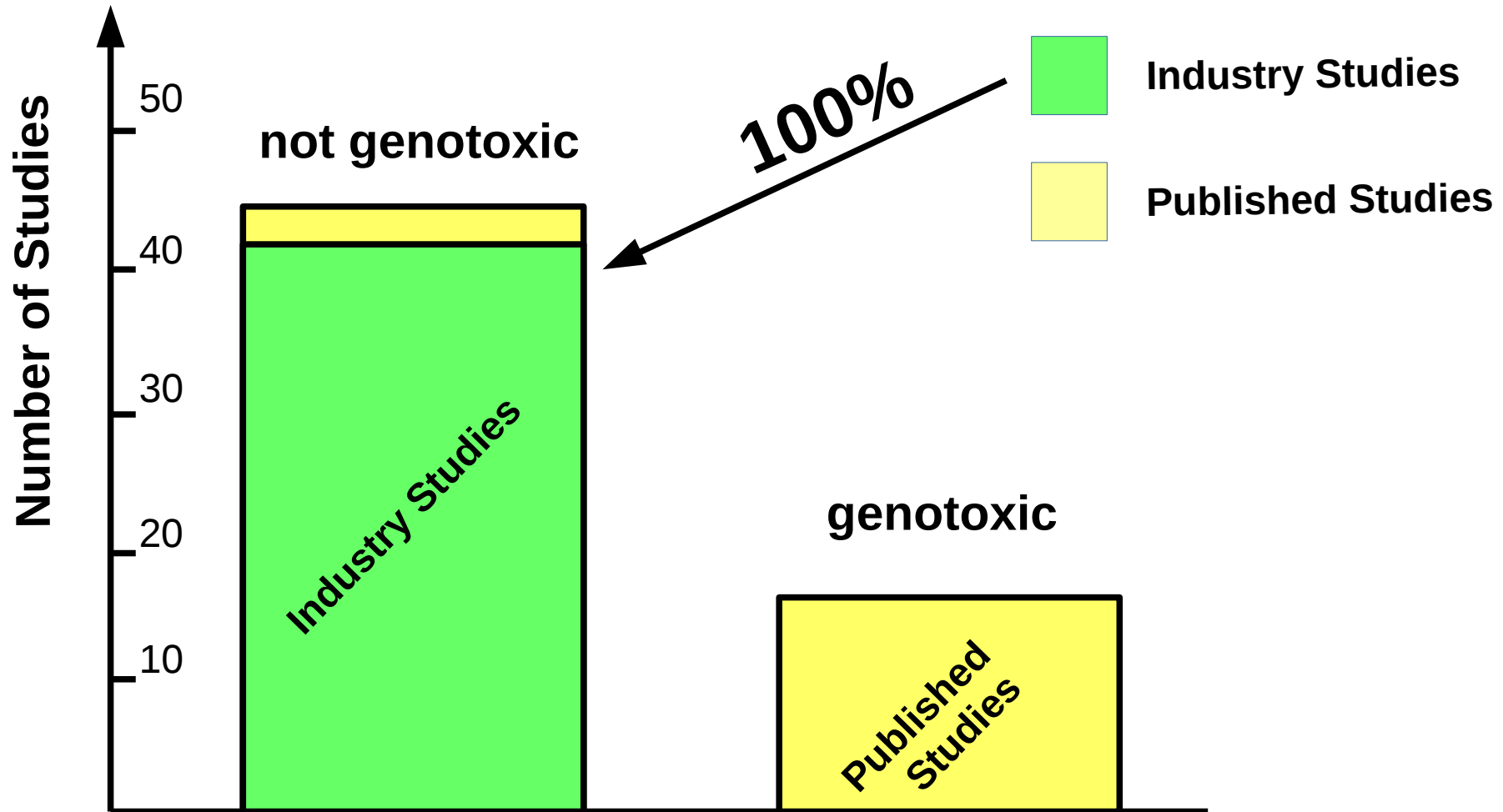
The Genotox Hole



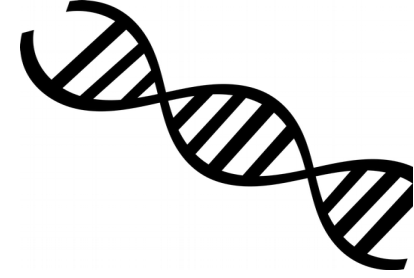
1. Has BfR been inappropriately influenced?



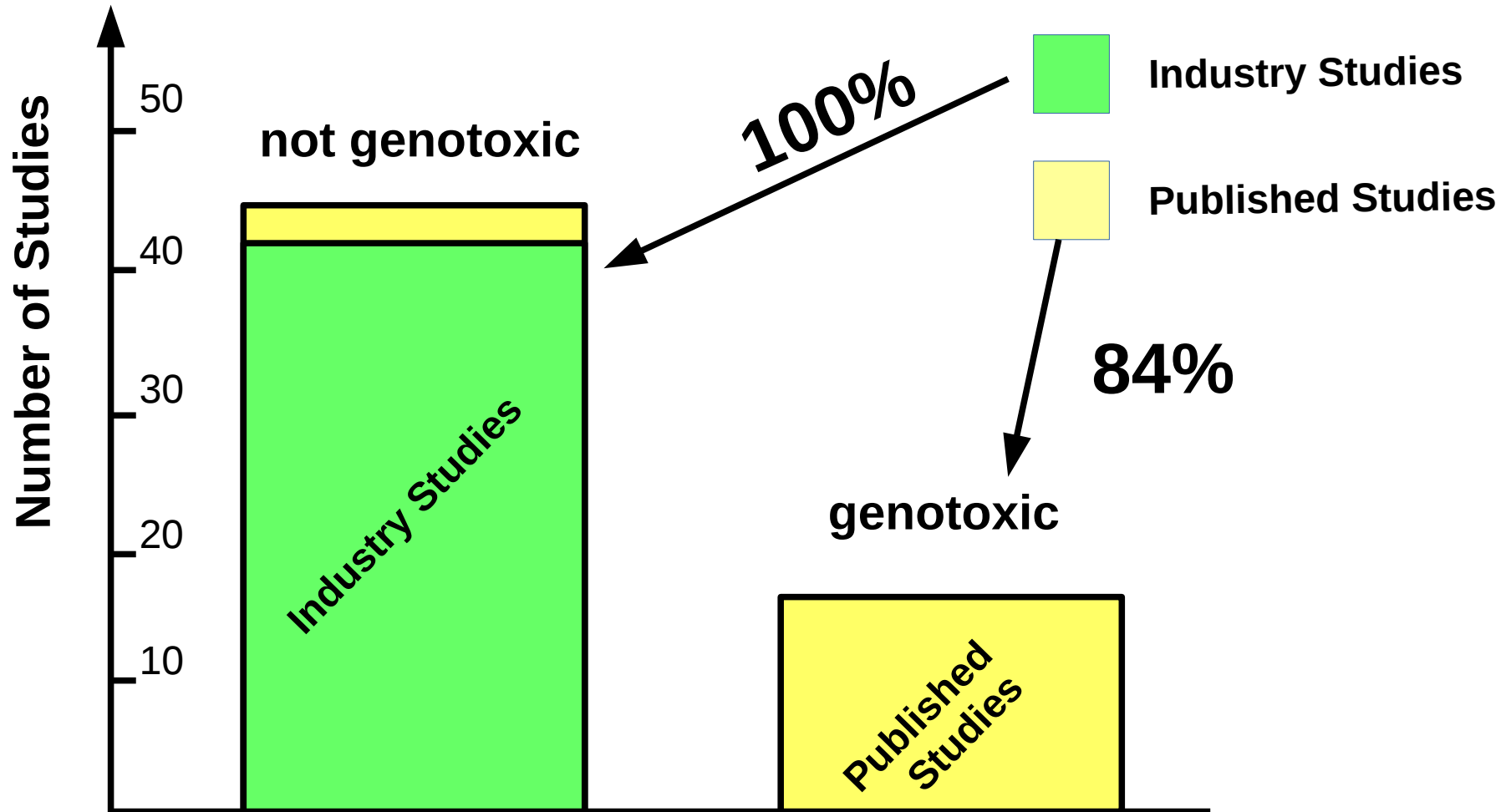
The Genotox Hole



1. Has BfR been inappropriately influenced?

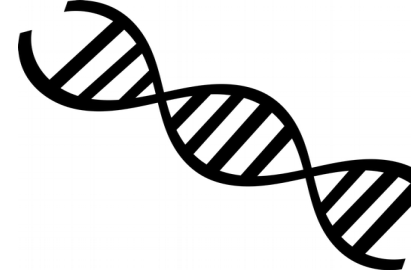


The Genotox Hole



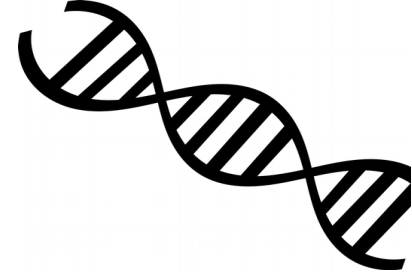
1. **Has BfR been inappropriately influenced?**

The Genotox Hole



1. **Has BfR been inappropriately influenced?**

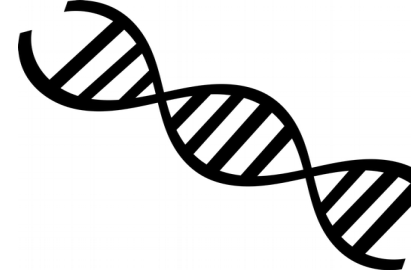
The Genotox Hole



Has the decision of BfR to dismiss evidence for the genotoxicity of glyphosate been inappropriately influenced by the Monsanto papers?

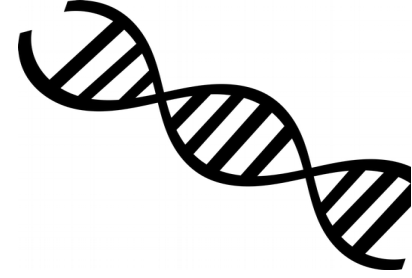
1. **Has BfR been inappropriately influenced?**

The Genotox Hole



1. Has BfR been inappropriately influenced?

The Genotox Hole

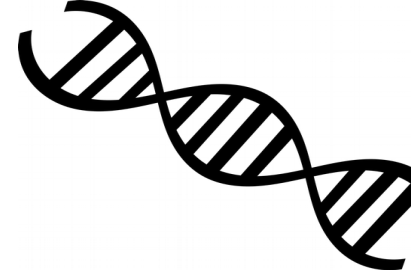


„[...] the studies under scrutiny were not prioritized by EFSA“

Berhard Url, executive director of EFSA

1. Has BfR been inappropriately influenced?

The Genotox Hole



- 391 -

Glyphosate – Annex B.6: Toxicology and metabolism

18 December 2013

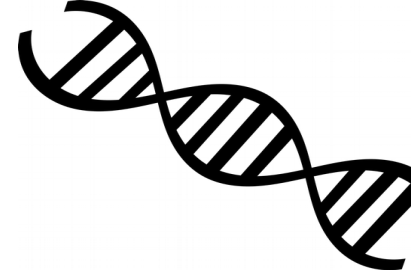
B.6.4.8 Published data (released since 2000)

B.6.4.8.1 Introduction

An earlier review of the toxicity of glyphosate and the original Roundup™ formulation concluded that neither glyphosate nor the formulation pose a risk for the production of heritable/somatic mutations in humans (Williams et al., 2000, ASB2012-12053). This review

1. Has BfR been inappropriately influenced?

The Genotox Hole



- 391 -

Glyphosate – Annex B.6: Toxicology and metabolism

18 December 2013

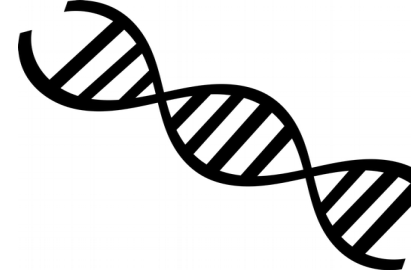
B.6.4.8 Published data (released since 2000)

B.6.4.8.1 Introduction

An earlier review of the toxicity of glyphosate and the original Roundup™ formulation concluded that neither glyphosate nor the formulation pose a risk for the production of heritable/somatic mutations in humans (Williams et al., 2000, ASB2012-12053). This review

1. Has BfR been inappropriately influenced?

The Genotoxicity Hole



- 391 -

Glyphosate – Annex B.6: Toxicology and metabolism

18 December 2013

B.6.4.8 Published data (released since 2000)

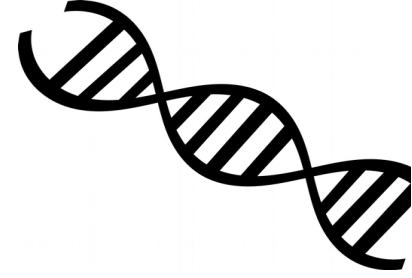
B.6.4.8.1 Introduction

An earlier review of the toxicity of glyphosate and the original Roundup™ formulation concluded that neither glyphosate nor the formulation pose a risk for the production of heritable/somatic mutations in humans (Williams et al., 2000, ASB2012-12053). This review

Monsanto's "ghost-written" article from Williams, Kroes and Monro, 2000 is cited 30 (!) times in the Genotoxicity-chapter on "Published data"

1. Has BfR been inappropriately influenced?

The Genotox Hole

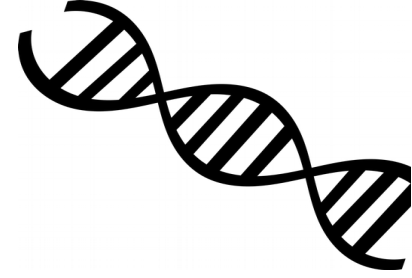


“We want to find / develop someone who is comfortable with the genetox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genetox issues arise.”

E-Mail from William Heydens, 09 16 1999

1. Has BfR been inappropriately influenced?

The Genotox Hole

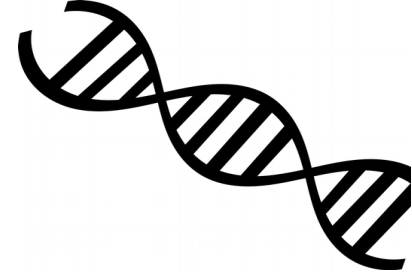


*“We want to find / develop someone who is comfortable with the genetox profile of glyphosate/Roundup and **who can be influential with regulators** and Scientific Outreach operations when genetox issues arise.”*

E-Mail from William Heydens, 09 16 1999

1. Has BfR been inappropriately influenced?

The Genotox Hole

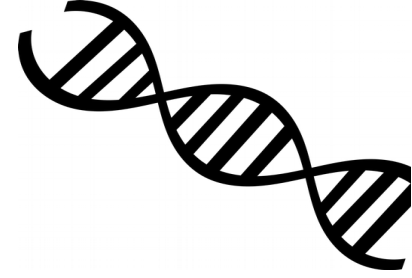


“My read is that Parry is not currently such a person, and it would take quite some time and \$ \$\$/studies to get him there.”

E-Mail from William Heydens 09 16 1999

1. **Has BfR been inappropriately influenced?**

The Genotox Hole

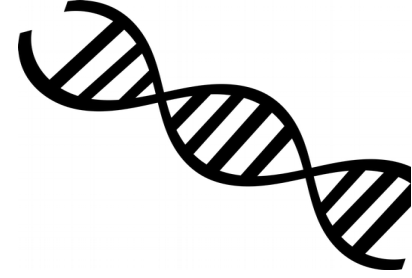


“We simply aren't going to do the studies Parry suggests.”

E-Mail from William Heydens , 09 16 1999

1. Has BfR been inappropriately influenced?

The Genotox Hole

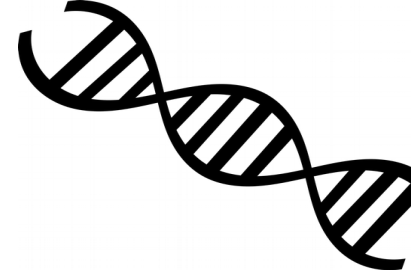


“We have not made much progress and are currently very vulnerable in this area. We have time to fix that, but only if we make this a high priority now.”

E-Mail from William Heydens, 09 16 1999

1. Has BfR been inappropriately influenced?

The Genotox Hole

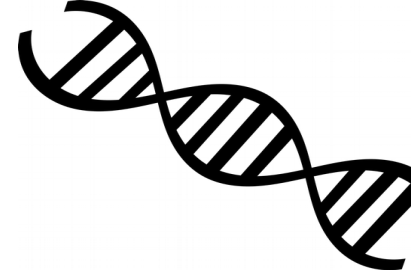


A former Monsanto-Scientist, whose job duties included: “**registration defense of Monsanto's pesticides in EU member states**”: Mark Martens

<https://usrtk.org/wp-content/uploads/2017/03/192series.pdf>

1. Has BfR been inappropriately influenced?

The Genotox Hole

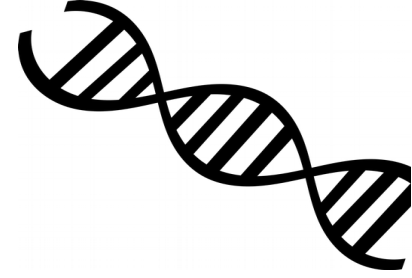


[Mark Martens]...*“has developed the data to gain key EU scientific support that the reported genotoxicity of Roundup herbicide was due to secondary consequences unrelated to glyphosate, thereby preventing adverse effect on Roundup business.”*

<https://usrtk.org/wp-content/uploads/2017/03/192series.pdf>

1. Has BfR been inappropriately influenced?

The Genotox Hole



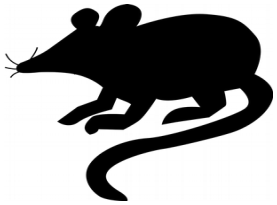
Interestingly, this is also a main argument provided in Monsanto's "ghost-written" paper by Williams et al, 2000, that genotoxicity of glyphosate and glyphosate based herbicides reported in published studies is due to secondary consequences unrelated to glyphosate.

<https://usrtk.org/wp-content/uploads/2017/03/192series.pdf>

To summarize:



Human evidence: BfR has been improperly influenced by obviously false claims in industry's dossier.



Animal evidence: BfR has "relied" on the inappropriate statistical evaluation provided with industry's dossier.

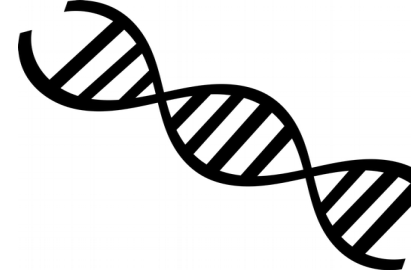


Mechanistic evidence: BfR was influenced by, or has massively relied on a Review Article, ghost-written by (still) unknown Monsanto-scientists.

Thank You

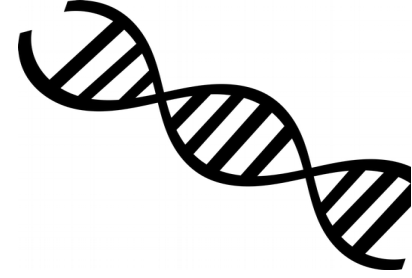
1. **Has BfR been inappropriately influenced?**

The Genotox Hole



1. Has BfR been inappropriately influenced?

The Genotoxicity Hole

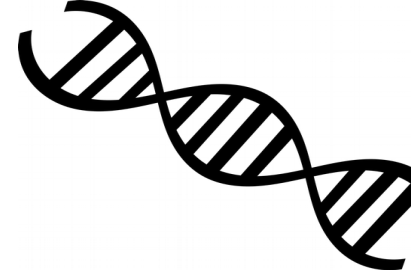


"We found that the most important contributions Mark has made to the organization [...] to be:

[...] Developed the data to gain key EU scientific support that the reported genotoxicity of Roundup herbicide was due to secondary consequences unrelated to glyphosate, thereby preventing adverse effect on Roundup business."

1. Has BfR been inappropriately influenced?

Genotoxicity in the ECHA proposal



"Reports of positive results for DNA damage endpoints indicate that glyphosate and GBFs tend to elicit DNA damage effects at high or toxic dose levels, but the data suggest that this is due to cytotoxicity rather than DNA interaction with GBF activity perhaps associated with the surfactants present in many GBFs."

BfR citing Kier & Kirkland, Final Addendum
Vol. 3 Annex B6.4, page 406



1. Has BfR been inappropriately influenced?

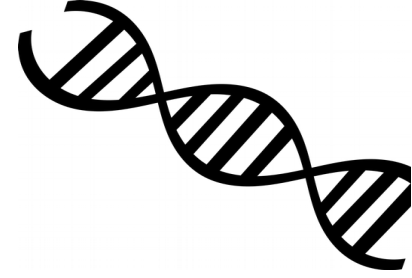
Genotoxicity in the ECHA proposal

"Reports of positive results for DNA damage endpoints indicate that glyphosate and GBFs tend to elicit DNA damage effects at high or toxic dose levels, **but the data suggest that this is due to cytotoxicity rather than DNA interaction with GBF** activity perhaps associated with the surfactants present in many GBFs."

BfR citing Kier & Kirkland, Final Addendum
Vol. 3 Annex B6.4, page 406

1. Has BfR been inappropriately influenced?

Genotoxicity in the ECHA proposal

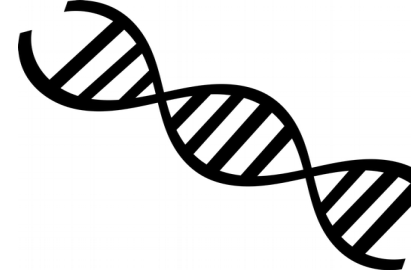


Addendum to the RAR, p 47:

"Principles for the evaluation of published studies used by the RMS"

[...] Kier & Kirkland (2013, ASB2014-9587) have summarized a number of relevant issues to be considered [.....]

→ **80 percent of this paragraph consist of a citation of *Kier & Kirkland 2013***



1. Has BfR been inappropriately influenced?

Genotoxicity in the ECHA proposal

"...an overwhelming preponderance of negative results in well-conducted bacterial reversion and in vivo mammalian micronucleus and chromosomal aberration assays indicates that glyphosate and typical GBFs are not genotoxic in these core assays"

Kier & Kirkland (p. 917 of the RAR)

"We found that the most important contributions Mark has made to the organization [...] to be: [...] developed the data to **gain key EU scientific support** that the reported genotoxicity of Roundup herbicide was due to secondary consequences unrelated to glyphosate, **thereby preventing adverse effect on Roundup business.**"

Principles for the evaluation of published studies used by the RMS

For the analysis of published studies, the RMS made generally a comparison to the criteria in guidelines used for regulatory purposes. However, these criteria do not represent an absolute judgment standard but can provide a way for evaluating the quality of the protocols used in various published studies. Kier & Kirkland (2013, [ASB2014-9587](#)) have summarized a number of relevant issues to be considered: *“Some of the criteria are rarely met in scientific publications and should be given little or no weight in evaluating the studies. For example, data for individual cultures and individual animals are not commonly included in publications in scientific journals. These data are presumably collected but are usually summarized as group means with a measure of variance for the treatment and control groups. This is not considered to be a significant omission in a scientific publication. However, other guideline features are more essential as scientific quality standards and should be considered as having greater weight in evaluating a study. For example, there are consistent recommendations that assays involving visual scoring (e.g. chromosomal aberration, micronucleus and sister chromatid exchange (SCE) endpoints) should use slides that are independently coded so that scoring is performed without any knowledge of the treatment or practice and studies that do not explicitly include a description of coding or “blind” scoring in the methodology would appear to have a deficiency either in the methodology, or perhaps a limitation in the description of the methodology used if coding was actually used and either not indicated or was assumed to be indicated by a reference citation. Other examples of guideline features that have clear experimental scientific value are the use of concurrent negative and positive controls and concurrent measurement and reporting of toxicity endpoints in main experiments, especially in in vitro mammalian cell assays.”*

Glyphosate:

Assessment and conclusion of IARC: