BUNDESINSTITUT FÜR RISIKOBEWERTUNG

BfR
Risiken erkennen – Gesundheit schützen

Human Health Risk Assessment of Glyphosate - between Science and Policy

Bernd Stein

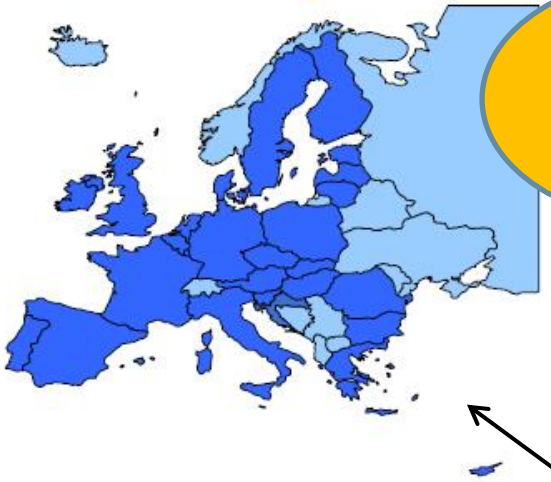
Work and Organizational Processes for Pesticides in BfR - Department Pesticides Safety

efsa
European Food Safety Authority

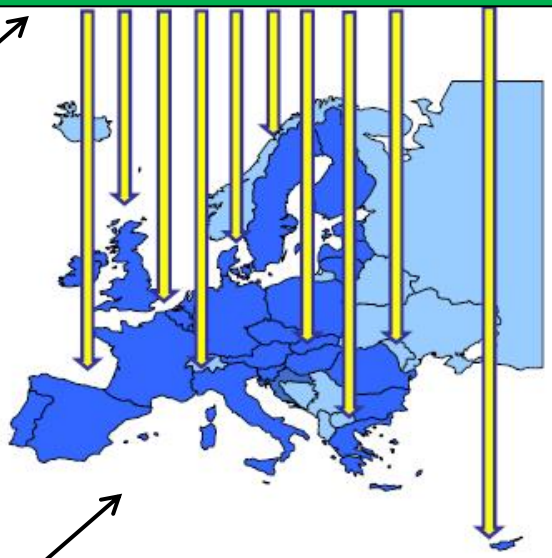
European Commission

Active Substance Approval

PPP Zonal Autorisation



MRL Setting



ECHA
EUROPEAN CHEMICALS AGENCY

AS Classification & Labelling

EU active substance approval

Zonal authorisation of PPP
ZV1, ZV3, ZVU

MRL setting

BfR
Pesticides Safety

Scientific advice for policy making

Public relations / Risk communication

Committees at national, EU and other level

German Plant Protection Act
§17, §18, §29

Research
Process optimization
Databanks

C&L

Renewal procedure of Glyphosate

March 2011	Application of the Glyphosate Task Force (GTF) in Germany (Dossier: 26 companies with 40 sources
August 2012	Start of evaluation and preparation of the Renewal Assessement Report (RAR)
September 2012	Dossier by public (EFSA call for data: - Agrar Koordination Hamburg, - Umweltinstitut München, - PAN)
April 2013	First draft of RAR
August 2013	Additional data submission by GTF
December 2013	RAR submitted to EFSA and COM
January – May 2014	Commenting phase of the RAR by applicants and the other member states
March – June 2014	Commenting phase of the RAR by public

Renewal procedure of Glyphosate

January 2015	Revised RAR
February 2015	PRAS-Meetings
March 2015	Information in „Lancet Oncology“ by IARC on cancerogenicity of glyphosate
April 2015	Final RAR by the RMS
May 2015	Decision by COM, EFSA and RMS to wait for the IARC-Monograph
July 2015	Publication of the IARC-Monograph
August 2015	Addendum to the RAR by the RMS to IARC assessment
September 2015	Commenting phase on the Addendum by applicants and the other member states
September 2015	PRAS-Meeting to the Addendum (Observers: EPA, IARC, WHO, ECHA)

Renewal procedure of Glyphosate

November 2015	Final EFSA Conclusion (EFSA Journal 2015;13(11):43029)
Januar 2016	SCoPAFF: First discussion on glyphosate
March 2016	CLH-Dossier prepared by Germany and submitted to ECHA
March 2016	SCoPAFF: Second discussion on glyphosate
March 2016	Informational meeting of the European Parlament and Committee for Environment, Public Health and Food Safety “GLYPHOSATE – YES or NO? Re-Approval of the World’s Most Popular Chemical”
09.-13.05.2016	JMPR (FAO/WHO): Re-evalution of glyphosate
18./19.05.2016	SCoPAFF: decision on Approval ???

Glyphosate - Reference Values – ADI, ARfD, AOEL

	Value	Study	Uncertainty factor
ADI	0.5 mg/kg bw	Developmental toxicity, rabbit	100
ARfD	0.5 mg/kg bw	Developmental toxicity, rabbit	100
AOEL	0.1 mg/kg bw per day	Developmental toxicity, rabbit	Overall 500* (100 + 20%*)

* Correction for low oral absorption (20%)

JMPR – May 2016:
ADI: 0-1 mg/kg bw
ARfD: not necessary

Glyphosate – Classification and Labelling

Harmonised classification – Annex VI of Reg. (EC) No 1272/2008:

Eye Damage 1, H318 - Causes serious eye damage

Proposal for Harmonised Classification and Labelling

Eye Damage 1, H318 - Causes serious eye damage
STOT RE 2, H373 - May cause damage to organs through prolonged or repeated exposure

Glyphosate - Exposure Scenarios and Risk Assessment

Consumer (EU-Review (RAR, 2015)):	
Long-term dietary intake:	0-3% of the ADI of 0.5 mg/kg bw
Short-term dietary intake:	up to 9% of the ARfD of 0.5 mg/kg bw (by barley consumption)

Glyphosate - Exposure Scenarios and Risk Assessment

Operator	
Field crop tractor-mounted (application rate: 2.16 kg glyphosate/ha):	
German model	
Without PPE (T-shirt and shorts)	28% of AOEL
Hand-held spray applications (application rate: 2.88 kg glyphosate/ha) under high crops	
German model (high crop, which is a worst case)	
With PPE (gloves during mixing/loading):	32% of AOEL

Glyphosate - Exposure Scenarios and Risk Assessment

Worker
29% of AOEL without PPE: worker wearing long sleeved shirt, long trousers (‘permeable’) but no gloves

Bystander & Residents	
Bystanders:	Adults: 4.1% of AOEL, children: 3.4% of AOEL
Residents:	Adults: 5.5% of AOEL, children: 20.8% of AOEL
(both for assumed applications on pasture, lawn or meadow, ‘worst case’)	

Under public discussion between science and policy - consideration of scientific literature

Public opinion

Only studies from the industrie are considered by BfR (RMS)!

BfR / EFSA

Hundreds of studies performed by manufacturers of glyphosate and thousands of references from open literature were evaluated for the human health risk assessment and reported in the RAR!

Sources: - dossier by the GTF, - public dossier, - literature research by BfR

Under public discussion between science and policy - glyphosate in urine

Public opinion

June 2013: BUND - 182 urine samples from individuals in 18 European countries were analysed, highest level 1.82 ng/mL

June 2015: Media reported on findings of glyphosate in 16 urine samples and labelled the measurement results "very concerning";

March 2016: Heinrich Böll Foundation - over 2000 non-representaive samples were analysed by a biological standard test; median content 1.08 ng/mL; highest value 4.2 ng/mL

BfR / EFSA

Seven studies on glyphosate in urine were evaluated in the RAR; measured glyphosate levels clearly below any level that would raise health concern.

Under public discussion between science and policy - glyphosate in breast milk

Public opinion

June 2015: media reported on findings of glyphosate in 16 breast milk and urine samples and labelled the measurement results "very concerning". (0.21 – 0.43 ng/mL)

BfR / EFSA

June 2015: BfR expressed scientific doubt regarding the reliability of the results and commissioned its own study in order to obtain reproducible and confirmed results.

February 2016: A study commissioned by the BfR has confirmed that no residues of the pesticidal active substance glyphosate are detectable in breast milk.

Under public discussion between science and policy - glyphosate in beer

Public opinion

February 2016 – media report:
14 different beer samples were analysed for glyphosate residues

up to 30 µg/L

BfR

From a scientific point of view, glyphosate residues in beer are plausible and to be expected in principle, since glyphosate-containing plant protection products are authorized for uses in cereals.

It would be necessary to drink more than 1000 L beer/day before a health risk would occur.

But what about alcohol?

Under public discussion between science and policy - genotoxicity of glyphosate

Public opinion

IARC - July 2015: “There is a strong evidence that exposure to glyphosate or glyphosate-based formulations is genotoxic based on studies in humans in vitro and studies in experimental animals.”

BfR / EFSA

Glyphosate is non-genotoxic based on the legal data requirements.

JMPR – May 2016: “The Meeting concluded that glyphosate is unlikely to be genotoxic at anticipated dietary exposures.”

Under public discussion between science and policy - cancerogenicity of glyphosate

Public opinion

IARC - July 2015: glyphosate is a carcinogenic substance Group 2A “Probably carcinogenic to humans”

Epidemiological studies: “limited evidence for cancer in humans”

Carcinogenicity studies: “sufficient evidence for cancer in experimental animals”

BfR / EFSA

BfR/ EFSA supported by JMPR (2004), US EPA: “non-carcinogenic to humans”

Epidemiological studies: non-consistent pattern of positive associations indicating a causal relationship between total cancer or any site-specific cancer and exposure to glyphosate - “very limited evidence for cancer in humans”

Carcinogenicity studies: “glyphosate is unlikely to pose a carcinogenic risk to humans”

Under public discussion between science and policy - cancerogenicity of glyphosate

JMPR – May 2016:

"Meeting concluded that glyphosate is not carcinogenic in rats but could not exclude the possibility that it is carcinogenic in mice at very high doses. In view of the absence of carcinogenic potential in rodents at human-relevant doses and the absence of genotoxicity by the oral route in mammals, and considering the epidemiological evidence from occupational exposures, **the Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet**. "

An (identified) hazard is not necessarily an (unacceptable) risk!

http://www.bfr.bund.de/cm/349/wha-fao-committee-jmpr-re-assesses-glyphosate-and-confirms-the-bfr-and-efsa-conclusion-that-a-carcinogenic-risk-is-not-to-be-expected.pdf

www.bfr.bund.de

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Bundesinstitut für Risikobewertung

WHO/FAO committee (JMPR) re-assesses glyphosate and confirms the BfR and EFSA conclusion that a carcinogenic risk is not to be expected

BfR Background Information No. 012/2016 of 16 May 2016

After the Joint Meeting of the Food and Agriculture Organization of the United Nations (FAO) Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization (WHO) Core Assessment Group on Pesticide Residues (JMPR) in Geneva from 9 to 13 May, the JMPR comes to the conclusion that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet. In this way, the divergence between the risk assessment of the responsible FAO/WHO committee for pesticides and the hazard identification of the International Agency for Research on Cancer (IARC), which considered glyphosate as probably carcinogenic to humans along with malathion and diazinon in March 2015, becomes obvious once again.

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Thank you for your attention

Dr. Bernd Stein
Bundesinstitut für Risikobewertung
Max-Dohrn-Str. 8-10, D-10589 Berlin
www.bfr.bund.de
☎ 030-18412-3270
✉ Bernd.Stein@bfr.bund.de