Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions

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The regulation of pesticides in the European Union (EU) relies on a network of hard law (legislation and implementing acts) and soft law (non-legally binding guidance documents and administrative and scientific practices). Both hard and soft laws govern how risk assessments are conducted, but a significant role is left to the latter. Europe's pesticide regulation is one of the most stringent in the world. Its stated objectives are to ensure an independent, objective and transparent assessment of pesticides and achieve a high level of protection for health and environment. However, a growing body of evidence shows that pesticides that have passed through this process and are authorised for use may harm humans, animals and the environment. The authors of the current paper – experts in toxicology, law and policy – identified shortcomings in the authorisation process, focusing on the EU assessment of the pesticide active substance glyphosate. The shortcomings mostly consist of failures to implement the hard or soft laws. But in some instances the law itself is responsible, as some provisions can only fail to achieve its objectives. Ways to improve the system are proposed, requiring changes in hard and soft laws as well as in administrative and scientific practices.

I. Introduction

The regulation of pesticides in the European Union (EU) relies on a network of hard law (legislation and implementing acts) and soft law (non-legally binding guidance

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documents and administrative and scientific practices). Both hard and soft laws govern how risk assessments are conducted, but a significant role is left to the latter.

The procedure for allowing pesticides on the market in the EU is governed by Regulation 1107/2009,[1] which is regarded as one of the most stringent pesticide regulations in the world. The Regulation requires that the assessment of a pesticide active substance is "independent, objective and transparent" and is performed "in the light of current scientific and technical knowledge".[2] Beyond safeguarding the competitiveness of EU agriculture, the Regulation's stated purpose is to "ensure a high level of protection of both human and animal health and the environment".[3] It stipulates that its provisions are "underpinned by the precautionary principle".[4] The precautionary principle is defined by the European Commission as the right to establish an "appropriate" level of protection of animal, human and plant health and the environment when "potentially dangerous effects deriving from a phenomenon, product or process have been identified" but "scientific evaluation does not allow the risk to be determined with sufficient certainty".[5]

The Regulation provides for a partly decentralised process for the risk assessment of pesticides. Pesticide products (formulations) are composed of "active substances" – their main components – and "co-formulants" that are added for various purposes, such as stability and strength of effect. The authorisation of active substances happens at the EU level and the authorisation of the final pesticide products happens at Member State/national level.

The process begins when industry submits its application dossier for authorisation of an active substance, containing the required tests and safety studies, to a Member State that will review the dossier as the "rapporteur" (often, one or more additional Member State join as "co-rapporteurs"). The Rapporteur Member State (RMS) produces the draft assessment report (DAR) or renewal assessment report (RAR), assessing whether the active substance can be expected to meet the approval criteria provided in the pesticide regulation. After an opportunity for comments from all Member States, the applicant and the public via a public consultation, the European Food Safety Authority (EFSA) does a final peer review and adopts a conclusion on whether the substance meets the approval criteria. Informed by EFSA's conclusion, the European Commission makes a proposal for authorisation to the Member State representatives in the Standing Committee on the Food Chain and Animal Health (SCoPAFF), who vote on the proposal. A positive vote by a qualified majority results in the authorisation of the pesticide active substance at the EU level. Once an active substance has been approved at this level, the applicant can apply for authorisation of

[1] European Parliament and Council, "Regulation (EC) No 1107/2009 of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC" (2009) Official Journal of the European Union 1 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009R1107>.

[2] ibid, Art 11(2).

[3] ibid, Recital 8.

[4] ibid, Arts 1(4), 13(2).

[5] European Commission, "EUR-Lex – 52000DC0001 – EN: Communication from the Commission on the Precautionary Principle /* COM/2000/0001 Final */" <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52000DC0001&from=EN> (last accessed 16 February 2020).

individual formulations based on the active substance at the level of the individual Member States where the products are intended to be used. The Member State then carries out an assessment.

Many actors are therefore involved in the risk assessment, and many implementing acts, as well as EU guidance and international guidance documents, govern the process. This legislative and "soft law" framework is complex, sometimes imprecise and not always up to date with the latest scientific developments. Thus, the relevant regulatory authorities – the Commission, Member States and EFSA – have many choices to make in how they exercise their judgements. Moreover, an error or misconduct is not easy to spot, denounce or stop.

This capacity to hide in complexity is dangerous, as what appear to be technical or benign choices may significantly affect the ability of the framework to deliver its aim: ensuring a high level of protection for human and animal health and the environment.

As a result, in spite of the EU's stringent regulatory framework, an ever-growing body of scientific evidence from the peer-reviewed literature shows that pesticides that have successfully passed through the authorisation process can cause harm to humans, animals and/or the environment. Findings include abnormally high rates of disease in farming families, rural residents and other exposed people,[6] residues of dangerous pesticides detected in food[7] and the environment[8] and the decline of insects,[9] including pollinators,[10] in agricultural regions.

This paper explores possible reasons for the discrepancy between the objectives of the pesticides Regulation and the failure to achieve a risk assessment process that fulfils its protective aims. In doing so, it builds on the work of an interdisciplinary group of scientists, lawyers and policy-makers – including the authors of this paper – who formed the coalition Citizens for Science in Pesticide Regulation.[11] The paper sheds

[6] M Bellanger et al, "Neurobehavioral Deficits, Diseases, and Associated Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union" (2015) 100 The Journal of Clinical Endocrinology and Metabolism 1256; MDP Navarrete-Meneses and P Pérez-Vera, "Pyrethroid Pesticide Exposure and Hematological Cancer: Epidemiological, Biological and Molecular Evidence" (2019) 34 Reviews on Environmental Health 197; S Mostafalou and M Abdollahi, "Pesticides: An Update of Human Exposure and Toxicity" (2017) 91 Archives of Toxicology 549.

[7] Pesticide Action Network Europe, "How Many Pesticides Did You Eat Today? Plenty According to European Food Safety Authority" (PAN Europe, 13 April 2017) <https://www.pan-europe.info/press-releases/2017/04/how-many-pesticides-did-you-eat-today-plenty-according-european-food-safety> (last accessed 2 July 2019); contra "Pesticide Residues in Food: Risk to Consumers Remains Low" (European Food Safety Authority, 11 April 2017) <http://www.efsa.europa.eu/en/press/news/170411> (last accessed 2 July 2019). In these reports, EFSA noted that the residues are mostly within legal limits and that the risk to consumers is "low", but PAN Europe stated that the safety of the mixtures found has never been evaluated.

[8] S Stehle and R Schulz, "Pesticide Authorisation in the EU – Environment Unprotected?" (2015) 22 Environmental Science and Pollution Research International 19632.

[9] CA Hallmann et al, "More than 75 Percent Decline over 27 Years in Total Flying Insect Biomass in Protected Areas" (2017) 12 PLoS ONE e0185809 <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0185809> (last accessed 2 July 2019).

[10] BA Woodcock et al, "Impacts of Neonicotinoid Use on Long-Term Population Changes in Wild Bees in England" (2016) 7 Nature Communications 12459 <https://www.nature.com/articles/ncomms12459> (last accessed 2 July 2019).

[11] Citizens for Science in Pesticide Regulation, "Citizens for Science in Pesticide Regulation – A European Coalition" (2018) <https://citizens4pesticidereform.eu/> (last accessed 5 July 2019); Pesticide Action Network Europe et al, "Ensuring a Higher Level of Protection from Pesticides in Europe: The Problems with Current Pesticide Risk Assessment Procedures in the EU – And Proposed Solutions. A White Paper. Prepared for "Citizens for Science in Pesticide Regulation", A European Coalition" (Pesticide Action Network Europe et al, 2018) <https://zenodo.org/record/2543743#.XVaR3ehKhhE>. The White Paper is also hosted at the website of Citizens for Science in Pesticide Regulation <https://citizens4pesticidereform.eu/wp-content/uploads/2018/12/White-Paper_Dec2018.pdf>.

light on how significant shortcomings in the risk assessment of pesticides undermine the fulfilment of the aims of the pesticides Regulation, placing public health and the environment at risk. Ways of improving the regulatory system are proposed, which require either amendments to the existing law, revision of relevant guidance documents or a better implementation of the existing regulatory procedure. The paper also discusses the progress that has been made in response to the 2017 European Citizens' Initiative on glyphosate.[12]

The authors of this paper draw upon their own experience of the implementation of the Regulation, as well as on information that came to light during the EU's evaluation of the pesticide active substance glyphosate, which culminated in 2017 with a renewed approval for a period of five years.[13]

Glyphosate is an informative case study. While it is the most widely used herbicide in the world for the major crops grown,[14] there is widespread scientific concern about its risks.[15] The intense public scrutiny on this case, as well as the US court cases in which exposure to glyphosate-based herbicides has been linked to cancer,[16] led to much information coming to light that is normally kept confidential or discreet. This information confirmed that the wrongdoings found in this case have systemic causes. Indeed, evidence is presented in this paper that many of the problems found are not exclusive to glyphosate.

The paper begins by examining how the objectivity and scientific rigour of pesticide regulatory assessments are undermined by different types of scientific misconduct (Section II). Most of these types of scientific misconduct consist of non-compliance with existing guidance documents. However, in some cases, the guidance documents themselves are at fault because they do not align with the most up-to-date scientific approach as required by the EU courts (Court of Justice of the European Union and the General Court).

Some systemic issues explored in Sections III and IV enable the types of scientific misconduct identified in Section II. These include lack of transparency and insufficient management of conflicts of interest. Some of the changes needed to resolve these issues require a change of EU legislation, but many could be achieved via enforcing compliance with guidance documents or the adoption of new guidance documents and administrative practices.

[12] European Commission, "Initiative Details – European Citizens' Initiative" (https://ec.europa.eu, 25 January 2017) <https://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002> (last accessed 19 July 2019).

[13] European Commission, "Glyphosate: Current Status of Glyphosate in the EU" (European Commission, 12 July 2017) <https://ec.europa.eu/food/plant/pesticides/glyphosate_en> (last accessed 4 July 2019).

[14] F Maggi et al, "PEST-CHEMGRIDS, Global Gridded Maps of the Top 20 Crop-Specific Pesticide Application Rates from 2015 to 2025" (2019) 6 Scientific Data 1 <https://www.nature.com/articles/s41597-019-0169-4> (last accessed 16 February 2020).

[15] JP Myers et al, "Concerns over Use of Glyphosate-Based Herbicides and Risks Associated with Exposures: A Consensus Statement" (2016) 15 Environmental Health <http://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0>; L Zhang et al, "Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence" (2019) Mutation Research/Reviews in Mutation Research <http://www.sciencedirect.com/science/article/pii/S1383574218300887> (last accessed 13 February 2019).

[16] Baum Hedlund Aristei Goldman, "Monsanto Court Papers and Depositions" (baumhedlundlaw.com, 2019) <https://www.baumhedlundlaw.com/toxic-tort-law/monsanto-roundup-lawsuit/monsanto-court-papers/> (last accessed 27 February 2020). Cases to date are *Dewayne Johnson v Monsanto Company*, *Edwin Hardeman v Monsanto Company* and *Pilliod v Monsanto Company*.

The long list of issues exposed below may seem overwhelming, yet it is a cause for optimism that significant improvements could be made by adjusting the practices of the risk assessors and managers and updating guidance documents. In sum, there is no excuse to delay the effective implementation of the pesticides Regulation.

II. Scientific misconduct

Scientific misconduct takes different forms in different settings.[17] For example, some Scandinavian countries established committees on scientific misconduct in the 1990s, which included scientifically and legally qualified members. Their definitions of scientific misconduct include: "Intention or gross negligence leading to falsification or distortion of the scientific message or a false credit or emphasis given to a scientist" (Denmark); "Presentation to the scientific community of fabricated, falsified, or misappropriated observations or results and violation against good scientific practice" (Finland); "serious deviation from accepted ethical research practice in proposing, performing, and reporting research" (Norway); and "Intention[al] distortion of the research process by fabrication of data; theft or plagiarism of data, text, hypothesis, or methods from another researcher's manuscript or application form or publication; or distortion of the research process in other ways" (Sweden).[18]

All of these types of scientific misconduct are frequently found in pesticide risk assessments. Such practices, which we illustrate in the examples below, can ultimately undermine the public's faith in the integrity of scientific assessments conducted with the purported aim of protecting health and the environment.

Within the EU pesticide framework, most of these practices belong to the complex sub-regulatory world of implementing regulations or soft law, including EU and international risk assessment guidance. Not all are explicitly prohibited by those documents, which leave – either by their wording or by the complexity of their interactions – a wide discretion to the persons in charge of risk assessment.

Wrongful practices could also, in principle, be challenged by the scrutiny of the EU courts, which should control whether risk assessments by EU authorities are based on the principles of "excellence, transparency and independence to ensure scientific objectivity and preclude arbitrary decisions".[19] However, access to justice regarding "arbitrary" pesticide authorisations is blocked by the EU courts' jurisprudence, which denies civil society organisations legal standing to challenge the decisions of EU institutions.[20]

[17] CHPS Consulting, "Analysis of Institutional Policies for Responding to Allegations of Scientific Misconduct" (US Department of Health & Human Services Office of Research Integrity 2000) <https://ori.hhs.gov/analysis-institutional-policies-responding-allegations-scientific-misconduct>.

[18] M Nylenna et al, "Handling of Scientific Dishonesty in the Nordic Countries" (1999) 354 The Lancet 57 <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(98)07133-5/abstract>.

[19] *Pfizer Animal Health SA v Council of the European Union* [2002] Court of First Instance (Third Chamber) T-13/99, ECLI:EU:T:2002:209, para 159.

[20] *Pesticide Action Network Europe (PAN Europe) and Others v European Commission* [2016] General Court (First Chamber) ECLI:EU:T:2016:601; A Berthier, "General Court Ruling: NGOs Cannot Challenge Decisions of EU Institutions before the EU Courts" ClientEarth (16 March 2017) <https://www.clientearth.org/general-court-ruling-ngos-cannot-challenge-decisions-eu-institutions-eu-courts/> (last accessed 27 February 2020).

Due to the shortcomings of the EU regulatory framework in protecting against wrongful practices, it is necessary to identify them precisely in order to assess case-by-case which solutions should be developed – and by whom.

1. Selective use and omission of published data

Selective use of published data constitutes a distortion of data and results. Under the EU pesticide regulation, peer-reviewed studies must be collected and evaluated by industry applicants in the dossier submitted in support of regulatory authorisation of a pesticide.[21] An EFSA guidance document stipulates that the search should be "extensive" and that study selection should be conducted in a way that is "systematic, transparent and reproducible", in order to "objectively" gather "as much relevant scientific peer-reviewed open literature as possible".[22] Regulation 1107/2009 stipulates that the RMS – the country responsible for carrying out the initial scientific evaluation of the pesticide – must check the admissibility of the industry dossier by assessing whether all elements are provided and request additional information if any are missing.[23] During EFSA's evaluation, studies from the peer-reviewed literature are incorporated in the assessment through public consultation or other means.

The General Court in *Bayer CropScience AG and Others v European Commission* affirmed that "the relevant scientific literature" must be "taken into consideration" and that "unless otherwise specified, the decisions which the Commission is required to take in the context of that regulation [1107/2009] must always take account of the latest scientific and technical knowledge".[24] However, the Regulation does not stipulate that "all" studies must be considered, and EFSA guidance documents are not legally binding. As a result, selective use and omission of published data and a preponderance of industry-funded studies that report no adverse effects are common features of several RARs, such as for 2,4-D, thiabendazole, amitrole, esfenvalerate and glyphosate. In the case of glyphosate, the final RAR produced by the German Federal Institute for Risk Assessment, BfR (Germany being the RMS) included just 52% (76 studies) of the peer-reviewed scientific literature available at the time that reported adverse effects following glyphosate exposure. Of these, only 31% were discussed.[25] Omission of peer-reviewed studies is problematic because they frequently detect harms that do not show up in industry-funded studies; being

[21] European Parliament and Council, "Regulation (EC) No 1107/2009 of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC", supra, note 1, Art 8(5).

[22] European Food Safety Authority (EFSA), "Submission of Scientific Peer-Reviewed Open Literature for the Approval of Pesticide Active Substances under Regulation (EC) No 1107/2009" (2011) 9 EFSA Journal 1 <http://www.efsa.europa.eu/en/efsajournal/doc/2092.pdf>.

[23] European Parliament and Council, "Regulation (EC) No 1107/2009 of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC", supra, note 1, Arts 7–9.

[24] *Bayer CropScience AG and Others v European Commission* [2018] General Court (First Chamber) ECLI:EU:T:2018:280, Art 358.

[25] Pesticide Action Network Europe and Générations Futures, "Missed and Dismissed" (Pesticide Action Network Europe, 2014) <http://www.pan-europe.info/old/Resources/Reports/PANE%20-%202014%20-%20Missed%20and%20dismissed.pdf>.

research rather than tests mandated by regulation, they tend to use more up-to-date and sensitive protocols and techniques.[26]

More specifically, BfR, in its glyphosate assessment, did not notice that the industry applicant failed to include scientific publications showing that glyphosate can cause oxidative stress to cells – a mechanism that can cause damage to DNA and that is thus an important risk factor in the development of cancer. The presumed lack of such a mechanism was an important argument for BfR to conclude that glyphosate is not carcinogenic.[27]

Although EFSA identified additional peer-reviewed studies in its evaluation, it considered them to be of low reliability and therefore these had insignificant impact on the overall evaluation. This is an issue of failing to follow good scientific practice rather than a breach of the law.

2. Invalid dismissal or exclusion of adverse effects

Even when published non-industry-sponsored studies are included in the assessment (either in the RAR or during the EFSA peer-review process), the adverse effects identified in them can be dismissed and excluded by industry and/or regulatory reviewers from the risk evaluation for invalid reasons. One common approach[28] is the use of the "Klimisch criteria" for assessing the extent to which a scientific study is of sufficient quality to be used for determining health risks or hazards from chemical exposures. The Klimisch criteria were developed and published in 1997 by employees of the chemical company BASF[29] and, although they have been in widespread use since, there are two major ways in which their use can bias a risk assessment.

The first is that the Klimisch quality judgement is heavily weighted by whether a study is performed according to Organisation for Economic Co-operation and Development (OECD) protocols and Good Laboratory Practice (GLP) rules. While almost all industry tests performed for regulatory purposes are conducted according to OECD and GLP standards, academic research, which is arguably more often free from industry interests and more attuned to the latest developments in scientific knowledge, is usually not. Applying the Klimisch criteria results in the systematic down-weighting and effective exclusion of independent academic research in pesticide risk assessment for reasons that are not relevant to assessing the credibility

[26] JP Myers et al, "Why Public Health Agencies Cannot Depend on Good Laboratory Practices as a Criterion for Selecting Data: The Case of Bisphenol A" (2009) 117 Environmental Health Perspectives 309<http://ehp.niehs.nih.gov/0800173/>; VA Buonsante and others, "Risk Assessment's Insensitive Toxicity Testing May Cause It to Fail" (2014) 135 Environmental Research 139 <http://www.sciencedirect.com/science/article/pii/S0013935114002473> (last accessed 4 October 2014); LN Vandenberg et al, "Is It Time to Reassess Current Safety Standards for Glyphosate-Based Herbicides?" (2017) 71 Journal of Epidemiology and Community Health 613 <https://jech.bmj.com/content/71/6/613> (last accessed 9 July 2018).

[27] Pesticide Action Network Germany and Testbiotech, "Does Glyphosate Cause Cancer? Important Gap in German Risk Assessment" (Pesticide Action Network Germany and Testbiotech, 2015) <https://tinyurl.com/y4wxl6dd>; Pesticide Action Network Europe and Générations Futures, "Missed and Dismissed", supra, note 25.

[28] Pesticide Action Network Europe and Générations Futures, "Missed and Dismissed", supra, note 25.

[29] HJ Klimisch, M Andreae and U Tillmann, "A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data" (1997) 25 Regulatory Toxicology and Pharmacology 1 <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=9056496>.

of such research.[30] Industry studies, on the other hand, due to their adherence to OECD protocols and GLP rules, are automatically judged as sufficiently "relevant" and "reliable" to be used in the risk assessment.[31]

OECD protocols and GLP rules are not benchmarks of scientific excellence and were never intended as such. They were developed in the wake of revelations of widespread industry fraud in the testing of chemicals (including glyphosate) in an attempt to ensure greater accountability and reliability of industry studies.[32]

An example of an important study being dismissed through inappropriate application of the Klimisch criteria is BfR's evaluation of an epidemiological study by De Roos et al (2003) conducted among farmers. The study found an association between reported use of glyphosate (as well as several other pesticides investigated individually) and an increased incidence of non-Hodgkin lymphoma (NHL), a form of cancer. BfR, in its RAR, assigned the study a low Klimisch reliability score of 3 (ie "not reliable")[33] based partly on alleged failings that in reality were not present (see Point 7 in this section). However, applying the Klimisch criteria to an epidemiological study is not appropriate because the criteria were developed to assess data from experimental and ecological toxicology studies, not epidemiological studies.

BfR's evaluation of De Roos et al (2003) stands in stark contrast with that of the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) in its evaluation of the carcinogenic potential of glyphosate, which culminated in the verdict that the chemical was a "probable human carcinogen". IARC noted several strengths of De Roos et al (2003) compared with other epidemiological studies[34] – an element completely absent from BfR's evaluation.

The second way in which the Klimisch criteria can bias an assessment is that they are under-defined and thus challenging to implement transparently or consistently.[35] This allows any assessor with an incentive to over- or under-state the value of a study to do so, while appearing to comply with a rigorous study appraisal process. The result is a failure to produce a fair and integrated assessment of both industry regulatory

[30] D Krauth, TJ Woodruff and L Bero, "Instruments for Assessing Risk of Bias and Other Methodological Criteria of Published Animal Studies: A Systematic Review" (2013) 121 Environmental Health Perspectives 985 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3764080/> (last accessed 28 August 2019); JP Myers et al, "Why Public Health Agencies Cannot Depend on Good Laboratory Practices as a Criterion for Selecting Data", supra, note 26; R Kase et al, "Criteria for Reporting and Evaluating Ecotoxicity Data (CRED): Comparison and Perception of the Klimisch and CRED Methods for Evaluating Reliability and Relevance of Ecotoxicity Studies" (2016) 28 Environmental Sciences Europe 7 <https://doi.org/10.1186/s12302-016-0073-x> (last accessed 28 August 2019); VA Buonsante et al, "Risk Assessment's Insensitive Toxicity Testing May Cause It to Fail", supra, note 26; J Kaltenhäuser et al, "Relevance and Reliability of Experimental Data in Human Health Risk Assessment of Pesticides" (2017) 88 Regulatory Toxicology and Pharmacology 227 <http://www.sciencedirect.com/science/article/pii/S0273230017301794> (last accessed 28 August 2019).

[31] E Ingre-Khans et al, "Reliability and Relevance Evaluations of REACH Data" (2019) 8 Toxicology Research 46.

[32] Organisation for Economic Cooperation and Development (OECD), "General Questions and Answers Concerning OECD Principles of Good Laboratory Practice (GLP) and Mutual Acceptance of Data (MAD)" (Organisation for Economic Cooperation and Development (OECD), 2015) <https://tinyurl.com/yy8czckz>.

[33] S Weber and H Burtscher-Schaden, "Detailed Expert Report on Plagiarism and Superordinated Copy Paste in the Renewal Assessment Report (RAR) on Glyphosate" (2019) p 39 <https://tinyurl.com/yxatq7e3>.

[34] International Agency for Research on Cancer, "IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides" (World Health Organization, 2015) <https://monographs.iarc.fr/iarc-monographs-on-the-evaluation-of-carcinogenic-risks-to-humans-4/>.

[35] R Kase et al, "Criteria for Reporting and Evaluating Ecotoxicity Data (CRED)", supra, note 30.

tests and peer-reviewed studies from the published literature. Instead, adverse effects seen in academic studies are often dismissed from regulatory reviews of pesticides without proper scientific evaluation, resulting in an incorrect conclusion of safety.

In principle, dismissing peer-reviewed studies on the grounds that they are non-GLP compliant is not encouraged by the relevant EFSA guidance document on implementing Regulation 1107/2009, which says, "The fact that a study may not be conducted in accordance with Good Laboratory Practice (GLP) does not imply that the study is irrelevant".[36] However, as noted above, EFSA guidance documents are not legally binding. Therefore, this is an issue of failing to follow good scientific practice rather than a breach of the law.

3. Misuse of historical control data

Historical controls are control animals from experiments other than the one under evaluation that have taken place in the past. The misuse of historical control data (HCD) is a practice employed by industry and regulatory authorities to dismiss adverse effects in animal toxicology studies. The practice consists of dismissing the adverse effects found in an exposed group as compared with the non-exposed control group of the experiment under evaluation (concurrent control) because the observed changes fall within the range of historical controls.

By way of illustration, an analysis of the RARs of 10 pesticides found that the misuse of HCD to dismiss carcinogenic effects in regulatory studies was the most common flaw observed. By applying the relevant EU guidelines and guidance documents, the analysis concluded that the carcinogenic potential of 7 out of the 10 pesticides examined had been underrated or inadequately described (with insufficient transparency) by the EU authorities.[37]

Misuse of HCD is a serious issue because data obtained from historical controls will vary widely due to different conditions in different experiments, such as animal genetics, laboratory conditions and feed composition and contaminants. Therefore, comparing the pesticide-exposed group of animals in one study with control animals from unrelated studies can result in adverse effects, caused by the exposure, being obscured by the "noise" created by the widely varying HCD. The conclusion will then be drawn that there is no adverse effect from the pesticide being tested. This can lead to the public being put at risk.

It is well recognised that there are proper ways to use HCD and that using such data to dismiss findings of adverse effects is unacceptable.[38] According to the applicable OECD

[36] European Food Safety Authority (EFSA), "Submission of Scientific Peer-Reviewed Open Literature for the Approval of Pesticide Active Substances under Regulation (EC) No 1107/2009", supra, note 20.

[37] P Clausing, "Chronically Underrated? A Review of the European Carcinogenic Hazard Assessment of 10 Pesticides" (Pesticide Action Network Germany and Health and Environment Alliance, 2019) <https://www.env-health.org/wp-content/uploads/2019/10/October-2019-Chronically-Underrated-web.pdf>.

[38] JK Haseman, "Statistical Issues in the Design, Analysis and Interpretation of Animal Carcinogenicity Studies" (1984) 58 Environmental Health Perspectives 385; JK Haseman, J Huff and GA Boorman, "Use of Historical Control Data in Carcinogenicity Studies in Rodents" (1984) 12 Toxicologic Pathology 126; KY Fung, D Krewski and RT Smythe, "A Comparison of Tests for Trend with Historical Controls in Carcinogen Bioassay" (1996) 24 The Canadian Journal of Statistics/La Revue Canadienne de Statistique 431 <https://www.jstor.org/stable/3315326> (last accessed 24 July 2019); T Yanagawa and DG Hoel, "Use of Historical Controls for Animal Experiments" (1985) 63 Environmental Health Perspectives 217 <https://ehp.niehs.nih.gov/doi/10.1289/ehp.8563217> (last accessed 24 July 2019); RE Tarone, "The Use of Historical Control Information in Testing for a Trend in Proportions" (1982) 38 Biometrics 215 <https://www.jstor.org/stable/2530304> (last accessed 24 July

guidance, the most important control data are the concurrent controls. The OECD specifies that experiments from which HCD is drawn should be conducted with the same strain of animals, in the same laboratory and under similar conditions within the five years prior to the study in question.[39]

While OECD guidance documents are not legally binding, the OECD guidance criteria for HCD quality cited above have been implemented into law in Regulation (EU) 283/2013, which sets out the data requirements for pesticide active substances. Regulation 283/2013 also stipulates that "the standard reference point for treatment responses shall be concurrent control data", though it adds that "historical control data may be helpful in the interpretation of particular reproductive studies".[40] These stipulations exclude the type of misuse of HCD that we criticise here: invoking HCD that fall outside the quality control measures and using such data to dismiss carcinogenic effects from pesticide exposure within any given experiment.

Yet in the EU assessment of glyphosate,[41] the BfR and EFSA frequently used HCD in violation of the OECD guidelines and of Regulation 283/2013 to dismiss findings of carcinogenicity, genotoxicity and other adverse effects.[42] They used HCD from time periods up to 17 years beyond the 5-year limit, from 7 different laboratories and from different animal sub-strains.[43] This appears to be illegal under the stipulations of Regulation 283/2013.

2019); SA Elmore and SD Peddada, "Points to Consider on the Statistical Analysis of Rodent Cancer Bioassay Data When Incorporating Historical Control Data" (2009) 37 Toxicologic Pathology 672; International Agency for Research on Cancer, "IARC Monographs on the Identification of Carcinogenic Hazards to Humans: Preamble" (IARC, 2019) <https://monographs.iarc.fr/wp-content/uploads/2019/01/Preamble-2019.pdf>; US Environmental Protection Agency (EPA), "Guidelines for Carcinogen Risk Assessment" (US Environmental Protection Agency, 2005) EPA/630/P-03/001F <https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment>.

[39] International Agency for Research on Cancer, "IARC Monographs on the Identification of Carcinogenic Hazards to Humans: Preamble" (IARC, 2019) <https://monographs.iarc.fr/wp-content/uploads/2019/01/Preamble-2019.pdf>; Organisation for Economic Cooperation and Development (OECD), "Guidance Document 116 on the Conduct and Design of Chronic Toxicity and Carcinogenicity Studies, Supporting Test Guidelines 451, 452 and 453" (OECD Publishing, 2014), 453 <https://www.oecd-ilibrary.org/environment/guidance-document-116-on-the-conduct-and-design-of-chronic-toxicity-and-carcinogenicity-studies-supporting-test-guidelines-451-452-and-453_9789264221475-en>.

[40] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Text with EEA relevance) 2013.

[41] European Food Safety Authority (EFSA), "Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate" (2015) 13 EFSA Journal 4302 <http://doi.wiley.com/10.2903/j.efsa.2015.4302> (last accessed 17 January 2017); European Food Safety Authority (EFSA), "Peer Review Report on Glyphosate" (EFSA, 2015) <http://registerofquestions.efsa.europa.eu/roqFrontend/outputLoader?output=ON-4302>.

[42] See, for example: RMS Germany (German Federal Institute for Risk Assessment, BfR), "Renewal Assessment Report: Glyphosate Addendum 1 to RAR: Assessment of IARC Monographs Volume 112 (2015): Glyphosate" (BfR, 2015) <http://www.gmwatch.org/files/Renewal_Assessment_Report_Glyphosate_Addendum1_RAR.pdf> p iii, para 3, "IARC also considered a review article containing information on five long-term bioassay feeding studies in mice, in which a statistically significant increase in the incidence of malignant lymphoma was reported, but the Working Group was unable to evaluate this study because of the limited experimental data provided in the review article and supplemental information. In three studies in CD-1 mice, the incidences of malignant lymphoma in male mice were reconsidered for statistical evaluation by the RMS. For two studies, the statistical analysis with the Cochran–Armitage trend test yielded a significant result, whereas the analysis by pair-wise comparisons indicated no statistically significant differences between the groups for all three studies. The incidences observed in the above studies, with a maximum of 12%, were all within the historical control range. Therefore, the observed malignant lymphomas were spontaneous and unrelated to treatment".

[43] P Clausing, C Robinson and H Burtscher-Schaden, "Pesticides and Public Health: An Analysis of the Regulatory Approach to Assessing the Carcinogenicity of Glyphosate in the European Union" (2018) 72 Journal of Epidemiology and Community Health <https://jech.bmj.com/content/72/8/668> (last accessed 8 July 2018); P Clausing, "Glyphosate

The European Chemicals Agency (ECHA), in its hazard assessment report concluding that glyphosate was non-carcinogenic, did mention the existence of guidance-compliant HCD.[44] However, it failed to point out that these data supported the observation of increased tumour incidences from glyphosate exposure.No valid HCD were presented by the EU authorities to support their conclusion that glyphosate is non-carcinogenic.[45] This is an example of bad scientific practice rather than a breach of the law.

4. Misuse of statistical analytical tools

Another form of scientific misconduct is the misuse of statistical analytical tools. For example, in a defence of the EU assessment that glyphosate was non-carcinogenic, staff from EFSA's Pesticides Unit and BfR published a response in which they claimed to have "balanced" the findings obtained from rodent toxicological studies by using one statistical analytical tool (trend test) against the findings obtained by using another tool (pairwise comparison).[46] Analysis using the trend test found a carcinogenic effect, but pairwise comparison found no statistically significant effect. EFSA and BfR concluded that the effect was not real.

However, the OECD guidelines state, "Significance in either kind of test is sufficient to reject the hypothesis that chance accounts for the result".[47] Thus, EFSA and BfR's insistence on both a positive trend test and positive pairwise test in order to treat the carcinogenic effect as real is a violation of the guidelines.[48]

The OECD guidelines also state that statistical significance in a finding does not necessarily mean that it is biologically relevant. However, in the case of glyphosate, evidence from epidemiological studies[49] as well as mechanistic evidence[50] point to a carcinogenic effect. Therefore, it is not defensible to "balance" positive evidence of carcinogenicity in some animal feeding studies against a lack of evidence of

and Cancer: Authorities Systematically Breach Regulations" (GLOBAL 2000, 2017) <http://www.gmwatch.org/files/GLO_02_Glyphosat_EN.pdf>.

[44] ECHA Committee for Risk Assessment (RAC), "Opinion Proposing Harmonised Classification and Labelling at EU Level of Glyphosate (ISO); N-(Phosphonomethyl)Glycine: EC Number: 213-997-4; CAS Number: 1071-83-6; CLH-O-0000001412-86-149/F. Adopted 15 March 2017" (ECHA 2017) <https://tinyurl.com/v9puxmp>.

[45] P Clausing, C Robinson and H Burtscher-Schaden, "Pesticides and Public Health", supra, note 43.

[46] JV Tarazona et al, "Glyphosate Toxicity and Carcinogenicity: A Review of the Scientific Basis of the European Union Assessment and Its Differences with IARC" (2017) 91 Archives of Toxicology 2723.

[47] Organisation for Economic Cooperation and Development (OECD), "Guidance Document 116 on the Conduct and Design of Chronic Toxicity and Carcinogenicity Studies, Supporting Test Guidelines 451, 452 and 453: 2nd Edition: Environment Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology" (2012).

[48] CJ Portier and P Clausing, "Re: Tarazona et al (2017): Glyphosate Toxicity and Carcinogenicity: A Review of the Scientific Basis of the European Union Assessment and Its Differences with IARC." (2017) 91 Archives of Toxicology 3195 <https://www.ncbi.nlm.nih.gov/pubmed/28620672>.

[49] P Clausing, C Robinson and H Burtscher-Schaden, "Pesticides and Public Health", supra, note 43; H Burtscher-Schaden, P Clausing and C Robinson, "Glyphosate and Cancer: Buying Science" (GLOBAL 2000, 2017) <http://www.gmwatch.org/files/Glyphosate_and_cancer_Buying_science_EN_0.pdf>.

[50] International Agency for Research on Cancer, "IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides" (World Health Organization 2015) <https://monographs.iarc.fr/iarc-monographs-on-the-evaluation-of-carcinogenic-risks-to-humans-4/>.

carcinogenicity in others and to conclude that that the latter cancels out the former, giving a conclusion of no effect.

The misuse of statistical analytical tools is not explicitly identified as illegal by the EU pesticides regulatory framework, but it is an example of bad scientific practice.

5. Dismissing adverse effects based on alleged inconsistency of data

If multiple studies of the same endpoint disagree, it is common practice to discard studies showing toxicity in favour of a finding of no toxicity, with no explanation other than that the findings are inconsistent.[51] The assumption behind such dismissals is that the findings of toxicity are "false positives" –results that indicate that a toxic effect is present when in reality it is not.

However, assuming that a finding of an adverse effect is a false positive and dismissing it from the evaluation without a thorough analysis of all of the evidence biases the assessment towards a finding of no toxicity (ie safety). It should be borne in mind that the existing methodologies in the environmental and health sciences for measuring adverse effects are in themselves biased towards false negatives[52] – that is, missing adverse effects even though they exist.

The history of regulatory risk assessment is littered with examples of false negatives (where early warnings of adverse effects were dismissed, leading to decades of health-damaging exposures). In contrast, false positives (where regulatory authorities have acted based on precaution but the action was later judged as unnecessary) turn out to be rare. An analysis in the European Environment Agency report *Late Lessons from Early Warnings* points to the pursuit by some industry groups of a deliberate strategy of "manufacturing doubt, disregarding scientific evidence of risks and claiming over-regulation" in order to "undermine precautionary decision-making".[53]

The practice of assuming that adverse effects found in studies are false positives without adequate evidence is apparent in the analysis by BfR of the IARC review of glyphosate. BfR claimed (and EFSA agreed) that findings of malignant lymphomas, kidney tumours and hemangiosarcomas in male mice were not related to glyphosate because of inconsistencies in the data.[54] However, they failed to provide any analysis to support this argument and ignored differences in the studies, such as duration of exposure and mouse strain, which would naturally lead to variation in the results. Dismissing adverse effects because they are not consistent across multiple studies incentivises industry to continue doing studies until one shows no effect, thus biasing the outcome of an assessment.

[51] P Clausing, "Glyphosate and Cancer: Authorities Systematically Breach Regulations", supra, note 43.

[52] D Gee, "Late Lessons from Early Warnings: Toward Realism and Precaution with Endocrine-Disrupting Substances" (2006) 114 Environmental Health Perspectives 152 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1874173/> (last accessed 3 October 2019).

[53] SF Hansen and JA Tickner, "The Precautionary Principle and False Alarms – Lessons Learned", Late Lessons from Early Warnings, Vol II (European Environment Agency (EEA), 2013) <https://www.eea.europa.eu/publications/late-lessons-2>.

[54] RMS Germany (German Federal Institute for Risk Assessment, BfR), "Renewal Assessment Report: Glyphosate Addendum 1 to RAR", supra, note 42, pp ii–iii; European Food Safety Authority (EFSA), "Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate", supra, note 41.

Dismissing adverse effects based on alleged inconsistency of data is not explicitly identified as illegal by the EU pesticides regulatory framework, but it is an example of bad scientific practice.

6. Misuse of the "weight of evidence" approach

EFSA defines the weight of evidence (WoE) approach as "a process in which evidence is integrated to determine the relative support for possible answers to a question". It considers the WoE approach as comprising three steps: assembling the evidence into lines of similar type, weighing the evidence and integrating the evidence.[55]

In addition, Regulation 1272/2008 on the classification, labelling and packaging of chemical substances (including pesticides) stipulates that in a WoE approach, "all available information bearing on the determination of hazard is considered together". The Regulation refers specifically to "in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations".[56]

Factors to be considered during the application of WoE, according to Regulation 1272/2008, are "the quality and consistency of the data", "information on substances or mixtures related to the substance or mixture being classified" and study results on the site of action and mechanism or mode of action. The Regulation states, "Both positive and negative results shall be assembled together in a single weight of evidence determination".[57]

BfR[58] and EFSA[59] defended their risk assessment evaluations of glyphosate, and ECHA its hazard assessment,[60] on the basis of claims that they used a WoE approach to reconcile contradictions in study results. However, they give no formal description of the weights used or how they apply to individual studies. This leads to a lack of transparency on how the final decision was achieved. The divergence of the verdicts of the IARC and the EU authorities on glyphosate's carcinogenicity are due to the widely differing norms governing which studies are selected and how the analysis of evidence is performed.[61]

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[55] European Food Safety Authority (EFSA), "Guidance on the Use of the Weight of Evidence Approach in Scientific Assessments" (2017) <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4971>.

[56] European Parliament and Council, "Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation (EC) No 1907/2006" (2008) Official Journal of the European Union 1.1.1.3 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R1272-20191201>.

[57] ibid.

[58] RMS Germany (German Federal Institute for Risk Assessment, BfR), "Renewal Assessment Report: Glyphosate Addendum 1 to RAR", supra, note 42.

[59] European Food Safety Authority (EFSA), "Peer Review Report on Glyphosate", supra, note 41.

[60] ECHA Committee for Risk Assessment (RAC), "Opinion Proposing Harmonised Classification and Labelling at EU Level of Glyphosate (ISO); N-(Phosphonomethyl)Glycine: EC Number: 213-997-4; CAS Number: 1071-83-6; CLH-O-0000001412-86-149/F. Adopted 15 March 2017" (ECHA, 2017) <https://tinyurl.com/v9puxmp>.

[61] E Bozzini, *Pesticide Policy and Politics in the European Union: Regulatory Assessment, Implementation and Enforcement* (1st edn, Palgrave MacMillan 2017).

Tools exist for performing formal weighted analyses such as meta-analyses and study pooling, but these are seldom used in regulatory decisions. For example, a meta-analysis of micronuclei[62] tests demonstrating the genotoxicity of glyphosate and its formulations is available in the literature,[63] but seems to have played no role in regulatory decisions. In addition, converging lines of evidence for NHL in humans, malignant lymphomas in mice and micronuclei in multiple strains of animals were not assessed as a whole. Instead, each line of evidence was considered in isolation and dismissed as not being sufficiently strong to classify glyphosate as carcinogenic.[64]

These practices by BfR and EFSA violated the EFSA guidance, in that neither agency "integrated" the evidence in forming their conclusions. ECHA similarly failed to integrate the different lines of evidence in its hazard classification of glyphosate as non-carcinogenic.

Although EFSA guidance documents are not legally binding, Regulation 1107/2009 stipulates that EFSA ("the Authority") shall adopt a conclusion in its opinion on the substance "in the light of current scientific and technical knowledge using guidance documents available at the time of application".[65] On these grounds, it may be argued that EFSA failed to perform its assessment in the light of current scientific knowledge and in line with its own guidance document.

On other grounds, the stipulation in Regulation 1272/2008 that "all available information ... is considered together" may be undermined by the authorities' practice of excluding non-GLP and non-OECD guideline studies as not reliable and not relevant (see Section II.2 above). If many or all of these studies are excluded at the start of the risk assessment, it is likely that even a consideration of "all of the evidence" that remains in the risk assessment will give a biased result, in the form of a conclusion of greater safety than is warranted.

7. Misrepresentation of research methodology

An example of misrepresentation of research methodology in the glyphosate renewal assessment is BfR's treatment of an epidemiological study[66] that reported a link between exposure to glyphosate and NHL in men. BfR dismissed the study as "not reliable" on the grounds that "no useful information" on confounding factors such as smoking and medical history was reported.[67] However, contrary to BfR's allegation,

[62] Micronuclei are bodies in cells that indicate damage to cell repair mechanisms and DNA; their presence is a potential sign of cancer development.

[63] N de Castilhos Ghisi, E Celton de Oliveira and A José Prioli, "Does Exposure to Glyphosate Lead to an Increase in the Micronuclei Frequency? A Systematic and Meta-Analytic Review" (2016) 145 Chemosphere 42 <http://www.sciencedirect.com/science/article/pii/S0045653515303763>.

[64] H Burtscher-Schaden, P Clausing and C Robinson, "Glyphosate and Cancer: Buying Science", supra, note 49.

[65] Art 12(2).

[66] AJ De Roos et al, "Integrative Assessment of Multiple Pesticides as Risk Factors for Non-Hodgkin's Lymphoma among Men" (2003) 60 Occupational and Environmental Medicine e11 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1740618/> (last accessed 2 February 2017).

[67] RMS Germany, "Renewal Assessment Report. 18 December 2013, Revised 29 January 2015, 31 March 2015. Glyphosate Volume 3: Annex B.6.1: Toxicology and Metabolism." (BfR, 2015), p 538 <http://www.gmwatch.org/files/Renewal_Assessment_Report_Glyphosate_genotox_and_cancer.pdf>.

this information was reported and these factors were controlled for, as stated in the studies used as the source data for the paper.[68]

Misrepresentation of research methodology is not stipulated in EU regulations as illegal, but it is contrary to the requirement of Regulation 1107/2009 that the assessment process for a pesticide is "objective".

8. Plagiarism

Plagiarism is defined as presenting someone else's work as one's own by incorporating it into one's work without acknowledgement.[69] This practice is (as acknowledged by BfR) common in regulatory DARs and RARs.[70] The issue from the public interest point of view is that text supplied by industry is often not distinguished from text or comments supplied by the RMS, and text copied and pasted from the industry dossier appears in the DAR or RAR without attribution. The result is that there is no way for the public to know if statements represent the view of the industry applicant or the regulatory reviewer.

Multiple instances of plagiarism have been documented in BfR's review of glyphosate.[71] This practice puts the public at risk because it often entails the regulator taking industry's interpretation of study results at face value.[72] BfR missed significant increases in tumours in glyphosate-exposed animalsas a result of initially relying on industry's own evaluation of the studies, without performing the necessary check of comparing the summaries with the original studies.[73]

There is no specific mention of plagiarism in the EU regulations on pesticides, but it is prohibited in scientific and academic publication. In addition, plagiarising from industry undermines the aim of Regulation 1107/2009 to ensure an "independent, objective and transparent" assessment.

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[68] E Greiser, "Expert Statement on Epidemiological Studies Which Examine the Possible Correlation between Exposure to Glyphosate-Based Herbicides and Non-Hodgkin's Lymphoma and Human Fertility Disorders in Relation to Evaluations Undertaken by the German Federal Institute for Risk Assessment (BfR) and the European Food Safety Authority (EFSA), on Behalf of GLOBAL 2000, Vienna, and Umweltinstitut, Munich" (GLOBAL 2000 and Umweltinstitut, 2016) <https://www.global2000.at/sites/global/files/Human%20evidence_Eberhard Greiser.pdf>.

[69] University of Oxford, "Plagiarism" (ox.ac.uk, 2019) <https://www.ox.ac.uk/students/academic/guidance/skills/plagiarism?wssl=1> (last accessed 22 August 2019).

[70] BfR, "Unfounded Allegations against Scientific Assessment Authorities" (bfr.bund.de, 5 October 2017) <https://www.bfr.bund.de/en/press_information/2017/40/unfounded_allegations_against_scientific_assessment_authorities-203462.html> (last accessed 22 August 2019).

[71] S Weber and H Burtscher-Schaden, "Detailed Expert Report on Plagiarism and Superordinated Copy Paste in the Renewal Assessment Report (RAR) on Glyphosate", supra, note 33.

[72] Pesticide Action Network Europe et al, "Ensuring a Higher Level of Protection from Pesticides in Europe", supra, note 11, 2.4.

[73] P Clausing, "Glyphosate: The European Controversy – A Review of Civil Society Struggles and Regulatory Failures" (2019) Business and Human Rights Journal 1 <https://www.cambridge.org/core/journals/business-and-human-rights-journal/article/glyphosate-the-european-controversy-a-review-of-civil-society-struggles-and-regulatory-failures/0A379F207A17CC7B18D2CC9079EAB29C> (last accessed 4 July 2019); P Clausing, "Glyphosate and Cancer: Authorities Systematically Breach Regulations", supra, note 43.

9. Failure to assess toxicity of mixtures

Pesticides are sold and used as mixtures ("formulations"): one or more active ingredients are mixed with co-formulants to increase the pesticidal activity. The whole formulations as sold and used are approved individually at the Member State level following EU approval for use of the active ingredient.

The co-formulants present in the mixtures can be more toxic than the active ingredients.[74] In addition, regarding glyphosate-based herbicides, the complete formulations as sold and used have been found to be more toxic than the declared active substance glyphosate alone, both in human cell culture[75] and in vivo studies by academic scientists.[76] However, the complete formulations are not tested by industry applicants for long-term toxicity for regulatory purposes.[77]

Ignoring the toxicity of co-formulants during pre-market testing has resulted in the commercialisation of pesticides containing co-formulants with problematic toxicity profiles, such as ethoxylated tallowamine in glyphosate-based herbicides, which were only discovered to be highly toxic by academic scientists after they were approved.[78]

Omitting to address cumulative and synergistic effects of chemicals is a violation of the law. Regulation 1107/2009 requires that "the residues" of any given pesticide, which would include any co-formulant residues, must not have harmful effects on human or animal health, "taking into account known cumulative and synergistic effects".[79] In addition, Regulation 396/2005 on setting pesticide residue limits in food requires that pesticide residues from sources other than the active substance, and their known cumulative and synergistic effects, are taken into account.[80] The toxicity of mixtures is being given insufficient scrutiny prior to pesticides being placed on the market.[81]

In *Procureur de la République v Mathieu Blaise and Others*, the European Court of Justice clarifies that Regulation No. 1107/2009 does not exempt industry applicants from submitting tests of long-term carcinogenicity and toxicity relating to formulated plant

[74] R Mesnage and MN Antoniou, "Ignoring Adjuvant Toxicity Falsifies the Safety Profile of Commercial Pesticides" (2018) 5 Frontiers in Public Health <https://www.frontiersin.org/articles/10.3389/fpubh.2017.00361/full> (last accessed 13 March 2018).

[75] R Mesnage, B Bernay and GE Seralini, "Ethoxylated Adjuvants of Glyphosate-Based Herbicides Are Active Principles of Human Cell Toxicity" (2013) 313 Toxicology 122 <http://www.ncbi.nlm.nih.gov/pubmed/23000283>.

[76] A Adam et al, "The Oral and Intratracheal Toxicities of ROUNDUP and Its Components to Rats" (1997) 39 Veterinary and Human Toxicology 147; L Janssens and R Stoks, "Stronger Effects of Roundup than Its Active Ingredient Glyphosate in Damselfly Larvae" (2017) 193 Aquatic Toxicology 210 <http://www.sciencedirect.com/science/article/pii/S0166445X17303156> (last accessed 2 September 2019).

[77] Organisation for Economic Cooperation and Development (OECD), "OECD Survey on How Pesticide Ingredients Other than the Stated Pesticide Active Ingredient(s) Are Reviewed and Regulated: Survey Results" (OECD, 2010) Series on Pesticides No. 55 <http://www.oecd.org/chemicalsafety/pesticides-biocides/pesticides-publications-chronological-order.htm>.

[78] R Mesnage, C Benbrook and MN Antoniou, "Insight into the Confusion over Surfactant Co-Formulants in Glyphosate-Based Herbicides" (2019) 128 Food and Chemical Toxicology 137 <http://www.sciencedirect.com/science/article/pii/S0278691519301814> (last accessed 12 August 2019).

[79] European Parliament and Council, "Regulation (EC) No 1107/2009 of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market", supra, note 1, Art 4(2a).

[80] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC 2005, Art 14(2b).

[81] A Arcuri and YH Hendlin, "The Chemical Anthropocene: Glyphosate as a Case Study of Pesticide Exposures" (2019) 30 King's Law Journal 234 <https://doi.org/10.1080/09615768.2019.1645436> (last accessed 30 September 2019).

protection products as sold and used.[82] Member States do not require such tests, even when evidence on long-term toxicity cannot be ruled out.

This ruling has the potential to ensure better compliance with the objectives of the pesticides regulation. It could result in many pesticide formulations being banned because they have not been tested in long-term studies. If such testing is carried out as a result of the new ruling, any adverse effects might be especially difficult to deny due to the generally more toxic effects of formulations.

The Court of Justice also ruled on whether the failure of the EU pesticide regulatory system to take into account the cumulative effects of toxic substances constituted a failure to comply with the precautionary principle. The court stated that under Regulation 1107/2009, the authorisation of a pesticide "must necessarily include an assessment not only of the specific effects of the active substances contained in that product, but also of the cumulative effects of those substances and their effects combined with other constituents of that product".[83] This aspect of the ruling also requires the Member States to reopen the pesticide authorisations that have been granted in order to re-evaluate their effects, according to what the Court has confirmed to be the compulsory approach under the pesticides regulation.

Adding to the mixtures issue is the fact that different pesticide formulations can be mixed in tanks by applicators[84] and in the environment,[85] leading to interactive and synergistic "cocktail" toxic effects in people and animals.[86]

An increasing number of in vivo studies in rodents show that toxic effects can result from exposure to mixtures of pesticide active substances where each is present at a level deemed by regulators to have no adverse effect.[87] Yet such studies are ignored in regulatory assessments.

10. Solutions to scientific misconduct issues

The solution to issues of scientific misconduct is to bring the process of assessing evidence on health risks from pesticide exposure up to date and onto a par with scientific practices being employed in other domains. Below, we offer three solutions: use of systematic review; proper use of the WoE approach; and improving assessment

[82] C-616/17 – *Procureur de la République v Mathieu Blaise and Others* (European Court of Justice 1 October 2019).

[83] ibid, [75].

[84] UK Health and Safety Executive, "The Applicant Guide: Tank-Mix Recommendations on Product Labels" (hse.gov.uk, 2019) <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-tank-mi.htm> (last accessed 29 August 2019).

[85] European Food Safety Authority (EFSA), "International Frameworks Dealing with Human Risk Assessment of Combined Exposure to Multiple Chemicals" (2013) 11 EFSA Journal 3313 <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2013.3313> (last accessed 12 August 2019).

[86] V Rizzati et al, "Effects of Pesticide Mixtures in Human and Animal Models: An Update of the Recent Literature" (2016) 254 Chemico-Biological Interactions 231 <http://www.sciencedirect.com/science/article/pii/S0009279716302198> (last accessed 30 August 2019).

[87] See, for example: C Lukowicz et al, "Metabolic Effects of a Chronic Dietary Exposure to a Low-Dose Pesticide Cocktail in Mice: Sexual Dimorphism and Role of the Constitutive Androstane Receptor" (2018) 126 Environmental Health Perspectives 067007; U Hass et al, "Combined Exposure to Low Doses of Pesticides Causes Decreased Birth Weights in Rats" (2017) 72 Reproductive Toxicology 97; U Hass et al, "Adverse Effects on Sexual Development in Rat Offspring after Low Dose Exposure to a Mixture of Endocrine Disrupting Pesticides" (2012) 34 Reproductive Toxicology 261.

of the toxicity of mixtures. All three practices should be underpinned by the precautionary principle and thus, in cases of different studies giving contradictory results, the adverse effects should be assumed to be real unless there is strong evidence that they are not. Application of the precautionary principle is the role of the risk manager (Commission and Member States), although there is little evidence that these authorities are performing this function with due diligence.

The procedure for the implementation of the precautionary principle under 1107/2009 was elucidated by the General Court in the Joined Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission*, as explained in the commentary by Bozzini and Stokes.[88]

a. Use of systematic review

Systematic review is an approach to locating, aggregating and appraising evidence in answer to a research question, which seeks to minimise bias and maximise transparency and reproducibility in the evidence review.[89] Over the last three decades, systematic review has become fundamental to evaluating the efficacy of medical interventions and is increasingly used by national and international bodies in risk assessment.[90]

Systematic reviews are methodologically complex. Comprehensive guidance on how they should be conducted is given elsewhere (eg by the US National Toxicology Program[91]). However, they share the following characteristics, which, if applied to pesticide risk assessments, would enhance their validity and transparency:

[88] E Bozzini and E Stokes, "Court Upholds Restrictions on Neonicotinoids – A Precautionary Approach to Evidence" (2018) 9 European Journal of Risk Regulation 585 <https://www.cambridge.org/core/journals/european-journal-of-risk-regulation/article/court-upholds-restrictions-on-neonicotinoids-a-precautionary-approach-to-evidence/71AD1AC4F5F55A33FD4857A71D5CB830> (last accessed 21 March 2020). The General Court explained the decision-making process based on the precautionary principle, which involves three main stages: "First, identification of the potentially adverse effects arising from a phenomenon; second, assessment of the risks to public health, safety and the environment which are related to that phenomenon; and, third, when the potential risks identified exceed the threshold of what is acceptable for society, risk management by the adoption of appropriate protective measures".

[89] P Whaley et al, "Implementing Systematic Review Techniques in Chemical Risk Assessment: Challenges, Opportunities and Recommendations" (2016) 92–93 Environment International 556.

[90] M Krzyzanowski, "WHO Air Quality Guidelines for Europe" (2008) 71 Journal of Toxicology and Environmental Health. Part A 47; D Mandrioli et al, "WHO/ILO Work-Related Burden of Disease and Injury: Protocol for Systematic Reviews of Occupational Exposure to Dusts and/or Fibres and of the Effect of Occupational Exposure to Dusts and/or Fibres on Pneumoconiosis" (2018) 119 Environment International 174; EE Yost et al, "Hazards of Diisobutyl Phthalate (DIBP) Exposure: A Systematic Review of Animal Toxicology Studies" (2019) 125 Environment International 579; US National Toxicology Program, "OHAT Systematic Review" (ntp.niehs.nih.gov, 2019) <https://ntp.niehs.nih.gov/pubhealth/hat/review/index-2.html>; US National Toxicology Program, "OHAT Systematic Review" (ntp.niehs.nih.gov, 2019) <https://ntp.niehs.nih.gov/pubhealth/hat/review/index-2.html>; EFSA Working Group on the Application of Systematic Review Methodology to Food and Feed Safety Assessments, "Application of Systematic Review Methodology to Food and Feed Safety Assessments to Support Decision Making" (2010) 8 EFSA Journal 1637 <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2010.1637> (last accessed 26 July 2019).

[91] National Toxicology Program, US Department of Health and Human Services, "Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration" (National Toxicology Program, 2015) <https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookjan2015_508.pdf>.

- Advance publication and peer review of review methods ahead of conducting analysis. This helps ensure that the methods are not determined by reviewers' prior knowledge of the findings of the included studies or their expectations in terms of desired result. Systematic reviews can be registered online in advance.[92]
- Comprehensive search strategies and explicit eligibility criteria for identifying relevant studies. This ensures that all relevant research is taken into account during an evidence review, which might otherwise be missed or disregarded and thus bias the results of an assessment.
- Critical appraisal of included studies using validated tools, which ensures that each study is assessed according to the same standard, regardless of its results. This helps prevent selective de-weighting of a study's value based on inappropriate criteria. Methods for critical appraisal have advanced significantly in the 20 years since the publication of the Klimisch criteria, with modern "risk of bias" assessment methods deployed by the National Toxicology Program's Office of Health Assessment and Translation (NTP OHAT)[93] and the Navigation Guide.[94]

For pesticide assessments, regulatory authorities should be required to ensure that all available and relevant published studies are reviewed. The "quality" of studies should be evaluated in terms of the likelihood of systematic error in results ("risk of bias") and the extent to which they provide a representative study model of human health or environmental risks from the exposure – not by potentially misleading proxies for such evaluation (eg whether they are GLP or OECD compliant).

b. Proper use of the WoE approach

If a WoE approach is used, adverse effects should be given weight according to explicit and consistent criteria that are established independently of the pesticide being reviewed in order to minimise the potential for bias in the evaluation. The current WoE approaches appear to be used to dismiss studies reporting adverse effects from exposure rather than to create an integrated approach to understanding the data. This is especially true when examining data across different species (eg humans and animals) or experimental platforms (eg animals versus cells), where there is a tendency to dismiss each piece of evidence in isolation as less than convincing, rather than assessing the evidence as a whole to see if the various threads lead to the same conclusion.

[92] See, for example: University of Adelaide/Joanna Briggs Institute, "Systematic Review Register" (joannabriggs.org, 2019) <https://joannabriggs.org/resources/systematic_review_register> (last accessed 30 September 2019).

[93] National Toxicology Program, US Department of Health and Human Services, "Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration", supra, note 91.

[94] TJ Woodruff and P Sutton, "The Navigation Guide Systematic Review Methodology: A Rigorous and Transparent Method for Translating Environmental Health Science into Better Health Outcomes" (2014) 122 Environmental Health Perspectives 1007 <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1307175> (last accessed 26 July 2019).

c. Improving assessment of the toxicity of mixtures

Regarding the issue of assessing the toxicity of mixtures, it is not feasible to apply the complete battery of regulatory toxicity tests to all pesticide formulations. However, actions can be taken to mitigate the issue. A worst-case reference formulation containing the highest concentration of active substance(s) and co-formulants that the applicant would consider marketing could be defined and tested in long-term in vivo studies. Alternatively, all pesticide ingredients could be tested in high-throughput assays in vitro to investigate endpoints such as endocrine disruption, neurotoxicity and genotoxicity. A positive result would trigger in vivo toxicological studies in rodents, which are necessary to assess endpoints that in vitro toxicity assays cannot assess.

In 2019, EFSA published a guidance document on methodologies to assess human and animal health risks from combined exposure to multiple chemicals. The guidance is intended to be applied "in all relevant areas of EFSA's work".[95] However, it only constitutes the beginning of an attempt to regulate this complex subject and makes many recommendations for future work. In the meantime, public health and the environment are not sufficiently protected from the effects of mixtures.

A major obstacle to resolving the issue of the toxicity of formulations is that the composition of pesticide formulations may in principle be treated as confidential business information and not disclosed,[96] although in the interests of public health, the law should require disclosure of all components of pesticide mixtures.[97] Under the new legal framework, as amended by Regulation 2019/1381,[98] which will come into force on 27 March 2021, confidentiality is not automatic. The principle is that industry studies have to be published. By exception, some information contained in industry studies and listed in the pesticide Regulation 1107/2009 – which includes the complete compositions of pesticide products – may be kept confidential if the applicant for authorisation justifies their demand for confidentiality with verifiable proof that disclosure would potentially cause a significant degree of harm to a legitimate interest. Importantly, even sensitive information has to be disclosed if it relates to emissions into the environment – but only upon request by a third party to an EU institution or a Member State. The European Court of Justice has confirmed

[95] SJ More et al, "Guidance on Harmonised Methodologies for Human Health, Animal Health and Ecological Risk Assessment of Combined Exposure to Multiple Chemicals" (2019) 17 EFSA Journal e05634 <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2019.5634> (last accessed 28 February 2020).

[96] European Parliament and Council, "Regulation (EC) No 1107/2009 of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC", supra, note 1, Art 63(2f); Organisation for Economic Cooperation and Development (OECD), "OECD Survey on How Pesticide Ingredients Other than the Stated Pesticide Active Ingredient(s) Are Reviewed and Regulated", supra, note 77.

[97] R Mesnage and MN Antoniou, "Ignoring Adjuvant Toxicity Falsifies the Safety Profile of Commercial Pesticides", supra, note 74; R Mesnage, C Benbrook and MN Antoniou, "Insight into the Confusion over Surfactant Co-Formulants in Glyphosate-Based Herbicides", supra, note 78.

[98] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance) 2019 (OJ L).

that the pesticides actually used in fields can be considered as emissions.[99] In short, the protection of commercial interests creates barriers that are difficult (although not impossible) to overcome, both now and post-2021.

To mitigate the problem of exposure to multiple chemicals, the possible combined effects of chemicals should be evaluated in an overarching risk assessment of the toxicological data of all mixture components (including adjuvants), where experimental data are available. In addition, an extra uncertainty factor of 10 could be applied to set the "safe" dose (acceptable daily intake (ADI)). Currently, the ADI is set by dividing the no observed adverse effect level (NOAEL), taken from an animal study, by an uncertainty factor of 100.[100] This 100-fold uncertainty factor supposedly accounts for differences in response across species (eg rats versus humans; 10-fold uncertainty factor), as well as individuals of the same species (additional 10-fold factor). The total default uncertainty factor applied to mixtures should thus be 1000. To clarify, this figure of 1000 is made up of an interspecies uncertainty factor of 10, multiplied by an individual uncertainty factor of 10, multiplied by a mixtures uncertainty factor of 10. The risk manager – the European Commission and Member States – has charge of this decision.

III. Lack of transparency

The above problems are enabled and magnified by the lack of transparency of the pesticide regulatory process. This gives rise to a situation in which public authorities with limited resources are placed in the role of the sole judge of the accuracy, reliability, completeness and relevance of the frequently vast amount of data provided by the industry. Transparency of this data is a safeguard against abuses because it allows external scientists and informed members of civil society to scrutinise industry documents and the rationale of decisions authorising pesticides.

Two important transparency shortcomings identified by Citizens for Science in Pesticide Regulation[101] have begun to be addressed:

- *Unpublished and confidential status of industry studies:* The full reports of the toxicology studies in animals that are provided by industry applicants in support of their applications are generally unpublished. Regulation 1107/2009 allows them to be kept secret on the basis of commercial confidentiality. Thus, they cannot be evaluated by independent experts and the public.

[99] T-329/17 – *Heidi Hautala and Others vs European Food Safety Authority (EFSA)* (European Court of Justice) [120]; T-545/11 RENV – Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe) (European Court of Justice) [92]–[93].

[100] Food and Agriculture Organization of the United Nations and World Health Organization, "Principles and Methods for the Risk Assessment of Chemicals in Food" (WHO, 2009) Environmental Health Criteria 240 <http://www.who.int/foodsafety/publications/chemical-food/en/> (last accessed 12 August 2019); European Parliament and Council, "Regulation (EC) No 1107/2009 of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC", supra, note 1, Annex II (3.6.1).

[101] Pesticide Action Network Europe et al, "Ensuring a Higher Level of Protection from Pesticides in Europe", supra, note 11, 1.3, 1.2.

- *Lack of registration of all industry studies enables "cherry-picking":* There is no requirement that all safety tests done by industry are registered in advance and all results reported. Thus, industry can keep studies secret if results are unfavourable, with the subsequent publication bias distorting the results of the assessment.

Both of these shortcomings were addressed in the Commission's proposal on transparency,[102] which came in response to the 2017 EU Citizens' Initiative (ECI) on glyphosate. The ECI demanded a ban on glyphosate and a change in the law to require that pesticide regulatory approvals are based only on published studies.[103]

In line with the ECI's latter demand (the former – a ban on glyphosate – was not obtained), the Commission's transparency proposal was adopted into law in 2019 as Regulation (EU) 2019/1381, which, as noted above, comes into force in 2021. It amended, among other changes, the transparency regime of the risk assessment as set by the EU's General Food Law and its "daughter" food and feed regulations, including the pesticide Regulation (EC) 1107/2009. The new provisions give the public access to the previously confidential toxicology data provided to the EU authorities to obtain market authorisations – with limited derogations allowed. EFSA will be required to proactively publish these data on receipt. The proposal also requires all studies commissioned by industry applicants to be registered in advance in a database.[104]

Considering, on the one hand, the historical opposition of industry to transparency and the economic interests at stake and, on the other hand, the high level of public concern about pesticide exposure, the interpretation of the wording of the new transparency provisions will be contentious. This is especially so as the provisions give considerable interpretational leeway to EFSA. EFSA has the power to adopt the final decisions on transparency – and also to adopt guidance that will inform on how it intends to interpret the new provisions. Whether the new provisions will result in the changes needed will therefore depend on how EFSA interprets its new powers, and in particular on how strictly it will assess the remaining protection of business secrets and intellectual property.[105] EFSA will adopt its policy in the next year, in consultation with industry and civil society stakeholders.

[102] European Commission, "Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain Amending Regulation (EC) No 178/2002 [on General Food Law], Directive 2001/18/EC [on the Deliberate Release into the Environment of GMOs], Regulation (EC) No 1829/2003 [on GM Food and Feed], Regulation (EC) No 1831/2003 [on Feed Additives], Regulation (EC) No 2065/2003 [on Smoke Flavourings], Regulation (EC) No 1935/2004 [on Food Contact Materials], Regulation (EC) No 1331/2008 [on the Common Authorisation Procedure for Food Additives, Food Enzymes and Food Flavourings], Regulation (EC) No 1107/2009 [on Plant Protection Products] and Regulation (EU) No 2015/2283 [on Novel Foods]: COM/2018/0179 Final – 2018/088 (COD)" (11 April 2018) <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1523604766591&uri=COM:2018:179:FIN> (last accessed 19 July 2019).

[103] European Commission, "Initiative Details – European Citizens' Initiative" (https://ec.europa.eu, 25 January 2017) <https://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002> (last accessed 19 July 2019).

[104] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance) 2019 (OJ L).

[105] ibid. See p 27, Art 32e amending Art 38, General Food: "The disclosure to the public of the information mentioned . . . shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be used, reproduced, or otherwise exploited and its use by third parties shall not engage the responsibility of the European Union".

IV. Conflicts of interest

Conflicts of interest undermine the independence and objectivity of the regulatory process. Examples and potential solutions are discussed below.

1. Industry does its own safety testing

Safety testing of pesticides is carried out by the pesticide companies themselves or their sub-contractors.[106] Then they report the results of studies to the RMS and the regulatory authorities. However, companies have a clear commercial interest in their pesticides being classified as safe. This conflict of interest creates inherent bias in the conduct and interpretation of studies, leading to toxic effects being hidden or misrepresented (eg as not exposure-related or spontaneously occurring[107]).

In the 1970s and early 1980s, it emerged that serious fraud at Industrial Bio-Test Laboratories in the USA was taking place in the safety testing of pesticides (including glyphosate[108]) and pharmaceutical drugs for regulatory purposes.[109] As a result, as noted in Section II.2, above, GLP regulations were established by US regulatory agencies in order to try to improve the reliability of such safety testing. Since that time, GLP has been viewed by regulators as the fundamental guarantor of reliability in toxicological studies.[110]

However, in 2019, it became clear that this view is incorrect, as yet another serious fraud case came to light at a GLP testing laboratory. The case, as reported by the ARD news magazine *FAKT*, involved the Laboratory of Pharmacology and Toxicology (LPT) Hamburg, a large contract laboratory that carries out regulatory studies on behalf of the pharmaceutical and pesticide industries. LPT produced studies that supported the EU-wide approval of glyphosate in December 2017. The frauds documented by *FAKT* included the replacement of dead experimental animals with live ones and falsification of data, such as renaming tumours as "inflammations".[111]

According to the German risk assessment authority BfR, 24 studies that provided the basis to grant re-approval for glyphosate came from LPT; just 3, on mutagenicity, were relevant to carcinogenicity. Based on its assessment of "many other studies from different sources", BfR said that it saw no reason to revise its assessment of glyphosate's carcinogenicity.[112]

[106] Pesticide Action Network Europe et al, "Ensuring a Higher Level of Protection from Pesticides in Europe", supra, note 11, 1.1.

[107] P Clausing, "Glyphosate and Cancer: Authorities Systematically Breach Regulations", supra, note 43.

[108] Monsanto, "Backgrounder: Testing Fraud: IBT and Craven Labs" (2005) <http://bit.ly/M4NsT1>.

[109] RA Novak, "The Long Arm of the Lab Laws" (2001) 10 Today's Chemist at Work 45 <http://pubs.acs.org/subscribe/journals/tcaw/10/i11/html/11regs.html>.

[110] JP Myers et al, "Why Public Health Agencies Cannot Depend on Good Laboratory Practices as a Criterion for Selecting Data", supra, note 26.

[111] Corporate Europe Observatory, PAN Germany and GLOBAL 2000, "Dangerous Confidence in 'Good Laboratory Practice'" (Corporate Europe Observatory, PAN Germany, and GLOBAL 2000, 2020) <https://www.global2000.at/sites/global/files/2020-GoodLaboratoryPractice-en.pdf>.

[112] BfR, "Animal Welfare Provisions and Good Laboratory Practice: German Federal States ('Länder') Investigate Possible Breaches by an Animal Experiment Laboratory" (2020) <https://www.bfr.bund.de/cm/349/animal-welfare-provisions-and-good-laboratory-practice-german-federal-states-investigate-possible-breaches-by-an-animal-experiment-laboratory.pdf>.

As explained in Section II, there are many reasons to question BfR's verdict of glyphosate's non-carcinogenicity. But that aside, the findings in the fraud case raise two major questions: whether risk assessments for pesticides based on LPT studies can be trusted; and whether GLP is sufficient to guarantee data quality when laboratories that claim to adhere to GLP rules are apparently able to falsify studies over years and decades without it being noticed by the relevant authorities.

As a general principle, it seems at odds with the findings of numerous scientific reviews to allow industry to do its own safety testing. Reviews assessing the role of funding bias in scientific evaluations of the safety of controversial products and technologies show that industry-sponsored studies and/or those with authors affiliated with industry are much more likely to reach a favourable conclusion of safety than studies carried out by scientists independent of industry.[113]

The pesticides Regulation places the burden of proof that substances are safe on industry, which is in principle a sound approach. Giving the full responsibility – as well as the obligation to follow GLP – to industry to conduct safety studies was originally conceived as the logical consequence of this burden of proof. However, this action has backfired badly, to the extent that it threatens the aim of the Regulation to protect health and environment. To resolve this situation, the law should be changed so that safety testing is performed by laboratories that are independent of industry. Tests should be commissioned not by industry, but by an independent public body such as EFSA. Industry should continue to pay for the full costs, but must not be able to choose the laboratory or scientists that carry out the studies, the design and conduct of the studies or the interpretation of results.

2. Independence of agencies involved in regulation is compromised

National and international agencies involved in the pesticide regulatory process have been widely criticized for their closeness to industry and biased structure and processes, as detailed below.

a. BfR and other agencies

BfR and other German agencies involved in the EU's 2002 and 2017 glyphosate assessments were the subject of a 2015 investigation by BUND (Friends of the Earth Germany). The investigation probed conflicts of interest at these agencies in the first

[113] See, for example: DE Barnes and LA Bero, "Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions" (1998) 279 JAMA 1566 <http://www.ncbi.nlm.nih.gov/pubmed/9605902>; J Lexchin, "Those Who Have the Gold Make the Evidence: How the Pharmaceutical Industry Biases the Outcomes of Clinical Trials of Medications" (2011) 18 Science and Engineering Ethics 247 <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=21327723>; A Huss et al, "Source of Funding and Results of Studies of Health Effects of Mobile Phone Use: Systematic Review of Experimental Studies" (2007) 115 Environmental Health Perspectives 1; J Diels et al, "Association of Financial or Professional Conflict of Interest to Research Outcomes on Health Risks or Nutritional Assessment Studies of Genetically Modified Products" (2011) 36 Food Policy 197 <http://www.sciencedirect.com/science/article/pii/S0306919210001302>.

EU assessment of glyphosate (culminating in the 2002 approval) and the renewal assessment (culminating in the 2017 approval).[114]

The investigation found that the agencies were inappropriately close to industry and operated in a non-transparent way. For example, for the 2002 authorisation of glyphosate, the BBA (Federal Biological Research Centre for Agriculture and Forestry) was one of three agencies responsible for compiling the DAR on the industry dossier. Yet throughout the 1990s, the BBA collaborated with agrochemical companies, including BASF, Bayer and Hoechst, on joint projects that included the development of commercial products and applications for patents on products.[115] For the 2017 authorisation, BfR refused to reveal the identity of its five employees who contributed to the EFSA peer review, so any conflicts of interest remain hidden.[116] BfR has a policy of allowing pesticide industry employees on its committees.[117]

Such conflicts of interest are not unique to the agencies that are the focus of this article, or to the pesticide industry. They are endemic to many agencies and industries worldwide.[118]

BUND's investigation also found that experts played double roles in committees. For example, experts who assessed glyphosate at the German national level were later employed at the EU level to reassess the chemical. In addition, key people in the 2002 EU evaluation were still in place for the 2017 evaluation. Such double roles also affected an international WHO/Food and Agriculture Organization (FAO) body, the Joint Meeting on Pesticide Residues (JMPR). BfR employees have sat for years in the JMPR and have written assessments of glyphosate for it. Thus, the JMPR's 2016 favourable assessment of glyphosate[119] was not an independent confirmation of the BfR's assessment, but (in part at least) only a reaffirmation of certain BfR employees' own previous decisions in favour of glyphosate. While there is overlap in these committees, BfR and industry use the congruence of these authorities' assessments as "proof" that glyphosate is not carcinogenic.[120]

[114] BUND (Friends of the Earth Germany), "Note 'Mangelhaft': Das EU-Zulassungsverfahren Für Glyphosat. Warum Glyphosat Vom Markt Genommen Und Das Zulassungsverfahren Für Pestizide Komplett Reformiert Werden Muss" (Bund für Umwelt und Naturschutz Deutschland eV, 2015) <https://tinyurl.com/y4utxvsv>; H Burtscher-Schaden, P Clausing and C Robinson, "Glyphosate and Cancer: Buying Science", supra, note 49.

[115] BUND, "Note 'Mangelhaft'", supra, note 114, p 7.

[116] Corporate Europe Observatory, "EU Review of Weedkiller Glyphosate Adds Secrecy to Controversy" (Corporate Europe Observatory, 14 January 2017) <https://corporateeurope.org/food-and-agriculture/2016/01/eu-review-weedkiller-glyphosate-adds-secrecy-controversy> (last accessed 20 January 2017).

[117] Corporate Europe Observatory, "The Glyphosate Saga and 'Independent Scientific Advice' According to Germany, the UK & France" (Corporate Europe Observatory, 2 April 2015) <https://corporateeurope.org/en/food-and-agriculture/2015/04/glyphosate-saga-independent-scientific-advice-according-germany-uk> (last accessed 20 January 2017).

[118] JM Lima and S Galea, "Corporate Practices and Health: A Framework and Mechanisms" (2018) 14 Globalization and Health 21 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5815179/> (last accessed 9 October 2019).

[119] JMPR, "Pesticide Residues in Food 2016. Special Session of the Joint FAO/WHO Meeting on Pesticide Residues. FAO Plant Production and Protection Paper 227" (World Health Organization, Food and Agriculture Organization of the United Nations, 2016) <http://www.fao.org/3/a-i5693e.pdf>.

[120] BfR, "Does Glyphosate Cause Cancer? BfR Communication No 007/2015" (BfR, 2015) <https://tinyurl.com/y4dumnkl>.

Another conclusion of BUND's research was that BfR does not consistently implement its own independence policy.[121] For example, Roland Solecki, head of BfR's Safety of Pesticides Department that was responsible for the health assessment of glyphosate for the 2017 renewal, is a long-time affiliate of the industry-funded group, the International Life Sciences Institute (ILSI).[122] ILSI lobbies for industry-friendly regulations of pesticides and other products.[123] Solecki has worked closely with industry in other fora.[124] He was also a member of EFSA's Scientific Committee until 2018.[125]

The JMPR is also compromised by conflicts of interest with ILSI. Among the JMPR experts that assessed the toxicity of glyphosate residues in food were Alan Boobis and Angelo Moretto, who have worked closely with ILSI.[126]

b. EFSA

Over the years, EFSA has been subject to criticism over its independence policy, which was seen as inadequate in preventing the "revolving door effect".[127] A 2017 report found that nearly half (46%) of all experts on EFSA's scientific panels had a financial conflict of interest with agribusiness and food industries.[128]

In order to improve its framework for independence, in 2017, EFSA adopted a new Independence Policy,[129] which is elaborated on by the Decision on Competing Interest Management.[130] These policies strengthen the rules covering the full employment cycle of EFSA's employees, starting with conflict of interest checks

[121] BfR, "Questions and Answers on Ensuring the Independence of the Federal Institute for Risk Assessment (BfR)" (bfr.bund.de, 30 May 2012) <https://www.bfr.bund.de/en/questions_and_answers_on_ensuring_the_independence_of_the_federal_institute_for_risk_assessment__bfr_-187332.html> (last accessed 28 February 2020).

[122] H Burtscher-Schaden, P Clausing and C Robinson, "Glyphosate and Cancer: Buying Science", supra, note 49.

[123] S Steele et al, "Are Industry-Funded Charities Promoting 'Advocacy-Led Studies' or 'Evidence-Based Science'?: A Case Study of the International Life Sciences Institute" (2019) 15 Globalization and Health 36 <https://doi.org/10.1186/s12992-019-0478-6> (last accessed 13 August 2019).

[124] H Burtscher-Schaden, P Clausing and C Robinson, "Glyphosate and Cancer: Buying Science", supra, note 49.

[125] European Food Safety Authority (EFSA), "Scientific Committee" (efsa.europa.eu, 2019) <https://www.efsa.europa.eu/en/panels/scientific-committee>.

[126] A Neslen, "UN/WHO Panel in Conflict of Interest Row over Glyphosate Cancer Risk" The Guardian (17 May 2016) <https://www.theguardian.com/environment/2016/may/17/unwho-panel-in-conflict-of-interest-row-over-glyphosates-cancer-risk> (last accessed 22 January 2017).

[127] C Robinson et al, "Conflicts of Interest at the European Food Safety Authority Erode Public Confidence" (2013) 67 Journal of Epidemiology and Community Health 717 <http://jech.bmj.com/content/early/2013/03/07/jech-2012-202185.extract>; M Macovei, "Discharge Postponed for Three Agencies – Correct Management of Conflict of Interests on EP Agenda [Press Release]" (EPP Group in the European Parliament, 2012) <http://www.eppgroup.eu/press/showpr.asp?prcontroldoctypeid=1&prcontrolid=11176&prcontentid=18685&prcontentlg=en>; J de Vrieze, "European Food Safety Official Resigns Amidst Conflict of Interest Controversy" (ScienceInsider, 9 May 2012) <http://news.sciencemag.org/scienceinsider/2012/05/european-food-safety-official-re.html?ref=hp>.

[128] Corporate Europe Observatory, "Nearly Half the Experts from the European Food Safety Authority Have Financial Conflicts of Interest" (corporateeurope.org, 14 June 2017) <https://corporateeurope.org/en/pressreleases/2017/06/nearly-half-experts-european-food-safety-authority-have-financial-conflicts> (last accessed 13 August 2019).

[129] European Food Safety Authority (EFSA), "EFSA's Policy on Independence: How the European Food Safety Authority Assures the Impartiality of Professionals Contributing to Its Operations" (EFSA, 2017) <https://www.efsa.europa.eu/en/howwework/independentscience>.

[130] European Food Safety Authority (EFSA), "Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management" (EFSA, 2018) <https://www.efsa.europa.eu/en/corporate/pub/independencepolicy17>.

prior to employment with EFSA, preliminary clearance for "outside activities" during employment and a two-year "cooling-off" period for EFSA employees after termination of employment.[131]

The new rules also prescribe a two-year cooling-off period for experts whose previous professional involvement conflicts with the matters within the mandate of the relevant scientific committee, scientific panels and working groups.[132] However, a more stringent provision would have entailed a cooling-off period for any interest that falls within the agency's remit.[133]

Unfortunately, EFSA's independence policy does not go far enough to prevent conflicts of interest that may result from the provision of research funding. The current provision, heavily criticised by the European Parliament,[134] allows for the involvement of experts funded by the private sector, provided that this funding does not exceed 25% of the total research budget.[135] This provision is problematic because the 25% ceiling constitutes a relatively high proportion of research funding that would not have a deterrent effect.[136]

There were also issues regarding the independence of representatives of Member States. For example, a large majority – 80% – of Member State experts involved in the glyphosate assessment refused to disclose their names to the public, meaning that it is impossible to verify potential conflicts of interest.[137] To address this, in 2018, EFSA introduced new rules that require those experts to comply with EFSA's policy on independence.[138]

To resolve issues of conflicts of interest at regulatory agencies, strict conflict of interest policies must be established and enforced, with close attention paid to closing loopholes. All experts involved in pesticide risk assessments must publicly declare their interests, and their interests should be considered in relation to the regulatory body's remit as a whole. Experts working on any EU-level or Member State-level pesticide risk

[131] European Food Safety Authority (EFSA), "EFSA's Policy on Independence", supra, note 129, para 3.

[132] ibid, para 3.2. See also: European Parliament, "European Parliament Decision of 18 April 2018 on Discharge in Respect of the Implementation of the Budget of the European Food Safety Authority for the Financial Year 2016 (2017/2159(DEC))" (European Parliament, 2018) <http://www.europarl.europa.eu/doceo/document/TA-8-2018-0146_EN.html>; T Laaninen, "EU Legislation in Progress: Reconsidering the General Food Law" (European Union, 2019) <http://www.europarl.europa.eu/RegData/etudes/BRIE/2018/630315/EPRS_BRI(2018)630315_EN.pdf>.

[133] Pesticide Action Network Europe et al, "Ensuring a Higher Level of Protection from Pesticides in Europe", supra, note 11, 1.4 p 15.

[134] European Parliament, "European Parliament Decision of 18 April 2018 on Discharge in Respect of the Implementation of the Budget of the European Food Safety Authority for the Financial Year 2016 (2017/2159(DEC))" (European Parliament, 2018) <http://www.europarl.europa.eu/doceo/document/TA-8-2018-0146_EN.html>.

[135] European Food Safety Authority (EFSA), "EFSA's Policy on Independence", supra, note 129, para 3.4.

[136] Corporate Europe Observatory, "New EFSA Independence Policy Likely Rejects Most Parliament Demands" (22 June 2017) <https://corporateeurope.org/en/efsa/2017/06/new-efsa-independence-policy-likely-rejects-most-parliament-demands> (last accessed 21 August 2019).

[137] Corporate Europe Observatory, "Glyphosate: One Pesticide, Many Problems" (corporateeurope.org, 28 June 2016) <https://corporateeurope.org/en/food-and-agriculture/2016/06/glyphosate-one-pesticide-many-problems>.

[138] European Food Safety Authority (EFSA), "Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management", supra, note 130; European Food Safety Authority (EFSA), "Annual Report on the Implementation of EFSA's Policy on Independence: Reporting Period: 1 January–31 December 2018" (EFSA, 2018) <https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/EFSA_report_on_Independence_2018.pdf> p 4.

assessment should not be allowed to conceal their identity. In addition, experts should not be allowed to assess their own previous opinions by playing "double roles" in committees.

3. Conflicts of interest in risk assessment methodology design

Risk assessment methodologies are methods of – and criteria for – evaluating data, which form the basis of regulatory decision-making. In some cases they are written into law, but in other cases they are defined and explained in guidance documents and/or peer-reviewed papers in the scientific literature. Risk assessment methodologies related to pesticides are not written into the core pesticide Regulation 1107/2009, but they are highly influential in pesticide risk assessment. They determine which data the regulatory authorities will look at, how they will interpret them and what they will – legally – remain blind to.

According to a survey of pesticide risk assessment methodologies, 11 out of 12 methodologies studied were developed and/or promoted by industry, with the effect that industry is "writing its own rules". These methodologies are used to dismiss tumours observed in animal toxicity testing of pesticides, to approve carcinogenic pesticides in food, to classify polluting pesticide metabolites in groundwater as irrelevant, to allow 50% of insects to be killed in each spray application and to construct "safe" levels for harmful pesticides without any experimental evidence. The effect is to lower the protection offered by the pesticides Regulation via the implementation of technical and – in appearance only – politically neutral documents.[139]

Methodologies still in use today were developed by civil servants in close cooperation with industry – for example, the bee[140] and insect risk assessments.[141] After 2004, EFSA started drafting the risk assessment guidelines, but many experts on EFSA's panels were recruited from the same pool of experts that drafted previous methods, and many had conflicts of interests with industry (50% in general,[142] sometimes a large majority[143]).

Solutions to this problem include a review of risk assessment methodologies by a panel of high-level, actively publishing scientists who are independent from industry. The scientists should screen the methodologies for bias, invalid and outdated assumptions and violations of the precautionary principle, and revise them independently of the regulatory authorities.[144]

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[139] H Muilerman, "Industry Writing Its Own Rules" (Générations Futures and Pesticide Action Network Europe, 2018) <https://www.pan-europe.info/press-releases/2018/02/industry-writing-its-own-rules>.

[140] ibid, p 45.

[141] ibid, pp 25–26.

[142] Corporate Europe Observatory, "More than Half of Experts at the EU Food Safety Authority Have Conflicts of Interest" (Corporate Europe Observatory, 23 October 2013) <https://corporateeurope.org/pressreleases/2013/10/more-half-experts-eu-food-safety-authority-have-conflicts-interest> (last accessed 24 January 2017).

[143] H Muilerman, "A Toxic Mixture? Industry Bias Found in EFSA Working Group on Risk Assessment for Toxic Chemicals" (Pesticide Action Network Europe, 2011) <http://www.pan-europe.info/Resources/index.html>. EFSA's working group on the Threshold of Toxicological Concern (TTC) methodology contained the same people that designed the TTC at ILSI. The TTC allows "safe" levels to be set for toxic chemicals without any experimental evidence.

[144] Pesticide Action Network Europe et al, "Ensuring a Higher Level of Protection from Pesticides in Europe", supra, note 11, 1.5.

V. Conclusion

This paper has investigated the reasons for the regulatory failures that lead to unsafe pesticides being allowed onto the EU market. The EU's evaluations of the controversial pesticide glyphosate were frequently used as examples of the failures of the system. While glyphosate is just one pesticide active substance, its relevance is broader. The case of glyphosate has revealed that the shortcomings in the implementation of the EU's pesticide regulation are systemic rather than isolated errors or abuses. The large market value of this product (projected to reach US$9.91 billion by 2022[145]) was without doubt an incentive for exploiting the available weaknesses of the system, but the same causes may produce the same results for other pesticides.

Evidencing the applicability of findings concerning glyphosate to other pesticides is difficult due to the fact that pesticide authorisation dossiers and the studies contained therein have historically been kept secret as confidential business information, although this will change in 2021 (see Section III). In addition, the sheer quantity of data submitted in support of regulatory authorisations presents a significant challenge to any researcher wishing to verify it.

However, this paper extended glyphosate-related observations to specific cases of certain other pesticides (as specified in the text) in cases where the relevant DAR or RAR could be examined. For example, as shown in Section II.1, it was found that unpublished industry studies were given undue prominence over studies from the peer-reviewed literature in the risk assessment of several pesticides, resulting in an underestimation of their toxicity.[146] As another example, as shown in Section II.3, for 7 out of 10 pesticides examined, the assessment of their carcinogenicity potential was underrated or inadequately described.[147]

Equally, some of the shortcomings stem from failures to properly implement and enforce the law and relevant guidance documents. A good illustration is the widespread scientific misconduct identified in this paper, such as the misuse of HCD and the use of invalid criteria to dismiss findings of adverse effects in animal toxicology studies. Guidance documents should be revised to reflect best scientific practice and their standards should be enforced.

It is not always possible to determine the reasons for scientific misconduct – whether a lack of expertise or resources, or conflicts of interest with industry. However, misconduct could be reduced or eliminated by the proper implementation of existing law and guidance, such as following OECD guidelines on the proper use of HCD and using systematic review methods to survey the full range of scientific research on any given pesticide. Transparency is essential to ensuring the accountability of institutions and stakeholders in adhering to good scientific practices and meeting their obligations

[145] MarketsandMarkets, "Glyphosate Market – Global Forecast to 2022" (marketsandmarkets.com, 2020) <https://www.marketsandmarkets.com/Market-Reports/glyphosate-market-8522593.html> (last accessed 28 February 2020).

[146] Pesticide Action Network Europe and Générations Futures, "Missed and Dismissed", supra, note 25.

[147] P Clausing, "Chronically Underrated? A Review of the European Carcinogenic Hazard Assessment of 10 Pesticides" (Pesticide Action Network Germany and Health and Environment Alliance, 2019) <https://www.env-health.org/wp-content/uploads/2019/10/October-2019-Chronically-Underrated-web.pdf>.

under the law. The reform to the General Food Law has the potential to facilitate improvements in these aspects of the regulatory process.

In addition, the most rigorous and up-to-date available scientific methodologies must be adopted. For example, systematic reviews are increasingly used by regulators in various fields of public health, and there is no reason why pesticide assessments should not similarly benefit from the adoption of such methods. Moreover, strict conflict of interest policies should be enforced.

Most of the changes needed are of an administrative or scientific nature and do not need to wait for an amendment of the hard law framework. These include: enforcing compliance with existing guidance; the review and amendment of out-of-date or biased guidance documents and methodologies; and the integration of the most up-to-date scientific practices by the risk assessors. As such, they are mostly in the hands of the Commission, EFSA and the national authorities of the Member States. However, in some cases, revision of the legislation is needed.

Many of the problems identified in this paper have long been recognised by regulatory authorities. BfR, an agency at the centre of many of the problems, conceded in 2011 that reform should be discussed at the highest level of the EU administration.[148] BfR stated this view in its response to criticisms of shortcomings in the 2002 EU evaluation of glyphosate.[149] BfR concluded that such general discussions "should be initiated by the Commission" before the start of the re-evaluation of glyphosate that culminated in the 2017 renewed approval.[150] Such discussions never occurred, to the best of our knowledge, and the problems persist.

These long-overdue discussions should begin now. If the current situation is allowed to persist, the EU regulatory framework will not achieve the level of human and animal health protection promised by the EU's pesticide regulation.

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[148] BfR, "Neue Daten Zu Gesundheitlichen Aspekten von Glyphosat? Eine Aktuelle, Vor-Läufige Facheinschätzung Des BfR (in Englisch) [New Data on Health Aspects of Glyphosate? A Current, Preliminary Assessment by BfR]. Stellungnahme Nr. 035/2011" (BfR, 2011) <http://bit.ly/2lZiXFq>.

[149] M Antoniou et al, "Roundup and Birth Defects: Is the Public Being Kept in the Dark?" (Earth Open Source, 2011) <http://earthopensource.org/earth-open-source-reports/roundup-and-birth-defects-is-the-public-being-kept-in-the-dark/>.

[150] BfR, "Neue Daten Zu Gesundheitlichen Aspekten von Glyphosat? Eine Aktuelle, Vor-Läufige Facheinschätzung Des BfR (in Englisch) [New Data on Health Aspects of Glyphosate? A Current, Preliminary Assessment by BfR]", supra, note 148.

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