Carcinogenicity of glyphosate: why is New Zealand's EPA lost in the weeds?

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ABSTRACT

In 2015, the International Agency for Research on Cancer (IARC) concluded that glyphosate is "probably carcinogenic to humans". The New Zealand Environmental Protection Authority (NZEPA) rejected this and commissioned a new report, concluding that glyphosate was unlikely to be genotoxic or carcinogenic to humans. The NZEPA has argued that the difference arose because IARC is a "hazard-identification authority", whereas NZEPA is a "regulatory body that needs to cast the net more widely". We conclude that the NZEPA process for evaluating the carcinogenicity of glyphosate was flawed and the *post hoc* justification invalid: there is no mention of risk assessment or "net-benefit approach" in the NZEPA report; and there is no discussion of current New Zealand glyphosate exposures. Further, the NZEPA report quotes heavily from the European Food Safety Authority (EFSA) report, which is itself markedly flawed, and like the NZEPA report, relies heavily on industry-funded and industry-manipulated reviews. Given the scientific flaws in both reports we urge that: the NZEPA report be withdrawn; the NZEPA respond to the concerns raised and for a reassessment to be conducted; and clearer process and better understanding of science be used to inform any future review of hazardous substances in New Zealand.

Glyphosate, an organophosphorus compound, is the most widely used herbicide in the world.[1] in New Zealand, glyphosate is found in approximately 90 products, of which the best known is Monsanto's 'Roundup'.[1,2] In addition to extensive use in farming, glyphosate is commonly used in gardens, streets and parks.[3]

California[4] and a number of countries, including France,[5] The Netherlands,[6] Norway, Denmark, Sweden, Sri Lanka, El Salvador, Brazil and India[7] have banned or restricted the use of glyphosate because of potential links with health problems, including cancer. A renewal of the glyphosate licence has been hotly contested in the EU,[8] resulting in a five-year renewal instead of the full 15-year renewal.[9] In New Zealand, there are no bans, although some local boards (eg, Great Barrier, Kaipātaki) have opted to use alternative weed-control methods. The New Zealand Environmental Protection Authority (NZEPA) recently concluded that glyphosate was "unlikely to be genotoxic and carcinogenic",[10] despite the International Agency for Research on Cancer's (IARC) classification of glyphosate as a "probable human carcinogen".[11] Here, we argue that the NZEPA process for evaluating the carcinogenicity of glyphosate is flawed and discuss the broader implications for future risk-assessment of other chemicals.

The IARC and NZEPA evaluations

In 2015, IARC (cancer agency of WHO) invited 17 scientists with relevant expertise from 11 countries (including one from New Zealand; A'tM) to assess the carcinogenicity of five organophosphate biocides including glyphosate.[11] The IARC Working Group concluded that, for glyphosate, there was "limited evidence" of carcinogenicity in humans on the basis of limited epidemiological evidence for a positive association with non-Hodgkin lymphoma (NHL) and

"sufficient evidence" for the carcinogenicity of glyphosate in experimental animals. The working group also considered potential mechanisms for induction of cancers and, based on *in vitro* studies and studies in experimental animals,[11] concluded that there is strong evidence that glyphosate is genotoxic and can act to induce oxidative stress. Taking the human, animal and mechanistic data together, the Working Group concluded that glyphosate is "probably carcinogenic to humans".

IARC is the world-leading authority undertaking assessments to establish whether agents have the capacity to cause cancer. A standard grading system, with well-documented and detailed criteria, is used to classify agents as: 1=carcinogenic to humans; 2A=probably carcinogenic; 2B=possibly carcinogenic; 3=not classifiable; and 4=probably not carcinogenic. Since 1971, approximately 1,000 agents have been evaluated, of which 120 were classified as Group 1 and 81 as Group 2A. The scientists selected to carry out these assessments are chosen for their expertise and a research history relevant to the agent being assessed; there are explicit processes to manage possible conflicts of interest among participants. The rules of evidence are clear: assessments involve careful consideration of the quality and strength of the evidence, drawing on all available peer-reviewed studies, including data on human exposure, human epidemiological studies, animal studies, toxicokinetics and carcinogenic mechanisms.[12] IARC assessments also take into account publicly available government documents that provide data on the circumstances and extent of human exposure. To minimise bias and conflicts of interest, unpublished data and reports that have not undergone independent peer review or are not publicly available (eg, unpublished industry-funded studies) are not taken into account.[12] Thus, IARC's Monographs on the Evaluation of Carcinogenic Risks to Humans provide, through independent, transparent and robust processes, the critical first step in the societal decision-making process to identify and then control carcinogenic hazards.[12]

It was therefore surprising, as others noted,[13] that the NZEPA decided to reject the expert assessment conducted by IARC and commissioned a new report.[10] The stated purpose of this report, written by a single author with input from one other scientist, neither with epidemiological backgrounds, and limited peer review by the NZEPA and the Ministry for Primary Industries, was the same as the IARC assessment: to review the evidence for carcinogenicity in humans. However, the NZEPA concluded that: "*based on a weight of evidence approach, taking into account the quality and reliability of the available data, glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification under HSNO as a carcinogen or mutagen*".[10] This was despite the Ministry of Health advising that it would be "*reluctant to criticise any [IARC] classification based on the review of one individual*".[13]

Why do IARC and NZEPA conclusions differ?

Hazard versus risk assessment

In response to questions raised by the Green Party's report[13] and subsequent media enquiries, the NZEPA chief scientist (Dr Rowarth) asserted that IARC is a hazard-identification authority, whereas NZEPA is a regulatory body that needs to cast the net more widely.[14] Dr Rowarth argued that "*We need to consider everything otherwise it is not the net benefit approach*" and "*we go to all sources because there is an economic implication within the use of glyphosate*", and subsequently also noted that "*We agree with them [IARC]—at high exposures and dosages, cancer could occur but we don't have these high exposures and dosages in New Zealand*".[15] There are several problems with this response.

Firstly, in the NZEPA report, there is no mention of a risk assessment. Even if the NZEPA report was, as claimed, based on a risk assessment, this would not change whether glyphosate and derived herbicides are carcinogenic. Although lack of exposure may affect risk assessment (and subsequent policy), this does not determine whether the agent has carcinogenic properties. As an analogy, if someone neither smokes nor is exposed to asbestos this does not mean that tobacco and asbestos are not carcinogenic. Both are recognised human carcinogens: most lung cancer and virtually all mesothelioma cases are attributable to these exposures,[16] even though most people are unexposed.

Secondly, there is no mention of a "net-benefit approach". In fact, the NZEPA report purported to assess the evidence for human carcinogenicity, exactly like IARC. Thus, the reasons provided by the NZEPA appear to be a *post hoc* justification for their decision to reject IARC's assessment.

Thirdly, the report does not include any data or discussion of current New Zealand exposures to glyphosate. Even if a risk assessment had been conducted (the NZEPA report itself is *prima facie* evidence that it was not) and current exposures were taken into account, on what scientific evidence would such a risk assessment be based? To our knowledge, no New Zealand exposure data are available; further, current knowledge on the human carcinogenicity of glyphosate does not allow conclusions on the existence or nature of safe levels.

So how was a benefit analysis conducted in the absence of exposure/dose data and detailed knowledge of exposure/dose-response associations? Was this "analysis" based on Monsanto's claim that "when used according to label instructions" glyphosate is safe,[17] as implied by Dr Rowarth? Finally, contradicting earlier statements, it appears that the NZEPA's chief scientist now agrees that glyphosate is a probable carcinogen, but "*only at high exposure and dosages*".[15] This suggests that the NZEPA has partially changed its views since the publication of their report. Although this would be a minor step in the right direction, it is still highly problematic because it is unclear what "high exposures" means and, as noted above, there are no data on safe levels.

Weighting of evidence and the use of unpublished industry-funded research

Other critical flaws in the NZEPA report relate to the interpretation of the science and the use of unpublished industry-funded and, in some cases, industry-manipulated (see below) research. These criticisms also apply to a 2016 European Food Safety Authority (EFSA) report.[18] As the EFSA report is heavily quoted in the NZEPA report, we will discuss criticisms of both reports and summarise the key issues identified in an extensive review of the shortcomings in the EFSA report.[19]

Firstly, the NZEPA report concluded that the epidemiological support for IARC's conclusion of "*limited evidence*" of carcinogenicity in humans was "*not convincing*". The EFSA report also concluded that human data were "*inconclusive for a causal or clear associative relationship*" with cancer and classified the epidemiological evidence for NHL as "*very limited*".[18] The IARC conclusion of "*limited evidence*" for NHL was based largely on case-control studies, which (provided they are of high quality) are ideally suited to assess associations with relatively rare conditions such as NHL.[19] Only one cohort study was available and this found no statistically significant association and no apparent exposure-response association. Although cohort studies have substantial strengths, this cohort study included only 92 NHL cases[20] (cf. 650 cases in a pooled case-control analysis[21]) and follow-up was 6.7 years, unlikely to be sufficient to account for NHL latency. Since the IARC, NZEPA and EFSA reports were published, an update of the cohort study has become available[22] involving a further 11 years of follow-up resulting in a total of 575 NHL cases. This study found no statistically significant associations between glyphosate and any solid tumours or lymphoid malignancies overall, including NHL. Some evidence of increased risk of acute myeloid leukaemia was found, particularly for workers in the highest exposure quartile. NZEPA and EFSA dismissed all the relevant case-control studies on the grounds they were not reliable or were of low quality. Consistent with others,[19] we consider this a mistake. We agree with IARC that the case-control studies were of high quality and note that, based on two meta-analyses, a consistent positive association was found between glyphosate and NHL.

Secondly, the NZEPA (and EFSA) report concluded that, based on animal studies, "*the overall weight of evidence does not indicate that glyphosate is carcinogenic*". This is in sharp contrast to IARC's conclusion that there was "sufficient evidence" for the carcinogenicity of glyphosate in experimental animals. The IARC conclusion was based on: 1) a statistically significant trend for renal tumours in male CD-1 mice; 2) a statistically significant trend for heman-

giosarcoma in male CD-1 mice; and 3) a statistically significant higher incidence of pancreatic islet cell adenomas in two studies in male Spraque-Dawley rats, with one of these studies also showing an increase in thyroid adenomas in female rats and liver adenomas in male rats. NZEPA and EFSA dismissed the IARC finding because: 1) comparisons between individual exposure groups and the control group (using pair-wise tests) were not statistically significant; 2) there was a lack of consistency in multiple animal studies (including several unpublished industry-provided studies not evaluated by IARC); 3) slightly increased risks were shown only at dose levels at or above the limit dose/maximum tolerated dose; and 4) no preneoplastic lesions were observed and effects were within historical control ranges.

Portier et al provided a detailed rebuttal,[19] arguing that trend analyses are more powerful than paired analyses, particularly for rare tumours where data are sparse, as was the case here. They also evaluated the additional unpublished studies (where possible) and found more consistent (rather than inconsistent) evidence of trends for renal tumours and hemangiosarcoma, as well as malignant lymphoma. They also argued that, although doses at or above maximum tolerated dose might cause cellular disruption leading to cancer, no evidence of this was reported in any study. Portier noted that international guidelines (including EC regulations cited in the EFSA report) favour the use of concurrent controls, instead of historic controls on which the EFSA report relied.

Thirdly, the NZEPA and EFSA reports dismissed IARC's conclusion that there is strong evidence that glyphosate is genotoxic and can act to induce oxidative stress. For its genotoxicity conclusions, NZEPA relied heavily on two industry-funded reviews[23,24] which, as discussed below, are likely to be biased. It also relied strongly on the EFSA report, which has previously been criticised for making extensive use of unpublished industry-provided data.[19] In addition, as noted by Portier,[19] the EFSA evaluation,[18] unlike IARC's,[11] excluded evidence of chromosomal damage in exposed humans or human cells. The reasons for dismissing IARC's conclusions on oxidative stress include IARC's use of studies on glyphosate formulations rather than pure glyphosate. As indicated by Portier, the IARC review included evidence on glyphosate formulations, glyphosate, and its metabolites. Finally, in both the NZEPA and EFSA reports, studies conducted according to good laboratory practice (GLP) guidelines received more weight than peer-reviewed studies. As argued by Portier, the weight of evidence should be based on study quality (not on compliance with guidelines) and GLP does not guarantee validity.

Overall, and consistent with others,[13,19] we do not consider the criticisms and associated alternative conclusions by NZEPA and EFSA regarding the carcinogenicity of glyphosate compelling and, in addition, have concerns about the transparency of the NZEPA process.

The need for good science and transparency

To maintain public confidence, it is critical not only that any hazard or risk evaluation be based on the best possible evidence, but also that it is done in an independent and transparent way that minimises conflicts of interest.[12] Unlike the IARC report, both the EFSA and NZEPA reports rely heavily on non-peer reviewed industry-funded studies that are not publicly available. This makes it impossible to assess the validity of the evidence presented and the conclusions drawn. This is not best practice, probably results in bias,[25] risks misleading the public and contributes to the different conclusions of IARC vs EFSA and NZEPA evaluations. The EFSA report provides no information on the authors/contributors and conflicts of interests are not disclosed. This is compounded by recent revelations that employees of Monsanto have ghost-written papers published in the scientific literature that claimed to be written by "independent" scientists and downplayed the human health impacts of glyphosate.[26] E-mails obtained through a court case against Monsanto[26–28] demonstrate the degree to which Monsanto was able to manipulate the literature through inducing "independent" scientists to publish articles[29] to counter IARC's conclusions and attack IARC's processes. These e-mails show that Monsanto scientists had major involvement in reviewing and editing drafts as well as in making decisions about

authorships, despite this not being noted in the declaration of interests. These are well-known tactics designed to undermine the evaluation of the link between glyphosate and NHL, and previously used by the tobacco and sugar industries.[30] It has recently been revealed that the EFSA report includes analyses copied and pasted from a Monsanto study; the Guardian newspaper reported that "dozens of pages of the paper" are identical to passages from material submitted on behalf of the Glyphosate Task Force, an industry body led by Monsanto.[31] There is a great deal at stake commercially, as agribusiness is a multi-billion dollar enterprise. It is more important than ever, then, that assessment of chemicals such as glyphosate are carried out transparently by independent experts, with conflicts of interest minimised, declared and made publicly available. Only then can the public have confidence in conclusions.

Despite the fact that Monsanto's attempts to manipulate the scientific literature are clear and a genuine concern for risk-assessment and regulatory processes worldwide, the NZEPA's chief scientist has implied that those who question the NZEPA and EFSA are lobbyists running a campaign against the chemical industry.[32] This does not describe the scientists who evaluated glyphosate as part of the IARC process or other scientists who have spoken out against the conclusions of the EFSA report. In an extraordinary attempt to discredit the IARC Working Group, a recent Reuter's article[33] suggested that the chair had withheld critical unpublished information relevant to the assessment of glyphosate and claimed that, if this information had been available, the Working Group's conclusions would have been different.[33] The Director of IARC responded by pointing out that, as per their strict guidelines, unpublished data are not permitted to be included in their evaluation. It is therefore noteworthy that the NZEPA's chief scientist chose to cite the Reuter's article in a recent publication,[34] hinting that the IARC evaluation was invalid. This approach is surprising, given that the standards of scientific rigour and transparency upheld by the IARC evaluations, are also, according to NZEPA's chief scientist, the standards to which NZEPA aspires.

The NZEPA's chief scientist recently commented that the NZEPA's role *"is to uphold and explain standards that can be defended rigorously, while explaining the reason for decisions that have been made in a manner that is appropriate for and understandable by the audience"*.[35] She has also appropriately highlighted the need for good science to underpin policy decisions and noted the critical role of peer review: "*it is still the best way we have in getting rigour into science*", particularly in a 'post-truth' world.[36] We agree with the need for good science and the critical role of peer review and urge the NZEPA to put these principles in place. Otherwise, the decisions taken by the NZEPA may be challenged on the grounds that they rely on work that is scientifically flawed, borrows heavily from unpublished non-peer reviewed studies funded by industry and follows processes that allow conflicts of interest.

Where to from here?

Given the scientific flaws in the NZEPA (and EFSA) report and the confused nature of the justifications made by the NZEPA's chief scientist, we ask that the NZEPA report be withdrawn and for the NZEPA to accept IARC's conclusion that glyphosate is a probable carcinogen. We note that this does not necessarily mean that glyphosate should be banned but, at the least, close review of policies to minimise exposure to glyphosate-based herbicides seems essential.

The issues discussed in this viewpoint have broader implications for future evaluations. In our view, these are the matters that warrant closer attention and, perhaps, remedial action: 1) lack of transparency about the relations NZEPA has with industry and management of conflicts of interest; 2) the implications of the Ministry of Health's lack of confidence in NZEPA's processes in relation to glyphosate; 3) the lack of clarity in NZEPA communications about the steps taken in the assessment of hazardous agents (which typically proceed from hazard identification to exposure assessment to risk characterization; these are not bundled together); and 4) the inappropriate application of "net benefit" thinking to the front end of risk management. Decisions on the best use of a chemical such as glyphosate must include a consideration of the benefits

derived from its application (as well as the availability of alternatives) but such considerations are not relevant to hazard assessment. We urge the NZEPA to respond to the concerns raised and recommend a reassessment of the hazard classification for glyphosate under the Hazardous Substances and New Organisms Act 1996, otherwise there is a risk of undermining public confidence. Worse, New Zealanders may be exposed to unacceptable and avoidable risks.

Competing interests:
JD is a member of the steering committee of the International Agricultural Cohort Consortium. International Agency for Research on Cancer (IARC), 2007–present; A'tM was a member of the IARC working group on the evaluation of carcinogenic risk to humans, Volume 112: evaluation of five organophosphate insecticides and herbicides (which included glyphosate); DMcL was a member of the IARC working group on the evaluation of carcinogenic risk to humans, Volume 117: evaluation of the carcinogenicity of pentachlorophenol and some related compounds; AW was on the panel that reviewed the Environment and Radiation Section of IARC in 2017; NP has participated in several IARC Monograph Working Groups, and was Visiting Scientist at IARC in 1993. JDP was the US Representative, Science Council, IARC, 2001–2006; Vice-Chair, Science Council, IARC, 2004; and Chair, Science Council, IARC, 2005–2006. He was awarded the IARC Medal of Honour in 2012.

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