Glyphosate 2020 – No public exposures

[4] Regulatory history of glyphosate authorisations & assessments & international bans.

Regulatory Bans

Europe: In 2017 glyphosate use was extended for five years. The implementation regulation released by the European Commission amended conditions of use to:

1. Remove co-ingredient POE-tallowamine from European glyphosate-based products.
2. 'Ensure that the use of plant protection products containing glyphosate is minimised or prohibited in areas such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds and in the close vicinity of healthcare facilities.'
3. Cease pre-harvest practices using glyphosate to control the point of harvest or optimise threshing as it is not good agricultural practice nor compliant with regulation (E.C., 2016).

Austria: Parliament voted to ban glyphosate as a precautionary measure from 2020 (this is currently blocked due to a technicality).

Belgium: Personal use banned. Banned in Brussels

Bermuda: Private and commercial use banned, although remains in use for roadside use (and an integrated monitoring regime accompanies this)

Czech Republic: Banned on food crops as a drying/desiccation agent.

Denmark: Banned on food crops as a drying/desiccation agent.

Germany: Banned from end 2023

Gulf Cooperation Council: The GCC of Saudi Arabia, Kuwait, the United Arab Emirates, Qatar, Bahrain, and Oman banned glyphosate after IARC decision.

France: Marketing license for 36 products withdrawn by health and environment agency ANSES from 2021. Applications for new products have been rejected.

India: Banned in five states: Kerala, Punjab, Maharashtra, Telangana and Andhra Pradesh.

Italy: Banned on food crops as a drying/desiccation agent. Banned in public areas.

Luxembourg: Will be banned from 2021.

Malawi: Import permits for glyphosate-based herbicides suspended following second U.S. court decision.

Malta: Banned in public areas.

Netherlands: Non-commercial use banned

Sweden: Products containing glyphosate and POE-tallowamine withdrawn.

Vietnam: Blanket ban.

Countries towns and regions have instituted protective restrictions despite central government inaction include: Argentina, Canada, Spain, Switzerland and the United Kingdom.

International Regulatory Positions

The IARC established that glyphosate is a hazard, and that exposures probably cause cancer (IARC Working Group, 2015). Regulatory agencies across the world have conducted separate assessments and diverged from the IARC to conclude glyphosate is not probably carcinogenic to humans.

- European Food Safety Authority (EFSA, 2015)
- US Environmental Protection Agency (US EPA, 2016; US EPA, 2019)
- World Health Organisation and Food and Agriculture Association Joint Meeting on Pesticides Residues (JMPR) (FAO-WHO, 2016)
- Health Canada (Health Canada, 2017)

All agencies have been criticised for depending excessively on industry data, downplaying genotoxic mechanisms, failing to consider formulation toxicity,

real world exposures and ignoring the published scientific literature (Benbrook, 2019; Portier, et al., 2016; Ecojustice, 2018).

A recent letter has drawn attention to the US EPA's failure to analyse changing use patterns that might draw attention to the ubiquity of GBHs. The paper also criticised US EPA's dismissal of data - the failure of the agency to respond to public submissions and the failure to utilise a wide range of toxicity studies and peer reviewed literature (CfFS, 2019).

Monsanto appears to have been involved in engaging scientists who supplied data to Health Canada, which has also been criticised for relying on industry studies (Ecojustice, 2018). The use of third-party academics as corporate defence has been criticised (McHenry, 2018). A coalition of Canadian groups have written to the Minister of Health, detailing the deficiencies of Health Canada's glyphosate assessment, and demanding a review.

Unlike the IARC, all regulatory agencies exclusively depended on industry supplied and selected literature to arrive at their conclusions. Europe and the US EPA were criticised for failing to comply with its own rules and guidance documents (Clausing, Robinson, & Burtscher-Schaden, 2018). In 2019 the US EPA released another reaffirmation (OCSPP, 2019). This was criticised for failing to failing to follow agency guidelines and for overdependence on private industry data (CBD, 2019).

The Approximation Game

Glyphosate, bacon, coffee and hot drinks.

While regulators continue to downplay the IARC conclusion, regulators and industry front groups use other substances classified by the IARC as 2A – (a probably carcinogen), as equivalency of glyphosates level of hazard. Hot drinks, acrylamide (the burnt proteins from barbeque meats or chips); bacon, coffee and talcum powder are used to as an analogue of 'risk'.

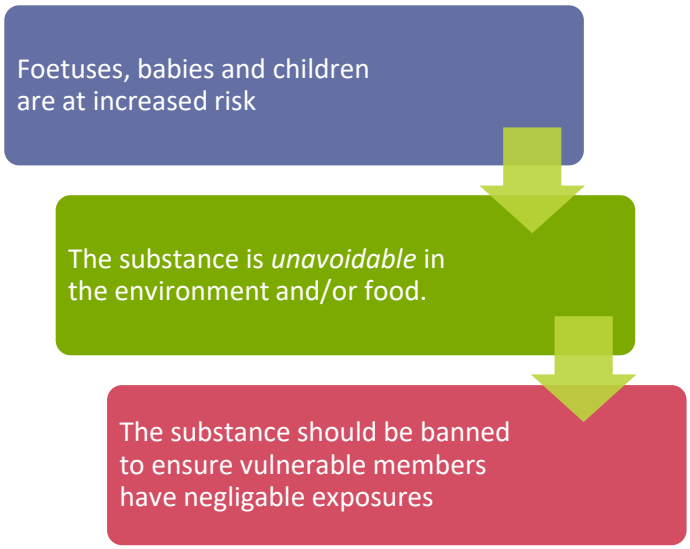
Does the thought that glyphosate sits at a similar hazard level as hot drinks suggest that exposures to glyphosate are inherently OK? Is the implication that coffee, hot drinks and bacon are not banned – so neither should glyphosate and its formulations be banned?

There are at least two problems that aren't being dealt with here, first is the capacity to *avoid* the hazard. Families can avoid eating bacon regularly, and coffee is rarely drunk with every meal. The second is the level of risk, at what *level* does exposure cause cancer? This latter question is not addressed by the IARC, who only looked at hazard, the probability that glyphosate causes cancer.

At what *level* does glyphosate cause cancer?

The study that New Zealand acceptable daily intake (ADI) of a 0-1mg per kilogram bodyweight is derived from a 1993 unpublished Monsanto study *Atkinson et al. 1993b* (FAO-WHO, 2006, p. 129) of the active ingredient glyphosate.

Would 1mg/kg per bodyweight of coffee or exposure to bacon over a lifetime probably cause cancer? This is unlikely.



1. Parental responsibility – *avoiding* coffee or bacon.

In response to the first point around hazard, Soil and Health have noted, 'parents may see the common-sense and logic of the IARCs hazard classification. The IARC have drawn attention to risk around coffee, bacon and talcum powder, which, like glyphosate and its toxic formulations, probably cause cancer. Many parents have stopped putting talcum powder on their babies. Not many parents feed their young children

bacon or pour them a coffee. Frequent exposures are unsafe. Glyphosate-based herbicides are similarly risky. This is not misleading.'

However, parents cannot monitor nor manage how much glyphosate (including the heavy metals and petroleum products in the formulation) their children consume in supermarket foods, nor prevent exposure in parks or on the way to school. These small constant exposures are referred to as 'chronic' exposures – over a day constitutes an acceptable daily intake (ADI).' New Zealand doesn't include glyphosate in dietary studies, nor does it scientifically

monitor glyphosate levels after it spraying of roadsides or in parks. There is no knowledge of daily glyphosate exposures in Aotearoa.

The exposures are by default compulsory – not elective, they are in foods that are commonly sprayed with glyphosate: cereals, soy products, corn-based ingredients, canola oil and so on; and the exposures are from parks, pathways and roadsides.

Europe

The European *Conclusion on the Peer Review of the pesticide risk assessment of the active substance glyphosate* diverged significantly from the IARC finding. Ninety-four scientists responded swiftly with a comprehensive criticism (Portier, et al., 2016). The *IARC category of 2A*, probably carcinogenic corresponds to *European category 1B*, presumed human carcinogen. If European regulators automatically accepted the IARC finding, EU legislation would then require population exposures of glyphosate would have to be negligible. Instead, the Europe assessment concluded that there was not sufficient evidence. This ensured GBHs could remain on the EU market. Scientists consider that a following August 2015 Addendum (EFSA, 2013) to the European report, demonstrated sufficient evidence of carcinogenicity that, if European decision-makers were following European regulatory rules and guidelines, glyphosate would have been categorised as a presumed human carcinogen (category 1B) (Clausing, Robinson, & Burtscher-Schaden, 2018).

European Regulation(EC) 1107/2009 is unique as it applies a hazard-based approach to particular toxic effects. The product is a hazard and there is no level at which exposures are deemed safe. If a pesticide or pesticides ingredient is a known or presumed carcinogen, mutagen and/or a reproductive toxicant, it can only be approved if population exposures are negligible (E.C., 2009).

The notion that there is a specific level below which an individual can safely be exposed to a mutagen, carcinogen, reproductive toxicant or endocrine disruptor - from conception onwards - is problematic (Demeneix & Slama, 2019). Such notions cannot take into account individual vulnerabilities and cumulative effects.

European regulation additionally requires that the Precautionary Principle is adopted in cases of scientific uncertainty, and that published scientific literature must be considered in addition to industry data.

New Zealand

In August 2016 the New Zealand Environmental Protection Authority (NZEPA) conducted a carcinogenicity review (Temple, 2016), by all appearances to refute the IARC finding that glyphosate and its formulations were a probable carcinogen (IARC Working Group, 2015). This was heavily criticised by New Zealand scientists who asked that the review be dropped due to numerous flaws, and that the IARC decision be accepted. (Douwes, et al., 2018).

The scientists stated that the NZEPA review depended heavily on the criticised European review (Douwes, et al., 2018; Portier, et al., 2016). New Zealand scientists have since spoken publicly to ask that the NZEPA acknowledge the IARC decision and change the chemical classification to probably carcinogenic (Mead, 2019) and calling the NZEPA decision to ignore the IARC finding, which is the NZEPA's own authority on cancer - 'bizarre' (TVNZ, 2019).

Another paper had earlier been released by the Green Party which criticised the review (Bruning & Browning, 2017).

The NZEPA has not responded to these criticisms, nor to the call that the review be retracted. Instead of responding to New Zealand scientists, the NZEPA

elects to defer to decisions made by the United States Environmental Protection Agency, and decisions made by the Joint Meeting on Pesticides Residues – a working group representing both the World Health Organisation and the Food and Agriculture Association. These are much weaker regulatory regimes than the European Commission (Donley, 2019). NZEPA rarely refer to European decisions, and as a result, many chemicals banned in Europe found in New Zealand rivers (Hageman, et al., 2019; Soil and Health & PSGR, 2019).

NZEPA selects regulators that it is culturally in alignment with. There has been no discussion by the NZEPA of the European decision to remove POEA-tallowamine from formulations, restrict pre-harvest applications, and ban in public places

The study that New Zealand uses to derive our safe exposure level, or acceptable daily intake (ADI), of 0-1mg per kilogram bodyweight, is derived from a 1993 unpublished Monsanto study Atkinson et al. 1993b established by the JMPR (FAO-WHO, 2006, p. 129). This was followed by another review in 2016, which again confirmed the 0-1mg/kg level.

This assessment that the NZEPA use for authority come from the Joint Meeting on Pesticides Residues – a working group representing both the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues who work out of Geneva, Switzerland. This group are not democratically accountable, nor do they rely on data that is publicly available, nor consider full formulation toxicity, which the IARC do.

The IARC headquarters are based in Lyon, France.

In the time between JMPR's 2006 and 2016 evaluation, many, many studies were published in the scientific literature demonstrating harm at much lower levels. Since this time many more studies show that at the level glyphosate is considered safe by regulators, it may not be.

What New Zealand can do

It is not unreasonable to request that New Zealand follows best practice. As other countries have shown, there is no need to undertake a risk assessment to ban use of a chemical, the decision can simply be taken to limit glyphosate use:

- Ban glyphosate on food and animal feed crops
- Ban in all public areas
- Severely restrict on roadsides
- Ban use in and along drains

In order for bans to be effective and practical other recommendations have been made to support these changes, encourage transparency and shift to chemical free vegetation control:

- Require StatsNZ document agrichemical import and production in New Zealand.
- Publish financial costs of parks and roadside vegetation management.
- Release Levels of Service standards be for public consultation and debate.
- Require public disclosure of all formulation ingredients on labels
- Publish details of local and regional government contracts for parks and roadside services.

Regulations and policy can be updated to reflect best practice and current scientific understanding:

- Ensure an overarching approach to the precautionary principle that places environmental and human health at the forefront of consideration.
- Require full formulation data 'ingredients' to be published on labels
- Require full formulation studies to be included in authorisation and assessment.
- Require independently published literature to be included in authorisation and assessment.
- Adopt a hazard-based approach to carcinogenicity, mutagenicity, reproductive toxicity and endocrine disruptions (as Europe does).
- Regulate chemicals by class (eg. total toxicity of triazines exposure must be considered).

These studies have been dismissed or not included because of political conventions that prevent the scientific literature being reviewed and because political conventions dictate that regulators obtain data directly from the chemical industry (rather than requiring a literature review of the published science).

New Zealand: Precautionary Principle

'Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'

Regions that adopt a stronger interpretation of the Precautionary Principle may act more swiftly to protect human and environmental health. The PP has been criticised for being ill-defined and undermining legal certainty, however it remains that the *'clearest benefits of the principle is its overt recognition of uncertainties and the negotiated nature of decision-making'* (EC, 2017).

Despite precaution being included in New Zealand hazardous substances legislation, the principle has historically only been applied weakly (Iorns, 2018; Scott, 2016). Several factors contribute to a weak application in decision-making relating to toxic chemicals. The regulatory methodology prescribes that caution must be considered as *another variable* along with other factors such as economic benefits. Catherine Iorns suggests the Precautionary Principle should instead be applied at a meta-level (Iorns, 2018, p. 52). Applying the Precautionary Principle (PP) as an overarching principle would ensure the PP could not be considered, then dismissed, (along with economic, cultural and other considerations) – the requirement would be to actually favour caution.

Without an obligation to favour caution, where there is doubt, favour shifts to benefit doubt in regulation.

The result is the potential for authorities, to incorrectly conclude there is no effect when one actually exists (a type II error). Type II errors result in regulators enabling harm to continue. Science tends to tilt towards committing Type II errors because of historic conventions – as a result it is preferable to incorrectly claim there is no effect than to incorrectly claim there is an effect (Scott, 2016, p. 68).

The likely result is that with continued production of doubt, regulators will continue to lack authoritative guiding principles to prevent diffuse accumulating environmental harm such as pollution.

European pesticides legislation includes a stronger, more overarching approach to the precautionary principle:

'*The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory'* (E.C., 2009, p. 309/6).

Outdated, Biased Legislation

'Regulatory agencies have historically been quick to approve products but slow to reconsider regulations after the decades of accumulated harms become apparent' (Arcuri & Hendlin, 2019).

Our legal and policy frameworks shape the way chemical regulators perceive and judge risk. This is intimately connected with processes of justice. Current regulatory frameworks do not base risk on health risk to most vulnerable members of society. They are biased towards estimating health effects on a healthy, robust adult. Similarly, they compartmentalise risk, failing to account for mixture risks or the fact that simultaneously a product such as glyphosate could cause hormone disruption, neurological delay *and* cancer(see Part 1).

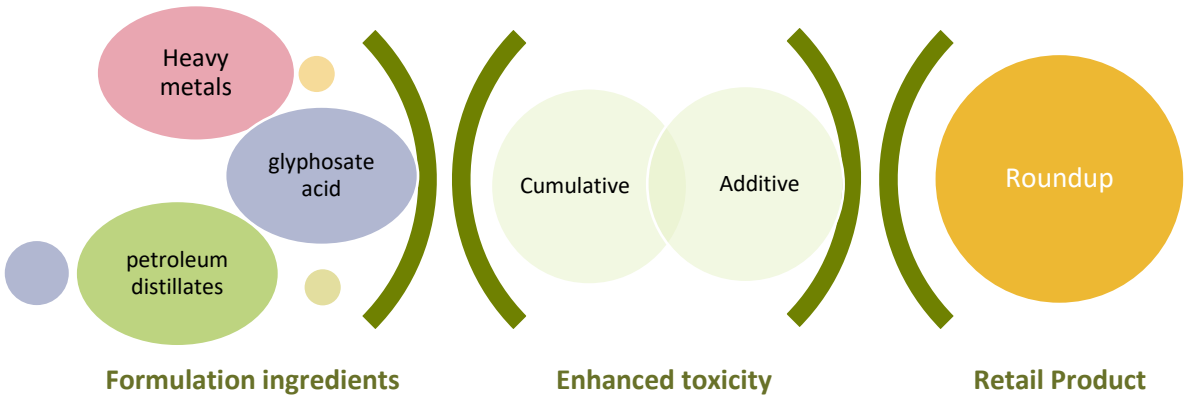
A 'politics of separation' is created by both excluding vulnerable members of society and ignoring complex effects. By retaining a linear viewpoint, regulators and public officials promote and maintain 'strategic ignorance' across civil society that certainly benefits the polluting industries. (Arcuri & Hendlin, 2019).

Consequently, New Zealand pesticides regulation is outdated (Iorns, 2018). Regulatory frameworks ignore formulation and mixture risk; the potential for comorbid conditions; the vulnerability of the child; and rely excessively on private industry data.

The NZEPA regulates pesticides under the Hazardous Substances and New Organisms Act and the Ministry for Primary Industries regulates pesticide formulations under the ACVM Act. The NZEPA continues to claim that products containing glyphosate are safe provided rules of use are followed, including wearing of personal protective equipment, applying sprays during calm and dry conditions at the correct rate, and storing substances appropriately.

environment to evaluate the degree of contamination.

So-called 'inert' ingredients in glyphosate formulations can be individually toxic and aid the active chemical to penetrate plant tissues and cells (but also dermal skin cells). Formulations have been found to be significantly more toxic than the active ingredient (Mesnage, Defarge, de Vendômois, & Séralini, 2014). Adjuvants can include trace metals and petroleum by-products, creating unanticipated



The ethical and moral implications of daily, unpreventable exposures of glyphosate to pregnant women, infant and childhood has never been discussed in New Zealand, despite the foetus, infant and child being much more vulnerable to synthetic chemicals (Landrigan & Belpoggi, 2018). The ethics relating to a toxic burden that predominantly falls on lower socio-economic groups who cannot afford organic, has not been discussed either.

The problem of adjuvants/additives

Glyphosate toxicity is frequently observed below this so-called safe exposure level of 0-1mg/kg.

Ingredients in glyphosate-based herbicides are considered inert and are not tested for separate toxicity. The classification of inert or active has no scientific basis (Mesnage & Antoniou, 2018, p. 6). Inert ingredients are normally kept confidential and are regulated differently from active ingredients. They do not undergo the conventional toxicity tests to evaluate health effects. If inert ingredients were found to be 'active' and require their own tests, this would create layers of complexity in authorisations and risk assessments. It would also require that they would be individually tested in mammals and in the

risks to human health and throughout the agricultural and commodity supply chain (Defarge, de Vendômois, & Séralini, 2018). The major adjuvant group of surfactants act to overcome surface tension and improve pesticides coverage. Organosilicon penetrants are also commonly added to glyphosate-based herbicides to dissolve or penetrate waxy vegetative surfaces.

There is an extraordinary volume of scientific papers demonstrating that formulations of glyphosate are much more toxic than the active ingredient (Evans, Martin, Faust, & Kortenkamp, 2016; Kortenkamp & Faust, 2018; Mesnage, Defarge, de Vendômois, & Séralini, 2014).

NZEPA will accept formulation studies from industry, however there is no requirement that the study that provides the lowest level of toxicity must be a mixture nor have the NZEPA reviewed independent published literature. Nor is the NZEPA insisting that the critical endpoints used to assess carcinogenicity, mutagenicity etc, research the *formulation toxicity*.

A recent European court case determined that, in regards to glyphosate-based herbicides, industry

secrecy should not be favoured over the public interest and the public had a right to know the ingredients in glyphosate-based herbicides. The court considered that the public right to examine data relating to:

> *'emissions into the environment' was 'deemed to be in the* ***overriding public interest****, compared with the interest in protecting the commercial interests of a particular natural or legal person, with the result that the protection of those commercial interests may not be invoked to preclude the disclosure of that information'* (General Court of the European Union, 2019).

International court cases in Europe and the U.S.A. are helping drive scientific precaution and requiring that judges consider more complex routes of risk than currently considered by regulatory decision-makers.

Addressing personal Injury

However, court action to generate justice for those directly harmed is unlikely in New Zealand. Farmers or spray contractors who are diagnosed with glyphosate related cancers are treated as 'accidents' under the Accident Compensation Corporation. The Accident Compensation Act 2001 restricts the capacity for people to sue for direct damages. Where people have cover under the ACA, it is unlikely that an award of compensatory damages can be obtained through recourse in the New Zealand Courts.

In New Zealand, cases of non-Hodgins lymphoma have increased significantly. Non-Hodgins lymphoma patients, when asked if they use glyphosate-based herbicides are informed they are just like the many other individuals who use glyphosate-based herbicides and are annually diagnosed with cancer.

The ACA and the Accident Compensation Corporation (ACC) activities may thereby diffuse and prevent court action that might establish new precedents that might signal to machinery of government mechanisms that regulatory convention and guidelines are not sufficiently protective. Nor is it evident that NZ Statistics data are sufficiently informing regulators and public health decision-makers of health risks, such as the increased rates of non-Hodgkin's lymphoma in rural communities.

Further, broader court action by non-government organisations is unlikely as the more resourced NGOs are not focussed on diffuse pollution from synthetic chemical cocktails.

The absence of avenues for civil society to compel decision-makers and regulatory actors to address new knowledge around chemical mixture toxicity is a weak spot in New Zealand health and environmental protection. Glyphosate is not the only chemical of risk, but due to its ubiquity, and the scientific evidence, it sits as a high-profile political pressure point in public and regulatory contestation.

In conclusion, firstly, Aotearoa New Zealand can immediately regulate to:

i. Remove co-ingredient POE-tallowamine from glyphosate-based products.
ii. 'Ensure that the use of plant protection products containing glyphosate is minimised or prohibited in areas such as public parks and gardens, sports and recreation grounds, schoolgrounds and children's playgrounds and in the close vicinity of healthcare facilities' as is ever more required in Europe.
iii. Cease pre-harvest practices using glyphosate to control harvest-time or optimise threshing as it is not good agricultural practice.
iv. Ensure StatsNZ stores data on all pesticide imports and locally produced pesticides
v. Transparently require all ingredients are published on the label (including adjuvants).

Secondly, due to the outdated nature of legislation and regulation in Aotearoa New Zealand, and the cultural preference of regulators to shaping risk assessment around industry supplied data, a risk assessment of glyphosate based around current conventions is not recommended. Instead a (first ever) risk assessment of glyphosate that requires the regulator to consider of the full formulation using only transparently available and published scientific literature is recommended.

Finally, it is imperative that the Precautionary Principle becomes an overriding principle. In instances where there is evidence harm may occur,

but doubt remains, lack of full scientific certainty shall not be used to delay regulation protective of human and environmental health.

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