PSGR

Physicians & Scientists for Global Responsibility

September 29, 2025

Submission

NZEPA: Consultation concerning the approval of Trifix Herbicide which contains triflusulfuron methyl

Submitted to the:

New Zealand Environmental Protection Authority (NZEPA)

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PSGR would welcome an opportunity to speak to this submission.

Physicians and Scientists for Global Responsibility Charitable Trust (PSGR) works to educate the public on issues of science, medicine, technology (SMT). PSGR work to encourage scientists and physicians to engage in debate on issues of SMT, particularly involving genetics and public and environmental health.

Thank you New Zealand Environmental Protection Authority (NZEPA) for the opportunity to respond to the consultation concerning the approval of Trifix Herbicide (APP204203) which contains triflusulfuron methyl, an active ingredient new to Aotearoa New Zealand, and is designed to target broadleaved weeds.

FMC New Zealand Limited has applied to import or manufacture Trifix Herbicide, which contains 500 g/kg of triflusulfuron methyl, a chemical new to Aotearoa New Zealand. **Close of submissions:** October 8, 2025.

August 2025: NZEPA Summary and submission guidance.

PSGR recommend that the ***approval to import or manufacture Trifix Herbicide is denied.***

The August 2025 draft Science Memo, concludes that the proposed use of Trifix is acceptable with the proposed controls. This conclusion is reached by discounting the likelihood of groundwater contamination (despite an absence of New Zealand monitoring data) and by not integrating the endocrine-disruptor hazard into the final risk characterisation. Such an approach is scientifically unsound and not appropriate for a regulatory authority.

The NZEPA state that they have 'carried out risk assessments for the product', however the documents listed in the APP204203 docket do not include any report that would constitute formal risk assessment.

The Science Memo expressly acknowledges Europe's conclusion that triflusulfuron methyl meets criteria for an endocrine disrupting compound (EDC, but then inconsistently pivots to conduct a 'qualitative' EDC assessment where the acceptability judgements rely on thresholds (AOEL/AAOEL/NOAEL, PDE) from non-ED critical effects and adult bodies. That is internally inconsistent with an ED hazard framing.

Triflusulfuron (formerly known as triflusulfuron-methyl) is not approved in the European Union under Regulation (EC) No 1107/2009. Approval expired in 2023 with use withdrawn August 2024.

New Zealand has no empirical local worker or residue datasets in the August 2025 draft Science Memo; it is effectively an adoption of EU hazard findings without NZ exposure quantification. The Science Memo (which does not and cannot constitute formal risk assessment) is a desk exercise, it piggybacks off EFSA's hazard classification. It doesn't present any NZ risk analysis for vulnerable human populations, and does not present any concern for the long-term health of long-lived dairy herds or breeding stock.

Fodder beet is primarily cultivated throughout New Zealand in all major dairying regions, and dairy cows may feed on fodder beet for up to six months. The August 2025 draft Science

Memo does not discuss risk to dairy cow health, including to breeding livestock (from the EDC properties).

PSGR's concerns revolve around the absence of data for New Zealand conditions, the dependence on foreign data (absence of domestic data), and then recommendation by the NZEPA that contradict Europe's' precautionary finding:

- The Memo does not present any NZ-specific worker exposure data (e.g. operator dermal or inhalation monitoring studies under NZ use conditions).
- The Memo imports EFSA operator/bystander exposure conclusions and then leans on generic control measures (NZS 8409 drift-management), not empirical NZ residue/bystander studies.
- Complete ignorance of domestic dietary exposure risk: no NZ dietary monitoring data are included; no NZ 'total diet study' references for sulfonylureas. The dietary risk section is absent, EFSA ADI/AOEL are cited but not tested against NZ residue monitoring.
- No NZ-specific developmental or reproductive exposure data are presented. No studies are cited on pregnant women, neonates, or children in NZ.
- NZ has no empirical groundwater concentration data for triflusulfuron-methyl or its metabolites, nor any knowledge of the class-based risk from the sulfonylurea class.
- The Draft Science Memo recognizes the lack of NZ monitoring data, instead referencing EU modelling and environmental fate studies.
- While often colder climates are more at risk from persistence of herbicides and their metabolites than warmer regions, Europe identified risk no matter the climate.
- Dietary exposures to cattle do not just occur from the feedstock, but via soil intake and will occur as long as the metabolites are present in soil. This has not been evaluated.
- No re-entry buffer is established even though the NZEPA acknowledge persistence in soil can be high.
- There is no discussion concerning any warning for longer-lived breeding stock.
- The information used for threshold data is problematic and inconsistent.

Triflusulfuron methyl is classed as a sulfonylurea herbicide. The sulfonylurea herbicides act as ALS inhibitors (mode-of-action group HRAC B) Triflusulfuron methyl carries similar resistance and environmental concerns as other chemicals in this class. However, there is no domestic knowledge of the cumulative impact from the sulfonylurea herbicide class: to groundwater, drinking water sources, farming families or livestock. The only pesticides detection programme in NZ water sources, the ESR groundwater study, consistently excludes the sulfonylurea herbicide class from screening.

The 2022 Peer review of the pesticide risk assessment of the active substance triflusulfuron-methyl identified missing information that was essential to the regulatory framework, and health concerns.[1] The European summary paper 2023/2513 identified the problems:

[1] European Food Safety Authority (EFSA) 2022. Peer review of the pesticide risk assessment of the active substance triflusulfuron-methyl. 20(5):e07303. https://doi.org/10.2903/j.efsa.2022.7303

- Critical concern: one toxicologically relevant metabolite of triflusulfuron-methyl, IN-JU122, which is predicted to occur above the parametric value of 0,1 µg/L in all geoclimatic conditions represented by the groundwater assessment scenarios for all proposed uses of triflusulfuron-methyl.(9)
- the Authority concluded that triflusulfuron-methyl has endocrine disrupting properties that may cause adverse effects in humans, as set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 (7 8). According to the Authority, negligible exposure cannot be demonstrated for triflusulfuron-methyl.(10)
- consumer dietary risk assessment could not be finalised. (10)

The European decision *found that a serious danger to plant health could not be identified that could not be contained by other methods including non-chemical methods* (October 2023 Renewal report).

TRIFLUSULFURON-METHYL AS AN ENDOCRINE DISRUPTOR

The European Food Safety Authority (EFSA) noted:

> *'The available evidence in the data set for the EAS-modalities for triflusulfuron-methyl was sufficient to conclude that triflusulfuron-methyl induces a pattern of adversity characterised by an increased incidence of testicular interstitial (Leydig) cell hyperplasia and adenomas in rat and testicular changes i.e. decrease in absolute and relative testicular weight, atrophy of tubular seminiferous epithelium and cytoplasmic vacuolation in the testes and aspermatogenesis and oligospermia in the epididymides, in dog.*
>
> *There are several possible molecular initiating events (MIEs) triggering these histological changes (including non EAS-modalities), with deregulation of the hypothalamus–pituitary–gonads (HPG) axis as a common key event (KE). In vivo endocrine activity was characterised by a decrease in the circulating levels of oestradiol, an increase in testosterone and an increase in luteinising hormone (LH) and FSH. In the available data set, there is indication for decrease in aromatase activity in vivo and in vitro. Therefore, a link between the endocrine activity and the pattern of observed adversity can be postulated, meeting the ED criteria, which represents a critical area of concern'*

The endocrine disrupting properties of triflusulfuron-methyl were acknowledged in the Science Memo (e.g. page 3)

> *the likelihood of endocrine disruption in non-target organisms other than mammals (for example, amphibians, birds, reptiles, and fish) cannot be disregarded based on an extensive mammalian data package including a range of in-vitro mechanistic assays*

Unfortunately, rather than considering that risk could not be ruled out which was the European position, the NZEPA adopted for the lack of confirmatory evidence as justification:

> *However, as population level effects cannot be demonstrated nor disregarded, a formal conclusion cannot be drawn as to the significance of the effect.*

NZEPA then claim that

> *It is considered that, excluding the likelihood of groundwater contamination and effects associated with endocrine disruption, the risks to the environment (for example, to the aquatic environment, soil organisms, non-target plants, and invertebrates) from the proposed use of Trifix are acceptable with the proposed controls.*

NZEPA state that:

> *It is considered that, excluding the likelihood of groundwater contamination and effects associated with endocrine disruption, the risks to the environment (for example, to the aquatic environment, soil organisms, non-target plants, and invertebrates) from the proposed use of Trifix are acceptable with the proposed controls.*
>
> *Effects associated with endocrine disruption in non-target organisms other than mammals (for example amphibians, birds, reptiles, and fish) are unlikely to be managed by the proposed controls. The significance of these effects at the population level is uncertain.*

The NZEPA seem to implicitly recognise that EDC's present risk at very low levels (for example, parts per billion), and that therefore the threshold for endocrine disruption is not established. Instead of recognising this problem and acting in a protective manner, the NZEPA seem to act protectively for the industry.

TRIFLUSULFURON-METHYL – BIOACCUMULATION/PERSISTENCE RISK IN WATER

The groundwater estimations failed to disclose whether the modelling considered the environmental fate in both warmer and colder climactic conditions and the difference in persistence and bioaccumulation potential. The groundwater modelling acknowledged that the predicted environmental concentrations in groundwater of two major soil metabolites IN-W6725 and IN-M7222 would exceed the European groundwater quality standard of 0.1 µg/L by 2.4-fold and 1.3-fold, respectively (page 137).

The NZEPA stated:

> *'the potential for leaching to groundwater of major metabolites IN-W6725 and IN-M7222 cannot be excluded.'*

NZEPA noted that (page 77): *all seven major metabolites are considered relevant to the groundwater assessment. All major soil metabolites are more persistent than the parent active ingredient, triflusulfuron methyl, and with the exception of IN-JM000, all major soil metabolites are more mobile in the soil environment than triflusulfuron methyl*. An accumulation in soil assessment is required for five of the major soil metabolites: IN-D8526, IN-W6725, IN-E7710, IN-M7222, and IN-JM000 as aerobic soil DT90 lab values are greater than 1 year.

NZEPA stated '*Risks to the groundwater community, aquatic life from resurfacing groundwater, and to human health from drinking water, are below the LOC.'*

NZEPA noted the European critical concern (page 27) '*Therefore, it cannot currently be established that the presence of metabolites of triflusulfuron methyl in groundwater will have no unacceptable effects on groundwater and no harmful effects on human health, as required by Article 4(3), point (b), of Regulation (EC) No 1107/2009.'*

TRIFLUSULFURON-METHYL – WONKY REASONING RE: THRESHOLD DATA

When PSGR take a closer look at the threshold data, NZEPA:

- Uses Acceptable Operator Exposure Levels (AOEL) thresholding and EFSA modelled exposures, but claims operator exposures are <10% of (A)AOEL with drift-reduction plus personal protective equipment, and concludes no re-entry interval is needed.
- Acknowledges exposure could exceed >20% of (A)AOEL, yet the acceptability narrative leans on mitigation, not on NZ-specific monitoring.
- Discusses thresholds but glides over the scientifically recognised problem that for endocrine disrupting hazards, 'safe thresholds' can be uncertain or not established, which is the case here.
- This is a category error, and the unmodelled by presumed covered claim, weakens confidence that safety can be protected.
- For example, sprayer-farmers can re-enter premises regularly post-spraying, many scenarios are assumed and EDC risk is not integrated into those thresholds.
- Acknowledges toddlers are a sensitive sub-population, but the metric remains the adult operator AOEL. Toddlers are more at risk from environmental exposures and absorb more by bodyweight than adults.
- Farming families could very well live on adjacent land and toddlers and children could be exposed to the formulation and metabolites, for weeks, if not months: 'IN-D8526 has low to high persistence in soil with aerobic soil DT50 values ranging from 3.6 to 444 days (n = 9) (page 72).

Seem to cherry pick how the approach to drinking water & ground water:

- The Science Memo seems to switch from an environmental quality standard (0.1 µg/L) to a toxicological PDE re-frames a precautionary, ambient standard into an adult dose-based threshold test. This is not not EDC-appropriate and it is not child-protective.
- the PECGW values are modelling-only, unverified locally. There is no broad knowledge of exposure risk of the total sulfonylurea class. This remains an ignored risk.

ENDOCRINE DISRUPTING POTENTIAL - LIVESTOCK HEALTH RISK

NZEPA have not assessed exposures to dairy herds. Exposure paths for livestock not only occur via ingestion of fodder beet, but, when grazing in pasture, exposures that occur from the sequestered herbicide and its breakdown metabolites in soil.

NZEPA have not discussed controls to limit exposures of cattle to the herbicide despite consumption occurring for up to 6 months of the year.

Longer-term dietary risks include potential groundwater contamination of drinking water sources.

NZEPA have no knowledge of the long-term impact to livestock from chronic exposures to this herbicide which is a potential endocrine disruptor.

The NZEPA effectively invoke EFSA's conclusion to give the appearance of scientific legitimacy, but then quietly sidestep the regulatory implications EFSA drew from that same evidence. In EFSA's framework, endocrine disruption is a cut-off hazard. Once identified, approval cannot continue. NZEPA, instead of following through, downplay the EFSA conclusion to a background note: 'poses an additional risk', but maintain it is still acceptable with controls.

That's a contradiction: NZEPA borrow EFSA's science, but not EFSA's consequence. This suggests regulatory cherry-picking: legitimacy from referring to EFSA data, but a deviation from findings in NZEPA conclusions.

CONCLUSION

NZEPA's reasoning across the spectrum of concerns reflected in the toxicity of triflusulfuron methyl, reflects the logic first articulated by industry toxicologist Robert Kehoe ('the Kehoe Rule') where incontestable evidence of proof of harm would be required to regulate.

NZEPA are required legally to take a precautionary stance, but PSGR observe that the NZEPA consistently fail to incorporate precautionary guidance in any policy documents. The Science Memo reflects the absence of any guidance on precaution, and fails to outline the potential for a precautionary position, despite, as we have noted, evidence of risk and a prevailing lack of data domestically that would contradict the risk identified in the European decision.

PSGR recommend that the approval to import or manufacture Trifix Herbicide is denied.