Comments on PRD2026-13 and PMRL2026-08

Epyrifenacil, S-3100 0.46 EC Herbicide and V-10488 0.94 SE Herbicide

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Introduction

Safe Food Matters Inc. (SFM) is a Canadian non-profit organization engaged in pesticide regulatory advocacy under the *Pest Control Products Act*, S.C. 2002, c. 28 ("PCPA"). SFM submits these comments in response to Health Canada's Pesticides Regulatory Directorate consultations on **Proposed Registration Decision PRD2026-13**, *Epyrifenacil, S-3100 0.46 EC Herbicide and V-10488 0.94 SE Herbicide* (posted 21 August 2026, comment deadline 20 September 2026), and **Proposed Maximum Residue Limit PMRL2026-08, Epyrifenacil** (posted 21 August 2026, comment deadline 4 November 2026).

Because PMRL2026-08 expressly incorporates the human health and dietary risk assessment developed in PRD2026-13 and states that "[c]onsultation on the proposed MRLs for epyrifenacil is being conducted via this document and PRD2026-13," SFM addresses both consultations in this submission, and reserves the right to submit further comment on the PMRL. Grounds relating to the underlying toxicology, dietary exposure methodology, and MRL derivation apply equally to both documents.

SFM's comments are summarized as follows:

- **Part I (Process):** the registration decision and the MRL that supports its dietary risk conclusion are being decided on staggered comment-period clocks, in a manner not in accord with s. 9 of the PCPA and offending the procedural fairness principles in the law, particularly *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817.
- **Part II (Human Health):** (A) a PCPA children's safety factor reduced without the reliable scientific data ss. 7(7)(b)(iii) and 11(2)(b) require, applying the same discounting reasoning to findings characterized as both serious and non-serious, and discounting the more sensitive species without a validated analysis; (B) a cancer weight-of-evidence conclusion asserted rather than demonstrated; (C) exclusion of epyrifenacil's own highest individual exposure estimate from a cumulative assessment whose relative-potency methodology is not scaled to the shared mechanism defining the assessment group, an acute-exposure exclusion of unclear basis, and circular reliance on epyrifenacil's own untested residue profile to support the absence of tiafenacil monitoring data; (D) reliance on stale, non-Canadian dietary consumption data and an undisclosed basic screening methodology for the highest-exposure subgroup, contrary to PMRA's own refinement policy; (E) an undisclosed livestock dietary burden methodology; (F) an MRL set at the limit of quantification without disclosure of the residue chemistry methodology, an unanalyzed and inconsistently-treated transformation product (TFA) excluded from the residue definition on reasoning SFM submits is scientifically and statutorily unsound, incomplete toxicity data across 18 transformation products, and unaddressed statutory obligations arising from a foreign OECD-member ban of six chemically related, Canadian-registered pesticides; (G) no aggregate dietary or occupational exposure assessment for the co-formulated product V-10488; (H) consistent hematotoxicity across every species and exposure route tested, without a dedicated ground of its own; and (I) confirmed

translocation of epyrifenacil into the harvested food commodity, with no assessment of its relevance to the gut microbiome.

- **Part III (Environmental):** (A) the Toxic Substances Management Policy Track 1 conclusion blends the parent's rapid dissipation with individual transformation products that independently meet the persistence criterion on Health Canada's own Table 27 data; (B) risk to non-target terrestrial plants and other terrestrial organisms (earthworms, bees, birds and mammals) is mitigated only by an unvalidated 275-metre buffer zone, unverified label statements for groundwater leaching, and property-based partitioning and bioaccumulation predictions the data do not support; (C) aquatic runoff risk exceedances are unscientifically dismissed by qualitative narrative, the marine/estuarine refinement rests on an unverified tidal-flushing assumption, and groundwater-dependent ecological risk is not assessed at all; and (D) PRD2026-13 does not address species at risk, including a formal adverse-effects finding the USEPA has already reached on this same active ingredient.
- **Part IV (Value):** (A) the value assessment omits the mandatory health, safety, and environmental benefits and social/economic impact components of PCPA s. 2(1); (B) it does not address the multi-year market-access and trade risk social/ economic impact created by registering a persistent, TFA-generating active ingredient on US-matched MRLs with no Codex or EU equivalent, against the backdrop of a European Commission report identifying Canada among 14 countries facing over $1.4 billion in export risk and the December 2025 diquat/lentil recall precedent; and (C) documented moderate canola rotational crop injury and single-season trial design are not reconciled with the compound's multi-year persistence, and the claimed value of managing pathogen, insect, and rodent pests through a herbicide is not explained.

Background

Epyrifenacil is a new active ingredient but its Canadian review does not occur in a vacuum. The United States Environmental Protection Agency ("USEPA") approved epyrifenacil on 30 June 2026, alongside diflufenican and trifludimoxazin, as part of what commentators have described as the fifth PFAS-class pesticide approval of the current U.S. administration.

PRD2026-13 does not use the term "PFAS," "per- and polyfluoroalkyl substance," or any equivalent term anywhere in connection with epyrifenacil itself; the only such reference in the entire document is in the title of a cited study concerning TFA in beer. PRD2026-13 accordingly neither classifies epyrifenacil as a PFAS-class pesticide nor explains why it should not be so classified. This matters because the classification is not settled by a single, universally-applied definition. The Organisation for Economic Co-operation and Development's 2021 definition, on which Pesticide Action Network Europe's 28-substance list and internal review request (discussed below) is based, captures any substance containing at least one fully fluorinated carbon atom —

a criterion epyrifenacil plainly meets, given the trifluoromethyl group already discussed throughout this submission and epyrifenacil's own confirmed degradation to TFA.

SFM submits that where a genuine choice exists between a broader, more protective classification and a narrower one, the protective purpose of the PCPA favours resolving that choice toward the classification that best serves that purpose. That purpose is expressed throughout the Act: in its long title ("to protect human health and safety and the environment"), in the Minister's primary objective under s. 4(1) "to prevent unacceptable risks," and in the "reasonable certainty of no harm" acceptability standard in s. 2(2). PMRA's own Chief Registrar confirmed that this standard is precautionary when stating: "**the risk assessment approach we take is essentially the precautionary approach. It's inherent in how we assess a pesticide**." A protective purpose applied on that basis does not support resolving a genuine definitional ambiguity in favour of the narrower, less protective classification. On that basis, epyrifenacil should be assessed as falling within the same class of TFA-generating, structurally fluorinated pesticides as the eight comparator compounds already discussed in this submission, regardless of whether PRD2026-13 itself applies that label.

Epyrifenacil has **never been approved for use in the European Union**. At its 77th meeting (1–5 June 2026), the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) reached final agreement that trifluoroacetic acid (TFA) — epyrifenacil's major environmental transformation product — should be classified as Reproductive Toxicity Category 1B (H360Df: "may damage the unborn child"), Acute Toxicity Category 3 for inhalation (H331), and Acute Toxicity Category 4 for ingestion (H302), and supported its classification as Persistent, Mobile and Toxic (PMT) and very Persistent, very Mobile (vPvM). This RAC opinion is not yet legally binding EU-wide — harmonized classification takes effect only once implemented through an Adaptation to Technical Progress (ATP) to the CLP Regulation — but German authorities consider it unlikely to change materially before that implementation (Bundesinstitut für Risikobewertung (BfR), *Trifluoressigsäure (TFA) in Lebensmitteln: Wie steht es um das gesundheitliche Risiko?*, FAQ, 29 July 2026). The underlying data include a Labcorp (2024) rabbit developmental toxicity study in which, at 750 mg/kg bw/day sodium trifluoroacetate, 32% of litters showed multiple folded retinas and 10.7% showed fused or partially fused ribs.

On 21 July 2026 — one month before PRD2026-13 and PMRL2026-08 were posted — EFSA published a formal scientific report establishing consumer health-based guidance values for TFA, including an **Acceptable Daily Intake of 0.014 mg/kg bw/day**, derived from a benchmark dose lower confidence limit ($BMDL_{20}$ = 8.6 mg/kg bw/day) for decreased thyroid hormone (T4) in an extended one-generation reproductive toxicity study in rats (EFSA Journal, 2026, doi:10.2903/j.efsa.2026.10227). Neither PRD2026-13 nor PMRL2026-08 references this EFSA opinion or applies the resulting TFA-specific ADI, notwithstanding that TFA is a confirmed transformation product of epyrifenacil quantifiable in the same field trial samples relied upon for the epyrifenacil MRLs (see Part II.F, below).

USEPA's own November 2025 decision memorandum on epyrifenacil found that the compound "led to increased liver- and blood-related health risks in animal studies" and confirmed its degradation to TFA. This is the same underlying data package the Directorate has relied on for

its own assessment (Table 1, Appendix II, PRD2026-13, p. 196 — MRLs derived from a data package "concurrently" reviewed for Canadian and American registration).

Part I: Process Grounds

A. Premature registration decision issued in advance of the maximum residue limit consultation

PRD2026-13, s. 3.9 (p. 35) states that dietary risks "were shown to be acceptable" and that "the following MRLs *will be specified* for residues of epyrifenacil" — language that concedes the MRLs relied upon to reach the registration decision's dietary risk conclusion are not yet legally established. Those MRLs are the subject of a separate consultation, PMRL2026-08, whose comment period runs to **4 November 2026** — six weeks after PRD2026-13's own comment deadline of **20 September 2026**.

Section 9 of the PCPA requires that maximum residue limits be established as an integral part of the registration decision process, not as an administratively deferred afterthought. Structuring the consultation so that the registration decision's comment period closes before the MRL consultation on which its own dietary risk conclusion depends undermines the ability of commenters to address the completed evidentiary record, contrary to the laws on procedural fairness principles articulated in *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817, and the duty of consistent, justified administrative decision-making in *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65 at paras. 102, 119–120.

SFM requests that Health Canada confirm that no final registration decision will issue for epyrifenacil until the PMRL2026-08 consultation has closed and any resulting changes to the proposed MRLs have been incorporated into, and made available for comment as part of, the registration decision.

Part II: Human Health Assessment Deficiencies

A. The Pest Control Products Act factor is reduced inconsistently, including in a manner unsupported by the endpoint to which it is applied

PRD2026-13, s. 3.1.2 (pp. 19–20) reduces the statutory PCPA children's safety factor to **threefold** for the acute reference dose (ARfD), where the point of departure is a developmental endpoint (offspring NOAEL from the 2-generation reproductive toxicity study), and to **onefold** — effectively eliminated — for the acceptable daily intake (ADI), citing the same s. 3.1.2 hazard characterization (s. 3.2.4, p. 22).

This reduction requires a statutory foundation that PRD2026-13 does not supply. Sections 7(7)(b)(iii) and 11(2)(b) of the PCPA each provide that the tenfold children's safety margin applies "unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate." PRD2026-13 does not identify any reliable scientific data establishing that the reduced threefold or onefold margins are themselves safe for infants and children; it identifies only the co-occurrence of maternal toxicity in the underlying developmental studies. A characterization of the hazard data is not itself the "reliable scientific data" the Act requires before departing from the statutory default — as the discussion below of SPN2008-01 and the OECD's own guidance on maternal-toxicity confounding demonstrates, that characterization does not even resolve the more basic question of whether the developmental findings remain of concern at the reduced dose.

Under Science Policy Note SPN2008-01 (*The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides*, H113-13/2008-1E, 29 July 2008), the sensitivity-of-the-young prong and the seriousness-of-the-endpoint are listed separately. PRD2026-13 itself characterizes the developmental findings — supernumerary lumbar vertebra, decreased anogenital distance, F1 male mortality — as "considered serious effects" (s. 3.1.2, p. 20), tempered only by the co-occurrence of maternal toxicity. Under SPN2008-01's two-prong structure, the presence of maternal toxicity bears on the sensitivity prong; it does not discharge the seriousness prong, which the Directorate's own document concedes is met.

More significantly, the ADI's point of departure is *not* a developmental endpoint at all — it is the lowest NOAEL (1.4 mg/kg bw/day) from the **oncogenicity study** in female rats (s. 3.2.4, p. 22). The onefold PCPA factor reduction is nonetheless justified by cross-reference to "the Pest Control Products Act hazard characterization section" — i.e., the developmental-toxicity, sensitivity-of-the-young analysis conducted for a different endpoint entirely. SFM submits that a PCPA factor reduction premised on the absence of offspring sensitivity in developmental studies cannot, without further explanation, be transposed to eliminate the same factor for a point of departure drawn from an unrelated oncogenicity study, where **no offspring-sensitivity analysis was performed at all**.

This same pattern — discounting the more sensitive species — recurs in the waiver record. PRD2026-13, s. 3.1.1 (p. 16) states that waiver rationales were provided for the conditionally required immunotoxicity, delayed neurotoxicity, and developmental neurotoxicity studies, "accepted based on the absence of immunotoxic effects in the database and *mouse PPO inhibition was not considered to be a suitable model for health risk assessment in humans nor for establishing toxicology reference values*." The mouse is the more sensitive species for the compound's primary toxicological findings (see Part II.B, below). Section 19(2) of the PCPA requires the Minister to apply "a scientifically-based approach," and the established default principle in that approach — reflected in OECD and WHO/IPCS guidance on interspecies extrapolation — is to select the most sensitive species or study as the point of departure unless a validated human-relevance analysis, following the IPCS/Sonich-Mullin Human Relevance Framework, demonstrates that the finding is not applicable to humans. A bare statement that

mouse data were "not considered suitable" is not the demonstrated human-relevance analysis that framework requires; it is the conclusion that framework is meant to test.

This approach is also difficult to reconcile with the OECD's own guidance on interpreting maternal toxicity in developmental toxicity studies — guidance within the same test-guideline framework PRD2026-13 purports to follow for the underlying studies themselves. The current edition, *Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment, Second Edition* (OECD Series on Testing and Assessment No. 446, ENV/CBC/MONO(2026)26, approved by the Chemicals and Biotechnology Committee 22 June 2026), explains that it is generally not possible to fully separate effects on in utero development caused by direct foetal exposure from effects caused or worsened by maternal toxicity, and concludes on that basis that "evidence of maternal toxicity does not automatically negate the observation of foetal toxicity" at a similar dose level. This is the same point SFM has developed at length elsewhere, and the academic literature is consistent with it: Chernoff, Rogers & Kavlock (1989) and Rogers, Chernoff, Keen & Daston (2005) both conclude that safety factors should be based on the developmental toxicity NOEL regardless of whether the effect is maternally mediated. This confirms the gap identified above: co-occurring maternal toxicity is not, without more, the "reliable scientific data" the Act requires.

The phrase "tempered by the fact that they were observed at dose levels also producing maternal toxicity" (s. 3.1.2, p. 20) is applied indiscriminately in PRD2026-13 — to the rat skeletal findings the Directorate itself calls non-serious, and to the rabbit malformations, decreased anogenital distance, and F1 mortality the Directorate itself calls "serious effects." If the same reasoning tempers concern regardless of whether the underlying finding is characterized as serious or non-serious, the seriousness characterization is doing no analytical work in this document: it is a label attached to a finding immediately before the finding is discounted by an argument that, per the OECD's own current guidance (above), does not depend on and is not resolved by seriousness in the first place. SFM submits that an assessment cannot coherently identify a finding as serious and then apply the identical discounting rationale it applies to a finding it has just called non-serious.

SFM requests that Health Canada identify the reliable scientific data, as opposed to a characterization of the hazard findings, that supports each reduction; explain, with reference to SPN2008-01's independent-prong framework and the OECD's own guidance on maternal-toxicity confounding (OECD Series on Testing and Assessment No. 446), why the seriousness of the developmental findings does not preclude the threefold ARfD reduction; explain why the identical "tempered by maternal toxicity" language is applied to findings characterized as both serious and non-serious without distinction; and separately justify the onefold ADI reduction by reference to the oncogenicity endpoint to which it is actually applied, and the basis on which mouse data were excluded from that endpoint's selection given the mouse's greater sensitivity.

B. Confirmed mouse liver tumours are dismissed via mode-of-action without a formal classification descriptor, and the weight-of-evidence conclusion is asserted rather than demonstrated

PRD2026-13, s. 3.1.1 (pp. 16–17) confirms "increased incidences of hepatocellular adenomas and/or carcinomas" in male mice at higher dose groups in the dietary carcinogenicity study.

Section 3.2.5 (p. 22) states, in its entirety on the point, that "there was adequate evidence to support a threshold-based mechanism for the liver tumours in male mice," and concludes without further analysis that "the toxicology reference values selected for use in the non-cancer risk assessment are considered to be protective of any concerns regarding potential tumourigenicity." No formal weight-of-evidence cancer classification descriptor is applied at any point.

"Adequate evidence" is a conclusion, not a demonstration. The recognized framework for evaluating whether a proposed mode of action is established and human-relevant — the IPCS/Sonich-Mullin (2001) Human Relevance Framework, incorporated into the U.S. EPA *Guidelines for Carcinogen Risk Assessment* (2005) that the Directorate has applied in practice in prior assessments — requires the assessor to work through defined criteria: biological plausibility of the proposed key events, consistency of the dose-response and temporal relationships between those key events and tumour formation, and analysis of whether the key events are qualitatively and quantitatively applicable to humans. PRD2026-13 does not walk through these criteria, cite this or an equivalent framework, or disclose a weight-of-evidence table or analysis; it states a conclusion where the framework calls for a demonstration.

The MOA itself rests on interspecies extrapolation data (PMRA Nos. 3738224 and related mechanistic studies, s. 3.1.1, p. 17) showing mouse hepatocytes approximately 10-fold more sensitive to PPO inhibition, and with markedly greater hepatic uptake of the causal metabolite S-3100-CA, than human hepatocytes — data generated by the applicant and not independently replicated. Under the significant trend test standard of the U.S. EPA *Guidelines for Carcinogen Risk Assessment* (2005), an accepted MOA dismissal should be accompanied by an explicit classification descriptor and disclosure of the weight-of-evidence analysis supporting it, not a bare conclusory statement of protectiveness.

SFM requests that Health Canada disclose the formal cancer weight-of-evidence classification applied to epyrifenacil, including an analysis addressing each criterion of the IPCS/Sonich-Mullin Human Relevance Framework or an equivalent recognized framework, and the basis on which the applicant-generated interspecies sensitivity data were accepted without independent replication.

C. Epyrifenacil's own highest individual exposure estimate is excluded from the cumulative risk assessment it is meant to inform, and the assessment has further, related gaps

PRD2026-13, s. 3.7 conducts a semi-quantitative cumulative risk assessment for ten PPO inhibitors registered in Canada, as contemplated by Science Policy Note SPN2018-02. For the nine PPO inhibitors with drinking water monitoring data, individual concentrations are adjusted for relative potency against an index chemical (fomesafen) and summed, yielding a combined cumulative exposure of 6.2% of the long-term human health reference value (s. 3.7.3.2, p. 33).

Water monitoring data are **not available** for epyrifenacil. Its individual chronic drinking water exposure is instead estimated using a basic Tier 1 modelled assessment at **74% of its own ADI** (s. 3.7.3.2, p. 33) — the highest individual exposure margin of any compound in the assessment group by a wide margin, and one arrived at through a materially less refined method than the

monitoring-data-based approach used for the other nine compounds. This 74% figure is reported but is **not incorporated** into the relative-potency-summed cumulative exposure calculation that produces the group's 6.2% headline conclusion (s. 3.7.4, p. 34). The compound with the largest individual exposure concern in the assessment group is, by virtue of lacking monitoring data, excluded from the very calculation meant to capture co-exposure risk across the group. Water monitoring data are also unavailable for a second compound, trifludimoxazin (chronic risk 0.6% of ADI); PRD2026-13 offers no explanation for the absence of monitoring data for either compound beyond the assertion that "dietary risks are expected to be much lower considering the conservatisms in the basic assessment" (s. 3.7.3.2, p. 33) — an assertion, not a quantified basis, and one that does not amount to the reasonable certainty of no harm PCPA s. 2(2) requires.

The cumulative assessment is limited to **chronic** exposure; PRD2026-13 states that "only chronic exposure was assessed in the cumulative risk assessment (CRA) since PPO inhibition or any other associated blood effects were not considered relevant to acute exposure" (s. 3.7, p. 31). SFM requests disclosure of the toxicokinetic or toxicodynamic basis for that conclusion — specifically, whether single-dose or short-duration studies were designed and powered to detect hematopoietic effects of the kind epyrifenacil itself produces (see Part II.H, below), given that such effects may require repeated dosing to manifest and an absence of an acute finding could reflect study design rather than an absence of acute hazard.

Food monitoring data are unavailable for tiafenacil, "first registered in 2022" (s. 3.7.3.1, p. 32). PRD2026-13 addresses this gap by stating that quantifiable residues are "also not expected based on 1) the residue data reviewed in support of the **epyrifenacil and tiafenacil registrations**" (s. 3.7.3.1, p. 32, emphasis added) — that is, the absence of monitoring history for tiafenacil is addressed in part by reference to epyrifenacil's own residue data, a compound with no monitoring history of its own and no Canadian or international registration history whatsoever prior to this same consultation. Two active ingredients without independent monitoring records are being used to support the absence-of-concern conclusion for each other.

Finally, the cumulative grouping is justified throughout s. 3.7 by the PPO inhibitors' shared mechanism of toxicity — inhibition of protoporphyrinogen oxidase and the resulting changes in hematopoietic parameters (s. 3.7, p. 31). Yet PRD2026-13 discloses that the relative potency factors used to combine the group's drinking water exposures were "calculated using the most conservative points of departure, that are not necessarily based on common effects of changes in hematopoietic parameters" (s. 3.7.4, p. 34). The cumulative calculation is accordingly not scaled by the shared endpoint that justifies treating these compounds as a cumulative group in the first place; it is scaled by whichever endpoint happened to produce the most conservative point of departure for each individual compound.

SFM requests that Health Canada either incorporate epyrifenacil's modelled 74% ADI drinking water exposure into the cumulative PPO-inhibitor exposure calculation using an appropriately conservative method, or explain the scientific basis on which its exclusion from that calculation is consistent with the tiered cumulative assessment obligation in SPN2018-02; disclose the basis for excluding acute exposure from the cumulative assessment; explain the circularity in using epyrifenacil's own untested residue profile to support the absence of tiafenacil monitoring data;

and explain why the relative potency factors used in the cumulative calculation are not based on the shared hematopoietic mechanism that defines the assessment group.

D. Dietary exposure assessment relies on stale, non-Canadian consumption data, an undisclosed screening methodology for its highest-exposure subgroup, and an unexplained absence of an acute assessment for the general population

PRD2026-13, s. 3.5.3 (p. 30) conducts acute and chronic dietary risk assessment using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 4.02), which incorporates consumption data from the U.S. National Health and Nutrition Examination Survey / What We Eat in America (NHANES/WWEIA) for **2005–2010** — American data now roughly two decades old, drawn from a different national population, and not benchmarked against Canadian consumption patterns. Health Canada's own Canadian Community Health Survey (CCHS – Nutrition) dataset is available and was not used or referenced.

This is significant because infants under one year already show the tightest margin in the assessment — 76% of the ADI from food and drinking water combined (s. 3.5.3.2, p. 30) — under a PCPA factor that, per Part II.A above, has been reduced to onefold. A dietary exposure estimate built on two-decades-stale, non-Canadian consumption data carries reduced reliability precisely where the safety margin is thinnest.

PRD2026-13 itself describes this 76% figure as a "basic" chronic dietary exposure estimate (s. 3.5.3.2, p. 30) — PMRA's terminology for a Tier 1, deterministic assessment using default assumptions of 100% crop treated and residues present at the MRL, rather than a refined or probabilistic estimate built on more realistic distributions of consumption and residue data. Under Science Policy Note SPN2003-01, *Choosing a Percentile of Acute Dietary Exposure as a Threshold of Concern*, it is PMRA's stated policy "to rely on a screening estimate of exposure only if the estimate indicates that risk would be acceptable," because "screening estimates overstate exposure" and are refined using more realistic data where they do not. Science Policy Note SPN2003-04, *General Principles for Performing Aggregate Exposure and Risk Assessments*, sets out the Tier 3/4 probabilistic refinement framework available for this purpose. PRD2026-13 does not disclose whether refinement beyond the basic Tier 1 estimate was considered or attempted for the infant subpopulation, notwithstanding that this subpopulation already sits at more than three-quarters of the ADI on the conservative screening method — precisely the circumstance in which PMRA's own policy contemplates refinement.

Separately, s. 3.5.3.1 (p. 30) states that an acute dietary exposure assessment was not conducted for the general population and most population subgroups because "an endpoint of concern attributable to a single dose was not identified in the oral toxicity studies." SFM requests confirmation of the study duration and dosing regimen used to reach that conclusion, given that epyrifenacil's principal toxicological findings — hematopoietic changes and hepatotoxicity (see Part II.H, below) — are described throughout PRD2026-13's toxicology summary as findings of repeat-dose and chronic studies. An absence of a single-dose endpoint in studies not designed to detect effects requiring repeated dosing to manifest does not establish that no acute hazard exists - particularly where, as here, the compound's principal toxicological findings (hematopoietic

effects) are of a kind that may require repeated dosing to manifest, and may not be detectable within a study designed to capture single-dose effects alone.

SFM requests that Health Canada disclose whether Canadian consumption data (CCHS-Nutrition) was considered for the infant and toddler subpopulations, and if not, why American consumption data from 2005–2010 was considered adequate for this purpose; disclose whether a probabilistic (Tier 3/4) refinement of the infant chronic dietary exposure estimate was considered or attempted, consistent with SPN2003-01 and SPN2003-04, given that subpopulation's proximity to the ADI on the basic screening method; and confirm the study duration and dosing regimen underlying the conclusion that no single-dose endpoint of concern was identified.

E. The livestock dietary burden calculation is undisclosed, and its residue inputs cannot be verified

PRD2026-13, Appendix I (pp. 98–99) reports dietary burden figures of 0.006 ppm (poultry), 0.009 ppm (beef cattle), 0.02 ppm (dairy cattle), and 0.006 ppm (swine), on the basis of which "[a] feeding study was not required based on the low dietary burden" in either laying hens or goats; the corresponding metabolism studies were instead used "to estimate the anticipated residues in the relevant livestock matrices." No feeding study was conducted in any species.

Dietary burden is a specific, calculable figure under the *Guidance Document on Residues in Livestock* accompanying OECD Test Guideline No. 505, and the *Guidance Document on Overview of Residue Chemistry Studies* (OECD Series on Pesticides No. 32): the theoretical maximum pesticide concentration in the animal's total diet, calculated by weighting the residue levels found in treated feed items (forage, hay, straw, grain) by their proportional contribution to that diet. PRD2026-13 discloses only the output figures; it does not disclose which feed items were used as inputs, what residue values were assigned to each, or what feeding scenario was assumed.

This matters because Appendix I's crop residue tables (pp. 110–113) report two distinct values for every relevant feed commodity: parent epyrifenacil — non-detect throughout, at LOQs of 0.010–0.015 ppm — and trifluoroacetic acid (TFA), a transformation product quantifiable at substantially higher levels in the *identical samples* — up to 3.0 ppm in wheat hay (mean 0.61 ppm) and 0.51 ppm in corn stover (mean 0.13 ppm). The dietary burden tables label their residue definition simply as "Epyrifenacil," suggesting the calculation may be confined to parent-compound residue values. If so, the 0.006–0.02 ppm dietary burden figures — and the feeding-study waiver built on them — do not account for the compound's own major, quantifiable transformation product. This concern parallels, at the livestock level, the residue-definition gap addressed in Part II.F below.

SFM requests that Health Canada disclose the methodology used to derive the dietary burden calculation for each livestock species — including which feed items were included and their proportional weighting in the assumed diet — and confirm whether TFA residue levels were included in or excluded from the residue definition applied to that calculation.

F. The maximum residue limits are set at the limit of quantification without disclosure of the residue chemistry inputs, and without accounting for the compound's own major transformation product

The crop MRLs proposed in PRD2026-13, s. 3.9 (p. 35) and PMRL2026-08 Table 1 are set at the limit of quantification (LOQ) for every commodity: epyrifenacil residues were non-detect in all 20 soybean trials, all 20 field corn trials, all 20 wheat trials, and all 13 canola trials (Appendix I, pp. 110–113). SFM notes, without contesting Health Canada's general practice of driving fully-censored-dataset MRLs by the achieved LOQ rather than by statistical extrapolation, four specific concerns raised by this MRL.

First, an MRL set at the exact LOQ of the enforcement analytical method is, by construction, coincident with its own measurement floor. A compliance sample can only ever read at or below that value; any apparent exceedance would reflect analytical variability rather than a genuine finding of excess residue. SFM requests that Health Canada explain how an MRL set at the LOQ retains independent enforcement content, and — consistent with the disclosure sought in SFM's prior submissions on other active ingredients — disclose whether the OECD MRL Calculator was run at any stage of the epyrifenacil residue chemistry review (including on any partially-censored dataset prior to a fully-censored conclusion being reached), and if so, disclose the Calculator's output and whether it generated any "high uncertainty of the residue limit estimate" warning of the kind the Calculator issues for small or partially-censored datasets.

Second, in the same field trial samples where the parent compound was consistently non-detect, TFA — epyrifenacil's own major transformation product, and a substance ECHA has recommended classifying as Toxic to Reproduction and as very Persistent/very Mobile (see Background, above) — was quantifiable at levels up to 60 times the parent's LOQ (3.0 ppm in wheat hay against a parent LOQ of 0.010–0.015 ppm). TFA is expressly excluded from the residue definition for epyrifenacil (s. 3.8, p. 34: "TFA was not included in the residue definitions for epyrifenacil"). An LOQ-based MRL confirms only that the parent is undetectable; it says nothing about the compound family's actual residue burden on the crop.

The residue definition decision itself rests on questionable footing. PRD2026-13 states that "in epyrifenacil soil metabolism studies (aerobic and anaerobic), TFA was not analyzed, but mass balance indicated that TFA did not form" (s. 3.8, p. 34). Mass balance closure — accounting for total applied radioactivity — cannot positively confirm the absence of a specific small polar molecule such as TFA unless a TFA-specific analytical method was employed; it confirms only that the radioactivity was found somewhere. An assertion that a compound did not form, based on a study that did not analyze for that compound, is an absence of evidence, not evidence of absence.

TFA was, in fact, identified as a major metabolite in the confined rotational crop metabolism studies (s. 3.5.1, p. 27). PRD2026-13 discounts this finding on the basis that such studies are conducted under "worst-case" conditions that may not reflect "real agricultural conditions." SFM notes that this selective skepticism is not applied consistently: elsewhere in the same document, worst-case and conservative assumptions are treated as the *correct* and protective methodology to adopt — for example, the terrestrial and aquatic screening assessments discussed in Part III

below expressly "conservatively assumed that no dissipation" of epyrifenacil or its transformation products occurred, precisely to ensure a protective, worst-case estimate. Worst-case assumptions are relied upon as appropriately protective throughout PRD2026-13 except where the worst-case result — TFA formation — is inconvenient to the residue definition and MRL conclusions, at which point the same type of study result is instead characterized as an artifact.

PRD2026-13 further reasons that "any TFA present in crops is expected to come from background environmental levels" (s. 3.8, p. 34) and, on that basis, need not be attributed to epyrifenacil or included in its residue definition. SFM submits that this inverts the precautionary logic PCPA s. 2(2) requires. An elevated environmental background of a substance now classified as reproductively toxic (see Background, above) is a reason for *greater* caution about any additional contributing source, not a basis for disregarding one. This reasoning is also self-perpetuating in a way directly relevant to the eight other TFA-precursor pesticides identified in s. 3.8: if every individual TFA-precursor registration decision may attribute the TFA present in its own field trial data to "background" levels created by the *other* registered TFA-precursor pesticides, no single registration decision ever needs to account for its own contribution to that background — even as the cumulative background itself is, by definition, the sum of all such individually-dismissed contributions.

Section 3.8 (p. 34) also states that "TFA is not considered to be a significant contributor" of epyrifenacil's own drinking water exposure. SFM submits that this conclusion, even if numerically accurate, does not resolve the underlying concern: TFA is a persistent, mobile, now reproductively-classified substance, and the question of consequence is not whether any single registration decision's incremental contribution is "significant" in isolation, but what results if every TFA-precursor registration decision reaches the same individually-reasonable conclusion. A cumulative contaminant cannot be managed by a series of individual assessments each concluding that its own contribution, considered alone, is not significant.

Third, Health Canada's own text acknowledges that "[t]he human health risk assessment of TFA, taking into account the multiple pesticidal sources, is currently in the initial planning phase" (s. 3.8, p. 34), citing a Cumulative Health Risk Assessment Operational Planning Framework published in December 2025. Section 3.8 names eight other registered pesticides that may degrade to TFA (cyclobutrifluram, cyflumetofen, fluazinam, fomesafen, saflufenacil, tiafenacil, trifloxystrobin, and trifluralin). The Directorate is accordingly approving individual TFA-precursor pesticides, including epyrifenacil, on a rolling basis while the cumulative TFA assessment covering all of them remains unstarted in substance.

Section 3.8 (p. 34) states in addition that "[t]o date, no comprehensive overview exists quantifying TFA formation from the full range of CF_3 containing chemicals, and the degradation pathways are not completely understood." PCPA s. 2(2) provides that health or environmental risks are "acceptable" only if there is *reasonable certainty that no harm* to human health, future generations or the environment will result, and s. 19(2) requires the Minister to apply *a scientifically-based approach* in reaching that determination. An admission that the formation pathways and quantities of a now reproductively-classified, persistent transformation product are "not completely understood" across the very class of chemicals to which epyrifenacil belongs is, on its face, in

tension with a finding of reasonable certainty specifically with respect to that transformation product. **SFM submits that this statutory standard cannot be met for TFA on the current record**, and that this alone is a sufficient basis to decline to finalize the registration decision until the cumulative TFA human health risk assessment referenced above is complete.

This concern is compoundded by the residue chemistry data themselves. Epyrifenacil forms up to **18 major transformation products** in soil and water (s. 4.1, p. 35). SFM's review of Appendix I indicates that independent toxicological testing — as opposed to environmental fate (persistence, mobility) characterization only — is available for only a small subset of these eighteen; the balance are addressed, where addressed at all, by a general statement that "the available data show that the major TPs are less toxic than epyrifenacil" (s. 4.2.2, p. 41) without disclosing which specific transformation products that statement is based on toxicological testing for, as opposed to assumed by analogy. A "less toxic" characterization applied across eighteen distinct chemical entities on the strength of testing for only a handful of them is not the scientifically-based, chemical-specific approach s. 19(2) requires, particularly given that several of these transformation products are, per Part III below, substantially more persistent than the parent compound itself.

Fourth, as set out in the Background above, EFSA published formal TFA-specific reference values on 21 July 2026, one month before this consultation opened. Health Canada's own epyrifenacil reference values are close to EFSA's revised TFA-specific figures on one measure and diverge sharply on the other: epyrifenacil's ADI (0.01 mg/kg bw/day, derived from an oncogenicity NOAEL — see Part II.A) sits just below EFSA's TFA ADI of 0.014 mg/kg bw/day (itself a reduction of more than 70% from EFSA's prior TFA reference value of 0.05 mg/kg bw/day (2024), reflecting a sharp precautionary tightening in under two years), while epyrifenacil's own ARfD for females 13–49 years (0.02 mg/kg bw, s. 3.2.3, p. 21) is more than three times lower than EFSA's newly established TFA acute reference dose of 0.07 mg/kg bw. This numerical proximity on the ADI measure is coincidental rather than substantive: epyrifenacil's ADI and ARfD are derived from an oncogenicity endpoint and a developmental endpoint respectively, neither of which is the thyroid-hormone-disruption endpoint underlying EFSA's TFA values. Closeness in magnitude between values derived from unrelated endpoints cannot substitute for an actual TFA-specific risk assessment — particularly given that TFA is present in the relevant field trial samples at levels far above its own LOQ while the parent compound is not. PRD2026-13 applies no TFA-specific reference value to the TFA residues quantified in its own field trial data, notwithstanding TFA's exclusion from the residue definition.

This is not a hypothetical concern. Flufenacet — a herbicide registered in Canada and named among the TFA-precursor pesticides identified in background research supporting SFM's cyclobutrifluram submission — was found by EFSA (27 September 2024) to be an endocrine disruptor whose use drives high TFA concentrations in groundwater and, ultimately, drinking water. On this basis, the European Commission declined to renew flufenacet's EU approval: Commission Implementing Regulation (EU) 2025/910 of 20 May 2025, in force from 10 June 2025, required EU member states to withdraw all flufenacet product authorizations by 10 December 2025, with only a stock-depletion grace period running to 10 December 2026.

This is not an isolated action. Pesticide Action Network Europe has since filed a formal internal review request with the European Commission covering **28 PFAS-class pesticide active substances** — every EU-approved active ingredient containing at least one trifluoromethyl (–CF_3) group — invoking Articles 21 and 69 of Regulation (EC) No. 1107/2009. That request rests on the same mechanism the Commission itself applied to reject flufenacet's renewal: under the EU's guidance on the relevance of metabolites in groundwater, any groundwater metabolite that qualifies for CLP classification as reproductively toxic is automatically deemed a "relevant metabolite," triggering the strict 0.1 µg/L groundwater limit under Annex II, point 2.5.1.2 of Regulation 1107/2009, and a failure of Article 4(3)(b)'s approval criteria if that limit is predicted to be exceeded. The Commission has already reached that conclusion for flufenacet; PAN Europe's request asks the Commission to apply the same reasoning across the full class of TFA-generating pesticides now that TFA itself qualifies for reprotoxic classification — a request the Commission has not yet ruled on for the other 27 substances. Separately, Denmark has already withdrawn market authorization for 23 PFAS pesticide products on its own initiative, ahead of any EU-wide decision, following its own "TriFluPest" assessment (with the Geological Survey of Denmark and Greenland) of six PFAS active substances used in 33 pesticide products.

This has a direct and immediate application to compounds already before the Directorate. Denmark's withdrawal, effective 15 July 2025, covered products containing fluazinam, fluopyram, diflufenican, mefentrifluconazole, tau-fluvalinate, and flonicamid — specifically because of TFA formation and groundwater contamination. **All six of these active ingredients are registered pest control products in Canada** (fluazinam is named in PRD2026-13, s. 3.8 itself as a TFA-precursor pesticide registered in Canada; fluopyram and mefentrifluconazole — the latter marketed as Revysol/Cevya/Maxtima — carry active PMRA registrations; diflufenican was the subject of a 2023 Canadian registration proposal alongside its MRL consultation, PMRL2023-39; flonicamid is registered as Beleaf 50SG Insecticide, PCP Registration No. 29796, with PMRA label expansions through at least 2018; tau-fluvalinate (CAS No. 102851-06-9) has three associated Canadian products and is currently the subject of an ongoing PMRA re-evaluation, per Health Canada's own Pesticide Product Information Database). Denmark is a founding member country of the Organisation for Economic Co-operation and Development, having ratified the OECD Convention on 30 May 1961. Section 17(2) of the PCPA provides that "when a member country of the Organisation for Economic Co-operation and Development prohibits all uses of an active ingredient for health or environmental reasons, the Minister shall initiate a special review of registered pest control products containing that active ingredient" — a **mandatory, non-discretionary duty** the Federal Court confirmed the Minister cannot decline to exercise once a qualifying foreign ban is confirmed (*Équiterre and David Suzuki Foundation v. Canada (Minister of Health)*, Federal Court, 17 May 2016). Denmark's national withdrawal of all six active ingredients' authorizations, for the same TFA, groundwater, and reproductive-toxicity reasoning underlying this entire submission, appears to satisfy the elements of s. 17(2) for each of them. As Europe's regulatory treatment of TFA-generating pesticides continues to tighten, epyrifenacil itself is likely to face comparable scrutiny if and when an EU approval is ever sought. SFM is not aware of any indication that the Directorate has initiated, or intends to initiate, special reviews of these six active ingredients on this basis.

Under the law as set out by the Supreme Court of Canada in *Vavilov*, 2019 SCC 65, the Directorate's assessment should explain why epyrifenacil's TFA-generating profile is treated differently from the class-wide treatment a peer regulatory system has applied to chemically equivalent precursor pesticides for the same underlying reason, and why compounds already subject to a foreign OECD-member prohibition have not triggered the Directorate's own mandatory review obligations.

The regulatory uncertainty this creates for TFA-precursor pesticides generally is the subject of recent academic analysis (see, e.g., the December 2025 review of regulatory decision-making under uncertainty for TFA and its precursors, Science of the Total Environment), and the rapid review of human TFA exposure data by Wipplinger et al. (2025) confirms that some documented acute human exposures already approach or exceed currently proposed threshold values, even as the authors caution that no study to date demonstrates clinically relevant effects attributable to TFA at those exposures. An active, evolving body of science on the compound Health Canada has excluded from epyrifenacil's residue definition should be addressed rather than left unmentioned.

Fifth, the availability of a TFA-specific reference value exposes a methodological flaw that runs through the Directorate's TFA-precursor assessments generally, not only this one. In PRD2025-06 (cyclobutrifluram), Health Canada dismissed TFA's dietary contribution as low on the basis that it represented "1% of the ADI and <0.04% of the ARfD *of cyclobutrifluram*" — that is, TFA exposure was measured against *cyclobutrifluram's own* toxicological reference values, not against any reference value for TFA itself, because none existed at the time. That denominator was never correct even on its own terms: a transformation product's exposure should be assessed against a reference value reflecting *its own* toxicological profile, not the unrelated profile of the parent compound whose registration happens to be under review. Now that EFSA has established TFA-specific values (ADI 0.014 mg/kg bw/day; ARfD 0.07 mg/kg bw/day), the same modelled TFA exposure figures underlying PRD2025-06's "1% of the ADI" conclusion can and should be recalculated against TFA's own reference values rather than cyclobutrifluram's.

This is directly relevant beyond the present consultation: SFM is currently pursuing Federal Court judicial review of the registration decisions for cyclobutrifluram (T-221-26) and isocycloseram (T-980-26), both of which rest in part on the same "low percentage of the *parent compound's* ADI/ARfD" framing for TFA exposure. If EFSA's TFA-specific reference values show materially higher fractional exposure when TFA's own modelled dietary intake is measured against TFA's own ADI and ARfD, rather than against the unrelated parent compound's values, that bears directly on the reasonableness of the TFA dismissals underlying both of those registration decisions, in addition to the epyrifenacil assessment now before the Directorate.

SFM requests that Health Canada disclose how many field trial results for each commodity were at versus above the limit of quantification, and what statistical method, if any, was applied to derive the proposed MRLs from that dataset; confirm whether the pending TFA cumulative human health risk assessment will be completed before further TFA-precursor pesticides are registered; explain why TFA is excluded from the residue definition despite its quantifiable presence in the same field trial samples; state whether EFSA's July 2026 TFA-specific reference values were considered in

the epyrifenacil assessment; recalculate epyrifenacil's own modelled TFA dietary exposure against EFSA's TFA-specific ADI and ARfD rather than against epyrifenacil's own reference values; explain why the EU's regulatory response to flufenacet — non-renewal driven materially by TFA-related findings — does not warrant equivalent scrutiny of epyrifenacil's own TFA-generating profile; and confirm whether Denmark's 15 July 2025 withdrawal of market authorization for fluazinam, fluopyram, diflufenican, mefentrifluconazole, tau-fluvalinate, and flonicamid — for TFA and groundwater contamination reasons — has triggered, or will trigger, mandatory special reviews of those six active ingredients' Canadian registrations under PCPA s. 17(2). SFM further requests that Health Canada disclose the analytical basis for concluding TFA "did not form" in soil metabolism studies where TFA was not analyzed; reconcile its treatment of the confined rotational crop TFA finding as an unrealistic "worst-case" artifact with its reliance on worst-case, conservative assumptions as the appropriately protective methodology elsewhere in this same document; explain why an elevated TFA background is treated as a reason to exclude epyrifenacil's own contribution rather than a reason for greater caution; confirm whether the registration decision can meet the "reasonable certainty of no harm" standard in PCPA s. 2(2) given the admitted absence of a comprehensive understanding of TFA formation and degradation pathways across CF3-containing chemicals; and disclose which of epyrifenacil's 18 major transformation products have independent toxicological testing, as distinct from environmental fate characterization alone, underlying the conclusion that they are less toxic than the parent. SFM also requests that Health Canada confirm whether epyrifenacil has been assessed against the OECD's 2021 PFAS definition or an equivalent structural criterion, and if it has not been so classified, explain the basis on which a narrower approach was applied given the protective purpose of the PCPA.

G. Dietary exposure from the co-formulated product is not assessed in aggregate, and one of its two co-active ingredients falls entirely outside the cumulative framework applied to the other

V-10488 0.94 SE Herbicide is a co-formulation of epyrifenacil with two already-registered active ingredients, flumioxazin and pyroxasulfone (PRD2026-13, p. 4). PRD2026-13 states that residues of the two co-active ingredients in commodities treated with V-10488 "will be covered under the existing MRLs for each active ingredient" (p. 4) — that is, each of the three co-applied active ingredients is assessed against its own, separately derived MRL and reference values. No combined or aggregate dietary exposure calculation is performed for a consumer eating a commodity that was, in fact, treated with all three active ingredients simultaneously, from the same tank mixture, on the same field, on the same day.

For epyrifenacil and flumioxazin, this gap is partially — though, per Part II.C above, imperfectly — addressed: flumioxazin is a PPO inhibitor and is one of the active ingredients included in the Section 3.7 cumulative assessment for PPO inhibitors alongside epyrifenacil (s. 3.7.1, p. 31). Pyroxasulfone, however, is a Group 15 (very-long-chain fatty acid synthesis inhibitor) herbicide with an entirely different mode of action, and does not appear anywhere in the Section 3.7 cumulative assessment. Pyroxasulfone's contribution to a V-10488-treated commodity is therefore assessed in complete isolation, with no aggregate or combined exposure calculation

linking it to the simultaneous epyrifenacil and flumioxazin residues in the same commodity, despite all three arising from a single co-formulated product application.

This gap extends to occupational exposure. Appendix I notes that "the mitigation measures required for V-10488 0.94 SE Herbicide were driven by the risk assessments of the co-formulated active ingredients flumioxazin and pyroxasulfone" (p. 92) — meaning the label's personal protective equipment requirements for the co-formulated product are set by whichever single active ingredient's individual risk assessment is most restrictive, not by a combined toxicological evaluation of a worker's simultaneous dermal, inhalation, and oral exposure to all three active ingredients as actually mixed, applied, and encountered in the field.

SFM requests that Health Canada disclose whether an aggregate dietary exposure assessment has been, or will be, performed for consumers of commodities treated with V-10488 0.94 SE Herbicide that accounts for simultaneous residues of epyrifenacil, flumioxazin, and pyroxasulfone, and explain why pyroxasulfone — co-formulated and co-applied with epyrifenacil and flumioxazin in the same product — is excluded from any cumulative or combined exposure framework applied to the other two active ingredients.

H. Repeat-dose toxicology shows consistent hematotoxicity across every species and route tested, including inhalation, without a dedicated ground of its own

PRD2026-13, s. 3.1.1 (pp. 14-16) reports that repeat-dose toxicity studies in mice, rats, and dogs consistently identify microcytic hypochromic anemia (decreased red blood cell count, hemoglobin, and hematocrit) via the oral, dermal, and inhalation routes of exposure. This hematotoxicity is not an isolated finding: it is the toxicological event from which the liver effects addressed in Part II.B above, and much of the compound's overall toxicological profile, are understood to follow, consistent with the shared heme-biosynthesis mechanism underlying the PPO-inhibitor cumulative assessment in Part II.C above. Notwithstanding its centrality to epyrifenacil's toxicological profile, PRD2026-13 does not address this finding as a distinct hazard in its own right anywhere in the document's discussion of risk characterization.

A 90-day rat inhalation study additionally found "degeneration and inflammatory cell infiltrate and/or squamous metaplasia of the olfactory epithelium in nasal turbinates" (s. 3.1.1, p. 16) - direct, portal-of-entry respiratory tract damage from repeated inhalation exposure, separate from the systemic hematotoxicity described above. This finding is directly relevant to occupational and bystander inhalation exposure during mixing, loading, and application, and to Part II.G above regarding the co-formulated product's combined exposure profile.

SFM requests that Health Canada disclose a dedicated hazard characterization of epyrifenacil's hematotoxicity, addressing its consistency across species and exposure routes, its relationship to the liver and cancer findings addressed elsewhere in this assessment, and its relevance to the point of departure selected for the ADI and ARfD.

I. Epyrifenacil is absorbed and translocated into the harvested food commodity, and the relevance of shared plant-human enzyme targets to the human and animal gut microbiome is not addressed

Unlike most PPO-inhibitor herbicides, epyrifenacil is translocated systemically within treated plants (s. 2.0, p. 4; s. 4.1, p. 35). PRD2026-13's own confined rotational crop metabolism study confirms this is not limited to the target weeds: epyrifenacil is applied as a pre-plant soil spray and is subsequently detected, via total radioactive residue analysis, in soybean forage, hay, green pods, and mature seed (s. 3.5.1, p. 27) - that is, in the harvested food and feed commodity itself, following root uptake and translocation from treated soil.

PRD2026-13 does not address the relevance of this finding to the human or animal gut microbiome. Protoporphyrinogen oxidase, the enzyme epyrifenacil and its class inhibit, and related plant-specific metabolic pathway enzymes, are present not only in plants but in bacteria and fungi that colonize the human and animal gut, and are accordingly recognized in the current scientific literature as plausible targets of herbicide activity in the gut microbiome (see, e.g., the 2026 review of shared plant-human biology and herbicide effects cited in the References below). SFM does not suggest this literature establishes a specific finding of harm; it submits that a systemically translocated, gut-microbiota-relevant compound found in the harvested seed of a treated food crop warrants inquiry and a risk assessment of this pathway that PRD2026-13 does not provide.

SFM requests that Health Canada disclose whether the potential effects of epyrifenacil, or its transformation products, on the human or animal gut microbiome were considered in this assessment, given the compound's confirmed translocation into the harvested seed and the recognized relevance of its molecular target to gut microbial enzymes.

Part III: Environmental Assessment Deficiencies

A. The TSMP Track 1 conclusion blends the parent's rapid dissipation with individual transformation products that independently meet the persistence criterion, rather than assessing each substance on its own data

PRD2026-13, s. 6.1 (p. 50) concludes that "epyrifenacil and its transformation products do not meet all of the TSMP Track 1 criteria," assessed per Regulatory Directive DIR99-03 against the policy's four criteria: persistence (in air, soil, water and/or sediment), bioaccumulation, predominantly anthropogenic origin, and CEPA toxicity. SFM does not contest the TR/DT50 methodology applied in Appendix I's environmental fate tables, which is consistent with DIR99-03. SFM does contest the conclusion reached from that methodology.

Appendix I, Table 27 shows that the CEPA-toxic-equivalent and predominantly-anthropogenic criteria are both met for epyrifenacil's transformation products, not only for epyrifenacil itself. On persistence, Table 27's own DT50 data show that several individual transformation products

independently exceed the Track 1 soil persistence threshold of 182 days: S-3100-CA-RD (24.5-471 days, meeting the threshold in 2 of 4 available values), S-3100-DA (58.5-1515 days, meeting the threshold in 2 of 3 available values), S-3100-CA-UR (578-6207 days, meeting the threshold on all available values), and S-3100-DA-RD (357-718 days, meeting the threshold on all available values). S-3100-CA-UR separately exceeds the water/sediment persistence threshold of 182 days (104-717 days). TFA and 1,1,1-trifluoroacetone both exceed the atmospheric persistence threshold of 2 days (predicted half-lives of 20.6 and 715 days, respectively). Table 27 also records, for several transformation products, that DT50 data are simply "not available" against one or more Track 1 criteria - the assessment proceeds without data to evaluate certain transformation products against certain criteria at all.

PRD2026-13's narrative conclusion (s. 6.1, p. 50) is nonetheless a single, blended statement for "epyrifenacil and its transformation products" as a set, rather than a substance-by-substance determination. Each transformation product is a distinct chemical entity with its own persistence, bioaccumulation, and toxicity profile; averaging or blending the parent's genuinely rapid dissipation together with individual transformation products that independently satisfy the Track 1 persistence criterion allows the parent's favourable profile to carry transformation products that, assessed on their own data, would not receive the same conclusion. TFA itself illustrates this: it is characteristically persistent and mobile in the environment independent of its parent - properties the RAC has found sufficient to classify TFA itself, as a standalone substance (CAS No. 76-05-1; EC No. 200-929-3; CLP index No. 607-091-00-1), as very Persistent and very Mobile (vPvM), alongside Reproductive Toxicity Category 1B, following the German competent authorities' (BAuA/UBA/BfR) CLH dossier and the RAC-77 opinion of 1-5 June 2026 (see Background, above). A substance-level TSMP determination specific to TFA, or to any of the individually-persistent transformation products identified in Table 27, does not appear in PRD2026-13; each is instead folded into the blended parent-plus-transformation-products conclusion.

SFM submits that treating a confirmed Track 1 persistence finding for an individual transformation product as resolved by the parent's more favourable profile - rather than by the substance-specific virtual-elimination response the TSMP calls for - is not a legitimate application of the policy. A transformation product does not become less persistent, less anthropogenic, or less toxic because the parent compound that generates it happens to dissipate quickly.

SFM requests that Health Canada disclose a substance-by-substance TSMP Track 1 determination for each transformation product identified in Table 27 as independently meeting one or more Track 1 criteria, rather than a single blended conclusion for epyrifenacil and its transformation products as a set; confirm whether TFA has been, or will be, separately assessed against the TSMP Track 1 criteria as a persistent transformation product common to multiple registered pesticides, independent of its assessment as a metabolite of any single active ingredient; and disclose the transformation products for which Track 1 persistence data are recorded as "not available" and whether that data will be obtained.

B. Risk to non-target terrestrial plants and other terrestrial organisms is mitigated only by an exceptionally large buffer zone, unverified label statements, and property-based predictions the data do not support

PRD2026-13, s. 4.2.1 (pp. 39–40) reports screening-level risk quotients (RQs) for non-target terrestrial plants of **16 to 1839** — as much as 1,839 times the Level of Concern (LOC) of 1 — for both seedling emergence and vegetative vigour, based on the most sensitive species tested (tomato). After refining the assessment to account for spray drift one metre downwind of application, RQs remained at **1.0 to 1103**. The Directorate's response to this exceedance is a spray buffer zone of **up to 275 metres**, on the basis of which "risks to non-target terrestrial plants are acceptable with the inclusion of spray buffer zones" (s. 4.2.1, p. 40).

SFM notes that the refined RQ of up to 1103 was calculated at only one metre downwind of application - the only distance PRD2026-13 actually models - and that the 275-metre figure is an extrapolation from that single modelled point, not itself a directly modelled or tested distance. A 275-metre radius is, in practical terms, a requirement that no sensitive non-target plant exist within roughly a quarter-kilometre of the treated field in the relevant downwind direction. SFM submits this is difficult to reconcile with the realities of Canadian farmland, where shelterbelts, hedgerows, roadside vegetation, waterway margins, and neighbouring properties routinely fall within that distance of a field boundary. PRD2026-13's own governing methodology statement (s. 4.2, p. 37) explains that "refinements to the risk assessment continued until the risk was adequately characterized or the available data did not permit further refinements" - **treating the exhaustion of available data as equivalent to a finding that risk is adequately characterized**. SFM submits these are not the same thing: an inability to refine further because the data run out is a **data gap**, not a demonstration of reasonable certainty of no harm under PCPA s. 2(2).

SFM does not contest the underlying toxicity data or the buffer-zone methodology in the abstract. SFM notes, however, that a 275-metre buffer zone is an unusually large mitigation distance, and that PRD2026-13 does not address whether it is practically achievable on the range of field configurations found in Canadian agriculture. Epyrifenacil's proposed uses include pre-plant and burndown applications on field crops via both ground and aerial application — the latter being the use pattern associated with the largest spray drift factor (60% for non-crop areas) and, correspondingly, among the largest RQs. A 275-metre buffer exceeds the width of many Canadian field parcels in at least one dimension, and **would functionally preclude treatment of substantial portions of a field** adjacent to any boundary, shared fence line, hedgerow, waterway, or neighbouring property within that distance — including neighbouring organic operations, for which off-field drift of a herbicide at phytotoxic concentrations carries additional regulatory consequences under organic certification standards. PRD2026-13 does not disclose how compliance with a mitigation measure of this magnitude is to be verified, **nor does the value assessment at s. 5.0 (see Part IV.A, above) address whether the practical land-use constraint imposed by a 275-metre buffer is consistent with the efficacy and utility claims made for the product.**

SFM further notes that modelled spray-drift buffer distances of this kind can diverge substantially from buffer distances subsequently validated under realistic field conditions. In a published, peer-reviewed field study, a modelled buffer requirement of 304 metres for the herbicide isoxaflutole

— derived using the same type of screening-level spray drift modelling approach applied to epyrifenacil — was found, when tested under realistic field conditions, to overstate the distance actually required to protect non-target plants by roughly 30-fold, with a validated buffer of 9.14 metres found sufficient even under worst-case bare-ground conditions (*Integrated Environmental Assessment and Management* 2022;18:757–769). SFM does not suggest this precedent applies to epyrifenacil without further information; it may cut in either direction, and epyrifenacil's substantially higher screening RQs relative to isoxaflutole's could equally indicate that field validation would confirm, rather than reduce, the modelled distance. SFM's point is narrower: given that modelled and field-validated buffer distances have been shown to diverge by an order of magnitude for at least one other herbicide, an untested modelled distance of 275 metres should not be treated as self-evidently accurate in either direction without disclosure of whether any field-validation data exists or is planned for epyrifenacil.

PRD2026-13's environmental fate data undermine confidence in the property-based predictions the assessment relies on elsewhere. Several major transformation products were measured in higher concentrations in sediment than in water during aquatic biotransformation studies, which PRD2026-13 itself describes as "contrary to what is expected based on their physical and chemical properties" (s. 4.1, p. 36) - all of the relevant transformation products are water-soluble with low log Kow and low Koc/Kd values, properties that predict the opposite partitioning behaviour to what was actually observed. Having conceded that property-based predictions failed for partitioning, PRD2026-13 nonetheless relies on the same type of property-based prediction, *without independent empirical confirmation*, to conclude that the transformation products are not expected to bioaccumulate ("based on their log Kow values (all less than 2)," s. 4.1, p. 36) - the only empirical bioaccumulation study conducted was on the parent compound alone, in bluegill sunfish. SFM submits that a property-based prediction which has already been shown not to hold for these same transformation products' partitioning behaviour warrants independent empirical confirmation before being relied on again, in the same paragraph, for a different property of the same compounds.

PRD2026-13 further confirms that TFA and 1,1,1-trifluoroacetone, unlike epyrifenacil and its other transformation products, "have intermediate to high volatilities" and are "expected to be slightly volatile from water surfaces and moist soils" (TFA) or "rapidly lost from a water surface or moist soil" (1,1,1-trifluoroacetone) (s. 4.1, p. 36). This atmospheric mobility is a distinct exposure and persistence pathway from the aquatic and groundwater pathways addressed elsewhere in this submission, and confirms that TFA generated by epyrifenacil use is capable of entering the same atmospheric transport and redeposition cycle already implicated as a major source of environmental TFA loading generally.

PRD2026-13 separately concludes that, while epyrifenacil itself is not expected to leach to groundwater, its major transformation products may do so, "based on the available weight-of-evidence" (s. 4.1, p. 35-36), and that the response to this finding is "a precautionary label statement to inform users to avoid the use of products containing epyrifenacil in areas where the soils are permeable, particularly where the water table is shallow." SFM submits that a label statement of this kind is advisory language, not a verified mitigation measure, for the same reasons set out above regarding the 275-metre buffer zone: PRD2026-13 does not disclose how

compliance with this instruction is verified. Groundwater is also a direct source of drinking water, so an unverified mitigation measure for transformation product leaching to groundwater bears on human health exposure (see Part II, above) and not solely on environmental risk.

Gaps of the same character recur across the terrestrial organism assessments generally. For earthworms, the submitted 56-day toxicity test could not capture transformation products expected to form or persist beyond that window (identified as 4"-OH-S-3100-CA, S-3100-CA-RD, and S-3100-CA-UR); PRD2026-13 concedes that "the toxicity of these major [transformation products] to earthworms was not investigated" (s. 4.2.1, p. 38) and resolves this by comparing the worst-case soil EEC for the rapidly-dissipating parent compound to the earthworm NOEC - a comparison that does not speak to the toxicity of the untested, and in several cases far more persistent (see Part III.A, above), transformation products that replace the parent in soil. For bees, PRD2026-13 discloses that "adverse effects on survival were observed in the larval toxicity and adult chronic toxicity laboratory tests" notwithstanding the compound's classification as "practically non-toxic to adult bees on an acute contact basis" (s. 4.2.1, p. 39) - a classification that rests on an exposure-margin argument rather than an absence of demonstrated lethality. For birds and small wild mammals, the screening-level risk quotients reach as high as 0.76 against a Level of Concern of 1 (s. 4.2.1, p. 39) - below the LOC, but with a materially narrower margin than most other endpoints in this assessment.

SFM requests that Health Canada disclose the basis for concluding that a 275-metre buffer zone is a practically achievable and enforceable mitigation measure across the range of Canadian field configurations and application methods for which epyrifenacil is proposed, including aerial application given that consideration is to be given to labels in an assessment; confirm what compliance verification mechanism, if any, applies to buffer zones of this magnitude; and disclose whether any field-validation study of the modelled buffer distance exists or is planned for epyrifenacil. SFM further requests that Health Canada disclose the empirical basis, beyond log Kow prediction alone, for the conclusion that epyrifenacil's transformation products do not bioaccumulate, given the same property-based approach did not correctly predict their sediment/water partitioning behaviour; address the atmospheric transport and redeposition implications of TFA and 1,1,1-trifluoroacetone's volatility; disclose the compliance verification mechanism, if any, for the groundwater-leaching label statement; and disclose the toxicity data for the transformation products not captured by the 56-day earthworm test window.

C. Aquatic runoff risk exceedances are dismissed by qualitative narrative, the marine/estuarine refinement rests on an unverified assumption, and groundwater-dependent ecological risk is not assessed

PRD2026-13, s. 4.2.2 (pp. 43–44) reports that runoff modelling using PWC version 2.0 produced screening-level RQs exceeding the LOC for amphibians, freshwater and estuarine/marine fish, freshwater algae, saltwater mysids, and marine diatoms — with a maximum RQ of 39 for freshwater algae and marine diatoms, and 27 for amphibians, under the highest-exposure modelled scenario (two applications of 40 g a.i./ha to bare ground in Prince Edward Island).

PRD2026-13 resolves these exceedances by asserting, rather than demonstrating, that the risk assessment "likely overestimates risk." The stated basis is that the modelled combined residue (epyrifenacil plus three transformation products, S-3100-CA, S-3100-DA, and S-3100-DP) was compared against toxicity effects metrics for epyrifenacil alone — the most toxic of the four — when, in the Directorate's own words, "the EEC would consist mostly of [transformation products] rather than epyrifenacil" given the parent's rapid environmental dissipation, and the dominant transformation product (S-3100-CA) is reported as 9 to 18 times less toxic than epyrifenacil to the relevant taxa (s. 4.2.2, p. 44). SFM does not dispute that comparing a mixed-residue exposure against the most toxic single component may in principle be a conservative and protective approach, but a scientifically based approach requires explanation of the transformation-product-weighted recalculation needed to demonstrate — rather than assert — that risk is in fact acceptable once the actual composition of the modelled residue is accounted for. A qualitative expectation that real-world risk is lower than the screening estimate is not a substitute for the quantified refinement PRD2026-13 performs elsewhere in this same document (for example, the spray-drift refinements at s. 4.2.1 and s. 4.2.2) when resolving other LOC exceedances.

PRD2026-13's marine/estuarine spray-drift refinement rests on an unverified hydrological assumption. Freshwater spray buffer distances are calculated assuming exposure from multiple applications; the estuarine/marine refinement instead considers only a single application, on the basis that "small, salt marshes are expected to be flushed/recharged by tidal action" such that "spray drift from multiple applications are not expected to accumulate" (s. 4.2.2, p. 42). This assumption is asserted without site-specific hydrological data, and is not obviously true of every estuarine or marsh configuration the label's use pattern could reach - restricted-flow, diked, or otherwise low-exchange marshes would not necessarily flush on the timescale the assumption requires. Spray buffer zones of up to 125 metres are required for freshwater habitat on this same refined basis (s. 4.2.2, p. 42), a distance subject to the same practical enforceability concerns raised for the 275-metre terrestrial buffer in Part III.B above.

The runoff risk assessment for aquatic organisms (Appendix I, Table 25) is expressly limited to "residues in surface water from runoff." PRD2026-13's separate groundwater modelling (s. 3.5.2, discussed in Part II, above) addresses drinking water exposure for human health purposes only; it is not an assessment of ecological risk to groundwater-dependent aquatic organisms or ecosystems, such as groundwater-fed wetlands or hyporheic zone communities, from the same transformation products already identified as capable of leaching to groundwater (Part III.B, above). SFM was unable to identify any ecological risk assessment addressing this pathway in PRD2026-13.

SFM requests that Health Canada disclose a transformation-product-weighted quantitative recalculation of the runoff risk assessment for amphibians, freshwater and estuarine/marine fish, freshwater algae, saltwater mysids, and marine diatoms, rather than a qualitative assertion that the screening-level and unrefined runoff RQs overestimate actual risk. SFM further requests that Health Canada disclose the site-specific hydrological basis for assuming tidal flushing prevents accumulation of spray drift residues in all estuarine and marsh habitats within the scope of the proposed label, and disclose whether ecological risk to groundwater-dependent aquatic organisms and ecosystems from transformation product leaching has been, or will be, assessed.

D. PRD2026-13 does not address species at risk, including a formal adverse-effects finding already reached by the agency whose data package it relies on

PRD2026-13 does not mention species at risk, the *Species at Risk Act* (SARA), or any equivalent consideration anywhere in its environmental risk characterization. This is notable in light of the United States Environmental Protection Agency's own Endangered Species Act Biological Evaluation for epyrifenacil, conducted using the same "concurrently" reviewed data package PRD2026-13 itself relies on for its residue chemistry and toxicology conclusions (see Background, above). USEPA's Biological Evaluation concluded that the proposed use of epyrifenacil products "may affect and are likely to adversely affect multiple listed species and designated critical habitats," and USEPA's final registration includes mitigation measures specifically addressing this finding, including spray drift buffers and runoff/erosion mitigation points tied to the presence of listed species and critical habitat.

Two of the species USEPA found likely to be adversely affected are themselves species Canada has extended its own domestic legal protection to. Of the 33 listed salmonid fish USEPA determined would be likely adversely affected by epyrifenacil use through effects to aquatic and wetland plants constituting juvenile habitat, Atlantic salmon (Salmo salar) is among them, assessed under joint U.S. Fish and Wildlife Service/National Marine Fisheries Service jurisdiction given its Atlantic coastal range. The inner Bay of Fundy population of Atlantic salmon has been listed as Endangered under Schedule 1 of the Species at Risk Act since SARA came into force in June 2003, with a final Recovery Strategy and a subsequent Action Plan in place. Bull Trout (Salvelinus confluentus), also among USEPA's likely-to-be-adversely-affected species, has its Saskatchewan-Nelson Rivers populations listed as Threatened under SARA Schedule 1 since 2019, with a final Recovery Strategy (2020) and a Critical Habitat Protection Order made under s. 58(4)-(5) of SARA (Canada Gazette, Part II, 31 March 2021). Neither the Directorate's environmental risk assessment in PRD2026-13, nor its Part 3.8 discussion of TFA-precursor pesticides, addresses Atlantic salmon, Bull Trout, or any other species listed under SARA.

Health Canada has itself acknowledged that its environmental risk assessments warrant strengthening on this point. Following the 2022 targeted review of the *Pest Control Products Act*, Health Canada's Notice of Intent NOI2023-01 (June 2023) and the subsequent Canada Gazette, Part I proposal (15 June 2024) both proposed giving the Minister of Health "explicit authority to require registrants and applicants to submit available information on species at risk" — an acknowledgement that species-at-risk information is relevant to the Directorate's risk assessments and that the Minister's authority to obtain it should be strengthened. PMRA has, in other individual pesticide assessments, considered species-at-risk information as part of its environmental risk characterization; PRD2026-13 does not indicate that any such consideration occurred here, nor does it engage with USEPA's contrary finding on the same active ingredient.

SFM requests that Health Canada confirm whether species-at-risk information, including USEPA's Endangered Species Act finding that epyrifenacil use is likely to adversely affect multiple listed species and designated critical habitats, was considered in the preparation of PRD2026-

13, and if not, explain why information already generated by the agency whose residue and toxicology data this assessment relies upon was not reviewed.

Part IV: Value Assessment Deficiencies

A. The value assessment omits the mandatory health, safety and environmental benefits and social/economic impact components of PCPA s. 2(1)

PRD2026-13, s. 5.0 (pp. 45–49) addresses only efficacy (support for burndown and residual weed control claims) and, briefly, resistance management (Group 14 mode of action, integrated pest management fit). "Value" as defined by subsection 2(1) of the *Pest Control Products Act* is the product's actual or potential contribution having regard to its condition of registration, including its efficacy *and* "its health, safety and environmental benefits and social and economic impact." Neither the health, safety and environmental benefits component, nor the social and economic impact component, is addressed anywhere in s. 5.0 of PRD2026-13.

SFM requests that Health Canada complete the value assessment required by PCPA s. 2(1) by addressing epyrifenacil's health, safety and environmental benefits and its social and economic impact, and make that analysis available for public comment before any final registration decision issues.

B. The value assessment does not address the market-access and trade risk created by epyrifenacil's MRLs matching United States tolerances with no Codex or European Union equivalent

The "social and economic impact" component of value under PCPA s. 2(1) — already shown above to be entirely absent from PRD2026-13's value assessment — should, at a minimum, address the market-access risk created by registering epyrifenacil on residue limits matched to United States tolerances (see Background and Part II.F, above) with no Codex Alimentarius MRL and no European Union approval of any kind. This risk is not speculative. The European Commission's Joint Research Centre published a study on 11 August 2026 examining the economic impact of lowering European Union import tolerances, for 18 specific hazardous pesticide active substances not approved in the EU, to the limit of quantification. Epyrifenacil, as a new active ingredient with no EU trade or monitoring history, is not and could not be among those 18 substances; SFM relies on the study for the direction of European Union policy and Canada's demonstrated exposure as an exporting nation, not as a finding specific to epyrifenacil. On that basis, the study found that, under its most severe modelled scenario, Canada is one of 14 countries with more than US$1.4 billion in exports of the affected commodities at risk, with lentils identified among the commodities most exposed. The Joint Research Centre itself notes that this study "does not meet the requirements of a full [Impact Assessment] as set out in the Better Regulation Guidelines," and is a preliminary economic analysis preceding any formal

impact assessment the European Commission may conduct — SFM relies on it accordingly, as an indication of policy direction and demonstrated Canadian exposure, not as a concluded EU legal or economic determination.

This is not a hypothetical risk for Canadian agricultural exports generally, or for epyrifenacil specifically. In 2018, Canada's Pest Management Regulatory Agency raised the maximum residue limit for diquat on dried peas and beans from 0.2 ppm to 0.92 ppm to match the United States tolerance; the European Union's limit remained at 0.2 ppm, the figure Canada abandoned. That gap surfaced directly in the December 2025 recall of Canadian lentil products in France over diquat residue. Canada's own pesticide export compliance program, Keep It Clean, acknowledges that "although a pesticide may be registered in Canada on a certain crop type, there can be market access issues" in export markets, and that shipments "containing even the smallest amount of unacceptable pesticide residue can be rejected, causing millions of dollars in losses" — a live concern given that Canada exports more than 90% of the canola it produces, one of the crops for which epyrifenacil proposes an MRL.

The risk is heightened, not lessened, by epyrifenacil's status as a TFA-generating pesticide. As set out at length in Part II.F above, the European Union treats any groundwater metabolite that qualifies for reprotoxic classification as automatically "relevant" for groundwater regulatory purposes, triggering a strict statutory limit; EFSA's July 2026 TFA-specific reference values, ECHA's confirmed classification of TFA as reproductively toxic, and the European Commission's non-renewal of flufenacet's approval collectively signal that TFA-generating pesticides are an area of active and tightening regulatory scrutiny in Canada's export markets — precisely the dynamic that produced the diquat/lentil recall. Registering a new TFA-generating active ingredient on US-matched residue limits, without Codex or EU equivalence, creates the same category of exposure for Canadian growers and exporters of soybean, corn, wheat, and canola treated with epyrifenacil.

This trade risk is not a one-time or self-correcting exposure. Because several of epyrifenacil's transformation products are, per Part III.A above, persistent in soil for periods extending to years, **a single season's use has consequences extending well beyond that season**, both agronomically (see below) and in terms of the residue and TFA burden left behind. A market-access risk created now, from a single year's registration and use, does not end when that year's crop is sold; it recurs, and potentially compounds, for as long as the persistent residues remain detectable and as long as export markets continue tightening their standards for TFA-generating pesticides. SFM submits that value under PCPA s. 2(1) cannot be assessed on a single-season efficacy basis alone when the trade and environmental consequences of a single season's use are multi-year.

SFM requests that Health Canada's value assessment address the market-access and trade risk arising from registering epyrifenacil on residue limits matched to United States tolerances with no Codex or European Union equivalent, including the risk of shipment rejection or recall in markets applying stricter or TFA-specific standards, consistent with the precedent already realized in the December 2025 diquat/lentil recall, and address the multi-year nature of that risk given the persistence of several of epyrifenacil's transformation products.

C. The value assessment's efficacy and rotational-crop claims are not reconciled with documented crop injury, and the practical meaning of certain claimed uses is not explained

PRD2026-13's value summary (s. 5.4, p. 48) states that epyrifenacil's uses include allowing "conservation tillage users to start with clean fields" and "manag[ing] other pest issues, such as pathogens, insects and rodents." PRD2026-13 does not explain the mechanism by which a herbicide manages pathogen, insect, and rodent pest issues; the only mechanism apparent from the rest of the document is that a herbicide capable of killing essentially all vegetation over a broad area ("to maintain bare ground non-crop areas," s. 5.4, p. 48) removes the plant hosts, shelter, and habitat those other pests would otherwise use. SFM requests that Health Canada clarify whether this is in fact the claimed mechanism, since "clean fields" and "bare ground" achieved by eliminating all vegetation is a different value proposition, with different environmental implications for the reasons set out in Part III above, than a claim of managing those pest categories through more targeted means.

PRD2026-13's rotational crop tolerance data (s. 5.3, pp. 47-48) show "moderate injury" to canola planted as a rotational crop one to three weeks (at 363 mL/ha) and two months (at 726 mL/ha) after application, addressed by a re-cropping interval and "a precautionary label statement," on the basis that "the moderate injury observed in the early season declined over time." Rotational crop tolerance data specific to canola planted three days after the lowest application rate (182 mL/ha) were not submitted at all; that scenario is instead "supported based on the host crop tolerance data" for a different crop-timing combination. SFM requests disclosure of the yield outcome, not merely the visual injury trajectory, associated with the documented moderate canola injury, and confirmation of whether commercial practice following such injury involves replanting or removal of the affected crop.

Each rotational crop tolerance trial reflects a single application, or a single season's applications, followed by observation of a single subsequent planting. Given that several of epyrifenacil's transformation products persist in soil for periods extending to years (Part III.A, above), a single-season, single-recrop trial design does not address whether repeated annual use on the same field could produce a cumulative carryover effect across multiple growing seasons that a one-time trial cannot detect. SFM requests that Health Canada disclose whether multi-year, repeated-application rotational crop tolerance data exist or are planned, given the persistence data already in the record for several of the compound's transformation products.

SFM requests that Health Canada clarify the mechanism by which a herbicide is claimed to manage pathogen, insect, and rodent pest issues; disclose the yield outcome associated with the documented moderate canola rotational injury and confirm whether affected crops are typically replanted or removed; disclose whether canola rotational crop tolerance data specific to the lowest application rate and shortest re-cropping interval exist; and disclose whether multi-year, repeated-application rotational crop tolerance data have been considered given the persistence of several transformation products.

Finally, SFM notes that the only information PRD2026-13 identifies as still required before or after registration is "five-batch data representing commercial-scale production and a final detailed commercial-scale manufacturing process" for the technical product, "manufactured only at pilot scale before registration" (Additional information being requested, p. 52). Given the extent of the scientific gaps identified throughout this submission — including incomplete transformation product toxicity data, an admittedly incomplete understanding of TFA formation pathways, an unvalidated 275-metre buffer zone, the absence of a species-at-risk assessment, and the absence of multi-year rotational crop data — SFM submits that a request limited to manufacturing quality-control data does not reflect the scope of outstanding scientific questions this submission has identified.

Conclusions and Requested Actions

For the reasons set out above, SFM submits that PRD2026-13 and PMRL2026-08 should not proceed to final decision in their current form. SFM requests that Health Canada respond to the concerns and requests set out above, specifically inlucuding:

- Confirm that no final registration decision will issue until the PMRL2026-08 consultation has closed and any resulting MRL changes have been made available for comment as part of the registration decision (Part I.A);
- Identify the reliable scientific data, as distinct from a characterization of the hazard findings, that PCPA ss. 7(7)(b)(iii) and 11(2)(b) require before departing from the statutory tenfold children's safety margin; explain why the identical maternal-toxicity discounting language is applied to findings characterized as both serious and non-serious; and disclose the basis on which mouse data were excluded from the point-of-departure selection given the mouse's greater sensitivity (Part II.A);
- Disclose the formal cancer weight-of-evidence classification applied to the confirmed mouse liver tumours, addressing each criterion of the IPCS/Sonich-Mullin Human Relevance Framework or an equivalent recognized framework (Part II.B);
- Incorporate epyrifenacil's modelled 74% ADI drinking water exposure into the cumulative PPO-inhibitor risk calculation, or justify its exclusion; disclose the basis for excluding acute exposure from that assessment; explain the circularity in using epyrifenacil's own untested residue profile to support the absence of tiafenacil monitoring data; and explain why the cumulative relative potency factors are not scaled to the shared hematopoietic mechanism defining the assessment group (Part II.C);
- Disclose whether Canadian consumption data was considered for infant and toddler dietary exposure; disclose whether a probabilistic refinement of the infant chronic exposure estimate was considered, consistent with PMRA's own SPN2003-

01/SPN2003-04 policy; and confirm the study design underlying the conclusion that no acute dietary endpoint of concern exists (Part II.D);

- Disclose the methodology used to derive the livestock dietary burden calculations, including which feed items were included and whether TFA residues were included in the residue definition applied (Part II.E);
- Disclose how many field trial results for each commodity were at versus above the limit of quantification; disclose the analytical basis for concluding TFA did not form in soil metabolism studies where it was not analyzed; reconcile the treatment of the rotational crop TFA finding as an unrealistic artifact with the reliance on worst-case assumptions elsewhere in the same document; explain why an elevated TFA background is treated as a reason to exclude epyrifenacil's own contribution rather than a reason for greater caution; confirm whether the registration decision can meet the reasonable-certainty standard in PCPA s. 2(2) given the admitted incomplete understanding of TFA formation; disclose which of the 18 major transformation products have independent toxicological testing underlying the conclusion that they are less toxic than the parent; and confirm whether epyrifenacil has been assessed against the OECD's 2021 PFAS definition or an equivalent structural criterion (Part II.F);
- Confirm whether Denmark's 15 July 2025 withdrawal of market authorization for all six active ingredients — fluazinam, fluopyram, diflufenican, mefentrifluconazole, tau-fluvalinate, and flonicamid — has triggered, or will trigger, mandatory special reviews of those Canadian registrations under PCPA s. 17(2) (Part II.F);
- Disclose whether an aggregate dietary exposure assessment has been, or will be, performed for consumers of V-10488-treated commodities accounting for simultaneous residues of epyrifenacil, flumioxazin, and pyroxasulfone, and explain pyroxasulfone's exclusion from any cumulative or combined exposure framework applied to the other two co-active ingredients (Part II.G);
- Disclose a dedicated hazard characterization of epyrifenacil's hematotoxicity and its relationship to the endpoints selected for the ADI and ARfD (Part II.H);
- Disclose whether the potential effects of epyrifenacil or its transformation products on the human or animal gut microbiome were considered, given the compound's confirmed translocation into the harvested seed (Part II.I);
- Disclose a substance-by-substance TSMP Track 1 determination for each transformation product Table 27 identifies as independently meeting one or more Track 1 criteria, rather than a single blended conclusion, and disclose the transformation products for which persistence data are recorded as unavailable (Part III.A);
- Disclose the basis for concluding that a 275-metre buffer zone is practically achievable and enforceable, and whether field-validation data exist or are planned; disclose the empirical basis for the transformation products' bioaccumulation conclusion given the same property-based approach failed to predict their partitioning behaviour; address the atmospheric transport implications of TFA and 1,1,1-trifluoroacetone's volatility; disclose the compliance verification mechanism for the groundwater-leaching label statement;

and disclose the toxicity data for transformation products not captured by the 56-day earthworm test window (Part III.B);

- Disclose a transformation-product-weighted quantitative recalculation of the aquatic runoff risk assessment; disclose the hydrological basis for the tidal-flushing assumption underlying the marine/estuarine refinement; and disclose whether ecological risk to groundwater-dependent aquatic organisms has been, or will be, assessed (Part III.C);
- Confirm whether species-at-risk information, including USEPA's Endangered Species Act finding that epyrifenacil use is likely to adversely affect multiple listed species and designated critical habitats, was considered in preparing PRD2026-13 (Part III.D);
- Complete the value assessment required by PCPA s. 2(1), addressing health, safety and environmental benefits and social and economic impact (Part IV.A);
- Address, as part of that value assessment, the multi-year market-access and trade risk arising from registering a persistent, TFA-generating active ingredient on US-matched residue limits with no Codex or EU equivalent (Part IV.B); and
- Clarify the mechanism by which epyrifenacil is claimed to manage pathogen, insect, and rodent pest issues; disclose the yield outcome associated with the documented moderate canola rotational injury; and disclose whether multi-year rotational crop tolerance data have been considered given the persistence of several transformation products (Part IV.C).

Respectfully submitted,

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