COMMENTS ON INCREASES OF MAXIMUM RESIDUE LIMITS (MRLS) UNDER PMRL 2023-34 AND PMRL 2023-38

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Introduction

We herein provide comments to PMRL 2023-34 concerning Fludioxonil (FL) and PMRL 2023-38 concerning Azoxystrobin (AZ). These two active ingredients are to be combined into one product of Syngenta. ~~Canada Inc.~~

No Jurisdiction to Approve or Import MRLs

Section 6 of the *Pest Control Products Act* (the Act) indicates that a pest control product cannot be imported or used unless it has been registered or authorized under the Act. With respect to MRLs for pest control products, the Act contemplates two scenarios: specifying an MRL when the Minister is "making a decision regarding the registration of a pest control product" (Section 9), and specifying an MRL with respect to uses that have not been registered (Section 10). It follows that, with respect to a Section 10 MRL and because of section 6, a Section 10 MRL use has to be authorized under the Act.

The Act allows authorizations under sections 41(1), 21(5), 48, 51 and 53-59 and the Regulations. **None of these provisions contemplate authorizing an MRL on an imported food commodity (an "Import MRL").** This means that PMRA's approval of the use of Import MRLs in is ***ultra vires* and without jurisdiction**. In other words, it is illegal. In the case of both FL and AZ, PMRA is acting without jurisdiction when it purports to set MRLs for imported food commodities.

Highly Uncertain MRL Estimates

In setting the proposed residue levels for both chemicals, PMRA used the OECD Calculator. This statistical approach "overestimates" or inflates values in situations where the data sets are small, as explained in the OECD White Paper (p. 57/69). For both FL and AZ, the data sets were small. The OECD MRL Calculator Output for both chemicals stated in red:

"High uncertainty of MRL estimate.

[Small dataset]".

For FL, the mean residue from the field trials was 1.2 ppm, but the proposed OECD MRL is 4 ppm.
For AZ, the mean residue from the field trials was 1.34 ppm, but the proposed OECD MRL is 5 ppm.

Failure to Assess Whole Product

PMRA does not assess the Syngenta product that is a co-formulation of AZ and FL, but chooses to assess the two chemicals separately. PMRA has jurisdiction to assess the entire co-formulated product, and its mandate to protect Canadians from the risk of pesticide requires it to take the most protective approach in its assessment.

PMRA has also not conducted an assessment of the cumulative risks presented to Canadians from exposure to a product that contains both chemicals. It indicates that a common mechanism of toxicity has not been identified, and there is insufficient evidence and a lack of identification of a general mechanism of toxicity. However, PMRA is aware that they both inhibit spore germination and stop mycelial growth.

Field Trial Problems

- The field trial data set out for both chemicals in PMRA # 3126656/3126772 indicates that only 6 trials were submitted, even thought 12 were required per OPPTS 860.1500. PMRA indicates the number of trials are not as critical for post-harvest treatment; however this does not obviate the problem of the small data set.
- In both the 2021 Integrated Assessments (PMRA # 3204993 for FL, PMRA # 3199583 for AZ), the PMRA evaluator did not look at the original data, but used the dietary evaluation record ~~exposure assessment (DEA)~~ of the US Environmental Protection Agency (EPA).

Health Risk Assessment

- For FL, there is no evidence that PMRA reviewed or updated the scientific literature for current toxicology information following the 2016 assessment.

- For AZ, we have requested but not yet received the confidential test data (CTD) on toxicology, so reserve comment on this aspect of the health risk assessment until such CTD has been reviewed.

- The food commodity subject to the MRL for both chemicals is sugar beet roots. The field trials looked at residues arising from post-harvest use.

- For both chemicals, no ~~residue~~ data was submitted for post-harvest metabolism on sugar beets.

  - For FL, DACO 6.3 Nature of the Residues in Plants, ~~residue~~ data was on file for peach, grape, tomato and green onions, all with **foliar** applications and PMRA uses this data to support metabolism studies based on a guideline that says a foliar application can be used to substitute for post harvest metabolism study if the mature commodity was present and exposed at application. There is no evidence that the named plants were mature at the time of application. For AZ, ~~(~~PMRA in PMRA#3199583 does use a foliar application in a pre-harvest situation on grapes in its DACO 6.3 (Nature of Residues in Plants) analysis for its post-harvest assessment. This is not valid because there is no evidence that the grape was mature at this time of pre-harvest.

  - Moreover, in PMRA# 3199583, regarding DACO 7.4 Crop Residue data, PMRA indicates that foliar applications can't be used to support post-harvest use. ~~(PMRA in PMRA#3199583 does use a foliar application in a pre-harvest situation in its DACO 6.3 (Nature of Residues in Plants) analysis for its post-harvest assessment. This is not valid because there is no evidence that the grape was mature at this time of pre-harvest.~~

- For both chemicals, the data source for the chronic dietary risk to females 13-49 years old is not provided. The provided studies did not contain such data. ~~-~~Also the PCPA Factor was reduced to one without valid scientific rationale.

- No acute assessment is provided for FL, because of a lack of an appropriate endpoint, and there is not a complete aggregate assessment for either chemical ~~.~~ This represents a failure to assess risk.

- No cancer assessment was required for either chemical for the reasons that a potency factor (q1*) had not been established. This represents a failure to assess risk.

- In relation to the acute dietary exposure assessment for AZ

  - the data is **reported at the 95th percentile, which** does not provide a reasonable certainty of no harm to the remaining 5 percent.

- At the 99.9th percentile, as reported in Appendix 13, Tables 1and 2 of PMRA#3053478, the refined acute assessments for children 1-2 (food only, and also food and drinking water), **show exceedances of the Acute Reference Dose** (108.25 and 108.32 % of ARfD respectively)

- The DEA for the Integrated Assessment for AZ was not updated by PMRA, even though increases in Canadian MRLs had occurred. The reason provided was sugar beet roots (post-harvest) were not expected by PMRA to result in a significant overall increase in exposure. This does not reflect a scientifically based approach.

- It is not appropriate to apply an assessment based upon post-harvest use on sugar beets to all sugar beet commodities which can include sugar beets exposed pre-harvest.

- PMRA does not create a separate MRL for the raw agricultural commodity (RAC) of sugar beets and sugar beets that have been processed into juice, sugar and pulp because it does not expect concentration of the chemicals to occur. However, no evidence of concentration testing was provided.

Removes Canadian Standard

- By inflating the Canadian MRL to align with the higher Import MRL, PMRA is removing the Canadian standard for pesticide residues – it leaves no measure for pesticide residue that may remain on or in food **grown in Canada** when a pesticide is used according to **Canadian** label directions. As such, PMRA is **removing a measure and check for the exposure of Canadians to pesticides**, a key measure of risk. This ~~this~~ opens the door for allowing higher pesticide levels to occur on Canadian foods without adequate checks.