SUBMISSION

+64 (0)4 499 4225 I PO Box 5069, Wellington 6140 New Zealand I www.aphanz.co.nz

To: notices@epa.govt.nz

Submission on: **Hazardous Substances International Regulators Notice**

NZBN: 9429042576433

Date: **5 pm, 24 May 2023,**

Submitter: Jo-Anne Stokes
Technical Adviser- Crop Protection
Animal and Plant Health Association of New Zealand

Email: Jo-Anne.Stokes@aphanz.co.nz

1. Introduction

1.1 The Animal and Plant Health Association of New Zealand (Animal and Plant Health NZ) welcomes the opportunity to provide feedback on the consultation document Hazardous Substances International Regulators Notice.

1.2 The listed information is gathered from our members, who represent 85 multinational and New Zealand based companies that manufacture, distribute and retail crop protection and animal remedy compounds.

1.3 Replies to the questions on the consultation document Hazardous Substances International Regulators Notice are noted in Appendix 1 of this document

2. Recommendations of Animal and Plant Health NZ

2.1 **Recommends** that the listed International regulators (Australia (APVMA and AICIS), Canada, PMRA) and US (USEPA)) along with the information data sources (highlighted) be considered by the Environment Protection Authority (EPA) as bodies that the EPA will recognise for the purposes of assessing HSNO pathways (including Section 28A(2)(ab)and section 63 of the Hazardous Substances and New Organisms Act (HSNO)). The international regulators are agreed as having a similar mindset and risk assessment protocols as the EPA identified in the HSNO Act.

2.2 **Recommends** Australia APVMA meets all the criteria of the Hazardous Substances and New Organisms Act (HSNO) amendment in that APVMA a) operate in a manner comparable to the EPA, and b) the legislative regime under which they operate and regulate hazardous substances, is comparable to HSNO. The agency is the most comparable of any trusted regulator.

2.3 **Seeks clarification** as to why the EPA are proposing to list both the PMRA and Health Canada as trusted regulators. PMRA is part of (Health Canada and is comparable to EPA (in operations and legislation). The recently Hazardous Substances and New Organisms Act (HSNO) . Whilst the PMRA meets both the requirements of the HSNO amendments (i.e., operate/legislate in a manner comparable to EPA/HSNO), Health Canada is a much larger entity, many parts of which will not operate in a manner comparable to the EPA or be subject to legislation and a regulatory system that is comparable to HSNO.

2.4 **Recommends** that the European Union (EFSA, ECHA, EC, MSCA) is considered with some caveats as the EU regulator does not have similar risk assessment process as the EPA. The EU has a set of restrictions that are based on a precautionary approach and not necessarily aligned to the science provided. EU differences, to the current EPA risk assessment, are outlined below where:

2.4.1 An applicant can apply for derogations throughout the EU process, where an applicant can make a case for allowing a product to be used although certain risk parameters are set that are restrictive and not science based. i.e., glyphosate

2.4.2 While assessments of Plant Protection Products and active ingredients in the European Union have a risk assessment, they do not consider risk versus

benefits, have an increasing number of hazard-based cut-off criteria, whereby active substances cannot receive a registration or not be renewed purely on the basis of exceeding an exposure threshold, mode of action, and physiochemical properties with no consideration of exposure and risk.

2.4.3 It is foreseeable that applications declined by EU are due to the above issues plus a lower threshold for most hazardous substances and does not consider a benefit of the chemical use. In addition, the EU has a mandate to be organic by 2030, therefore consideration of hazardous substances for the EU market is restricted. It is uncertain from the consultation document how the differences will be considered in comparing international regulators decisions, data, and information.

2.4.4 EPA may wish to reconsider the assertion of the consultation document (Page 13) that "all of the agencies… use an evidence and risk-based approach". APHANZ contend that this is an incorrect assumption for the European Commission and EFSA. Whilst both agencies claim to use evidence-based criteria to make decisions, the agencies **do not** use risk-based criteria (as per the EPA), particularly the EC, where decisions are regularly made that are highly political. Both agencies follow a hazard-based approach, which is contradictory rather than comparable to HSNO.

2.4.5 ECHA are known for taking science-based decisions and are less vulnerable to political pressure, however it is unknown as to what approach ECHA will take to decisions, such as endocrine disruption and mobility criteria – i.e. it isn't clear if their approach will continue to be risk-based or hazard-based.

2.4.6 Member State Competent Authorities (MSCA) is made up of various Member State Competent Authorities . It is unclear from the consultation document that each member state has been assessed independently or that the EPA is conferring acceptance of the MSCA as a group. APHANZ submits that MSCA's are assessed as to the risk assessment model each MSCA complies with to conclude if the authorities operate/legislate in a manner comparable to EPA/HSNO .

2.4.7 All the above points make the EU system **not comparable** to how the EPA operates or how the HSNO system works, which are the two key criteria that the HSNO Amendment Act directs the EPA to consider when selecting Trusted regulators. Therefore, further comparisons are required.

2.5 **Recommends that another data source** Joint Meeting on Pesticide Residues (JMPR) are also considered. JMPR publishes their assessments and should be only accepted as valid if background data/studies are also provided. A JMPR report should not be used as a source of data, but in the same fashion of the proposed Trusted Regulator approach, where the report plus studies is supplied.

2.6 **Submits** that there is no transparency for the reason why EPA trusts the information and data from the specified international regulators. It is unclear from the consultation document that there a peer review process as there is for JMPR (Reviews) that is consistent and provides consistent science-based decisions.

2.7 **Requests information** as to why Japan (Ministry for Environment, and Ministry of Agriculture, Forestry and Fisheries) is not included on the list. Japan is listed as a jurisdiction in EPA application forms for Import or Manufacture of Pesticide but is not included in the list of trusted international regulators.

2.8 **Requests information** as to why United Kingdom (Department of Environment Farming Rural Affairs), which has recently exited the EU, is excluded from the list.

2.9 **Recommends** the original intent of the project (to include international regulators) *is to make assessments and reassessments of hazardous substances more efficient so that we can better protect human health, safety, and the environment*. Therefore, broadening both the number of international regulators (i.e., consider the United Kingdom and Japan as trusted international regulators) and international reviews of information sources would assist in meeting the intent.

2.10 **Recommends** that more is done to facilitate data recognition in the next part of this consultation process. Applicants are not able to submit data for an application from any of the data resources quoted (points 1, 2 and 3) unless the applicant owns the data information behind the report. This restricts the use of an international regulators source of information to that which the applicant owns or has permission to use. However, this is not acknowledged in the consultation document.

2.11 **Recommends** that the EPA consider other pathways (not just Section 28A(2)(ab) Rapid Assessment and Section 63D Reassessment) to recognise specified international regulators. Section 28 of the HSNO Act allows for recognition of international regulators for other pathways within section 28 applications (i.e.,28 (2) a,b,c). The original intent (as included in the HSNO select committee) was to enable improved processing to occur through use of international regulators decisions if the pathways were expanded.

2.11.1 Pathways, such as that for a novel active ingredient that are new to New Zealand but approved by an international regulator, would provide an improved process.

2.11.2 The pathways outlined (Section 28 and 63) would be only using tier 1 applications. The Tier 2 applications would be general agronomical benefits and related to the ACVM Act.

2.11.3 The EPA is not set up to establish agronomical benefits (such benefits relate to ACVM Act) Therefore it would seem difficult to assess when the pathway Section 28A(2)(ab) would be used and that the current prediction is theory that may not translate to practical application in the short term. There are no examples provided (and our members have not come up with an example) and it may be that this incorporation of trusted international regulators will not

have the benefits (provide regulatory peer reviewed data) as thought without some opening of the pathway base.

2.12 **Submits** that the limitations (pathway and data sources) selected by the EPA are. limiting the usefulness of the initiative to members (and therefore number of applications that could be more efficiently processed) in that,

2.12.1 The data relied on by the regulator's decision is owned (or approved to be used) by the applicant. This would implicate that only multinational organisations will have access to such data.

2.12.2 New Zealand based companies would be limited unless a reciprocal trusted regulator programme is in place (i.e., data generated by NZ based businesses are recognised by the listed trusted regulators).

2.12.3 Section 28A(2)(ab) (rapid assessment) is a newly introduced pathway and is not an often-used pathway. As rapid response would necessitate a look at any available data, the proposed change is not anticipated by members, to be significantly different than that which happens currently.

2.12.4 Section 63 (reassessment) relies on EPA assessing decisions made by international regulators or occurrences in the New Zealand context in response to additional information (generally from international regulators) and from other data sources. International regulatory approvals or decisions are already used in this pathway. The proposed reassessment list is predominantly from international regulators decisions (i.e. Hydrogen cyanamide reassessment came about as a result of EFSA update) and there is anticipated that there is no difference to the efficiency of processing such applications.

3. Next Steps recommended by Animal and Plant Health NZ

3.1 **Submits** that further detail is required in the next steps to establish the precedent for varying scenarios in the use of international regulators for EPA decision making, namely:

3.1.1 Details of what makes the EU system comparable to how the EPA operates or how the HSNO system works (I.e., the two key criteria that the HSNO Amendment Act directs the EPA to consider) when selecting trusted regulators, particularly that the EPA has assessed and compared:

3.1.1.1.1 the various Member State Competent Authorities (MSCA) individually and the risk assessment model is comparable to EPA and HSNO. APHANZ submits that MSCA's are assessed as to the risk assessment model each MSCA complies with and that this is comparable with the two key criteria.

3.1.1.2 the reliance on European Commission and EFSA decisions where evidence-based criteria are used to make decisions, but the agencies **do not** use risk-based criteria (as per the EPA). That both agencies follow a hazard-based approach, which is contradictory rather than comparable to HSNO.

3.1.2 clarify if ECHA decision making will continue to be risk-based or hazard- based.

3.1.3 Consideration of the outcome of decisions where one regulator I.e., EU (with higher thresholds and a higher number of banned substances) declines an approval, but the trade chemical is approved in other regulators jurisdiction with similar data. There is no clarity as to what information held by a preferred international regulator would have precedent over another.

3.1.4 Consider that the pathway selected for international regulation does not relate, for our members, to the area that EPA is responsible for (HSNO Act) but relates to the ACVM Act (that MPI is responsible for). Clarification is sought where the two regulators cross over and who takes the lead.

3.1.5 Provide likely scenarios or examples of the use of the selected pathways (Section 28A(2)(ab) and Section 63D) and the type of information and data that would be used. It has been difficult for members to provide feedback without looking to the information provided by the individual international regulators.

3.1.6 To consider that information generated from research into hazardous chemicals may be found in different portals than that listed by the consultation document and to consider other options i.e., JMPR Review.

3.1.7 Consideration of Japan (Ministry for Environment, and Ministry of Agriculture, Forestry and Fisheries) and United Kingdom (Department of Environment Farming Rural Affairs)as trusted international regulators.

3.2 **Submits** that international regulators can be removed from consideration under Section 76E of HSNO Act and it would appear that the onus of considering additional or removal of trusted international regulators (to that already listed in the consultation document) is likely to fall on the applicant or a group of applicants. This would seem a barrier to utilising international regulators. Additionally, the next phase of consultation should consider the process or requirements for the EPA to consider of adding additional trusted international regulators. Consideration should be provided to:

a. Once selected is the regulator base set for all time or until EPA reassess the international regulator?
b. Are all chemicals rejected by a trusted international regulator going to be rejected by the EPA? Noting EU has a different way of assessing risk.
c. Is there any reciprocity between the listed international regulators and the EPA ? Does the EU accept NZ based regulators and information. ? Are there examples of this?

3.3 **Submits** that while some regions might see increasing the level of protection as a good thing, being overprotective has a cost through potentially losing or restricting the use of the tools available to farmers to maintain food security.

4. About Animal and Plant Health NZ

We are the peak industry association representing more than 85 multinational and New

Zealand based companies that manufacture, distribute, and sell crop protection and animal health products that keep our animals healthy and crops thriving. Our mission is to protect and enhance the health of crops, animals, and the environment, through innovation and the responsible use of quality products and services.

Our objectives are to:

- Strive for effective and sustainable animal health and crop protection technology through industry leadership and advocacy.
- Achieve a balanced and science-based regulatory environment that gives members freedom to operate and grow in New Zealand.
- Enable farmers and growers to supply high quality food and fibre into domestic and global markets.
- Create an environment that encourages competition through innovation.
- Promote stewardship and responsible use of products.
- Support the health and wellbeing of pets, livestock, and people.

Appendix 1:

Submission form: international regulators notice.

Summary

Submitter details

Your submission

Are the views expressed on behalf of an individual or an organisation?

☐ I am representing my own personal views
☒ I am representing the views of a company, organisation, business, group

Please indicate which submitter group you belong to:

☐ Government Organisation

☒ Industry Group

☐ Iwi

☐ Manufacturer

☐ Importer

☐ Private Business

☐ Researcher

☐ Community Group

☐ Indivdiual

☐ Other

Questions

1. **Do you have any comments regarding the international regulators proposed in Table 1 of the consultation document?**

   ☒ Yes
   ☐ No

   Noted in Point 2

2. **Do you disagree with any of the international regulators proposed in Table 1 of the consultation document?**

   ☐ Yes
   ☒ No

   Point 2 of the submission
   There are concerns regarding the risk assessment processes of the EU decision makers (EFSA, ECHA, EC, MSCA) and a need to review the comparability between each with the EPA/HSNO in Point 2 of this document

3. **Do you believe there are any overseas bodies which are missing from Table 1 and which the EPA should recognise as international regulators for the purposes of section 28A and 63D of the HSNO Act?**

   If so, please indicate which overseas bodies you believe are missing and the reasons why the EPA should recognise these as international regulators. In providing your feedback, please consider the criteria the EPA must consider before recognising overseas bodies (as described in section 5 of this consultation document).

   ☒ Yes
   ☐ No

   Refer to Point 2.9 and 3,
   - consider Japan or United Kingdom and
   - consider other data sources 2.5.

4. **Do you have any other general comments on points you believe the EPA should consider when finalising our proposals for the overseas bodies we will recognise as international regulators?**

   ☒ Yes
   ☐ No

   Please note comments raised in the submission document specifically in point 2 (in regards EU) and point 3 regarding the inclusion of pathways for novel chemicals.