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**ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE****Cancels & replaces the same document of 17 December 2021****REPORT ON OECD SURVEYS ON PESTICIDE PRODUCT LABEL DATA ELEMENTS TO
SUPPORT THE SHARING OF PESTICIDE LABEL DATA****Series on Pesticides
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OECD Environment, Health and Safety Publications
Series on Pesticides
No. 106

REPORT ON OECD SURVEYS ON PESTICIDE PRODUCT LABEL
DATA ELEMENTS TO SUPPORT THE SHARING OF PESTICIDE LABEL
DATA

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

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Environment Directorate
ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
Paris 2021

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FOREWORD

In 2019 the OECD Expert Group on the Electronic Exchange of Pesticide Data (EGEPPD), a sub-group of the OECD Working Party on Pesticides, initiated a project focused on identifying common global terminology for pest control product labels with the aim to enhance OECD member countries' common understanding of labelling requirements and existing e-tools across jurisdictions, to assist regulatory authorities to explore standardizing and creating a global pesticide labelling terminology crosswalk, and to support efforts to modernise labelling processes among OECD members.

The Canadian Pest Management Regulatory Agency (PMRA), the project lead, designed two different surveys in consultation with the Expert Group with the goal of providing an overview of common label data elements, an overview of regulatory processes of reviewing and approving pest control product labels, a comparison of region specific label data element naming conventions, and identification of label data elements required for risk assessments in each member country.

The OECD Expert Group on the Electronic Exchange of Pesticide Data (EGEPPD) were invited to participate in the two surveys in 2019 and 2020, respectively. Responses were received to parts of one or both surveys from the following: six OECD member countries of the Expert Group, (Australia, Canada, Germany, Japan, New Zealand, and the United Kingdom), the European Food Safety Authority (EFSA) and an industry via Business at OECD.

This report, drafted by PMRA with input from the Expert Group, contains a collation of findings from the survey and recommendations to OECD member countries.

The information in the Report is a “snapshot” of information from respondents at the time of the survey and may not contain national, regional, or international initiatives that were on-going at the time.

This Report was approved by the Working Party on Pesticides on 1-2 July 2021.

This document is being published under the responsibility of the OECD Chemicals and Biotechnology Committee, which has agreed that it be declassified and made available to the public.

This report has been produced with the financial assistance of the European Union. The views expressed herein can in no way be taken to reflect the official opinion of the European Union.



Table of contents

1. EXECUTIVE SUMMARY	8
2. INTRODUCTION	9
2.1. Background and objectives	9
2.2. Project scope	9
2.3. Report of results	9
3. SUMMARY OF SURVEY RESULTS.....	10
3.1. 2019 Survey results summary on common label data elements and similarities regarding the regulatory process of reviewing and approving pest control product labels.....	10
3.1.1. Summary and analysis.....	10
3.1.2. Analysis of Common Label Data Elements across Survey Respondents.....	14
3.2. 2020 Survey results summary on the naming convention of common label data elements, and label data elements required for risk assessments.....	16
3.2.1. Summary and analysis.....	16
3.2.2. Comparison of Naming Convention of Common Label Data Elements across Survey Respondents	17
3.2.3. Comparison of Label Data Elements Required for Risk Assessments across Survey Respondents	23
4. RECOMMENDATIONS	27
5. ANNEX 1 - 2019 Survey with Example Canadian Input.....	28
6. ANNEX 2 - 2020 Survey with Example Canadian Input.....	39
7. ANNEX 3 - Individual Country Responses to 2019 Survey.....	55
7.1. Australia.....	55
7.2. Germany.....	64
7.3. Japan	69
7.4. New Zealand.....	72
7.5. United Kingdom	81
7.6. European Food Safety Authority (EFSA).....	88
8. ANNEX 4 – Individual Country Responses to 2020 Survey	93
8.1. Australia.....	93
8.2. Japan	120
8.3. New Zealand.....	144
8.4. United Kingdom	179
8.5. BIAC (Gowan Crop Protection Limited).....	249

Tables

Table 1. Analysis of Common Label Data Elements across Survey Respondents	14
Table 2. Comparison of Common Label Data Elements across Survey Respondents	17
Table 3. Comparison of Label Data Elements Required for Risk Assessments across Survey	23

1. EXECUTIVE SUMMARY

This report provides interested parties with information that will support and inform the development of structured electronic pesticide labels, and facilitate exchange of international data.

Members of the OECD Expert Group on the Electronic Exchange of Pesticide Data were invited to respond to two different OECD surveys in 2019 and 2020 on plant protection product label data elements, naming conventions and element justifications.

This report contains a collation of findings from responses received to parts of one or both surveys from six OECD member countries, (Australia, Canada, Germany, Japan, New Zealand, and the United Kingdom), the European Food Safety Authority (EFSA) and an industry via Business at OECD. Collated findings include the following tables of information:

- Analysis of Common Label Data Elements Across Survey Respondents
- Comparison of Common Label Data Elements Across Survey Respondents
- Comparison of Label Data Elements Required for Risk Assessments Across Survey Respondents

Recommendations to OECD member countries as an outcome of the OECD surveys are:

- a. OECD member countries, when developing labelling guidelines for pesticide products, should (where possible) utilize the report in considering options with a view to harmonizing data elements, their naming conventions, and prioritizing structured data elements, for pesticide products with other member countries that would facilitate data sharing.
- b. OECD member countries, when developing IT solutions to enable the transmission, receipt, management, and output of label data, should (where possible) consider common label data elements, and their naming conventions, as identified in this exercise, to support the interoperability of electronic labelling applications.
- c. To support a more global approach to pesticide product registration, member countries should examine further work to expand data sharing across OECD member countries

The Canadian Pest Management Regulatory Agency (PMRA) led this project of the OECD Expert Group on the Electronic Exchange of Pesticide Data, a sub-group of the OECD Working Party on Pesticides.

2. INTRODUCTION

2.1. Background and objectives

In June 2019, the OECD Working Group on Pesticides approved a project under the OECD Expert Group on the Electronic Exchange of Pesticide Data (EGEEDP) to support the development of structured electronic pesticide labels.

The project has focused on identifying common global terminology for pest control product labels with the aim to enhance OECD member countries' common understanding of labelling requirements and existing e-tools across jurisdictions, to assist regulatory authorities to explore standardizing and creating a global pesticide labelling terminology crosswalk, and to support efforts to modernise labelling processes among OECD members.

2.2. Project scope

In 2019 and 2020 members of the EGEEDP were invited to participate in two surveys with the goal of providing an overview of common label data elements, an overview of regulatory processes of reviewing and approving pest control product labels, a comparison of region specific label data element naming conventions, and identification of label data elements required for risk assessments in each member country.

The EGEEDP includes government regulatory authorities from OECD member countries, representatives from the European Union, and industry via Business at OECD (BIAC).

Six OECD member countries, the European Food Safety Authority (EFSA) and an industry responded to parts of one or both surveys: Australia, Canada, Germany, Japan, New Zealand, the United Kingdom, EFSA, and BIAC (Gowan Crop Protection Limited).

2.3. Report of results

The following report is a collation of findings pertaining to four key areas of pesticide labels:

- Common pesticide label data elements and naming conventions
- Regulatory mechanisms that support review and approval processes
- Region specific naming conventions
- Data elements required for risk assessments.

The report also contains recommendations that are principally focused on:

- Harmonisation of label data requirements
- Interoperability of IT systems
- Facilitating exchange of label data between member countries.

Continued discussions amongst OECD member countries on label data principles will enhance the potential for the exchange and use of label data where possible.

The Canadian Pest Management Regulatory Agency (PMRA) designed the surveys in consultation with the EGEEDP working group members. PMRA also compiled and analysed the survey responses.

The results were presented to the EGEEDP, and feedback from members has been incorporated into the final report.

3. SUMMARY OF SURVEY RESULTS

3.1. 2019 Survey results summary on common label data elements and similarities regarding the regulatory process of reviewing and approving pest control product labels

3.1.1. Summary and analysis

The OECD conducted a survey in 2019 to identify commonalities regarding the regulatory process of the review and approval of pest control product labels across OECD members and identify common data elements for labels to support a more data centric business model.

Six OECD member countries and the European Food Safety Authority (EFSA) responded: Australia, Canada, Germany, Japan, New Zealand, United Kingdom, EFSA.

The questions and summaries of responses followed by an analysis of those responses follows below.

1. Describe the Process and Format for receipt of label information.

- a. **Australia (APVMA):** Applicants must use the e-label template to submit the required label elements -> The e-label is reviewed as per APVMA's evaluation process -> The approved label is sent to the applicant. -> Label content not covered by the template does not need to be assessed or approved by the APVMA -> Changes to label content covered by the template can only be made by application for variation. -> Changes to label content NOT covered by the template can be made without formal APVMA approval but must remain compliant with the relevant Labelling Code.
- b. **Canada:** MS Word label submitted to PMRA via eIndex builder -> MS Word label annotated by PMRA using track changes -> Label changes accepted by Registrant -> MS Word label finalized and approved by PMRA and emailed to Registrant -> Approved label published to PMRA website Label Search database as PDF.
- c. **Germany (BVL):** Applicants submit MS Word label and enter information via Applicant portal -> Transfer of Applicants suggestions into in-house system -> validation of label information during risk assessment -> authorisation certificate is automatically generated -> label requirements published to on line database.
- d. **Japan:** There is no procedure.
- e. **New Zealand (MPI & EAD):** Electronic label submitted to ACVM (Word or pdf) – plus highlighted tracked changes version for variations -> ACVM suggests label changes to applicant -> Registrant supplies amended label (clean + tracked copies) -> Label finalised and ACVM content approved by ACVM and emailed to Registrant with other registration documentation -> Approved label published to ACVM public register (website) as PDF.
- f. **United Kingdom (HSE):** Applicants provide copy of a draft label with application -> Draft label is screened for required claims and recommendations -> Label text is reviewed by CRD scientific evaluators -> Any proposed amendments to the draft label are sent to the applicant to be incorporated into their final label.

- g. **EFSA:** The European Food Safety Authority (EFSA) does not have a direct role in the process for labelling requirements of pest control products.

Analysis: Most countries follow a version of the same process where a label is received electronically as a flat-file (.doc or .pdf), the label content validated against defined criteria (scientific, regulatory, etc.), the label is approved/authorized, and in most cases either a version of the label, or information about the label is then published online for the public to access. In no instance is the label received in the format of structured data.

2. List the Label Data Elements Required For Risk Assessments.

See Section 3.1.2: Analysis of Common Label Elements across survey respondents.

3. In what format are the final approved labels available?

- a. **Australia (APVMA):** online – PDF.
- b. **Canada:** Internally, label information is entered into a relational database to allow querying of label data. Externally (PMRA website, mobile app), approved labels are available online as pdf.
- c. **Germany (BVL):** There is no approved label in Germany. However, preliminary labels have to be submitted prior to authorization which are checked for completeness and correctness by BVL. On line database of label information and required label statements.
- d. **Japan:** labels are not approved, therefore they do not need to be made available.
- e. **New Zealand (MPI & EAD):** online – PDF.
- f. **United Kingdom (HSE):** does not publish final authorised labels and does not keep a database of final printed labels.
- g. **EFSA:** electronic format via member state database, or hard copy format (depends on the Member State Authority).

Analysis: There is a wide range of accepted practices; from providing a copy of an approved label online as a PDF, to not approving labels and therefore not making them available to the public, to providing a searchable online database of label requirements only. In all cases where label information is made publically available via a searchable database, the data is manually extracted from the approved/authorized label by the regulatory authority.

4. What are the main labelling challenges?

- a. **Australia (APVMA):** no cyclical re-registration (re-evaluation), labels are complex and long, old labels are not automatically removed from the system (versioning issues).
- b. **Canada:** Large set of labels (~8000), labels are complex and long, manually extracting label information, and administering label amendments from re-evaluation is resource intensive.
- c. **Germany (BVL):** ability to provide up-to-date label requirements via online database, label information manually entered into the in-house system, processing label amendments are an administrative burden.

- d. **Japan:** complexity of labels, readability.
- e. **New Zealand (MPI & EAD):** labels are complex and long, data from labels has to be manually extracted (resource intensive), can take up to 5 years before all labels are updated (renewal process), large # of applications to process in a year, difficulty reconciling content between regulatory jurisdictions (MPI vs. EPA), non-standardized content (hazard and precautionary info. – GHS and non-GHS).
- f. **United Kingdom (HSE):** over-labelling or complex text – clarity of instructions.
- g. **EFSA:** n/a – no direct role in the labelling requirements of pest control products.

Analysis: Label complexity, clarity of content (easy to understand wording and phrasing), and mechanisms to maintain up-to-date labels seem to be a common challenge for each regulatory authority. In countries that maintain an in-house database of label information it is an administrative burden to extract and maintain up-to-date label information for the public.

5. Are there current label initiatives underway?

- a. **Australia (APVMA):** review of labelling codes, revision of the e-label portal
- b. **Canada:** Standardizing label statements and site-pest nomenclature, improve clarity of label statements, leveraging use of IT tools to capture and publish (APIs) structured label data, legislative and regulatory review to support labelling initiatives.
- c. **Germany (BVL):** Yes. Standardizing and publishing structured label as a voluntary commitment by companies. Implementation of IT tools to capture and publish structured label data is planned in order to achieve machine readability and allow machine to machine communication.
- d. **Japan:** standardization of label content, leveraging use of IT tools to improve access to label info., emphasis of human and pollinator safety.
- e. **New Zealand (MPI & EAD):** improving label content (standardized content and clear language). Updating the EPA Labelling Notice for the move to the GHS Revision (reconciling label language to reflect one standard).
- f. **United Kingdom (HSE):** develop a process where the authorisation notice is accompanied by the final agreed authorised label text (rather than a draft and amendments), which will provide greater clarity.
- g. **EFSA:** n/a – no direct role in the labelling requirements of pest control products

Analysis: The following initiatives are underway in the response of at least one respondent:

- Standardizing of label statements (risk mitigation statements and application instructions, etc.)
- Improved clarity of label statements (risk mitigation statements and application instructions, etc.)
- Effective use of IT tools to provide access to label information

- Regulatory process improvements to ensure label content is compliant and up-to-date.

6. What are the drivers for label improvement?

- a. **Australia (APVMA):** Updating the Labelling Codes to better reflect the needs of holders and end-users, regulatory reform and changes to legislation, adoption of enabling technology solutions.
- b. **Canada:** Health and Safety – timely changes to risk mitigation measures, data as a strategic asset – efficiencies in gathering data and improving access to data.
- c. **Germany (BVL):** standardized content, clear language, safe use of products, providing up-to-date product info. via database. Standardized structure, compatibility to IT-tools to capture and publish structured label data in order to achieve machine readability and allow machine to machine communication.
- d. **Japan:** introduction of re-evaluation framework (periodic review of labels based on latest scientific knowledge), inclusion of risk assessments to protect end-users and pollinators during pre- and post-market reviews.
- e. **New Zealand (MPI & EAD):** Consistency and clarity in labelling for provision of sufficient Consumer Information, to make registrants aware of obligations and expectations before applications are made.
- f. **United Kingdom (HSE):** to provide clear and concise labels, which can be easily read and understood by the user.
- g. **EFSA:** N/A – no direct role in the labelling requirements of pest control products.

Analysis: A key driver for label improvement is to provide end-users with improved access to pesticide label information that is easier to understand through clear and concise language, and standardized content.

3.1.2. Analysis of Common Label Data Elements across Survey Respondents

Table 1. Analysis of Common Label Data Elements across Survey Respondents

Pesticide Label Data Element Name (Future State)	Canada	Australia	Japan	United Kingdom*	EFSA*	New Zealand	Germany*
Registration Number	•	•	•	•	•	•	•
Product Name	•	•	•	•	•	•	•
Geographic Area	•	•					
Marketing Type/Class	•	•		•	•	•	•
Active Ingredient (name & quantity)	•	•	•	•	•	•	•
Resistance Management Group/Mode of Action	•	•		•	•	•	•
Product Description/ Statement of claims for use	•	•		•	•	•	•
Product Type	•		•	•	•	•	•
Formulation Type	•		•	•	•	•	•
Net Contents	•	•	•	•	•	•	•
Registrant Contact Info	•	•	•	•	•	•	•
Signal Words	•	•	•	•	•	•	•
Hazard Statements	•	•	•	•	•	•	•
Use Restrictions	•	•		•	•		•
Human Health Precautions	•	•	•	•	•	•	•
Environmental Precautions	•	•	•	•	•	•	•
Companion Animal Precautions	•	•	•	•	•	•	•
Personal Protective Equipment (PPE)/ Engineering Controls	•	•		•	•	•	•
First Aid Instructions	•	•	•	•	•	•	•
Toxicological Information	•		•	•		•	
Directions For Use	•	•	•	•	•	•	•
Method of Application	•	•		•	•	•	•
Rotational Crops/ Plant-Back Interval	•	•		•	•	•	•

Pesticide Label Data Element Name (Future State)	Canada	Australia	Japan	United Kingdom*	EFSA*	New Zealand	Germany*
Restricted-Entry Intervals	•	•		•	•	•	•
Pre-Harvest/Grazing/Slaughter Intervals	•	•		•	•	•	•
Spray Drift Management/ buffer zone	•	•		•	•	•	•
Runoff Management/ Vegetative Filter Strips	•	•		•	•		•
Mixing-Loading Restrictions	•	•		•	•	•	•
Tank Mix/Adjuvant Information	•	•		•	•	•	•
Resistance Management Information	•	•		•	•	•	•
Storage and Disposal	•	•	•	•	•	•	•
Site/Host	•	•		•	•	•	•
Pest (life stage and control claim)	•	•	•	•	•	•	•
Aerial Application Indicator	•					•	
Product Rate/ Concentration	•	•		•	•	•	•
Max Number of Applications per Year or Crop Cycle	•	•		•	•	•	•
Spray Volume	•	•		•	•	•	•
Application Equipment	•	•		•	•	•	•
Re-Treatment Interval	•	•		•	•	•	•
Application Timing	•	•		•	•	•	•

Note: * [EU Regulation 547/2011](#)

3.2. 2020 Survey results summary on the naming convention of common label data elements, and label data elements required for risk assessments.

3.2.1. Summary and analysis

The OECD survey conducted in 2020 requested comments on similarities and differences across jurisdictions on the naming convention of common label data elements and label data elements required for risk assessments.

Six OECD member countries and industry via Business at OECD (BIAC) responded.

Three OECD member countries and industry via Business at OECD (BIAC) responded to the survey section, *naming convention of common label data elements*: Australia, Canada, the United Kingdom, and BIAC (Gowan Crop Protection Limited). New Zealand and Japan did not provide input for this section.

Five OECD member countries responded to the survey section, *label data elements required for risk assessments*: Australia, Canada, Japan, New Zealand, and United Kingdom. Gowan Crop Protection Limited did not provide input for this section.

Comments:

- PMRA naming conventions are based on planned label data structuring, and may not reflect current labels. Naming conventions were mapped across regions based on common interpretation of label data elements. The intent of the mapping exercise is to identify common label data elements, and to inform potential future harmonization efforts, without compromising distinct regional language requirements tied to Acts and/or Regulations (and/or legal framework documents).
- Gowan Crop Protection Limited noted an additional field expected as a requirement in 2021 “UFI (Unique Formula Identified)” – at the time of this report, PMRA is not aware which regulatory body/product types will be requiring this field.

3.2.2. Comparison of Naming Convention of Common Label Data Elements across Survey Respondents

Table 2. Comparison of Common Label Data Elements across Survey Respondents

Canada (PMRA)	Australia (APVMA)	United Kingdom†
Product Name	Distinguishing name	Product tradename
Product description	Statement of Claims	Biological use phrase
Product Type		Field of use
Formulation Type	Formulation Type	Formulation type
Class designation	Pack Grouping	Professional/Amateur or Experimental authorisations
Signal Words	Signal Headings	Signal words
Hazard Symbols		Hazard symbols/pictograms
Hazard Statements		Hazard phrases
Read the label before using	Cautionary Phrases and SD	Read the label before use
Active Ingredient	Active constituent	Amount and name of the active substance(s)
Allergens		Sensitising ingredients identified
Preservatives		
Registration Number	Distinguishing number	Product registration number
Private Label Number	Approval Number	Product batch number
Net Contents	Net Contents	Net quantity of product
Contact information	Identifying information for the holder of the approval	Authorisation holder and/or marketing company details
Resistance Management Group for the Active Ingredient	Mode of Action	Mode of Action
Expiry date	Expiry date	use-by date
Notice to user		Read the label before use

Canada (PMRA)	Australia (APVMA)	United Kingdom†
First Aid Instructions	First Aid Instructions	First aid/medical advice
Companion Animal and Livestock First Aid		
Toxicological Information		Medical advice
Human Health Precautions	Safety Directions	Safety Precautions
Personal Protective Equipment (PPE)/ Engineering Controls	Safety Directions	Operator Protection Safety Precautions
Companion Animal and Livestock Precautions	Protection of livestock	Safety Precautions / Other specific restrictions
Environmental Precautions	Protection Statements	Environmental protection Safety Precautions
Environmental Precautions – Aquatic organisms		Environmental protection Safety Precautions
Environmental Precautions - Birds		Environmental protection Safety Precautions
Environmental Precautions – Wild Mammals	Protection Statements	Environmental protection Safety Precautions
Environmental Precautions - Bees		Environmental protection Safety Precautions
Environmental Precautions – Beneficial Arthropods		Environmental protection Safety Precautions
Environmental Precautions - Earthworms		Environmental protection Safety Precautions
Environmental Precautions – Non-Target Terrestrial Plants	Protection Statements	Environmental protection Safety Precautions
Environmental Precautions – Burrow Treatments		Environmental protection Safety Precautions
Environmental Precautions – Persistence/ Accumulation/ Carryover	Protection Statements	Environmental protection Safety Precautions / Other specific restrictions
Environmental Precautions – Leaching	Protection Statements	Environmental protection Safety Precautions / Other specific restrictions
Environmental Precautions – Runoff	Protection Statements	Environmental protection Safety Precautions / Other specific restrictions
Environmental Precautions - Volatilization	Protection Statements	Environmental protection Safety Precautions / Other specific restrictions
Environmental Precautions - Products Containing Aromatic Petroleum Distillates	Protection Statements	Environmental protection Safety Precautions / Other specific restrictions.
General information	General Instructions	Directions for use 'Important Information Box'
Directions For Use (General)	Directions for Use	Directions for use 'Important Information Box'

Canada (PMRA)	Australia (APVMA)	United Kingdom†
Use Limitations	Restrains	Other specific restrictions (PPP)/ instructions for use or risk mitigation measures' (Biocides)
General Application Instructions	General Instructions	Directions for use 'Important Information Box'
Application Method	Application	Directions for use 'Important Information Box' Safety Precautions
Application target	Crop/pest or situation	Field of use 'Important Information Box' Directions for use
Application equipment	Application equipment	Directions for use Safety Precautions
Chemigation	Application	Directions for use
Runoff Management	Protection (Environment)	Environmental protection Safety Precautions / Other specific restrictions
Spray Drift Management	Spray drift restraints	Environmental protection Safety Precautions / Other specific restrictions
General Mixing Instructions	Mixing	Mixing and spraying
Generic Tank Mix Statement	Compatibility	Compatibility Section
Tank Mix Partner Information	Compatibility	Compatibility Section
Tank Mix Partner Mixing-Loading Instructions	Mixing (Found within the General Instructions)	Compatibility Section
Rotational Crops/ Plantback Interval	Re-cropping intervals	Directions For Use 'Important Information Box' Other specific restrictions (following crops)
Restricted-Entry Intervals	Re-Entry Period	'Important Information Box' Other specific restrictions
Preharvest Intervals	Withholding Period (Harvest)	'Important Information Box' Other specific restrictions
Pregrazing Intervals/ Feeding Restriction	Withholding Period (Grazing)	'Important Information Box' Other specific restrictions
Preslaughter Intervals	Export Slaughter Interval	
Resistance Management Information	Resistance warnings	Directions For Use (Resistance)

Canada (PMRA)	Australia (APVMA)	United Kingdom†
Storage and Disposal	Storage and Disposal	Storage and disposal Safety Precautions
Labelling of Treated Seed (Seed Tag)	seed pigment or dye	Safety Precaution phrases – treated seed bag agreement
Labelling of Treated Article (Hang Tag)	Hang Tag	Labelling of Treated Article (Biocides)
Imported Treated Seed Information	seed pigment or dye	
Direct Application to Water	Protection Statements	Environmental protection Safety Precautions Other specific restrictions
Requirements for Vertebrate and Insect Baits	Protection statements/ Restricted Chemical product	Instructions for use' and/or 'risk mitigation measures (Biocides)
Products Discharged Into Water Bodies	Protection Statements	Other specific restrictions (PPP)/ Instructions for use' and/or 'risk mitigation measures (Biocides)
Wood Uses		Instructions for use' and/or 'risk mitigation measures (Biocides)
Cranberry		
Greenhouse		Other specific restrictions (PPP) OR Instructions for use' and/or 'risk mitigation measures (Biocides)
Mushroom House		Other specific restrictions (PPP) OR Instructions for use' and/or 'risk mitigation measures (Biocides)
IMEP (Importation for Manufacturing and Export Program)		
Use-Site Category (USC)	Situation	Trials permit
Site/Host/Crop	Crop/pest	Directions for use (crop/ soil type) (PPP) OR Instructions for use (Biocides)
Site/Host/Crop Subtype	Crop or situation	Directions for use (greenhouse/outdoor) (PPP) Instructions for use (Biocides)
Geographic Area	State	Directions for use
Effects on treated objects or sites	Crop Safety	Directions for use
Pest	Pest	Target organisms (Biocides)
Pest Subtype	Growth stage	Development stage (Biocides)
Pest Control Claim	Statement of Claims	Directions for use Biological use phrase Field of use (PPP) OR Field of use description (Biocides)
Duration of Efficacy against Pest(s)	Statement of Claims	Field of use description, Application rate & Instructions for use (Biocides)

Canada (PMRA)	Australia (APVMA)	United Kingdom†
Product Rate/ Concentration and residual to be maintained, if applicable	Rate	Directions for Use 'Important Information Box' (PPP) OR Application rate & Instructions for use (Biocides)
Product Rate/ Concentration/ Residual to be Maintained Units	Rate	Directions for Use 'Important Information Box' (PPP) Maximum individual dose OR Application rate & Instructions for use (Biocides)
Rate of Active Ingredient(s)		Amount and name of the active substance
Adjuvant	Adjuvant	Directions for Use Compatibility
Rate of Adjuvant	Rate of Adjuvant	Directions for Use Compatibility
Rate of Adjuvant Units	Rate of Adjuvant	Directions for Use Compatibility
Maximum Cumulative Rate of Active Ingredient per Year	Restraints	Maximum total dose
Minimum Number of Applications	Minimum Number of Applications	Directions for Use - Other specific restrictions
Maximum Number of Applications	Maximum Number of Applications	Maximum number of treatments
Maximum Number of Applications per Year or Crop Cycle	Maximum Number of Applications per Year	Maximum number of treatments or maximum total dose
Spray Volume	Spray Volume	Directions for Use AND (if required) Other specific restriction
Spray pressure	Spray pressure	Directions for Use
Application Target	Application Target	Bystander/residents exposure – other specific restriction (PPP) OR 'Instructions for use' and/or 'risk mitigation measures' (Biocides)
Application Type	Application Type	Directions for Use (PPP) OR 'Instructions for use' and/or 'risk mitigation measures' (Biocides)
Application Equipment	Application Equipment	Directions for use Safety precautions (PPP) OR 'Instructions for use' and/or 'risk mitigation measures' (Biocides)

Canada (PMRA)	Australia (APVMA)	United Kingdom†
Minimum Re-Treatment Interval (RTI)	Minimum Re-Treatment Interval	Other specific restriction (Minimum interval between applications) (PPP) OR 'Instructions for use' and/or 'risk mitigation measures' (Biocides)
Maximum Re-Treatment Interval (RTI)	Maximum Re-Treatment Interval	Directions for Use - Other specific restrictions (PPP) OR 'Instructions for use' and/or 'risk mitigation measures' (Biocides)
Application Timing	Application Timing	Latest time of application (PPP) OR 'Instructions for use' and 'Number and timing of application' (Biocides)
Application Instructions (Specific Uses)	Application Instructions	Use specific instructions for use (Biocides)
User Requested Minor Use Label Expansion (URMULE)		Extension of Authorisation
User Requested Minor Use Registration (URMUR)		Extension of Authorisation
Restricted Use	RESTRICTED CHEMICAL PRODUCT	Other specific restriction
Aerial Application	Aerial Application	Important Information Box
Emergency Use		
Emergency Use Date of Expiry		
Imported Treated Seed Use		

Note: † Unless specified as PPP (Plant Protection Product) or Biocides, entries are PPP only

3.2.3. Comparison of Label Data Elements Required for Risk Assessments across Survey Respondents

Table 3. Comparison of Label Data Elements Required for Risk Assessments across Survey

Data Element Name	Canada (PMRA)	Australia (APVMA)	New Zealand (ACVM/EPA)	United Kingdom	Japan
Product Name	N	Y	N	N	N
Product description	N	Y	N	Y	N
Product Type	Y	N	Y	Y	Y
Formulation Type	Y	Y	Y	Y	Y
Class designation	Y	Y	N	Y	N
Signal Words	N	Y	Y	Y	N
Hazard Symbols	N	N	Y	Y	N
Hazard Statements	N	N	Y	Y	N
Read the label before using	N	Y	N	N	N
Active Ingredient	N	Y	Y	Y	N
Allergens	N	N	Y	Y	N
Preservatives	N	N	N	Y	N
Registration Number	N	N	N	N	N
Private Label Number	N	N	N	N	N
Net Contents	Y	Y	Y	Y	Y
Contact information	N	N	N	N	N
Resistance Management Group for the Active Ingredient	N	Y	Y	N	N
Expiry date	N	Y	Y	Y	Y
Notice to user	N	N	N	N	N
First Aid Instructions	N	Y	Y	N	N
Companion Animal and Livestock First Aid	N	N	N	N	N
Toxicological Information	N	Y	N	Y	N
Human Health Precautions	N	Y	Y	Y	N
Personal Protective Equipment (PPE)/ Engineering Controls	N	Y	Y	Y	N
Companion Animal and Livestock Precautions	N	Y	Y	Y	N
Environmental Precautions	N	Y	Y	Y	N

Data Element Name	Canada (PMRA)	Australia (APVMA)	New Zealand (ACVM/EPA)	United Kingdom	Japan
Environmental Precautions – Aquatic organisms	N	?	Y	Y	
Environmental Precautions - Birds	N	?	Y	Y	
Environmental Precautions – Wild Mammals	N	?	n/a	Y	
Environmental Precautions - Bees	N	Y	Y	Y	
Environmental Precautions – Beneficial Arthropods	N	?	Y	Y	N
Environmental Precautions - Earthworms	N	?	Y	Y	
Environmental Precautions – Non-Target Terrestrial Plants	N	?	Y	Y	
Environmental Precautions – Burrow Treatments	N	?		Y	
Environmental Precautions – Persistence/ Accumulation/ Carryover	N	Y	Y	Y	N
Environmental Precautions – Leaching	N	Y	Y	Y	N
Environmental Precautions – Runoff	N	Y	Y	Y	N
Environmental Precautions - Volatilization	N	Y	Y	Y	N
Environmental Precautions - Products Containing Aromatic Petroleum Distillates	N	Y	Y	Y	N
General information	N	Y	N	Y	N
Directions For Use (General)	N	Y	N	Y	N
Use Limitations	N	Y	Y	Y	N
General Application Instructions	N	Y	Y	Y	N
Application Method	Y	Y	Y	Y	Y
Application target	Y	Y	Y	Y	Y
Application equipment	Y	Y	Y	Y	Y
Chemigation	N	Y		Y	N
Runoff Management	N	Y	Y	Y	N
Spray Drift Management	N	Y	Y	Y	N
General Mixing Instructions	N	N	N	Y	N
Generic Tank Mix Statement	N	N	N	Y	N
Tank Mix Partner Information	N	N	N	Y	N
Tank Mix Partner Mixing-Loading Instructions	N	Y	N	Y	N
Rotational Crops/ Plantback Interval	Y	Y	Y	Y	Y
Restricted-Entry Intervals	Y	Y	Y	Y	N
Preharvest Intervals	Y	Y	Y	Y	Y
Pregrazing Intervals/ Feeding Restriction	Y	Y	Y	Y	N
Preslaughter Intervals	Y	Y	Y	Y	N

Data Element Name	Canada (PMRA)	Australia (APVMA)	New Zealand (ACVM/EPA)	United Kingdom	Japan
Resistance Management Information	N	Y	Y	Y	N
Storage and Disposal	N	Y	Y	Y	N
Labelling of Treated Seed (Seed Tag)	N	N	Y	Y	N
Labelling of Treated Article (Hang Tag)	N	Y	N	PPPs - n/a Biocides - N	N
Imported Treated Seed Information	N	Y	N	N	N
Direct Application to Water	N	Y	Y	Y	N
Requirements for Vertebrate and Insect Baits	N	Y	Y	Y	N
Products Discharged Into Water Bodies	N	Y	N	Y	N
Wood Uses	N	N	N	Y	N
Cranberry	N	N	N	N/A	N
Greenhouse	N	N	N	Y	N
Mushroom House	N	N	N	Y	N
IMEP (Importation for Manufacturing and Export Program)	N	N	Y	N	N
Use-Site Category (USC)	Y	Y		PPPs - Y Biocides - n/a	N
Site/Host/Crop	Y	Y	Y	Y	Y
Site/Host/Crop Subtype	Y	Y	Y	Y	Y
Geographic Area	Y	Y	Y	Y	N
Effects on treated objects or sites	N	Y	Y	Y	N
Pest	Y	Y	Y	Y	Y
Pest Subtype	Y	Y	Y	Y	Y
Pest Control Claim	N	Y	Y	Y	N
Duration of Efficacy against Pest(s)	N	Y	Y	Y	N
Product Rate/ Concentration and residual to be maintained, if applicable	Y	Y	Y	Y	Y
Product Rate/ Concentration/ Residual to be Maintained Units	Y	Y	Y	Y	Y
Rate of Active Ingredient(s)	Y	N	Y	Y	Y
Adjuvant	Y	Y	Y	Y	N
Rate of Adjuvant	Y	Y	Y	Y	N
Rate of Adjuvant Units	Y	N	Y	Y	N
Maximum Cumulative Rate of Active Ingredient per Year	Y	Y	Y	Y	N
Minimum Number of Applications	Y	Y	Y	Y	Y

Data Element Name	Canada (PMRA)	Australia (APVMA)	New Zealand (ACVM/EPA)	United Kingdom	Japan
Maximum Number of Applications	Y	Y	Y	Y	Y
Maximum Number of Applications per Year or Crop Cycle	Y	Y	Y	Y	N
Spray Volume	Y	Y	Y	Y	Y
Spray pressure	Y	N	Y	Y	N
Application Target	Y	N	Y	Y	Y
Application Type	Y	N	Y	Y	Y
Application Equipment	Y	Y	Y	Y	Y
Minimum Re-Treatment Interval (RTI)	Y	Y	Y	Y	N
Maximum Re-Treatment Interval (RTI)	Y	Y	Y	Y	N
Application Timing	Y	Y	Y	Y	Y
Application Instructions (Specific Uses)	N	?	N	Y	Y
User Requested Minor Use Label Expansion (URMULE)	N	N	N	Y	N
User Requested Minor Use Registration (URMUR)	N	N	N	Y	N
Restricted Use	N	Y	Y	Y	N
Aerial Application	Y	Y	Y	Y	Y
Emergency Use	N	N	N	Y	N
Emergency Use Date of Expiry	N	N	N	Y	N
Imported Treated Seed Use	N	N	N	N	N

4. RECOMMENDATIONS

This report provides interested parties with information that will support and inform the development of structured electronic pesticide labels, and facilitate exchange of international data.

It is therefore recommended that:

- d. OECD member countries, when developing labelling guidelines for pesticide products, should (where possible) utilize the report in considering options with a view to harmonizing data elements, their naming conventions, and prioritizing structured data elements, for pesticide products with other member countries that would facilitate data sharing.
- e. OECD member countries, when developing IT solutions to enable the transmission, receipt, management, and output of label data, should (where possible) consider common label data elements, and their naming conventions, as identified in this exercise, to support the interoperability of electronic labelling applications.
- f. To support a more global approach to pesticide product registration, member countries should examine further work to expand data sharing across OECD member countries.

5. ANNEX 1 - 2019 Survey with Example Canadian Input

OECD Survey: Labelling Initiatives

Canada: Pest Management Regulatory Agency



Purpose:

- The survey aims to identify commonalities regarding the regulatory process of the review and approval of pest control product labels across OECD members.
- Identification of common data elements for labels will enable a more data centric business model:
 - Industry submits label information via structured forms using standardized statements and nomenclature.
 - Regulator receives label information in a structured format expediting assessments and issuance of approved/amended labels
 - Users can search and access pesticide information (precautions, directions for use) that is specific to their needs which results in safer use of pesticides.

Q1: What is the Regulatory Authority on labelling requirements?

What are the authorities to amend pest control product labels?

Pest Control Products Act (PCPA):

<https://laws-lois.justice.gc.ca/eng/acts/p-9.01/>

- **21 (1)** If the Minister considers that the health and environmental risks and the value of a pest control product are acceptable after any required evaluations and consultations have been completed, the Minister shall confirm the registration.

Amendment or cancellation

- **(2)** If the Minister does not consider that the health or environmental risks or value of a pest control product are acceptable, the Minister shall
 - **(a)** amend the registration if the Minister considers that the health and environmental risks and value of the product **would be acceptable after the amendment**; or
 - **(b)** cancel the registration.

Pest Control Products Regulations (PCPR):

<https://laws-lois.justice.gc.ca/eng/Regulations/SOR-2006-124/index.html>

- Section 22-29, 34 of the PCPR outlines the required contents of the Pest Control Pesticide Labels used within Canada.

What additional authorities are needed?

- No current authority for PMRA to change labels (outside post-market review) without an application - delays in addressing health / env / legal risks
- Labelling content structure is not mandatory

Q2: Describe the Process and Format for receipt of label information.

In 2003 PMRA eliminated the requirement for submission of a paper copy labels prior to issuance of a certificate of registration.

Current process:



Q3: List of common label sections

Primary Panel:	Secondary Panel:
<ul style="list-style-type: none"> •Product Name •Signal Words, Hazard Symbols and statements •Registration Number •Active Ingredient •Product Classification (Domestic, Commercial, Restricted) •READ THE LABEL BEFORE USING •Net contents •Registrant name and contact information 	<ul style="list-style-type: none"> •Precautions <ul style="list-style-type: none"> •Environmental •Personal Protective Equipment •First Aid •Toxicological Information •Directions for Use <ul style="list-style-type: none"> •Rotational Crops/Plant back Intervals •Restricted Entry Intervals •Pre Harvest Intervals •Tank Mix Instructions •Buffer zones •Use Restrictions •Aerial Application •Mixing and Loading •Application Equipment •Storage and Disposal Information

Q4 List the Label Data Elements Required For Risk Assessments.

- Aerial Application
- Class
- Formulation Type
- Guarantee Value
- Guarantee Unit
- Geographic Area
- Use Site Category
- Site
- Pest
- Pre Harvest Interval
- Pre Slaughter Interval
- Pre Grazing Interval
- Spray volume
- Max. No. Appl. per Year
- Min. Interval Between App
- Appl Equipment
- Plant Back Interval
- Appl Timing
- Personal Protective Equipment
- Buffer Zone
- Application Instructions
- Re-Entry Interval
- Min Appl Rate Value
- Max Appl Rate Value
- EUP Appl Rate Unit
- EUP Max Appl Rate Cumulative Value (label)
- EUP Max Appl Rate Cumulative Unit (label)
- AI Min Appl Rate Value
- AI Max Appl Rate Value to Area
- AI Max Appl Rate Cumulative Value
- AI Min Appl Rate Value to Area (calc) in g a.i./ha
- AI Max Appl Rate Value to Area (calc)g in a.i./ha
- Closed and/or Open Mixing/Loading/Applying?
- Seeds Treated in Canada and/or Imported
- AI Min Appl Rate to Seed Value
- AI Max Appl Rate to Seed Value
- AI Appl Rate per Unit Seed
- AI Min Appl Rate Value to Area (calc) in g a.i./ha
- AI Max Appl Rate Value to Area (calc)g in a.i./ha
- AI Max Appl Rate for the Crop per Season Value
- AI Max Appl Rate for the Crop per Season Unit

*EUP= End Use Product

**AI= Active Ingredient

Q5: In what format are the final approved labels available?

Internal:

Pesticide Label Database (PLD):

- Currently a manual process where one employee extracts (copies) label data from PDF label file and manually enters (pastes) it into a structured relational database (PLD)
- Data is extracted from the PLD through a data reporting software (APEX) and is used to generate reports of label information required for the risk assessment for post market regulatory review.

External:

- Final electronic Word labels are sent to the registrant via email.
- PMRA website: Electronic Label Search
 - Search by 1. free text 2. CAS number 3. Active Ingredient 4. Product Name 5. Registrant Name 6. Registration Number
 - <http://pr-rp.hc-sc.gc.ca/lr-re/index-eng.php>
- PMRA Label App:
 - <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/tools/pesticide-label-search.html>

Q6: What are the main labelling challenges?

- PMRA maintains information from nearly **8000** pesticide labels
- Pesticide labels can be very complex - some labels are **100+ pages** long and can include **hundreds** of different use scenarios (site-pest-rate combinations).
- Manually extracting and summarizing label information for pre and post market risk assessments is resource and time intensive due to the sheer volume of data that needs to be processed (see slide 5).
- Label amendments currently take up to **2 years** following the publication of a re-evaluation decision before appearing on market place labels.
- Re-evaluation of **176 actives** are slated to be initiated between 1 April 2019 and 31 March 2024.
- This represents **1812 individual products** that will require label amendments as a result of re-evaluation over the next 5 years.

Q7: Are there current label initiatives underway?**• Updating Label Statements:**

– Ongoing efforts to:

- standardize label statements –as a result of re-evaluations, pre-market submissions; and developing new content
- make statements clear for users (applicators), and the public.
- use language that is enforceable.

• Legislative and Regulatory Modernization:

– Fall 2018, the Health Minister and Treasury Board approved “Label Modernization for Pest Control Products”:

- Includes Structured labels, Ministerial authority, Electronic labels & GHS (Globally Harmonized System)

• Business Improvement / IT:

- Move towards a more data centric business model in order to streamline business processes (e.g. creation of a structured electronic label)

Q8: What are the drivers for label improvement?

- Health and Safety:
 - Timely changes to labels reflecting required mitigation measures for health and environment risks
 - standardizing and harmonizing pesticide labelling terminology
- Data as a strategic asset:
 - Industry submits label information via structured forms which will enable more data centric business model
- Efficiencies in data gathering:
 - Regulator receives label information in a structured format expediting assessments and issuance of approved/amended labels
 - Standardized wording of label statements and site-pest-rate nomenclature using standardized and/or harmonized picklist options
 - Access to pesticide label information in the context of specific needs
- Access to data:
 - Users can search and access pesticide information (precautions, directions for use) that is specific to their needs which results in safer use of pesticides.
 - API enabled for open data access (potential for 3rd party applications)

6. ANNEX 2 - 2020 Survey with Example Canadian Input

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
Product Name	Unique text identifier assigned to each individual product used for tracking and reporting purposes.		N	PCPR 26 (1)(a)
Product description	Provides a brief description for easy identification of the general uses (sites and pests) of the product.		N	
Product Type	<p>Unique text identifier assigned to each individual product type used for tracking and reporting purposes.</p> <p>Identifies the general type of organism targeted by the product (e.g., fungicide, insecticide, vertebrate repellent).</p> <p>Determines the use pattern assessed in the value and risk assessments.</p> <p>Some data requirements and label information and restrictions are directly linked to the product type and used in risk assessment and risk management</p>		Y	PCPR 26 (1)(b)
Formulation Type	<p>Unique text identifier assigned to each individual formulation type used for tracking and reporting purposes.</p> <p>Residue data may be dependent on the formulation type; used in the dietary risk assessment.</p> <p>The exposure values used in the occupational/residential risk assessments are dependent on the formulation type.</p>		Y	PCPR 26 (1)(b) and PCPR 26 (1)(c)
Class designation	<p>Unique text identifier assigned to each individual marketing class used for tracking and reporting purposes.</p> <p>The parameters used in the occupational/residential risk assessment are different for</p>		Y	PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
	commercial-class and domestic-class product. Also, restricted-class may be used as a mitigation measure to prevent occupational/residential human health risk or environmental risk.			products
Signal Words	Needed to identify the acute health hazards to users. May trigger the need for additional personal protection equipment (PPE). Determined by the acute toxicity and physical and chemical properties of the pest control products (TGAI, MUP, EP).		N	PCPR 26 (1)(e) schedules 3 and 4
Hazard Symbols	“Pictograms” inform users of acute health hazards.		N	PCPR 26 (1)(e) schedules 3 and 4
Hazard Statements	Statements inform users of acute health hazards.		N	PCPR26(1) (e)
Read the label before using	Instructs users to read the label (and booklet, if applicable) before using to ensure they are informed as to how to use the product safely and effectively.		N	PCPR 26(1)(f) and 28 (2)(a)
Active Ingredient	Required for value, environment, human health hazard and risk characterization. The active ingredient includes common chemical name of the active ingredient or, if none, its chemical name or another name, and the concentration of the active ingredient in the appropriate form. Information on viscosity, specific gravity, particle size or any other property may also be required.		N	PCPR 26 (1)(h)
Allergens	Label identification of formulants that are common allergens known to be associated with anaphylactic reactions.		N	DIR2006-02
Preservatives	Label identification of active ingredients that are present in the end-use formulation		N	DIR2006-02

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
	as formulation preservatives.			
Registration Number	Statement containing unique numerical identifier assigned to each individual product used for tracking and reporting purposes. If one is not yet assigned, a placeholder will be needed.		N	PCPR 26 (1)(i)
Private Label Number	Unique numerical identifier assigned to each individual product used for tracking and reporting purposes.		N	PCPR 26 (1)(i)
Net Contents	May have an impact on occupational risk assessment and mitigation measures.		Y	PCPR 26 (1)(j) Weights and Measures Act (metric)
Contact information	Required to allow users to contact the registrant with inquiries about the product. At minimum, registrant name and postal address and telephone number to which public inquiries may be directed.		N	PCPR 26(1)(k)(l) and 27 (1)(2)
Resistance Management Group for the Active Ingredient	Unique alphanumeric identifier assigned to fungicide, herbicide and insecticide active ingredient; used in value determination. Appears on commercial or restricted class product labels as part of the identification for resistance management purposes. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.		N	DIR 2013-04
Expiry date	For products that have a limited shelf life, ex: live organisms		N	
Notice to user	To stress the importance of reading the label.		N	PCPR 26(2)(g)

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
First Aid Instructions	<p>In the case of human health issues, the instructions identify the steps to take to help the person experiencing the symptoms.</p> <p>The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.</p>		N	PCPR 26(2)(e)
Companion Animal and Livestock First Aid	<p>In the case of animal health issues, the instructions identify the steps to take to help the pet experiencing the symptoms.</p>		N	PCPR 26(2)(e); DIR2002-01
Toxicological Information	<p>Information for doctor/physician</p> <p>The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.</p>		N	PCPR 26(2)(f)
Human Health Precautions	<p>The label statements in this section inform users of potential human health hazards or risk and/or measures to mitigate the hazards and/or risks.</p>		N	PCPR 26(2)(c) and 26(2)(d)
Personal Protective Equipment (PPE)/ Engineering Controls	<p>Mandatory protective equipment such as clothing, respirators, goggles and gloves required as a result of the acute hazard and/or human health risk assessment to reduce exposure to workers in contact with pest control products.</p> <p>Engineering controls (e.g. closed-cab tractor) may be required to prevent/mitigate exposures and/or risk while performing their work with pesticides.</p>		N	PCPR 26(2)(c)
Companion Animal and Livestock Precautions	<p>The label statements in this section inform users of potential animal health hazards or risk and/or measures to mitigate the risks.</p>		N	PCPR 26(2)(c) and 26(2)(d)
Environmental Precautions	<p>The label statements in this section inform users of potential hazards or risks to the environment and/or of measures to mitigate the risks to the environment. Each</p>		N	PCPR 26(2)(c)

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
	subsection is separate to allow for tracking and reporting purposes in the future.			
Environmental Precautions – Aquatic organisms	Statements inform users of potential hazards or risks and/or of measures to mitigate risks.		N	
Environmental Precautions - Birds				
Environmental Precautions – Wild Mammals				
Environmental Precautions - Bees				
Environmental Precautions – Beneficial Arthropods				
Environmental Precautions - Earthworms				
Environmental Precautions – Non-Target Terrestrial Plants				
Environmental				

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory[†]/ Policy and Guidelines^{††} Requirement
Precautions – Burrow Treatments				
Environmental Precautions – Persistence/ Accumulation/ Carryover	Statements inform users of the potential for accumulation and carryover and recommend practices to minimize the potential for accumulation and carryover.		N	
Environmental Precautions – Leaching	Statements inform users of the potential for leaching and recommend practices to minimize the potential for leaching to groundwater.		N	
Environmental Precautions – Runoff	Statements recommend practices to minimize runoff into adjacent waterbodies.		N	
Environmental Precautions - Volatilization	Statements to minimize the release into the environment from volatilization.		N	
Environmental Precautions - Products Containing Aromatic Petroleum Distillates	Statements inform users of potential hazards or risks to aquatic organisms.		N	
General information	Provides general directions on the use of the product. Includes but is not limited to a brief product description/ information and geographic restrictions (if applicable).		N	
Directions For Use (General)	Communicates the PMRA supported use pattern to the end user of the pest control product.		N	PCPR 26(2)(a)

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
Use Limitations	<p>To identify situations that may pose potential risks of concern to health or the environment.</p> <p>To communicate limitations in the use pattern for which a risk assessment was not performed or for which risks of concern were identified (i.e. DO NOT apply in greenhouses.)</p> <p>To identify restrictions related to dietary and occupational exposure: preharvest intervals, restricted-entry intervals, pregrazing interval/feeding restrictions, preslaughter interval</p>		N	PCPR26(2)(a)
General Application Instructions	General information on how to apply the product including ground or aerial application, the application type (broadcast, drench, chemigation, etc.), the application target (foliar, soil, seed, etc.) and permitted equipment.		N	PCPR26(2)(a)
Application Method	<p>Required for the risk and value assessments</p> <p>Statements for various application methods provide measures to minimize spray drift to non-target sensitive habitats for certain application equipment.</p> <p>Parameters used in the occupational/residential health risk assessments are dependent upon the application method.</p> <p>For residue chemistry, data requirements and residue trials are required for each type of applications. Residue data are used in the risk assessment.</p>		Y	PCPR26(2)(a)
Application target	The application target (foliar, soil, seed, etc.)		Y	PCPR26(2)(a)
Application equipment	Provides information on the type of application equipment that is approved for use.		Y	PCPR26(2)(a)
Chemigation	Instruction on the use of chemigation		N	DIR93-13

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
Runoff Management	Mandatory vegetative filter strips provide measures required to mitigate risks to aquatic organisms from runoff of pesticide into adjacent waterbodies.		N	
Spray Drift Management	Spray buffer zone statements and spray buffer zone table provide measures required to mitigate risks to sensitive terrestrial and aquatic habitats from spray drift downwind from the site of application.		N	
General Mixing Instructions	Mixing instructions that apply to all uses on the label including tank mixing sequencing		N	
Generic Tank Mix Statement	Instructions for tank mixes not specifically described on the label.		N	
Tank Mix Partner Information	Used for tracking and identifying specific tank mixes		N	
Tank Mix Partner Mixing-Loading Instructions	Instructions for proper mixing of specific tank mix partners (e.g., order to introduce the partners into the spray tank)		N	
Rotational Crops/ Plantback Interval	Required for the risk and value assessments To inform users of the time interval to respect before planting rotational crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern. Also phytotoxicity, field bioassay statements/instruction		Y	
Restricted-Entry Intervals	To inform users of the interval between application, and when workers can enter areas treated with pest control products.		Y	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
	Can be used to mitigate risks to postapplication workers.			
Preharvest Intervals	To inform users of the time interval to respect before harvesting the food crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern.		Y	
Pregrazing Intervals/ Feeding Restriction	To inform users of the time interval to respect before harvesting the feed crops or letting livestock graze in the treated field in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.		Y	
Preslaughter Intervals	To inform users of the time interval to respect before slaughtering livestock in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.		Y	
Resistance Management Information	Recommendations to reduce the risk of pesticide resistance by arthropods, plant diseases and weeds. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.		N	DIR 2013-04
Storage and Disposal	Storage statement to prevent contamination of food or feed and provide disposal information.		N	PCPR 26(2)(b) and DIR 1999-04
Labelling of Treated Seed (Seed Tag)	<p>Statements on seed tags are used to inform users of measures to mitigate environmental risks.</p> <p>Precautionary statements on seed tags are used to inform workers of the required PPE/engineering controls while handling and planting treated seed.</p> <p>May include restrictions such as pregrazing interval/feeding restrictions or plantback intervals/rotational crops.</p>		N	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
Labelling of Treated Article (Hang Tag)	<p>Statements on hang tags are used to inform users/consumers of proper handling, care and use of the garment/article</p> <p>Precautionary statements on hang tags are used to inform users/consumers of potential skin sensitizing risks from the use/exposure to manufactured garments/articles</p> <p>May include restrictions or storage and disposal requirements</p>		N	
Imported Treated Seed Information	To inform importers of treated seed that a human health risk assessment for planters has been conducted and that it is acceptable to import the treated seed into Canada.		N	
Direct Application to Water	Statements provide measures to mitigate risks to non-target aquatic organisms and inform users of legislative requirements when applying pesticides directly to water.		N	
Requirements for Vertebrate and Insect Baits	<p>Required for the risk and value assessments</p> <p>Statements provide measures to mitigate risks to children, pets, livestock or wildlife such as non-target birds or wild mammals.</p>		N	
Products Discharged Into Water Bodies	Statement provide measures to mitigate potential risks to aquatic organisms from discharge of effluent.		N	
Wood Uses	<p>Required for the risk assessments</p> <p>Statements provide measures to minimize releases into the environment.</p>		N	
Cranberry	Statements provide measures to mitigate potential risks of effluent water from cranberry fields to aquatic organisms.		N	
Greenhouse	Statements provide measures to mitigate risks to aquatic organisms from effluent or		N	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
	runoff.			
Mushroom House	Statements provide measures to mitigate risks to aquatic organisms from effluent or runoff.		N	
IMEP (Importation for Manufacturing and Export Program)	Statements provide measures to mitigate risks to aquatic organisms from a product imported solely for the purpose of manufacturing and export.		N	
Use-Site Category (USC)	Required to help guide determination of data required in support of an application to register, amend, or conduct research with a pest control product. Each USC has a list of required and conditionally required data called data-code or DACO tables.		Y	
Site/Host/Crop	Required for the risk and value assessments (i.e., area of use, site of application, surface type or material to be treated)		Y	PCPR26(2)(a)
Site/Host/Crop Subtype	This would be for additional information on a site/host such as age and weight of products used on companion animals or type of growing environment (greenhouse, outdoor field, etc.). Required for value and risk assessments.		Y	PCPR 26(2)(a)
Geographic Area	May have an impact on the residue chemistry data requirements (i.e. reduce the number of field trials required), residue data used in the human health risk assessment May have an impact on the input used in the dietary risk assessment for drinking water		Y	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
Effects on treated objects or sites	This would include information on the potential for damage to treated sites (e.g., phytotoxicity) Required for value assessment.		N	DIR2016-02
Pest	Identifies the pest being targeted, Required for the value assessment Determine the type of human health risk assessment is required based on how the specific pest is treated or where the pest found in relation to human activities.		Y	PCPR 26(2)(a)
Pest Subtype	Required for the value assessment Required for determining the magnitude of postapplication exposure use patterns. This would be for any additional details on the target pest (e.g., lifestage, nest treatment).		Y	PCPR 26(2)(a)
Pest Control Claim	Required for the value assessment (ie., type/level of control such as control, suppression, reduces infection/damage, prevents fouling vs removes established fouling, type of protection- prevents degradation, discoloration)		N	PCPR 26(2)(a)
Duration of Efficacy against Pest(s)	Required for the value assessment of personal insect repellents, other repellents, attractants, products with residual claims, companion animal product, etc.		N	PCPR 26(2)(a)
Product Rate/ Concentration and residual to be maintained, if applicable	Required for the risk and value assessments Directions for use, including method and application rates or residual concentration to be maintained, target retention (kg/m ³) or target deposition (µg/cm ²), expected coverage (m ² per litre of paint), the contact time, dilution and rinse if applicable. When pesticide rates are given as a range, instructions may be required as to when to use the lower and higher application rates.		Y	PCPR 26(2)(a)

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
Product Rate/ Concentration/ Residual to be Maintained Units	Required for the risk and value assessments		Y	PCPR 26(2)(a)
Rate of Active Ingredient(s)	Required for the risk and value assessments		Y	PCPR 26(2)(a)
Adjuvant	Adjuvant product name or adjuvant type. Required for the acute hazard, dietary risk assessment for the active ingredient with which it is co-formulated and value assessments		Y	PCPR 26(2)(a)
Rate of Adjuvant	Required for the acute hazard, dietary risk assessment for the active ingredient with which the adjuvant is co-formulated and value assessments Human health risk assessments are not required for the adjuvant itself.		Y	PCPR 26(2)(a)
Rate of Adjuvant Units	Required for the risk and value assessments		Y	PCPR 26(2)(a)
Maximum Cumulative Rate of Active Ingredient per Year	Required for the risk assessments		Y	PCPR 26(2)(a)
Minimum Number of Applications	Required for occupational exposure risk assessment (required as sometimes there is a range in the number of applications) May be required to refine or mitigate the occupational exposure risk assessment		Y	
Maximum Number of	Required for the risk assessments		Y	PCPR 26(2)(a)

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
Applications	Can be used as a tool to mitigate postapplication exposure, and determine the total amount of active ingredient applied to a crop in a single year or crop cycle.			
Maximum Number of Applications per Year or Crop Cycle	Required for the risk assessments		Y	PCPR 26(2)(a)
Spray Volume	Required for the risk and value assessments Spray volume is also included in buffer zone calculations for aerial application Converts user application rates on labels to rates required to complete a human health risk assessment.		Y	PCPR 26(2)(a)
Spray pressure	Required for the risk assessments		Y	
Application Target	Required for the risk assessments Parameters used in the occupational/residential health risk assessments are dependent on the application target.		Y	PCPR 26(2)(a)
Application Type	Required for the risk and value assessments Parameters used in the occupational/residential health risk assessments are dependent on the application type.		Y	PCPR 26(2)(a)
Application Equipment	Required for the risk assessments and value assessments Application equipment is also considered in the buffer zone calculations. Parameters used in the occupational/residential health risk assessments are dependent on the application equipment.		Y	PCPR 26(2)(a)

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
Minimum Re-Treatment Interval (RTI)	Required for the risk and value assessments One of the parameters in the occupational/residential risk assessment		Y	PCPR 26(2)(a)
Maximum Re-Treatment Interval (RTI)	Required for the risk assessments Required for occupational exposure risk assessments (required as sometimes there is a range of RTIs) - May be required to refine or mitigate the occupational exposure risk assessment		Y	
Application Timing	Used to identify the application timing for effective management of the listed pest(s); EAD: used to determine exposure considerations in environmental risk assessments for aquatic organisms and pollinators. Considered in the human health risk assessment to determine the potential exposure to workers, users and bystanders For residue chemistry, if application timing is early and very specific, may not need a preharvest interval. Required for the value assessments – preventative vs curative claims.		Y	PCPR 26(2)(a)
Application Instructions (Specific Uses)	Instructions that identify the PMRA supported/approved use of a product in the context of a specific use pattern (e.g. site-pest-rate combination) Any other information pertinent to the value of the pest control product (pre-cleaning or surface preparation, etc.)		N	PCPR 26(2)(a)
User Requested Minor Use Label Expansion (URMULE)	Used for tracking and reporting on the expansion of a label for a new minor use of a pesticide for which the active ingredient(s) and the end use product are currently registered in Canada under the URMULE program		N	DIR2001-01

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment	Regulatory [†] / Policy and Guidelines ^{††} Requirement
User Requested Minor Use Registration (URMUR)	Used for tracking and reporting on the registration of products/uses under the URMUR program		N	DIR99-05
Restricted Use	Used to identify specific product applications that can only be used under certain circumstances by specially trained individuals.		N	PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products
Aerial Application	Required for the risk and value assessments		Y	DIR1996-04
Emergency Use	Used to identify products that are required for emergency control of pest infestations that are seriously detrimental to public health, domestic animals, natural resources or other things, for a period not exceeding one year.		N	DIR2017-03
Emergency Use Date of Expiry	Used to identify and expire emergency use(s) from a label after a pre-defined date.		N	PCPR 18 DIR2017-03
Imported Treated Seed Use	To identify the use rate at which the imported treated seed would have been treated in order to conduct the occupational exposure risk assessment for planters.		N	

7. ANNEX 3 - Individual Country Responses to 2019 Survey

7.1. Australia

OECD Labelling Survey

APVMA Responses

November 2019

Purpose

- The survey aims to identify commonalities regarding the regulatory process of the review and approval of pest control product labels across OECD members.
- Identification of common data elements for labels will enable a more data centric business model:
 - Industry submits label information via structured forms using standardized statements and nomenclature.
 - Regulator receives label information in a structured format expediting assessments and issuance of approved/amended labels
 - Users can search and access pesticide information (precautions, directions for use) that is specific to their needs which results in safer use of pesticides.

Q1: What is the Regulatory Authority on labelling requirements?

The APVMA is responsible for the safe manufacture and supply of agricultural chemicals, veterinary medicines, and other products (e.g., antifouling paints, pool and spa sanitisers).

The APVMA must have regard to certain matters or details in order for it to satisfy itself that a label meets the labelling criteria and approve the label (sections 5D and 14 of the Agvet Code).

A detailed summary of how the APVMA interprets and implements the legislative requirements is available on the APVMA website.

The Labelling Codes draws together the requirements of the Agvet Code and the Agvet Code Regulations into a single document. The Agricultural and Veterinary Labelling Codes are available on the APVMA website.

The APVMA also has specific labelling requirements for home and garden products and antifouling paints.

Q1: What is the Regulatory Authority on labelling requirements?

AgVet Code:

- Section 5D – defines the labelling criteria
- Section 6A – gives authority to make guidelines for label approvals
- Section 6E – gives authority to draft legislative instruments to establish standards for labels
- Section 8 – describes a label
- Sections 14 and 29: Establishes the criteria that, when met, compel the APVMA to approve the active constituent or label, or register the chemical product

(d) for a label for a chemical product—that the label:

(i) meets the labelling criteria; or

(ii) complies with the established standard for the product.

- Section 15: Restriction on power of APVMA to register products and approve labels – Requires that the APVMA must not register a product without registering a label, and vice versa
- Section 21: Establishes how approval of a label takes place
- Section 26: Allows the APVMA to address an error in the label of our own making
- Section 29A: Allows the APVMA to alter a label with permission from the holder

AgVet Code (continued):

- Section 31: Gives the APVMA the authority to reconsider a registration, including the label approval
- Section 34: Establishes the criteria that, when met, compel the APVMA to affirm the approval of the active constituent or label, or register the chemical product

- Section 34AA(2): Establishes the criteria that, when met, require the APVMA to suspend or cancel the label approval
- Section 34AF: Empower the APVMA to reconsider a label approval without notice under certain circumstances
- Section 36: Empower the APVMA to suspend or cancel a label approval if conditions of registration are breached
- Section 41(2): Empower the APVMA to suspend or cancel a label if it no longer meets the labelling criteria or other requirements established in the Regulations
- Section 44(2): Empowers the APVMA to cancel or suspend a label when they cancel or suspend the product registration
- Section 45A: Compels the APVMA to give notice of intention to cancel or suspend a label

Q1: What is the Regulatory Authority on labelling requirements?

AgVet Code (continued):

- Section 47(4): Automatically cancels a label when a product registration is not renewed
- Section 51: Renewal of label when a chemical product is renewed
- Sections 80 and 81: Deal with supply of a product without an attached label or with an unapproved label
- Section 84: Prohibits a holder from making claims that are inconsistent with the label
- Section 85: Prohibits changes to the expiry date on the label
- Section 86: Prohibits removal of a label from the container of a chemical product
- Sections 91 and 92: Deals with label requirements for date-controlled products
- Section 95: Establishes label requirements for restricted chemical products
- Section 103: Empowers the APVMA to recall products with non-compliant labels

Q1: What is the Regulatory Authority on labelling requirements?

AgVet Code Regulations:

- Section 8AE: Deals with signal words based on poisons scheduling as well as storage conditions for date-controlled products

- Section 8AF: Defines the requirements that must be established in the labelling standard
- Section 8AHA: Requires the APVMA to publish a notice of label approval or variation
- Section 8AN: Prescribes the APVMA's publication requirements for label approvals – This includes the requirement for the APVMA to give the label a unique distinguishing number
- Section 17: Prescribes the required label particulars
- Subdivision 2.1.6 outlines the conditions of approvals for labels
 - Section 18B: Prescribed conditions for approval of labels
 - Section 18C: Label must be attached to containers for chemical products
 - Section 18D: Information on label
 - Section 18E: Labelling standards and requirements
 - Section 18F: Requirements for information on labels
 - Section 18G: Requirements about claims inconsistent with labels
 - Section 18H: Retention of label and information about label
 - Section 18I: Providing label and information about label to APVMA
 - Section 18J: Identifying information recorded for holder and nominated agent

Q1: What is the Regulatory Authority on labelling requirements?

AgVet Code Regulations (continued):

- Subdivision 2.1.6A: Empowers the APVMA to address incorrect particulars and conditions
- Section 42: Establishes the prescribed standards for chemical products
- Section 65: Requires that applicants submit label information related to an application under Section 10(1)(c) or 27(1)(c) to the APVMA electronically

Q2: Describe the Process and Format for receipt of label information.

- Applicants must use the e-label template to submit the required label elements to the APVMA.
- Once submitted, the e-label is reviewed as part of the APVMA's assessment evaluation process.
- A copy of the approved label is sent to the applicant with the registration notice once the application has been approved.
- Other label content does not need to be assessed or approved by the APVMA and is not covered by the template.
- Changes to the information covered by the template can only be made by application for variation.
- Changes to information not covered by the template may be made without formal APVMA approval but must remain compliant with the relevant Labelling Code.
- More details on how to apply for a label approval are available here.

Q3: List of common label sections

Section 8AF(4A): *For the purposes of subparagraph 6(2)(a)(iii) of the Act, a labelling standard must include requirements relating to one or more of the following:*

(a) the presentation of the label, including the size, colour, legibility, dimensions, layout and format of the label;

(b) the display of the label;

(c) the information contained on the label.

Section 17: Prescribes the required label particulars

The Ag Labelling Code explains the information that must be placed on labels to meet the legislative requirements. It also provides examples of acceptable wording for certain statements where specific words are not mandated by the legislation. A list of common label sections has been included on the next slide.

Q3: List of common label sections

Common label sections are as follows:

7. Signal heading
8. Product name

9. Constituent statements
10. 'Mode of action' indicator
11. Statement of claims for use
12. Restricted chemical product statements
13. 'Net contents' statement
14. Name and address of person primarily responsible for marketing the product
15. Directions for use
16. 'Not to be used' statement
17. Other limitations and prohibitions
18. 'Withholding period' statements
19. 'Trade advice' statements
20. General instructions
21. Resistance warnings
22. Compatibility statements
23. 'Precaution' statements
24. 'Protection' statements
25. 'Storage and disposal' statements
26. Safety directions
27. First aid instructions
28. Batch number
29. Date of manufacture and/or expiry date of product
30. APVMA label approval number

31. Dangerous goods and worker safety legislative requirements

Q4 List the Label Data Elements Required For Risk Assessments.

- Label presentation and layout is summarized here
- The current Ag Labelling Code is available here
- The relevant particulars for label approval include adequate instructions **and** prescribed particulars (see next two slides for summary of required content)
- Australia and New Zealand have harmonized requirements for the labelling of aerosol products (available here).
- There are specific requirements for the expression of certain active constituents (available here)
- Certain organophosphorous and carbamate products require a specific anticholinesterase statement (available here)
- There are specific guidelines for Directions for Use table headings that apply to different categories of products (available here)
- There are specific labelling requirements to mitigate potential spray drift (available here).

Q4 List the Label Data Elements Required For Risk Assessments.

- Adequate instructions include the following:
 - Circumstances in which the product should be used
 - how the product should be used
 - the times when the product should be used
 - the frequency of the use of the product
 - the withholding period after the use of the product
 - the re-entry period after the use of the product
 - the disposal of the product when it is no longer required
 - the disposal of the product's containers

- the safe handling of the product and first aid in the event of an accident caused by the handling of the product
- any matters prescribed by the Agvet Code Regulations, which include:
- the prevention of undue prejudice to trade or commerce between Australia and places outside Australia
- the appropriate signal words (if any) required by the current Poisons Standard
- the storage of containers for the product (for a chemical product that is a date-controlled chemical product)
- any other matter determined by the APVMA CEO.

Q4 List the Label Data Elements Required For Risk Assessments.

- Prescribed label particulars are as following:
 - the appropriate signal words required by the current Poisons Standard
 - the name of the chemical product
 - the name of each active constituent in the product
 - the proportion of each active constituent in the product
 - the name of each constituent for the product that is:
 - not an active constituent and
 - classified as a poison in the current Poisons Standard
 - the proportion of each constituent that is:
 - not an active constituent and
 - classified as a poison in the current Poisons Standard
 - the net contents of the product
 - other particulars determined by the APVMA CEO.

Q5: In what format are the final approved labels available?

- Labels (and other details) are searchable through the Public Chemicals Registration Information System (PubCRIS)

Q6: What are the main labelling challenges?

- E-label portal has limited functionality
- Elements of the current labelling code are outdated and need to be updated
- Old labels are not automatically removed from the system when an updated label is approved, so older cancelled label approval numbers may still be visible
- Labels can be extremely complex, with upwards of 50+ pages of instructions in some cases
- Note: there is no cyclical re-registration process in the Australian legislation

Q7: Are there current label initiatives underway?

- The APVMA is in the early stages of initiating a review of the Ag and Vet Labelling Codes
- Business Improvement initiatives
 - APVMA is currently revising our workflow management system (i.e., our application Portal), which hopefully will result in a more functional elabel Portal
- Regulatory Reform
 - The Government has recently launched a review of the AgVet Code, which may result in changes to the labelling requirements.

Q8: What are the drivers for label improvement?

- Updating the Labelling Codes to better reflect the needs of holders and end-users
- Regulatory reform and changes to legislation
- Adoption of enabling technology solutions

7.2. Germany

OECD Survey:

Labelling Initiatives

Germany: Federal Office of Consumer Protection and Food Safety (BVL)

Q1: What is the Regulatory Authority on labelling requirements?

BVL

What additional authorities are needed?

The assessment authorities (JKI, BfR, UBA).

What are the authorities to amend pest control product labels?

BVL, based on the reports of the assessment authorities. Regulation (EC) No. 1272/2008 assigns the responsibility for classification, labeling and packaging to the manufacturers, importers and downstream users. Consequently the authorities are not responsible for correct labeling.

However, all specific restrictions which were found to be essential during risk and efficacy assessment by the authorities in order to ensure safe use and which are linked mandatory to the PPP or to specific intended uses are made binding by the BVL. BVL also has specific labelling requirements for non-professional users for home and garden products.

Information on the labelling of the plant protection product according to Regulation (EC) No 1272/2008 is provided in the authorisation certificate by the BVL.

Changes of the classification and labelling require an amendment of the authorisation certificate either by application or new data from the risk assessment

Regulation (EC) No 1272/2008 implements the Globally Harmonised System (GHS) for classifying and labelling chemicals in European law. The Regulation assigns the responsibility for classification, labelling and packaging to manufacturers, importers and downstream users. Together with the application for the authorisation of a plant protection product, the classification and labelling of all hazardous substances which are contained in the plant protection product at a concentration of equal to or greater than 0.1 % has to be reported (e.g. by submitting MSDS).

Q2: Describe the Process and Format for Receipt of label information.**Current process**

The label is submitted as MS Word draft to the BVL. Applicants' suggestions are documented in an in-house system, validated and changed or supplemented on basis of the risk assessment if necessary. Afterwards, the automatically generated authorisation certificate contains the label information. Changes require an amendment of the authorisation certificate. Label requirements (without classification) for approved products are available online in the PPP database hosted by BVL (mirroring the data from in-house system).

Q3: List of common label sections**Labelling according to**

- Regulation (EU) 547/2011 Annex I
- **National law** for the protection of crops (Plant Protection Act - PflSchG) § 31 Labelling (...) (2) Plant protection products may only be placed on the market or moved within the Community if, in addition to labelling pursuant to sections 13 and 14 of the Chemicals Act, the information required pursuant to Annex I to Regulation (EC) No 547/2011 of the Commission of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products (OJ L155, 11.6.2011, p. 176), appears prominently in German, in easily readable, indelible writing on the containers and finished packages. In this regard the information prescribed in Annex I (1) (h), (i), (l), (m) and (u) of Regulation (EC) No 547/2011 under the heading "Areas of use and provisions on use stipulated by the authorisation authority" shall be included in a manner that is clearly separate from the other information and markings.
- **PLUS national applications rules**

e.g.	SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
NB6611		The product is classified as hazardous to bees (B1). It must not be used on plants which are in flower or which are visited by bees; this also applies to weeds. See Bee Protection Ordinance of 22 July 1992, BGBl. (Federal Law Gazette) I p. 1410.
VA274		In order to protect bystanders, the product must be applied with loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and is registered in at least drift reducing class 50%.

Which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and is registered in at least drift reducing class 50%.

Q4 List the Label Data Elements Required For Risk Assessments.

According to GHS:

- GHS symbol
- Signal word
- H sentences
- P sentences
- Packaging information

Restrictions linked to the PPP

(The authorization of the PPP may be linked to a mandatory labelling in the following sections)

- Human Health protection
- Integrated pest management (IPM)/sustainable use
- Environmental protection/geographic areas

According to GAP table:

- Product name/code
- Formulation type
- Active substance
- Conc. of as
- Safener
- Conc. of safener

- Synergist
- Conc. of synergist
- Applicant (authorisation holder)
- Professional use/ Non professional use
- Field of use
- Crop and/or situation
- Field, greenhouse, indoor use
- Pests or Group of pests controlled

Application

- method / kind
- Timing / Growth stage of crop & season
- Max. number a) per use, b) per crop/ season
- Min. interval between applications (days)
- kg or L product / ha

a) max. rate per appl. (plant protection product)

b) max. total rate per crop/season (plant protection product)

- Water L/ha, min / max
- PHI (days)

Specific restrictions linked to the intended uses

(The authorised uses may be linked to a mandatory labelling in the following sections)

- Human Health protection
- Integrated pest management (IPM)/sustainable use

- Environmental protection/geographic areas

Q5: In what format are the final approved labels available?

- There is no approved label in Germany.
- In-house system archives the applied and validated classification and labelling information
- Information on classification and labelling of the plant protection product according to Regulation (EC) No 1272/2008 is provided in the authorisation certificate by BVL.
- Changes require an amendment of the authorisation certificate.
- Label requirements (without classification) for approved products are available online in the PPP database hosted by BVL (mirroring the data from in-house system).
- The plant protection service (state level) is responsible for the control and implementation of the Plant Protection Act and the regulations and the implementation of EU decisions.

Q6: What are the main labelling challenges?

- Guarantee up-to-dateness of the online database (updated monthly)
- After risk assessment, validated classification and labelling information are entered manually into the in-house system
- Changes require an amendment of the authorization certificate (administrative process)

Q7: Are there current label initiatives underway?

- Yes. Standardizing and publishing structured label as a voluntary commitment by companies. Implementation of IT tools to capture and publish structured label data is planned in order to achieve machine readability and allow machine to machine communication.

Q8: What are the drivers for label improvement?

- Transparency for user, worker, bystander
- Safe uses

- Sustainable use of PPPs
- Harmonisation of wording
- Up-to-dateness of available data
- Achieving machine readability and allow machine to machine communication.

7.3. Japan

OECD Survey: Labelling initiatives

Reply from Japan

Q1 What is the Regulatory Authority on labelling requirements?

Although the items listed in the answer to Q3 must be described on the labels in accordance with the registration certificates of agricultural chemicals, labels themselves are not authorized in Japan.

REF: Article 16 of Agricultural Chemicals Regulation Act (Act No 82 of 1948)

Q2 Describe the process and format for receipt of label information.

There is no procedure.

Q3 List of common label sections.

The following items must be described on the label (the items are numbered according to Article 16 of Agricultural Chemicals Regulation Act):

- (i) Registration number;
- (ii) Type, name, physical and chemical properties of the registered agricultural chemical, and type and concentration of each ingredient by separating active ingredients from other ingredients;
- (iii) Volume;

(x) Name and address of the manufacturing plant of the agricultural chemical; and

(xi) End of valid month and year.

The following items must be described either on the label or in a document attached to the agricultural chemical product:

(iv) Scope of the applied pests¹ and usage pertaining to the registration;

(v) If the agricultural chemical falls under water polluting agricultural chemicals, the letters "Water polluting agricultural chemical";

(vi) For agricultural chemicals toxic to humans or animals, a statement to that effect, damage prevention measures to be taken when the agricultural chemicals are used and method of detoxification;

(vii) For agricultural chemicals toxic to flora and fauna in the human living environment, a statement to that effect;

(viii) For agricultural chemicals that are liable to cause danger such as catching fire, exploding, or damaging skin, a statement to that effect; and

(ix) Precautions for the storage or use of the agricultural chemicals (except for the matters set forth in the item (vi)).

Q4 List the label data elements required for risk assessment.

- Physical and chemical properties of the registered agricultural chemical, and type and concentration of each ingredient by separating active ingredients from other ingredients;
- Scope of the applied pests and usage pertaining to the registration; and
- For agricultural chemicals toxic to humans or animals, damage prevention measures to be taken when the agricultural chemicals are used.

Q5 In what format are the final approved labels available?

(There is no need for the labels themselves to be approved so no format either.)

¹ "Pests" in the Act means bacteria, nematodes, mites, insects, rats, weeds, or other animals or plants or viruses that harm crops (including trees, and agricultural and forestry products).

Q6 What are the main labelling challenges?

- Unreadable to older people due to too small letters
- Too much complicated label (due to limited area)

Q7 Are there current label initiatives underway?

- Only essential information should be on the label and for others in attached documents
- Standardize label statements and utilize pictograms
- Easier to read – use larger fonts
- Specify and emphasize damage prevention measures (for pesticide users or bees) based on a risk assessment procedure
- Use of IT, e.g. QR code

Q8 What are the drivers for label improvement?

- In 2018, Agricultural Chemicals Regulation Act (Act No 82 of 1948) was amended to:
 - Introduce a periodic review framework for all active ingredients based on the latest scientific knowledge;
 - Include risk assessment for damage prevention measures for pesticide users or bees when agricultural chemicals are newly registered or periodically reviewed; and
 - Evaluate technical grade active ingredients including impurities.

This amendment of the Act intended to enhance safety of agricultural chemicals, which is also assured by proper use of final products based on appropriate and understandable labeling for pesticide users. Therefore, before the amendment of the Act will fully enter into force in April 2020, improvements in pesticide labeling are to be discussed and implemented.

7.4. New Zealand

OECD Survey: Labelling Initiatives

New Zealand: Ministry for Primary Industries (MPI) and Environmental Protection Authority (EPA)

Purpose:

- The survey aims to identify commonalities regarding the regulatory process of the review and approval of pest control product labels across OECD members.

New Zealand

- Pesticide labels are approved as Word/pdf documents by the regulator under the ACVM Act
- Labels are published to their website for users to access
- Pesticide labels also have requirements under the HSNO Act

Q1: What is the Regulatory Authority on labelling requirements?

What are the authorities to amend pest control product labels?

Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) administered by MPI
<http://www.legislation.govt.nz/act/public/1997/0087/latest/whole.html>

- **21 Decision on application**

(1) The Director-General must consider any application made under section 9 and must—

- (a) identify the risks and benefits likely to result from the manufacture and use of the trade name product, and any known practicable alternative methods of managing those risks; and
- (b) evaluate the likely risks and benefits of each alternative method identified in accordance with paragraph (a); and
- (c) refuse to grant the application if, in the opinion of the Director-General,—
 - (i) the risks likely to result from the use of that product cannot be sufficiently reduced by imposing conditions on the registration of the trade name product; or

(ii) insufficient information is available to assess the risks likely to result from the use of the trade name product; or
 (d) in every other case, grant the application and register the trade name product without conditions, or with the conditions imposed in accordance with section 23 that the Director-General, after taking into account the costs of those conditions, considers will—

(i) manage the risks from the use of the product; and

(ii) impose the least cost on the public.

• **23 Conditions on trade name products**

(1) The Director-General may register a trade name product in accordance with section 21, subject to all or any of the following conditions:

(d) a condition specifying the labelling, advertising, or other information requirements for the trade name product Format specified in Labelling Guidance for Agricultural Chemicals (currently undergoing revision Oct 2019):

<https://www.mpi.govt.nz/dmsdocument/19481-acvm-requirement-labelling-agricultural-chemicals>

Q1: What is the Regulatory Authority on labelling requirements?

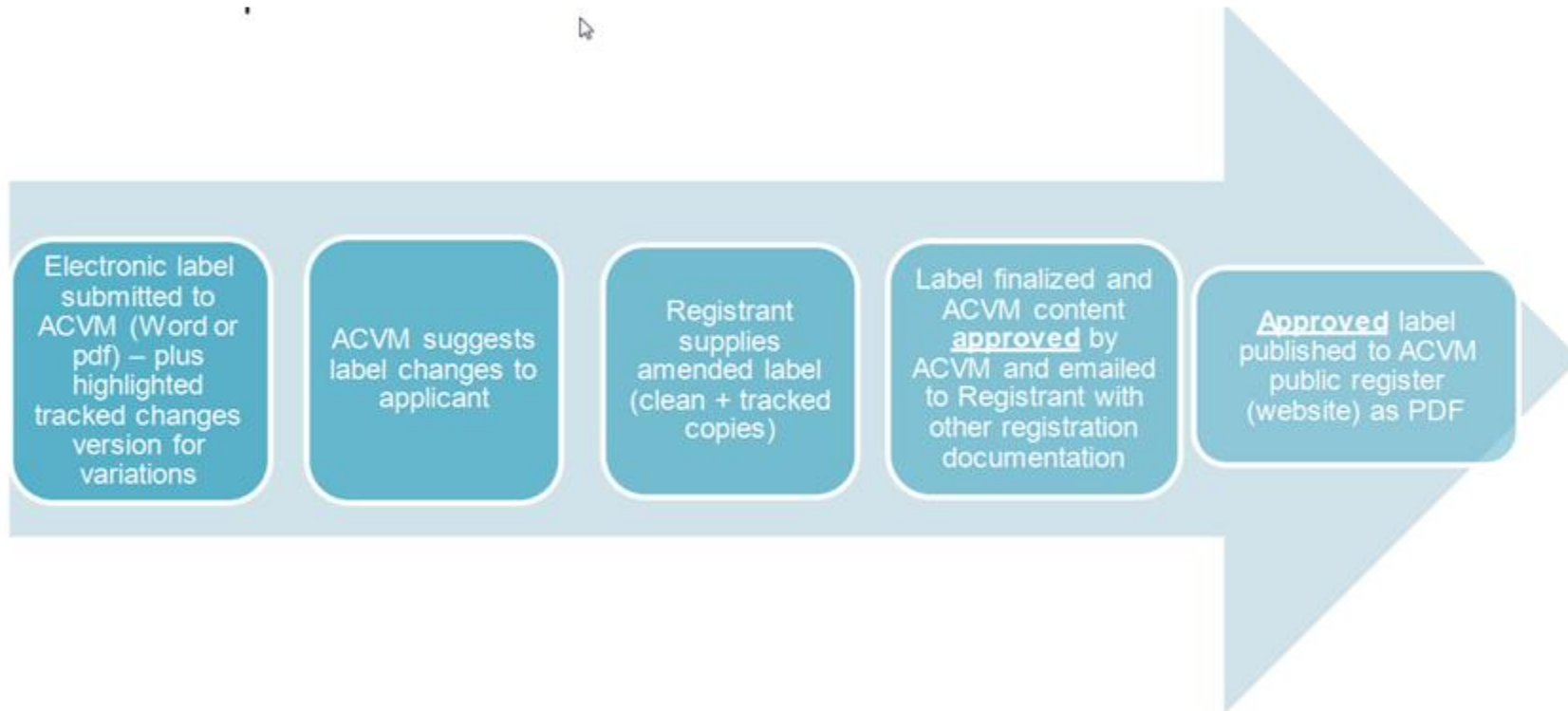
What additional authorities are needed?

- EPA NZ
 - (under Hazardous Substances and New Organisms Act 1996)
<http://www.legislation.govt.nz/act/public/1996/0030/latest/DLM381222.html>
 - No approval of labels, but they must contain GHS label statements as per the EPA Labelling Notice 2017.
 - <https://www.epa.govt.nz/industry-areas/hazardous-substances/rules-for-hazardous-substances/epa-notice-for-hazardoussubstances/>
 - Labelling Notice also has duties on importers, manufacturers and suppliers to ensure substances are correctly labelled.
 - Acceptance (in part) of labels from EU, Canada, USA, and Australia.
 - In addition to GHS label statements, precautionary statements are required for terrestrial ecotoxicity risks, including to pollinators.
- Worksafe

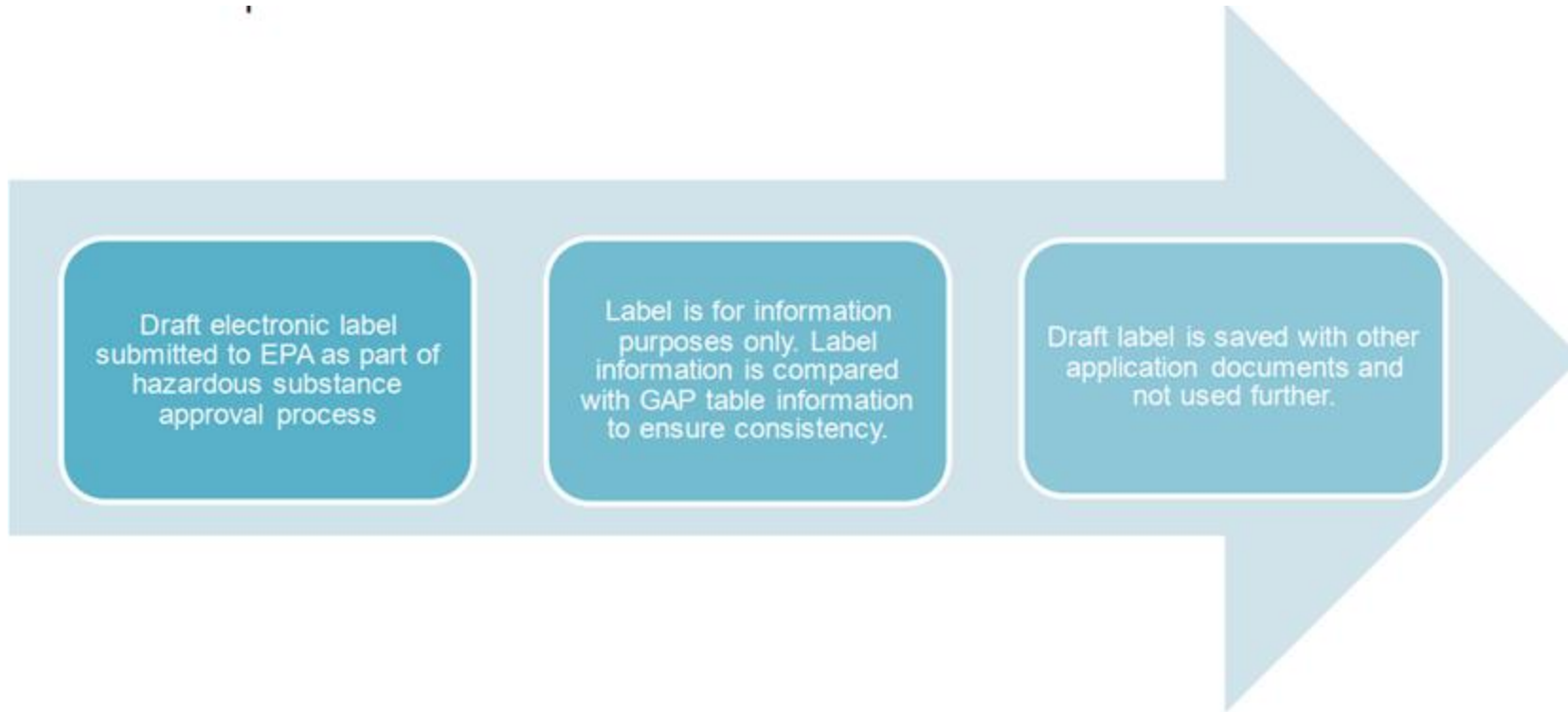
- (under Health and Safety at Work Act 2015) <http://legislation.govt.nz/act/public/2015/0070/latest/DLM5976660.html>
- HSW Regulations have requirements for labelling in the workplace, including bulk containers and decanted substances. WorkSafe would expect most workplaces with pesticide products to be maintaining the label that is on the supplied product.
- The HSW Regulations for labelling are designed to work with the EPA Labelling Notice.

Q2: Describe the Process and Format for receipt of label information.

MPI Current Process



EPA Current Process



Q3: List of common label sections

<p>Common</p> <p>Trade Name, Storage, Active Ingredient statement, Use Claims, Net Contents</p>
--

<p>MPI</p> <ul style="list-style-type: none"> • Registration Number and registration statement • Registrant name and contact information • Directions for Use <ul style="list-style-type: none"> • Withholding Periods • Rotational Crops/Plant back Intervals • Tank Mix Instructions • Aerial Applications • Regulatory statements • Resistance management statement • Compatibility • Batch number, DOM, expiry date • Adverse effects, cautions and contraindications 	<p>EPA</p> <ul style="list-style-type: none"> • Importer/manufacturer contact details • 24 hour freephone emergency contact number • Restricted Entry Intervals • Buffer zones • Use restrictions • Mixing and loading • Application equipment • Additional requirements for consumer products (Keep out of reach of children, Read label before use etc) • GHS pictograms, signal words, hazard statements and precautionary statements • Environmental precautions • Identification of toxic and corrosive ingredients • Disposal information
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Q4 List the Label Data Elements Required For Risk Assessments.

- | | |
|--|--|
| • Application method | • <i>Re-Entry Interval</i> |
| • Class | • Min Appl Rate Value |
| • Formulation Type | • Max Appl Rate Value |
| • <i>Guarantee Value</i> | • FP Appl Rate Unit |
| • <i>Guarantee Unit</i> | • FP Max Appl Rate Cumulative Value (label) |
| • <i>Geographic Area</i> | • FP Max Appl Rate Cumulative Unit (label) |
| • <i>Use Site Category</i> | • AI Min Appl Rate Value |
| • <i>Site</i> | • AI Max Appl Rate Value to Area |
| • Pest | • AI Max Appl Rate Cumulative Value |
| • <i>Pre Harvest Interval</i> | • AI Min Appl Rate Value to Area (calc) in g a.i./ha |
| • Pre Slaughter Interval | • AI Max Appl Rate Value to Area (calc)g in a.i./ha |
| • Pre Grazing Interval | • <i>Closed and/or Open Mixing/Loading/Applying?</i> |
| • Spray volume | • <i>Seeds Treated in Canada and/or Imported</i> |
| • Max. No. Appl. per Year | • AI Min Appl Rate to Seed Value |
| • Min. Interval Between App | • AI Max Appl Rate to Seed Value |
| • Appl Equipment | • AI Appl Rate per Unit Seed |
| • Plant Back Interval | • AI Min Appl Rate Value to Area (calc) in g a.i./ha |
| • Appl Timing | • AI Max Appl Rate Value to Area (calc)g in a.i./ha |
| • <i>Personal Protective Equipment</i> | • AI Max Appl Rate for the Crop per Season Value |
| • <i>Buffer Zone</i> | • AI Max Appl Rate for the Crop per Season Unit |
| • Application Instructions | Tank mix directions |
| Resistance management instructions | Crop or use situation |
| Withholding Period | |

*FP= Formulated Product

**AI= Active Ingredient

Q5: In what format are the final approved labels available?

MPI Internal:

- Data is contained in a database (not guaranteed completely accurate, staff member enters this during appraisal process). Database is no longer supported.
- Approved final labels are saved in the product's electronic files.

EPA Internal:

- Draft labels are saved with the application files and are not available publically

MPI External:

- Final electronic Word labels are sent to the registrant via email.
- Public register
 - Search by 1. Active Ingredient 2. Product Name 3. Registrant Name 4. Registration Number 5. Product Type 6. Registration date

<https://eatsafe.nzfsa.govt.nz/web/public/acvm-register>

Q6: What are the main labelling challenges?

MPI

- MPI maintains information from nearly 1500 pesticide labels
- Pesticide labels can be very complex and can include hundreds of different use scenarios (site-pest-rate combinations).
- Manually extracting and summarizing label information for consumer information has not been done due to resource and time required. Label files must be opened and searched individually.
- Data for pre and post market risk assessments has been extracted for an internal database but this is in general terms only and data must still be verified against approved labels before use.

- MPI can only consider ACVM content. There is some cross-over between HSNO and ACVM requirements and it is currently unclear whether requirements are for ACVM or HSNO purposes (eg EPA may set a maximum use rate for environmental purposes, and this may be greater than the maximum use rate in the
- Direction for Use, which may imply that this has been considered under ACVM legislation in terms of residue profile)
- Labels must be resubmitted and approved with every application made, with a minimum of 5 years before renewal. There are average 950 applications received per year?
- It can therefore take up to 5 years before all products are updated with routine changes.
- Label amendments are able to be made at the next label reprint following an application. This may involve a lengthy delay before labels reach the marketplace.
- For renewal and administrative applications, staff from an administrative team consider the label

Q6: What are the main labelling challenges?

EPA

- Labelling requirements under the HSNO Act are currently in transition, as both the EPA Labelling Notice 2017 and the earlier Hazardous Substances (Identification) Regulations 2001 apply (pesticides approved since 1 December 2017 must comply with the Notice). The Labelling Notice requires GHS label elements, whereas the earlier regulations were performance based which allowed for the use of GHS elements but did not mandate it. This currently leads to a variety of presentations of hazard and precautionary information on labels which makes determining compliance complex.
- All existing pesticide approvals are expected to be transferred to coverage under the Labelling Notice by April 2021, after which a transitional period will apply. Once this period is complete, all pesticides will be subject to the standard GHS-based labelling requirements of the EPA Labelling Notice, which will simplify compliance and enforcement.

Q7: Are there current label initiatives underway?

MPI

- **Updating Labelling Guidance**
- **Updating Label Statements:**

- Ongoing efforts to:
 - standardize label statements –as a result of re-evaluations, pre-market submissions; and developing new content
 - make statements clear for users (applicators), and the public.

EPA

- Updating the EPA Labelling Notice for the move to the GHS Revision 7 in April 2021

Q8: What are the drivers for label improvement?

- Consistency and clarity in labelling for provision of sufficient Consumer Information
- Registrants are aware of obligations and expectations before applications are made.

7.5. United Kingdom

Health and Safety

Executive

OECD Survey: Labelling initiatives

UK response

November 2019

Q1: What is the Regulatory Authority on labelling requirements?

- The Chemicals Regulation Division (CRD) of the Health and Safety Executive are the competent authority for regulation of plant protection products (PPPs) in the UK. All UK PPPs are authorised under the directly acting EU Regulation 1107/2009 and UK labelling requirements are implemented under Regulation 547/2011.
- The PPP authorisation Notice includes requirements for the labelling of each product in the ‘conditions for sale and supply’. This includes reference to the agreed text (in the form of an applicant-supplied draft text and HSE set amendments) plus acceptable formatting options in the Labelling Handbook.
- Some label requirements are also specified under *other* non-PPP legislation *e.g.*
 - The classification of a product is a requirement of Regulation EC 1272/2008 (Classification, Labelling and Packaging of Substances and Mixtures (the CLP Regulation).
 - The weight/amount of material must be specified in accordance with the Weights and Measures Act 1985.

Q2: Describe the Process and Format for receipt of label information (1)

- Applicants for UK authorisation must provide a copy of a draft label with any application for:
 - authorisation of a **new product**.
 - **changes to an existing authorised product** where changes are required to the label text *e.g.* for authorisation on new crops; for claims to control new pests, diseases or weeds.

- A new draft label is **not required** where there are **no changes to the authorised** label *e.g.* those addressing confirmatory data requirements or those for minor changes to the formulation; new ‘identical’ products submitted via the Administrative Stream (latter will include a new amendment to the tradename/ MAPP number/ Authorisation/Permit holder).
- The draft label text (other than formatting of the final printed label) must include all claims and recommendations set out in line with the guidance in;
 - the general requirements specified in the Labelling Handbook/ Volume 1 (all products); plus
 - Volumes 2 (professional products) or 3 (amateur products).
- All the proposed text must be justified by the supporting safety and efficacy data package and risk/efficacy assessment.
- It is not necessary at this stage to reflect all the formatting requirements set out in the Labelling Handbook (*e.g.* legibility, fonts, final artwork and colours).

Q2: Describe the Process and Format for receipt of label information (2)

- The text of the label is considered by the CRD Assessment manager and specialists in each area of risk assessment and efficacy during evaluation and amendments are specified.
- Authorisation is issued with the legal Notice referring to:
 - The draft label text as identified in the product authorisation by date submitted, company reference number and an HSE reference number.
 - Amendments to the draft label text are specified on the covering letter to the authorisation (it is a requirement in the authorisation Notice itself that these must be implemented);
 - Classification and labelling under the CLP Regulation.
 - Structure and format of the final printed label in line with the Labelling Handbook Volumes 1 and 2 or 3 (professional and amateur products respectively).
 - For professional products, an optional Company Advisory Information section at the discretion of the authorisation holder in line with the guidance at Labelling Handbook Volume 2/ Section 8.
- It is the responsibility of the applicant to ensure that these amendments are incorporated into the final printed label and that it complies with all the formatting requirements set out in the Labelling Handbook.

- There is no requirement for the routine submission of the final printed label. However, authorisation holders may be asked to submit the final label as part of our rolling programme of label checks required under Article 68 of Regulation (EC) No 1107/2009.

Q3: List of common label sections (1)

- The **‘Main Area’** of the label (*e.g.* the front panel) should contain at least:
 - Product tradename;
 - Product registration (MAPP) number;
 - Formulation type;
 - Amount and name of the active substance;
 - The anticholinesterase warning phrase (if appropriate);
 - Biological use phrase;
 - Product classification under CLP and associated phrases.
- The **‘Subsidiary Area’** (*e.g.* the back panel) should contain the remainder of the ‘Authorised Text’ if it does not already appear on the front panel.
- **Important Information Box (not on amateur products)**
 - Key information about the safe and effective use of the product which appears in the ‘Conditions of Use’ section of the product Notice of Authorisation (in effect the authorised GAP for the product - crop/maximum individual dose/maximum number of treatments/total dose/latest time of application and any other restrictions on application).
- Safety Precautions
 - Operator protection;
 - Consumer protection;
 - Environmental protection;
 - Storage and disposal.

Q3: List of common label sections (2)

- **Medical Advice**
- **Directions for Use (professional product)/Instructions for Use (amateur product)**
 - Pest/weed/disease control claims, application doses and timings;
 - Application method, water volume and spray quality;
 - Tank cleaning instructions;
 - Agronomic advice/general recommendations for use;
 - Positive/convenience tank-mixes and acceptable sequences;
 - Other restrictions and warnings.
- The above sections are known as ‘Authorised Text’ whereas the following is at the discretion of the authorisation holder:
- **Company Advisory Information (professional products only)**
 - Optional to include additional information the applicant wants to appear on the label e.g.:
 - agronomic information and additional information relating to the use of the product;
 - additional Health and Safety information;
 - other information not directly related to the authorisation, e.g. company disclaimers.
 - The information in this section does not need to be supported by safety and efficacy data, is not checked (acceptable information is detailed in the Labelling Handbook/Volume 2/Section 8) but must not contradict the ‘Authorised Text’.

Q3: List of common label sections (3)

- Where (due to space constraints) it is impossible to include all of the ‘Authorised Text’ on the label fixed to the container, a separate leaflet or similar with the Directions for Use (professional products) or Instructions for Use (amateur products) may be used (the leaflet must repeat all of the other text on the main and subsidiary areas of the label).
- This may be:
 - directly fixed to the container label (e.g. a fold-out leaflet); or

- a booklet supplied separately with the product.
- Where affixed labels are too small to include all the information on safe handling (i.e. text other than Directions for Use and Company Advisory Information), then it may be possible to further reduce the requirements for the label text on a case-by-case basis.

Q4: List the Label Data Elements Required for Risk Assessments

- The label text is the driver for the evaluation of:
 - safety/risk (chemistry/storage stability, mammalian toxicology, operators/bystanders/worker exposure, residues/consumer exposures, environmental fate and ecotoxicology; and
 - efficacy (effectiveness and crop safety).
- All label text/claims/recommendations must be supported by data and safety/risk efficacy assessment. This includes:
 - Amateur or professional use;
 - Field of use;
 - Precautionary phrases;
 - Crops/situation of use;
 - Minimum/Maximum individual application dose;
 - Maximum number of treatments or maximum total dose per crop/year;
 - Pest/weed/disease to be controlled including susceptibilities where necessary with any specific recommendation for application regimes for each crop;
 - Pre harvest Interval (crop growth stage or days before harvest) and/or pre-grazing interval;
 - Use/worker re-entry period;
 - Minimum and maximum water volumes;
 - Recommended application equipment;
 - Following crop recommendations;

- Personal protective equipment (PPE);
- Buffer zones for protection of surface waters/aquatic life or non-target arthropods.

Q5: In what format are the final approved labels available?

- HSE do not publish final authorised labels and do not keep a database of final printed labels.
- There is no requirement for the routine submission of the final printed label. However, authorisation holders may be asked to submit the final label as part of our rolling programme of label checks required under Article 68 of Regulation (EC) No 1107/2009.
- In cases of enquiries for a copy of the final label, we refer the enquirer to the authorisation holder. A copy of the draft label and amendments will be provided in cases where requests are submitted under the Freedom of Information Act/ Environmental Information Regulation.

Q6: What are the main labelling challenges?

- Discouraging over-labelling or complex text, although the responsibility for clarity essentially rests with the authorisation holder in drafting the label. More is not necessarily better, and the real test of label text is whether all users read, understand the instructions and guidance and act accordingly.
- Providing simplified labels that can be easily followed by amateur users to enable safe and efficacious use and safe disposal.
- Incorporating all required information on small packaging.

Q7: Are there current label initiatives underway?

- As detailed under Q1 and Q2 when Chemicals Regulation Division authorise a Plant Protection Production, the legal documents consist of a Notice of Authorisation with the conditions of use, and a recommendation letter which references the submitted draft product label and details any label amendments. These label amendments reflect the conclusion of the assessment and may result in a requirement to delete or amend uses/target/pests, risk phrases, or conditions of use. A project is being set up to develop a process where the authorisation notice is accompanied by the final agreed authorised label text (rather than a draft and amendments), which will provide greater clarity. This may include publication of the final authorised text with the Notice.
- The Labelling Handbook is updated with any changes to UK requirements where necessary.

Q8: What are the drivers for label improvement?

- Please see our responses to Q6.

7.6. European Food Safety Authority (EFSA)

OECD Survey:

Labelling Initiatives

Evidence Management Unit and Pesticide Residues Unit 6/11/2019

- *“The survey aims to identify commonalities regarding the regulatory process of the review and approval of pest control product labels across OECD members.”*
- *“Identification of common data elements for labels will enable a more data centric business model:*
- *Industry submits label information via structured forms using standardized statements and nomenclature.*
- *Regulator receives label information in a structured format expediting assessments and issuance of approved/amended labels*
- *Users can search and access pesticide information (precautions, directions for use) that is specific to their needs which results in safer use of pesticides.”*

Purpose: 2

Q1: What is the Regulatory Authority on labelling requirements?

- The Regulatory Authority for the authorization and labelling of plant protection products (pesticide formulations) are the competent authorities of EU Member States.
- The European Food Safety Authority (EFSA) does not had a direct role in the labelling requirements of pest control products.

Q1: What is the Regulatory Authority on labelling requirements?

- Active substances used in plant protection products are authorized at EU level in accordance with
- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market.

- The EU labelling requirements of plant protection products, including standard phrases for special risks to human or animal health or to the environment and standard phrases for safety precautions for the protection of human or animal health or to the environment, are implemented in:
- Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products.
- A special rule for the labelling of plant protection products is also included in:
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Annex II Part 4 thereof).

Q2: Describe the Process and Format for receipt of label information.

- The European Food Safety Authority (EFSA) does not had a direct role in the process for labelling requirements of pest control products.

Q3: List of common label sections

Commission Regulation (EU) No 547/2011, Annex I

- (a) the trade name or designation of the plant protection product;
- (b) the name and address of the holder of the authorisation and the authorisation number of the plant protection product and, if different, the name and address of the person responsible for the final packaging and labelling or for the final labelling of the plant protection product on the market;
- (c) the name of each active substance expressed as provided for in Article 10 (2.3) of Directive 1999/45/EC of the European Parliament and of the Council (1) with clear indication of the chemical form. The name must be as given in the list contained in Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (2) or, if not included therein, its ISO common name. If the latter is not available, the active substance shall be designated by its chemical designation according to IUPAC rules;
- (d) the concentration of each active substance expressed as follows:

(i) for solids, aerosols, volatile liquids (maximum boiling point 50 °C) or viscous liquids (lower limit 1 Pa s at 20 °C), as % w/w and g/kg,

(ii) for other liquids/gel formulations, as % w/w and g/l,

(iii) for gases, as % v/v and % w/w.

If the active substance is a micro-organism, its content shall be expressed as the number of active units per volume or weight or any other matter that is relevant to the micro-organism, e.g. colony forming units per gram (cfu/g);

- (e) the net quantity of plant protection product given in: g or kg for solid formulations, g, kg, ml or l for gases and ml or l for liquid formulations;
- (f) the formulation batch number and production date;
- (g) information on first aid;

Q3: List of common label sections

Commission Regulation (EU) No 547/2011, Annex I (continued)

- (h) the nature of any special risks to human or animal health or to the environment, by means of standard phrases selected by the competent authority, as appropriate, from those set out in Annex II;
- (i) safety precautions for the protection of human or animal health or of the environment, in the form of standard phrases selected by the competent authority, as appropriate, from those set out in Annex III;
- (j) the type of action of the plant protection product (e.g. insecticide, growth regulator, herbicide, fungicide, etc.) and the mode of action;
- (k) the type of preparation (e.g. wettable powder, emulsifiable concentrate, etc.);
- (l) the uses for which the plant protection product has been authorised and any specific agricultural, plant health and environmental conditions under which the product may be used or shall not be used;
- (m) directions for and conditions of use and the dose rate including where appropriate the maximum dose per hectare per application and the maximum number of applications per year. The dose rate is expressed in metric units, for each use provided for under the terms of the authorisation;

- (n) where appropriate, the safety interval for each use between the last application and:
 - (i) sowing or planting of the crop to be protected,
 - (ii) sowing or planting of succeeding crops,
 - (iii) access by humans or animals,
 - (iv) harvesting,
 - (v) use or consumption;

Q3: List of common label sections

Commission Regulation (EU) No 547/2011, Annex I (continued)

- (o) particulars of possible phytotoxicity, varietal susceptibility, and any other direct or indirect adverse side effects on plants or products of plant origin together with the intervals to be observed between application and sowing or planting of:
 - the crop in question, or
 - subsequent and adjacent crops;
- (p) if accompanied by a leaflet, as set out in point 2, the sentence ‘Read accompanying instructions before use’;
- (q) directions for appropriate conditions of storage, safe disposal of the plant protection product and of the packaging;
- (r) where necessary, the expiry date for normal conditions of storage;
- (s) a prohibition concerning the re-use of packaging, except by the authorisation holder and on condition that packaging has been specifically designed in order to allow re-use by the authorisation holder;
- (t) any information required by the authorisation in accordance with Articles 31, 36(3), 51(5) or 54 of Regulation (EC) No 1107/2009;
- (u) the categories of users allowed to use the plant protection product, where use is limited to certain categories.

Q4: List the Label Data Elements Required For Risk Assessments.

- The Label Data Elements for the proposed Good Agricultural Practices (GAP) are required in the format of a GAP table based on the OECD Form for use in reporting details of intended uses (GAP information).
- The data requirements for the risk assessments and approval of the active substance are set out in the Annex to the Regulation:
- COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.
- The data requirements for the risk assessments and approval of the plant protection products are set out in the Annex to the Regulation:
- COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

Q5: In what format are the final approved labels available?

- The final approved labels may be available in electronic format in the databases of the competent authorities of EU Member States or in physical format depending on the format of acceptance of the dossier that each Member State has implemented.

Q6: What are the main labelling challenges?

- Not applicable - the European Food Safety Authority (EFSA) does not had a direct role in the labelling requirements of pest control products.

Q7: Are there current label initiatives underway?

- Not applicable - the European Food Safety Authority (EFSA) does not had a direct role in the labelling requirements of pest control products.

Q8: What are the drivers for label improvement?

- Not applicable - the European Food Safety Authority (EFSA) does not had a direct role in the labelling requirements of pest control products.

8. ANNEX 4 – Individual Country Responses to 2020 Survey

8.1. Australia

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment Australia (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Product Name	Unique text identifier assigned to each individual product used for tracking and reporting purposes.	Distinguishing name	N	Y	PCPR 26 (1)(a)	r16(a)	
Product description	Provides a brief description for easy identification of the general uses (sites and pests) of the product.	Statement of Claims	N	Y		s5D(1) r8AE	
Product Type	Unique text identifier assigned to each individual product type used for tracking and reporting purposes. Identifies the general type of organism targeted by the product (e.g., fungicide, insecticide, vertebrate repellent). Determines the use pattern assessed in the value and risk assessments. Some data requirements and label information and restrictions are directly linked to the product type and used in risk assessment and risk management	N/A	Y	N	PCPR 26 (1)(b)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment Australia (Yes or No)	Regulatory [†] /Policy and Guidelines ^{††} Requirement	Regulatory [†] /Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Formulation Type	Unique text identifier assigned to each individual formulation type used for tracking and reporting purposes. Residue data may be dependent on the formulation type; used in the dietary risk assessment. The exposure values used in the occupational/residential risk assessments are dependent on the formulation type.	Formulation Type	Y	Y	PCPR 26 (1)(b) and PCPR 26 (1)(c)		Does not have to go on the label
Class designation	Unique text identifier assigned to each individual marketing class used for tracking and reporting purposes. The parameters used in the occupational/residential risk assessment are different for commercial-class and domestic-class product. Also, restricted-class may be used as a mitigation measure to prevent occupational/residential human health risk or environmental risk.	Pack Grouping	Y	Y	PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products		Does not have to go on the label

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Signal Words	Needed to identify the acute health hazards to users. May trigger the need for additional personal protection equipment (PPE). Determined by the acute toxicity and physical and chemical properties of the pest control products (TGAI, MUP, EP).	Signal Headings	N	Y	PCPR 26 (1)(e) schedules 3 and 4	s 21(a), regulation 17) s 5D(1), regulation 8AE	
Hazard Symbols	“Pictograms” inform users of acute health hazards.	N/A to APVMA (GHS)	N	N	PCPR 26 (1)(e) schedules 3 and 4		SafeWork Australia
Hazard Statements	Statements inform users of acute health hazards.	N/A to APVMA (GHS)	N	N	PCPR26(1) (e)		SafeWork Australia
Read the label before using	Instructs users to read the label (and booklet, if applicable) before using to ensure they are informed as to how to use the product safely and effectively.	Cautionary Phrases and SD	N	Y	PCPR 26(1)(f) and 28 (2)(a)		Signal word(s) and cautionary statements required by the Poisons Standard (SUSMP

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Active Ingredient	Required for value, environment, human health hazard and risk characterization. The active ingredient includes common chemical name of the active ingredient or, if none, its chemical name or another name, and the concentration of the active ingredient in the appropriate form. Information on viscosity, specific gravity, particle size or any other property may also be required.	Active constituent	N	Y	PCPR 26 (1)(h)	s 21(a), regulation 17)	
Allergens	Label identification of formulants that are common allergens known to be associated with anaphylactic reactions.	N/A	N	N	DIR2006-02		
Preservatives	Label identification of active ingredients that are present in the end-use formulation as formulation preservatives.	N/A	N	N	DIR2006-02		
Registration Number	Statement containing unique numerical identifier assigned to each individual product used for tracking and reporting purposes. If one is not yet assigned, a placeholder will be needed.	Distinguishing number	N	N	PCPR 26 (1)(i)	s 21(b)	

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Private Label Number	Unique numerical identifier assigned to each individual product used for tracking and reporting purposes.	Approval Number	N	N	PCPR 26 (1)(i)		
Net Contents	May have an impact on occupational risk assessment and mitigation measures.	Net Contents	Y	Y	PCPR 26 (1)(j) Weights and Measures Act (metric)	s 21(a), regulation 17)	
Contact information	Required to allow users to contact the registrant with inquiries about the product. At minimum, registrant name and postal address and telephone number to which public inquiries may be directed.	Identifying information for the holder of the approval	N	N	PCPR 26(1)(k)(l) and 27 (1)(2)	(s21(c)(i),(iva)) regulation 17(3)(a)	
Resistance Management Group for the Active Ingredient	Unique alphanumeric identifier assigned to fungicide, herbicide and insecticide active ingredient; used in value determination. Appears on commercial or restricted class product labels as part of the identification for resistance management purposes. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.	Mode of Action	N	Y	DIR 2013-04	s 5D(1), regulation 8AE	

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Expiry date	For products that have a limited shelf life, ex: live organisms	Expiry date	N	Y		Reg 18 D	Date controlled products only.
Notice to user	To stress the importance of reading the label.	N/A	N	N	PCPR 26(2)(g)		
First Aid Instructions	In the case of human health issues, the instructions identify the steps to take to help the person experiencing the symptoms. The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.	First Aid Instructions	N	Y	PCPR 26(2)(e)	s 5D(1), regulation 8AE	
Companion Animal and Livestock First Aid	In the case of animal health issues, the instructions identify the steps to take to help the pet experiencing the symptoms.	N/A	N	N	PCPR 26(2)(e); DIR2002-01		Could this be an Antidote for a poison? Or Advice to veterinarian
Toxicological Information	Information for doctor/physician The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.	Additional User safety (Veterinary Products)	N	Y	PCPR 26(2)(f)	s 5D(1), regulation 8AE	
Human Health Precautions	The label statements in this section inform users of potential human health hazards or risk and/or measures to mitigate the hazards and/or risks.	Safety Directions	N	Y	PCPR 26(2)(c) and 26(2)(d)	s 5D(1), regulation 8AE	

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Personal Protective Equipment (PPE)/ Engineering Controls	Mandatory protective equipment such as clothing, respirators, goggles and gloves required as a result of the acute hazard and/or human health risk assessment to reduce exposure to workers in contact with pest control products. Engineering controls (e.g. closed-cab tractor) may be required to prevent/mitigate exposures and/or risk while performing their work with pesticides.	Safety Directions	N	Y	PCPR 26(2)(c)	s 5D(1), regulation 8AE	
Companion Animal and Livestock Precautions	The label statements in this section inform users of potential animal health hazards or risk and/or measures to mitigate the risks.	Protection of livestock	N	Y	PCPR 26(2)(c) and 26(2)(d)	s 5D(1), regulation 8AE	
Environmental Precautions	The label statements in this section inform users of potential hazards or risks to the environment and/or of measures to mitigate the risks to the environment. Each subsection is separate to allow for tracking and reporting purposes in the future.	Protection Statements	N	Y	PCPR 26(2)(c)	s 5D(1), regulation 8AE	

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Environmental Precautions – Aquatic organisms	Statements inform users of potential hazards or risks and/or of measures to mitigate risks.		N				
Environmental Precautions - Birds							
Environmental Precautions – Wild Mammals		Protection Statements				s 5D(1), regulation 8AE	
Environmental Precautions - Bees				Y			
Environmental Precautions – Beneficial Arthropods							
Environmental Precautions - Earthworms							
Environmental Precautions – Non-Target Terrestrial Plants		Protection Statements					

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Environmental Precautions – Burrow Treatments							
Environmental Precautions – Persistence/ Accumulation/ Carryover	Statements inform users of the potential for accumulation and carryover and recommend practices to minimize the potential for accumulation and carryover.	Protection Statements	N	Y		s 5D(1), regulation 8AE	
Environmental Precautions – Leaching	Statements inform users of the potential for leaching and recommend practices to minimize the potential for leaching to groundwater.	Protection Statements	N	Y		s 5D(1), regulation 8AE	
Environmental Precautions – Runoff	Statements recommend practices to minimize runoff into adjacent waterbodies.	Protection Statements	N	Y		s 5D(1), regulation 8AE	
Environmental Precautions - Volatilization	Statements to minimize the release into the environment from volatilization.	Protection Statements	N	Y		s 5D(1), regulation 8AE	
Environmental Precautions - Products Containing Aromatic Petroleum Distillates	Statements inform users of potential hazards or risks to aquatic organisms.	Protection Statements	N	Y		s 5D(1), regulation 8AE	

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General information	Provides general directions on the use of the product. Includes but is not limited to a brief product description/ information and geographic restrictions (if applicable).	General Instructions	N	Y		s 5D(1), regulation 8AE	
Directions For Use (General)	Communicates the PMRA supported use pattern to the end user of the pest control product.	Directions for Use	N	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Use Limitations	To identify situations that may pose potential risks of concern to health or the environment. To communicate limitations in the use pattern for which a risk assessment was not performed or for which risks of concern were identified (i.e. DO NOT apply in greenhouses.) To identify restrictions related to dietary and occupational exposure: preharvest intervals, restricted-entry intervals, pregrazing interval/feeding restrictions, preslaughter interval	Restrains	N	Y	PCPR26(2)(a)	s 5D(1), regulation 8AE	

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General Application Instructions	General information on how to apply the product including ground or aerial application, the application type (broadcast, drench, chemigation, etc.), the application target (foliar, soil, seed, etc.) and permitted equipment.	General Instructions	N	Y	PCPR26(2)(a)	s 5D(1), regulation 8AE	
Application Method	Required for the risk and value assessments Statements for various application methods provide measures to minimize spray drift to non-target sensitive habitats for certain application equipment. Parameters used in the occupational/residential health risk assessments are dependent upon the application method. For residue chemistry, data requirements and residue trials are required for each type of applications. Residue data are used in the risk assessment.	Application	Y	Y	PCPR26(2)(a)	s 5D(1), regulation 8AE	
Application target	The application target (foliar, soil, seed, etc.)	Crop/pest or situation	Y	Y	PCPR26(2)(a)	s 5D(1), regulation 8AE	
Application equipment	Provides information on the type of application equipment that is approved for use.	Application equipment	Y	Y	PCPR26(2)(a)	s 5D(1), regulation 8AE	

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Chemigation	Instruction on the use of chemigation	Application	N	Y	DIR93-13	s 5D(1), regulation 8AE	
Runoff Management	Mandatory vegetative filter strips provide measures required to mitigate risks to aquatic organisms from runoff of pesticide into adjacent waterbodies.	Protection (Environment)	N	Y		s 5D(1), regulation 8AE	
Spray Drift Management	Spray buffer zone statements and spray buffer zone table provide measures required to mitigate risks to sensitive terrestrial and aquatic habitats from spray drift downwind from the site of application.	Spray drift restraints	N	Y		s 5D(1), regulation 8AE	
General Mixing Instructions	Mixing instructions that apply to all uses on the label including tank mixing sequencing	Mixing (Found within the General Instructions)	N	N			Best Practice guide states that the applicant may include how to mix the product, including general tank mixing information

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Generic Tank Mix Statement	Instructions for tank mixes not specifically described on the label.	Compatibility	N	N			The inclusion of general information on compatibility is not a relevant particular of a label and is not mandatory. This statement is not checked or considered by the APVMA in approving a label.
Tank Mix Partner Information	Used for tracking and identifying specific tank mixes	Compatibility	N	N			This could also include mandatory tank mix's in the DFU
Tank Mix Partner Mixing-Loading Instructions	Instructions for proper mixing of specific tank mix partners (e.g., order to introduce the partners into the spray tank)	Mixing (Found within the General Instructions)	N	Y		s 5D(1), regulation 8AE	

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Rotational Crops/ Plantback Interval	Required for the risk and value assessments To inform users of the time interval to respect before planting rotational crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern. Also phytotoxicity, field bioassay statements/instruction	Re-cropping intervals	Y	Y		s 5D(1), regulation 8AE	Generally in General Instructions. In Ag labelling code
Restricted-Entry Intervals	To inform users of the interval between application, and when workers can enter areas treated with pest control products. Can be used to mitigate risks to postapplication workers.	Re-Entry Period	Y	Y		s 5D(1), regulation 8AE	
Preharvest Intervals	To inform users of the time interval to respect before harvesting the food crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern.	Withholding Period (Harvest)	Y	Y		s 5D(1), regulation 8AE	

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Pregrazing Intervals/ Feeding Restriction	To inform users of the time interval to respect before harvesting the feed crops or letting livestock graze in the treated field in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.	Withholding Period (Grazing)	Y	Y		s 5D(1), regulation 8AE	
Preslaughter Intervals	To inform users of the time interval to respect before slaughtering livestock in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.	Export Slaughter Interval (Within Trade Advice Statements)	Y	Y		s 5D(1), regulation 8AE	
Resistance Management Information	Recommendations to reduce the risk of pesticide resistance by arthropods, plant diseases and weeds. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.	Resistance warnings	N	Y	DIR 2013-04	s 5D(1), regulation 8AE	
Storage and Disposal	Storage statement to prevent contamination of food or feed and provide disposal information.	Storage and Disposal	N	Y	PCPR 26(2)(b) and DIR 1999-04	s 5D(1), regulation 8AE	

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Labelling of Treated Seed (Seed Tag)	<p>Statements on seed tags are used to inform users of measures to mitigate environmental risks. Precautionary statements on seed tags are used to inform workers of the required PPE/engineering controls while handling and planting treated seed. May include restrictions such as pregrazing interval/feeding restrictions or plantback intervals/rotational crops.</p>	seed pigment or dye	N	N		s 5D(1), regulation 8AE	
Labelling of Treated Article (Hang Tag)	<p>Statements on hang tags are used to inform users/consumers of proper handling, care and use of the garment/article. Precautionary statements on hang tags are used to inform users/consumers of potential skin sensitizing risks from the use/exposure to manufactured garments/articles. May include restrictions or storage and disposal requirements.</p>	Hang Tag	N	Y			

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Imported Treated Seed Information	To inform importers of treated seed that a human health risk assessment for planters has been conducted and that it is acceptable to import the treated seed into Canada.	seed pigment or dye	N	Y			
Direct Application to Water	Statements provide measures to mitigate risks to non-target aquatic organisms and inform users of legislative requirements when applying pesticides directly to water.	Protection Statements	N	Y		s 5D(1), regulation 8AE	
Requirements for Vertebrate and Insect Baits	Required for the risk and value assessments Statements provide measures to mitigate risks to children, pets, livestock or wildlife such as non-target birds or wild mammals.	Protection statements/ Restricted Chemical product	N	Y			
Products Discharged Into Water Bodies	Statement provide measures to mitigate potential risks to aquatic organisms from discharge of effluent.	Protection Statements	N	Y		s 5D(1), regulation 8AE	
Wood Uses	Required for the risk assessments Statements provide measures to minimize releases into the environment.		N	N			

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Cranberry	Statements provide measures to mitigate potential risks of effluent water from cranberry fields to aquatic organisms.		N	N			
Greenhouse	Statements provide measures to mitigate risks to aquatic organisms from effluent or runoff.		N	N			
Mushroom House	Statements provide measures to mitigate risks to aquatic organisms from effluent or runoff.		N	N			
IMEP (Importation for Manufacturing and Export Program)	Statements provide measures to mitigate risks to aquatic organisms from a product imported solely for the purpose of manufacturing and export.		N	N			
Use-Site Category (USC)	Required to help guide determination of data required in support of an application to register, amend, or conduct research with a pest control product. Each USC has a list of required and conditionally required data called data-code or DACO tables.	Situation	Y	Y			

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Site/Host/Crop	Required for the risk and value assessments (i.e., area of use, site of application, surface type or material to be treated)	Crop/pest - Could be a restraint i.e. no more than Xgai per season or situation	Y	Y	PCPR26(2)(a)	s 5D(1), regulation 8AE	
Site/Host/Crop Subtype	This would be for additional information on a site/host such as age and weight of products used on companion animals or type of growing environment (greenhouse, outdoor field, etc.). Required for value and risk assessments.	Crop or situation (For veterinary medicines it comes under claims and dosage and administration)	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Geographic Area	May have an impact on the residue chemistry data requirements (i.e. reduce the number of field trials required), residue data used in the human health risk assessment May have an impact on the input used in the dietary risk assessment for drinking water	State	Y	Y		s 5D(1), regulation 8AE	
Effects on treated objects or sites	This would include information on the potential for damage to treated sites (e.g., phytotoxicity) Required for value assessment.	Crop Safety	N	Y	DIR2016-02	s 5D(1), regulation 8AE	

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Pest	Identifies the pest being targeted, Required for the value assessment Determine the type of human health risk assessment is required based on how the specific pest is treated or where the pest found in relation to human activities.	Pest	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Pest Subtype	Required for the value assessment Required for determining the magnitude of postapplication exposure use patterns. This would be for any additional details on the target pest (e.g., lifestage, nest treatment).	Growth stage	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Pest Control Claim	Required for the value assessment (ie., type/level of control such as control, suppression, reduces infection/damage, prevents fouling vs removes established fouling, type of protection-prevents degradation, discoloration)	Statement of Claims	N	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	

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Duration of Efficacy against Pest(s)	Required for the value assessment of personal insect repellents, other repellents, attractants, products with residual claims, companion animal product, etc.	Statement of Claims	N	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Product Rate/ Concentration and residual to be maintained, if applicable	Required for the risk and value assessments Directions for use, including method and application rates or residual concentration to be maintained, target retention (kg/m ³) or target deposition (µg/cm ²), expected coverage (m ² per litre of paint), the contact time, dilution and rinse if applicable. When pesticide rates are given as a range, instructions may be required as to when to use the lower and higher application rates.	Rate (within Directions for Use)	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Product Rate/ Concentration/ Residual to be Maintained Units	Required for the risk and value assessments	Rate (within Directions for Use)	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Rate of Active Ingredient(s)	Required for the risk and value assessments		Y	N	PCPR 26(2)(a)		

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Adjuvant	Adjuvant product name or adjuvant type. Required for the acute hazard, dietary risk assessment for the active ingredient with which it is co-formulated and value assessments	Adjuvant	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Rate of Adjuvant	Required for the acute hazard, dietary risk assessment for the active ingredient with which the adjuvant is co-formulated and value assessments Human health risk assessments are not required for the adjuvant itself.	Rate of Adjuvant	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Rate of Adjuvant Units	Required for the risk and value assessments		Y	N	PCPR 26(2)(a)		
Maximum Cumulative Rate of Active Ingredient per Year	Required for the risk assessments	Found within restraints	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Minimum Number of Applications	Required for occupational exposure risk assessment (required as sometimes there is a range in the number of applications) May be required to refine or mitigate the occupational exposure risk assessment	Minimum Number of Applications (found within the critical comments in the directions for use)	Y	Y		s 5D(1), regulation 8AE	

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Maximum Number of Applications	Required for the risk assessments Can be used as a tool to mitigate postapplication exposure, and determine the total amount of active ingredient applied to a crop in a single year or crop cycle.	Maximum Number of Applications (found within the critical comments in the directions for use)	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Maximum Number of Applications per Year or Crop Cycle	Required for the risk assessments	Maximum Number of Applications per Year (found within the critical comments in the directions for use)	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Spray Volume	Required for the risk and value assessments Spray volume is also included in buffer zone calculations for aerial application Converts user application rates on labels to rates required to complete a human health risk assessment.	Spray Volume	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Spray pressure	Required for the risk assessments	Spray pressure	Y	N			
Application Target	Required for the risk assessments Parameters used in the occupational/residential health risk assessments are dependent on the application target.	Application Target	Y	N	PCPR 26(2)(a)		

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Application Type	Required for the risk and value assessments Parameters used in the occupational/residential health risk assessments are dependent on the application type.	Application Type	Y	N	PCPR 26(2)(a)		
Application Equipment	Required for the risk assessments and value assessments Application equipment is also considered in the buffer zone calculations. Parameters used in the occupational/residential health risk assessments are dependent on the application equipment.	Application Equipment	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Minimum Re-Treatment Interval (RTI)	Required for the risk and value assessments One of the parameters in the occupational/residential risk assessment	Minimum Re-Treatment Interval	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Maximum Re-Treatment Interval (RTI)	Required for the risk assessments Required for occupational exposure risk assessments (required as sometimes there is a range of RTIs) - May be required to refine or mitigate the occupational exposure risk assessment	Maximum Re-Treatment Interval	Y	Y		s 5D(1), regulation 8AE	

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Application Timing	Used to identify the application timing for effective management of the listed pest(s); EAD: used to determine exposure considerations in environmental risk assessments for aquatic organisms and pollinators. Considered in the human health risk assessment to determine the potential exposure to workers, users and bystanders. For residue chemistry, if application timing is early and very specific, may not need a preharvest interval. Required for the value assessments – preventative vs curative claims.	Application Timing (Found within Directions for Use)	Y	Y	PCPR 26(2)(a)	s 5D(1), regulation 8AE	
Application Instructions (Specific Uses)	Instructions that identify the PMRA supported/approved use of a product in the context of a specific use pattern (e.g. site-pest-rate combination) Any other information pertinent to the value of the pest control product (pre-cleaning or surface preparation, etc.)	Application Instructions	N		PCPR 26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment Australia (Yes or No)	Regulatory [†] /Policy and Guidelines ^{††} Requirement	Regulatory [†] /Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
User Requested Minor Use Label Expansion (URMULE)	Used for tracking and reporting on the expansion of a label for a new minor use of a pesticide for which the active ingredient(s) and the end use product are currently registered in Canada under the URMULE program		N	N	DIR2001-01		This use is covered by a minor use permit
User Requested Minor Use Registration (URMUR)	Used for tracking and reporting on the registration of products/uses under the URMUR program		N	N	DIR99-05		This use is covered by a minor use permit
Restricted Use	Used to identify specific product applications that can only be used under certain circumstances by specially trained individuals.	RESTRICTED CHEMICAL PRODUCT	N	Y	PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products	s 5D(1), regulation 8AE	
Aerial Application	Required for the risk and value assessments	Aerial Application	Y	Y	DIR1996-04	s 5D(1), regulation 8AE	
Emergency Use	Used to identify products that are required for emergency control of pest infestations that are seriously detrimental to public health, domestic animals, natural resources or other things, for a period not exceeding one year.		N	N	DIR2017-03		This use is covered by an emergency permit

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Emergency Use Date of Expiry	Used to identify and expire emergency use(s) from a label after a pre-defined date.		N	N	PCPR 18 DIR2017-03		This use is covered by a permit
Imported Treated Seed Use	To identify the use rate at which the imported treated seed would have been treated in order to conduct the occupational exposure risk assessment for planters.		N	N			

8.2. Japan

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory ⁺ / Policy and Guidelines ⁺⁺ Requirement	Regulatory ⁺ / Policy and Guidelines ⁺⁺ Requirement (Yes or No)	Additional Comments
Product Name	Unique text identifier assigned to each individual product used for tracking and reporting purposes.		N	N	PCPR 26 (1)(a)	Y	
Product description	Provides a brief description for easy identification of the general uses (sites and pests) of the product.		N	N		N	
Product Type	Unique text identifier assigned to each individual product type used for tracking and reporting purposes. Identifies the general type of organism targeted by the product (e.g., fungicide, insecticide, vertebrate repellent). Determines the use pattern assessed in the value and risk assessments. Some data requirements and label information and restrictions are directly linked to the product type and used in risk assessment and risk management		Y	Y	PCPR 26 (1)(b)	N	
Formulation Type	Unique text identifier assigned to each individual formulation type used for tracking and reporting purposes.		Y	Y	PCPR 26 (1)(b) and PCPR 26 (1)(c)	Y	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
	Residue data may be dependent on the formulation type; used in the dietary risk assessment. The exposure values used in the occupational/residential risk assessments are dependent on the formulation type.						
Egeepd1Class designation	Unique text identifier assigned to each individual marketing class used for tracking and reporting purposes. The parameters used in the occupational/residential risk assessment are different for commercial-class and domestic-class product. Also, restricted-class may be used as a mitigation measure to prevent occupational/residential human health risk or environmental risk.		Y	N	PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products	N	
Signal Words	Needed to identify the acute health hazards to users. May trigger the need for additional personal protection equipment (PPE). Determined by the acute toxicity and physical and chemical properties of the pest control products (TGAI, MUP, EP).		N	N	PCPR 26 (1)(e) schedules 3 and 4	Y	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Hazard Symbols	“Pictograms” inform users of acute health hazards.		N	N	PCPR 26 (1)(e) schedules 3 and 4	N	
Hazard Statements	Statements inform users of acute health hazards.		N	N	PCPR26(1) (e)	Y	
Read the label before using	Instructs users to read the label (and booklet, if applicable) before using to ensure they are informed as to how to use the product safely and effectively.		N	N	PCPR 26(1)(f) and 28 (2)(a)	N	Not on the label, but requested by the law.
Active Ingredient	Required for value, environment, human health hazard and risk characterization. The active ingredient includes common chemical name of the active ingredient or, if none, its chemical name or another name, and the concentration of the active ingredient in the appropriate form. Information on viscosity, specific gravity, particle size or any other property may also be required.		N	N	PCPR 26 (1)(h)	Y	
Allergens	Label identification of formulants that are common allergens known to be associated with anaphylactic reactions.		N	N	DIR2006-02	N	
Preservatives	Label identification of active		N	N	DIR2006-02	N	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
	ingredients that are present in the end-use formulation as formulation preservatives.						
Registration Number	Statement containing unique numerical identifier assigned to each individual product used for tracking and reporting purposes. If one is not yet assigned, a placeholder will be needed.		N	N	PCPR 26 (1)(i)	Y	
Private Label Number	Unique numerical identifier assigned to each individual product used for tracking and reporting purposes.		N	N	PCPR 26 (1)(i)	N	
Net Contents	May have an impact on occupational risk assessment and mitigation measures.		Y	Y	PCPR 26 (1)(j) Weights and Measures Act (metric)	Y	
Contact information	Required to allow users to contact the registrant with inquiries about the product. At minimum, registrant name and postal address and telephone number to which public inquiries may be directed.		N	N	PCPR 26(1)(k)(1) and 27 (1)(2)	N	
Resistance Management Group for the Active	Unique alphanumeric identifier assigned to fungicide, herbicide and insecticide active ingredient; used in value determination.		N	N	DIR 2013-04	N	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Ingredient	Appears on commercial or restricted class product labels as part of the identification for resistance management purposes. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.						
Expiry date	For products that have a limited shelf life, ex: live organisms		N	Y		Y	
Notice to user	To stress the importance of reading the label.		N	N	PCPR 26(2)(g)	N	
First Aid Instructions	In the case of human health issues, the instructions identify the steps to take to help the person experiencing the symptoms. The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.		N	N	PCPR 26(2)(e)	Y	
Companion Animal and Livestock First Aid	In the case of animal health issues, the instructions identify the steps to take to help the pet experiencing the symptoms.		N	N	PCPR 26(2)(e); DIR2002-01	N	
Toxicological Information	Information for doctor/physician The information may be generic or specific to the active ingredient and/or formulation of the TGAI,		N	N	PCPR 26(2)(f)	Y	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
	MUP, and EP.						
Human Health Precautions	The label statements in this section inform users of potential human health hazards or risk and/or measures to mitigate the hazards and/or risks.		N	N	PCPR 26(2)(c) and 26(2)(d)	Y	
Personal Protective Equipment (PPE)/ Engineering Controls	Mandatory protective equipment such as clothing, respirators, goggles and gloves required as a result of the acute hazard and/or human health risk assessment to reduce exposure to workers in contact with pest control products. Engineering controls (e.g. closed-cab tractor) may be required to prevent/mitigate exposures and/or risk while performing their work with pesticides.		N	N	PCPR 26(2)(c)	Y	
Companion Animal and Livestock Precautions	The label statements in this section inform users of potential animal health hazards or risk and/or measures to mitigate the risks.		N	N	PCPR 26(2)(c) and 26(2)(d)	Y	
Environmental Precautions	The label statements in this section inform users of potential hazards or risks to the environment and/or of measures		N	N	PCPR 26(2)(c)	Y	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
	to mitigate the risks to the environment. Each subsection is separate to allow for tracking and reporting purposes in the future.						
Environmental Precautions – Aquatic organisms	Statements inform users of potential hazards or risks and/or of measures to mitigate risks.		N				
Environmental Precautions – Birds							
Environmental Precautions – Wild Mammals							
Environmental Precautions – Bees							
Environmental Precautions – Beneficial Arthropods				N		Y	
Environmental Precautions – Earthworms							
Environmental Precautions –							
Environmental Precautions –							

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Non-Target Terrestrial Plants							
Environmental Precautions – Burrow Treatments							
Environmental Precautions – Persistence/ Accumulation/ Carryover	Statements inform users of the potential for accumulation and carryover and recommend practices to minimize the potential for accumulation and carryover.		N	N		N	
Environmental Precautions – Leaching	Statements inform users of the potential for leaching and recommend practices to minimize the potential for leaching to groundwater.		N	N		N	
Environmental Precautions – Runoff	Statements recommend practices to minimize runoff into adjacent waterbodies.		N	N		Y	
Environmental Precautions – Volatilization	Statements to minimize the release into the environment from volatilization.		N	N		Y	
Environmental Precautions – Products	Statements inform users of potential hazards or risks to aquatic organisms.		N	N		N	

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Containing Aromatic Petroleum Distillates							
General information	Provides general directions on the use of the product. Includes but is not limited to a brief product description/ information and geographic restrictions (if applicable).		N	N		Y	
Directions For Use (General)	Communicates the PMRA supported use pattern to the end user of the pest control product.		N	N	PCPR 26(2)(a)	Y	
Use Limitations	To identify situations that may pose potential risks of concern to health or the environment. To communicate limitations in the use pattern for which a risk assessment was not performed or for which risks of concern were identified (i.e. DO NOT apply in greenhouses.) To identify restrictions related to dietary and occupational exposure: preharvest intervals, restricted-entry intervals, pregrazing interval/feeding		N	N	PCPR26(2)(a)	Y	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
	restrictions, preslaughter interval						
General Application Instructions	General information on how to apply the product including ground or aerial application, the application type (broadcast, drench, chemigation, etc.), the application target (foliar, soil, seed, etc.) and permitted equipment.		N	N	PCPR26(2)(a)	Y	
Application Method	Required for the risk and value assessments Statements for various application methods provide measures to minimize spray drift to non-target sensitive habitats for certain application equipment. Parameters used in the occupational/residential health risk assessments are dependent upon the application method. For residue chemistry, data requirements and residue trials are required for each type of applications. Residue data are used in the risk assessment.		Y	Y	PCPR26(2)(a)	Y	
Application target	The application target (foliar, soil, seed, etc.)		Y	Y	PCPR26(2)(a)	Y	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Application equipment	Provides information on the type of application equipment that is approved for use.		Y	Y	PCPR26(2)(a)	Y	If necessary.
Chemigation	Instruction on the use of chemigation		N	N	DIR93-13	N	
Runoff Management	Mandatory vegetative filter strips provide measures required to mitigate risks to aquatic organisms from runoff of pesticide into adjacent waterbodies.		N	N		N	
Spray Drift Management	Spray buffer zone statements and spray buffer zone table provide measures required to mitigate risks to sensitive terrestrial and aquatic habitats from spray drift downwind from the site of application.		N	N		N	
General Mixing Instructions	Mixing instructions that apply to all uses on the label including tank mixing sequencing		N	N		N	
Generic Tank Mix Statement	Instructions for tank mixes not specifically described on the label.		N	N		N	
Tank Mix Partner Information	Used for tracking and identifying specific tank mixes		N	N		N	

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Tank Partner Mixing-Loading Instructions	Instructions for proper mixing of specific tank mix partners (e.g., order to introduce the partners into the spray tank)		N	N		N	
Rotational Crops/ Plantback Interval	Required for the risk and value assessments To inform users of the time interval to respect before planting rotational crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern. Also phytotoxicity, field bioassay statements/instruction		Y	Y		N	
Restricted-Entry Intervals	To inform users of the interval between application, and when workers can enter areas treated with pest control products. Can be used to mitigate risks to postapplication workers.		Y	N		N	
Preharvest Intervals	To inform users of the time interval to respect before harvesting the food crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially		Y	Y		Y	

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	pose a health risk of concern.						
Pregrazing Intervals/ Feeding Restriction	To inform users of the time interval to respect before harvesting the feed crops or letting livestock graze in the treated field in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.		Y	N		N	
Preslaughter Intervals	To inform users of the time interval to respect before slaughtering livestock in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.		Y	N		N	
Resistance Management Information	Recommendations to reduce the risk of pesticide resistance by arthropods, plant diseases and weeds. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.		N	N	DIR 2013-04	N	
Storage and Disposal	Storage statement to prevent contamination of food or feed and provide disposal information.		N	N	PCPR 26(2)(b) and DIR 1999-04	Y	

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Labelling of Treated Seed (Seed Tag)	Statements on seed tags are used to inform users of measures to mitigate environmental risks. Precautionary statements on seed tags are used to inform workers of the required PPE/engineering controls while handling and planting treated seed. May include restrictions such as pregrazing interval/feeding restrictions or plantback intervals/rotational crops.		N	N		N	
Labelling of Treated Article (Hang Tag)	Statements on hang tags are used to inform users/consumers of proper handling, care and use of the garment/article Precautionary statements on hang tags are used to inform users/consumers of potential skin sensitizing risks from the use/exposure to manufactured garments/articles May include restrictions or storage and disposal requirements		N	N		N	
Imported Treated Seed Information	To inform importers of treated seed that a human health risk assessment for planters has been conducted and that it is acceptable		N	N		N	

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	to import the treated seed into Canada.						
Direct Application to Water	Statements provide measures to mitigate risks to non-target aquatic organisms and inform users of legislative requirements when applying pesticides directly to water.		N	N		Y	
Requirements for Vertebrate and Insect Baits	Required for the risk and value assessments Statements provide measures to mitigate risks to children, pets, livestock or wildlife such as non-target birds or wild mammals.		N	N		N	
Products Discharged Into Water Bodies	Statement provide measures to mitigate potential risks to aquatic organisms from discharge of effluent.		N	N		Y	
Wood Uses	Required for the risk assessments Statements provide measures to minimize releases into the environment.		N	N		N	
Cranberry	Statements provide measures to mitigate potential risks of effluent water from cranberry fields to aquatic organisms.		N	N		N	
Greenhouse	Statements provide measures to mitigate risks to aquatic		N	N		N	Possibly included in general caution

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	organisms from effluent or runoff.						
Mushroom House	Statements provide measures to mitigate risks to aquatic organisms from effluent or runoff.		N	N		N	
IMEP (Importation for Manufacturing and Export Program)	Statements provide measures to mitigate risks to aquatic organisms from a product imported solely for the purpose of manufacturing and export.		N	N		N	
Use-Site Category (USC)	Required to help guide determination of data required in support of an application to register, amend, or conduct research with a pest control product. Each USC has a list of required and conditionally required data called data-code or DACO tables.		Y	N		N	
Site/Host/Crop	Required for the risk and value assessments (i.e., area of use, site of application, surface type or material to be treated)		Y	Y	PCPR26(2)(a)	Y	
Site/Host/Crop Subtype	This would be for additional information on a site/host such as age and weight of products used on companion animals or type of growing environment		Y	Y	PCPR 26(2)(a)	Y	

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	(greenhouse, outdoor field, etc.). Required for value and risk assessments.						
Geographic Area	May have an impact on the residue chemistry data requirements (i.e. reduce the number of field trials required), residue data used in the human health risk assessment May have an impact on the input used in the dietary risk assessment for drinking water		Y	N		N	
Effects on treated objects or sites	This would include information on the potential for damage to treated sites (e.g., phytotoxicity) Required for value assessment.		N	N	DIR2016-02	N	
Pest	Identifies the pest being targeted, Required for the value assessment Determine the type of human health risk assessment is required based on how the specific pest is treated or where the pest found in relation to human activities.		Y	Y	PCPR 26(2)(a)	Y	
Pest Subtype	Required for the value assessment Required for determining the magnitude of postapplication exposure use patterns. This would be for any additional		Y	Y	PCPR 26(2)(a)	Y	

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	details on the target pest (e.g., lifestage, nest treatment).						
Pest Control Claim	Required for the value assessment (ie., type/level of control such as control, suppression, reduces infection/damage, prevents fouling vs removes established fouling, type of protection-prevents degradation, discoloration)		N	N	PCPR 26(2)(a)	N	
Duration of Efficacy against Pest(s)	Required for the value assessment of personal insect repellents, other repellents, attractants, products with residual claims, companion animal product, etc.		N	N	PCPR 26(2)(a)	N	
Product Rate/ Concentration and residual to be maintained, if applicable	Required for the risk and value assessments Directions for use, including method and application rates or residual concentration to be maintained, target retention (kg/m ³) or target deposition (µg/cm ²), expected coverage (m ² per litre of paint), the contact time, dilution and rinse if applicable. When pesticide rates are given as a range, instructions may be required		Y	Y	PCPR 26(2)(a)	Y	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
	as to when to use the lower and higher application rates.						
Product Rate/ Concentration/ Residual to be Maintained Units	Required for the risk and value assessments		Y	Y	PCPR 26(2)(a)	Y	
Rate of Active Ingredient(s)	Required for the risk and value assessments		Y	Y	PCPR 26(2)(a)	Y	
Adjuvant	Adjuvant product name or adjuvant type. Required for the acute hazard, dietary risk assessment for the active ingredient with which it is co-formulated and value assessments		Y	N	PCPR 26(2)(a)	N	
Rate of Adjuvant	Required for the acute hazard, dietary risk assessment for the active ingredient with which the adjuvant is co-formulated and value assessments Human health risk assessments are not required for the adjuvant itself.		Y	N	PCPR 26(2)(a)	N	
Rate of Adjuvant Units	Required for the risk and value assessments		Y	N	PCPR 26(2)(a)	N	
Maximum Cumulative	Required for the risk assessments		Y	N	PCPR 26(2)(a)	N	

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Rate of Active Ingredient per Year							
Minimum Number of Applications	Required for occupational exposure risk assessment (required as sometimes there is a range in the number of applications) May be required to refine or mitigate the occupational exposure risk assessment		Y	Y		N	
Maximum Number of Applications	Required for the risk assessments Can be used as a tool to mitigate postapplication exposure, and determine the total amount of active ingredient applied to a crop in a single year or crop cycle.		Y	Y	PCPR 26(2)(a)	Y	
Maximum Number of Applications per Year or Crop Cycle	Required for the risk assessments		Y	N	PCPR 26(2)(a)	N	
Spray Volume	Required for the risk and value assessments Spray volume is also included in buffer zone calculations for aerial application Converts user application rates on		Y	Y	PCPR 26(2)(a)	Y	

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	labels to rates required to complete a human health risk assessment.						
Spray pressure	Required for the risk assessments		Y	N		N	
Application Target	Required for the risk assessments Parameters used in the occupational/residential health risk assessments are dependent on the application target.		Y	Y	PCPR 26(2)(a)	Y	
Application Type	Required for the risk and value assessments Parameters used in the occupational/residential health risk assessments are dependent on the application type.		Y	Y	PCPR 26(2)(a)	Y	
Application Equipment	Required for the risk assessments and value assessments Application equipment is also considered in the buffer zone calculations. Parameters used in the occupational/residential health risk assessments are dependent on the application equipment.		Y	Y	PCPR 26(2)(a)	Y	If necessary.
Minimum Re-Treatment Interval (RTI)	Required for the risk and value assessments One of the parameters in the occupational/residential risk		Y	N	PCPR 26(2)(a)	N	

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	assessment						
Maximum Re-Treatment Interval (RTI)	Required for the risk assessments Required for occupational exposure risk assessments (required as sometimes there is a range of RTIs) - May be required to refine or mitigate the occupational exposure risk assessment		Y	N		N	
Application Timing	Used to identify the application timing for effective management of the listed pest(s); EAD: used to determine exposure considerations in environmental risk assessments for aquatic organisms and pollinators. Considered in the human health risk assessment to determine the potential exposure to workers, users and bystanders For residue chemistry, if application timing is early and very specific, may not need a preharvest interval. Required for the value assessments – preventative vs curative claims.		Y	Y	PCPR 26(2)(a)	Y	
Application Instructions	Instructions that identify the PMRA supported/approved use of		N	Y	PCPR 26(2)(a)	Y	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
(Specific Uses)	a product in the context of a specific use pattern (e.g. site-pest-rate combination) Any other information pertinent to the value of the pest control product (pre-cleaning or surface preparation, etc.)						
User Requested Minor Use Label Expansion (URMULE)	Used for tracking and reporting on the expansion of a label for a new minor use of a pesticide for which the active ingredient(s) and the end use product are currently registered in Canada under the URMULE program		N	N	DIR2001-01	N	
User Requested Minor Use Registration (URMUR)	Used for tracking and reporting on the registration of products/uses under the URMUR program		N	N	DIR99-05	N	
Restricted Use	Used to identify specific product applications that can only be used under certain circumstances by specially trained individuals.		N	N	PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products	Y	For quarantine uses.
Aerial Application	Required for the risk and value assessments		Y	Y	DIR1996-04	Y	
Emergency Use	Used to identify products that are required for emergency control of pest infestations that are seriously		N	N	DIR2017-03	N	

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (Japan) (Yes or No)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
	detrimental to public health, domestic animals, natural resources or other things, for a period not exceeding one year.						
Emergency Use Date of Expiry	Used to identify and expire emergency use(s) from a label after a pre-defined date.		N	N	PCPR 18 DIR2017-03	N	
Imported Treated Seed Use	To identify the use rate at which the imported treated seed would have been treated in order to conduct the occupational exposure risk assessment for planters.		N	N		N	

8.3. New Zealand

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Product Name	Unique text identifier assigned to each individual product used for tracking and reporting purposes.		N	N	PCPR 26 (1)(a)		A product identifier is required on the label, but not needed for risk assessment
Product description	Provides a brief description for easy identification of the general uses (sites and pests) of the product.		N	N			Not required for risk assessment but required risk assessment

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Product Type	<p>Unique text identifier assigned to each individual product type used for tracking and reporting purposes.</p> <p>Identifies the general type of organism targeted by the product (e.g., fungicide, insecticide, vertebrate repellent).</p> <p>Determines the use pattern assessed in the value and risk assessments.</p> <p>Some data requirements and label information and restrictions are directly linked to the product type and used in risk assessment and risk management</p>		Y	Y	PCPR 26 (1)(b)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Formulation Type	<p>Unique text identifier assigned to each individual formulation type used for tracking and reporting purposes.</p> <p>Residue data may be dependent on the formulation type; used in the dietary risk assessment.</p> <p>The exposure values used in the occupational/residential risk assessments are dependent on the formulation type.</p>		Y	Y	PCPR 26 (1)(b) and PCPR 26 (1)(c)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Class designation	Unique text identifier assigned to each individual marketing class used for tracking and reporting purposes. The parameters used in the occupational/residential risk assessment are different for commercial-class and domestic-class product. Also, restricted-class may be used as a mitigation measure to prevent occupational/residential human health risk or environmental risk.		Y	N	PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products		
Signal Words	Needed to identify the acute health hazards to users. May trigger the need for additional personal protection equipment (PPE). Determined by the acute toxicity and physical and chemical properties of the pest control products (TGAI, MUP, EP).		N	Y	PCPR 26 (1) schedules 3 and 4		Yes, as per GHS requirements but includes chronic health hazards as well as acute health hazards.

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory[†]/ Policy and Guidelines^{††} Requirement	Regulatory[†]/ Policy and Guidelines^{††} Requirement (Yes or No)	Additional Comments
Hazard Symbols	“Pictograms” inform users of acute health hazards.		N	Y	PCPR 26 (1)(e) schedules 3 and 4		
Hazard Statements	Statements inform users of acute health hazards.		N	Y	PCPR26(1) (e)		
Read the label before using	Instructs users to read the label (and booklet, if applicable) before using to ensure they are informed as to how to use the product safely and effectively.		N	N	PCPR 26(1)(f) and 28 (2)(a)		Only applies to consumer products

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Active Ingredient	Required for value, environment, human health hazard and risk characterization. The active ingredient includes common chemical name of the active ingredient or, if none, its chemical name or another name, and the concentration of the active ingredient in the appropriate form. Information on viscosity, specific gravity, particle size or any other property may also be required.		N	Y	PCPR 26 (1)(h)		
Allergens	Label identification of formulants that are common allergens known to be associated with anaphylactic reactions.		N	Y	DIR2006-02		Respiratory and skin sensitisation as per GHS classifications.
Preservatives	Label identification of active ingredients that are present in the end-use formulation as formulation preservatives.		N	N	DIR2006-02		No, unless triggers classification as a toxic or corrosive ingredient.

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Registration Number	Statement containing unique numerical identifier assigned to each individual product used for tracking and reporting purposes. If one is not yet assigned, a placeholder will be needed.		N	N	PCPR 26 (1)(i)		
Private Label Number	Unique numerical identifier assigned to each individual product used for tracking and reporting purposes.		N	N	PCPR 26 (1)(i)		
Net Contents	May have an impact on occupational risk assessment and mitigation measures.		Y	Y	PCPR 26 (1)(j) Weights and Measures Act (metric)		
Contact information	Required to allow users to contact the registrant with inquiries about the product. At minimum, registrant name and postal address and telephone number to which public inquiries may be directed.		N	N	PCPR 26(1)(k)(1) and 27 (1)(2)		Is required on the label but not for risk assessment.

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Resistance Management Group for the Active Ingredient	Unique alphanumeric identifier assigned to fungicide, herbicide and insecticide active ingredient; used in value determination. Appears on commercial or restricted class product labels as part of the identification for resistance management purposes. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.		N	Y	DIR 2013-04		
Expiry date	For products that have a limited shelf life, ex: live organisms		N	Y			
Notice to user	To stress the importance of reading the label.		N	N	PCPR 26(2)(g)		Is required for consumer products.

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
First Aid Instructions	In the case of human health issues, the instructions identify the steps to take to help the person experiencing the symptoms. The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.		N	Y	PCPR 26(2)€		From GHS precautionary statements
Companion Animal and Livestock First Aid	In the case of animal health issues, the instructions identify the steps to take to help the pet experiencing the symptoms.		N	N	PCPR 26(2)(e); DIR2002-01		
Toxicological Information	Information for doctor/physician The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.		N	N	PCPR 26(2)(f)		Required in the SDS.

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Human Health Precautions	The label statements in this section inform users of potential human health hazards or risk and/or measures to mitigate the hazards and/or risks.		N	Y	PCPR 26(2)(c) and 26(2)(d)		As per GHS
Personal Protective Equipment (PPE)/ Engineering Controls	Mandatory protective equipment such as clothing, respirators, goggles and gloves required as a result of the acute hazard and/or human health risk assessment to reduce exposure to workers in contact with pest control products. Engineering controls (e.g. closed-cab tractor) may be required to prevent/mitigate exposures and/or risk while performing their work with pesticides.		N	Y	PCPR 26(2)©		
Companion Animal and Livestock Precautions	The label statements in this section inform users of potential animal health hazards or risk and/or measures to mitigate the risks.		N	Y	PCPR 26(2)(c) and 26(2)(d)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Environmental Precautions	The label statements in this section inform users of potential hazards or risks to the environment and/or of measures to mitigate the risks to the environment. Each subsection is separate to allow for tracking and reporting purposes in the future.		N	Y	PCPR 26(2)(c)		
Environmental Precautions – Aquatic organisms	Statements inform users of potential hazards or risks and/or of measures to mitigate risks.		N	Y			N/A to New Zealand
Environmental Precautions - Birds				Y			
Environmental Precautions – Wild Mammals							
Environmental Precautions - Bees				Y			
Environmental Precautions – Beneficial Arthropods				Y			

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Environmental Precautions - Earthworms				Y			
Environmental Precautions – Non-Target Terrestrial Plants				Y			
Environmental Precautions – Burrow Treatments							
Environmental Precautions – Persistence/ Accumulation/ Carryover	Statements inform users of the potential for accumulation and carryover and recommend practices to minimize the potential for accumulation and carryover.		N	Y			If necessary as determined by the risk assessment.
Environmental Precautions – Leaching	Statements inform users of the potential for leaching and recommend practices to minimize the potential for leaching to groundwater.		N	Y			If necessary as determined by the risk assessment.
Environmental Precautions – Runoff	Statements recommend practices to minimize runoff into adjacent waterbodies.		N	Y			If necessary as determined by the risk assessment.

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory[†]/ Policy and Guidelines^{††} Requirement	Regulatory[†]/ Policy and Guidelines^{††} Requirement (Yes or No)	Additional Comments
Environmental Precautions - Volatilization	Statements to minimize the release into the environment from volatilization.		N	Y			If necessary as determined by the risk assessment.
Environmental Precautions - Products Containing Aromatic Petroleum Distillates	Statements inform users of potential hazards or risks to aquatic organisms.		N	Y			
General information	Provides general directions on the use of the product. Includes but is not limited to a brief product description/ information and geographic restrictions (if applicable).		N	N			
Directions For Use (General)	Communicates the PMRA supported use pattern to the end user of the pest control product.		N	N	PCPR 26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Use Limitations	<p>To identify situations that may pose potential risks of concern to health or the environment.</p> <p>To communicate limitations in the use pattern for which a risk assessment was not performed or for which risks of concern were identified (i.e. DO NOT apply in greenhouses.)</p> <p>To identify restrictions related to dietary and occupational exposure: preharvest intervals, restricted-entry intervals, pregrazing interval/feeding restrictions, preslaughter interval</p>		N	Y	PCPR26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
General Application Instructions	General information on how to apply the product including ground or aerial application, the application type (broadcast, drench, chemigation, etc.), the application target (foliar, soil, seed, etc.) and permitted equipment.		N	Y	PCPR26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Application Method	Required for the risk and value assessments Statements for various application methods provide measures to minimize spray drift to non-target sensitive habitats for certain application equipment. Parameters used in the occupational/residential health risk assessments are dependent upon the application method. For residue chemistry, data requirements and residue trials are required for each type of applications. Residue data are used in the risk assessment.		Y	Y	PCPR26(2)(a)		
Application target	The application target (foliar, soil, seed, etc.)		Y	Y	PCPR26(2)(a)		
Application equipment	Provides information on the type of application equipment that is approved for use.		Y	Y	PCPR26(2)(a)		
Chemigation	Instruction on the use of chemigation		N		DIR93-13		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory ⁺ / Policy and Guidelines ⁺⁺ Requirement	Regulatory ⁺ / Policy and Guidelines ⁺⁺ Requirement (Yes or No)	Additional Comments
Runoff Management	Mandatory vegetative filter strips provide measures required to mitigate risks to aquatic organisms from runoff of pesticide into adjacent waterbodies.		N	Y			
Spray Drift Management	Spray buffer zone statements and spray buffer zone table provide measures required to mitigate risks to sensitive terrestrial and aquatic habitats from spray drift downwind from the site of application.		N	Y			
General Mixing Instructions	Mixing instructions that apply to all uses on the label including tank mixing sequencing		N	N			This information can be included on the label based on information provided by the manufacturer.
Generic Tank Mix Statement	Instructions for tank mixes not specifically described on the label.		N	N			This information can be included on the label based on information provided by the manufacturer.

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Tank Mix Partner Information	Used for tracking and identifying specific tank mixes		N	N			This information can be included on the label based on information provided by the manufacturer.
Tank Mix Partner Mixing-Loading Instructions	Instructions for proper mixing of specific tank mix partners (e.g., order to introduce the partners into the spray tank)		N	N			This information can be included on the label based on information provided by the manufacturer.
Rotational Crops/ Plantback Interval	Required for the risk and value assessments To inform users of the time interval to respect before planting rotational crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern. Also phytotoxicity, field bioassay statements/instruction		Y	Y			

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Restricted-Entry Intervals	To inform users of the interval between application, and when workers can enter areas treated with pest control products. Can be used to mitigate risks to postapplication workers.		Y	Y			
Preharvest Intervals	To inform users of the time interval to respect before harvesting the food crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern.		Y	Y			
Pregrazing Intervals/ Feeding Restriction	To inform users of the time interval to respect before harvesting the feed crops or letting livestock graze in the treated field in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.		Y	Y			

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Preslaughter Intervals	To inform users of the time interval to respect before slaughtering livestock in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.		Y	Y			
Resistance Management Information	Recommendations to reduce the risk of pesticide resistance by arthropods, plant diseases and weeds. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.		N	Y	DIR 2013-04		
Storage and Disposal	Storage statement to prevent contamination of food or feed and provide disposal information.		N	Y	PCPR 26(2)(b) and DIR 1999-04		

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Labelling of Treated Seed (Seed Tag)	<p>Statements on seed tags are used to inform users of measures to mitigate environmental risks. Precautionary statements on seed tags are used to inform workers of the required PPE/engineering controls while handling and planting treated seed. May include restrictions such as pregrazing interval/feeding restrictions or plantback intervals/rotational crops.</p>		N	Y			For risks to birds.

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Labelling of Treated Article (Hang Tag)	Statements on hang tags are used to inform users/consumers of proper handling, care and use of the garment/article Precautionary statements on hang tags are used to inform users/consumers of potential skin sensitizing risks from the use/exposure to manufactured garments/articles May include restrictions or storage and disposal requirements		N	N			
Imported Treated Seed Information	To inform importers of treated seed that a human health risk assessment for planters has been conducted and that it is acceptable to import the treated seed into Canada.		N	N			

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Direct Application to Water	Statements provide measures to mitigate risks to non-target aquatic organisms and inform users of legislative requirements when applying pesticides directly to water.		N	Y			
Requirements for Vertebrate and Insect Baits	Required for the risk and value assessments Statements provide measures to mitigate risks to children, pets, livestock or wildlife such as non-target birds or wild mammals.		N	Y			
Products Discharged Into Water Bodies	Statement provide measures to mitigate potential risks to aquatic organisms from discharge of effluent.		N	N			
Wood Uses	Required for the risk assessments Statements provide measures to minimize releases into the environment.		N	N			
Cranberry	Statements provide measures to mitigate potential risks of effluent water from cranberry fields to aquatic organisms.		N	N			

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Greenhouse	Statements provide measures to mitigate risks to aquatic organisms from effluent or runoff.		N	N			
Mushroom House	Statements provide measures to mitigate risks to aquatic organisms from effluent or runoff.		N	N			
IMEP (Importation for Manufacturing and Export Program)	Statements provide measures to mitigate risks to aquatic organisms from a product imported solely for the purpose of manufacturing and export.		N	Y			If classified as aquatic hazards under GHS.
Use-Site Category (USC)	Required to help guide determination of data required in support of an application to register, amend, or conduct research with a pest control product. Each USC has a list of required and conditionally required data called data-code or DACO tables.		Y	?			Data is required for contained field trials for R&D.

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Site/Host/Crop	Required for the risk and value assessments (i.e., area of use, site of application, surface type or material to be treated)		Y	Y	PCPR26(2)(a)		
Site/Host/Crop Subtype	This would be for additional information on a site/host such as age and weight of products used on companion animals or type of growing environment (greenhouse, outdoor field, etc.). Required for value and risk assessments.		Y	Y	PCPR 26(2)(a)		
Geographic Area	May have an impact on the residue chemistry data requirements (i.e. reduce the number of field trials required), residue data used in the human health risk assessment May have an impact on the input used in the dietary risk assessment for drinking water		Y	Y			

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Effects on treated objects or sites	This would include information on the potential for damage to treated sites (e.g., phytotoxicity) Required for value assessment.		N	Y	DIR2016-02		
Pest	Identifies the pest being targeted, Required for the value assessment Determine the type of human health risk assessment is required based on how the specific pest is treated or where the pest found in relation to human activities.		Y	Y	PCPR 26(2)(a)		
Pest Subtype	Required for the value assessment Required for determining the magnitude of postapplication exposure use patterns. This would be for any additional details on the target pest (e.g., lifestage, nest treatment).		Y	Y	PCPR 26(2)(a)		

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Pest Control Claim	Required for the value assessment (ie., type/level of control such as control, suppression, reduces infection/damage, prevents fouling vs removes established fouling, type of protection- prevents degradation, discoloration)		N	Y	PCPR 26(2)(a)		
Duration of Efficacy against Pest(s)	Required for the value assessment of personal insect repellents, other repellents, attractants, products with residual claims, companion animal product, etc.		N	Y	PCPR 26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Product Rate/ Concentration and residual to be maintained, if applicable	Required for the risk and value assessments Directions for use, including method and application rates or residual concentration to be maintained, target retention (kg/m ³) or target deposition (µg/cm ²), expected coverage (m ² per litre of paint), the contact time, dilution and rinse if applicable. When pesticide rates are given as a range, instructions may be required as to when to use the lower and higher application rates.		Y	Y	PCPR 26(2)(a)		
Product Rate/ Concentration/ Residual to be Maintained Units	Required for the risk and value assessments		Y	Y	PCPR 26(2)(a)		
Rate of Active Ingredient(s)	Required for the risk and value assessments		Y	Y	PCPR 26(2)(a)		

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Adjuvant	Adjuvant product name or adjuvant type. Required for the acute hazard, dietary risk assessment for the active ingredient with which it is co-formulated and value assessments		Y	Y	PCPR 26(2)(a)		
Rate of Adjuvant	Required for the acute hazard, dietary risk assessment for the active ingredient with which the adjuvant is co-formulated and value assessments Human health risk assessments are not required for the adjuvant itself.		Y	Y	PCPR 26(2)(a)		
Rate of Adjuvant Units	Required for the risk and value assessments		Y	Y	PCPR 26(2)(a)		
Maximum Cumulative Rate of Active Ingredient per Year	Required for the risk assessments		Y	Y	PCPR 26(2)(a)		

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Minimum Number of Applications	Required for occupational exposure risk assessment (required as sometimes there is a range in the number of applications) May be required to refine or mitigate the occupational exposure risk assessment		Y	Y			
Maximum Number of Applications	Required for the risk assessments Can be used as a tool to mitigate postapplication exposure, and determine the total amount of active ingredient applied to a crop in a single year or crop cycle.		Y	Y	PCPR 26(2)(a)		
Maximum Number of Applications per Year or Crop Cycle	Required for the risk assessments		Y	Y	PCPR 26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Spray Volume	Required for the risk and value assessments Spray volume is also included in buffer zone calculations for aerial application Converts user application rates on labels to rates required to complete a human health risk assessment.		Y	Y	PCPR 26(2)(a)		
Spray pressure	Required for the risk assessments		Y	Y			
Application Target	Required for the risk assessments Parameters used in the occupational/residential health risk assessments are dependent on the application target.		Y	Y	PCPR 26(2)(a)		
Application Type	Required for the risk and value assessments Parameters used in the occupational/residential health risk assessments are dependent on the application type.		Y	Y	PCPR 26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Application Equipment	Required for the risk assessments and value assessments Application equipment is also considered in the buffer zone calculations. Parameters used in the occupational/residential health risk assessments are dependent on the application equipment.		Y	Y	PCPR 26(2)(a)		
Minimum Re-Treatment Interval (RTI)	Required for the risk and value assessments One of the parameters in the occupational/residential risk assessment		Y	Y	PCPR 26(2)(a)		
Maximum Re-Treatment Interval (RTI)	Required for the risk assessments Required for occupational exposure risk assessments (required as sometimes there is a range of RTIs) - May be required to refine or mitigate the occupational exposure risk assessment		Y	Y			

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Application Timing	<p>Used to identify the application timing for effective management of the listed pest(s); EAD: used to determine exposure considerations in environmental risk assessments for aquatic organisms and pollinators. Considered in the human health risk assessment to determine the potential exposure to workers, users and bystanders</p> <p>For residue chemistry, if application timing is early and very specific, may not need a preharvest interval. Required for the value assessments – preventative vs curative claims.</p>		Y	Y	PCPR 26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Application Instructions (Specific Uses)	Instructions that identify the PMRA supported/approved use of a product in the context of a specific use pattern (e.g. site-pest-rate combination) Any other information pertinent to the value of the pest control product (pre-cleaning or surface preparation, etc.)		N	N	PCPR 26(2)(a)		
User Requested Minor Use Label Expansion (URMULE)	Used for tracking and reporting on the expansion of a label for a new minor use of a pesticide for which the active ingredient(s) and the end use product are currently registered in Canada under the URMULE program		N	N	DIR2001-01		
User Requested Minor Use Registration (URMUR)	Used for tracking and reporting on the registration of products/uses under the URMUR program		N	N	DIR99-05		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment New Zealand	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Restricted Use	Used to identify specific product applications that can only be used under certain circumstances by specially trained individuals.		N	Y	PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products		
Aerial Application	Required for the risk and value assessments		Y	Y	DIR1996-04		
Emergency Use	Used to identify products that are required for emergency control of pest infestations that are seriously detrimental to public health, domestic animals, natural resources or other things, for a period not exceeding one year.		N	N	DIR2017-03		
Emergency Use Date of Expiry	Used to identify and expire emergency use(s) from a label after a pre-defined date.		N	N	PCPR 18 DIR2017-03		
Imported Treated Seed Use	To identify the use rate at which the imported treated seed would have been treated in order to conduct the occupational exposure risk assessment for planters.		N	N			

8.4. United Kingdom

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Product Name	Unique text identifier assigned to each individual product used for tracking and reporting purposes.	Product tradename	N	UK - N	PCPR 26 (1)(a)		
Product description	Provides a brief description for easy identification of the general uses (sites and pests) of the product.	Biological use phrase	N	UK - Y			

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Product Type	Unique text identifier assigned to each individual product type used for tracking and reporting purposes. Identifies the general type of organism targeted by the product (e.g., fungicide, insecticide, vertebrate repellent). Determines the use pattern assessed in the value and risk assessments. Some data requirements and label information and restrictions are directly linked to the product type and used in risk assessment and risk management	Field of use	Y	UK - Y	PCPR 26 (1)(b)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Formulation Type	Unique text identifier assigned to each individual formulation type used for tracking and reporting purposes. Residue data may be dependent on the formulation type; used in the dietary risk assessment. The exposure values used in the occupational/residential risk assessments are dependent on the formulation type.	Formulation type	Y	UK - Y	PCPR 26 (1)(b) and PCPR 26 (1)(c)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Class designation	Unique text identifier assigned to each individual marketing class used for tracking and reporting purposes. The parameters used in the occupational/residential risk assessment are different for commercial-class and domestic-class product. Also, restricted-class may be used as a mitigation measure to prevent occupational/residential human health risk or environmental risk.	Professional/Amateur or Experimental authorisations	Y	UK - Y	PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Signal Words	Needed to identify the acute health hazards to users. May trigger the need for additional personal protection equipment (PPE). Determined by the acute toxicity and physical and chemical properties of the pest control products (TGAI, MUP, EP).	Signal words	N	UK - Y	PCPR 26 (1)(e) schedules 3 and 4		
Hazard Symbols	“Pictograms” inform users of acute health hazards.	Hazard symbols/pictograms	N	UK - Y	PCPR 26 (1)(e) schedules 3 and 4		
Hazard Statements	Statements inform users of acute health hazards.	Hazard phrases	N	UK - Y	PCPR26(1) (e)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Read the label before using	Instructs users to read the label (and booklet, if applicable) before using to ensure they are informed as to how to use the product safely and effectively.	Read the label before use	N	UK - N	PCPR 26(1)(f) and 28 (2)(a)		The following phrase must be included at the bottom of the 'Important Information' area of the product label in bold text: 'Read the label before use. Using this product in a manner that is inconsistent with the label may be an offence. Follow the Code of Practice for using plant protection products'.

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Active Ingredient	Required for value, environment, human health hazard and risk characterization. The active ingredient includes common chemical name of the active ingredient or, if none, its chemical name or another name, and the concentration of the active ingredient in the appropriate form. Information on viscosity, specific gravity, particle size or any other property may also be required.	Amount and name of the active substance(s)	N	UK - Y	PCPR 26 (1)(h)		

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Allergens	Label identification of formulants that are common allergens known to be associated with anaphylactic reactions.	Sensitising ingredients identified	N	UK - Y	DIR2006-02		
Preservatives	Label identification of active ingredients that are present in the end-use formulation as formulation preservatives.	Not routinely stated	N	UK - Y	DIR2006-02		Not routinely stated on the label (but considered as part of the formulation assessment)

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Registration Number	Statement containing unique numerical identifier assigned to each individual product used for tracking and reporting purposes. If one is not yet assigned, a placeholder will be needed.	Product registration number	N	UK - N	PCPR 26 (1)(i)		A unique 5 digit identifying registration number is allocated (currently prefixed with 'MAFF' or 'MAPP' depending on when we first allocated to a product).
Private Label Number	Unique numerical identifier assigned to each individual product used for tracking and reporting purposes.	Product batch number	N	UK - N	PCPR 26 (1)(i)		The formulation batch number (or some means of identifying it) plus the date of manufacture must appear.

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Net Contents	May have an impact on occupational risk assessment and mitigation measures.	Net quantity of product	Y	UK - Y	PCPR 26 (1)(j) Weights and Measures Act (metric)		
Contact information	Required to allow users to contact the registrant with inquiries about the product. At minimum, registrant name and postal address and telephone number to which public inquiries may be directed.	Authorisation holder and/or marketing company details	N	UK - N	PCPR 26(1)(k)(1) and 27 (1)(2)		

Resistance Management Group for the Active Ingredient	Unique alphanumeric identifier assigned to fungicide, herbicide and insecticide active ingredient; used in value determination. Appears on commercial or restricted class product labels as part of the identification for resistance management purposes. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.	Companies will follow the relevant MoA from each RAC group. There is flexibility on format/position of the reference on the label, although it is expected most will include within the resistance management section. https://www.frac.info/fuistance-management/by-frac-mode-of-action-group https://irac-online.org/modes-of-action/ https://hracglobal.com/tools/hrac-mode-of-action-classification-2020-map	N	UK - N	DIR 2013-04		UK CRD will be issuing an e-bulletin soon to implement adding MoA information for new chemical professional products as from now, and for existing products by 2023 (which is the crop life proposed date). Revised guidance will be included on the UK CRD website (a link can be provided when available). Some ‘biopesticide’ actives do also have a MoA designated – this will be optional to add.
Expiry date	For products that have a limited shelf life, ex: live organisms	For PPPs an appropriate ‘ use-by date ’ must appear if the 2-year storage stability data	N	UK - Y			

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		<p>evaluated for authorisation indicates an acceptable shelf-life of less than 2 years.</p> <p>Live organisms - no specific requirement particularly for microbials (although advice may be given on product label re: storage/shelf-life of product).</p>					
Notice to user	To stress the importance of reading the label.	Read the label before use	N	UK - N	PCPR 26(2)(g)		

First Aid Instructions	In the case of human health issues, the instructions identify the steps to take to help the person experiencing the symptoms. The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.	First aid/medical advice	N	UK - N	PCPR 26(2)(e)	Where the toxicity of the product justifies it, statements on First Aid and Guide to Doctor or Poisons Centre must appear. This Medical Advice must appear as appropriate in the Safety Precautions or as a separate section on the Container Label and any separate Leaflet. Also, Authorisation/marketing company emergency contact number is given on the label.
Companion Animal and Livestock First Aid	In the case of animal health issues, the instructions identify the steps to take to	Not routinely stated	N	UK - N	PCPR 26(2)(e); DIR2002-01	Authorisation/marketing company emergency

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	help the pet experiencing the symptoms.						contact number is given on the label
Toxicological Information	Information for doctor/physician The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.	Medical advice (within hazard and safety phrases)	N	UK - Y	PCPR 26(2)(f)		Please see page 5 'First aid/medical advice Column 8. Also, Authorisation/ marketing company emergency contact number is given on the label

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Human Health Precautions	The label statements in this section inform users of potential human health hazards or risk and/or measures to mitigate the hazards and/or risks.	Safety Precautions	N	UK - Y	PCPR 26(2)(c) and 26(2)(d)	Risk and Safety Precautions phrases in Annexes II and III of Commission Regulation (EU) No 547/2011 (previously Annexes IV and V of Directive 91/414/EEC	Sub-headings - operator protection and/or consumer protection

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Personal Protective Equipment (PPE)/ Engineering Controls	Mandatory protective equipment such as clothing, respirators, goggles and gloves required as a result of the acute hazard and/or human health risk assessment to reduce exposure to workers in contact with pest control products. Engineering controls (e.g. closed-cab tractor) may be required to prevent/mitigate exposures and/or risk while performing their work with pesticides.	Operator Protection Safety Precautions	N	UK - Y	PCPR 26(2)(c)		

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Companion Animal and Livestock Precautions	The label statements in this section inform users of potential animal health hazards or risk and/or measures to mitigate the risks.	Safety Precautions / Other specific restrictions	N	UK - Y	PCPR 26(2)(c) and 26(2)(d)		
Environmental Precautions	The label statements in this section inform users of potential hazards or risks to the environment and/or of measures to mitigate the risks to the environment. Each subsection is separate to allow for tracking and reporting purposes in the future.	Environmental protection Safety Precautions	N	UK - Y	PCPR 26(2)(c)		

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Environmental Precautions – Aquatic organisms	Statements inform users of potential hazards or risks and/or of measures to mitigate risks.	Environmental protection Safety Precautions (statements related to these specific data elements would be included under the general heading of ‘Environmental protection Safety Precautions’ and not split out by organism)	N	UK - Y			
Environmental Precautions - Birds		As above		UK - Y			
Environmental Precautions – Wild Mammals		As above		UK - Y			
Environmental Precautions - Bees		As above		UK - Y			

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Environmental Precautions – Beneficial Arthropods		As above		UK - Y			
Environmental Precautions - Earthworms		As above		UK - Y			
Environmental Precautions – Non-Target Terrestrial Plants		As above		UK - Y			
Environmental Precautions – Burrow Treatments		As above		UK - Y			

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Environmental Precautions – Persistence/ Accumulation / Carryover	Statements inform users of the potential for accumulation and carryover and recommend practices to minimize the potential for accumulation and carryover.	Environmental protection Safety Precautions / Other specific restrictions	N	UK - Y			
Environmental Precautions – Leaching	Statements inform users of the potential for leaching and recommend practices to minimize the potential for leaching to groundwater.	Environmental protection Safety Precautions / Other specific restrictions	N	UK - Y			
Environmental Precautions – Runoff	Statements recommend practices to minimize runoff into adjacent waterbodies.	Environmental protection Safety Precautions / Other specific restrictions	N	UK - Y			

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Environmental Precautions - Volatilization	Statements to minimize the release into the environment from volatilization.	Environmental protection Safety Precautions / Other specific restrictions	N	UK - Y			

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Environmental Precautions - Products Containing Aromatic Petroleum Distillates	Statements inform users of potential hazards or risks to aquatic organisms.	<p>PPP - (Not separately stated on label but would be within here if relevant):</p> <p>Environmental protection Safety Precautions / Other specific restrictions.</p> <p>Biocides - In general environmental precautions are labelled in accordance with CLP (Reg. 1272/2008). Product specific precautions may be identified as part of product risk assessment.</p>	N	UK – Y (PPP and Biocides)			

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
General information	Provides general directions on the use of the product. Includes but is not limited to a brief product description/ information and geographic restrictions (if applicable).	Directions for use 'Important Information Box'	N	UK - Y			
Directions For Use (General)	Communicates the PMRA supported use pattern to the end user of the pest control product.	Directions for use 'Important Information Box'	N	UK - Y	PCPR 26(2)(a)		

Use Limitations	<p>To identify situations that may pose potential risks of concern to health or the environment.</p> <p>To communicate limitations in the use pattern for which a risk assessment was not performed or for which risks of concern were identified (i.e. DO NOT apply in greenhouses.)</p> <p>To identify restrictions related to dietary and occupational exposure: preharvest intervals, restricted-entry intervals, pregrazing interval/feeding restrictions, preslaughter interval</p>	<p>PPP - Other specific restrictions</p> <p>Biocides - Any such requirement would likely be listed in 'instructions for use or risk mitigation measures'.</p>	N	UK – Y (PPP and Biocides)	PCPR26(2)(a)		
General Application Instructions	<p>General information on how to apply the product including ground or aerial application, the application type (broadcast, drench, chemigation, etc.), the application target</p>	<p>Directions for use 'Important Information Box'</p>	N	UK - Y	PCPR26(2)(a)		

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	(foliar, soil, seed, etc.) and permitted equipment.						

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Application Method	Required for the risk and value assessments Statements for various application methods provide measures to minimize spray drift to non-target sensitive habitats for certain application equipment. Parameters used in the occupational/residential health risk assessments are dependent upon the application method. For residue chemistry, data requirements and residue trials are required for each type of applications. Residue data are used in the risk assessment.	Directions for use 'Important Information Box' Safety Precautions	Y	UK - Y	PCPR26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Application target	The application target (foliar, soil, seed, etc.)	Biological use phrase Field of use 'Important Information Box' Directions for use	Y	UK - Y	PCPR26(2)(a)		
Application equipment	Provides information on the type of application equipment that is approved for use.	Directions for use Safety Precautions	Y	UK - Y	PCPR26(2)(a)		
Chemigation	Instruction on the use of chemigation	Directions for use	N	UK - Y	DIR93-13		
Runoff Management	Mandatory vegetative filter strips provide measures required to mitigate risks to aquatic organisms from runoff of pesticide into adjacent waterbodies.	UK refers to filter strips as buffer zones Environmental protection Safety Precautions / Other specific restrictions	N	UK - Y			

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Spray Drift Management	Spray buffer zone statements and spray buffer zone table provide measures required to mitigate risks to sensitive terrestrial and aquatic habitats from spray drift downwind from the site of application.	UK refers to as buffer zone Environmental protection Safety Precautions / Other specific restrictions	N	UK - Y			

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General Mixing Instructions	Mixing instructions that apply to all uses on the label including tank mixing sequencing	Mixing and spraying	N	UK - Y			This section would include information on water volumes (if not specified for each crop in the crop specific information section), application methods, spray quality (BCPC) and the method for cleaning application equipment.

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory ⁺ / Policy and Guidelines ⁺⁺ Requirement	Regulatory ⁺ / Policy and Guidelines ⁺⁺ Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Generic Tank Mix Statement	Instructions for tank mixes not specifically described on the label.	Compatibility section (lists positive and convenience tank mixes (i.e. those for which specific claims and recommendations are made in the 'Directions For Use' or those for which no specific recommendations and claims for use are made respectively))	N	UK - Y			

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Tank Mix Partner Information	Used for tracking and identifying specific tank mixes	Compatibility section (lists positive and convenience tank mixtures (i.e. those for which specific claims and recommendations are made in the 'Directions For Use' or those for which no specific recommendations and claims for use are made respectively))	N	UK - Y			

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Tank Mix Partner Mixing-Loading Instructions	Instructions for proper mixing of specific tank mix partners (e.g., order to introduce the partners into the spray tank)	Compatibility section (lists positive and convenience tank mixtures (i.e. those for which specific claims and recommendations are made in the 'Directions For Use' or those for which no specific recommendations and claims for use are made respectively))	N	UK - Y			

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Rotational Crops/ Plantback Interval	Required for the risk and value assessments To inform users of the time interval to respect before planting rotational crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern. Also phytotoxicity, field bioassay statements/instruction	Directions For Use 'Important Information Box' Other specific restrictions (following crops)	Y	UK - Y			

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Restricted-Entry Intervals	To inform users of the interval between application, and when workers can enter areas treated with pest control products. Can be used to mitigate risks to postapplication workers.	'Important Information Box' Other specific restrictions	Y	UK - Y			
Preharvest Intervals	To inform users of the time interval to respect before harvesting the food crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern.	'Important Information Box' Other specific restrictions	Y	UK - Y			

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Pregrazing Intervals/ Feeding Restriction	To inform users of the time interval to respect before harvesting the feed crops or letting livestock graze in the treated field in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.	'Important Information Box' Other specific restrictions	Y	UK - Y			

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Preslaughter Intervals	To inform users of the time interval to respect before slaughtering livestock in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.	PPP - Not routinely stated on label Biocides - As for PPP, this is not routinely stated.	Y	UK – Y (PPP and Biocides)			Will be considered as part of authorised GAP.
Resistance Management Information	Recommendations to reduce the risk of pesticide resistance by arthropods, plant diseases and weeds. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.	Directions For Use (Resistance)	N	UK - Y	DIR 2013-04		

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Storage and Disposal	Storage statement to prevent contamination of food or feed and provide disposal information.	Storage and disposal Safety Precautions	N	UK - Y	PCPR 26(2)(b) and DIR 1999-04		

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Labelling of Treated Seed (Seed Tag)	Statements on seed tags are used to inform users of measures to mitigate environmental risks. Precautionary statements on seed tags are used to inform workers of the required PPE/engineering controls while handling and planting treated seed. May include restrictions such as pregrazing interval/feeding restrictions or plantback intervals/rotational crops.	Safety Precaution phrases – treated seed bag agreement	N	UK - Y			Treated seed bag label considered as part of the authorisation alongside the label (note voluntary treated seed labelling guidelines available)

Labelling of Treated Article (Hang Tag)	Statements on hang tags are used to inform users/consumers of proper handling, care and use of the garment/article Precautionary statements on hang tags are used to inform users/consumers of potential skin sensitizing risks from the use/exposure to manufactured garments/articles May include restrictions or storage and disposal requirements	PPP - not applicable Biocides -Art. 58 of the BPR stipulates the requirements for the labelling of treated articles . Generally speaking a treated article should be labelled to indicate that it incorporates biocidal products, the biocidal property attributed to the treated article, the names of all active substances contained in the biocidal products, name of all nanomaterials contained in the biocidal products (followed by the word 'nano' in brackets) and any relevant instructions for use (including any necessary precautions to be taken because of the biocidal products incorporated/used for treatment).	N	UK - PPPs – n/a UK - Biocides - N	Regulation (EU) 528/2012, Art 58. Further guidance document CA-May15-Doc.6.1 - Final - Labelling of TAs		
Imported Treated Seed	To inform importers of treated seed that a	Please refer to Column 8.	N	UK - N			Imported treated material

Information	human health risk assessment for planters has been conducted and that it is acceptable to import the treated seed into Canada.						is not covered by the labelling requirements in the UK (Regulation 547/2011). There are, however, provisions in Art. 49 of Regulation 1107/2009 which are relevant and have the effect of limiting trade in treated seed to stocks treated in accordance with a use authorised in at least one EU member State. We operate an assumption that the risk assessment has already been conducted and found acceptable. Art. 49 also requires that labels and documents
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							<p>accompanying treated stocks specify the PPP used, the active substance, and safety and risk mitigation measures relevant to the PPP. The EU has over some years been developing guidance on treated seed to clarify these requirements, but it is not yet available.</p>

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Direct Application to Water	Statements provide measures to mitigate risks to non-target aquatic organisms and inform users of legislative requirements when applying pesticides directly to water.	Environmental protection Safety Precautions Other specific restrictions	N	UK - Y			
Requirements for Vertebrate and Insect Baits	Required for the risk and value assessments Statements provide measures to mitigate risks to children, pets, livestock or wildlife such as non-target birds or wild mammals.	Biocides – ‘Instructions for use’ and/or ‘risk mitigation measures’	N	UK - Y			

<p>Products Discharged Into Water Bodies</p>	<p>Statement provide measures to mitigate potential risks to aquatic organisms from discharge of effluent.</p>	<p>PPP - Other specific restrictions Biocides – ‘Instructions for use’ and/or ‘risk mitigation measures’</p>	<p>N</p>	<p>UK – Y (PPP and Biocides)</p>		<p>Any use of a pesticide which is expected to result in discharge to waters (e.g. bulb or tuber washings, use in or near water) includes an ‘other specific restriction’ reminding users of the requirement to seek Environment Agency (EA – water regulatory body) consents before using. The Code of Practice includes a general obligation on growers to report any spillages which could enter water or contaminate a large area of soil.</p>
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Wood Uses	Required for the risk assessments Statements provide measures to minimize releases into the environment.	Biocides – ‘Instructions for use’ and/or ‘risk mitigation measures’	N	UK - Y			
Cranberry	Statements provide measures to mitigate potential risks of effluent water from cranberry fields to aquatic organisms.	n/a	N	UK – n/a			
Greenhouse	Statements provide measures to mitigate risks to aquatic organisms from effluent or runoff.	PPP - Other specific restrictions Biocides – ‘Instructions for use’ and/or ‘risk mitigation measures’	N	UK – Y (PPP and Biocides)			Different assessments conducted for different types of greenhouse (in accordance with EFSA guidance on clustering and ranking of emissions).

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Mushroom House	Statements provide measures to mitigate risks to aquatic organisms from effluent or runoff.	PPP - Other specific restrictions Biocides – ‘Instructions for use’ and/or ‘risk mitigation measures’	N	UK – Y (PPP and Biocides)			In line with certain greenhouse uses – authorisations restrict to ‘permanent protection’ situations which provide full enclosure (including continuous top and side barriers down to below ground level) and which are present and maintained over a number of years.

<p>IMEP (Importation for Manufacturing and Export Program)</p>	<p>Statements provide measures to mitigate risks to aquatic organisms from a product imported solely for the purpose of manufacturing and export.</p>	<p>PPP - n/a Biocides -Please see Column 8</p>	<p>N</p>	<p>UK - N</p>		<p>Importing biocidal products into the EU Custom Territory is classified as 'placing a product on the market' in the EU BPR, when it is intended that the biocidal product will be supplied for distribution or use on the UK/EU market. You must ensure the biocidal product you intend to import into the UK complies with the requirements of the EU BPR and any relevant national legislation as necessary before it is imported. If exporting</p>
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							<p>from the UK to an EU country you must meet the requirements of the EU BPR (and any relevant national legislation in that EU country). If you are exporting directly from the UK to a non-EU country the requirements of the EU BPR do not apply, but there may be other UK legislation you need to comply with such as that on Prior Informed Consent (PIC) or specific customs and export rules. In order to be exempt from the requirements of</p>
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							the EU BPR there must be no supply of the product within the UK/EU prior to being exported.
Use-Site Category (USC)	Required to help guide determination of data required in support of an application to register, amend, or conduct research with a pest control product. Each USC has a list of required and conditionally required data called data-code or DACO tables.	PPP - Trials permit Biocides – does not apply. Testing which may result in release to the environment must be notified before taking place, we may place conditions/prohibit. But any labelling requirements for R&D would be assessed on a case by case basis.	Y	UK – Y (PPP) UK - n/a (Biocides)			PPP - Standard label text is required but not checked – refer to Volume 4 of the Labelling Handbook.

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Site/Host/Crop	Required for the risk and value assessments (i.e., area of use, site of application, surface type or material to be treated)	PPP - Directions for use (crop/ soil type) Biocides - Instructions for use	Y	UK – Y (PPP and Biocides)	PCPR26(2)(a)		
Site/Host/Crop Subtype	This would be for additional information on a site/host such as age and weight of products used on companion animals or type of growing environment (greenhouse, outdoor field, etc.). Required for value and risk assessments.	PPP - If applicable (greenhouse/outdoor) Directions for use Biocides - If required these would be included in 'Instructions for use'.	Y	UK – Y (PPP and Biocides)	PCPR 26(2)(a)		

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Geographic Area	May have an impact on the residue chemistry data requirements (i.e. reduce the number of field trials required), residue data used in the human health risk assessment May have an impact on the input used in the dietary risk assessment for drinking water	Directions for use	Y	UK - Y			
Effects on treated objects or sites	This would include information on the potential for damage to treated sites (e.g., phytotoxicity) Required for value assessment.	Directions for use	N	UK - Y	DIR2016-02		

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Pest	Identifies the pest being targeted, Required for the value assessment Determine the type of human health risk assessment is required based on how the specific pest is treated or where the pest found in relation to human activities.	Biocides - Target organisms	Y	UK - Y	PCPR 26(2)(a)		
Pest Subtype	Required for the value assessment Required for determining the magnitude of postapplication exposure use patterns. This would be for any additional details on the target pest (e.g., lifestage, nest treatment).	Biocides - Under 'Target organisms' you must indicate 'Development stage' (i.e. adult, juvenile, nymph, larvae etc.)	Y	UK - Y	PCPR 26(2)(a)		

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Pest Control Claim	Required for the value assessment (ie., type/level of control such as control, suppression, reduces infection/damage, prevents fouling vs removes established fouling, type of protection- prevents degradation, discoloration)	PPP - Directions for use Biological use phrase Field of use Biocides -Field of use description	N	UK – Y (PPP and Biocides)	PCPR 26(2)(a)		
Duration of Efficacy against Pest(s)	Required for the value assessment of personal insect repellents, other repellents, attractants, products with residual claims, companion animal product, etc.	Biocides - Field of use description, Application rate & Instructions for use	N	UK - Y	PCPR 26(2)(a)		

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Product Rate/ Concentration and residual to be maintained, if applicable	Required for the risk and value assessments Directions for use, including method and application rates or residual concentration to be maintained, target retention (kg/m ³) or target deposition (µg/cm ²), expected coverage (m ² per litre of paint), the contact time, dilution and rinse if applicable. When pesticide rates are given as a range, instructions may be required as to when to use the lower and higher application rates.	PPP - Directions for Use 'Important Information Box' Biocides -Application rate & Instructions for use	Y	UK – Y (PPP and Biocides)	PCPR 26(2)(a)		

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Product Rate/ Concentration / Residual to be Maintained Units	Required for the risk and value assessments	PPP - Directions for Use 'Important Information Box' Maximum individual dose e.g. grain silo/ fruit warehouse (use of ethylene) Biocides - Application rate & Instructions for use	Y	UK – Y (PPP and Biocides)	PCPR 26(2)(a)		
Rate of Active Ingredient(s)	Required for the risk and value assessments	Amount and name of the active substance	Y	Y	PCPR 26(2)(a)		

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Adjuvant	Adjuvant product name or adjuvant type. Required for the acute hazard, dietary risk assessment for the active ingredient with which it is co-formulated and value assessments	Directions for Use Compatibility	Y	UK - Y	PCPR 26(2)(a)		
Rate of Adjuvant	Required for the acute hazard, dietary risk assessment for the active ingredient with which the adjuvant is co-formulated and value assessments Human health risk assessments are not required for the adjuvant itself.	Directions for Use Compatibility	Y	UK - Y	PCPR 26(2)(a)		Considered if it is a positive recommendation on the label
Rate of Adjuvant Units	Required for the risk and value assessments	Directions for Use Compatibility	Y	UK - Y	PCPR 26(2)(a)		

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Maximum Cumulative Rate of Active Ingredient per Year	Required for the risk assessments	Maximum total dose	Y	UK - Y	PCPR 26(2)(a)		
Minimum Number of Applications	Required for occupational exposure risk assessment (required as sometimes there is a range in the number of applications) May be required to refine or mitigate the occupational exposure risk assessment	Directions for Use - Other specific restrictions	Y	UK - Y (Maximum number is more key)			

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Maximum Number of Applications	Required for the risk assessments Can be used as a tool to mitigate postapplication exposure, and determine the total amount of active ingredient applied to a crop in a single year or crop cycle.	Maximum number of treatments	Y	UK - Y	PCPR 26(2)(a)		
Maximum Number of Applications per Year or Crop Cycle	Required for the risk assessments	Maximum number of treatments or maximum total dose	Y	UK - Y	PCPR 26(2)(a)		

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Spray Volume	Required for the risk and value assessments Spray volume is also included in buffer zone calculations for aerial application Converts user application rates on labels to rates required to complete a human health risk assessment.	Directions for Use Could be an 'other specific restriction' in some cases if required by risk assessment in addition to the 'Directions for Use'	Y	UK - Y	PCPR 26(2)(a)		
Spray pressure	Required for the risk assessments	Directions for Use	Y	UK - Y			

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Application Target	Required for the risk assessments Parameters used in the occupational/residential health risk assessments are dependent on the application target.	PPP - Bystander/residents exposure – other specific restriction Biocides - If required would be included in ‘Instructions for use’ and/or ‘risk mitigation measures’	Y	UK – Y (PPP and Biocides)	PCPR 26(2)(a)		
Application Type	Required for the risk and value assessments Parameters used in the occupational/residential health risk assessments are dependent on the application type.	PPP - Directions for Use Biocides -If required would be included in ‘Instructions for use’ and/or ‘risk mitigation measures’	Y	UK – Y (PPP and Biocides)	PCPR 26(2)(a)		

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Application Equipment	Required for the risk assessments and value assessments. Application equipment is also considered in the buffer zone calculations. Parameters used in the occupational/residential health risk assessments are dependent on the application equipment.	PPP - Directions for use Safety precautions Biocides - If required would be included in 'Instructions for use' and/or 'risk mitigation measures'	Y	UK – Y (PPP and Biocides)	PCPR 26(2)(a)		

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Minimum Re-Treatment Interval (RTI)	Required for the risk and value assessments One of the parameters in the occupational/residential risk assessment	PPP - Other specific restriction (Minimum interval between applications) Biocides -If required would be included in 'Instructions for use' and/or 'risk mitigation measures'	Y	UK – Y (PPP and Biocides)	PCPR 26(2)(a)		

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Maximum Re-Treatment Interval (RTI)	Required for the risk assessments Required for occupational exposure risk assessments (required as sometimes there is a range of RTIs) - May be required to refine or mitigate the occupational exposure risk assessment	PPP - Directions for Use - Other specific restrictions? Biocides -If required would be included in 'Instructions for use' and/or 'risk mitigation measures'	Y	UK – Y (PPP and Biocides)			

Application Timing	Used to identify the application timing for effective management of the listed pest(s); EAD: used to determine exposure considerations in environmental risk assessments for aquatic organisms and pollinators. Considered in the human health risk assessment to determine the potential exposure to workers, users and bystanders For residue chemistry, if application timing is early and very specific, may not need a preharvest interval. Required for the value assessments – preventative vs curative claims.	PPP – ‘Latest time of application’ Biocides - ‘Instructions for use’ and ‘Number and timing of application’	Y	UK – Y (PPP and Biocides)	PCPR 26(2)(a)		
Application Instructions (Specific Uses)	Instructions that identify the PMRA supported/approved use of a product in the context of a specific use pattern (e.g. site-pest-rate combination) Any other information	Biocides - ‘Use specific instructions for use’	N	UK - Y	PCPR 26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
	pertinent to the value of the pest control product (pre-cleaning or surface preparation, etc.)						
User Requested Minor Use Label Expansion (URMULE)	Used for tracking and reporting on the expansion of a label for a new minor use of a pesticide for which the active ingredient(s) and the end use product are currently registered in Canada under the URMULE program	Extension of Authorisation (separate section on label)	N	UK - Y	DIR2001-01		
User Requested Minor Use Registration (URMUR)	Used for tracking and reporting on the registration of products/uses under the URMUR program	Extension of Authorisation (separate section on label but full use details are within the extension of authorisation itself.)	N	UK - Y	DIR99-05		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
Restricted Use	Used to identify specific product applications that can only be used under certain circumstances by specially trained individuals.	Other specific restriction e.g. restriction to specific generators, specialist operators	N	UK - Y	PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products		

Aerial Application	Required for the risk and value assessments	Aerial application crop qualifier 'Important Information Box' (strictly regulated and falls within Sustainable Use Directive)	Y	UK - Y	DIR1996-04		Aerial application is very rare in UK and not usually on-labels (we have had very wet autumns which have triggered emergency applications for aerial use). There will be restrictions such as buffer zones and protection of ground nesting birds on the label. Anyone wishing to apply a PPP aerially must apply for a specific permit for the specific location – which may impose other restrictions e.g. timing due to nesting birds.
Emergency Use	Used to identify products that are required for	Separate emergency (Article 53) authorisations	N	UK - Y	DIR2017-03		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development of Crosswalk) (UK - unless specified as PPP or Biocides entries are PPP only)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No) * UK - Please see final page of this document for details of relevant UK legislation/ guidelines	Additional Comments
	emergency control of pest infestations that are seriously detrimental to public health, domestic animals, natural resources or other things, for a period not exceeding one year.	wouldn't be on the label (if emergency authorisation on an imported product then a draft label would be agreed with the applicant)					
Emergency Use Date of Expiry	Used to identify and expire emergency use(s) from a label after a pre-defined date.	Authorisation only granted for 120-day use – this is stated on the notice (not the label)	N	UK - Y	PCPR 18 DIR2017-03		

<p>Imported Treated Seed Use</p>	<p>To identify the use rate at which the imported treated seed would have been treated in order to conduct the occupational exposure risk assessment for planters.</p>	<p>Please refer to Column 8.</p>	<p>N</p>	<p>UK - N</p>			<p>Imported treated material is not covered by the labelling requirements in the UK (Regulation 547/2011). There are, however, provisions in Art. 49 of Regulation 1107/2009 which require that labels and documents accompanying treated stocks specify the PPP used, the active substance, and safety and risk mitigation measures relevant to the PPP.</p>
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*** Legislation/guidelines relevant to UK labelling of plant protection products (PPPs):**

- EU Regulation 1107/2009 - [1107/2009](#)
- Regulation 547/2011 - [547/2011](#)
- Classification of a product is a requirement of Regulation EC 1272/2008 - [1272/2008](#)
- EU guidelines - https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en
- UK Labelling Handbook – [Labelling Handbook](#)
- EU data requirements – active substance (Regulation (EC) 283/2013) and product (Regulation (EC) 284/2013)– [Data Requirements](#)
- Application Overview - [Application Overview](#)
- Codes of Practice - <https://www.hse.gov.uk/pesticides/using-pesticides/codes-of-practice/index.htm>

Legislation/guidelines relevant to UK labelling of biocides:

- BPR (Reg. 528/2012) - [Regulation 528/2012](#)
- Classification of a product is a requirement of Regulation EC 1272/2008 - [1272/2008](#)
- EU guidelines - [EU guidance documents and data requirements](#)

In general under the labelling requirements for biocides assessed under the BPR (Reg. 528/2012) there isn't a specific structure required for product labels. Article 69 of the Regulation covers the labelling of products. Article 69 (1) stipulates that the Authorisation holder shall ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics (SPC) - we provide the approved SPC when authorising a product. Article 69 (2) does list some specific information requirements for labels. In the table above the relevant SPC sections that would include the information are indicated.

8.5. BIAC (Gowan Crop Protection Limited)

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_)	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Product Name	Unique text identifier assigned to each individual product used for tracking and reporting purposes.		N		PCPR 26 (1)(a)		
Product description	Provides a brief description for easy identification of the general uses (sites and pests) of the product.		N				
Product Type	Unique text identifier assigned to each individual product type used for tracking and reporting purposes. Identifies the general type of organism targeted by the product (e.g., fungicide, insecticide, vertebrate repellent). Determines the use pattern assessed in the value and risk assessments. Some data requirements and label information and restrictions are directly linked to the product type and used in risk assessment and risk management		Y		PCPR 26 (1)(b)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Formulation Type	Unique text identifier assigned to each individual formulation type used for tracking and reporting purposes. Residue data may be dependent on the formulation type; used in the dietary risk assessment. The exposure values used in the occupational/residential risk assessments are dependent on the formulation type.		Y		PCPR 26 (1)(b) and PCPR 26 (1)(c)		
Class designation	Unique text identifier assigned to each individual marketing class used for tracking and reporting purposes. The parameters used in the occupational/residential risk assessment are different for commercial-class and domestic-class product. Also, restricted-class may be used as a mitigation measure to prevent occupational/residential human health risk or environmental risk.		Y		PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Signal Words	Needed to identify the acute health hazards to users. May trigger the need for additional personal protection equipment (PPE). Determined by the acute toxicity and physical and chemical properties of the pest control products (TGAI, MUP, EP).		N		PCPR 26 (1)(e) schedules 3 and 4		
Hazard Symbols	“Pictograms” inform users of acute health hazards.		N		PCPR 26 (1)(e) schedules 3 and 4		
Hazard Statements	Statements inform users of acute health hazards.		N		PCPR26(1) (e)		
Read the label before using	Instructs users to read the label (and booklet, if applicable) before using to ensure they are informed as to how to use the product safely and effectively.		N		PCPR 26(1)(f) and 28 (2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Active Ingredient	Required for value, environment, human health hazard and risk characterization. The active ingredient includes common chemical name of the active ingredient or, if none, its chemical name or another name, and the concentration of the active ingredient in the appropriate form. Information on viscosity, specific gravity, particle size or any other property may also be required.		N		PCPR 26 (1)(h)		
Allergens	Label identification of formulants that are common allergens known to be associated with anaphylactic reactions.		N		DIR2006-02		
Preservatives	Label identification of active ingredients that are present in the end-use formulation as formulation preservatives.		N		DIR2006-02		
Registration Number	Statement containing unique numerical identifier assigned to each individual product used for tracking and reporting purposes. If one is not yet assigned, a placeholder will be needed.		N		PCPR 26 (1)(i)		No always is a numerical code

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Private Label Number	Unique numerical identifier assigned to each individual product used for tracking and reporting purposes.		N		PCPR 26 (1)(i)		
Net Contents	May have an impact on occupational risk assessment and mitigation measures.		Y		PCPR 26 (1)(j) Weights and Measures Act (metric)		
Contact information	Required to allow users to contact the registrant with inquiries about the product. At minimum, registrant name and postal address and telephone number to which public inquiries may be directed.		N		PCPR 26(1)(k)(1) and 27 (1)(2)		
Resistance Management Group for the Active Ingredient	Unique alphanumeric identifier assigned to fungicide, herbicide and insecticide active ingredient; used in value determination. Appears on commercial or restricted class product labels as part of the identification for resistance management purposes. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.		N		DIR 2013-04		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Expiry date	For products that have a limited shelf life, ex: live organisms		N				
Notice to user	To stress the importance of reading the label.		N		PCPR 26(2)(g)		
First Aid Instructions	In the case of human health issues, the instructions identify the steps to take to help the person experiencing the symptoms. The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.		N		PCPR 26(2)(e)		
Companion Animal and Livestock First Aid	In the case of animal health issues, the instructions identify the steps to take to help the pet experiencing the symptoms.		N		PCPR 26(2)(e); DIR2002-01		
Toxicological Information	Information for doctor/physician The information may be generic or specific to the active ingredient and/or formulation of the TGAI, MUP, and EP.		N		PCPR 26(2)(f)		
Human Health Precautions	The label statements in this section inform users of potential human health hazards or risk and/or measures to mitigate the hazards and/or risks.		N		PCPR 26(2)(c) and 26(2)(d)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Personal Protective Equipment (PPE)/ Engineering Controls	Mandatory protective equipment such as clothing, respirators, goggles and gloves required as a result of the acute hazard and/or human health risk assessment to reduce exposure to workers in contact with pest control products. Engineering controls (e.g. closed-cab tractor) may be required to prevent/mitigate exposures and/or risk while performing their work with pesticides.		N		PCPR 26(2)(c)		
Companion Animal and Livestock Precautions	The label statements in this section inform users of potential animal health hazards or risk and/or measures to mitigate the risks.		N		PCPR 26(2)(c) and 26(2)(d)		
Environmental Precautions	The label statements in this section inform users of potential hazards or risks to the environment and/or of measures to mitigate the risks to the environment. Each subsection is separate to allow for tracking and reporting purposes in the future.		N		PCPR 26(2)(c)		

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Environmental Precautions – Aquatic organisms	Statements inform users of potential hazards or risks and/or of measures to mitigate risks.		N				
Environmental Precautions - Birds							
Environmental Precautions – Wild Mammals							
Environmental Precautions - Bees							
Environmental Precautions – Beneficial Arthropods							
Environmental Precautions - Earthworms							
Environmental Precautions – Non-Target Terrestrial Plants							

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Environmental Precautions – Burrow Treatments							
Environmental Precautions – Persistence/ Accumulation/ Carryover	Statements inform users of the potential for accumulation and carryover and recommend practices to minimize the potential for accumulation and carryover.		N				
Environmental Precautions – Leaching	Statements inform users of the potential for leaching and recommend practices to minimize the potential for leaching to groundwater.		N				
Environmental Precautions – Runoff	Statements recommend practices to minimize runoff into adjacent waterbodies.		N				
Environmental Precautions - Volatilization	Statements to minimize the release into the environment from volatilization.		N				

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Environmental Precautions - Products Containing Aromatic Petroleum Distillates	Statements inform users of potential hazards or risks to aquatic organisms.		N				
General information	Provides general directions on the use of the product. Includes but is not limited to a brief product description/ information and geographic restrictions (if applicable).		N				
Directions For Use (General)	Communicates the PMRA supported use pattern to the end user of the pest control product.		N		PCPR 26(2)(a)		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Use Limitations	<p>To identify situations that may pose potential risks of concern to health or the environment.</p> <p>To communicate limitations in the use pattern for which a risk assessment was not performed or for which risks of concern were identified (i.e. DO NOT apply in greenhouses.)</p> <p>To identify restrictions related to dietary and occupational exposure: preharvest intervals, restricted-entry intervals, pregrazing interval/feeding restrictions, preslaughter interval</p>		N		PCPR26(2)(a)		
General Application Instructions	<p>General information on how to apply the product including ground or aerial application, the application type (broadcast, drench, chemigation, etc.), the application target (foliar, soil, seed, etc.) and permitted equipment.</p>		N		PCPR26(2)(a)		

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Application Method	Required for the risk and value assessments Statements for various application methods provide measures to minimize spray drift to non-target sensitive habitats for certain application equipment. Parameters used in the occupational/residential health risk assessments are dependent upon the application method. For residue chemistry, data requirements and residue trials are required for each type of applications. Residue data are used in the risk assessment.		Y		PCPR26(2)(a)		
Application target	The application target (foliar, soil, seed, etc.)		Y		PCPR26(2)(a)		
Application equipment	Provides information on the type of application equipment that is approved for use.		Y		PCPR26(2)(a)		
Chemigation	Instruction on the use of chemigation		N		DIR93-13		

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Runoff Management	Mandatory vegetative filter strips provide measures required to mitigate risks to aquatic organisms from runoff of pesticide into adjacent waterbodies.		N				
Spray Drift Management	Spray buffer zone statements and spray buffer zone table provide measures required to mitigate risks to sensitive terrestrial and aquatic habitats from spray drift downwind from the site of application.		N				
General Mixing Instructions	Mixing instructions that apply to all uses on the label including tank mixing sequencing		N				
Generic Tank Mix Statement	Instructions for tank mixes not specifically described on the label.		N				
Tank Mix Partner Information	Used for tracking and identifying specific tank mixes		N				
Tank Mix Partner Mixing-Loading Instructions	Instructions for proper mixing of specific tank mix partners (e.g., order to introduce the partners into the spray tank)		N				

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Rotational Crops/ Plantback Interval	Required for the risk and value assessments To inform users of the time interval to respect before planting rotational crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern. Also phytotoxicity, field bioassay statements/instruction		Y				
Restricted-Entry Intervals	To inform users of the interval between application, and when workers can enter areas treated with pest control products. Can be used to mitigate risks to postapplication workers.		Y				
Preharvest Intervals	To inform users of the time interval to respect before harvesting the food crops in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) and/or potentially pose a health risk of concern.		Y				

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Pregrazing Intervals/ Feeding Restriction	To inform users of the time interval to respect before harvesting the feed crops or letting livestock graze in the treated field in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.		Y				
Preslaughter Intervals	To inform users of the time interval to respect before slaughtering livestock in order to ensure that the residues will not exceed the Maximum Residue Limit (MRL) in meat, milk and eggs and/or potentially pose a health risk of concern.		Y				
Resistance Management Information	Recommendations to reduce the risk of pesticide resistance by arthropods, plant diseases and weeds. Required for herbicide, fungicide/bactericide and insecticide/acaricide products used in agriculture.		N		DIR 2013-04		

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Storage and Disposal	Storage statement to prevent contamination of food or feed and provide disposal information.		N		PCPR 26(2)(b) and DIR 1999-04		
Labelling of Treated Seed (Seed Tag)	Statements on seed tags are used to inform users of measures to mitigate environmental risks. Precautionary statements on seed tags are used to inform workers of the required PPE/engineering controls while handling and planting treated seed. May include restrictions such as pregrazing interval/feeding restrictions or plantback intervals/rotational crops.		N				
Labelling of Treated Article (Hang Tag)	Statements on hang tags are used to inform users/consumers of proper handling, care and use of the garment/article. Precautionary statements on hang tags are used to inform users/consumers of potential skin sensitizing risks from the use/exposure to manufactured garments/articles. May include restrictions or storage and disposal requirements.		N				

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Imported Treated Seed Information	To inform importers of treated seed that a human health risk assessment for planters has been conducted and that it is acceptable to import the treated seed into Canada.		N				
Direct Application to Water	Statements provide measures to mitigate risks to non-target aquatic organisms and inform users of legislative requirements when applying pesticides directly to water.		N				
Requirements for Vertebrate and Insect Baits	Required for the risk and value assessments Statements provide measures to mitigate risks to children, pets, livestock or wildlife such as non-target birds or wild mammals.		N				
Products Discharged Into Water Bodies	Statement provide measures to mitigate potential risks to aquatic organisms from discharge of effluent.		N				
Wood Uses	Required for the risk assessments Statements provide measures to minimize releases into the environment.		N				

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Cranberry	Statements provide measures to mitigate potential risks of effluent water from cranberry fields to aquatic organisms.		N				
Greenhouse	Statements provide measures to mitigate risks to aquatic organisms from effluent or runoff.		N				
Mushroom House	Statements provide measures to mitigate risks to aquatic organisms from effluent or runoff.		N				
IMEP (Importation for Manufacturing and Export Program)	Statements provide measures to mitigate risks to aquatic organisms from a product imported solely for the purpose of manufacturing and export.		N				
Use-Site Category (USC)	Required to help guide determination of data required in support of an application to register, amend, or conduct research with a pest control product. Each USC has a list of required and conditionally required data called data-code or DACO tables.		Y				

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Site/Host/Crop	Required for the risk and value assessments (i.e., area of use, site of application, surface type or material to be treated)		Y		PCPR26(2)(a)		
Site/Host/Crop Subtype	This would be for additional information on a site/host such as age and weight of products used on companion animals or type of growing environment (greenhouse, outdoor field, etc.). Required for value and risk assessments.		Y		PCPR 26(2)(a)		
Geographic Area	May have an impact on the residue chemistry data requirements (i.e. reduce the number of field trials required), residue data used in the human health risk assessment May have an impact on the input used in the dietary risk assessment for drinking water		Y				
Effects on treated objects or sites	This would include information on the potential for damage to treated sites (e.g., phytotoxicity) Required for value assessment.		N		DIR2016-02		

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Pest	Identifies the pest being targeted, Required for the value assessment Determine the type of human health risk assessment is required based on how the specific pest is treated or where the pest found in relation to human activities.		Y		PCPR 26(2)(a)		
Pest Subtype	Required for the value assessment Required for determining the magnitude of postapplication exposure use patterns. This would be for any additional details on the target pest (e.g., lifestage, nest treatment).		Y		PCPR 26(2)(a)		
Pest Control Claim	Required for the value assessment (ie., type/level of control such as control, suppression, reduces infection/damage, prevents fouling vs removes established fouling, type of protection-prevents degradation, discoloration)		N		PCPR 26(2)(a)		
Duration of Efficacy against Pest(s)	Required for the value assessment of personal insect repellents, other repellents, attractants, products with residual claims, companion animal product, etc.		N		PCPR 26(2)(a)		

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Product Rate/ Concentration and residual to be maintained, if applicable	Required for the risk and value assessments Directions for use, including method and application rates or residual concentration to be maintained, target retention (kg/m ³) or target deposition (µg/cm ²), expected coverage (m ² per litre of paint), the contact time, dilution and rinse if applicable. When pesticide rates are given as a range, instructions may be required as to when to use the lower and higher application rates.		Y		PCPR 26(2)(a)		
Product Rate/ Concentration/ Residual to be Maintained Units	Required for the risk and value assessments		Y		PCPR 26(2)(a)		
Rate of Active Ingredient(s)	Required for the risk and value assessments		Y		PCPR 26(2)(a)		
Adjuvant	Adjuvant product name or adjuvant type. Required for the acute hazard, dietary risk assessment for the active ingredient with which it is co-formulated and value assessments		Y		PCPR 26(2)(a)		

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Rate of Adjuvant	Required for the acute hazard, dietary risk assessment for the active ingredient with which the adjuvant is co-formulated and value assessments Human health risk assessments are not required for the adjuvant itself.		Y		PCPR 26(2)(a)		
Rate of Adjuvant Units	Required for the risk and value assessments		Y		PCPR 26(2)(a)		
Maximum Cumulative Rate of Active Ingredient per Year	Required for the risk assessments		Y		PCPR 26(2)(a)		
Minimum Number of Applications	Required for occupational exposure risk assessment (required as sometimes there is a range in the number of applications) May be required to refine or mitigate the occupational exposure risk assessment		Y				

Proposed Data Element Name	Justification for Data Elements	Region Specific Data Element Naming Convention (for Development. of Crosswalk)	Required for Risk Assessment Canada	Required for Risk Assessment (insert country) (Yes or No_	Regulatory [†] / Policy and Guidelines ^{††} Requirement	Regulatory [†] / Policy and Guidelines ^{††} Requirement (Yes or No)	Additional Comments
Maximum Number of Applications	Required for the risk assessments Can be used as a tool to mitigate postapplication exposure, and determine the total amount of active ingredient applied to a crop in a single year or crop cycle.		Y		PCPR 26(2)(a)		
Maximum Number of Applications per Year or Crop Cycle	Required for the risk assessments		Y		PCPR 26(2)(a)		
Spray Volume	Required for the risk and value assessments Spray volume is also included in buffer zone calculations for aerial application Converts user application rates on labels to rates required to complete a human health risk assessment.		Y		PCPR 26(2)(a)		
Spray pressure	Required for the risk assessments		Y				
Application Target	Required for the risk assessments Parameters used in the occupational/residential health risk assessments are dependent on the application target.		Y		PCPR 26(2)(a)		

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Application Type	Required for the risk and value assessments Parameters used in the occupational/residential health risk assessments are dependent on the application type.		Y		PCPR 26(2)(a)		
Application Equipment	Required for the risk assessments and value assessments Application equipment is also considered in the buffer zone calculations. Parameters used in the occupational/residential health risk assessments are dependent on the application equipment.		Y		PCPR 26(2)(a)		
Minimum Re-Treatment Interval (RTI)	Required for the risk and value assessments One of the parameters in the occupational/residential risk assessment		Y		PCPR 26(2)(a)		
Maximum Re-Treatment Interval (RTI)	Required for the risk assessments Required for occupational exposure risk assessments (required as sometimes there is a range of RTIs) - May be required to refine or mitigate the occupational exposure risk assessment		Y				

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Application Timing	Used to identify the application timing for effective management of the listed pest(s); EAD: used to determine exposure considerations in environmental risk assessments for aquatic organisms and pollinators. Considered in the human health risk assessment to determine the potential exposure to workers, users and bystanders. For residue chemistry, if application timing is early and very specific, may not need a preharvest interval. Required for the value assessments – preventative vs curative claims.		Y		PCPR 26(2)(a)		
Application Instructions (Specific Uses)	Instructions that identify the PMRA supported/approved use of a product in the context of a specific use pattern (e.g. site-pest-rate combination) Any other information pertinent to the value of the pest control product (pre-cleaning or surface preparation, etc.)		N		PCPR 26(2)(a)		

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User Requested Minor Use Label Expansion (URMULE)	Used for tracking and reporting on the expansion of a label for a new minor use of a pesticide for which the active ingredient(s) and the end use product are currently registered in Canada under the URMULE program		N		DIR2001-01		
User Requested Minor Use Registration (URMUR)	Used for tracking and reporting on the registration of products/uses under the URMUR program		N		DIR99-05		
Restricted Use	Used to identify specific product applications that can only be used under certain circumstances by specially trained individuals.		N		PCPR 26 (1)(d) 29(1) & 29(2) – RESTRICTED class products		
Aerial Application	Required for the risk and value assessments		Y		DIR1996-04		
Emergency Use	Used to identify products that are required for emergency control of pest infestations that are seriously detrimental to public health, domestic animals, natural resources or other things, for a period not exceeding one year.		N		DIR2017-03		

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Emergency Use Date of Expiry	Used to identify and expire emergency use(s) from a label after a pre-defined date.		N		PCPR 18 DIR2017-03		
Imported Treated Seed Use	To identify the use rate at which the imported treated seed would have been treated in order to conduct the occupational exposure risk assessment for planters.		N				
<u>UFI (Unique formula identifier)</u>	<u>Will be required on a certain product labels from 2021.</u>	<u>EU</u>	<u>N</u>		<u>Annex VIII to the CLP</u>		<u>16 alpha-numerical characters.</u>