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OECD SURVEY ON HOW PESTICIDE INGREDIENTS OTHER THAN THE STATED PESTICIDE ACTIVE INGREDIENT(S) ARE REVIEWED AND REGULATED: SURVEY RESULTS

Series on Pesticides
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INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among FAO, ILO, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

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FOREWORD

This document is the report of an OECD survey on "How Pesticide Ingredients other than the Stated Pesticide Active Ingredient(s) are Reviewed and Regulated".

Issues surrounding the regulation of pesticide ingredients other than the stated pesticide active ingredient(s) were discussed at several OECD pesticide meetings. As a matter of fact, regulation of such ingredients has come under increasing scrutiny in many countries in recent years. Because review and regulation of pesticide ingredients other than the stated pesticide active ingredient(s) have not been a primary focus of OECD, it was concluded that it would be useful to conduct a survey to obtain baseline information on how these ingredients are currently reviewed and regulated, as well as any plans for changes in the future. This would provide a basis for identifying common issues, possible work sharing opportunities, and possible areas for regulatory harmonisation.

The survey questionnaire (in Annex 3) was sent to OECD Governments and EC Delegations on 23 February 2010 with a deadline for responses by 22 March 2010.

It has to be noted that various terms for "pesticide ingredients other than the stated pesticide active ingredient(s)" were investigated. Some of these terms and their definitions (from the internet) are listed in the "glossary" that is provided with the survey questionnaire (Annex 3). Many different terms are used for these ingredients and, in many cases, there is no clear distinction between the various terms since one term often appears in the definition for another term (for example, excipient, inactive, inert, formulant). The survey therefore invited countries to list the term(s) by which they referred to "pesticide ingredients other than the stated pesticide active ingredient(s)" – see in particular question 1.

The survey results and recommendations were considered in a closed session at the 17-18 May 2010 meeting of the Working Group on Pesticides which approved the draft survey report and recommended that it be forwarded to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology for consideration as an OECD publication.

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which has agreed that it be unclassified and made available to the public.

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SURVEY RESULTS AND ANALYSIS

1. Fourteen responses were received to the OECD survey from Australia, Belgium, Canada, Germany, Ireland, Japan, Korea, New Zealand, Norway, Poland, Slovak Republic, Sweden, United Kingdom (UK), and the United States (US). Responses to questions that were easily tabulated are summarized in tables in Annex 1. Questions with more lengthy responses are summarized in Annex 2 including any additional details provided in response to the questions in the tables in Annex 1.

Situation in respondent countries

2. There was wide variation in the detail in which pesticide ingredients other than the stated pesticide active ingredients(s) (ai) are defined (Question 1) and how they are regulated (Question 2). Most responders (11 of 14) do not, generally, conduct assessments on individual pesticide ingredients other than the ai (Question 3a). Most do not conduct assessments on mixtures of these ingredients (Question 3b), although two countries do for adjuvant products and one does, usually as an aggregate of each individual component. All responders conduct assessments on the formulated end-use products (Question 3c).

3. Regarding mixtures (Questions 4 a, b, c), half of the responders (6 of 11), generally, do not assess the components separately and generally, do not assess the mixture as a whole. All responders stated that there are no instances in which they do not know (or find out) the components of the mixtures.

4. Four responders categorize these ingredients into food-use and non-food use categories (Question 5). Most responders (7 of 9), generally, base their assessments on a combination of hazard and exposure while the rest (2 of 9) base their assessment on hazard (Question 6). All of those who do assessments consider both human and ecological risks in their assessments (Question 7). Only one responder includes non-pesticidal uses in their assessment (Question 8).

5. Of those who do evaluations it was evenly split between those who do not, generally, make them publicly available and those who, generally, do (Question 9). Most responders have publicly available lists of approved pesticide ingredients other than the stated pesticide ai and provided the internet sites for these (Question 10).

6. Most (7 of 11) do not currently have or plan to conduct a re-assessment programme (Question 11). Generally, there are no set data requirements for these ingredients with the exception of, in some cases, safeners and synergists having the same requirements as pesticide ais (Question 12). Several responders noted they have a tiered approach to the assessment of these ingredients in which initial information from, for example, safety data sheets or other sources is analyzed and if there may be a concern then data may be required. There was a wide variation in the other data/information that is used to conduct the assessments (Question 13). This included: safety data sheets; all of the sources listed in the question-- publicly available data, regulatory documents from other authorities, WHO, JEFCA type documents, Structure Activity Relationships (SAR); and the Nordic Project regarding co-formulants in plant protection products.

7. With two exceptions, responders seemed to indicate that there are no specific data protection/compensation programmes specifically for these ingredients (Question 14), which is not unexpected since there are few instances where there are specific data requirements. Many responders did indicate that data on the formulations is confidential; and for those who conduct assessments on safeners and adjuvants where the data required are the same as for an ai, these data are protected in the same way as data for an ai; data provided on the formulated products is also protected. It was mentioned that the new EU regulations make provision for data protection.

8. Regarding disclosure of ingredients on the label (Question 15), all respondents said that, in general, components of the formulation are not disclosed on the labels, however, there are provisions for disclosing components variously described as "dangerous" or "hazardous" and/or which are contained on specific lists, e.g., in EU Directive 99/45, EPA List 1. Some require labeling for allergens (see Question 17). One mentioned requirements for identification of the formulation preservative as well as its concentration.

9. Regarding how these substances are regulated when there is a concern (Question 16), most indicated that decisions are taken case-by-case and actions mentioned included: limitations on concentrations in the products; risk mitigation for the formulated product itself; limitation of the ingredient to particular uses; requirement for reformulation using a safer ingredient; or cancellation of the product containing the ingredient(s).

10. Regarding any other requirements including regulations relating to allergens (Question 17), most respondents indicated that there were no other requirements and no regulation relating to allergens:

- one respondent noted that allergens applied to edible crops must be appropriately labelled;
- one indicated that allergens must be listed on the label, but are otherwise not regulated;
- one noted that for preparations that contain at least one substance classified as sensitising and being present in a concentration of $\geq$0.1% or in a concentration greater than or equal to that specified within the Classification Labelling and Packaging Regulation must carry the wording *"Contains (name of sensitising substance). May produce an allergic reaction"* and that this requirement applies to the product irrespective of whether applied to edible of non-edible crops;
- one noted that plant protection products containing allergens may not be authorized as consumer products; and
- one noted there are use limitations for food commodity forms of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacean and wheat in pesticide formulations applied to crops.

11. Most responders (10 of 14) indicated that they have plans to change how they currently handle these ingredients (Question 18). Most commonly cited was the new EU regulation No. 1107/2009 which will enter into force in 2011 and will: introduce a list of co-formulants which are not accepted for inclusion in a plant protection product, lay down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, establish rules for adjuvants and co-formulants, and treat synergist and safeners like active ingredients; in addition two others mentioned developing more comprehensive data/information requirements (still based on a tiered approach) for certain aspects; one mentioned possible new requirements for broader disclosure of these ingredients on the label; and one mentioned the intention to develop an "Approved Pesticide Ingredients" list.

Possible areas for cooperation

12. In regard to the question concerning whether there are any recommendations for co-operative efforts that might be undertaken for review/regulation of these ingredients (Question 19) some (6 of 14) had no suggestions and one suggested that there would be difficulties with cooperating on these ingredients. However, among those facing challenges with new regulations and those with substantial review requirements associated with their current programmes, it was suggested by some that it makes sense to review these ingredients in a globally harmonized way and, therefore it would be useful to explore opportunities for joint reviews and work sharing especially for new formulants and safeners. It was noted that the new EU regulation establishes cooperation between EU member states regarding the evaluation of ais and this extends also to some of these ingredients. One respondent suggested that it would be useful to develop an internationally accepted/OECD-wide listing of excipients. It was also noted that the exchange of information from this survey would be a useful first step in identifying areas for co-operation.

Confidentiality of survey information

13. In response to the last question (Question 20) regarding whether the information provided in response to the survey is considered to be confidential, all responders said no.

ANNEX 1

Summary of Responses to Questions 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 15, 18, 20

Australia	Belgium	Canada	Germany	Ireland	Japan	Korea	New Zealand[1]	Norway	Poland	Slovak Republic	Sweden	UK	US
3a. Do you conduct assessments on individual pesticide ingredients other than the ai?													
No	No (case-by-case basis)	Yes	No (case-by-case basis)	No	No	No	No	Yes (see note)	No	No	No	No (see note)	Yes
3b. Do you conduct assessments on mixtures of pesticide ingredients other than the ai?													
No	No (case-by-case basis)	Yes (adjuvant products)	Yes for adjuvants	No	No	No	No	No (for adjuvants yes)	No	No	No	No (see note)	Yes (typically aggregate of each component)
3c. Do you conduct assessments on formulated (end-use products)?													
Yes	Yes	Yes	Yes	Yes	Yes	Yes	1 & 2 Yes	Yes	Yes	Yes	Yes	Yes	Yes
4a. For mixtures of pesticide ingredients other than the ai—are the components assessed separately?													
N/A	No	Yes	Yes for adjuvants	No	No	Yes	No	Yes	No	N/A	N/A	No (see note)	Yes

[1] **NZ has two regulatory authorities overseeing pesticides. Therefore, the responses have been split between (1) ERMA NZ (2) NZFSA which are referred to in the table as 1) and 2).**

Australia	Belgium	Canada	Germany	Ireland	Japan	Korea	New Zealand	Norway	Poland	Slovak Republic	Sweden	UK	US
4b. For mixtures of pesticide ingredients other than the ai—is the mixture assessed as a whole?													
N/A	Rarely (for suspected properties)	No (Only as part of the end-use product)	Yes for adjuvants	No	Yes	No	1) Yes 2) N/A	Yes (safety data sheets always req.)	No	N/A	N/A	No (see note)	Yes (typically aggregate of each component)
4c. For mixtures of pesticide ingredients other than the ai—are there instances in which you do not know the components of the mixtures?													
N/A	No	No	No	No	No	No	1) No 2) N/A	No	No	N/A	N/A	No	No
5. Do you categorize pesticide ingredients other than the ai into food-use and non-food use categories?													
Generally Yes (a case by case approach is taken; if it is a known food additive this is taken into account)	No	No	No	N/A	N/A	No	1 & 2 No	Yes	N/A	Yes	No	No	Yes
6. Is the assessment based on hazard or exposure or a combination?													
Comb	Comb	Comb-(Human Health)	Comb-(hazard for certain substances, e.g. CMR substances)	N/A	N/A	N/A	1) Comb 2) N/A	Hazard	N/A	Comb	Hazard	N/A	Comb
7. Do you consider human and ecological risk in your assessment?													
Yes	Yes	Yes	Yes	N/A	N/A	N/A	1) Yes 2) N/A	Yes	N/A	Yes	Yes	N/A	Yes (eco case-by-case as part of overall end-use assess.)

Australia	Belgium	Canada	Germany	Ireland	Japan	Korea	New Zealand	Norway	Poland	Slovak Republic	Sweden	UK	US
8. Do you include non-pesticidal uses in your assessment?													
Generally No (Only if such uses linked to label claims and legislation)	No	No	No	N/A	N/A	N/A	1) No 2) No	No	N/A	No	No	N/A	Yes (for food-use inerts, residential uses considered in human health assess.)
9. Do you make your evaluations publicly available?													
Yes. Reports are not published, but are available upon written request.	No	No (Yes for new stand-alone safeners and adjuvants)	No (results available & for serious concerns more info can be published)	N/A	N/A	N/A	1) Yes 2) No	Yes (part of risk assessment documents)	N/A	N/A	Conclusions (entire evaluation on demand)	N/A	Yes (for food-use inerts; non-food use soon)
10. Do you have publicly available lists of approved pesticide ingredients other than the stated pesticide ai?													
No (interest in doing so in the future)	No	Yes	Yes	Yes	N/A	N/A	1) Yes 2) No	No (see note)	N/A	No (see note – this is in new EU legislation)	No	Yes	Yes
11. Do you currently have or do you plan to conduct a re-assessment programme for pesticide ingredients other than the stated pesticide ai?													
No	No	Yes	No (see note)	Yes	N/A	No	1) & 2) No	No	N/A	N/A	No	Yes (see Q18)	Yes (for food use—see note)

Australia	Belgium	Canada	Germany	Ireland	Japan	Korea	New Zealand	Norway	Poland	Slovak Republic	Sweden	UK	US
12a. Are there any toxicity data requirements for approval or registration of pesticide ingredients other than the stated pesticide ai?													
No	Generally No (synergists & safeners—same as ais)	Yes (see note; also safeners—same as ais; for others tiered req.)	No (see note)	Not Currently	No	No	1) Yes (only for end use product) 2) N/A	Yes (Safety data sheet, additional if a potential concern)	No (see note -- required to provide Material Data Sheets for every component of formulation)	No (required to provide Material Data Sheets for every component of formulation)	Yes (Safety data sheet—see note)	Generally No (safeners—same as ais)	No (tiered requirements—see note)
12b. Are there any residue data requirements for approval or registration of pesticide ingredients other than the stated pesticide ai?													
No (see note)	Generally No (synergists & safeners—same as ais; wetters considered to stimulate uptake of pesticides)	No (for safeners only—same as ais)	No (see note)	Not Currently	No	No	1) None (under HSNO) 2) Yes (see note)	No	No	No	Yes (Safety data sheet—see note)	Generally No (safeners—same as ais—see note)	No (for safeners only—same as ais)
14. What data protection/compensation legislation/policies do you have with respect to data for pesticide ingredients other than the stated pesticide ai?													
Yes (see note)	Same as for ais	Yes (for safeners & adjuvants)	Data are confidential	None currently (new regulation provides)	None	None	1) None 2) No (data protection assigned to products containing innovative ais)	Data are confidential	None	N/A	No (no studies so no issue; data protection same as for safety data sheets)	No (data prot. provisions apply to formulated prod.)	Yes (for food-use inerts—see note)

Australia	Belgium	Canada	Germany	Ireland	Japan	Korea	New Zealand	Norway	Poland	Slovak Republic	Sweden	UK	US
15. Do you require disclosure of pesticide ingredients other than the stated pesticide ai on the label?													
No	No (only if required by Dir 99/45—dangerous substances)	No (except List 1 & allergens & formulation preservatives)	No (only if required by Dir 99/45—dangerous substances; also changes—see note)	No (only if required by Dir 99/45—dangerous preparations)	No	No	1) No (may require disclosure when above certain threshold - see note) 2) No	No (only if required by Dir 99/45—dangerous substance)	Generally No (see note—exceptions for various categories)	No (see note – for hazardous ingredient)	No (only ingredients that contribute to classification of product)	No (only for "dangerous" ones—see note)	No (only if it has been determined that it poses a hazard)
18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?													
Yes	Yes	Yes	Yes	Yes	No	No	1) & 2) No	No	Yes (EU regulation)	Yes (EU regulation)	Yes	Yes	Yes
20. Do you consider the responses you have provided to this survey to be confidential information that needs to remain internal to OECD?													
No	No	No	No	No	No	No	1) & 2) No	No	No		No	No	No

ANNEX 2

Detailed responses, by country, are provided below to questions 1, 2, 13, 16, 17, 19 and any other questions listed above where significant additional details were provided.

Australia

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

The Australian Pesticides and Veterinary Medicines Authority (APVMA) seeks advice from the Office of Chemical Safety and Environmental Health (OCSEH) on public health aspects and Department of Environment, Water, Heritage and the Arts (DEWHA) on Environmental safety aspects of a pesticide. An ingredient of a pesticide formulation other than the stated pesticide active ingredient (s) is referred to as a 'Non-active constituent (excipient)'. The definition is:

Any ingredient, other than an active constituent, that is part of a formulated product. Non-active constituents are added at the time of manufacture for various reasons, e.g. to improve formulation characteristics such as stability, solubility and spreadability.

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

Excipients are regulated in Australia by the following approaches:

- Requires details of the chemical and physical properties of all the ingredients including excipients for a complete toxicological evaluation of the product.

- All the ingredients must be clearly identified by name and Chemical Abstracts Service (CAS) registry number; the use of trade names alone is not acceptable. All available information relevant to the hazard assessment of non-active constituents used in the product must be provided. This information must include, but not be limited to, a material safety data sheet (MSDS).

- In certain cases the OCSEH estimates the toxicity of a formulation by extrapolation from toxicity data on the active constituent and non-active ingredients. However, data based on the product to be registered is always preferable.

The above approaches are applicable to all non-active ingredients, including synergists.

12b. Are there any residue data requirements for approval or registration of pesticide ingredients other than the stated pesticide ai?

There is no formal requirement for approval or registration of excipients. The criteria for requiring an MRL or granting an exemption are set differently by different governments based on legislation and definitions of what constitutes a pesticide. In Australia, each situation is considered on a case-by-case basis taking into account the use pattern and likely exposure of the excipient. Although policy guidance could be developed, it would have to take into account various operating legislations and impositions of those legislative frameworks upon any generalised guidance.

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

Australia uses data/information listed in the question and the OCSEH also frequently uses information from the Registry of Toxic Effects of Chemical Substances for excipients. Australia expects to use information from other sources where appropriate.

14. What data protection/compensation legislation/policies do you have with respect to data for pesticide ingredients other than the stated pesticide ai?

Data underpinning the formulation is protected in certain circumstances and therefore any data on ingredients other than the active ingredient that is supplied in support of the product formulation is protected. For information on the circumstances where data protection applies, please refer to the APVMA policies for data protection at http://www.apvma.gov.au/registration/data_protection/index.php

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

If we have concerns about the hazard, exposure, or risk of an excipient, we may not support approval of the product or we may set appropriate Safety Directions to mitigate the risks. However we do not put limitations on the amount of an ingredient that can be used in formulations although the applicant may decide to change the formulation to remove a concern for a particular ingredient.

For example, liquid hydrocarbons are frequently used as excipients in many pesticidal products and in many cases they are the driving forces for the product toxicity. In this case, Safety Directions are primarily set to mitigate the toxicity of hydrocarbon. The following is an entry from the current First Aid Instructions and Safety Directions handbook published by the OCSEH.

Pyrethrins Hydrocarbons	AE 2 g/kg or less in liquid	160 162 164 210 211

This is translated into “May irritate the eyes and skin, avoid contact with eyes and skin”

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

Yes, we do have other regulatory requirements for pesticide excipients. Some excipients are scheduled by the National Drugs and Poisons Schedule Committee. For example, HYDROCARBONS, LIQUID,

including kerosene, diesel (distillate), mineral turpentine, white petroleum spirit, toluene, xylene and light mineral and paraffin oils (but excluding their derivatives), are in Schedule 5 of the "Standard for the Uniform Scheduling of Drugs and Poisons" **except**:

a) toluene and xylene when included in Schedule 6;

b) benzene and liquid aromatic hydrocarbons when included in Schedule 7;

c) food grade and pharmaceutical grade white mineral oils;

d) in solid or semi-solid preparations;

e) in preparations containing 25 per cent or less of designated solvents;

f) in preparations packed in pressurised spray packs;

g) in adhesives packed in containers each containing 50 grams or less of adhesive;

h) in writing correction fluids and thinners for writing correction fluids packed in containers having a capacity of 20 mL or less; or

i) in other preparations when packed in containers with a capacity of 2 mL or less.

The SUSDP gives the following definition for Schedule 5 substances:
Schedule 5. Caution – Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

For the use of allergens, particularly in pesticide formulations applied to edible crops the OCSEH recommend appropriate label statements.

18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?

Australia wishes to work towards the establishment or adopting of an 'Approved Pesticide Ingredients' list based on international best practice.

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

Australia would be interested in participating in any cooperative effects towards developing an internationally accepted/OECD – wide listing of excipients.

Belgium

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

National legislation :

Wetters, stickers, synergists, safeners and other additives that are intended to stimulate the activity of plant protection product (as defined by Directive 91/414/EEC), as long as they are placed on the market with that intention.

EU Regulation 1107/2009 (in application from 14/06/10), art 2.3:

a) substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants, hereinafter referred to as "safeners";

b) substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, hereinafter referred to as "synergists";

c) substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, hereinafter referred to as "co-formulants";

d) substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties, hereinafter referred to as "adjuvants".

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

National Legislation :

- Synergists, safeners : as active ingredients (annex II of Dir 91/414/EEC).

- Other additives (within formulation of pesticides) : Not regulated. Possibility to exclude substances, like nonylphenolethoxylates (negative list), based on risk assessment. Data requirements : full description of composition required (also for complex mixtures), MSDS; possibility to require same data as for plant protection products (annex III of dir 91/414/EEC).

- Products placed on the market as such (adjuvants): as plant protection products of Dir 91/414/EEC; e.g. wetters containing paraffin oils.

- Products packaged with the pesticide products : no special requirements, unknown practice in Belgium.

Regulation 1107/2009

- Yes, see 1). Review programs to be developed, data requirements still to be determined.
- Regulation of safeners, synergists as active substances
- Regulation of adjuvants as pesticides
- Negative list for co-formulants

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

None, only studies.

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

Decisions taken ad hoc. Limitations of concentrations, risk mitigation for the product on the market

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

No

18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?

New European legislation to be followed (See 2.)

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

No

Canada

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

Formulant – any component of a pest control product that is added intentionally to the product and that is not an active ingredient.

Adjuvant – a compound or substance that is not an ingredient of a pest control product but is added to (e.g. as a tank mix), or used with a pest control product to enhance or modify its physical or chemical characteristics. (Adjuvants whose intended purpose is to directly improve the efficacy or enhance the biological performance of a pest control product must be registered under the Pest Control Products Act.)

Safener – a compound or substance that is added to, or is part of a pest control product and is used to modify an effect on host organisms in connection with which the product is intended to be used (e.g. substance used with herbicides to mitigate the adverse affects of the pesticide on the host crop.)

Reactant – a component formulated into a pest control product that reacts chemically with an active ingredient to modify its form, e.g., a reactant added to a formulation containing an acid form of an active ingredient to make a corresponding amine form of the same active ingredient.

Formulation preservatives are pesticidal active ingredients added to pesticide formulations in order to protect the formulation from being denatured or degraded by pests while in the container.

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

Formulants are regulated in accordance with the PMRA Formulants Policy and Implementation Guidance Document. The policy was based on the EPA's approach to the regulation of inert ingredients at the time the policy was published in 2006. It involves the categorization of formulants into lists based on the level of potential concern with respect to human health and the environment. List 1 contains formulants of toxicological concern. List 2 contains formulants considered to be potentially toxic. List 3 contains formulants that do not meet criteria for the other lists. List 4A formulants are of minimal concern and List 4B formulants are of minimal concern under specific conditions of use. The PMRA adopted the criteria for categorization to the various lists based on the US EPA criteria with the addition of certain criteria based on Canadian specific requirements e.g. The Toxic Substances Management Policy. As a starting point, the PMRA adopted the US EPA categorization for substances that were common to both countries. Formulants that were unique to Canada were generally categorized to List 3 unless information was available indicating potential toxicological concern in which case the formulants were assigned to List 2. In general, the PMRA will accept the use of formulants in Canadian products where the formulant has been assessed by the US EPA and is included in their list of approved food or non-food inert lists. here a formulant is new to both Canada and the US, the PMRA will conduct an assessment of the formulant before permitting its use in Canadian pest control products.

Adjuvants whose intended purpose is to directly improve the efficacy or enhance the biological performance of a pest control product must be registered under the Pest Control Products Act. There are specific data requirements for adjuvants outlined in Regulatory Directive DIR93-15. All the individual

ingredients in an adjuvant are also subject to requirements for formulants as outlined in the PMRA's Formulant Policy and Implementation Guidance Document (DIR2006-02).

Synergists are considered to be active ingredients and thus the requirements for registration are the same as those for active ingredients.

Safeners are considered to be formulants but because of their biological activity have essentially the same data requirements as for active ingredients. Safeners may be included in a pest control product formulation or may be registered as stand-alone pest control products.

Formulation preservatives will be required to be registered by 2011. Requirements for formulation preservatives are currently being developed.

5. Do you categorize pesticide ingredients other than the ai into food-use and non-food use categories?

Formulants are not currently categorized into food-use and non-food use categories. However conditions applied to the use of a formulant might limit its use, e.g., to nonfood use applications only.

In the case of safeners, the data requirements would depend upon whether the requested uses were for food or non-food. For uses on food and/or feed crops, all food residue chemistry and toxicology data for a food use safener are required to conduct a risk assessment.

6. Is the assessment based on hazard or exposure or a combination?

With respect to human health effects, the assessment of non-active ingredients (formulants, adjuvants, safeners, etc.) in Canadian pesticide products is based upon a combination of identified hazard and expected exposure.

With respect to environmental effects, the assessment could be based on both hazard and exposure.

The approach that was taken for one formulant was based on exposure as it was a List 1 formulant that was registered in only 3 pest control products (one technical product and 2 end-use formulations) and was present in a small concentration to stabilize the active ingredient. In this case, the active ingredient was much more toxic than the formulant, therefore the identified environmental risk and any environmental mitigation measures were covered off by the risk assessment and mitigation measures for the end-use product containing the active ingredient. It is not certain that an approach based on exposure would be feasible for a formulant that is present in a larger number of products. A hazard based assessment might be more appropriate for most formulants.

Some adjuvant/adjuvant mixtures" contain fairly "inert" ingredients, but as they are being proposed as adjuvants for use with pest control products, they are subject to a certain amount of evaluation .(However with respect to environmental effects assessment, this may not result in data being required). Tiered data/information requirements have been developed for biochemical and non-conventional pest control products (PRO2007-02) which could be utilized in the evaluation of some types of adjuvant/adjuvant mixtures, if necessary.

In the evaluation of the environmental effects for certain petroleum hydrocarbon formulants, data was requested and a risk assessment was conducted. The assessment of risk was based on review of the submitted toxicity data, followed by comparison of toxicity endpoints and exposure.

10. Do you have publicly available lists of approved pesticide ingredients other than the stated pesticide ai?

A list of all formulants currently used in registered Canadian pest control products is published and updated regularly which includes individual chemicals as well as trade name formulants (some of which may be mixtures). The list is available in PDF format on the Health Canada website at: http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/reg2007-04/index-eng.php

11. Do you currently have or do you plan to conduct a re-assessment programme for pesticide ingredients other than the stated pesticide ai?

The PMRA plans to conduct a reassessment of formulants currently on the PMRA lists 2 and 3. The timeframe for the reassessment has not yet been determined. Nearly all List 1 formulants have been eliminated from use or have been reassessed and determined to be acceptable for certain uses.

12a. Are there any toxicity data requirements for approval or registration of pesticide ingredients other than the stated pesticide ai?

The toxicity data requirements for the approval or registration of safeners are the same as those specified for active ingredients in Canada.

With respect to human health effects assessment, for new pesticide ingredients (not present in a registered Canadian pest control product or contained on any USEPA listings of inert ingredients) other than the stated pesticide active ingredient and safeners, the pesticide petitioner is requested to submit information that would address the key areas included in a toxicity assessment (e.g. Oncogenicity, genotoxicity, reproductive toxicity, developmental toxicity, effects following repeated dosing, etc.) These areas may be addressed by submission of public literature references, data waivers, toxicology data, etc. The requirement for additional data/information would be determined following an initial assessment of the submitted information.

With respect to environmental effects assessment, there are no special requirements for data over and above that required for the active ingredient. The Environmental Assessment Directorate of the PMRA has provided input to a draft Regulatory Proposal for the assessment of formulants and the proposed data requirements are listed in Table 2 of the attached document. The proposed data requirements are taken from the current data requirements for an active ingredient.

With regard to adjuvants, there are data tables available. There are no required data. All data are conditionally required depending on the proposed use. As indicated in PRO2007-02, the conditionally-required data are tiered, where only data on toxicity are requested initially.

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

With respect to human health assessment, any additional data/information that has been provided or is accessible will be used to conduct our assessment. All data/information listed in a-d of this question are considered important.

Other data/information frequently consulted to conduct an assessment includes US EPA Data Evaluation Records (DERs) and Re-registration Eligibility Documents (REDs) and EU monographs and JMPR reviews, when available.

With respect to environmental effects assessment, the PMRA would accept all of the above-mentioned sources of data, except for Structure Activity Relationship (SAR), as a policy on the use of SARs has not yet been established. A list of potential data/information sources can be found in the draft PMRA Regulatory Proposal for the assessment of formulants (Section 4.1), that is attached.

For additional information on Canada's Formulants Policy which outlines the policy on the regulation of formulants contained in pest control products (Part I) please consult Regulatory Directive: Formulants Policy and Implementation Guidance Document (DIR2006-02, May 31, 2006) [Health Canada, 2006].

14. What data protection/compensation legislation/policies do you have with respect to data for pesticide ingredients other than the stated pesticide ai?

Under the current data protection provisions provided under the Protection of Proprietary Interests in Pesticide Data in Canada (PPIP) Policy (DIR2007-03), formulant data is only afforded protection if it is submitted as part of an application to register an end-use pesticide product.

Safeners and adjuvants which are registered themselves, would be subject to data protection provisions as pest control products under PPIP.

15. Do you require disclosure of pesticide ingredients other than the stated pesticide ai on the label?

List 1 formulants and formulants that are allergens are required to be disclosed on the pesticide label. List 1 disclosure must include the identity of the formulant as well as the concentration in the EP. Allergen disclosure requires disclosure of the name of the formulant. In addition, formulation preservatives must be disclosed on the pesticide label by identifying the preservative as well as its concentration.

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

Should information/data become available on a formulant which would indicate a potential concern with respect to human health or the environment, the formulant could as a result be recategorized to a List reflective of increased concern. As a result, the formulant would be subject to action applicable to that list.

In some cases, conditions for use may be established based on the assessment of a formulant, i.e., the formulant may be limited to particular uses and particular concentrations.

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

There is currently no policy in place to limit the use of formulants that are allergens to non-food applications, although the PMRA will be considering changes to current practice in this regard, in the future. As previously noted, allergens must be disclosed on pest control product labels.

18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?

We are currently developing more comprehensive data/information requirements for new formulants based on a tiered approach.

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

It would be useful to explore opportunities for joint reviews of new formulants and safeners.

Germany

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

We would prefer the term "co-formulant". This refers to substances or mixtures added intentionally to the formulation to gain/improve certain properties. These substances are used to ensure the necessary properties for the application in order to achieve the maximum target deposition. Therefore, they can enhance exposure of pests and efficiency of the active ingredient.

The following allocation of co-formulants is used in DE:

BVL-Kode	Funktion (deutsch)	function (english)
A	Antioxidant	*antioxidant*
B	Brechmittel (Emetikum)	*emetic*
C	Dünger, Nährstoff	*fertilizer*
D	Dispergiermittel	*dispersing agent*
E	Emulgator	*emulsifier*
F	Farbstoff	*dye*
G	Frostschutzmittel	*antifreeze*
H	Haftmittel	*adhesive (sticker)*
I	Verdickungsmittel	*thickener*
J	Antiverbackungsmittel	*anticlumping agent*
K	Konservierungsmittel	*preservative*
L	Lösungsmittel	*solvent*
M	Fließmittel	*free-flowing agent*
N	Netzmittel	*wetting agent*
O	Synergist	*synergist*
P	Parfum, Deodorant	*perfume, deodorant*
Q	Treibgas	*propellant*
R	Riechstoff (Repellent)	*repellent*
S	Stabilisator	*stabilizer*
T	Trägerstoff	*carrier*
U	Schmiermittel	*lubricant*
V	Schaumverminderer	*antifoaming agent*
W	Safener	*safener*
X	Sonstiges (spezifizieren)	*miscellaneous (specify)*
Y	Puffer	*buffer*
Z	Bindemittel	*binder*

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

There are no special regulations for co-formulants. They are assessed on a case-by-case-decision.

Toxicological hazard assessment of pesticide ingredients is usually performed according to the criteria in Directives 67/548/EEC or 1999/45/EC and in Regulation (EC) No. 1272/2008, respectively.

In the case of toxicological concern regarding a particular pesticide ingredient threshold values are derived and risk assessment is performed comparable to the active ingredient (e.g. for some safeners and synergists).

Synergists and safeners are treated as co-formulants in the EU. There might be additional data requirements in the case maximum residue levels are set.

10. Do you have publicly available lists of approved pesticide ingredients other than the stated pesticide ai?

There is a list of all co-formulants (mixtures) in authorized plant protection products available at the web-site of the BVL.

http://www.bvl.bund.de/DE/04__Pflanzenschutzmittel/00__doks__downloads/zul__info__liste__beistoffe__EN,templateId=raw,property=publicationFile.pdf/zul_info_liste_beistoffe_EN.pdf

11. Do you currently have or do you plan to conduct a re-assessment programme for pesticide ingredients other than the stated pesticide ai?

There is currently no re-assessment programme for co-formulants. However, according to the new Regulation (EC) No. 1107/2009 safener and synergists will be treated similar to active substances and a list of co-formulants that should not be included in plant protection products will be provided.

12a. Are there any toxicity data requirements for approval or registration of pesticide ingredients other than the stated pesticide ai? & 12b. Are there any residue data requirements of approval or registration of pesticide ingredients other than the stated pesticide ai? & 13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

With regard to toxicological data acute tests are generally available for the pesticide product. Material safety data sheets must be submitted for all co-formulants. Residue data requirements could be necessary on a case by case decision. Data requirements for the future as indicated in the answer to question 11 will be elaborated.

A list of unwanted substances in plant protection products is available at the web-site of the BVL:

http://www.bvl.bund.de/cln_027/nn_1156712/EN/04__PlantProtectionProducts/09__ProductChemistry/ListUndesiredFormulants.html

In addition to the above mentioned information, we use published data on a case by case basis, e.g.

Tobiassen, Lea Stine, Elsa Nielsen, Pia Nørhede and Ole Ladefoged; Report on the Health Effects of Selected Pesticide Coformulants; Pesticides Research Nr. 80 (2003); Danish Veterinary and Food Administration, Institute of Food Safety and Nutrition

Stubberud, Hege E., The Norwegian Agricultural Inspection Service, Norway; Annika Boye Petersen, Danish EPA, Denmark; Agneta Ohlsson, National Chemicals Inspectorate, Sweden; Hans Blomqvist, Plant Production Inspection Centre, Finland; A Nordic Project Regarding Co Formulants in Plant Protection Products; TemaNord 2004:504

Scientific peer-reviewed open literature will be always taken into consideration (Regulation (EC) No. 1107/2009).

15. Do you require disclosure of pesticide ingredients other than the stated pesticide ai on the label?

No, only in special cases (see answer to question 14).

According to Directive 1999/45/EC the name of the substances which have given rise to the classification of the preparation in one or more of the following danger categories:

- carcinogen category 1, 2 or 3,
- mutagen category 1, 2 or 3,
- toxic for reproduction category 1, 2 or 3,
- very toxic, toxic or harmful due to non-lethal effects after a single exposure,
- toxic or harmful due to severe effects after repeated or prolonged exposure,
- sensitising;

shall be mentioned on the label.

According to Regulation (EC) No. 1272/2008 (mandatory for pesticide formulations by 2015) generally the product identifier for a mixture shall consist of both of the following:

a) the trade name or the designation of the mixture;

b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard.

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

Depending on the risk of the ingredient.

In some cases legal limits for the content of ingredients were set, e.g. for nonylphenolethoxylates.

In general, we are concerned about harmful ingredients other than the stated active ingredient, if the current risk assessment does not cover harmful effects of these ingredients. Reference values could be established for these substances, if necessary.

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

The national and European legislation concerning chemicals and hazard substances does apply. In the future, pesticide ingredients will be assessed according to European chemicals legislation (REACH).

18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?

The European regulation No. 1107/2009 will enter into force in 2011 and will introduce a list of co-formulants which are not accepted for inclusion in a plant protection product. This regulation lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, rules for adjuvants and co-formulants will be also established.

Synergist and safeners will be treated like active ingredients.

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

No

Ireland

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

Adjuvants are often sold as part of a twin pack or indeed in separate containers but with distinct recommendations on the PPP label.

We do not consider any ingredients to be pesticides unless they have specific pesticidal claims, and therefore can be considered as being under the scope of Directive 91/414/EEC. All other ingredients are considered co-formulants.

Adjuvants are formulations that enhance the effect of plant protection products, while having no direct effects when applied alone.

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

In the case of adjuvants, we have a system in pace whereby it is legally required for companies or persons wishing to place adjuvants on the market to provide a basic data set relating to the chemical make up and specification. This is then looked at and a registration number issued.

10. Do you have publicly available lists of approved pesticide ingredients other than the stated pesticide ai?

Yes, we have a register of adjuvants and this can be seen on our website www.pcs.agriculture.gov.ie

11. Do you currently have or do you plan to conduct a re-assessment programme for pesticide ingredients other than the stated pesticide ai?

Under the guise of the new PPP regulation in the EU (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 and repealing Council Directives 79/117/EEC and 91/414/EEC), a full re appraisal of the adjuvants on our register shall be undertaken.

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

All of the above would be considered**.**

15. Do you require disclosure of pesticide ingredients other than the stated pesticide ai on the label?

Ingredients covered by Directive 91/414/EEC (PPP) and Directive 98/8/EEC (Biocides) are the only ingredients considered as pesticides. All others are either adjuvants safeners and synergists. When a PPP or indeed an adjuvant is being placed on the market, there is an obligation to disclose all formulants.

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

Current requirements ensure that the products concerned are classified, packaged and labeled in accordance with Directive 67/548/EEC and Directive 99/45/EC

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

No

18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?

Yes, 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 and repealing Council Directives 79/117/EEC and 91/414/EEC, will necessitate the complete re-evaluation of all adjuvants, safeners and synergists.

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

As is the case with pesticidal active substances, it makes sense to review these ingredients in a globally harmonized way. Therefore, there should be scope to allow either global workshare projects with regional risk assessments, or indeed allocate different ingredients to different OECD member countries with a view to the hazard assessment, and subsequently allow each region/country to conduct internal risk assessments.

Japan

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

There is no definition of each term.

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

We conduct the assessment for formulate (end-use product) only.

Therefore, we don't conduct the special assessment for each inert ingredient.

We advise manufacturers not to use nonyl phenol and substances listed in EPA list I for pesticide ingredients other than the stated pesticide active ingredient(s).

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

Publicly available data and regulatory documents from EPA, RDA, and other countries (a.& b. in the question)

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

Similar to the formulation.

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

No

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

As we stated in OECD MRL survey, pesticide ingredients other than the stated pesticide active ingredient(s) in formulations (end products) are different, depending on the usage or use pattern of each countries. From this viewpoint, we think it seems to be some difficulties to carry out this work.

Korea

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

a) The term *"agrochemicals"* shall mean fungicides, insecticides and herbicides used for controlling germs, insects, aphids, mires, virus, weeds and other animals and plants which are determined by the Ordinance of the Ministry of Agriculture and Forestry (hereinafter referred to as "diseases by insects"), and other medicine as prescribed by the Ordinance of the Ministry of Agriculture and Forestry, which is utilized to facilitate or reduce the physiological functions of agricultural crops;

b) The term *"items"* shall mean the kinds of agrochemicals which are composed of the same operative ingredients and are prepared by the same method;

c) The term *"technical ingredients"* shall mean the materials in which the operative components of agrochemicals are condensed;

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

Publicly available data; regulatory documents such as from EPA, FDA and other countries; WHO, JEFCA type documents (a., b., and c. in the question)

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

No

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

No

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

No

New Zealand

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

NZ has two regulatory authorities overseeing pesticides. Therefore, the responses have been split between (1) ERMA NZ (2) NZFSA and are referred to in the table and below as 1) and 2).

1) ERMA New Zealand uses 'component'- any substance other than the active ingredient. Products separate to the pesticide product will be assessed separately.

2) NZFSA uses the term **Excipient:** All other intentionally added components of an agricultural compound excepting those active ingredients upon which the biological activity is dependent as defined above. Also known as formulants, inerts and non-active ingredients.

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

1) ERMA New Zealand: Yes, we do regulate substances other than the active ingredient in a pesticide product. We regulate the mixture, or end-use product, and this may include assessments of all components, both active and non-active. If the product is separate, it will be assessed separately.

2) NZFSA: we regulate non active ingredients with respect to the end-use product.

10. Do you have publicly available lists of approved pesticide ingredients other than the stated pesticide ai?

1) Yes- the register of substances- http://www.ermanz.govt.nz/hs/index.html

11. Do you currently have or do you plan to conduct a re-assessment programme for pesticide ingredients other than the stated pesticide ai?

1) ERMA: not currently, but have ability to reassess excipients/components in relation to the end use product.

2) NZFSA: not currently, but have ability to reassess excipients/components in relation to the end use product.

12b. Are there any residue data requirements of approval or registration of pesticide ingredients other than the stated pesticide ai?

2) NZFSA: Under the ACVM Act there is a requirement to consider the residue profile of excipient ingredients, however as the MRL standard has a default level of 0.1mg/kg in place this is generally sufficient to address any likely residue of these components. In rare cases for example with the synergist piperonyl butoxide additional data has been necessary to establish higher MRLs

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

a) Publicly available data (scientific papers)? 1) ERMA NZ: Yes

b) Regulatory documents such as from EPA, FDA and other countries? 1) ERMA NZ: Yes

c) WHO, JEFCA type documents? 1) ERMA NZ: Yes

d) Structure Activity Relationships (SAR) 1) ERMA NZ: Not currently

e) Other: please describe.

1) ERMA NZ: We also use EFSA data. The importance varies, although we use data from b and c more frequently

2) NZFSA: Residue data can be considered from any source of a-c, SAR and QSAR are not used yet in residue assessments

15. Do you require disclosure of pesticide ingredients other than the stated pesticide ai on the label?

1) ERMA NZ: Yes, we may require disclosure of any component. We have a cut-off trigger for hazardous components, which determines that when a component is above a certain percentage of the product, requirements regarding labeling and safety data sheets take effect.

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

1) ERMA NZ: We assess the final end-use product, so controls will be placed upon the product as a whole, rather than the ingredients of the product.

2) NZFSA: As part of our risk assessment and risk management process under the ACVM Act, we would take into consideration any components in the formulation that may impact in the risk areas under this Act.

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

1) ERMA NZ: No to part 1. As all substances are included within assessments the regulatory requirements do not differ between actives and other components.

2) NZFSA: No to part 1, and no specifically for the part 2, but we can require the applicant to provide information on any component in the formulation, if we deem it necessary to manage a risk for a specific component.

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

1) ERMA NZ No

2) NZFSA No

Norway

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

Co-formulants are substances or preparations which are used in a plant protection product (PPP) or in adjuvants. This definition does not include synergists.

Adjuvant is a mixture of co-formulants that is mixed with a PPP by the user.

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

Co-formulants are assessed as part of the registration of PPP (formulated products). Lists based on Nordic Project regarding co-formulants in plant protection products, lists from US EPA and harmonized classification and labeling lists of the European Union are used when making decision on the safety of the co-formulants. Safety data sheets for co-formulants are always required.

3a. Do you conduct assessments on individual pesticide ingredients other than the ai?

Assessments are conducted for individual pesticide ingredients other than pesticide active ingredient based on lists mentioned above and toxicity data in the safety data sheets. Additional toxicity data may be required if potential concern is identified.

Formulated (end-use) products are tested for acute toxicity, skin and eye irritation and skin sensitization.

Adjuvants: testing for acute toxicity, skin and eye irritation and skin sensitization are required. Additional data may be required.

10. Do you have publicly available lists of approved pesticide ingredients other than the stated pesticide ai?

No, but the Nordic project regarding co-formulants in plant protection products established lists of co-formulants used in plant protection products.

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

We use the results of the Nordic project regarding co-formulants in plant protection products, lists from US EPA and harmonized classification and labeling lists of the European Union. Public available data is used when it has a good quality.

The report of the Nordic project regarding co-formulants in plant protection products is available on the following website: **http://www.norden.org/en/publications/publications/2004-504**

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

The notifier is asked to replace a co-formulant of concern with a safer co-formulant or to reduce the amount below the limit that triggers classification and labeling according to the directive 1999/45/EC.

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

No

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

No

Poland

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

Adhesive (sticker), antifoaming agent, antifreeze, binder, buffer, carrier, deodorant, dispersing agent, dye, emetic, emulsifier, fertiliser, preservative, odourant, perfume, propellant, repellent, solvent, stabiliser, thickener, wetting agent, biomarker, miscellaneous (to be specified) – lack of definition

Safener, synergist, co-formulant – definitions stated in Chapter II of the 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 and repealing Council Directives 79/117/EEC and 91/414/EEC* (application from 14 June 2011)

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

Currently, there is no specific regulation envisaged for ingredients other than active ingredient(s). The 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 and repealing Council Directives 79/117/EEC and 91/414/EEC*, which regulate some aspects of plant protection ingredients other than active substance, shall apply from 14 June 2011 – the list of approved safeners and synergists will be established.

12a. Are there any toxicity data requirements for approval or registration of pesticide ingredients other than the stated pesticide ai?

Ingredients other than pesticide active substance do not undergo any approval or registration. However, the applicants for registration of plant protection products are obliged to provide Material Safety Data Sheets for every component of the formulation. MSDSs contain information concerning hazards identification, toxicological and ecological issues.

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

None

14. What data protection/compensation legislation/policies do you have with respect to data for pesticide ingredients other than the stated pesticide ai?

None

15. Do you require disclosure of pesticide ingredients other than the stated pesticide ai on the label?

Yes. Pursuant to regulation of the Minister of Health of 5th March 2009 on *labeling of dangerous substances and preparations* label contains name(s) of substance(s) classified as very toxic, toxic, harmful or corrosive present in the preparation in quantities exceeding quantities envisaged on the separate list and/or name(s) of substance(s) classified as carcinogenic (category 1, 2 or 3), mutagenic (category 1, 2 or 3), toxic for reproduction (category 1, 2 or 3) and allergic.

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

regulatory action – see above

limitations – no

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

No

18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?

There are no plans on national level, since the 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 and repealing Council Directives 79/117/EEC and 91/414/EEC* envisaged some regulations concerning ingredients other than pesticide active substances.

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

Not yet.

Slovak Republic

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

As far as "inert" we conceptualize as "inactive" – These substances are not assessed by the Authority responsible for registration of plant protection products in the Slovak Republic (next "Registration Authority"), but the data presented in MSDS and following opinion of experts from particular areas (toxicology, ecotoxicology etc.) are taken into account.

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

Registration Authority assesses plant protection products as one entity without assessment of individual inert ingredients.

10. Do you have publicly available lists of approved pesticide ingredients other than the stated pesticide ai?

Not yet, but this topic is mentioned in the new EU legislation – negative list of co-formulants.

(Regulation (EC) No 1107/2009 of the European Parliament and the Council – article 27 and Annex III).

11. Do you currently have or do you plan to conduct a re-assessment programme for pesticide ingredients other than the stated pesticide ai?

12a. Are there any toxicity data requirements for approval or registration of pesticide ingredients other than the stated pesticide ai?

This topic is mentioned in the new EU legislation – Regulation (EC) No 1107/2009 of the European Parliament and the Council – article 27.

Currently there is the obligation for registration to provide MSDS for each substance present in plant protection product.

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?
N/A.

15. Do you require disclosure of pesticide ingredients other than the stated pesticide ai on the label?

There is the obligation to indicate hazardous ingredients (inert formulants incl.) on the label. (according to national legislation: Chemical substances Act. 163/2001 Coll.)

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

According to the opinions of expert institutions, which are conducted during registration process (toxicology, ecotoxicology, etc.)

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

No

18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?

See new EU legislation: Regulation (EC) No 1107/2009 of the European Parliament and the Council – article 27 and Annex III.

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

See new EU legislation: Regulation (EC) No 1107/2009 of the European Parliament and the Council – article 27, Annex III.

When the negative list of co-formulants is created by the European Commission, it could be possible to cooperate with other non EU countries (OECD members)

Sweden

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

- **Official inactives**; all ingredients other than the active substance that have to be declared on the label and instructions for use.

- **Inofficial inactives**; all ingredients other than the active substance that don't need to be declared on the label and instructions for use.

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

Inactives are regulated according regulation 1272/2008/EC (CLP)

12a. Are there any toxicity data requirements for approval or registration of pesticide ingredients other than the stated pesticide ai? & 12b. Are there any residue data requirements of approval or registration of pesticide ingredients other than the stated pesticide ai?

In both cases data provided by the substance's data sheet according regulation 1907/06/EC (REACH) is assessed.

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

In some cases, when new, acute and relevant data is presented publicly available data (scientific papers) are used. However, safety data sheet according regulation 1907/06/EC (REACH) is the most important source

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take?

The first risk management action would be to restrict the authorization for consumer products and instead authorize a given product only for professional use if possible.

Do you put limitations on the amount of an ingredient that can be used in formulations?

No legally binding limits can be proposed, other than those defined in regulation 1272/2008/EC (CLP).

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)?

No

Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

Plant protection products containing allergens may not be authorized as consumer products.

18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?

With the implementation of the new regulation on plant protection products, 1107/2009/EC on 14 June 2011, the assessment of safeners, synergists and other inactives becomes mandatory.

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

The new regulation on plant protection products, 1107/2009/EC, establishes cooperation between EU-members states in zones regarding the evaluation of active substances. This cooperation extends also to inactives.

United Kingdom

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

Currently:

Co-formulants
Substances or preparations, other than active substances, safeners or synergist, which are used or intended to be used in a plant protection product or adjuvant.

Safener
A substance which reduces or eliminates the phytotoxic effects of a plant protection product on certain plant species.

Synergist
A substance or preparation which shows no or weak activity but can give enhanced activity to the active substance(s) in a plant protection product.

The definitions used in the 'new' EU Regulation (Regulation 1107/2009), referred to in response to question 18) below, are as follows:

- substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants, referred to as '**safeners'**;

- substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, referred to as '**synergists'**;

- substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, referred to as '**co-formulants'**;

- substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties, referred to as '**adjuvants'**.

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

Under Directive 91/414 we request data on a pesticide product and its active substance(s). Full details of the composition of the product must be provided.

The co-formulant details must include:

(i) Trade name, including alternatives if required (See note below)

(ii) Chemical name (IUPAC and CAS)

(iii) CAS number

(iv) ELINCS or EINECS number

(v) Structure, structural formula or chemical description

(vi) Function e.g. antifreeze, emulsifier etc

Up to date (in principle less than 2 years old) Material Safety Data Sheets (MSDS), in English, are required for all co-formulants. The MSDSs must comply with EU requirements i.e. the classification and labelling would need to be in accordance with EU requirements). Details on whether any of the co-formulants are permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with Community legislation are required.

Where alternative trade names are listed, the components must be identical in

- chemical composition. Where the alternatives are not chemically identical then a
- reasoned scientific case must be submitted showing why the change will not adversely affect the physical or chemical properties of the preparation.

The information submitted for each preparation component must be sufficient to

- chemically characterise that component, for example, for polyethoxylated
- components the information should include the degree of ethoxylation and the
- number of mole equivalents of ethylene oxide. Where a co-formulant is itself a mixture full details of the composition must be submitted.
- For granular preparations, details of the method of manufacture of the granules must be submitted e.g. whether the active substance is incorporated into the granule or sprayed on the surface of the granule

If a company wishes to change the formulation of an approved product it would need to submit further data or an acceptable case to cover the new ingredients or changes. Depending on the extent of the formulation change the details needed could cover: toxicity; operator exposure; ecotoxicity; environmental effects; residues; pesticide chemistry and efficacy (see documents embedded at 3 below). Formulation details are normally treated as commercially confidential – any co-formulants would only have to be disclosed (i.e. on the product label) if it contributed to the classification and labelling of the product.

Safeners in the UK are considered as active substances and would require data equivalent to that required to support an active substance risk assessment.

Adjuvants are not covered in response to the questions below as they are generally not *packaged with* the pesticide product – if information on adjuvants is required please refer to: http://www.pesticides.gov.uk/applicant_guide.asp?id=1289

3a. Do you conduct assessments on individual pesticide ingredients other than the ai?

Assessments are conducted on formulated (end use) products. The two embedded word documents indicate the general approach taken to the assessment – the main areas specifically relevant to formulation changes are given in yellow highlight.

The co-formulants themselves may also have been subject to individual consideration under other Community legislation. Applicants are required to identify if any of the co-formulants are permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with Community legislation. Co-formulants may have been considered under the Community regimes established for chemicals/biocides. As mentioned before, and in the embedded documents, up to date Material Safety Data Sheets are required for all co-formulants and are considered within the assessment of toxicology, with particular emphasis on the classification established for the co-formulant and its impact on the plant protection product. Specific consideration is given to the present of dyes.

All applications for new products, re-registration and major formulation changes that require a review of the human health risk assessment must include a consideration of the combined toxicity of the components. If two co-formulants or a co-formulant and the active substance are known to have the same toxic mechanism of action or target tissue at low doses the potential for combined action should be addressed. It is accepted that for many co-formulants there is limited information on the toxicity following repeated exposures. However, when the toxicity is known to be similar to that of an active substance in the product, consideration should be given to potential combined toxicity other than simple additivity of effects.

4a. For mixtures of pesticide ingredients other than the ai—are the components assessed separately? & 4b. For mixtures of pesticide ingredients other than the ai—is the mixture assessed as a whole?

The mixture as a whole is assessed within the formulation risk assessment. However consideration is given to the components in the formulation as described in the embedded documents above. Where a co-formulant is itself a mixture full details of the composition must be submitted.

In some specific cases where a formulation contains a high percentage of a known hazardous substance (e.g. a solvent) a specific risk assessment may be conducted.

10. Do you have publicly available lists of approved pesticide ingredients other than the stated pesticide ai?

The applicant is required to identify co-formulants that are permitted in food, animal feeding stuffs, medicines (e.g. European Pharmacopoeia) or cosmetics in accordance with Community legislation and would consult information under those regimes.

As examples -

Animal feed additive information can be accessed at:
http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm

The cosmetics database can be found at: http://ec.europa.eu/enterprise/sectors/cosmetics/cosing/

CRD provides, on its website, a specific document in relation to national consideration of dyes at:
http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/dyeslist(1).pdf

12b. Are there any residue data requirements of approval or registration of pesticide ingredients other than the stated pesticide ai?

As mentioned, the residues assessment is conducted on the basis of the end use product.

However, safeners in the UK are considered as active substances and would require data equivalent to that required to support an active substance risk assessment. This would include a full residues data package including plant metabolism data and, if necessary, animal metabolism/feeding studies and supervised field residue trials (which can be conducted in application with the product in compliance with the supported GAP).

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

In general the consideration would rely on the product submission as previously described which would include information on the co-formulants and include information on consideration under other Community regimes. The agreed up to date classification for the co-formulant would be checked. In most cases therefore reference would not be made to the above. In exceptional cases where an individual assessment is considered appropriate all of the above may be considered.

15. Do you require disclosure of pesticide ingredients other than the stated pesticide ai on the label?

Yes this is required under certain circumstances. The identity of any 'dangerous' co-formulants must be specified if it contributes to the classification and labelling of the plant protection product (usually in the 'contents' statement along with information on the active substance).

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

Where unacceptable risks are identified limitations or restrictions can be put in place in relation to products containing ingredients where a concern is identified.

For example:

- the use of certain compounds is restricted by EU legislation. EC Directive 2003/53/EC concerns the reduction and replacement of nonylphenol, octylphenol and their ethoxylates (NPE's and OPE's) in pesticide formulations. In order to implement this PSD (now CRD) carried out an exercise with existing registrants to identify pesticide product formulations which contain nonylphenol, octylphenol and/or their ethoxylates (NPE's and OPE's) at greater than 0.1% w/w concentration. A series of Official Notices were then issued revoking the approvals (including 'off-label' approvals) for all pesticide products, containing NPE's in their formulations in excess of the specified limit.

- during formulation evaluations changes to the health and safety data sheets for Solvesso 100 and Shellsol A were noted reporting a revised classification which indicated that they were respiratory irritants. Consequently the conditions of approval were amended for formulations requiring amendment to the product classification and requiring label amendments for all products where the Solvesso 100/ Shellsol A content was > 40%.

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

Only as described previously.

In relation allergens, for preparations that contain at least one substance classified as sensitising and being present in a concentration of ≥0.1% or in a concentration greater than or equal to that specified within the Classification Labelling and Packaging Regulation must carry the wording *"Contains (name of sensitising substance). May produce an allergic reaction."* This requirement applies to the product irrespective of whether applied to edible of non-edible crops.

18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?

The processes will change with the application of Regulation 1107/2009. This Regulation replaces Directive 91/414/EEC and will apply from 14 June 2011 within the European Union. The Regulation provides for:

- an approval system for safeners and synergists and establishes safety criteria with which they are required to comply and requires that similar data requirements to those established for active substances will apply to these substances

- requires that a review process be established for safeners and synergists already on the market. A Regulation setting out such a review programme and establishing deadlines for data submission must be adopted by 14 December 2014

- establishes a 'negative' list of co-formulants that are not accepted for inclusion in a plant protection product i.e. those co-formulants where -

  - its residues, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment; or

  - its use, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, has a harmful effect on human or animal health or an unacceptable effect on plants, plant products or the environment

Rules for the implementation of this process are required to be developed

- allows the Commission to review co-formulants at any time

- provides for an authorisation process (rules to be developed)

It should be noted that although the Regulation applies from 14 June 2010 it contains derogations for the use of national rules for products to be applied for transitional periods beyond that date in relation to safeners, synergists, co-formulants and adjuvants pending the implementation of rules/programmes in relation to the regulation of such substances.

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

Given the work programmes that will follow from the 'new' Regulation (as referred to at 18 above) an exchange of information on current procedures in OECD countries as a result of this survey would be a useful first step in identifying areas for co-operation.

United States

1. Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s).

Inert (or "other) ingredient: Any substance other than an active ingredient which is intentionally included in a pesticide product.

2. Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s).

Pesticide inert ingredients are regulated a) by considering their contribution to the overall risk/benefits of a pesticide product determining that the use of the inert ingredient in a pesticide product will result in no unreasonable adverse effects on the environment (EPA's FIFRA standard), and b) for those inert ingredients used in food use pesticide formulations, a determination is made that dietary and residential exposure to the inert ingredient poses a reasonable certainty of no harm (EPA's FFDCA/FQPA safety standard).

Known synergists (e.g., piperonyl butoxide) are regulated as pesticide active ingredients by EPA.

Products packaged with a pesticide product are generally considered by EPA to be part of the overall pesticide product and the ingredients of such products are considered by EPA to be pesticide inert ingredients and regulated as such.

10. Do you have publicly available lists of approved pesticide ingredients other than the stated pesticide ai?

A publicly available listing of approved inert ingredients is available at EPA's website at **http://www.epa.gov/opprd001/inerts/lists.html**

11. Do you currently have or do you plan to conduct a re-assessment programme for pesticide ingredients other than the stated pesticide ai?

All inert ingredients used in food use pesticide formulations have been reassessed.

Reassessment of inert ingredients used in nonfood use pesticide products is currently done only in those instances where there may be some potential risk concerns. A formal plan for an overall reassessment of all nonfood use inert ingredients has not yet been fully developed.

12a. Are there any toxicity data requirements for approval or registration of pesticide ingredients other than the stated pesticide ai?

There are no data requirements *per se* for pesticide product inert ingredients as they themselves are not registered under FIFRA. However, the toxicity data needed to conduct an inert ingredient assessment mirror those data that are required for a pesticide active ingredient under FIFRA. More specifically, a tiered approach is used in which the results of acute and subchronic toxicity tests and genotoxicity studies are considered in determining whether there may be toxicological concerns that would warrant the need for

additional data needs for additional toxicity tests (e.g., carcinogenicity testing, reproductive toxicity testing).

13. What other data/information do you use to conduct your risk assessment and which data are considered most important?

a) Publicly available data (scientific papers)?

b) Regulatory documents such as from EPA, FDA and other countries?

c) WHO, JEFCA type documents?

d) Structure Activity Relationships (SAR)

e) Other: please describe.

All of the above sources of data may be utilized in conducting inert ingredient risk assessments. The most useful of these sources would be peer-reviewed risk/hazard assessments such as (b) and (c) above.

14. What data protection/compensation legislation/policies do you have with respect to data for pesticide ingredients other than the stated pesticide ai?

Inert ingredient data submitted to support or maintain a pesticide registration, or to allow for the establishment of a tolerance or exemption from the requirement of a tolerance for a food use inert ingredient (i.e., an approval for food use of an inert ingredient) are statutorily protected under section 3 of FIFRA. Inert ingredient data not meeting the above conditions are not protected.

16. If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the ai, what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

Regulatory actions related to hazard/exposure/risk concerns of inert ingredients can range from not granting (or canceling) the registration of a pesticide product that contains the inert ingredient of concern to not approving (or revoking the approval of) a food use inert to posing limitations on use of the inert ingredient such as limitations on amount in a product formulation, limitations on use rate, to limitations on use patterns (e.g., approved for indoor nonfood use only) to other label use limitations.

17. Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

There are use limitations for food commodity forms of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacean and wheat in pesticide formulation in pesticide formulations applied to crops (see 40 CFR §180.1071).

18. Do you have any plans to change how you currently handle pesticide ingredients other than the stated ai?

EPA will be evaluating potential options for broader disclosure of inert ingredient identities in products following the issuance of an advance notice of proposed rulemaking on December 23, 2009. The

public comment period ends on April 23, 2010 at which point EPA will consider possible regulatory and non-regulatory options for increasing public availability of the identities of the inert ingredients in pesticide products.

Reassessment of inert ingredients used in nonfood use pesticide products is currently done only in those instances where there may be some potential risk concerns. A more formal plan for an overall reassessment of nonfood use inert ingredients is under consideration but has not yet been fully developed.

19. Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

Enhanced exchange of data and evaluations that member countries may have and be able to share would be extremely valuable. Possible joint reviews for inert ingredients with significant use and/or potential risk concerns.

ANNEX 3: SURVEY QUESTIONNAIRE

OECD Survey on How Pesticide Ingredients other than the Stated Pesticide Active Ingredient(s) are Reviewed & Regulated

For Delegations of the OECD Working Group on Pesticides (WGP) in OECD Governments and the European Commission

Please respond by 22 March 2010

To: Sylvie.Poret@oecd.org and Rossi.Lois@epamail.epa.gov

OECD Survey on How Pesticide Ingredients Other Than the Stated Pesticide Active Ingredient(s) Are Reviewed & Regulated

BACKGROUND

Issues surrounding the regulation of pesticide ingredients other than the stated pesticide active ingredient(s) have been discussed at previous OECD meetings. It was concluded that it would be useful to conduct a survey to obtain baseline information on how these ingredients are currently reviewed and regulated, as well as any plans for changes in the future.

PURPOSE OF SURVEY & POSSIBLE USES OF INFORMATION

Regulation of ingredients other than the stated pesticide active ingredient(s) has come under increasing scrutiny in many countries in recent years. In the U.S., for example, the way that these ingredients are handled has dramatically changed over the past several years and, currently, there is a strong push to begin listing these ingredients on the label. Because review and regulation of pesticide ingredients other than the stated pesticide active ingredient(s) has not been a primary focus of OECD, it was thought that doing a survey to establish the baseline of what various member countries are currently doing and any plans for the future, would provide a basis for identifying common issues, possible work sharing opportunities, and possible areas for regulatory harmonization.

ANALYSIS OF SURVEY INFORMATION

The U.S. commits to analyzing the results of the survey and presenting this analysis to the Working Group on Pesticides (WGP), possibly at the May 2010 meeting if time permits.

REPOSITORY OF INFORMATION

Initially it was proposed that, due to the possibly confidential nature of the information, the use of the survey would likely be internal to the OECD only. However, several comments indicated that the type of information being collected in the survey would not be considered confidential in their countries. Thus, a final question (question #20) has been added to the draft survey concerning whether the information provided in the survey is considered to be confidential and needs to remain internal to OECD.

SCOPE OF THE SURVEY

As suggested during the Registration Steering Group (RSG) meeting in Tokyo in November 2009 various terms for pesticide ingredients other than the stated pesticide active ingredient(s) were investigated. Some of these terms and their definitions (from the internet) are listed in the "glossary" below. The conclusion was that many different terms are used for these ingredients and, in many cases, there is no clear distinction between the various terms since one term often appears in the definition for another term (for example, excipient, inactive, inert, formulant). Thus, these ingredients are not named in the survey, rather an initial question was added to the survey asking for the term(s) used for these ingredients and how these terms are defined.

The survey begins with an explanation that the scope of the survey should be interpreted very broadly and includes any pesticide ingredient that is reviewed and/or regulated including products that are separate from the pesticide product but are *packaged with* the pesticide product.

"GLOSSARY" OF TERMS

Note: No claims are made that these are the "correct" definitions of the following terms. Rather, they were selected from various internet dictionaries and are provided to illustrate the wide variety of terms and definitions!

Co-formulant:
- Any substance other than the active ingredient that is intentionally added to a pesticide product
- A chemical within a pesticide formulation, other than the active ingredient.

Excipient:
- An inactive substance used as a carrier for the active ingredients. Excipients are also sometimes used to bulk up formulations that contain very potent active ingredients, to allow for convenient and accurate dosage. In addition to their use in the single-dosage quantity, excipients can be used in the manufacturing process to aid in the handling of the active substance concerned.
- A largely inert substance that is added to a formulation to improve administration or absorption.
- Any component of a finished dosage form other than the claimed therapeutic ingredient or ingredients.

Formulant
- Any inactive or inert substance added to a formulation (of pesticides, pharmaceuticals, etc).

Inactive:
- A usually inert substance that forms a vehicle (as for a drug or antigen); especially one that in the presence of sufficient liquid gives a medicated mixture the adhesive quality needed for the preparation of pills or tablets.
- A substance that is added to a formulation to provide benefits to the processing of the active ingredient.
- Any component of a finished dosage form other than the active ingredients.

Inert:
- Alternative term for inactive ingredient.
- Any substance, other than an active ingredient, which is intentionally included in any pesticide product.
- Product component that is not directly responsible for the primary function of that product. For example, an inert ingredient in a pesticide does not kill the pests.

Synergist:
- An agent that acts with or enhances the action of another
- Something (as a chemical) that enhances the effectiveness of an active agent

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QUESTIONNAIRE

SCOPE OF SURVEY:

The scope of this survey should be interpreted very broadly and includes any pesticide ingredient, other than the active ingredient(s), that is reviewed and/or regulated including products that are separate from the pesticide product but are packaged with the pesticide product. The first question asks that you provide the term(s) by which you refer to these ingredients as well as your definition of the term(s). In the remainder of the survey, if there are different answers to a question depending upon which type of ingredient is being referred to, please provide separate answers for each type of ingredient and clearly indicate to which type of ingredient the answer refers.

1) **Please list the term(s) by which you refer to pesticide ingredients other than the stated pesticide active ingredient(s). Include products that are separate from the pesticide product *but are packaged with* the pesticide product. Please provide your definition of each term.**

2) **Briefly describe how you regulate pesticide ingredients other than the stated pesticide active ingredient(s) and then answer the following specific questions as appropriate. [In particular, please explicitly state whether you regulate substances other than the active ingredient that are intentionally added to a pesticide; synergists (as a separate category of ingredients); and products that are separate from the pesticide product but are packaged with the pesticide product.]**

3) **Do you conduct assessments on:**
   - **a) individual pesticide ingredients other than pesticide active ingredient(s)**
   - **b) mixtures of pesticide ingredients other than pesticide active ingredient(s)**
   - **c) formulated (end-use) products**

4) **For *mixtures* of pesticide ingredients other than pesticide active ingredient(s):**
   - **a) Are the components assessed separately?**
   - **b) Is the mixture as a whole assessed?**
   - **c) Are their instances in which you do not know the components of the mixtures? If so, how is this situation handled?**

If you conduct assessments on individual pesticide ingredients other than the stated pesticide active ingredient(s):

5) Do you categorize pesticide ingredients other than the stated pesticide active ingredient(s) into food-use and non-food use categories?

6) Is the assessment based on hazard or exposure or a combination?

7) Do you consider human and ecological risk in your assessment?

8) Do you include non-pesticidal uses in your assessment?

9) Do you make your evaluations publicly available?

10) Do you have publicly available lists of approved pesticide ingredients other than the stated pesticide active ingredient(s)? If so, please describe and provide web address, if available.

11) Do you currently have or do you plan to conduct a re-assessment program for pesticide ingredients other than the stated pesticide active ingredient(s)?

Data used to conduct assessments:

12 a) Are there any *toxicity* data requirements for approval or registration of pesticide ingredients other than the stated pesticide active ingredient(s)? If so what are the required data?

b) Are there any *residue* data requirements for approval or registration of pesticide ingredients other than the stated pesticide active ingredient(s)? If so what are the required data?

13) What other *(toxicity, residue or other)* data/information do you use to conduct your assessment and which data are considered most important?

- **a. Publicly available data (scientific papers)?**
- **b. Regulatory documents such as from EPA, FDA and other countries?**
- **c. WHO, JEFCA type documents?**
- **d. Structure Activity Relationships (SAR)**
- **e. Other: please describe.**

14) What data protection/compensation legislation/policies do you have with respect to data for pesticide ingredients other than the stated pesticide active ingredient(s)?

Regulation of pesticide ingredients other than the stated pesticide active ingredient(s):

15) Do you require disclosure of pesticide ingredients other than the stated pesticide active ingredient(s) on the label; if so what is the requirement?

16) If you are concerned about the hazard, exposure, or risk of a pesticide ingredient other than the stated pesticide active ingredient(s), what regulatory action do you take? Do you put limitations on the amount of an ingredient that can be used in formulations?

17) Do you have any other regulatory requirements for pesticide ingredients other than the stated pesticide active ingredient(s)? Do you have any regulation related to the use of allergens, particularly in pesticide formulations applied to edible crops?

Future Plans:

18) Do you have any plans to change how you currently handle pesticide ingredients other than the stated pesticide active ingredient(s)? If so, please describe.

Possible Areas for Cooperation:

19) Do you have any recommendations on co-operative efforts that might be undertaken for review/regulation of pesticide ingredients other than the stated pesticide active ingredient(s)?

Confidentiality of Survey Information:

20) Do you consider the responses you have provided to this survey to be confidential information that needs to remain internal to OECD?