Environmental Protection Authority
Te Mana Rauhī Taiao

File Ref: ENQ-28195-L9H4H3

20 March 2015

John Small
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Dear Mr Small

Request for Official Information

Thank you for your request dated 22 February 2015, in which you requested information relating to pesticide safety in New Zealand. The Environmental Protection Authority (EPA) has treated your request as a request for information under section 12 of the Official Information Act 1982 (OIA).

We are only able to answer your request in part at this point in time due to the fact that the following question is too broad in scope:

If the answer differs across formulations, please separately identify any full formulations that have been safety tested?

We have set out our reasons for not being able to answer this question in Part 2 of our letter. We also invite you to narrow the question so we may be able to answer it more appropriately.

Part 1 – Our response

Please find the answers to the questions we are able to answer, below.

You asked:

> *When assessing the safety of pesticides does the EPA rely on:*
>
> a. *Safety testing of active ingredients,*
>
> b. *Safety testing of formulation components separately, or*
>
> c. *Safety testing of full formulations?*

The EPA relies on safety data in all these categories. The EPA considers the data in a hierarchical manner. EPA preference is for safety information on formulations (c). The combination of information from categories (a) and (b) is used when data for the formulation is not available, in which case mixture rules are used to assess the contribution of each component to the toxicity of the overall formulation. These mixture rules are published on the EPA website and the link to this publication has been provided to you in the email.

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The Hazardous Substances and New Organisms (HSNO) Act 1996 classifications for human health and ecotoxicity that are most relevant to pesticides are:

Toxicity

Acute toxicity 6.1 (for three routes of exposure: oral, dermal and inhalation)

Skin irritation/corrosion (6.3/8.2)

Eye irritation/corrosion (6.4/8.3)

Sensitisation (6.5)

Mutagenicity/Genotoxicity (6.6)

Carcinogenicity (6.7)

Reproductive/developmental toxicity (6.8)

Target organ systemic toxicity (6.9)

Ecotoxicity

Aquatic ecotoxicity (9.1) (for fish, crustacea and algae/plants)

Ecotoxicity to the soil environment (9.2)

Ecotoxicity to terrestrial vertebrates (9.3)

Ecotoxicity to terrestrial invertebrates (9.4) [includes bees]

The availability of information in these different categories (a, b and c, previous page) often differs between these classifications. Information about active ingredients is usually available for all these classifications. Formulation data will be available for some of these classifications, typically classification for 6.1 – 6.5, and may also be provided for the longer term ecotoxicity classifications (6.6- 6.9)

You asked:

What is the source of the information that the EPA relies on in this process?

The data provided for the EPA evaluation is usually generated overseas. Studies done in overseas laboratories are equally relevant in New Zealand and the repetition of studies, particularly those involving animals, cannot ethically be repeated in every jurisdiction for which approval is sought. There are international agreements relating to the mutual acceptance of data that have been developed, in particular by the OECD, which New Zealand supports.

Where field studies are involved, the studies the EPA reviews are usually done overseas, but the EPA may require information to justify the applicability of that data to New Zealand conditions (such as climate, soils). Food residue trials to satisfy the requirements of the Ministry for Primary Industries are usually carried out in New Zealand to reflect the local growing conditions.

You asked:

> *Does the EPA require studies to be conducted by persons financially independent of manufacturers? If independence is not required, does the EPA place a higher weight on independent studies?*

The EPA does not require studies to be conducted by persons financially independent of manufacturers. The studies are required to be conducted to good laboratory standards and in accordance with international test guidelines. This is considered to be sufficient to ensure the data are reliable. The studies are often conducted by contract research laboratories on behalf of the applicant/ manufacturer.

You asked:

> *Sellers recommend that separate adjuvants be added to increase effectiveness. Please explain how the EPA assesses risk in this situation?*

The impact of adjuvants (additives added to the diluted formulations prior to use) are not directly assessed by the EPA because these are "in use" preparations that are not packaged for sale or distribution. The spray mixture does not require a separate EPA evaluation or approval, as the mixing of the pesticide and the additives for use does not constitute manufacture of a new substance requiring a HSNO approval. The additives themselves, if they are hazardous, require a separate approval.

Part 2 – Narrowing your question

> You asked: *If the answer differs across formulations, please separately identify any full formulations that have been safety tested?*

As it currently stands, the broad scope of this question means it relates to a very large amount of information. To answer this question in full (if possible) would require searching through information relating to each application for plant protection products which the EPA (and its predecessor, the Environmental Risk Management Authority) has assessed since 2 July 2001 (the date when applications for hazardous substances under the Hazardous Substances and New Organisms Act 1996 were first able to be made). For example, approximately 350 applications for substances relevant to this request have been made since the beginning of 2008. Therefore, we would not be able to answer the question without significant collation or research, and if we were to undertake this, it may result in a cost to you.

We invite you to consider refining your request so that we can look into it further once the scope has been narrowed. I suggest refining your request by date and active ingredient if necessary and by classification – for example, you may be particularly interested in the Carcinogenicity (6.7) classification for full formulations. The EPA would normally receive formulation data for some of the relevant classifications when an application is received for a formulation containing a new active ingredient.

We have extended the time limit for this OIA by 20 working days from this letter's release date in order to allow you to refine your question.

Please reply to us with your response to these options within 20 working days of this letter. Accordingly, we have extended the time limit that would ordinarily apply to an OIA response, in order to accommodate our request that you narrow and refine your question. If we do not hear from you within this time, we will assume that this letter has satisfactorily answered your questions, and this OIA request will be closed.

You have a right to contact the Ombudsman if you have any complaints or concerns about our response to your request for information under the OIA. We hope this information is of assistance to you.

Yours sincerely

Johanne Spring
Acting General Manager
Applications and Assessment