Risk Assessment Methodology for Hazardous Substances

**How to assess the risk, cost and benefit of new hazardous substances for use in New Zealand**

January 2020

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# Executive Summary

All new hazardous substances, whether a formulated product or single chemical, need an approval before they can be manufactured in, or imported into New Zealand. This is required by New Zealand law, under the Hazardous Substances and New Organisms (HSNO) Act 1996.

The Environmental Protection Authority Te Mana Rauhī Taiao(EPA) processes and evaluates all applications for new hazardous substances. Each application must include an assessment of the hazards, risks, costs and benefits of using the substance in the New Zealand context. This assessment should include enough information so that we at the EPA can evaluate it, including a classification of the level of its hazard and a demonstrated understanding of its life cycle (where it would be released, where it would end up, how it would be disposed of). The risks of using the substance will be weighed against the benefits during our evaluation; these should be identified and information about the risks, in particular, should be supported by data and modelling.

This document is intended as a resource for applicants, and other interested parties, to show the type of information that we look for when we evaluate one of these applications when preparing our advice to decision makers. The main part of the document contains a step-by-step guide to assessing the hazards and risks posed by a hazardous substance, and advice on how to assess its benefits. The appendices provide additional technical detail on the models and are focussed on allowing applicants to conduct their own risk assessments.

This document is designed for a wide range of our customers and stakeholders, including applicants and their consultants. Sometimes we hold a public notification on a particular substance (meaning the public are consulted about a hazardous substance that is under consideration); members of the public may also find this document useful if they are interested in submitting a response to a public notification.

Lastly, please note that different substances may require different approaches to risk and benefit assessment and that this document is intended to provide only high-level guidance.

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Quality Assurance

**QA - Sign Off**

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1. Introduction
   1. Context

Hazardous substances surround us in our everyday lives. They are in our homes: in toiletries, cosmetics and cleaning products. Some hazardous substances help New Zealand’s economic sectors thrive. Our economy benefits from the chemicals used in manufacturing, for increasing productivity in farming, forestry and fishing, and for controlling new invasive pests that threaten our unique ecosystems. At the same time, some hazardous substances are harmful to humans and the environment if they are used in the wrong places, in the wrong amounts or with the wrong methods.

The Environmental Protection Authority Te Mana Rauhī Taiao (the EPA) regulates the use of hazardous substances in New Zealand, and processes applications for the approval to import and manufacture new hazardous substances in this country. This is required by New Zealand law, under the Hazardous Substances and New Organisms (HSNO) Act 1996.

A thorough assessment of the ‘positive effects’[[1]](#footnote-2) (or benefits) and the ‘adverse effects’ (or risks and costs) of using the new hazardous substance is a crucial part of the application process. This assessment helps us at the EPA decide whether a new hazardous substance will be safe to use with appropriate restrictions (or ‘controls’) and whether it can be approved for use in New Zealand.

When the application for the new hazardous substance is made, the applicant is expected to supply an assessment of the risks, costs and benefits. The applicant is best-placed to collect this information, as they have the best knowledge about the advantages of making their product available in New Zealand, and they should be aware of the associated risks of their hazardous substance, whether it is a formulated product or single chemical. For this reason, we recommend that applicants make their own assessment. This assessment should be supported by evidence and be appropriate to the level of hazard associated with the substance and the resulting risk.

Where needed, the applicant’s assessment may be further supplemented by EPA fact-finding, analysis and modelling while the application is being evaluated. Sometimes interested parties or the general public are also notified about the application before it is approved, and are given the opportunity to submit further information.

All of this information and analysis about the substance – from the applicant, from the EPA assessment, and from the notified parties – are considered together when deciding whether to approve the importation or manufacture of a new hazardous substance in New Zealand, or not.

* 1. Purpose

This document shows how we at the EPA recommends assessing a new hazardous substance, from a high-level framework approach, to considering the risks, cost and benefits, through to the models we use and detail about general and New Zealand-specific parameters for these models.

We have created this document for the following reasons:

1. So that applicants, their consultants and the public have an understanding of the sort of analysis and information that we are looking for when we receive and evaluate these applications. Receiving consistent and comprehensive information to support applications at the outset will help us process them more efficiently. Applications can be declined if they are submitted with insufficient supporting information. We want to encourage applicants to provide a complete and comprehensive application.
2. To ensure that our current approach for assessing and evaluating the risks, costs and benefits of new hazardous substances is shared in the public domain, and we are open about which models and parameters that we use for this sort of work at present.
3. As a resource, to help applicants assess the risks, costs and benefits of new substances themselves, during product development, to support their applications to import or manufacture new hazardous substances. Note, applicants are also free to use other evidence and modelling approaches to support their applications.

If you are unsure about whether this document is for you, for example, if you do not know if your new substance is hazardous, or if it is already covered by an existing approval for manufacture and import, you can apply to the EPA to find out. This is, called a ‘*Section 26 Determination*’ to find out. You will be charged a fee for this service.

[For more information on our website about applying for a *Section 26 Formal Determination*, to find out if your substance is hazardous, or an existing approval is relevant](https://www.epa.govt.nz/industry-areas/hazardous-substances/making-an-application/section-26-formal-determination/)

* 1. The role of the risk assessment

During a risk assessment, a wide range of possible outcomes of an activity are identified (in this case, the exposure of people and the environment to a substance, if an application is approved) to determine what might happen and how. Although we call it a ‘risk assessment’ here, it is important to remember that in this context this analysis includes the assessment of risks, costs, and benefits.

Risks, costs and benefits are assessed by estimating the extent of the possible effects and the likelihood of their occurrence. Our recommended approach involves a number of steps, including a tiered approach to the risk assessment and modelling, followed by benefit and costs assessments. Each of these steps plays an important part in managing the risk of approving a hazardous substance for use in New Zealand.

Once the risks are understood, we assign suitable controls (for example, how the substance can be used, who it is available to, storage requirements and environmental limits). This allows the risks to be minimised. If we are not satisfied that suitable controls are available, including appropriate workplace controls under health and safety at work legislation, or that the residual risk or effects would outweigh the benefits, then the application to import or manufacture the hazardous substance is not approved.

In addition, and unique to New Zealand, the cultural perspective of Māori is considered as part of evaluating an application to manufacture or import a hazardous substance, and this will be discussed within this document. All applications under the HSNO Act must take the Tiriti o Waitangi (the Treaty of Waitangi) into account, so all applications must take Māori perspectives of the risks and benefits into account. Additionally, the guidance documents *‘He Whetu Mārama’* (EPA, 2015a, b), ‘*Incorporating Māori perspectives into decision making*’ (EPA, 2016a), *‘Māori Impact Assessment Tool’* (EPA, *in prep*), and ‘*The EPA’s mātauranga framework*’ (EPA, *in prep*), explain how the positive and adverse effects on Māori culture and traditions are taken into consideration. Note that the requirements of Part 2 of the HSNO Act also require persons exercising functions and powers to consider other aspects.

[For more information on our website about our work to incorporate Māori perspectives](https://www.epa.govt.nz/applications-and-permits/engaging-with-maori/incorporating-maori-perspectives/)

[To download a copy of *Incorporating Māori perspectives into decision making*](https://www.epa.govt.nz/assets/Uploads/Documents/Te-Hautu/EPA-Maori-Perspectives.pdf)

* 1. Using this document: a flexible approach

This document is intended to be used flexibly, depending on the circumstances. Each individual substance needs an assessment which is tailored for its proposed use and to its type of hazard. So the approach used to assess the benefits, cost and risk for one substance may be different to another.

For instance, more information and assessment would be needed to support applications for hazardous substances that contain ingredients that are completely new to New Zealand, that are being used in a new way, or where significant new risks are identified for existing substances. Conversely, less work may be needed to complete an assessment to support an approval for an already-approved substance that was since reformulated and is now made with less hazardous components. So this document provides high-level guidance and a suggested framework to help applicants perform these different types of assessment consistently.

The document steps you through the sort of information that we need to evaluate an application and to recommend whether a substance can be approved, or not. The information we need includes:

* A proposed hazard classification for the substance, with a justification for setting it at this level. In New Zealand, hazardous substances are classified under the HSNO Classification system, which is based on an international system. See **section 2** for more information about this, and about identifying and classifying hazards.
* A demonstrated understanding of the substance’s life cycle, that is when, where and how people and the environment might be exposed to the substance during its manufacture, import, transport, storage and disposal. There is more about this in **section 3.1**.
* An analysis of the risk posed by the substance, based on its hazardous properties, its lifecycle, and how it might come into contact with people and the environment. We recommend a tiered approach to analysing this. If it is appropriate, your application could be supported by a qualitative risk assessment, as detailed in **section 3.2**. If a qualitative risk assessment is not enough to fully understand the risks, or is unable to constrain the restrictions (or ‘controls’) when using a substance, then quantitative modelling should be carried out. **Section 3.3** discusses the quantitative models that we use at the EPA and talks about modelling approaches generally. Whichever approach is taken, you must justify the type of models that were used in this sort of assessment, and the parameters used in the modelling. If models and parameters were changed or adapted to be different from industry standards, or completely different models were used, you must explain why this approach was taken. Technical details about the models we use are included in the **Appendices**.
* The information supplied about the risk assessment should reflect the restrictions, or ‘controls’ that would be placed on the substance during use. For more information about controls, see **section 4**.
* An important part of evaluating and considering the approval of a new hazardous substance includes identifying the benefits. These are often overshadowed by the assessment of the risk, but are equally important to include as they are considered during the decision on an application. Sometimes, EPA’s Senior Leadership initiates a reassessment of an existing substance and when this happens, we seek comments from the public and industry, as part of a call for information, to better understand the benefits of that substance. **Section 5** includes tools for assessing the benefits of a hazardous substance.

Lastly, **section 6** describes how the decision on an application is made, and who makes it, with some more information about how the evidence is weighed up. If you follow the risk assessment approach outlined in this document, and supply this information to us at the EPA when you apply for approval for a hazardous substance in New Zealand, your application is more likely to be complete, consistent, clearer for us to evaluate, and processed in a timely manner.

It is assumed that users of this document already have a reasonably good knowledge about the process of applying for approval for new hazardous substances in New Zealand. If you need more information about this, please see our website:

[For general information on our website about the steps involved in making an application](https://www.epa.govt.nz/industry-areas/hazardous-substances/making-an-application/what-is-the-process/)

Note also, there are different types of applications for hazardous substances whose risk assessments would be assisted by the approach described this document:

* [For ‘Release applications’, the general application to import or manufacture a hazardous substance](https://www.epa.govt.nz/industry-areas/hazardous-substances/making-an-application/release-approvals/) (this is different from a ‘Containment approval’, which is assessed against the different requirements in the HSNO Act 1996)
* [To apply for a reassessment or amendment to a previous hazardous substance approval](https://www.epa.govt.nz/industry-areas/hazardous-substances/reassessments-and-reviews/applying-for-a-reassessment-or-review/)
* [For approvals under emergency situations](https://www.epa.govt.nz/industry-areas/hazardous-substances/making-an-application/emergency-approvals/)
  1. Future updates

Lastly, this document contains our current approach for assessing and evaluating the risks, costs and benefits of new hazardous substances in New Zealand, and it is intended to be a living document.

Note that this documents sets out our current approach and that this approach will be revisited in the future. We are aware that some of the quantitative models that we use are hard to access, and that in some cases newer models are now available. At the time of writing, we are actively reviewing our quantitative models, starting with our approach to groundwater and the water environment, which will also consider the regulatory contexts of the various models and how they interact with each other.

In the future, we plan to make details of the latest updates and which models and parameters we use available on our website. From time-to-time, we will update this document to ensure it includes the most recent information.

* 1. Glossary

A glossary of terms, acronyms and abbreviations is included in Appendix A.

1. Hazard identification: how hazardous is the substance?

The first step towards assessing the risk posed by a substance is understanding how hazardous it is, and by classifying the level of hazard. This section explains the hazard classification system that is used in New Zealand, and describes robust approaches to classifying materials accurately. Materials that are not covered by this system are listed at the end of the section.

* 1. The New Zealand hazard classification system

Hazard classification systems are used around the world to consistently identify the potential impacts that could result from the physical and chemical properties of a substance, including the acute (short‑term) and chronic (long-term) impacts on human health and the environment. They classify different sorts of hazards into classes, which have levels of severity within them.

The system used in New Zealand was introduced under the HSNO Act 1996, and is described in the Hazardous Substances (Classification) Notice 2017. The thresholds and classification categories in New Zealand reflect international discussions to make chemical management consistent across the world, and this system is based on international discussions during the development of the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2003, no date-a, no date-b).

The New Zealand system has the following classes:

* Class 1 – explosiveness
* Class 2 – flammability (gases)
* Class 3 – flammability (liquids)
* Class 4 – flammability (solids)
* Class 5 – capacity to oxidise
* Class 6 – toxicity
* Class 8[[2]](#footnote-3) – corrosiveness
* Class 9 – ecotoxicity.

Each of these classes is divided into numbered sub-classes that define a level of hazard (for example, 6.1 for acute toxicity). Each of these sub-classes contains lettered categories that indicate the degree of hazard, where ‘A’ is the most hazardous (for example, a classification of ‘6.1A’ for substances that are acutely toxic – fatal), whereas classifications of 6.1B, 6.1C and 6.1D have decreasing levels of hazard. Note that classifications 6.1E, 6.5B, and 6.8C represent (or can represent in the case of 6.1E) a different hazard sub-class rather than lower degrees of hazard.

The thresholds for these different subclasses and categories are set out in the Hazardous Substances (Minimum Degrees of Hazard) Notice 2017. A substance is defined as a ‘hazardous substance’ (unless other regulations or notices state otherwise), when it has a level of hazard greater than the threshold(s) for one or more of the sub-classes.

If none of the thresholds, or related definitions, in these notices or regulations are met, then the substance is not defined as hazardous under this system. If a substance does not meet the threshold(s) or definitions for any of the eight classes then it is ‘non-hazardous’ and does not need an approval to be manufactured or imported under the HSNO Act 1996.

Applicants are expected to classify the hazard level of their substances appropriately as a part of their risk assessment, when applying for approval to manufacture or import a new hazardous substance in New Zealand. We will check the classification is correct when your application is evaluated.

**Note:** we intend to move to a published version of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) in future. We will make further announcements on our website in due course.

[See our information sheet showing the correlation between the GHS and the New Zealand classification system](https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Guidance/08115c3875/Correlation-between-GHS-and-New-Zealand-HSNO-Hazard-Classes-and-Categories.pdf)

* 1. How to classify the substance

Two widely-accepted approaches to collecting the evidence to support the hazard classification of a substance are outlined in this section. It is preferable to include data from scientific studies to support a classification, particularly for new active ingredients. If data are not available for a new active ingredient, or a new substance containing one, then we may not have enough information to evaluate the application and may not approve the substance.

If data from scientific studies are not available for the hazardous substance, but there is sufficient information available on its components, a method called ‘mixture rules’ can be used to combine the hazards of each component to obtain a hazard classification for the substance.

Other approaches include in-silico modelling results, reading-across from existing similar hazardous substances and professional judgement. Although not discussed in this document, more information about these can be found in *‘Thresholds and Classifications under the Hazardous Substances and New Organisms Act 1996: User guide’* (EPA, 2012).

2.2.1 Classification using data from scientific studies

Our preferred approach for classifying hazardous substances is to use product data; that is, material properties relating to the hazard which are found during experimental studies on the formulated product. Some classifications can be assigned from the physical and chemical properties of a product, such as pH and flashpoint, and it is expected that these tests will be carried out as standard. For new active ingredients, the results from a variety of studies are expected to be submitted with an application.

To help applicants gather and submit a suitable data package with their application, the guidance document ‘*Data Requirements Checklist and File Index for HS Applications’* (EPA, 2016b) lists the studies that are needed and those we would expect to see as part of an application. Where a suitable standard or guideline exists for a test, the most up-to-date version should be followed. When studies have been conducted with other test methods, reports of these studies must also be provided. These studies should be performed according to Good Laboratory Practice (GLP). Non-GLP studies will be evaluated on a case-by-case basis.

In some circumstances, an applicant might not be the owner of the required study data. In this situation, the data might still be used if the original studies have already been reviewed or provided, or letters of access to the data are provided, as long as the protection of confidential information requirements of the Agricultural Compounds and Veterinary Medicines Act 1997 or Medicines Act 1981 are followed, where relevant. Studies published in peer-reviewed journals may also be considered if the investigation methodology and results are clear, transparent and applicable to the way a hazardous substance is intended to be used.

If a hazardous substance, active ingredient or new component was reviewed and approved by a regulator in another country (for example, the [Australian Pesticides and Veterinary Medicines Authority](http://www.google.co.nz/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwj1xrTG6erSAhWKUbwKHeQ1Dy4QFggYMAA&url=http%3A%2F%2Fapvma.gov.au%2F&usg=AFQjCNGKmyLEdPBX2aJBmMyeJpD07NS7ng), APVMA) then we will consider the relevant documents as part of the evaluation. All of the relevant regulatory reviews must be provided, along with the original studies (or a letter of access to them) submitted to these overseas regulators. This information will help reduce the time taken to evaluate a particular hazardous substance and will improve consistency across different international markets.

More information about the type of studies required can be found in the data requirements section of our website (EPA, 2016b, 2018a). The *‘Thresholds and Classifications under the Hazardous Substances and New Organisms Act 1996: User guide’* (EPA, 2012) describes how study data are used to classify the different hazard classes, subclasses and categories.

We expect that the most-up-to-date information to be used when classifying (and assessing the risks of) a substance. Suitable sources for information to be used in hazard identification and risk assessments are provided in existing EPA documents (EPA, 2012, 2014). We do not prioritise one source of information over another.

2.2.2 Classification by mixture rules

When the formulated product was not studied scientifically and there are no data available on the formulation, it might be possible to classify the substance based on the data available on individual components. A series of ‘mixture rules’ is used to assign the product’s classifications based on those of its components and how much of each is present.

To achieve an accurate assessment of the class of hazard using these mixture rules, a knowledge of the full composition of the product is needed. Different hazard sub-classes use different mixture rules, and more information about this is available in *‘Thresholds and Classifications under the Hazardous Substances and New Organisms Act 1996: User guide’* (EPA, 2012) and the guidance document *‘Assigning a Product to a HSNO Approval’* (EPA, 2014).

* 1. Exceptions

There are several groups of substances that are exempt or excluded from the HSNO Act 1996, and further exemptions for substances that are hazardous if they are only going to be used in certain types of laboratory’[[3]](#footnote-4).

The application process and type of risk assessment described in this document does not apply to these substances and circumstances, although some of them may need to follow a different approval process for manufacture or import, if they are covered by different regulations that are administered by other New Zealand agencies.

These substances include:

* radioactive materials, unless they also have other hazardous properties – radiation safety is managed by the Ministry of Health[[4]](#footnote-5)
* medicines intended for human use, except for some special circumstances (and except for the ingredients in medicines, which are covered by the HSNO Act) – medicines are also regulated by the Ministry of Health[[5]](#footnote-6)
* ready-to-eat food[[6]](#footnote-7) (except for food additives, which are included in the HSNO Act)
* infectious substances, unless they also have other hazardous properties – the movement of infectious substances is managed by transport rules[[7]](#footnote-8)
* substances that are being used only in certain laboratory facilities (this excludes persistent organic pollutants, which need approval even if they are being used only in an exempt laboratory)
* psychoactive substances
* non-hazardous substances.

[More information about exempt substances and laboratories is available on our website](https://www.epa.govt.nz/industry-areas/hazardous-substances/rules-for-hazardous-substances/exempt-substances-and-laboratories/)

* 1. Can an existing approval apply?

If the new substance has identical hazards to an approved substance or group of substances, a similar composition, and will be used in the same way, under the HSNO Act 1996, importers or manufacturers can assign their formulated product to an existing individual hazardous substance approval or a group standard approval. This means they don’t have to go through the full application process.

In this case, applicants must classify their product according to its hazards and show that these hazards match those of an existing group standard. They must record their decision with justifications, even when they consider it to be non-hazardous, and supply this record to the appropriate regulators when requested. The controls (or restrictions) assigned for the use of the new hazardous substance in New Zealand, must be the same as the group standard the new substance is being matched to. In the case where an applicant matches their substance to an existing approved substance, they should follow this approach to be able to easily demonstrate to the EPA that the assignment is correct when we are using our powers to check that substances have a valid approval.

Further information on self-classifying and self-assigning can be found in our guidance document *‘Assigning a Product to a HSNO Approval’* (EPA, 2014). More information on controls can be found in section 4.

* 1. For help classifying your substance

Data and information about known substances, which may help with the hazard classification of your substance, is available in the following New Zealand databases:

* Chemical Classification and Information database ([CCID](https://www.epa.govt.nz/database-search/chemical-classification-and-informatihttps:/www.epa.govt.nz/database-search/chemical-classification-and-information-database-ccid/on-database-ccid/))
* New Zealand Inventory of Chemicals ([NZIOC](https://www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/)).

You are also welcome to use other international databases.

If you are unsure whether your new substance is hazardous, or would like us at the EPA to carry out this step, you can apply for an investigation into this, called a ‘Section 26 Formal Determination’. You will be charged a fee for this service.

[For more information about applying for a Section 26 Formal Determination to find out if your substance is hazardous](https://www.epa.govt.nz/industry-areas/hazardous-substances/making-an-application/section-26-formal-determination/)

* 1. Information confidentiality

Note that when supplying confidential or commercially-sensitive information, you have legal rights to data confidentiality. At the same time, as a government organisation, we must follow the rules for holding and sharing information under the Official Information Act 1982; New Zealand law allows any New Zealand citizen, resident, or company to ask to see or be given a copy of the information that we hold.

We understand that this might cause you concern about sharing your information with us. However, the law does allow for certain situations where information will be protected from being released to the public or to a specific person making a request under the OIA. This is stated in more than one piece of legislation for specific situations. For more information about your rights, see our guide:

[Supplying confidential information to the EPA: your rights and our obligations](https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Guidance/88d0ce39e6/Supplying-confidential-information-to-the-EPA-your-rights-and-our-obligations.pdf)

1. Analysing the risk

This section describes the approach that we recommend for analysing, or assessing, the risk resulting from the use of a hazardous substance. It begins at a high-level, recommending applicants first consider the life cycle and exposure paths of the substance, before discussing qualitative and quantitative approaches to modelling and understanding the risk.

Identifying the hazards from a substance is the first step to analysing the risks. There may be times when a qualitative or quantitative risk assessment is appropriate, even where a particular HSNO classification is not triggered; for example, a classification may be concerned with acute risks but there is information available from the required studies that suggest chronic risks need assessing, or at least reviewing. This may also be the case when the conceptual understanding of how a hazardous substance behaves means that a risk assessment is appropriate even if the relevant HSNO classifications are not triggered.

Where an evaluation includes the use of a substance in a workplace, we consult Worksafe New Zealand for their input and contribution on the risks and appropriate control measures required. As discussed in section 4.2, workplace controls are now largely set in the Health and Safety at Work (Hazardous Substances) Regulations.

* 1. Problem definition: understanding exposure paths during the life cycle of the substance

Once the type of hazard posed by your substance is understood, the next step towards assessing the risk is to think about when, where and how people and the environment could be exposed to that hazard.

We recommend starting this analysis from the straightforward concept that there are three parts to analysing the risk from hazardous substances: the source of the hazardous substance, the pathways where things can be exposed to the substance, and the ‘receptor’. In this document, we define the receptor as the people or part of the environment that could be exposed to the substance.

Pathways of exposure to the hazardous substance

A risk to people or the environment occurs if all three are connected and there is enough of the substance to cause an adverse effect. If they aren’t connected, a source of the hazardous substance, a pathway and a receptor in a location can exist without harm. It is important to consider all of these three elements: source, pathway and receptor, while assessing the risk of using that substance.

In some complex or long-term situations involving people, particularly where the (suspected) effect of a hazardous substance is on a particular human organ or where cumulative risks are considered, then the conceptual understanding might be better represented by five elements: the source, how it moves through different parts of the environment (such as, through soil, water, groundwater, air)[[8]](#footnote-9), receptors, points of exposure to people (for example, whether at home, school), and lastly, exposure routes – or how it gets into the body (such as eating, drinking[[9]](#footnote-10), absorption through skin). When five elements are being considered in a conceptual model then all five must be present for there to be a risk.

Points of human exposure

Pathways through the environment

It is likely, of course, that there is more than one pathway through which a substance in a location could reach people or the environment, whether directly or indirectly. A single hazardous substance could be distributed into the environment in many ways. For example, a hazardous substance in a treated seed coating might be taken up by the plant in a form that could be available for insects feeding on any subsequent pollen. As another example, the droplets of a hazardous substance sprayed from an aircraft can move away from the target area: the substance might land on plants and animals outside the area meant to be treated or in water courses, or they could get into the water after running off from the intended area.

A single type of hazardous substance may have multiple options for how it is used. For example, pesticides and herbicides are sprayed from planes, helicopters, farm booms, from all-terrain vehicles, backpacks and hand held spray bottles, as well as painted on, or injected into, plants. Each of these methods will change how much of the hazardous substance ends up on the plants, and how much ends up in the wider environment.

Ultimately, a robust risk assessment relies on developing conceptual models to anticipate the effect of releasing the hazardous substance. An example of this sort of conceptual model from the Queensland Government Environment Protection Agency is shown in Figure 1.



Figure 1 Example conceptual model (OzCoasts, 2015)

Hazardous substances are used all over New Zealand. In most cases, this means that the conceptual model has to be broad and generic. For example, the environmental setting, such as the soil type and local water environment, can influence how the substance moves through the environment. It also influences the exposure pathways by which receptors could become vulnerable to the hazardous substance. Models of this type can become complex. This is why we have produced this document, to make some of the models and parameters that we use available for this sort of analysis. For example, rather than carrying out an assessment for every location, we use a single default soil type to allow one assessment to cover all of New Zealand. We give more information about this in the sections on modelling below and in the appendices.

The nature of the hazardous substance (its physical and chemical properties, how it behaves in and moves through the environment[[10]](#footnote-11), and its toxicity to people and a variety of environmental receptors) is key to determining: the likelihood of receptors being exposed to the substance and the potential risk of that exposure.

The risk assessment should cover the substance’s whole life cycle: including the manufacture (if it is in New Zealand), transport (including import), storage, use, and disposal. This is required in New Zealand law, under the HSNO Act 1996.

This way of developing an understanding of the concepts to assess risk is well-established in the contaminated-land sector and further information on developing this sort of conceptual model, and revising it when further information becomes available, is available in Contaminated Land Management Guideline 5 (Ministry for the Environment, 2016).

Risk (and benefit) assessments are conducted in a phased manner, increasing in complexity. If the risks of a substance cannot be discounted at an early stage (a lower tier approach) then a more detailed assessment, with more intensive data and more complex modelling requirements (a higher tier approach), might be needed to improve the understanding of the risks.

A qualitative assessment is an example of a lower tier approach, whereas a quantitative assessment is more likely to include a higher tier approach. In the next sections, we discuss approaches to qualitative and quantitative modelling for hazardous substance risk assessment, and the context for using them.

* 1. Qualitative assessment

If a new hazardous substance’s life cycle and the hazards it poses is understood to be close to that of an existing substance, it may be possible to describe the similarities and differences in a qualitative risk assessment. A qualitative risk assessment may also be useful when working out which exposure pathways need a more detailed quantitative risk assessment or when a suitable quantitative model for a particular pathway is not available.

Qualitative assessments build on the understanding of a hazardous substance’s life cycle, as was described in section 3.2 above. These types of assessment use this understanding to describe, in words, the exposure pathways that link the source of the hazardous substance (generally during its use) with the receptors, and the level of resulting risk expected. They take into account the magnitude of the resulting adverse effect and the likelihood of it occurring.

In addition to the scientific assessment and unique to New Zealand, the impacts of hazardous substances on Māori culture and traditions are also considered in the assessment and evaluation of hazardous substances applications. This assessment considers the hazards of the substance and the potential to affect, amongst other things, various taonga, or species treasured by Māori. Please see the guidance documents *‘He Whetu Mārama’* (EPA, 2015a, b), ‘*Incorporating Māori perspectives into decision making*’ (EPA, 2016a), *‘Māori Impact Assessment Tool’* (EPA, *in prep*), and ‘*The EPA’s mātauranga framework*’ (EPA, *in prep*) for more information.

[For more information on our website about our work to incorporate Māori perspectives](https://www.epa.govt.nz/applications-and-permits/engaging-with-maori/incorporating-maori-perspectives/)

The benefits of a new hazardous substance can be described in words or summarised in monetary terms. A qualitative benefit assessment describes the positive effects of the new substance in words rather than using an estimated dollar value. The benefits to Māori also must be considered. Section 5 below contains further discussion on benefit assessments.

The HSNO Act 1996 allows controls, or restrictions, to be set to reduce or adequately manage risks from hazardous substances. Qualitative assessments may also be used to consider the residual risks (after setting or varying controls) for different exposure pathways, assuming that these controls are appropriate and are practical for compliance. This approach can be useful to indicate the balance between the residual risks and benefits of a hazardous substance, after recommended controls, to decision makers.

3.2.1 Qualitative descriptors: standard language to use in a qualitative risk assessment

As mentioned above, a qualitative risk assessment explains in words how the substance might impact people or the environment. The language used must be consistent for this sort of risk assessment, and be clear enough that qualitative risk assessments accompanying applications can be understood and assessed. In this section, some standard examples of the sort of language and description we would expect to see in this sort of risk assessment are given, to help applicants.

In a qualitative risk assessment, it is helpful to remember that the level of risk (or benefit) that a hazardous substance poses is a combination of:

* the **magnitude** of the possible effects, and
* the **likelihood** of that effect occurring.

**The magnitude** is described in terms of how the substance affects several areas of impact (for example: public health, environment, economy or community). In Table 1 and Table 2, descriptors for the size of adverse and positive effects are shown as examples. Their generic nature means that it might be difficult to use them in all circumstances, but they are included here to help illustrate how qualitative tables may be used to represent levels of adverse and positive effects. These qualitative descriptors are measures that should be used to gauge the end effect, or a ‘what if’ aspect.

Table 1 Adverse effect qualitative descriptors

| **Descriptor** | **Criteria** | **Examples of descriptions** |
| --- | --- | --- |
| Minimal | Reversibility  Severity  Extent | Mild reversible short-term adverse health effects to individuals in highly localised area  Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact  Local/regional short-term adverse economic effects on small organisations (businesses, individuals), temporary job losses  No social disruption |
| Minor | Mild reversible short-term adverse health effects to identified and isolated groups  Localised and contained reversible environmental impact, some local plant or animal communities temporarily damaged, no discernible ecosystem impact or species damage  Regional adverse economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job losses  Potential social disruption (community placed on alert) |
| Moderate | Minor irreversible health effects to individuals and/or reversible medium-term adverse health effects to larger (but surrounding) community (requiring hospitalisation)  Measurable long-term damage to local plant and animal communities, but no obvious spread beyond defined boundaries, medium-term individual ecosystem damage, no species damage  Medium-term (one to five years) regional adverse economic effects with some national implications, medium term job losses  Some social disruption (for example, people delayed) |
| Major | Significant irreversible adverse health effects affecting individuals and requiring hospitalisation and/or reversible adverse health effects reaching beyond the immediate community  Long-term/irreversible damage to localised ecosystem but no species loss  Measurable adverse effect on GDP, some long-term (more than five years) job losses  Social disruption to surrounding community, including some evacuations |
| Massive | Significant irreversible adverse health effects reaching beyond the immediate community and/or deaths  Extensive irreversible ecosystem damage, including species loss  Significant on-going adverse effect on GDP, long-term job losses on a national basis  Major social disruption with entire surrounding area evacuated and impacts on wider community |

(From ERMA, 2009)

Table 2 Positive effect qualitative descriptors

|  |  |  |
| --- | --- | --- |
| **Descriptor** | **Criteria** | **Examples of descriptions** |
| Minimal | Reversibility  y  Size of benefit  Extent | Mild short term positive health effects to individuals in highly localised area  Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact  Local/regional short-term beneficial economic effects on small organisations (businesses, individuals), temporary job creation  No social effect |
| Minor | Mild short-term beneficial health effects to identified and isolated groups  Localised and contained beneficial environmental impact, no discernible ecosystem impact  Regional beneficial economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job creation  Minor localised community benefit |
| Moderate | Minor health benefits to individuals and/or medium term health impacts on larger (but surrounding) community and health status groups  Measurable benefit to localised plant and animal communities expected to pertain to medium-term  Medium-term (one to five years) regional beneficial economic effects with some national implications, medium-term job creation  Local community and some individuals beyond immediate community receive social benefit |
| Major | Significant beneficial health effects to localised community and specific groups in wider community  Long-term benefit to localised ecosystem(s)  Measurable beneficial effect on GDP, some long-term (more than five years) job creation  Substantial social benefit to surrounding community, and individuals in wider community |
| Massive | Significant long-term beneficial health effects to the wider community  Long-term, widespread benefits to species and/or ecosystems  Significant on-going effect beneficial on GDP, long-term job creation on a national basis  Major social benefit affecting wider community |

(From ERMA, 2009)

When considering and assessing **the likelihood** qualitatively, the standard way to do this is to estimate the likelihood of the end effect – this means working out how likely it is that the hazardous substance reaches the receptors: people or the environment. This involves thinking about the likelihood of all steps in the three- or five-step models that were discussed at the beginning of section 3.1. So, when consideringthe likelihood for a qualitative risk assessment, we mean the likelihood of the end result, and not the likelihood of a single, earlier event alone (such as the likelihood of a spill or the likelihood of which pathway the substances travel along).

The likelihood of an event is not, for example, the frequency of accidents involving trucks transporting hazardous substances; it would be the likelihood of a specific effect, such as a large fish kill resulting from a truck accident. The best way to determine the likelihood is to think about the complete pathway from source to impact.

There are a few ways to describe ‘likelihood’ of an event occurring, including:

* How often an event occurs (its frequency), such as the number of times a year it happens or how many people are affected for every 1,000 members of the population.
* The chance, or probability, of the event occurring (expressed as a number between 0 and 1 or 0 and 100%).
* Qualitatively, using words such as ‘highly likely’, ‘likely’ and ‘improbable’.

When words are used to describe likelihood, the experiences of the reader can influence how they interpret that description, even if tables are provided to explain how the words translate to, for example, a probability (Teigen, 2014; Budescu, et al. 2014). To clarify and improve how ‘likelihood’ is understood for hazardous substances assessments, we now use the verbal-numerical descriptors in Table 3 to combine both word and percentage descriptions. The cut-offs between these verbal-numerical descriptors are based on Budescu et al. (2014) and EFSA (2016, 2017).

Table 3 Likelihood qualitative descriptors

|  |  |
| --- | --- |
| Descriptor | Description |
| Improbable (< 1%) | Considered to occur only in very rare circumstances |
| Very unlikely (< 10%) | Considered to occur only in very unusual circumstances |
| Unlikely (< 33%) | Could occur but is not expected to occur under normal operating conditions |
| As likely as not (33 – 66%) | Might or might not occur depending on conditions |
| Likely (> 66%) | Good chance that it might occur under normal operating conditions |
| Very likely (> 90%) | Almost certain or expected to occur if all conditions met |

Using these magnitude and likelihood tables, a matrix representing a level of risk or benefit can be constructed (see Table 4). The four levels of risk and benefit were chosen to avoid confusion with the descriptors used for likelihood and magnitude. The HSNO Act (and delegated legislation under it) leads to a different approach depending on whether the risks are ‘negligible’ or ‘non-negligible’. In the matrix below, ‘low’, ‘medium’ and ‘high’ risks are defined as non-negligible. For non-negligible risks, the benefits of a substance must outweigh those risks to get an approval to manufacture or import the substance in New Zealand.

For adverse effects, the levels are used to show how risks can be reduced by the application of additional controls, or restrictions on use (we explain more about this later in this document). Where the table is used for positive effects it might also be possible for controls to be applied to ensure that a particular level of benefit is achieved, but this is not a common approach.

The purpose of developing similar tables for both risk and benefit is so that the risks and benefits can be compared.

Table 4 Risk and benefit matrix

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Likelihood | Magnitude of effect (positive or adverse) | | | | |
| Minimal | Minor | Moderate | Major | Massive |
| Very likely (> 90%) | Low 1 | Medium | Medium | High | High |
| Likely (> 66%) | Low 1 | Low 1 | Medium | Medium | High |
| As likely as not (33 – 66%) | Negligible | Low 1 | Low 1 | Medium | Medium |
| Unlikely (< 33%) | Negligible | Negligible | Low 1 | Low 1 | Medium |
| Very unlikely (< 10%) | Negligible | Negligible | Negligible | Low 1 | Low 1 |
| Improbable (< 1%) | Negligible | Negligible | Negligible | Negligible | Low 1 |

1. A low risk is non-negligible and the benefits of an application must outweigh the risks

3.2.2 Rapid applications

The HSNO Act allows for the EPA to choose to process new applications via a quicker route where certain criteria are met. This is a discretionary activity and we, the EPA, may choose to not follow this “rapid assessment”, and will decide whether to use it or not on a case-by-case basis. The criteria for a “rapid assessment” are when a substance has:

* a similar composition and similar hazardous properties to an already approved substance
* been formulated to have a lesser degree of hazard than an already approved substance
* the lowest degree of hazard for each sub-class triggered (see section 2).

We would normally expect a substance going through the rapid assessment process to have the same active ingredient and the same proposed use pattern as the already approved substance used as a reference.

In these cases, the EPA is evaluating the adverse effects of a substance in comparison to hazardous substances already approved in New Zealand.

* 1. Quantitative assessment

A quantitative assessment is needed for situations where a qualitative assessment is not certain enough, cannot accurately describe the risks posed by a hazardous substance or where greater certainty is required, or cannot identify suitable controls (or restrictions) to manage the risks. (We discuss controls later in this document.) Quantitative risk assessments are usual when we are considering new active ingredients used in agricultural products, or when we initiate a review of existing hazardous substances.

3.3.1 Quantitative models used by the EPA

Hazardous substances are used in a wide variety of settings: around the home, in manufacturing, in and around commercial buildings, in forests, in horticulture and in agriculture. The characteristics of the New Zealand landscape and climate means that there is a wide range of environmental circumstances that affect how a hazardous substance moves through soils and into watercourses and groundwater.

To make it easier to assess the risks from hazardous substances, where possible we use quantitative models that are scientifically robust, easy to use, publicly available, and validated or used by other regulators.

The models used depend on which exposure pathway is being assessed for risk. Some situations can be covered by one model. For some pathways, it might be appropriate to use one model to assess the preliminary risks, and then use other models to refine them. Some of the models have their own internal methods for identifying when further work is required.

We use a number of models to estimate the risk to human health and to the environment. These models are publicly available for use. Models to assess potential risks to human health are recommended and listed in Table 5; models for environmental risk assessment are listed in Table 6. The details of each of these models are discussed further in the appendices.

Applicants are, of course, welcome to use other models, providing they are scientifically robust. The choice of model used for a risk assessment for a new hazardous substance always depends on the situation (source, pathway and the receptor affected). The model’s suitability will depend on whether its assumptions are valid for a given scenario. The reasons that any model is used, whether it is one of the models in Tables 5 and 6, or another model, must be explained at the time the risk assessment is submitted with the application.

At the time of writing, we are aware of some of the limitations of these models, particularly that improvements are needed for the approach to modelling and assessing the risks to groundwater and surface water from pesticides and their pathways within water systems in New Zealand. We are always actively thinking about improving our methods, and will be reviewing appropriate and available models in due course.

Table 5 Models for assessing human health impacts

|  |  |  |
| --- | --- | --- |
| Exposure pathway | Model 1 | Appendix (and section) where discussed further |
| Operator for plant protection products | BBA CRD version | Appendix B (B.4) |
| Re-entry modelling for plant protection products | EUROPOEM | Appendix B (B.5) |
| Bystander exposure estimation from plant protection products | EPA customised approach using EFSA and US EPA elements | Appendix B (B.7 and B.8) |
| Pesticides used outside the home | UK POEM  UK POEM [for amateurs2] | Appendix B (B.9)  Appendix B (B.10) |
| Chemicals used within the home | ConsExpo 4.1  US SOP | Appendix B (B.11) |

1. BBA: German Federal Biological Research Centre of Agriculture and Forestry; CRD: Chemicals Registration Division (of United Kingdom’s Health and Safety Executive); EFSA: European Food Standards Agency; EUROPOEM: European Predictive Operator Exposure Model database; UK POEM: United Kingdom Predictive Operator Exposure Model; US EPA: United States Environmental Protection Agency; US SOP: United States Standard Operating Procedure. 2. This model is for those substances that are used by non-professionals or hobbyists, rather than professional contractors.

Table 6 Models for assessing environmental impacts

|  |  |  |
| --- | --- | --- |
| Exposure pathway | Model 1 | Appendix (and section) where discussed further |
| Combined spray-drift and field run-off | GENEEC2 | Appendix C (6.C.4) |
| Spray drift from ground-based applications | AgDRIFT | Appendix C (C.5) |
| Spray drift from aerial applications | AgDISP | Appendix C (C.6) |
| Field run-off | RexTox | Appendix C (C.7) |
| Groundwater | Sci-Grow 2 | Appendix C (6.C.8) |
| Sediment dwelling organisms | ECHA guidance | Appendix C (6.C.9) |
| Soil-dwelling organisms | Modified FOCUS 2007 equations | Appendix C (6.C.10) |
| Non-target plants | BBA spray drift curves | Appendix C (6.C.11) |
| Birds | EFSA | Appendix C (6.C.12) |
| Bees | US EPA pollinator risk assessment | Appendix C (6.C.13) |
| Non-target arthropods | ESCORT2 | Appendix C (6.C.14) |

1. AgDISP: Agricultural Dispersal, ECHA: European Chemicals Agency, GENEEC2: Generic Estimated Environmental Concentration Model v2. 2. We are actively investigating alternatives to the groundwater and water environment approaches.

3.3.2 Selecting inputs for quantitative models

As explained above, the risks from hazardous substances have to be assessed across a wide range of environmental settings. Model input values must be appropriate for how the hazardous substance is intended to be used.

All of the models above have default parameters, and many of these have been retained, though where appropriate information is available they can be changed to be more specific to New Zealand. The parameters used in each model are discussed more in the appendices.

If epidemiological, field, or microcosm/mesocosm studies are available for a particular chemical or hazardous substance, these can be taken into account when deriving the input values for quantitative models, or to help interpret the results of the quantitative models.

In future, we may improve the parameter values in the models that represent the built and natural environment of New Zealand. If we update the parameter values, we will make this information available on our website (EPA, 2018a, 2018b). If an applicant wishes to use alternative parameter values they must provide robust justification in the risk assessment submitted with their application.

Whether or not you include a quantitative risk assessment with your application to import or manufacture a new hazardous substance in New Zealand, you must supply the following information:

* application rate (the quantity of the hazardous substance and active ingredient being applied per area)
* application type (how it is being applied)
* formulation type (whether the substance is solid, granule, a concentrate, ready-to-use etc)
* work rate (how much a user is expected to apply in a given timeframe).

If input values for models are available for the hazardous substances as it is formulated then use these. If data are only available for the active ingredients, then this is an acceptable approach if you can demonstrate how the model results relate to the substance in the application.

3.3.3 Understanding uncertainty in quantitative models

During our evaluation of a hazardous substance application, our goal is to understand the best possible assessment of the risks (and benefits) from the use of that substance. As we have detailed, this understanding is based on models of how the world works and how that particular substance interacts with people and the environment. Data supplied with an application or collated during the EPA’s evaluation are used to support this understanding. All these steps help improve the assessments made, however, like all scientific endeavours, there are limitations or uncertainties associated with risk assessments.

Uncertainties in risk assessment arise from different areas, we discuss four key areas of uncertainty here and how to address them. Firstly, there can be uncertainty about how a substance behaves in the environment and how people and the environment can be exposed to it. This is why carefully building an understanding of the source and all of the exposure pathways is important, as is discussed in section 3.1. Missing a critical exposure pathway from the analysis could have a significant impact on the accuracy and final conclusion of the risk assessment. To address this, it is important to know how and where a substance is intended to be used, in what volumes and how frequently. Environmental fate and toxicology studies in the laboratory and beyond (such as field trials, microcosm and mesocosm studies) help inform this view. This is known as ‘knowledge uncertainty’ – or gaps in knowledge about how the substance behaves in the environment.

The second key uncertainty lies with the toxicity and parameter values that are selected to support the assessment (‘value uncertainty’). The quality and reliability of the studies from which these values are selected and the methods used are important. Data from unreliable sources may mean that the resulting classification or risk assessment is also unreliable. To find appropriate studies and values, an international system known as a Klimisch Score (see Klimisch et al., 1997) is assigned to every reviewed study to help select the best data (see Table 7). These scores can help with understanding how significant any data gaps are for the classification and the assessment of a substance.

Table 7 Klimisch scores for study reliability

| Klimisch Score | Description | Comments |
| --- | --- | --- |
| 1 | Reliable without restriction | There are no concerns and useful for all aspects; study follows test guideline; study to Good Laboratory Practice (GLP) requirements |
| 2 | Reliable with restriction | Good but some issues (eg may be good for classification but not risk assessment, or vice-versa); no guideline available; guideline not followed completely with reasonable explanations as to why not; old study and old guidelines |
| 3 | Not reliable | Cannot be used; guideline not referenced; guideline not followed |
| 4 | Not assignable | Generally cannot be used; did not report the right things; may be acceptable if from reputable review |

From Klimisch et al. (1997)

The third source of uncertainty is whether the selected studies are representative of the receptors in question (also a type of ‘value uncertainty’). For example, many toxicological tests are conducted on the same surrogate species across the world, rather than on people or New Zealand specific species.

In this case, we use the most conservative toxicology value with the highest value of confidence to classify the hazard of (and to assess the risk for) the hazardous substance. This conservatism allows for some uncertainty to be taken into account, and provides a margin for error.

For models involving human health, the variability within the human population and the test species, and the variability between the test species and humans must both be considered, taking into account the number, type and quality of the tests involved. When modelling the environment, the type and quality of the studies that are the source of the information, and whether the species to be protected are threatened must be considered. These are incorporated into assessment factors (or multipliers to reflect value uncertainties), which are either taken into account when calculating risk quotients (see next section for more about risk quotients), acceptable daily exposures or determining a level of concern (see section 3.3.6, Appendix B and Appendix C).

The fourth uncertainty is whether the selected model sufficiently represents the real world interactions that are being assessed (‘structural uncertainty’). By their very nature, all models make assumptions to simplify the real world. The assumptions made, and the uncertainties that they create, must be considered when forming conclusions from the models. We have taken these into account when selecting the models we use. A different model may be more appropriate for how a particular substance is used and may be acceptable if due justification and explanation is provided. When screening for risks, a simple conservative model that appropriately captures the main risks is often useful because if a concern is not identified in the conservative model then the risks via that exposure route can be considered to be negligible.

3.3.4 Threatened and ‘at risk’ species

Assessments of risk to native New Zealand species can be performed using data on standard surrogate species, most of which are from Europe or North America. We don’t require studies to be conducted directly on native New Zealand species, as we can use data from testing on surrogate species and the following approach.

To take into account the impact on threatened species, the United States Environmental Protection Agency’s (US EPA’s) approach for assessing the risks to endangered species is followed in New Zealand (US EPA, 2004, 2016a). This approach adds additional assessment factors depending on the type of organism being assessed. It uses higher factors when organisms cannot escape the exposed area (for aquatic organisms, for instance) than for organisms that can move away, such as birds. Although not used by the US EPA, we also use these higher factors for soil invertebrates as they too cannot escape the treated area easily.

For the purposes of New Zealand risk assessments, the threatened species are those included in the following categories of the New Zealand Threat Classification System (Department of Conservation, 2017):

* ‘Threatened’ (Nationally critical, Nationally endangered, Nationally vulnerable)
* ‘At risk’ (declining, recovering, relict, naturally uncommon).

See further details of when and how to consider such species in Appendix C.

3.3.5 Standardising terminology

The models used at the EPA in quantitative assessments come from other regulators in other parts of the world. They were developed by specialists for particular receptor groups: for example, people or bees. The multiple sources of these models mean that the guidance documents do not all use the same terminology to express their outputs (see Table 8).

To improve clarity for the readers of the risk assessments, we decided to adopt one term for future assessments, ‘risk quotients’, to be internally consistent within our documents, our guidance documents and evaluations of applications and their risk assessments. For the models that do not use ‘risk quotients’, the original term should be used when refining the model output within the framework of the relevant guidance document, and the final output then converted into a ‘risk quotient’. We will be transitioning to using ‘risk quotients’ consistently within our documents in due course.

In human health assessments, the models are used to calculate a predicted internal exposure dose. The toxicology data used to classify the hazardous substance are also used to generate an acceptable operator exposure level (AOEL); though an existing AOEL value from an international regulator may be used instead.

The models and equations calculate how much of a hazardous substance, or the active ingredient, will be present in the environment after its use. This is the predicted environmental concentration (PEC), or estimated environmental concentration (EEC).

The toxicology values used to classify the hazards for a particular active ingredient (or product) can also be used when assessing the environmental risks from a substance. These toxicology values (TV) are multiplied by assessment factors (AF) to calculate a predicted no-effect concentration (PNEC), where the assessment factors take into account uncertainty of the effects of the component between the tested animals and the wider environment, the quality/type of study used to derive the toxicology value or the exposure pathway being assessed. Some of the models already take assessment factors into account, in which case the step doesn’t need to be repeated; see the appendices listed in Table 5 and Table 6 for more details.

These different values are used together to calculate a risk quotient (RQ), with some model guidance documents using the terms hazard quotients (HQ) or tolerable exposure ratio (TER) instead:

Table 8 Alternative assessment terms

|  |  |
| --- | --- |
| Term to use | Other terms used in model guidance documents |
| Predicted environmental concentration (PEC) | Estimated environmental concentration (EEC) |
| Risk quotient (RQ) | Hazard quotient (HQ)  Tolerable exposure ratio (TER) |

3.3.6 Using quantitative model outputs

The tools we use at the EPA and described in this document are designed for specific exposure routes. The overall risk assessment is always more than just a compilation of the numbers generated by these models. The relation between different exposure routes because of things like partitioning needs to be understood when relating the outcomes of a model through the assumptions in that model to what is likely to happen in the real world.

The risk quotient, in conjunction with the conceptual understanding and the model’s assumptions, are used to evaluate whether there will be a risk via that exposure pathway. For each of the different exposure pathways quantitatively assessed, the EPA set a risk quotient at a level where further work may be required, based on Urban and Cook (1986). In general, we use these values directly (converted to RQs as explained above) rather than normalise them to where an RQ > 1 is of concern. If the risk quotient is below a level of concern (see Table 9) the risks via that exposure pathway are considered negligible.

Table 9 Levels of concern

| Receptor | Acute or chronic exposure? | RQ at LOC (normal) | RQ at LOC (threatened species) |
| --- | --- | --- | --- |
| Human health (operator, re-entry worker, bystander) | All | 1 | N/A |
| Aquatic (fish, invertebrates, algae, aquatic plants) | Acute | 0.1 | 0.05 a |
| Chronic | 1 | 0.1 a |
| Sediment dwelling organisms | All | 1 | N/A |
| Soil organisms (earthworms) | Acute | 0.1 | 0.01 |
| Chronic | 0.2 | 0.02 |
| Terrestrial vertebrates (birds) | Acute | 0.1 | 0.05 |
| Chronic | 0.2 | 0.1 |
| Bees | Acute | 0.4 | N/A |
| Chronic | 1 | N/A |
| Terrestrial invertebrates | All | 2 | N/A |
| Non-target plants | Acute (based on EC25) | 1 | - |
| Acute (based on EC50) | 0.2 | - |
| Acute (based on NOEC or EC50/10) | - | 1 |

a. Excludes algae

The extent to which the level of concern is exceeded can be used to consider the level of risk posed, see Table 10. We used this approach previously when assessing risks to the marine environment (EPA, 2016c). Due to the levels of dilution possible in the open ocean compared to the aquatic and terrestrial environments, lower cut-off values between the different levels of risk are considered. Caution is required, though, if using these extra levels when considering the risks to people from chemicals that can have an impact at any dose. These indicative levels can be used to align the results of the quantitative assessment with the qualitative descriptors (see Table 4) to enable comparison with other exposure pathways, effects on Māori and the benefits.

Table 10 Indicative levels of risk from level of concern

|  |  |  |  |
| --- | --- | --- | --- |
| Negligible risk | Low risk a,b | Medium risk a | High risk a |
| < 1 x LOC | ≥ 1 x LOC | ≥ 10 x LOC | ≥ 100 x LOC |

a. Caution is required when considering these divisions to assess the risks to people. b. A low risk is non-negligible and the benefits of an application must still outweigh the risks.

3.3.7 Data made available to other regulatory agencies

The outputs from the quantitative risk assessments can be useful for other agencies in New Zealand.

For human health, how much of a chemical can be safely taken in by the body, called the acceptable daily exposure (ADE), can be calculated and has many applications elsewhere. A predicted daily exposure (PDE) via a few standard pathways can then be calculated, with the defaults as follows:

* PDE (food) = 70% of ADE
* PDE (drinking water) = 20% of ADE
* PDE (other) = 10% of ADE.

Where supported by an understanding of the life cycle and the risk levels, these PDE values are used to set tolerable exposure levels (TELs) for particular pathways.

For the environment, how much of a chemical can be safely present can be calculated, called the environmental exposure limit (EEL). Where appropriate, EELs will be set for new and existing hazardous substances, or the active ingredients and components within them.

As an example, the Ministry for Primary Industries uses the values from risk modelling to help them calculate maximum levels for chemical residues (or maximum residue levels, MRLs) in food[[11]](#footnote-12).

1. Risk mitigation: controls required to manage risks
   1. The purpose of controls

Controls are restrictions or conditions that state how a hazardous substance can and cannot be used, if it is approved for manufacture or import in New Zealand. Their purpose is to prevent or manage the risks of a hazardous substance, to the health and safety of people, and to the environment. A product that is used in line with all of its controls should be safe for people and the environment.

Controls could include, for example, limits on where the substance cannot be used (such as, not in waterways or near an open fire), or a maximum concentration or amount per product volume, or maximum amount that can be applied in a certain area, or that it can only be handled by someone with suitable training or qualifications.

An application will be approved only if the decision makers – when considering the risk assessment – are satisfied that the benefits outweigh any residual risks and costs after the controls are applied, and that these residual risks are acceptable given the proposed uses (see section 6 for information about who considers and approves the applications). You have probably already identified some recommended controls during your analysis of the hazard classification, life cycle and risk assessment of your substance.

In New Zealand, there is a framework of controls prescribed under the HSNO Act 1996 and requirements prescribed under the Health and Safety at Work Act 2015, to ensure that they are applied consistently across all hazardous substances in use, and appropriate to the level of risk. There are two types: prescribed controls and modified/additional controls, and we will explain some more about these here.

* 1. Prescribed controls

Prescribed controls are controls that are set in New Zealand law.

There are two areas of New Zealand law where controls are set:

* First, under the HSNO Act 1996, classifying a substance as ‘hazardous’ automatically means that a set of controls is needed. These controls are outlined in several EPA Notices. The exact controls often depend on the class, sub-class and hazard class of the intrinsic properties the substance (see section 2 for an overview of how hazardous substances are classified). These controls are set by the EPA.
* Second, there are rules to protect people from workplace activities involving hazardous substances set under the Health and Safety at Work (Hazardous Substances) Regulations 2017. We, the EPA, support Worksafe New Zealand to determine some new controls by performing pertinent calculations, such as restricted entry intervals. Workplace controls are set in health and safety regulations or Safe Work Instruments; and they are enforced by Worksafe New Zealand.

Group standards also contain prescribed controls that must be followed when a substance is assigned to a specific group standard.

More information is available in the HSNO Control Regulations guidance document and our website (EPA, 2018c, 2018d).

* 1. Modified/additional controls

In certain circumstances, additional controls may be added where the evaluation of the risk assessment identifies that there are some risks not managed by the prescribed controls. A frequently-used example of an additional control is where the use of an agricultural pesticide is limited to ground-based uses only, and aerial spraying is banned.

Modified controls are regulated under the HSNO Act 1996: sections 77 and 77A of the Act cover deleting or modifying existing controls, or adding new controls. Section 77B can be used to set exposure limits at any time, including for substances that are already approved (see section 3.3 for more details).

When modified controls are considered necessary for an application to be considered for approval, their effectiveness in managing a particular risk, their cost-effectiveness and whether they are realistic (that is, if they will be likely to achieve the reason for modifying the controls) are taken into account.

1. Benefit and cost assessments
   1. The importance of understanding the benefits

Knowing and communicating the benefits of a new hazardous substance is an important part of applying for approval to import or manufacture the substance. It is so important that it is part of New Zealand law and is written into the HSNO Act – we must evaluate the positive effects (the benefits) of a hazardous substance and its adverse effects (the risks and costs). So when assessing and evaluating a new hazardous substance, the benefits of the substance are considered. When a reassessment of an existing substance is initiated, we seek comments from the public and industry, as part of a call for information, to better understand the benefits of that substance; the subsequent reassessment proposals are then publicly notified or consulted upon.

A new hazardous substance can only be approved under the HSNO Act if the benefits outweigh the risks. If there are no stated benefits in an application, or if it is clear that the presented benefits do not outweigh the risks, an application seeking approval for a hazardous substance will be declined. Including a comprehensive benefits assessment with all applications is therefore important.

* 1. Who is responsible for collating this information?

As mentioned earlier, the applicant, or their consultants and advisors, are in the best position to collect and present this information, as they have the best knowledge about the benefits of making their product available in New Zealand.

When making an application for a new hazardous substance, we recommend that the case for the benefits is made separately from that of the risks, as a separate report. While we may look for more information about the *risks* when evaluating an application, we are not as likely to seek additional information on the benefits of a substance, if it wasn’t already supplied with the application. If we do seek additional information, however, this could result in a delay to reach a decision.

If the public was consulted over an application (publicly notified) and people have asked to share their views, then there will be an opportunity for the applicant or the public to present further benefits at a hearing. However, not every application will be publicly notified, and not all publicly notified applications result in a hearing. Therefore, it is more efficient for all parties if the benefits are provided at an early stage and with the application.

If we initiate a reassessment of a hazardous substance that is already approved and in use in New Zealand, we will work with interested parties to identify the benefits of the hazardous substance, and the consequences if the substance is withdrawn or its availability is restricted.

* 1. What to include in a benefits assessment

The HSNO Act 1996 and the related Hazardous Substances and New Organisms (Methodology) Order 1998 both list several areas of impact that must be considered when evaluating and considering an application, which include the natural environment, human health, economy, people and communities, and Māori. Table 11 summarises some useful questions to ask to help identify benefits. If there are other relevant benefits that are outside of these questions, these should also be included with your application. These same questions could be used in the opposite sense to identify the costs associated with a substance or with its non-availability. Benefits and costs that are included in support of an application for approval of a hazardous substance should be pertinent to the potential use in New Zealand rather than to overseas interests (ERMA, 2005).

The benefits must be related to the application being considered. While both direct and indirect benefits may be relevant to the consideration, how far indirect benefits will be considered will depend on the nature of the application. With hazardous substances, the benefits may be primarily related to substitution of one product for another with the new (proposed) product expected to be ‘less risky’ than the current product. The realisation of these benefits will depend on the market share that the new product achieves, and it may be useful to consider, compare and substantiate a range of scenarios for evaluating such benefits.

Table 11 Benefits assessment example questions

| Benefit type | Beneficiary | Questions to ask |
| --- | --- | --- |
| Environmental | Environmental loss | How could it prevent/reduce environmental loss? How much damage would pests do to our environment without the substance? Are there any biosecurity concerns? |
| Environmental enhancement | How might it enhance the environment? Will vegetation be saved, ecosystems enhanced, at-risk species supported? Is it less persistent and/or bioaccumulative than the chemicals currently used for the job? |
| Ecosystems | How might it enhance the environment? Vegetation saved, ecosystems enhanced, at-risk species supported? |
| Economic | User | Is it a unique product, cost effective or efficacious (ie works well enough to perform the intended function)? |
| Community | Will it contribute to jobs or capital investment to a community? |
| New Zealand | Will it enhance our GDP, knowledge or innovative capacity? |
| International | Harmonisation | Will approving the substance align New Zealand with international practices? |
| Māori culture and traditions | Kaitiaki tanga | Will it allow for kaitiaki tanga (intergenerational guardianship and stewardship) and enhance their role as kaitiaki (guardians)? |
| Manaakitanga | Will it enhance/protect manaakitanga (care and respect for people and the environment)? |
| Mahinga kai | Will it enhance/protect mahinga kai (food resources and related environments)? |
| Taonga species | Will it enhance/protect culturally taonga (culturally significant) species? |
| Taha hauora | Will it enhance/protect (taha hauora) human health and wellbeing? |
| Economics | Will it provide employment for Māori or profit to Māori enterprises? |
|  |  |  |
| Social | Social and cultural wellbeing | Are lifestyle or values enhanced by the use of this substance? |
| Health | Will it keep us safe from the spread of diseases? |
| Jobs | Will it enhance industry or help create/save jobs? |
| Animal welfare | Will it improve the welfare of pets or livestock? |
| Intrinsic values | Will it enhance/save local landscapes/sites of significance? |
| Safety | Will it improve the safety of people? Is it safer for people to use? |
| Choice | What is the benefit to families of being able to live and work in an area of their choosing? |
| Recreation | Does a pest impede access to or enjoyment of a site? Might an activity be lost altogether? What are the additional costs of alternative recreational activities, because this is the benefit of keeping the current one? |

As with the risk assessments, a benefit assessment can be conducted qualitatively or quantitatively (that is, with a monetary value in this case). Examples of qualitative descriptors are presented in Table 2 and discussed in section 3.2. The more detailed quantitative assessment is generally required only if the qualitative benefits assessment, or the balance between benefits and risks, indicate that further work is required by the applicant to confirm that the benefits outweigh the risks.

A detailed assessment of benefits should also show an understanding of how they are distributed across different groups, demographics and geographies, and over different timescales.

* 1. The costs of a substance

The HSNO Act 1996 and HSNO (Methodology) Order 1998 also require that the costs of a substance are taken into account. These costs can relate to how the application will affect the health of New Zealanders, their social interactions and sense of place/amenity, New Zealand’s ecology, and its market economy.

They can be associated with the introduction or exclusion of a new substance or a new use pattern. In a full reassessment of a substance, these can be associated with retaining an approval, retaining an approval but with tighter controls or use patterns, or the approval being revoked.

When considering the costs of a substance or application, the questions in Table 11 could be asked in reverse. Other questions could include, for example, “*Are there any known deaths or hospital visits because of this substance or product?*”

ERMA (2005) provides further advice on what to consider when assessing the impacts of a substance’s presence or absence on New Zealand’s market economy.

1. Risk evaluation: reaching a decision on a hazardous substance

We, the EPA, have the role of ‘protecting the environment while enhancing New Zealanders’ way of life and the economy’. As a part of this role, when we consider an application to import or manufacture a new hazardous substance, we are evaluating whether the positive effects of the substance outweigh any negative effects on people or the environment. We consider: the impact on human and public health, the natural environment, social and community matters, cultural and spiritual concerns, and economic aspects.

Ultimately, the decision to approve a new hazardous substance for import or manufacture, or not, is a form of risk management: evaluating the risks against the benefit of introducing the new substance to New Zealand, its inhabitants and its environment. This means a risk assessment is crucial for our decision on whether to approve the use of the substance, or not.

There are two ways that an application to import or manufacture a hazardous substance can be approved in New Zealand. It depends on whether the public or interested parties were notified about the application or not, and whether other information related to the application was received from them (as a submission):

* For a ‘non-notified application’, meaning the public or other parties[[12]](#footnote-13) were not notified about the application, a member of our Senior Leadership team (the CEO or authorised member of the Executive Leadership team) makes the final decision about whether to approve the application.
* For a ‘notified application’, meaning the public or other interested parties were consulted about the application, the decision is made by a decision-making committee (typically of three people) drawn from the HSNO Committee. The HSNO Committee is a group of external experts who are appointed by the EPA Board and is chaired by a member of the EPA Board.

[For more information on our website about current HSNO Committee members](https://www.epa.govt.nz/about-us/our-people/hsno-committee/)

Regardless of whether the decision is made by the EPA or by members of the HSNO Committee, the decision on an application to import or manufacture a hazardous substance is based primarily on the information that was supplied with the application. All details of the application and the assessment of the risk, cost and benefits are considered, including:

* the applicant’s supporting information
* further investigation and evidence collected by us at the EPA
* if the public or interested parties were notified, the information or views that they submitted
* a recommendation by EPA technical experts about whether to approve the application, based on an evaluation of the information above.

The EPA’s technical recommendation, and consequently the final decision, are based on the quality of information received. When a decision is made, it is not only a case of weighing up the direct balance between the risks and benefits. The wider context is relevant. The impact, distribution and fairness of these risks, costs and benefits may also be considered. For example, if the benefits of a substance will be gained by one group but the costs (or risks) will be carried by another group, then this may be an important factor in the evaluation. The timescale over when the risks, costs and benefits are likely to occur is also an important consideration.

This is why we emphasise, throughout this document, the importance of applicants providing as much relevant and succinct information as possible at the time of an application. If there is not enough information available to support the application, or if the case outlining the benefits is not strong enough to outweigh the costs and risks, the application may not be approved.

# Glossary

A glossary of the key terms from the main document are presented in Table A‑1. A list of abbreviations and acronyms used in Table D.1.

Table A‑1 Glossary

| Term | Explanation |
| --- | --- |
| Active ingredient | Key ingredient that provides the formulated product with the power to do its job |
| Applicant | The party applying for a hazardous substance to be approved for import or manufacture in New Zealand |
| Assess | Process of identifying and assessing risks, costs, and benefits associated with the introduction of hazardous substances |
| Benefit | The value of a particular positive effect expressed in monetary or non-monetary terms |
| Control | Restrictions or conditions that state how a hazardous substance can and cannot be used |
| Cost | The value of a particular adverse effect expressed in monetary or non-monetary terms |
| Dose | The amount of substance available to the receptor |
| Evaluate | Evaluation of the combined assessments of risks, costs, and benefits for the purposes of deciding whether an application should be approved, approved with conditions, or declined |
| Exposure assessment | An assessment of how much of a substance can reach people, plants, animals or water |
| Formulated product | A named product, designed for distribution by an applicant to achieve a particular job, containing one or more components. A single hazardous substance may relate to multiple formulated products. |
| Hazard | The intrinsic negative properties of a substance/event. The hazard doesn’t change with: how the substance is used, how much is used, or how often the substance is used or the event occurs. |
| Hazard assessment | An assessment of the intrinsic properties of a substance, which do not change with volume or exposure |
| Hazardous substance | Unless expressly provided otherwise by regulations/notices, any substance:  (a) with 1 or more of the following intrinsic properties:   1. explosiveness 2. flammability 3. a capacity to oxidise 4. corrosiveness 5. toxicity (including chronic toxicity) 6. ecotoxicity, with or without bioaccumulation; or   (b) which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any 1 or more of the properties specified in paragraph (a) |
| Level of concern | The point at or above which further work is required to address or manage risks |
| Notified parties | People or organisations that are notified that the EPA is assessing an application for approval to import or manufacture a new hazardous substance, and who are given an opportunity to submit additional information. |
| Product | See ‘formulated product’ |
| Receptor | Organism (including humans) or environmental body potentially at risk from a hazardous substance |
| Risk | The combination of the magnitude of an adverse effect and the probability [/likelihood] of its occurrence |
| Risk quotient | Calculated representation of risk by comparing a predicted concentration or dose to one where a variety of effects have or have not been noticed or predicted (depending on assessment being made and the parameters being used). |

# Human health risk assessments

* + - * 1. Introduction to human health modelling

Most applications received in New Zealand for the release of new hazardous substances under the HSNO Act are for pesticides and other plant protection products. The EPA’s approach to human health risk assessments is therefore focussed on estimating how much of a particular pesticide people could be exposed to while using the products. The results of this assessment are used to consider whether any modified or additional controls are needed, in addition to the hazard-based controls that are automatically prescribed under the HSNO Act 1996 (see section 4 of this document for more details on controls).

For commercial agricultural pesticides, this approach calculates acceptable operator exposure levels (see section B.2) and risk quotients, and uses these to decide on controls to reduce bystander, operator and re-entry worker exposure to acceptable levels. A similar approach is followed for pesticides used in and around the home.

Although not described here as they are not used frequently, this sort of risk assessment is also carried out for veterinary medicines, applications of pesticides and other chemicals within glasshouses/greenhouses, and seed treatments. The number of models used for different scenarios will be expanded upon in future revisions of this document, at the moment we only cover pesticides used outside in agricultural/horticultural settings and pesticides used in and around the home. As part of continuous improvements, the EPA will review the models and their suitability for use in New Zealand regularly. Updates will be provided on the EPA website as they are available (see EPA, 2018a, 2018b).

An important aspect of human exposure to hazardous substances is how the substance will move through the skin. As such the approach to dermal absorption is discussed before the different exposure pathways in turn (see section B.3).

The models described for each of the exposure pathways described below were originally developed by others. We do not repeat the original guidance documents prepared for these models, which should be consulted before using the models. Each section below discusses any uncertainties specific to that particular model (see section [3.3.3](#Section_333) for more discussion on uncertainty).

Although some models allow for the predicted exposures to be reduced with the introduction of PPE, we acknowledge that Worksafe New Zealand consider that stakeholders and persons controlling business units should try to eliminate risks at the outset in line with the risk reduction hierarchy presented in their legislation and guidance, with PPE used only when more favourable risk mitigation measures (to WorkSafe New Zealand) have not managed the risks.

* + - * 1. Acceptable Operator Exposure Level

The risks to human health are estimated by comparing the modelled exposure to the Acceptable Operator Exposure Level (AOEL). The AOEL is a health-based exposure guidance value against which non-dietary exposures to pesticides are currently assessed. It is intended to define a level of daily exposure throughout a spraying season, below which no adverse systemic health effects would be expected (EFSA, 2014a). The AOEL is normally derived by applying an assessment factor to a No Observed Adverse Effect Level (NOAEL) from a toxicological study in which animals were dosed daily for 90 days or longer. This assessment factor is most often 100. If appropriate, it will be corrected for incomplete oral absorption in the study from which the NOAEL is derived. Less often, the critical NOAEL comes from a study with a shorter dosing period (eg a developmental study) or a longer dosing period (eg a chronic toxicity/carcinogenicity study). The AOEL represents the internal (absorbed) dose available for systemic distribution from any route of exposure and is expressed as an internal level, usually in milligrams per kilogram of body weight per day (mg/kgbw/d).

* + - * 1. Dermal absorption

The European Food Safety Authority (EFSA) has published guidance on the assessment of dermal absorption of pesticides which can be used to inform the interpretation of dermal absorption studies (EFSA, 2012). The EFSA guidance also includes details of procedures to follow when reading across dermal absorption information between formulations and for the extrapolation of dermal absorption data on an active ingredient to a formulated product.

When substance-specific dermal absorption data are not available, default values may be used in the assessment. The default values proposed by Aggarwal et al., based on a review of studies on over 150 active ingredients, were adopted rather than the default values listed in the EFSA guidance (see Table B‑1 below; Aggarwal et al., 2015). The EFSA guidance includes options to further refine dermal absorption values based on physco-chemical properties or data on oral absorption. Guidance from The Organisation for Economic Co‑operation and Development (OECD) can also be used to inform decisions on the appropriate dermal absorption value to be used (OECD, 2011).

Table B‑1 Dermal absorption defaults

|  |  |
| --- | --- |
| Form | Default value (%) |
| Liquid concentrate | 6 |
| Solid concentrate | 2 |
| Spray dilution | 30 |

* + - * 1. Commercial pesticide operators

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to people operating commercial equipment during the mixing and application of pesticides. How personal protective equipment (PPE) reduces these risks if used correctly is also considered.

The aerial use of agricultural pesticides, the use of pesticides inside and outside the home, as well as the risks to bystanders and users of recreational land, are discussed in separate sections of this appendix.

Model used

The UK Chemicals Regulation Directorate (CRD) version of the German Federal Biological Research Centre for Agriculture and Forestry’s (Biologische Bundesanstalt für Land- und Forstwirtschaft, BBA) operator assessment model is used. This is often referred to as the ‘BBA CRD version’. The CRD exposure model calculates exposure using the results of actual measurements carried out in the field (Chemicals Regulation Directorate, 2016a).

This is considered a suitable model for operator exposure because it:

* is an internationally developed model based on a robust dataset
* estimates the total internal dose of a pesticide for the operator from dermal and inhalation exposures
* is most appropriate when assessment exposure and risk using AOEL where comparison with an internal dose is appropriate
* allows the estimates to be modified to take account of use of personal protective equipment, gloves, overalls, goggles and respirators in a relatively flexible way
* allows the risk assessor to apply New Zealand specific values for application rates, application methods (air blast/boom/backpack sprayer), work rates per day and hectares per day treated.

Assumptions and uncertainties

The CRD version of the BBA operator exposure model calculates exposure using the results of actual measurements carried out in the field (Chemicals Regulation Directorate, 2016a). These values represent the geometric mean values of these studies and so may not be as conservative as some other operator exposure models which are based on the 75th percentile of exposure datasets. However, this approach is considered more realistic for long-term work patterns and the EPA is satisfied that this is an acceptable approach.

Pesticide application technology is improving and engineering controls evolve. The assumptions in this model are for older equipment and, are hence, conservative.

New Zealand specific parameters

The risks to an adult worker during a standard working day, as set out in Table B‑2 below, are typically assessed. No other parameters were amended to be New Zealand-specific.

Table B‑2 Worker default values

|  |  |
| --- | --- |
| Parameter | Value |
| Body weight | 70 kg |
| Working day | 8 hours |

Default values

The work rate, or area to be treated per day, should be based on that proposed by the applicant, or from user feedback for reassessments. If this information is not available, then the default values in the EFSA exposure assessment model are used (see Table B‑3, below). These values are consistent with feedback received during the organophosphate and carbamates reassessment. For handheld applications, one hectare is considered to be treated per day.

Table B‑3 Work rate

| **Crop** | **Area treated per day (ha)** |
| --- | --- |
| Bare soil | 50 |
| Berries and other small fruits (low) | 50 |
| Brassica vegetables | 50 |
| Bulb vegetables | 50 |
| Cane fruit | 10 |
| Cereals | 50 |
| Citrus fruit | 10 |
| Fruiting vegetables | 50 |
| Golf course turf or other sports lawns | 50 |
| Grassland and lawns | 50 |
| Grapes | 10 |
| Hops | 10 |
| Leaf vegetables and fresh herbs | 50 |
| Legume vegetables | 50 |
| Oil fruits (high crops) | 10 |
| Oilseeds | 50 |
| Ornamentals | 10 |
| Pome fruit | 10 |
| Root and tuber vegetables | 50 |
| Stone fruit | 10 |
| Tree nuts | 10 |

From EFSA 2014a

The impact of wearing different forms of PPE is estimated using empirically-derived exposure reduction factors. These protection factors are based on the 2014 EFSA exposure model (EFSA, 2014a) and are outlined below in Table B‑4.

Table B‑4 PPE exposure reduction factors

|  |  |  |  |
| --- | --- | --- | --- |
| **PPE** | **Exposure reduction coefficients** | | |
| **Dermal** | **Component** | **Inhalation** |
| Gloves (liquid) | 0.1 | Hands | NA |
| Certified protective coverall | 0.05 | Body | NA |
| Hood and visor | 0.05 | Head | NA |
| FP1, P1 and similar respirators | 0.8 | Head | 0.25 |
| FP2, P2 and similar respirators | 0.8 | Head | 0.1 |
| Gloves (solids mixing and loading) | 0.05 | NA | NA |

Model outputs

The CRD model produces predicted exposure concentrations. Exposure values are derived for several scenarios with different levels of PPE:

* No PPE during mixing, loading and application
* Gloves only during mixing and loading
* Gloves only during application
* Full PPE during mixing, loading and application (excluding respirator)
* Full PPE during mixing, loading and application (including FFP1, P1 and similar respirator achieving 75% inhalation exposure reduction)
* Full PPE during mixing, loading and application (including FFP2, P2 and similar respirator achieving 90% inhalation exposure reduction.

Risk

The level of PPE that is required is determined based on which scenario reduces exposure, compared to the AOEL, so that the RQ is less than one and therefore at an acceptable level:

Equation B‑1

If the RQ is greater than one, then other options may be considered in conjunction with the conceptual model; for example, measurements of relevant real-life exposures to refine the understanding (such as OECD, 1997).

Alternative options considered

The CRD variation of the BBA exposure model is used in New Zealand to take advantage of the model and documents’ translation into English.

A number of parameter values from the 2014 EFSA operator, worker, resident and bystander exposure model (EFSA, 2014a) are used as they are more recently available. This model is not currently used because it does not consider aerial uses; a use pattern for which several agricultural products are approved.

The UK Predictive Operator Exposure Model, or UK POEM (described further in section B.9), can also be used to assess the risks to commercial operators. However, as it has fewer options for operator PPE, the EPA has decided not to use it when conducting the risk assessment.

* + - * 1. Aerial operators

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to people using, mixing and loading pesticides intended to be released by aerial methods. The impact on other receptors, such as re-entry workers, bystanders and the environment, are considered as detailed in other sections of this document.

Model used

The UK Chemicals Regulation Directorate (CRD) version of the German Federal Biological Institute’s (BBA) operator assessment model is used (Chemicals Regulation Directorate, 2016a) to understand the exposure of workers during mixing and loading. See section B.4 for more details on this model.

Assumptions and uncertainties

In addition to the assumptions about the CRD model in section B.4.3, we assume that the pilot will be separate to the nozzles etc distributing the pesticide, often in an enclosed space, so exclude these operator risks.

New Zealand specific parameters

The risks to a working adult are considered in Table B‑2. No other parameters were amended to be New Zealand-specific.

Default values

See Table B‑4 for parameters taken into account when assessing the risks from mixing and loading.

Model outputs

The CRD model produces predicted exposure concentrations. Exposure values are derived for several scenarios with different levels of PPE (see section B.4.6 for further details).

Risk

The level of PPE that is required is determined based on which scenario reduces exposure, compared to the AOEL, so that the RQ is less than one and therefore at an acceptable level:

Equation B‑2

If the RQ is greater than one, then other options may be considered in conjunction with the conceptual model; for example, measurements of relevant real-life exposures to refine the understanding (such as OECD, 1997).

Alternative options considered

Alternative options were proposed in response to our consultation on this document. This may be considered in due course.

* + - * 1. Re-entry workers

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to people working in fields treated with pesticides shortly after treatment has taken place. The exposure of these re-entry workers is based on dermal exposure through contact with foliar residues only. Any exposure to other contaminated surfaces (for example, soil) or via inhalation pathways is not considered.

Model used

The European Predictive Operator Exposure Model database (EUROPOEM) approach developed by other international regulators (EUROPOEM, 2002; Chemicals Regulation Directorate, 2016b) is used, including the following equation:

Equation B‑3

where:

REWE = re-entry worker exposure (µg/kgbw/d)

DFR = dislodgeable foliar residue (µg/cm2 per kgai/ha)

TC = transfer coefficient for the anticipated activity being performed (cm2/h)

WR = work rate per day (h/d)

AR = application rate (kg/ha)

DA = dermal absorption (expressed as a proportion)

BW = body weight (kg).

This is considered a suitable model for re-entry worker assessment because it:

* is an internationally developed model based on a robust dataset
* assesses internal dose in comparison to the AOEL
* allows for dermal absorption estimates
* enables parameters such as dislodgeable foliar residue (DFR) to be taken into account, which means that the impact of multiple applications and length of the application intervals can be taken into account based on the application pattern in New Zealand
* gives an estimate of exposure when re-entry to the crop with no PPE or with basic PPE (gloves only) occurs and compares this with the AOEL
* estimates when unrestricted re-entry to the treated crops should be permitted for some crop types.

Multiple applications are taken into account by using guidance from the Forum for the Coordination of Pesticide Fate Models and their Use (FOCUS, 1997). The dislodgeable foliar residue in the above equation is the only parameter that is altered by multiple applications. Immediately after the nth treatment, the dislodgeable foliar residue (DFRn(a)) is estimated assuming first-order dissipation and the following equation from FOCUS, 1997:

Equation B‑4

where:

n = number of applications

k = rate constant for foliar dissipation

i = interval between applications (days).

When more than one application is used, a multiple application factor (MAF) is sometimes used. The MAF is derived by rearranging Equation B‑4, which becomes:

Equation B‑5

and:

Equation B‑6

The dislodgeable foliar residue will decrease over time following a treatment application, with the residual residue given by the equation:

Equation B‑7

where t = time since last application (days).

Assumptions and uncertainties

The model assumes that substances are absorbed through skin as a worker pushes past foliage that was sprayed. It does not consider inhalation or contact with impacted soils. It is important to check that the activities of re-entry workers match this assumption before using this model. If inhalation is an important pathway, then it must be considered separately.

The model assumes that the substance follows a first-order dissipation rate, with a default foliar life of 10 days (from FOCUS, 2003). Product and active ingredient specific data should be provided if available.

The more conservative dislodgeable foliar residue (DFR) factor for spray or concentrate use patterns may not always be relevant when the substance has dried; however, it is considered to be sufficiently conservative to be used in the risk assessment.

New Zealand specific parameters

The risks to a working adult are considered in Table B‑2. No other parameters have been amended to be specific to New Zealand.

Default values

In the absence of specific dislodgeable foliar residue and foliar dissipation data, the default values in Table B‑5 are used.

Table B‑5 Re-entry worker default values

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter | Symbol | Value | Source |
| Dislodgeable foliar residue | DFR | 3 µg/cm2 per kgai/ha | HSE (no date-a) |
| Foliar dissipation | k | 0.0693 | Corresponding to a foliar half-life of 10 days (FOCUS, 2003) |

Transfer coefficients refer to the amount of contact between a re-entry worker and foliage. These are regarded as independent of the active ingredient/product used and depend on the crop type and the activity that the re-entry worker is carrying out (EUROPOEM, 2002). In the absence of data, values obtained from overseas regulators are used (see Table B‑6). If there is a substance for which the crop or activity is unknown, a default reasonable worst case of 5,200 cm2/hr is used, unless judgement indicates that an alternative value may be more appropriate.

Table B‑6 Default transfer coefficients

|  |  |  |  |
| --- | --- | --- | --- |
| **Crop** | **Activity** | **Transfer coefficient (cm2/hr)** | **Source of transfer coefficient** |
| Vegetables | Reach/Pick | 2,500 | EUROPOEM (2002) |
| Fruit from trees | Search/Reach/Pick | 4,500 | EUROPOEM (2002) |
| Berries | Reach/Pick | 3,000 | EUROPOEM (2002) |
| Ornamentals | Cut/Sort/Bundle/Carry | 5,000 | EUROPOEM (2002) |
| Turf | Mowing | 1,000 | NOHSC re-entry exposure model |
| Turf | Transplanting, Hand weeding | 20,000 | NOHSC re-entry exposure model |
| Pasture | Mowing | 500 | EFSA (2005) |
| Cereals | Scouting, Irrigation, Weeding mature/full foliage plants | 1,000 | US EPA (2007) |
| Default in absence of any data | | 5,200 | - |

NOHSC: [Australian] National Occupational Health and Safety Commission

These transfer coefficients all assume that re-entry workers are wearing long trousers and long sleeved shirts and are not wearing gloves. The impact of wearing gloves on worker exposure can be considered using the transfer coefficient values outlined in the EFSA operator, worker, resident and bystander model (EFSA, 2014a). The impact of wearing gloves cannot be calculated for some crops/activities because transfer coefficients attributable to hands only are not available. The available crops where the use of gloves and the resulting transfer coefficients are considered are shown in Table B‑7.

Table B‑7 Impact of gloves on transfer coefficients

|  |  |  |
| --- | --- | --- |
| **Crop** | **Transfer coefficients for workers not wearing gloves (cm2/hr)** | **Transfer coefficients for re-entry workers wearing gloves (cm2/hr)** |
| Vegetables | 2,500 | 580 |
| Ornamentals | 5,000 | 1,400 |
| Berries | 3,000 | 750 |
| Fruit trees | 4,500 | 2,250 |

From EFSA (2014a)

Model outputs

The EUROPOEM equations calculate an absorbed dose by merging Equation B‑3 and Equation B‑4:

Equation B‑8

where:

C = (TC)(WR)(AR/BW)

D = dermal absorption.

This equation is sometimes re-arranged as *Absorbed dose = (TC)(MAF)(WR)(D)(AR/BW)*.

Risk

Risks to re-entry workers immediately after the final treatment are estimated by calculating an RQ that compares the modelled exposure to the AOEL:

Equation B‑9

The length of time required for the exposure to reduce to an acceptable level is also calculated; that is, so that:

Equation B‑10

By rearranging this equation and incorporating Equation B‑7, the restricted-entry interval (REI, also known as re-entry interval) is given by:

Equation B‑11

If an applicant identifies that a risk quotient will be greater than one, then substance- or ingredient- specific information on the following parameters can be used to refine the risk assessment:

* dermal absorption
* DFR data
* DT50 for foliar data.

Particular care is required to ensure that the correct units or unit conversions are used when calculating DFR, RQ and REI values for this exposure pathway. This is because DFR values are often presented in µg, whereas AOELs (used to calculate RQs and REIs) are often presented in mg – they need to be in the same units.

Alternative options considered

Please see section B.4.8 for reasons why the 2014 EFSA operator, worker, resident and bystander exposure model is not used.

* + - * 1. Bystanders to commercial pesticide use

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to bystanders (that is, those not using or operating the pesticide equipment). This applies to those near a field where pesticides are sprayed, the families and children of those using pesticide equipment in the home, and those using treated recreational surfaces (described separately in section B.8).

Children are likely to be most at risk due to their potential for high amounts of contact and hand to mouth exposure, exploratory nature and low body weight. Risks through direct contact with or inhalation of the spray are not assessed.

Model used

An amended version of the bystander elements of the EFSA operator, worker, resident and bystander exposure model (EFSA, 2014a) is used, incorporating exposure the US EPA approach to soil ingestion (US EPA, 1997) to supplement the dermal exposure and hand- and object-to-mouth activity of the EFSA approach. The equation for this modified approach is:

Equation B‑12

where:

PEC = predicted environmental concentration following a single application

SE(d) = systemic exposure via the dermal route

SE(h) = systemic exposure via the hand-to-mouth route

SE(o) = systemic exposure via mouthing activity

ADOD = soil ingestion oral dose on day of application.

It is considered to be a suitable model for bystanders because it:

* estimates the exposure to a child (toddler) bystander as our most sensitive target human
* takes into account dermal exposure, hand and object to mouth activity (consistent with UK and EFSA approaches) and soil ingestion exposure (an addition based on the US EPA approach)
* allows the spray droplet size and height of application for the use pattern in New Zealand to be taken into account with the spray drift.

The four elements that make up the model in Equation B‑12 are calculated using the following EFSA and US EPA equations:

Equation B‑13

Equation B‑14

Equation B‑15

Equation B‑16

where:

AR = field application rate

BW = body weight

DA = percent dermal absorption

DF = spray drift value

F = fraction or residue retained on uppermost 1 cm of soil (this is an adjustment from surface area to volume)

Freq = frequency of hand to mouth events

H = exposure duration for a typical day

IgRg = ingestion rate for mouthing grass/day

IgRs = ingestion rate of soil

OA = oral absorption (fraction)

SA = surface area of the hands

SDF = soil density factor = volume of soil (cm3) per milligram of soil

SE = saliva extraction factor

TC = transfer coefficient

TTR = turf transferable residues.

If it is known that multiple applications are intended, the exposure is estimated immediately after the final application, with the concentration of the pesticide in soil and grass calculated using Equations B‑17 orB‑18*,* which assume first-order degradation to estimate the cumulative concentration in soil (FOCUS, 1997):

Equation B‑17

or

Equation B‑18

where:

PECmultiple = predicted environmental concentration after several applications

n = number of applications

I = interval between two consecutive applications (days)

k = ln2/DT50 (days)

DT50 = foliar half-life (days) for dermal, hand to mouth and object to mouth systemic exposure and soil half-life (days) for the oral dose from soil on the day of application

MAF = multiple application factor (see Equation B‑5).

Assumptions and uncertainties

A toddler is assumed to be exposed to all of the spray that is deposited on a surface. This could potentially overestimate exposure as it assumes spray stays on the surface where it is applied and there is no dissipation before or during exposure. The toddler is also assumed to be in contact with the sprayed surface for two hours a day and will be exposed multiple times.

Risks to bystanders are calculated by comparing predicted exposure to the AOEL. Although it could be argued that it is more appropriate to compare bystander exposures with an acute reference dose, it is possible that a bystander who resides adjacent to a treated area or who regularly walks around areas treated with plant protection products could receive repeated exposures. There is also the potential for bystanders to be ‘residents’ and have a longer-term exposure. Therefore the use of the default AOEL based on studies with a duration of up to 90 days is also considered to be an appropriate health-based exposure guidance value to be protective of bystanders (EC, 2006).

The assumptions for decay curves, wind direction and particle sizes are the same as for the spray drift refinements in sections C.5 and C.6.

New Zealand specific parameters

For aerial pesticide applications, the applicant is required to provide New Zealand specific parameters, from which spray drift values (DFs) are derived. These are discussed in more detail in Section C.6, and the aircraft parameters previously used by the EPA are summarised in Table C‑7.

Default values

The parameter values in Table B‑8 are used as defaults in the bystander assessment. Substance (or active ingredient) specific foliar half-lives should be used when they are available.

Table B‑8 Bystander assessment default parameter values

| Parameter | Value | Source |
| --- | --- | --- |
| Distance from the edge of the application area at which a toddler’s exposure will be estimated | 8 m | Lloyd and Bell (1983) |
| Turf transferable residue grass | 0.05 | EFSA (2014a) |
| Turf transferable residue object | 0.2 | EFSA (2014a) |
| Transfer coefficients | 2,600 cm2/hr | EFSA (2014a) |
| Exposure duration | 2 hr | EFSA (2014a), US EPA (2011) a |
| Toddler body weight | 15 kg b | Chemicals Regulation Directorate (2016c) |
| Saliva extraction factor | 0.5 | EFSA (2014a) |
| Surface area of hands | 20 cm2 c | EFSA (2014a) |
| Frequency of hand to mouth events | 9.5 events per hour | EFSA (2014a) |
| Ingestion rate grass | 25 cm2/day | EFSA (2014a) |
| Ingestion rate soil | 100 mg/day | Chemicals Regulation Directorate (2016a) |
| Fraction of residue retained on uppermost 1 cm of soil | 1 | US EPA (2012) |
| Soil density factor | 6.7 x 10-4 cm3/mg | US EPA (2012) |
| Dermal absorption | 0.3 d | Aggarwal et al. (2015) |
| Foliar half life | 10 days | FOCUS (2003) |

a. 75th percentile for toddlers playing on grass in the US EPA Exposure Factors Handbook (US EPA, 2011). b. Average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 years. c. Skin area is contacted each time a child puts a hand in his or her mouth, equivalent to the palmar surface of three figures. d. Dermal absorption value for a diluted spray (see section B.3 and Table B‑1).

Model outputs

The output of the model used is the combined exposure value from Equation B‑12.

Risk

The risks to bystanders adjacent to a treatment area immediately after the final treatment are estimated by calculating a RQ, comparing the modelled exposure to the AOEL:

Equation B‑19

The results of this additional modelling (spray drift deposition data) can then be used for the exposure assessment.

A buffer zone can protect bystanders by increasing the distance between the treatment area and the bystander and so reduce the bystanders’ exposure. This is a two-step process:

* the percentage of the application rate that would deliver an exposure equal to the AOEL is calculated
* the distance at which this percentage is deposited is calculated.

More information on buffer zones is provided in sections C.5 and C.6.

Alternative options considered

Please see section B.4.8 for reasons why the 2014 EFSA operator, worker, resident and bystander exposure model is not used.

* + - * 1. Bystanders to recreational land and residential pesticide use

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to people using outdoor areas treated with pesticides after this treatment has occurred; that is, bystanders using recreational land, sports fields, and outdoor areas around the home.

Model used

The same amended version of the bystander elements of the EFSA operator, worker, resident and bystander exposure model (EFSA, 2014a) is used as for bystanders to commercial applications (see section B.7).

It is considered a suitable model for the bystanders because it:

* estimates the exposure to a child (toddler) bystander as the most sensitive target human
* takes into account dermal exposure, hand and object to mouth activity (consistent with UK and EFSA approaches) and soil ingestion exposure (an addition based on the US EPA approach)
* allows the assessment of risks from home use.

Assumptions and uncertainties

In addition to the assumptions in section B.7.3, bystanders are assumed to be zero metres from the treatment area for this exposure pathway.

New Zealand specific parameters

For aerial pesticide applications, the applicant is required to provide New Zealand specific parameters, from which spray drift values are derived. These are discussed in more detail in section C.6, and the aircraft parameters previously used by the EPA are summarised in Table C‑7.

Default values

The default parameters in Table B‑8 are used for this exposure pathway, except for those parameters in Table B‑9.

Table B‑9 Recreational and outdoor home-use bystander assessment default parameter values

| Parameter | Value | Source |
| --- | --- | --- |
| Distance from the edge of the application area at which a toddler’s exposure will be estimated | 0 m | Assumes toddler uses treated area |
| Drift factor | 1 | Assumes no drift away from treated area |

Model outputs and risk

To assess the risks from recreational exposure, that is exposure of toddlers to a surface such as a lawn or sports field treated with pesticides, the approach in Equation B‑19 is used, with updated default parameters from Table B‑9 used in Equation B‑13 to Equation B‑16.

Alternative options considered

There are a number of other models available to assess the risks to people at home. UK POEM and UK POEM for Amateurs (see sections B.9 and B.10 respectively) consider the risks to home-use operators and so are not relevant to this pathway. ConsExpo and United States Standard Operating Procedure (US SOP, see section B.11) are for the indoor uses of pesticides and so are not relevant to this pathway. The bystander approach described in section B.7 is not applicable to using chemicals around the home.

* + - * 1. Outdoor home-use concentrated pesticides

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to people using concentrate versions of pesticides in outdoor areas around the home. The risks to bystanders are considered separately (see section B.8).

Model used

The UK predictive operator exposure model (HSE, no date-b) is used to assess the risks to users of pesticide concentrates in areas outside the home.

It is considered a suitable model for home use pesticide applications because it:

* is an internationally developed model based on a robust dataset
* it allows for small handheld sprayers and smaller container sizes for the mixing and loading making it more suitable for a home user
* specifically includes user scenarios that more accurately reflect home applications than the commercial models.

Assumptions and uncertainties

The UK POEM model allows for PPE to be worn by home users of pesticides; however, as not all non-professionals will wear the correct PPE, it is assumed that none is worn.

The model also assumes that the pesticides are sprayed uniformly around the garden in a dispersive manner rather than as spot treatments. This might result in the risk quotients for spot treatments using this method being unrealistically high.

Default values

The default parameters in Table B‑10 are used for this exposure pathway. The body weight of non-professional users in the model uses the New Zealand consistent value in Table B‑11 (Ministry for the Environment, 2011; Ministry of Health, 2018).

Table B‑10 UK POEM default parameters

| Parameter | Value |
| --- | --- |
| Exposure duration, ie duration of spraying | 30 minutes |
| Treatment area | 0.01 ha/day or 100 m2/day |
| PPE | None |

Table B‑11 New Zealand specific default parameters for home-use products

| Parameter | Value |
| --- | --- |
| Non-professional users’ weight | 70 kg |

Model outputs

The UK POEM spreadsheets calculate a predicted operator exposure separately for liquid and solid concentrate formulations. If an AOEL value is included in the model, the spreadsheets will also calculate the risks as a percentage of the AOEL.

Risk

The risk quotient approach is used when assessing the risks to the private users of concentrate pesticides outside the home (see Equation B‑*1*).

Alternative options considered

There are a number of other models available to assess the risks to people at home. UK POEM for Amateurs (see section B.10) considers the risks to home use operators from dilute ready to use products and so would underestimate the risks from this pathway. ConsExpo and US SOP (see section B.11) are for the indoor uses of pesticides and so are not relevant to this pathway. The approach described in section B.8 is for bystanders and so is not relevant to users of chemicals outside the home.

* + - * 1. Outdoor home-use diluted pesticides

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to people using dilute, ie ready-to-use, versions of pesticides in outdoor areas around the home. The risks to bystanders are considered separately (see section B.8).

Model used

The UK amateur POEM model (HSE, no date-b, no date-c) is used to assess the risks to users of ready-to-use pesticides outside the home.

This is considered to be a suitable model for home use pesticide applications because it:

* is an internationally developed model based on a robust dataset
* it allows for small handheld sprayers and smaller container sizes for the mixing and loading making it more suitable for a home user
* specifically includes user scenarios that more accurately reflect home applications than the commercial models.

Assumptions and uncertainties

The UK POEM for Amateurs model does not allow for PPE to be worn by home users of pesticides. As not all non-professionals will wear the correct PPE, the EPA agrees with this model assumption.

The model assumes that the pesticides are sprayed uniformly around the garden in a dispersive manner rather than as spot treatments. This might result in the risk quotients for spot treatments using this method being unrealistically high.

Default values in New Zealand

The default values in Table B‑10 and Table B‑11 are used when assessing how much users of home-use concentrates in outside areas around the home are exposed to the pesticide.

Model outputs

The UK POEM spreadsheets calculates a predicted operator exposure separately for liquid and solid concentrate formulations. Although the spreadsheets will also calculate the risks as a percentage of the AOEL if an AOEL value is entered, the EPA prefers to not use this option.

Risk

The risk quotient approach is used to assess the risks to the private users of concentrate pesticides outside the home (see Equation B‑1).

Alternative options considered

There are a number of other models available to assess the risks to people at home. UK POEM (see section B.9) considers the risks to home-use operators from concentrated products and so would likely overestimate the risks from this pathway. ConsExpo and US SOP (see section B.11) are for the indoor uses of pesticides and so are not relevant to this pathway. The approach described in section B.8 is for bystanders and so is not relevant to users of chemicals outside the home.

* + - * 1. Indoor chemicals

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to people using hazardous substances designed for use within the home.

Model used

The ConsExpo 4.1 (National Institute for Public Health and the Environment, 2016a, 2016b) model is used for assessing products intended for use within the home. It can be used for bystanders as well as users with minor parameter value modifications.

It is considered to be a suitable model for home use applications because it:

* is an internationally developed model created by a consortium of regulators led by the National Institute for Public Health and the Environment (RIVM) in The Netherlands
* is a risk assessment tool for home use products, used widely and internationally including by the US EPA, Health Canada, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the European Chemicals Agency (ECHA)
* allows for a wide range of application types within the built environment (such as insect/deodorant sprays, carpet treatments, painting etc) to be considered
* can be used for complicated home use exposure pathways that other models do not cover.

Assumptions and uncertainties

Not all non-professionals will wear the correct PPE and so it is assumed that none is worn.

Ventilation is an important pathway by which chemicals used indoors are dispersed and diluted. The ConsExpo ventilation parameters are based on data from European housing stock data. With a longer interest in energy efficiency in Europe, these are likely to be conservative for New Zealand homes. These parameters can be altered to be country specific. Future reviews of this document will consider if these parameters need to be updated to be more representative of New Zealand.

The model default assumes that the chemicals are not volatile and this must be confirmed for each substance.

Different options in ConsExpo are available for those pesticides sprayed uniformly in a dispersive manner, and those used for spot-and-crevice treatments. The correct option for the pertinent use pattern is required to ensure that the risk quotients using this method are realistic for that use pattern.

Default values in New Zealand

The default values in Table B‑12 are used, in addition to the defaults in the ConsExpo guidance documents, when assessing how much users of home-use products are exposed to the chemicals in them.

Table B‑12 ConsExpo default parameters

|  |  |
| --- | --- |
| Parameter | Value |
| Exposure duration, ie duration of spraying | 30 minutes |
| Treatment area | 0.01 ha/day or 100 m2/day |
| Non-professional users’ weight | 60 kg |
| PPE | None |

Model outputs

The result of the ConsExpo modelling is an exposure estimate. The model, algorithms, supporting equations and guidance documents are available from RIVM (National Institute for Public Health and the Environment, 2016a, 2016b).

Risk

The risk quotient approach is used when assessing the risks to the private users of concentrate pesticides outside the home.

Alternative options considered

The main alternative to ConsExpo is US SOP (US EPA 2012, 2016b). The equations in this model, created by the US EPA, are also present in ConsExpo. However, it is an easy-to-use spreadsheet that means that the indoor risks to users and bystanders of some insecticides and pesticides can be assessed more quickly than with ConsExpo. Care needs to be taken with the American units in the model because of the metric system in New Zealand. Although US SOP can calculate RQ values, the estimated exposures from the US SOP model are used to calculate the RQ separately.

There are a number of other models available to assess the risks to people at home. The UK POEM models (see sections B.9 and B.10) are for the outdoor uses of pesticides and so are not relevant to this pathway. The bystander approach described in section B.8 is not applicable to the users of chemicals inside the home.

# Environmental risk assessments

* + - * 1. Introduction to environmental modelling

The EPA’s approach to environmental risk assessments is focussed on estimating how much of a particular pesticide different environmental receptors would be exposed to when the products are being used. This is because most applications received in New Zealand for the release of new hazardous substances under the HSNO Act are for pesticides and other plant protection products.

The methodology calculates risk quotients and control measures required to reduce environmental exposure to acceptable levels. Where the environmental model guidance documents use the alternative hazard quotients or tolerable exposure ratios, these were converted into risk quotients to be consistent with the rest of the document. Although not described here as they are not used frequently, where appropriate risk assessments can also be conducted for veterinary medicines, and for where they or vertebrate toxic agents might cause secondary poisoning. The number of models used for different scenarios will be expanded in future revisions of this document. As part of continuous improvements, the EPA will conduct a regular review of the models and their suitability for use in New Zealand. Updates will be provided on the EPA website when relevant (EPA, 2018a, 2018b).

The EPA acknowledges that further work is required to improve the model used to assess the impacts of pesticides on groundwater and is actively reviewing its assessment of this exposure pathway. The EPA will commence a review of a suitable replacement model as part of the review of its groundwater risk assessment framework in due course.

The EPA wishes to encourage environmentally safer chemistry and better compliance with our controls. To support this aim, in the future the EPA will consider if New Zealand industries might benefit from the release of internal EPA quantitative tools so as to understand better how the EPA calculates environmental exposures and related controls, such as buffer zones. The EPA is interested in the developments of international regulators making their tools more accessible to the users of hazardous substances, and will follow this closely to see what lessons can be learned.

The guidance documents have not been repeated for each of the exposure pathways, and risk assessors and report writers should refer to those documents when conducting and recording their risk assessments. The discussion on uncertainties and uncertainty factors in section [3.3.3](#Section_333) is not repeated for each pathway; instead, the focus is on any additional uncertainty and related factors particular to that assessment, or where they are applied during a different step in the equation.

* + - * 1. Environmental fate – mobility

Area assessed

This section discusses the approach used when considering how mobile a substance is through soil.

Scheme used

The McCall *et al*. (1981; as referenced in ECHA, 2019) mobility classification scheme is used (see Table C‑1).

It is considered to be a suitable approach because of the EPA’s understanding of how widely it is already used.

Table C‑1 Mobility classification scheme

|  |  |
| --- | --- |
| Range of Koc | Mobility class |
| 0 – 50 | Very high |
| 50 – 150 | High |
| 150 – 500 | Medium |
| 500 – 2,000 | Low |
| 2,000 – 5,000 | Slightly |
| > 5,000 | Immobile |

McCall *et al*. (1981; as referenced in ECHA, 2019)

Risk

The McCall classification scheme is not used to directly describe a risk. Instead, it is used to categorise the Koc values measured for a substance, so mobility in soil and sediment can be qualitatively described.. It can be used to clarify the importance of model outputs, particularly those that are of borderline concern, or to understand the importance of data gaps.

* + - * 1. Environmental fate - persistence

Area assessed

This section discusses the approach used, including the models, when further consideration of the hazardous substance’s persistence is required.

Model used

The UK CRD approach (HSE, no date-d, no date-e) is used to calculate the predicted environmental concentration (accumulation) in soil after 20 years application for persistent substances.

It is considered a suitable model for assessing the persistence in soil because it:

* is an internationally developed model
* is easily available
* allows a way to further evaluate the increasing number of applications for the approval of substances with long DT50 values.

The UK host website (HSE, no date-d) includes a link to a spreadsheet (HSE, no date-e) that performs the calculations required to establish the plateau concentration (‘steady state” in sheet) and peak values for the predicted accumulated concentration. This spreadsheet can model up to 10 applications per year.

Assumptions and uncertainties

The “PEC soil” tab (HSE, no date-e) is used as a parameter input screen only for this assessment.

New Zealand specific parameters

The only New Zealand specific parameters used in this assessment relate to the use of the substance being assessed.

Default values

The default parameter values in Table C‑2 are used in the soil risk assessment.

Table C‑2 Default parameters for persistence assessment

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter | Unit | Value | Source |
| Soil depth | cm | 5 | EFSA (2014b) |
| Dry soil bulk density | g/cm3 | 1.5 | EFSA (2014b) |
| Crop interception value | - | variable | EFSA (2014b) |

Model outputs

The peak and steady state values from the “PEC soil accumulation” output tab (HSE, no date-e) after 20 years are used for the further refinement of the persistence of a substance.

Risk

There are a series of steps undertaken to understand if the persistence of a substance is acceptable. The peak concentration after 20 years is compared with the NOEC value determined for section C.10. If the peak concentration is less than the NOEC, then the persistence is acceptable and no further work is required.

If the peak concentration is higher than the NOEC, the steady state value is compared with the NOEC. If this steady state value is less than the NOEC, then the persistence is acceptable and no further work is required. On the other-hand, if it is higher than the NOEC then concerns around the persistence of the substance remains and further work (in the form of field dissipation studies if not already conducted) or risk mitigation measures are required.

Alternative options considered

We are aware of a Nordic PECsoil calculator that is used to calculate PECsoil and can be used to evaluate the persistence of a substance (Kemi, 2018). It is used for Europe’s “Northern Zone” countries (Denmark, Estonia, Finland, Latvia, Lithuania, Norway and Sweden), following EFSA’s zonal approach, and takes into account the specific soil and lower temperature conditions in those countries where degradation is likely to be slower. “Northern Zone” countries are further north than New Zealand is south, and this model has not been considered any further as it is not considered representative of typical agricultural New Zealand soil and temperature conditions.

* + - * 1. Aquatic risk assessment (combined spray drift and run-off)

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the combined risks from spray drift and field run-off to the aquatic environment. Further sections below discuss how the risks from spray drift and run-off using different models are refined (see sections C.5 to C.7).

Model used

The Generic Estimated Environmental Concentration Model, version 2 (GENEEC2) surface water exposure model (US EPA, 2001) is used to estimate the concentration of a substance in surface water which may arise as a result of surface runoff and spray drift.

It is considered a suitable model for screening risks to the aquatic environment because it:

* is an internationally developed model based on a robust dataset
* is a simple conservative screening model
* combines spray drift and run-off in screening step
* is freely available.

Assumptions and uncertainties

The GENEEC2 model assumes that the chemical modelled enters a ‘standard farm pond’ 1 ha big and 2 m deep. This value cannot be changed in GENEEC2. Although it is not representative of New Zealand water bodies, the studies by Effland et al. (1999) and the US EPA (2001) consider it to be a good predictor for the upper level of pesticide concentrations in small but ecologically important upland streams.

The field run-off is from a 10 ha field with less than 10% of the sprayed chemicals running overland into the water body. Run-off is assisted by a single rainstorm event two days after the application of the pesticide; reduced to one day for those pesticides that need wetting in.

The model can assess a number of different land use patterns. However, there is only one orchard use pattern that is considered the worst case and is likely to need refining.

The GENEEC2 model only considers fine or medium-coarse droplets. Fine droplets are considered the worst case and are likely to need refining.

The GENEEC2 model does not indicate whether the predicted concentrations in the water environment are from spray drift or from run-off. If there are concerns after this screen then both elements need refining.

New Zealand specific parameters

New Zealand specific parameters are not used in this aquatic screening assessment.

Default values

In the absence of any study data, the default parameters from the GENEEC2 guidance document (US EPA, 2001) are used, as indicated in Table C‑3, below.

Table C‑3 Default GENEEC2 input parameters

| Input parameter | Symbol | Default value | Alternate value |
| --- | --- | --- | --- |
| Soil half-life | DT50(soil) | 80th percentile of aerobic data from laboratory studies |  |
| Sorption coefficient | kd | Lowest value from non-sandy soil |  |
| Partition coefficient | Koc | Lowest value from non-sandy soil | 0.35 x Kow |
| Aquatic half life | DT50(aquatic) | Data from longest aerobic study (whole system value used) | 2 x DT50(soil) |
| Hydrolysis half-life | DT50(hydrolysis) | Value at ph7 |  |
| Receiving water | - | 1 ha, 2 m deep farm pond | Default within GENEEC2 and not able to change |
| Run-off | - | 10% of sprayed volume over 10 ha field |  |

Model outputs

The GENEEC2 model outputs a text file summarising the input parameters, half-life values of the active ingredient in different environment media, peak calculated estimated environmental concentrations (EECs) and calculated EECs at a number of different time steps (four, 21, 60 and 90 days). An example of a GENEEC2 output is shown in Figure C‑1; these outputs must be presented in a table within the risk assessment report. This output should be summarised in the associated report, using the term predicted environmental concentration (PEC) as explained in Table 10 and section 3.3.5.

Figure C‑1 GENEEC2 example output

RUN No. 1 FOR <active ingredient> ON <crop> \* INPUT VALUES \*

--------------------------------------------------------------------

RATE (#/AC) No.APPS & SOIL SOLUBIL APPL TYPE NO-SPRAY INCORP

ONE(MULT) INTERVAL Kd (PPM ) (%DRIFT) ZONE(FT) (IN)

--------------------------------------------------------------------

0.114( 0.114) 1 1 0.7 3.5 GRLOME( 0.8) 0.0 0.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

--------------------------------------------------------------------

METABOLIC DAYS UNTIL HYDROLYSIS PHOTOLYSIS METABOLIC COMBINED

(FIELD) RAIN/RUNOFF (POND) (POND-EFF) (POND) (POND)

--------------------------------------------------------------------

451.00 2 0.00 124.00-15376.00 127.00 125.96

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

--------------------------------------------------------------------

PEAK MAX 4 DAY MAX 21 DAY MAX 60 DAY MAX 90 DAY

GEEC AVG GEEC AVG GEEC AVG GEEC AVG GEEC

--------------------------------------------------------------------

5.80 5.77 5.61 5.27 5.03

Risk

For the aquatic screening assessment, the risk quotient approach is used to assess the preliminary risks:

Equation C‑1

where:

RQ = risk quotient

PEC = predicted environmental concentration from modelling

L(E)C50 = toxicity value representing concentration killing (or affecting) 50% of the tested organisms

NOAEC = toxicity value representing no observed adverse effect level.

If the RQ exceeds the predefined levels of concern in Table 9, then further work to refine the risk assessment might be appropriate or appropriate controls may be required on any approval to minimise movement of the substance away from the treatment area. Such work could include the modelling described in sections C.5 or C.6 to assess the exposure from spray drift, and in section C.7 from overland run-off. Conversely, if a worst-case scenario is used and the level of concern is not exceeded then it might be appropriate to conclude that there is a negligible risk.

Alternative options considered

It is possible to miss the screening step afforded by using the GENEEC2 model and go straight to the refined assessments described in sections C.5 to C.7. However, GENEEC2 is considered a useful conservative screening tool that also gives an overall view of the combined effects on the aquatic environment via spray drift and run-off. Its speed and ease of use are helpful within New Zealand statutory timeframes, allowing the EPA to concentrate its time with the refined assessments for those substances that are of a higher concern.

The European Union FOCUS models were considered previously. The FOCUS models consider more parameters than GENEEC2, including the time of year a substance is used and take into account how changing concentrations affect partitioning (the Freundlich constant, kf, and exponent, 1/n; rather than the traditional linear relationship (kd) used in GENEEC2). The FOCUS models can also identify if elevated predicted concentrations are due to spray drift or run-off, for which further refinement is required for GENEEC2 (see sections C.5 to C.7). However, it was not possible to select a single climatic scenario in FOCUS that is applicable to all New Zealand, particularly with the rainfall extremes within a small geographical area (Müller et al, 2008).

* + - * 1. Aquatic environment (refined ground-based spray drift)

Exposure linkage assessed

This section discusses the approach used, including the models, to refine the risks to the aquatic environment from ground-based spray equipment. This assessment is focussed on the size of buffer zones required to reduce the amount of a substance entering the water environment so that the risk quotient reduces to an acceptable level. It can be used when the GENEEC2 screening tool is not available or where the resulting RQ from GENEEC2 are above the levels of concern in Table 9.

Model used

The AgDRIFT model (Teske et al., 2002), created by the Spray Drift Task Force for the US EPA and Canadian regulators, is used to estimate the buffer zone that would reduce exposure through spray drift to such a concentration that the resulting acute risk quotient would be less than 0.1. The calculated predicted concentration is used to derive a drift factor (see Equation C‑2 and Equation C‑3, below). The Australian Pesticide and Veterinary Medicine Authority (APVMA) spray curve appropriate for the intended use pattern is then used to find the buffer zone required to achieve this drift factor (APVMA, 2010). The APVMA data are based on the AgDRIFT model (APVMA, 2010). To calculate buffer zones from aerial applications the Agricultural Dispersal (AgDISP) model is used instead (see section C.6).

Equation C‑2

Equation C‑3

* where:
* DF = drift factor
* C = exposure concentration
* C0 = initial concentration
* pdeg = reduction due to degradation
* pss = reduction due to partitioning to suspended solids
* psed = reduction due to partitioning to sediment
* dilution = reduction due to dilution in the water body
* LC50 = toxicology value where 50% of tested populations die.

This is considered a suitable model for ground-based spray drift modelling because:

* it is an internationally and collaboratively developed model (between the US EPA, the US Department of Agriculture’s Forest Service, and the Spray Drift Task Force (SDTF; a consortium of approximately 40 pesticide registrants)
* the AgDRIFT spray curves are extensively validated (such as Teske et al., 2002, Hewitt et al., 2001, Hewitt 2002, Bird et al, 2002)
* the APVMA spray curves align us with other international regulators (noting APVMA curves are under review)
* it incorporates method for evaluating off-site deposition of orchard and ground applied pesticides
* it acts as a tool for evaluating the potential of buffers zones to protect sensitive aquatic and terrestrial habitats from undesired exposures.

The exposure concentration, C, can be viewed as a point estimate with no dilution within the receiving water; that is, the concentration in a receiving water at a certain distance from the field. However, if there is instantaneous mixing within the water body then C0 will also be affected by dilution, as a function of the width and depth of the water body:

Equation C‑4

where:

AR = application rate (gai/ha)

z = water body depth (cm)

0.01 = unit conversion.

The initial concentration of pesticide that would result from over-spraying a water body, C0, is reduced by degradation and partitioning to suspended solids and sediment. In line with the FOCUS model, degradation and partitioning are assumed not to occur on the day of application. Partitioning is assumed to occur within 24 hours from day 1 with that to suspended solids and sediments calculated with different equations (ECB, 2003, and FOCUS, 2012):

Equation C‑5

Equation C‑6

where:

foc(ss) = fraction of organic carbon in suspended solids

foc(sed) = fraction of organic carbon in sediment

Koc = the organic carbon normalised sorption value (L/kg)

suspwater = density of suspended solids in water

ESD = effective sediment depth; that is the depth of sediment to which sediment will sorb

SBD = sediment bulk density

10-6 = units conversion.

No degradation is assumed to occur on Day 0 so that the reduction in the concentration due to degradation (FOCUS, 2003) becomes:

Equation C‑7

where:

k = degradation rate constant = ln2/DT50

t = averaging period.

Exposure of the aquatic environment following multiple exposures uses the same equation as for bystander exposure (see section B.7.2), except that the aquatic half-life is used instead of the foliar or soil half-lives. The DT50 value used is the degradation value for the whole system. This avoids potential double counting, for example, the partitioning between water and sediments if a DT50 value for water and a Kd value were used together. Care needs to be taken when the DT50 value is not for the whole system to avoid this double counting as it could underestimate exposure to the substance.

Assumptions and uncertainties

The empirical data behind the AgDRIFT look up tables and spray curves are based on trials on relatively flat land in the USA (Hewitt et al., 2001, Hewitt, 2002). The technologies used in the tests, and the topography and climate of the test area need to be considered for their applicability to New Zealand when interpreting the results of this model.

The APVMA modified the AgDRIFT curves to create different use scenarios that were more applicable to Australian than the American use patterns. They refined the approach to take a more conservative approach to the droplet size distribution and added a coarse droplet option (see Table C‑6; APVMA, 2010). These Australian use patterns are considered close to those used in New Zealand and so the EPA has not recreated New Zealand specific scenarios. We are aware, however, that APVMA are in the process of updating their curves, which are less over-conservative compared to the above versions (APVMA, *pers comm*; Australian Environment Agency Pty Ltd, *pers comm*). We will consider these new curves when we review the approach and models for this exposure pathway; though as APVMA consider the curves we use to be overly conservative, we consider that it is acceptable to use them in the meantime.

The empirical data come from one particular sprayer, with some New Zealand booms having more nozzles over a longer length than the boom used in the field trials. The use of different boom heights and nozzle sizes in these tests, however, were more important than boom length for effects on spray drift (Gil and Sinfort, 2005). The different droplet sizes and boom heights used in the original monitoring and the resulting model allow the important New Zealand application parameters to be represented.

The original empirical tests were conducted over a wide range of temperatures and relative humidity conditions (Hewitt et al., 2001). Comparison to New Zealand data indicates that these ranges cover a reasonable proportion of our weather conditions.

The wind speeds during the original empirical tests are assumed to be representative of wind speeds during reasonable operating practices. The operational requirements of New Zealand Standard NZS8409 place limits on when boom sprays etc. should be used to help minimise spray drift (Standards New Zealand, 2004).

The DT50 used in when assessing this exposure pathway must be that for the whole system for the reasons explained in section C.5.2.

Based on the extent of the empirical studies behind the spray drift data, the buffer zone limit in the model is 254 m.

New Zealand specific parameters

The amount of a substance available in the water environment was adapted by incorporating sorption into the approach to calculate the predicted concentrations in sediment and suspended solids. These are already incorporated into the equations above.

Default values

The parameter values in Table C‑4 are used as defaults in the refined aquatic assessment for spray drift from ground-based equipment.

The relevant default scenarios in Table C‑5 AgDRIFT scenariosare considered, with the relevant droplet size from the APVMA modifications as in Table C‑6. For the orchard and vineyard scenarios, APVMA estimated the 90th and 95th percentile of the droplet distribution based on the available 50th percentile information. If there is any uncertainty the most conservative scenario should be used.

Table C‑4 AgDRIFT default input parameters

| Parameter | Symbol | Value | Source |
| --- | --- | --- | --- |
| Fraction of organic carbon in suspended solids | Foc(ss) | 0.1 | ECB (2003) |
| Fraction of organic carbon in sediment | Foc(sed) | 0.05 | ECB (2003) |
| Density of suspended solids in water | suspwater | 15 mg/L | ECB (2003) |
| Water depth | z | 30 cm | FOCUS (2003) |
| Effective sediment depth | ESD | 1 cm | FOCUS (1997) |
| Sediment bulk density | SBD | 0.8 | FOCUS (2003) |

Table C‑5 AgDRIFT scenarios

| Scenario | Details |
| --- | --- |
| High boom | 1.27 m above the ground, fine droplets |
| High boom | 1.27 m above the ground, coarse droplets |
| Low boom | 0.5 m above the ground, fine droplets |
| Low boom | 0.5 m above the ground, coarse droplets |
| Sparse orchard | Sparse orchards or small trees |
| Dense orchard | Citrus/tall trees |
| Vineyard | Grapes |

Table C‑6 APVMA modifications of droplet sizes

|  |  |  |
| --- | --- | --- |
| Scenario | Droplet size | Percentile |
| Boom (high or low) | Fine | 90th percentile of very fine to fine droplets scenario |
| Medium | 90th percentile of fine to medium/coarse droplets scenario |
| Coarse | 50th percentile of fine to medium/coarse droplets scenario |
| Orchards (sparse or dense) and vineyards | - | Estimated by the APVMA |

Model outputs

The output of Equation C‑2 is used to calculate the reduction required in the receiving waters to reduce the predicted concentration to an acceptable level (see Equation C‑3). This information is then used, along with the data from the APVMA spray drift curves and related look up tables, to calculate the buffer zone required to reduce the environmental concentration to an acceptable level.

Risk

Following this approach, a risk quotient alone is not used as an indicator of risk. Instead, the size of the buffer zone needed to reduce the predicted concentration to an acceptable level is used; a larger buffer zone is associated with a risk.

Alternative options considered

The original AgDRIFT curves could also be used to determine a suitable buffer zone. However, the improvements made by the APVMA, particularly around coarse droplet sizes, are considered to be more appropriate for New Zealand use patterns.

The AgDISP model (see section C.6) also has capability for a ground-based model. However, the model performed very poorly in a New Zealand validation study, over-predicting deposition by a factor of 3.5 to 100 (Woodward et al., 2008).

The European Union FOCUS models have previously been considered (see section C.4.8). It has not been possible to select a single climatic scenario that is applicable to all New Zealand, particularly with the rainfall extremes within a small geographical area. The model can also take days to run which is not compatible with the EPA operating within tight statutory deadlines.

The EPA is aware of other models available for this refining work. However, they are not aware of any that have been validated or used by other regulators.

If the applicant is able to produce an alternative spray drift deposition dataset which has been collected using international best practice and is considered to be acceptable, these data could be used for the exposure assessment. The applicant must justify why this alternative is more appropriate than the SDTF data used in deriving the APVMA spray drift curves.

* + - * 1. Aquatic environment (refined aerial-based spray drift)

Exposure linkage assessed

This section discusses the approach used, including the models, to refine the risks to the aquatic environment from aerial-based spray equipment. This assessment is focussed on the size of buffer zones required to reduce the amount of a substance entering the water environment so that the risk quotient reduces to an acceptable level. It can be used when the GENEEC2 screening tool is not available or where the resulting RQ from GENEEC2 are above the levels of concern in Table 9.

Model used

AgDISP model, created by United States Department of Agriculture (USDA) Forestry Service (see Continuum Dynamics, 2015), is used to calculate the buffer zone that would reduce exposure through spray drift to such a concentration that the resulting acute risk quotient would be less than 0.1.

It is considered a suitable model for refining the risks from aerial applications because it:

* is an internationally developed model
* is a true Lagrangian model
* has been well validated (Bird et al, 2002)
* is used by other regulators registering pesticides.

Assumptions and uncertainties

The aerial component of AgDISP used has been validated, though it has been found to over-predict spray drift at distances greater than 100 m and under-predict spray drift at distances less than 100m. It also performs less well at slower aircraft speeds (Bird et al., 2002).

It is possible to create standard scenarios in a similar way that APVMA have done for AgDISP (see section C.5). Such scenarios may allow the assessment to be progressed more quickly. Where standard scenarios are used it is very important that the proposed use pattern and the likely terrain match the assumptions in the created scenarios. If there is any doubt, AgDISP can be used to create specific exposure patterns for the proposed uses.

New Zealand specific parameters

As this is a true model, it is possible to modify many of the input parameters to be New Zealand specific.

Meteorological parameters, including wind speeds, from the New Zealand Standard NZS8409 are used when running the model as it is assumed that application will occur only in reasonable worst case scenarios (Standards New Zealand, 2004).

Applicants must include the intended aircraft, set-up and other application parameters for their proposed aerial use. In the past, the EPA has used the default input variables in Table C‑7 following discussions with representatives of the New Zealand Agricultural Aviation Association.

The values for slope, canopy and roughness should be altered in the AgDISP model as required for relevant applications. For example, for those substances intended to be applied aerially over hill country, the slope angles should be updated appropriately.

Table C‑7 New Zealand default aerial parameters for AgDISP

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter** | **Aerial Agricultural Fungicide/ Insecticide** | **Aerial Agricultural Herbicide** | **Aerial Forestry Fungicide/ Insecticide** | **Aerial Forestry Herbicide** |
| Aircraft | FW Air Tractor AT-402B | FW Air Tractor AT-402B | Bell 206B JetRanger III | Bell 206B JetRanger III |
| Wing semi-span | 7.79 m | 7.79 m | NA | NA |
| Rotor radius | NA | NA | 5.08 m | 5.08 m |
| Weight | 4,000 kg | 4,000 kg | 1,451 kg | 1,451 kg |
| Typical speed | 60 m/s | 60 m/s | 25 m/s | 25 m/s |
| Propeller / Rotor RPM | 2,000 | 2,000 | 274 | 274 |
| Propeller radius | 1.33 m | 1.33 m | NA | NA |
| Biplane separation | 0 | 0 | NA | NA |
| Platform area | 26.02 m2 | 26.02 m2 | NA | NA |
| Engines | 1 | 1 | NA | NA |
| Engine vertical | 0 m | 0 m | NA | NA |
| Engine forward | 4.35 m | 4.35 m | NA | NA |
| Engine horizontal | 0 m | 0 m | NA | NA |
| Wing vertical | 0.3622m | 0.3622m | NA | NA |
| Boom vertical | 0.38 m | 0.38 m | -2.74 m | -2.74 m |
| **Parameter** | **Aerial Agricultural Fungicide/ Insecticide** | **Aerial Agricultural Herbicide** | **Aerial Forestry Fungicide/ Insecticide** | **Aerial Forestry Herbicide** |
| Boom forward | 0.3 m | 0.3 m | 1 m | 1 m |
| Release height | 3 m | 3 m | 25 m | 5 m |
| Swath[[13]](#footnote-14) width | 24 m | 20 m | 20 m | 7.5 m |
| Swath displacement | 2 m | 2 m | 9 m | 2 m |
| Droplet size | American Society of Agricultural and Biological Engineers (ASAE, 2018) Very Fine to Fine, ASAE Fine to Medium, ASAE Medium to Coarse | ASAE Medium to Coarse, ASAE Coarse to Very Coarse and ASAE Very Coarse to Extremely Coarse | ASAE Very Fine to Fine, ASAE Fine to Medium, ASAE Medium to Coarse | ASAE Medium to Coarse and ASAE Coarse to Very Coarse, ASAE Very Coarse to Extremely Coarse |
| Water rate[[14]](#footnote-15) | 20 L/ha | 20 L/ha | 80 L/ha | 80 L/ha |
| Spray lines | 10 (typical width of a NZ spray block assumed to be 240 m; sensitivity analysis showed this was not very important for predicting spray drift) | 10 (typical width of a NZ spray block assumed to be 240 m; sensitivity analysis showed this was not very important for predicting spray drift) | 10 (typical width of a NZ spray block assumed to be 240 m; sensitivity analysis showed this was not very important for predicting spray drift) | 10 (typical width of a NZ spray block assumed to be 240 m; sensitivity analysis showed this was not very important for predicting spray drift) |
| Side slope angle[[15]](#footnote-16) | 0 degrees (assume flat terrain) | 0 degrees (assume flat terrain) | 20 degrees (assume forestry planted on steep terrain) | 20 degrees (assume forestry planted on steep terrain) |
| Canopy height | 0 m (assume no canopy) | 0 m (assume no canopy) | 10 m (insecticides/ fungicides may be used on trees at any age, 10 m a reasonably conservative value) | 0 m (assumed herbicides applied pre-planting or in very early stages of establishment) |
| Active Fraction | 0.075 | 0.075 | 0.019 | 0.019 |
| Non-volatile fraction | 0.075 | 0.075 | 0.019 | 0.019 |
| **Parameter** | **Aerial Agricultural Fungicide/ Insecticide** | **Aerial Agricultural Herbicide** | **Aerial Forestry Fungicide/ Insecticide** | **Aerial Forestry Herbicide** |
| Boom length relative to wingspan | 73% | 73% | 80% | 80% |
| Number of nozzles | 60 (67 used on typical NZ boom but 60 is maximum that can be used in AGDISP) | 60 (67 used on typical NZ boom but 60 is maximum that can be used in AGDISP) | 44 | 44 |
| Wind Speed | 3 m/s | 3 m/s | 3 m/s | 3 m/s |
| Temperature | 21 °C | 21 °C | 21 °C | 21 °C |
| Relative Humidity | 46% | 46% | 46% | 46% |
| Surface roughness | 0.005 m (lowest value recommended equivalent to grass) | 0.005 m (lowest value recommended equivalent to grass) | NA | 0.0488 m (highest value recommended equivalent to longer grass) |
| Canopy roughness | NA | NA | 1.4 m | NA |
| Canopy displacement | NA | NA | 7 m | NA |
| Atmospheric stability | Overcast | Overcast | Overcast | Overcast |

Default values

The parameter values in Table C‑8 are used as defaults in the refined aquatic assessment for spray drift from aerial fixed boom equipment.

Table C‑8 AgDISP default parameters

| Parameter | Symbol | Value | Source |
| --- | --- | --- | --- |
| Fraction of organic carbon in suspended solids | Foc(ss) | 0.1 | ECB (2003) |
| Fraction of organic carbon in sediment | Foc(sed) | 0.05 | ECB (2003) |
| Density of suspended solids in water | suspwater | 15 mg/L | ECB (2003) |
| Water depth | z | 30 cm | ECB (2003) |
| Effective sediment depth | ESD | 1 cm | FOCUS (1997) |
| Sediment bulk density | SBD | 0.8 | ECB (2003) |

Model outputs

The AgDISP deposition curve model outputs showing the predicted concentration of the substance at a range of distances is used to calculate the buffer zone required to reduce the environmental concentration to an acceptable level.

Risk

Following this approach, a risk quotient alone is not used as an indicator of risk. Instead, the size of the buffer zone needed to reduce the predicted concentration to an acceptable level is used; a larger buffer zone is associated with a risk.

Alternative options considered

The AgDRIFT model (see section C.6) also has capability for assessing aerial applications. However, proprietary issues around this module when selecting models meant that it was not considered further. The equations behind the aerial AgDRIFT module appear very similar to AgDISP (APVMA, 2008).

The European Union FOCUS models have also been previously considered. The constraints for aerial application are the same as for ground-based applications (see section C.5.8). In addition, aerial applications are much less frequently used in Europe; as such, the FOCUS scenarios and models are not necessarily fit for purpose for this type of application.

* + - * 1. Aquatic environment (refined runoff)

Exposure linkage assessed

This section discusses the approach used, including the equations, to refine the risks to the aquatic environment from over-ground run-off. This assessment is focussed on the size of buffer zones required to reduce the amount of a substance entering the water environment so that the risk quotient reduces to a level considered to minimise risk to the aquatic environment. It can be used when the GENEEC2 screening tool is not available or where the resulting RQ from GENEEC2 are above the levels of concern in Table 9.

Model used

The adapted sub-model of the OECD’s RexTox model, proposed and validated by Probst et al. (2005), is used to calculate the buffer zone that would reduce exposure through runoff to such a concentration that the resulting risk quotient is acceptable, including the following equation:

Equation C‑8

where:

PEC = predicted environmental concentration in the stream (Pc in Probst et al., 2005); µg/L

L%runoff = percentage of application dose available in runoff as dissolved substance

Pa = amount of pesticide applied to application area; µg

Qstream = peak flow rate of water body

∆T = duration of heavy rain event.

It is considered a suitable model for refining the risks from field runoff because it:

* is readily available
* is a simplified formula that is possible to adapt for New Zealand specific scenarios
* is validated against field data
* has room to incorporate geographical factors
* is an internationally developed model.

The following equations support the calculation of the predicted concentration (please note that the factors f3, f4 and f5 are an EPA variation to Probst et al., (2005):

Equation C‑9

Equation C‑10

*= 1; if slope ≥ 20%*

Equation C‑11

Equation C‑12

where:

Q = runoff volume (mm/day)

P = daily precipitation (mm)

Crsoilsurface = amount of pesticide relative to dose applied available for run-off three days after application

f1slope = correction factor for the slope of fields

f2bufferzone = correction factor for the buffer zone

f3foliarapplication = correction factor for foliar application

f4heterogeneityfactor = heterogeneity factor

f5suspendedpesticide = correction factor for how much of pesticide will be suspended in run-off rather than dissolved

DT50soil = half-life in soil (days)

Kd = partition coefficient

crop interception = fraction of spray intercepted by vegetation (varies from crop to crop)

slope = slope of fields (%)

bufferwidth = buffer zone size (m).

The assessment is conducted in a tiered manner, with more details required during subsequent tiers, as shown in Table C‑9. The final tier involves rearranging Equation C‑8 to Equation C‑12 to find the buffer zone (‘bufferwidth’) required for the RQ to be less than the level of concern in Table 9.

Assumptions and uncertainties

The original model was developed to calculate pesticide concentrations in runoff and was extended to predict concentrations in the receiving stream from a 1 ha field (Probst et al., 2005).

The default value for Q/P is 20/100; however, the model adaptation presented by Probst et al. (2005) allows runoff volume to be calculated based on the soil type, soil moisture, crop and time of application if required.

New Zealand specific parameters

See Table C‑9 for New Zealand specific parameters.

Default values

See Table C‑9 for the default parameters used in New Zealand.

Table C‑9 Tiered approach to RexTox

| Tier | Change from previous tier | New default values | New substance parameter values required in tier |
| --- | --- | --- | --- |
| Screen | Conservative screen | L%runoff = 5 %  Qstream∆T = 200 | - |
| Tier 1 | Account for DT50soil and Kd | Q/P = 20/100  f1slope = 0.5  f2bufferzone = 1  f3foliarapplicaiton = 1  f4heteregeneityfactor = 0.5  f5suspendedpesticide = 0 | DT50soil  Kd |
| Tier 2 | Consider inception by crops | - | Crop inception |
| Tier 3 | Consider the slope | - | Slope angle of fields used for crops (degrees) |
| Tier 4 | Consider a buffer zone | - | Calculate buffer zone |

Model outputs

The outputs of the screening level and tiers 1 to 3 are revised predicted exposure concentrations. The output of tier 4 is a buffer zone size required to reduce the risk quotients to an acceptable level.

Risk

The risk quotient approach is used to help inform the level of risk via this exposure route. If the risk cannot be discounted after the third tier then the buffer zone needed to reduce the predicted concentration down to an acceptable level is also a measure of the level of risk; with the larger the buffer zone, the higher the risk.

Alternative options considered

The US EPA has an alternate model that combines estimating the concentration of pesticides in surface water and groundwater, called the ‘Pesticide in Water Calculator’, or PWC (US EPA 2016c). This model is more complicated than a spreadsheet based on the equations in Probst et al. (2005) and duplicates the exposure calculations conducted for other exposure pathways.

Runoff is considered as part of the FOCUS suite of models; however, the constraints identified in section C.5.8 are valid for the assessment of runoff.

* + - * 1. Groundwater

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to groundwater.

Model used

The US EPA Screening Concentration in Ground Water (Sci-Grow) model (US EPA, 2003, 2016d) is used to estimate pesticide concentrations in groundwater.

It is considered a suitable model for assessing the risks to groundwater because it is:

* an internationally developed model
* a conservative screening tool.

The Sci-Grow model has been replaced by the US EPA’s ‘Pesticide in Water Calculator’ (PWC, US EPA 2016c) and is currently only available on an archive page of the US EPA website. The EPA is actively investigating tools for this exposure pathway and will be reviewing alternative models to Sci-Grow in due course.

Assumptions and uncertainties

The Sci-Grow model is based on basic environmental fate data (including aerobic soil degradation half-life and linear adsorption coefficient normalised for soil organic carbon content) and USA field studies with 10 pesticides. The model was developed by the US EPA based on the groundwater monitoring results from sensitive shallow aquifers at maximum USA application rates and frequencies for the trialled pesticides at that time. Different soils and pesticides might have different responses in the ground to the model.

New Zealand specific parameters

The only New Zealand specific parameters used in this assessment relate to the use of the substance being assessed.

Default values

Substance-specific parameter values are required for Sci-Grow.

Model outputs

The output of this approach is a predicted environmental concentration in groundwater.

Risk

The predicted groundwater concentration is compared with the EU limit for the maximum permissible concentration of pesticide active ingredients and their relevant metabolites of 0.1 µg/L. Where the predicted concentration is above this screening value, environmental fate studies, particularly the soil column leaching study and field dissipation studies provided, can refine the understanding of how the substance will move down through the soil and into groundwater.

Alternative options considered

Other groundwater assessment models are available. Some of these, such as the UK’s Remedial Targets Methodology (Environment Agency, 2006) are more relevant for cleaning up sites where chemicals have already escaped into the environment.

The US EPA has an alternate model that combines estimating the concentration of pesticides in surface water and groundwater (PWC, US EPA 2016c). This model is more complicated than Sci-Grow and duplicates the exposure calculations conducted for other exposure pathways.

The FOCUS model suite includes groundwater. The constraints identified in C.5.8 on these models apply to groundwater also.

The EPA is actively looking at replacing the Sci-Grow model and will be reviewing alternatives in due course.

The Sci-Grow model will continue to be used as a screening tool for the time being.

* + - * 1. Sediment organisms

Exposure linkage assessed

This section discusses the approach used, including the equations, to assess the risks to benthic organisms; that is, those living in river sediments.

Sediments can act as both a sink for chemicals through sorption of contaminants to particulate matter and a source of chemicals through re-suspension. Sediments integrate the effects of surface water contamination over time and space, and may thus present a hazard to aquatic communities (both pelagic and benthic) which is not directly predictable from concentrations in the water column.

Model used

ECHA guidance (ECHA, 2008, 2010, 2016) on sediment assessments is followed, including the following equation:

Equation C‑13

where:

PEClocalsed = predicted environmental concentration in sediment (mg/kg)

PEClocalwater = concentration in surface water during release episode typically estimated using the GENEEC2 model (mg/L)

Kp(susp-water) = suspended matter-water partitioning coefficient (m3/m3)

RHOsusp = bulkdensity of suspended matter (kg/m3).

It is considered a suitable model for assessing the risks to sediment-dwelling organisms because it:

* is an internationally developed model
* can be combined with the outputs of the GENEEC2 model.

Assumptions and uncertainties

The concentration in freshly deposited sediment is taken as the predicted concentration for sediments (PECsed) using the properties of suspended matter. This assumes that the sorption of chemicals to sediment follows a first order thermodynamic equilibrium (Di Toro et al., 1991).

When results from whole-sediment tests with benthic organisms are available, the predicted no effect concentration in sediment (PNECsediment) should be derived from these tests using assessment factors. The available sediment tests should be carefully evaluated. Special attention should be given to the pathways through which the test organisms are exposed to the chemical, and the test protocol should be checked carefully to determine whether feeding with unspiked food has possibly reduced exposure via sediment ingestion. For assessing the toxicity of spiked sediment it is necessary to address adequately all possible routes of exposure. Sediment organisms can be exposed via their body surfaces to substances in solution in the overlying water and in the pore water and to bound substances by direct contact or via ingestion of contaminated sediment particles. The route that is most important is strongly influenced by species-specific feeding mechanisms and the behaviour of the organism in, or on, the sediment. Test design parameters can have a bearing on the route of uptake of a substance.

The assessment factors in Table C‑10 are used to take into account the uncertainties from the number and variety of available test data on sediment dwelling organisms.

Table C‑10 Assessment factors for derivation of PNECsed

|  |  |
| --- | --- |
| **Available test result** | **Assessment factor** |
| One long-term test (NOEC or EC10) | 100 |
| Two long-term tests (NOEC or EC10) with species representing different living and feeding conditions | 50 |
| Three long-term tests (NOEC or EC10) with species representing different living and feeding conditions | 10 |

New Zealand specific parameters

The only New Zealand specific parameters used in this assessment relate to the use of the substance being assessed.

Default values

The default parameter values in Table C‑11 are used in the sediment risk assessment.

Table C‑11 Default parameters for sediment assessment

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter | Symbol | Value | Source |
| Bulkdensity of suspended matter | RHOsusp | 1150 kg/m3 | ECHA (2016) |

The concentration in surface water (PEClocalwater) is from the GENEEC2 modelling (see section C.4).

Model outputs

The outputs of this approach are the PEClocalsed values given by Equation C‑13.

Risk

The risk quotient approach is used to assess the risks to sediment-dwelling organisms (see Equation C‑14), with the level of risk as in Table 9 and Table 10:

Equation C‑14

where:

PNECsed = predicted no effect concentration in sediment-dwelling organisms

NOEC = no observed effect concentration (an EC10 may be used instead if available)

AF = assessment factor (see Table C‑10).

Alternative options considered

The FOCUS scenarios could be an alternative option. In addition to the constraints identified in section C.5.8, there are also some concerns over the relevance of their soil organic matter assumptions for the compositions of New Zealand soils.

* + - * 1. Soil organisms

Exposure linkage assessed

This section discusses the approach used, including the equations, to assess the risks to earthworms as a proxy for soil organisms.

Model used

The following equations, based on FOCUS (1997), are used to calculate the predicted environmental concentration within the top layers of soil:

Equation C‑15

where:

PECsingle = predicted environmental concentration in treatment area in a single application (mg/kg)

AR = application rate (g/ha)

fint = fraction intercepted by crop canopy

zs = soil depth (cm)

bd = dry soil bulk density (g/cm3).

It is considered a suitable approach to assess the risks to soil organisms because:

* it is an internationally developed equation
* soil organisms have a clear role in ecosystem functioning and services
* it can be incorporated into an easy to use spreadsheet
* it considers soil mixing
* it allows us to incorporate crop cover
* it allows us to incorporate drift factors to assess risk outside the treatment area
* the predicted concentrations correspond to test regimes.

At the default values used, Equation C‑15 becomes:

Equation C‑16

For multiple applications, the following FOCUS (1997) equation is used to calculate the soil concentration immediately after the last application in any particular treatment cycle:

Equation C‑17

where:

PECmultiple = predicted environmental concentration after in multiple applications (mg/kg)

n = number of applications

i = interval between consecutive treatments (days)

k = dissipation constant = ln2/DT50 (days-1)

DT50 = half-life in soil (days).

When more than one application is used, a multiple application factor (MAF) is sometimes used (see Equation B‑5).

To assess the potential risks to soil organisms outside the treatment area, a drift factor is added to Equation C‑15 (which can then be carried through for multiple applications by including the MAF):

Equation C‑18

where:

PECoff-field = predicted concentration outside the treatment area after a single application (mg/kg)

DF = drift factor.

When a hazardous substance is considered to be persistent and further evaluation of that persistence is required, the approach described in section C.3 is used.

Assumptions and uncertainties

The initial PEC concentrations from the FOCUS guidance are used rather than their time-weighted average approach for both acute and chronic risks. Acute and reproductive earthworm tests are static tests with the study substance applied only once at the beginning of the test. The nominal dose levels from these tests are equivalent to the initial concentrations in the field and the initial PEC values are considered appropriate.

Unless alternative information is available, the FOCUS assumption that soil residue level follow a first-order decay curve is used.

The treated area and off-field areas are assumed not to be ploughed to be able to protect the environment during different uses of the same hazardous substance over different land uses or cropping types. This increases the conservatism of our approach compared to allowing a deeper soil mixing that would result from the ploughing option. Taking the concentration at the soil surface immediately after treatment is considered unrealistic for how soil organisms would be exposed.

The initial assumption is that a hazardous substance is being sprayed onto bare earth and so will not be intercepted by any crops (ie fint = 0) before it permeates into the ground. This can be modified during refinement of the risk assessment if applicable for the identified exposure pathways.

The half-life (DT50) value in soil must be from laboratory tests conducted at 10 to 20 °C and a pH of five to nine. When there are DT50 values of several soils available, typically the GENEEC2 formula are used to determine the relevant DT50 for modelling purposes.

The calculations for predicted concentrations within the treatment area are conservative as they assume that all of the hazardous substance remains within the treatment area.

For the off-field calculations, the 90th percentile of the spray drift values from the BBA model for ground-based booms and AgDISP for aerial applications are used.

New Zealand specific parameters

The only New Zealand specific parameters used in this assessment relate to the use of the substance being assessed.

Default values

The default parameter values in Table C‑12 are used in the soil risk assessment.

Table C‑12 Default parameters for soil assessment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter | Symbol | Unit | Value | Source |
| Soil depth | zs | cm | 5 | EFSA (2014b) |
| Dry soil bulk density | bd | g/cm3 | 1.5 | EFSA (2014b) |
| Crop interception value | fint | - | variable (start with fint=0) | EFSA (2014b); (assumes bare soil in first case) |

For lipophilic substances (that is, where Log Kow > 2), the toxicological endpoints from the artificial soil tests (ie, LC50 or NOEC) should be divided by a factor of two

Model outputs

The outputs of the calculations are the estimated exposure concentrations provided by the relevant PEC values from Equation C‑15 to Equation C‑18.

Risk

The guidance document supporting this approach goes on to calculate toxicity exposure ratios (TERs). The TER approach is to be used during the risk assessment, including during any refinements, in line with the guidance document and then converted into an RQ value for reporting and comparison with the risks to other receptors (see section 3.3.5), so that:

Equation C‑19

Alternative options considered

The spray curve data from the BBA (Ganzelmeier et al., 1995, Rautmann et al., 2001) are used in this model though the spray drift curves from the Spray Drift Task Force are also used in the AgDRIFT model. The adopted model follows the European approach which recommends that the (European) BBA curves are used. The spray curve tables from the BBA easy to use.

* + - * 1. Non-target plants

Exposure linkage assessed

This section discusses the approach used to assess the risks to non-crop plants located outside the intended treatment area, known as non-target plants.

Whether a substance is deposited directly onto a non-target plant (such as, via spray drift) or is taken into a non-target plant that emerges through soil that has previously been impacted by previous spraying. As such, the risks from both pre-emergent and post-emergent treatments are considered.

Model used

The spray drift models produced by the BBA for the exposure assessment of aquatic organisms are used as a surrogate for the exposure of terrestrial plants to hazardous substances (Ganzelmeier et al., 1995, Rautmann et al., 2001).

The estimated exposure of non-target to plants is calculated by the following equation:

PEC = (DF)(AR)(MAF)

Equation C‑20

where:

PEC = predicted environmental concentration

DF = drift factor

AR = application rate (g/ha)

MAF = multiple application factor – from Equation B‑5.

It is considered a suitable model for assessing the risks to non-target plants because:

* spray drift is considered the key exposure route for plants close to the treatment area
* plants have a clear role in ecosystem services.

Assumptions and uncertainties

The BBA drift data were generated with regard to deposition onto surface waters. In particular, there is no vegetation barrier between the spray boom and the collector plates. In terrestrial scenarios, however, horizontal and vertical interception by in-crop or off-crop vegetation as well as patchy distribution is relevant (‘three-dimensional-situation’). If more realistic spray drift curves become available then they may be more applicable for this scenario; however, the current approach is considered reasonably conservative to protect New Zealand’s environment.

New Zealand specific parameters

The only New Zealand specific parameters used in this assessment relate to the use of the substance being assessed.

Default values

The BBA spray curves at a distance of 1 m from the field edge are used for field crops, vegetables or ground applications such as for herbicides, and 3 m for other crops.

Model outputs

The predicted concentrations from the BBA drift curves in section C.11.5 are used as an estimate of plants’ exposure to the hazardous substance.

Risk

The risk quotient (RQ) approach is used, with a No Observed Effect Concentration (NOEC) in the calculation for the more conservative assessment of threatened species instead of an ER(C)25 or ER(C)50. The guidance documents suggest using the TER approach when an EC50 toxicity value is used; in this case the TER approach is to be used during the risk assessment, including during any refinements, in line with the guidance document and then converted into an RQ value for reporting and comparison with the risks to other receptors (see section 3.3.5):

Equation C‑21

where:

PEC = predicted environmental concentration

ER(C)25 = effect ratio (or concentration) where 25% of tested population affected

ER(C)50 = effect ratio (or concentration) where 50% of tested population affected.

The trigger values in Table 9 may be increased if information on multiple species is available (see the discussion in section 3.3.5).

Risk mitigation measures based on buffer zones within the crop area can also be quantified using BBA drift values.

Alternative options considered

The spray curve data from the BBA (Ganzelmeier et al. 1995, Rautmann et al. 2001) are used in this model though the spray drift curves from the Spray Drift Task Force are also used in the AgDRIFT model. The adopted model follows the European approach which recommends that the (European) BBA curves are used. The spray curve tables from the BBA are easy to use.

* + - * 1. Terrestrial vertebrates

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to birds as the environmental terrestrial vertebrates of interest.

The risks to mammals are considered during the human health risk assessment, with many of the toxicology values for our human health risk assessments and classifications coming from mammalian tests.

Model used

The EFSA Bird Model and the associated spreadsheets are used (EFSA, 2009). EFSA provides different spreadsheets to calculate exposure following spray application, granular application and seed treatment.

The EFSA model is considered a suitable model for assessing the risks to birds because it:

* is open source
* is easy to use
* is comprehensible
* uses focal species which can be transferred into different ecosystems
* has a screening level suitable for New Zealand
* is used by other international regulators.

The EFSA methodology calculates exposure as the dose that a bird will receive when feeding on crops that have been treated. To avoid doing detailed evaluations for low-risk scenarios, assessments are performed in tiers of increasing complexity (Table C‑13); progression to the next tier is halted if the exposure dose is below the threshold of concern and therefore the risk via that exposure route is acceptable. Only the lower two tiers are described here; please see the EFSA guidance and consult the EPA if your risk assessment requires a higher tier study.

Table C‑13 Bird risk assessment tiers

|  |  |
| --- | --- |
| Acute assessment | Reproductive (chronic) assessment |
| Screening assessment | Screening assessment |
| Tier 1 assessment | Phase-specific assessment |
| Higher tier assessment | Higher tier assessment |

The dose that a bird receives is referred to as the Daily Dietary Dose, or DDD, and is calculated from the application rate and a so-called ‘shortcut value’ for the residue per unit dose (RUD), reflecting the concentration of the active ingredient on the bird’s food and the quantity of food consumed. Quantities consumed are based on a bird’s energy requirements, its energy assimilation and the energy content of its food (by dry weight). Birds’ energy requirements are based on an algorithm based on body weight and bird type (for example, passerine or non-passerine). For further details, refer to the EFSA technical guidance document (EFSA, 2009).

Both screening step assessments (acute and reproduction) select from 6 ‘indicator species’, each applicable to a particular type of crop. The short-cut values for these species are then used to calculate acute and chronic exposures:

Equation C‑22

where:

DDDsingle = daily dietary dose from single application related to acute risks

DDDmultiple = daily dietary dose from multiple applications related to acute risks

DDDchronic = daily dietary dose related to chronic risks

AR = application rate (kg/ha)

SV = shortcut value for the residue per unit dose

MAFx = multiple application factor

TWA = time weighted average.

The tier 1 assessments use the same general approach as the screening assessments. However, they require more specific exposure scenarios, starting with identifying all general focal species that are relevant for the intended use(s) (see Table I.1 (Annex I) of the EFSA’ technical guidance documents (EFSA, 2009). Acute and phase-specific reproduction assessments exposure is calculated for generic focal species, applicable to particular crops. Such assessments refine the screening step assessments in that:

* there are more bird ‘species’ (19 No.) and crop options (21 No.)
* the growth stage of the crop is taken into account, affecting the residues on the feed
* more than one bird species may be considered for any one crop
* a bird’s diet can be calculated to include more than one food item.

The larger number of bird species, crop types and growth stages of the crops leads to a total of 138 average residue unit dose (RUD) shortcut options, each with a mean and 90th percentile value.

The same model is used to assess the risks to birds via secondary poisoning if there are any issues relating to bioconcentration factor (BCF ≥ 500) or log Kow values (≥4) (EPA, 2012; Hazardous Substances (Minimum Degrees of Hazard) Notice 2017). The risks via secondary poisoning might also be considered if there are concerns based on the molecular size of the component.

Assumptions and uncertainties

The indicator species are not real species. Instead, by virtue of their size and feeding habits, their exposure is considered by EFSA to be the worst case scenario for birds in a particular crop type. For example, the representative species for orchards is described as a ‘small insectivorous bird’. It is assumed that the relevant indicator species feeds only on contaminated food and the concentration of pesticide on the food is not affected by the growth stage of the crop. In the absence of indicator species specific for New Zealand’s birds, the available EFSA indicator species for particular land uses are considered the best available.

New Zealand specific parameters

The daily food intake of New Zealand birds relevant from the Department for Environment, Food and Rural Affairs (Defra, 2007) are used when they are applicable. The values in Crocker et al. (2002) are used when applicable if there relevant value is not in Defra (2007).

Default values

The EFSA documents parameters are used, except for daily food intake (see above). The screening types, indicator species, ninetieth percentile short-cut values, time-weighted averages, and the ninetieth percentile MAF values come from EFSA (2009; Tables 5, 6, 6, 11, and 7 respectively). The exposure and toxicity measures used in the reproduction risk assessment are shown in Table C‑14.

Table C‑14 Exposure and toxicity measures in reproductive assessment

| **Breeding phase** | **Test endpoint used as surrogate** | **Short-term exposure** | **Long-term exposure** |
| --- | --- | --- | --- |
| Pair formation/ breeding site selection | 0.1 x LD50 a | 1 day DDD | 21 day TWA DDD |
| Copulation and egg laying (5 days pre-laying through end of laying | NOAEL for the number of eggs laid per hen | 1 day DDD | 21 day TWA DDD |
| NOAEL for mean eggshell thickness | 1 day DDD | 21 day TWA DDD |
| Incubation and hatching | 0.1 x LD50 | 1 day DDD | 21 day TWA DDD |
| NOAEL for proportion of viable eggs/eggs set/hen | 1 day DDD | 21 day TWA DDD |
| NOAEL for proportion of hatchlings/viable eggs/hen | 3 day TWA DDD | 21 day TWA DDD |
| Juvenile growth and survival until fledging | 0.1 x LD50 (extrinsic adult) | 2 day TWA DDD | 21 day TWA DDD |
| 0.1 x LD50 (extrinsic juvenile) | 1 day DDD based on chick shortcut values of 3.8 and 22.7b | 21 day TWA DDD based on chick shortcut value of 3.8 and 22.7b |
| NOAEL for proportion of 14-day old juveniles/number of hatchlings/hen | 3 day TWA DDD | 21 day TWA DDD |
|  |  |  |  |
| Post-fledging survival | 0.1 x LD50 | 1 day DDD based on chick shortcut values of 3.8 and 22.7b | 21 day TWA DDD based on chick shortcut value of 3.8 and 22.7b |
| NOAEL for 14 day old juvenile weights/hen | 3 day TWA DDD | 21 day TWA DDD |

a. From acute study. b. The two values are to account for ground and foliar dwelling arthropods with mean residue unit doses of 3.5 and 21 respectively. Assessments are made with both values. If the RQ are exceeded with either value, then an assessment based on the actual composition of the diet of relevant species should be performed.

Model outputs

The EFSA models have several outputs worksheets for the acute dietary risks, chronic risks, granular and seed treatments, and for bioaccumulation risks. These output sheets include a calculated TER value.

Risk

As explained in section 3.3.5, the EPA use risk quotients (RQ). The TER values from the EFSA Bird Model should be used during the risk assessment, including during any refinements, in line with the EFSA guidance document (EFSA, 2009). For the purposes of reporting this TER (see Equation C‑23) will be converted into an RQ value (Equation C‑24; see section 3.3.5):

Equation C‑23

Equation C‑24

Where a NOEC is not available, the EFSA guidance describes how to convert from an acute value by dividing the LC50 by 10 (EFSA, 2009).

This RQ value is compared with the levels of concern in Table 9, in conjunction with the conceptual understanding and Table 10, to indicate the risk to birds.

Where higher tier studies are used, then these must be carefully considered and the EFSA output transcribed from the TER-paradigm to the RQ-paradigm when reporting the outcome.

Alternative options considered

The US EPA’s Terrestrial Investigation Model (US EPA, 2015) could be used as an alternative. The US EPA bird model is a probabilistic model, which uses multiple iterations of the relevant equations with population distributions of the parameters to calculate the output. In contrast, the EFSA bird model is a deterministic model, which uses a single iteration of the relevant equations with a single value for each parameter. This often results in conservative parameter values being chosen which might result in an unintended overly conservative answer. The other models described in Appendix B and Appendix C are deterministic; a deterministic model is used for assessing the risks to birds for consistency with these other models.

* + - * 1. Pollinators

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to honeybees as a proxy for the risks to other pollinators.

The exposure of adult bees and larvae are considered via direct contact with hazardous substances and through their diet. A number of exposure routes are considered depending on how the pesticide is to be used:

* systemic / non-systemic pesticides
* foliar sprays
* soil applications
* trunk treatments
* seed treatments.

Model used

The US EPA Guidance for Assessing Pesticide Risks to Bees (US EPA, 2014) and the related BeeRex model are used.

It is considered a suitable model for assessing the risks to bees because it:

* is an internationally developed model (as a collaboration of the US EPA Office of Pesticide Programs, Health Canada Pesticide Management Regulatory Agency, and California Department of Pesticide Regulation)
* is based on current scientific knowledge and testing methods
* considers consumption of different brood castes
* can be refined
* does not introduce unnecessary requirements on pesticides of low concern.

The US EPA bee risk assessment is a tiered risk assessment. At Tier 1, there are a number of different equations taking into account the different exposure routes above and the different classes and ages of bees within the hive (see Table C‑15 for summary and the US EPA guidance document for more details). This tier is a screening step and so is conservative. The US EPA bee approach starts with the worst-case scenario of products being sprayed directly on to flowers and the risk assessment is refined to create an acceptable interval between spraying and bee contact.

If the risks cannot be discounted at this stage, then the second and third tiers within the US EPA guidance document may also be considered; that is, semi-field and full-field trials of the active ingredient at appropriate application rates and conditions.

Table C‑15 Bee exposure assessment parameters

| Measurement endpoint | Exposure route | Exposure estimate (EEC)a | Acute effect endpoint | Chronic effect endpointb |
| --- | --- | --- | --- | --- |
| **Foliar application** | | | | |
| Individual survival (adults) | Contact | Application rate (kgai/ha) x 2.4 µgai/bee | Acute contact LD50 | None |
| Individual survival (adults) | Diet | Application rate (kgai/ha) x 98 µgai/g x 0.292 g/day | Acute oral LD50 | Chronic adult oral NOAEC (effects to survival or longevity) |
| Brood size and success | Diet | Application rate (kgai/ha) x 98 µgai/g x 0.124 g/day | Larval LD50 | Chronic larval oral NOAEC (effects to adult emergence, survival) |
| **Soil treatment** | | | | |
| Individual survival (adults) | Diet | Briggs EEC x 0.292 g/day | Acute oral LD50 | Chronic adult oral NOAEC (effects to survival or longevity) |
| Brood size and success | Diet | Briggs EEC x 0.124 g/day | Larval LD50 | Chronic larval oral NOAEC (effects to adult emergence, survival) |
| **Seed treatment**c | | | | |
| Individual survival (adults) | Diet | 1 µgai/g x 0.292 g/day | Acute oral LD50 | Chronic adult oral NOAEC (effects to survival or longevity) |
| Brood size and success | Diet | 1 µgai/g x 0.124 g/day | Larval LD50 | Chronic larval oral NOAEC (effects to adult emergence, survival) |
| **Tree trunk application**c | | | | |
| Individual survival (adults) | Diet | µgai applied to tree/gfoliage x 0.292 g/day | Acute oral LD50 | Chronic adult oral NOAEC (effects to survival or longevity) |
| Brood size and success | Diet | µgai applied to tree/gfoliage x 0.124 g/day | Larval LD50 | Chronic larval oral NOAEC (effects to adult emergence, survival) |

a. Based on food consumption rates for larvae (0.124 g/day) and adult (0.292 g/day) worker bees and concentration in pollen and nectar. b. To calculate RQs for chronic effects, NOAEC can be used as the effect endpoint to compare with the exposure estimate. c. Assume that pesticide concentration in pollen and nectar of seed treated crops is 1 mgai/kg (1 μgai/g). No adjustment is made for application rate (based on the European and Mediterranean Plant Protection Organization’s (EPPO’s) recommended screening value). d. Note that concentration estimates for tree applications are specific to the type and age of the crop to which the chemical is applied. From US EPA 2014.

Assumptions and uncertainties

The BeeRex model is individual-based and is not intended to assess exposures and effects at the colony level (US EPA, 2014).

The US EPA acknowledges five notable limitations to the modified Briggs’ approach used in BeeRex: (i) empirical data from only one type of plant; (ii) data represent only two classes of pesticides; (iii) based on non-ionic chemicals only; (iv) based on passive transport into xylem and so ignore phylum transport; and (v) estimated concentrations in vegetative plant matrix (ie shoots) used as surrogate for nectar and pollen. These limitations also apply when the US EPA’s incorporation of the modified Briggs’ approach is used in New Zealand.

New Zealand specific parameters

The only New Zealand specific parameters used in this assessment relate to the use of the substance being assessed.

Default values

The default values from US EPA guidance document (US EPA, 2014) are used.

Model outputs

The BeeRex calculations result in calculated environmental exposure concentrations for each of the different castes in the model at both larval and adult stages. For consistency, the synonym ‘predicted environmental concentration’ (PEC) is used instead (see section 3.3.5).

Direct contact with pesticides is considered only for those adults collecting pollen and nectar. The different dietary requirements of the different larvae and adult castes are considered when calculating dietary doses.

Risk

The risk quotient (RQ) approach is used to assess the risks to individuals within each caste of the brood. An RQ for different classes and ages of bees is calculated depending on the exposure pathway (see Equation C‑25). The highest RQ value for an adult bee and a larvae, via contact (acute only) and diet (acute and chronic), from these individual calculations is taken as the protective RQ for individuals within the hive. This RQ is then compared with the levels of concern shown in Table 9 and Table 10.

Equation C‑25

If the RQs are greater than the trigger levels in Table 9, then a non-contact period might be considered appropriate to delay the bees coming into contact with the hazardous substance. Residual concentrations of the substance are calculated using its half-life in foliage (DT50foliage) and a first-order decay curve. The non-contact period is the time required for the substance’s predicted environmental concentration to reduce so that the RQs become acceptable.

Alternative options considered

There are two alternative models to assess the risks to bees.

EFSA has its own version of a bee risk assessment (EFSA, 2013). This EFSA model was not selected because their first tier does not allow pesticides of low concern to be differentiated from those of high concern. This results in semi-field and field-studies being required for all pesticides (fungicides and herbicides as well as insecticides). The additional requirements of the EFSA approach, particularly for low concern pesticides, will not necessarily introduce better management of bee health as they are less pragmatic than the requirements for BeeRex.

As an alternative to using the results of estimated (or predicted) exposure calculations for assessing the risks to bees, Sanchez-Bayo and Goka (2014) propose using internationally available field residue data as the exposure concentration values. They propose comparing how long it would take for that residue to build up to the LD50 value in the different brood castes (called a T50) to get a better understanding of the chronic risks posed to bees. Mullin et al. (2010) acknowledge that it is not clear what the exposure routes are for this international data, as they could not tell which residues were from hives sprayed directly or from crops sprayed in bloom (activities restricted by conditions on approvals in New Zealand where appropriate). Although this alternative T50 approach may have some merits, the EPA is not confident that the residue data used is applicable to the control mechanisms used in New Zealand.

* + - * 1. Non-target invertebrates

Exposure linkage assessed

This section discusses the approach used, including the models, to assess the risks to non-target beneficial arthropods. The risks to these invertebrates are considered within (in-field) and without (off-field) the treatment area. The risks to bees and other pollinators are considered separately (see section C.13).

Model used

The results of the ESCORT2 workshop (ESCORT2, 2000) are used to calculate the risks to non-target beneficial arthropods.

It is considered a suitable model for assessing these risks because it:

* is an internationally developed model
* is a simple generic model
* considers spray drift.

The ESCORT2 calculations provide values for hazard quotients (HQ) for in-field and off-field invertebrates. For consistency, the synonym ‘risk quotient’ (RQ) is used instead of HQ so that the equations become:

Equation C‑26

Equation C‑27

where:

RQin-field = in-field risk quotient

RQoff-field = off-field risk quotient

AR = application rate

LR50 = lethal rate for 50% of tested population

MAF = multiple application factor (see Equation B‑5)

DF = drift factor

VGF = vegetation distribution factor

CF = correction factor.

Assumptions and uncertainties

The application rate and the LR50 value must be in the same units and for the same chemical, ie the formulated substance or the active ingredient. The US EPA approach to threatened species does not consider the threat to invertebrates. As such, extra uncertainty factors have not been introduced for New Zealand threatened species in this group.

The nominal lethal rate (LR50) is to come from relevant toxicological tests rather than the measured concentrations.

New Zealand specific parameters

The only New Zealand specific parameters used in this assessment relate to the use of the substance being assessed.

Default values

The default values presented in Table C‑16 are used in the assessment of non-target beneficial insects.

Table C‑16 Non-target arthropod assessment default values

| Parameter | Symbol | Value | Source | Alternatives |
| --- | --- | --- | --- | --- |
| Drift factor | DF | 0.0277 | Equivalent to 2.77 % based on minimum drift of 1 m or single application on field crops (ESCORT2, 2000, EC, 2002) | BBA curves (Ganzelmeier et al., 1995, Rautmann et al., 2001) if scenario isn’t single application on field crops or if need to refine risk assessment |
| Vegetation distribution factor | VDF | 10 | ESCORT2 based on general approvals | - |
| Correction factor | CF | 10 | ESCORT 2 based on general approvals | - |

Model outputs

The outputs of this approach are the risk quotient values from Equation C‑26 and Equation C‑27.

Risk

The RQ (HQ in the ESCORT2 documents) is derived from the crop-specific application rates for in-field assessments or drift rates for off-field scenarios, and the LR50 value generated with *A. rhopalosiphi* and *T. pyri*. If the resulting RQ is equal to or higher than two, a potential hazard to non-target arthropods is concluded and further assessment as per that recommended in the ESCORT workshop document is recommended. Subsequent RQ values are compared with the levels of concern in Table 9 and Table 10.

The risks to off-field arthropods are only considered if the in-field risks cannot be discounted.

Alternative options considered

The ESCORT2 model is the only approach that has been considered by the EPA for the exposures of, and risks to, non-target invertebrates to date.

# Acronyms and abbreviations

A list of abbreviations and acronyms used in this document are shown in Table D.1.

Table D‑1 Acronyms and abbreviations

| Abbreviation | Definition |
| --- | --- |
| 1/n | Freundlich exponent (when used in conjunction with kf) |
| μg | Microgram |
| μm | Micrometre (micron) |
| ai | Active ingredient |
| ADE | Acceptable Daily Exposure |
| ADI | Acceptable Daily Intake |
| AgDISP | Agricultural Dispersal [model] |
| AOEL | Acceptable Operator Exposure Level |
| APVMA | Australian Pesticide and Veterinary Medicine Authority |
| BBA | Biologische Bundesanstalt für Land- und Forstwirtschaft, or German Federal Biological Research Centre of Agriculture and Forestry |
| BBCH | Biologische Bundesanstalt, Bundessortenamt und Chemische Industrie |
| BCF | Bioconcentration Factor |
| bw | Body weight |
| CCID | Chemical Classification and Information Database |
| cm | Centimetres |
| CRD | Chemicals Registration Division (of United Kingdom’s Health and Safety Executive) |
| CRfD | Chronic Reference Dose |
| DDD | Daily Dietary Dose |
| Defra | Department of Environment, Food and Rural Affairs |
| DF | Spray Drift Factor |
| DFR | Dislodgeable foliar residue |
| DMC | Decision-Making Committee |
| DT50 | Dissipation Time (days) for 50% of the initial residue to be lost |
| dw | Dry weight |
| EbC50 | EC50 with respect to a reduction of biomass |
| EC | European Commission |
| EC25 | Effective Concentration at which an observable adverse effect is caused in 25 % of the test organisms |
| EC50 | Effective Concentration at which an observable adverse effect is caused in 50 % of the test organisms |
| ECHA | European Chemicals Agency |
| EEC | Estimated Environmental Concentration |
| EEL | Environmental Exposure Limit |
| EFSA | European Food Safety Authority |
| EPA | Environmental Protection Authority Te Mana Rauhī Taiao |
| EPPO | European and Mediterranean Plant Protection Organization |
| ErC50 | EC50 with respect to a reduction of growth rate (r) |
| ER50 | Effective Residue concentration to 50% of test organisms |
| EUROPOEM | European Predictive Operator Exposure Model [database] |
| FFP1 | Filters at least 80% of airborne particles (at air flow of 95 L/min), with inward leakage less than 22% |
| FFP2 | Filters at least 94% of airborne particles(at air flow of 95 L/min), with inward leakage less than 8% |
| FOCUS | Foum for the co-ordination of pesticide fate models and their use |
| g | Gram |
| GAP | Good Agricultural Practice |
| GDP | Gross Domestic Product |
| GENEEC2 | Generic Estimated Environmental Concentration model, version 2 |
| GHS | United Nations Globally Harmonised System of Classification and Labelling of Chemicals |
| GLP | Good Laboratory Practice |
| ha | Hectare |
| HQ | Hazard Quotient |
| HSE | Health and Safety Executive |
| HSNO | Hazardous Substances and New Organisms [Act] |
| Kd | Partition (distribution) coefficient |
| Kf | Freundlich constant |
| Koc | Organic carbon adsorption coefficient |
| Kow | Octanol water partition coefficient |
| Kg | Kilogram |
| L | Litres |
| LC50 | Lethal Concentration that causes 50% mortality |
| LD50 | Lethal Dose that causes 50% mortality |
| LOAEC | Lowest Observable Adverse Effect Concentration |
| LOAEL | Lowest Observable Adverse Effect Level |
| LOC | Level Of Concern |
| LOD | Limit Of Detection |
| LOEC | Lowest Observable Effect Concentration |
| LOEL | Lowest Observable Effect Level |
| LR50 | Lethal Rate that causes 50% mortality |
| M | Molar |
| m3 | Cubic metre |
| MAF | Multiple Application Factor |
| mg | Milligram |
| mg/kgbw/d | Milligrams per kilogram of bodyweight per day |
| mol | Mole(s) |
| NAEL | No Adverse Effect Level |
| ng | Nanogram |
| NICNAS | National Industrial Chemicals Notification and Assessment Scheme |
| NOAEC | No Observed Adverse Effect Concentration |
| NOAEL | No Observed Adverse Effect Level |
| NOEC | No Observed Effect Concentration |
| NOEL | No Observed Effect Level |
| NOHSC | [Australian] National Occupational Health and Safety Commission |
| NZIoC | New Zealand Inventory of Chemicals |
| OECD | Organisation for Economic Cooperation and Development |
| P1 | Filters at least 80% of airborne particles (at air flow of 95 L/min) |
| P2 | Filters at least 94% of airborne particles(at air flow of 95 L/min) |
| PDE | Potential Daily Exposure |
| PEC | Predicted Environmental Concentration |
| pKa | Acid dissociation constant (base 10 logarithmic scale) |
| PNEC | Predicted No Effect Concentration |
| POW | Partition coefficient between n-octanol and water |
| ppb | Parts per billion (10-9) |
| PPE | Personal Protective Equipment |
| ppm | Parts per million (10-6) |
| PWC | Pesticide in Water Calculator |
| REI | Restricted Entry Interval, also known as re-entry interval |
| RIVM | Rijksinstituut voor Volksgezondheid en Milieu or National Institute for Public Health and the Environment, the Netherlands |
| RPE | Respiratory Protective Equipment |
| RQ | Risk Quotient |
| RUD | Residue per Unit Dose |
| Sci-Grow | US EPA Screening Concentration in Ground Water model |
| SDTF | Spray Drift Task Force |
| TER | Tolerable Exposure Ratio |
| UK POEM | UK Predictive Operator Exposure Model |
| USDA | United States Department of Agriculture |
| US EPA | United States Environmental Protection Agency |
| US SOP | United States Standard Operating Procedure |

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1. The phrases ‘positive effects’ and ‘adverse effects’ are the terms used in the HSNO Act 1996. For ease of reading and use of this document, we will refer to these as ‘benefits’ and ‘risk and costs’ throughout the rest of this document. [↑](#footnote-ref-2)
2. UN Class 7 (radioactivity) is not included in this list because it is managed under a different piece of legislation in New Zealand. [↑](#footnote-ref-3)
3. More information on laboratories can be found on the [WorkSafe New Zealand website](https://worksafe.govt.nz/topic-and-industry/hazardous-substances/guidance/industry-guidance/managing-hazardous/). [↑](#footnote-ref-4)
4. [For radioactive materials, please see this information on the Ministry of Health website](https://www.health.govt.nz/our-work/radiation-safety) [↑](#footnote-ref-5)
5. [For queries about importing or manufacturing medicines, please see this information on the Ministry of Health website](https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-act-1981) [↑](#footnote-ref-6)
6. [Food safety is managed by the Ministry of Primary Industries](http://www.mpi.govt.nz/law-and-policy/legal-overviews/food-safety/) [↑](#footnote-ref-7)
7. [For more information about transporting infectious substances, see the Ministry of Transport website](https://www.transport.govt.nz/about/publications/reports/transportingdangerousgoodssafely/regulatoryauthoritiesandlegislationinnewzealand/) [↑](#footnote-ref-8)
8. Also known as ‘environmental media and transport mechanisms’. [↑](#footnote-ref-9)
9. Controls to manage maximum residue limits and drinking water exposure standards are set by the Ministry for Primary Industries and Ministry of Health rather than the EPA. [↑](#footnote-ref-10)
10. Also known as the hazardous substance’s environmental fate and transport characteristics. [↑](#footnote-ref-11)
11. See the [New Zealand Food Safety website](https://www.mpi.govt.nz/growing-and-harvesting/plant-products/pesticide-maximum-residue-levels-mrls-for-plant-based-foods/) for more details [↑](#footnote-ref-12)
12. The EPA consults other government departments and agencies regularly on applications to import or manufacture hazardous substances in New Zealand: WorkSafe NZ, Department of Conservation, Ministry of Health, and Ministry of Primary Industries. The EPA does not consider consulting these bodies to be public notification of applications. [↑](#footnote-ref-13)
13. sic [↑](#footnote-ref-14)
14. These are the default water rates the EPA has historically used. Feedback suggests that water rates can vary between 20 and 100 L/ha. Appropriate values to the scenarios being considered will be required. [↑](#footnote-ref-15)
15. These slope angles are the defaults used by the EPA. These can be changed in AgDISP if the use scenarios being modelled require it; for example, when used substances are being used on forage brassicas. [↑](#footnote-ref-16)