Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

4 AUGUST 2020

Summary

Substances	Boxer Gold
Application code	APP203736
Application type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 (“the Act”)
Applicant	Syngenta Crop Protection Limited
Purpose of the application	To import for release Boxer Gold into New Zealand for use as a herbicide on potato crops
Information requests and time waivers	The timeframe for the holding of the hearing of this application was waived under section 59 of the Act
Submissions received	Mary Hobbs, New Zealand Outside Limited Dr Benita Wakefield and Stephanie Dijkstra, Ngāi Tahu HSNO Committee Clifford Mason
Considered by	A Decision-Making Committee of the Environmental Protection Authority (“the Committee”): Dr Kerry Laing (Chair) Dr Derek Belton
Decision	Approved with controls
Approval code	**HSR101435**
Hazard classification	3.1D, 6.1E (oral), 6.3B, 6.9B (oral, inhalation), 9.1A, 9.2A

Application dates	
Date application formally received	5 July 2019
Submission period	19 July 2019 – 30 August 2019
Hearing date	30 June 2020
Consideration date	30 June 2020 – 4 August 2020
Date decision signed	4 August 2020

1. Application context

Background

1.1. Boxer Gold is an emulsifiable concentrate containing 800 g/L of prosulfocarb and 120 g/L of S-metolachlor as the active ingredients.

1.2. Prosulfocarb is a new active ingredient to New Zealand, and has been approved in Europe, Australia and Japan. S-metolachlor is currently approved in New Zealand and is approved in other jurisdictions including the USA, Canada, Europe and Australia.

1.3. Boxer Gold is intended to be used as a herbicide for the treatment of broadleaf and grass weeds in potato crops. The applicant has proposed an application rate of 3.2 - 4 kg prosulfocarb/ha and 0.48 – 0.60 kg S-metolachlor/ha (equivalent to 4 - 5 L/ha Boxer Gold), with a maximum frequency of one application per year. The applicant sought to have Boxer Gold approved for ground-based methods only.

Process, consultation and notification

1.4. The application was formally received on 5 July 2019 under section 28 of the Act.

Notification to government departments

1.5. The Minister for the Environment was advised of the application in writing in accordance with section 53(4) of the Act. The Ministry for the Environment, the Department of Conservation and the Agricultural Compounds and Veterinary Medicines (ACVM) group of the Ministry for Primary Industries were advised of the application and notified of the consultation period. No comments or submissions on the application were received from these parties.

1.6. WorkSafe New Zealand (“WorkSafe”) is the agency responsible for overseeing the Health and Safety at Work Act 2015 (HSW Act) and Health and Safety at Work (Hazardous Substances) Regulations 2017 (HSW (HS) Regulations). Advice was sought from WorkSafe on whether the HSW requirements are adequate to manage the risks associated with the use of this substance in the workplace. WorkSafe noted that Boxer Gold contains a non-active ingredient component that may not be required for efficacy and that introduces an additional hazard classification. Under sections 39 - 42 of the HSW Act, manufacturers, importers and suppliers have a duty to ensure that substances manufactured, imported or supplied are without risk. WorkSafe identified that the PCBU may not have gone so far as reasonably practical to ensure Boxer Gold is without risk, and so advised that the duties under sections 39 - 42 may not have been met for this substance. However, WorkSafe did not propose setting any additional requirements for Boxer Gold. The full advice is available in a separate report provided by WorkSafe.

Public notification

1.7. The application was publicly notified in accordance with section 53 of the Act, and public submissions were sought from 19 July 2019 to 30 August 2019. The EPA received three submissions on the application.

Timeframe waiver

1.8. The statutory timeframe for the holding of the hearing of this application was waived on 30 September 2019 under section 59 of the Act to allow for finalisation of the technical assessment and the formation of a decision-making committee.

Submissions received

1.9. All three of the submissions received opposed approving the application. These were from Ngāi Tahu HSNO Committee, Mary Hobbs of NZ Outside Limited, and a member of the public.

Hearing

1.10. The hearing was held on 30 June 2020 by video conference. Present via video were the Decision-Making Committee, the applicant and representatives, the EPA staff, and the Ngāi Tahu HSNO Committee. Mary Hobbs was present via phone. The hearing closed on 30 June 2020.

Information available for consideration

1.11. The information available to the Committee for consideration of this application consisted of the:

- application form, including the confidential material submitted by the applicant
- associated documents, including about 500 studies
- submissions
- hearing presentations made by the applicant, EPA staff and submitters
- EPA Staff Report and Science Memorandum

1.12. After considering all relevant information, the Committee decided that it had sufficient information to make a decision on this application.

2. The EPA Staff Report

2.1. The Staff Report is the EPA review of the application and available information. It provides information to assist the Committee's decision-making process.

2.2. The EPA identified the classifications and properties of the active ingredient prosulfocarb in Boxer Gold based on toxicological and ecotoxicological studies conducted with this active ingredient. The other active ingredient, S-metolachlor, is already approved in New Zealand (HSR003363) and is present in formulated products (HSR002521, HSR100968 and HSR000392), so the quantitative risk assessment was focussed on the new active ingredient prosulfocarb, using data on the mixture product Boxer Gold where relevant. The EPA then identified the classifications of the substance Boxer

Gold, which are based on formulation data, the composition of the substance, and the properties of its components.

2.3. The EPA conducted quantitative human health and environmental risk assessments. These assessments considered the exposure and subsequent effects on people and the environment throughout the life cycle of the substance. Based on all the available information, the EPA assessed the potential risks the substance may pose to the environment, human health, the relationship of Māori to the environment, society, community and to the market economy.

2.4. The EPA also considered whether there were benefits associated with the use of the substance.

2.5. The EPA identified a suite of prescribed controls based on the hazard classifications of Boxer Gold, and considered variations to these controls and the addition of extra controls, in accordance with sections 77 and 77A of the Act.

2.6. The Staff Report (dated May 2020) concluded that there was sufficient information available to assess the application to import or manufacture Boxer Gold for release. The Staff Report also concluded that, with the proposed controls in place, the risks to human health and the environment from the importation, manufacture and use of Boxer Gold would be negligible; and that the use of Boxer Gold would provide some benefits to farmers.

2.7. The Staff Report concluded that with the proposed controls in place, the positive effects of the substance would outweigh the adverse effects of the substance.

3. The hearing

3.1. On 30 June 2020, a hearing was held virtually over video conference. Kevin Patterson, Michelle Hickman and Dale Neil presented for the applicant (Syngenta Crop Protection Limited). Régis Lapage and Michael Berardozzi presented on behalf of the EPA, and a Kaupapa Kura Taiao senior advisor was also present. Presentations were made by submitters Stephanie Dijkstra and Benita Wakefield on behalf of the Ngāi Tahu HSNO Committee, and Mary Hobbs on behalf of NZ Outside Limited.

Applicant's presentation

3.2. The applicant began with an overview of Boxer Gold, explaining that it is a herbicide intended to control weeds in potato crops and contains two active ingredients: prosulfocarb and S-metolachlor. Prosulfocarb was developed over 30 years ago but is a new active ingredient to New Zealand. S-metolachlor is approved for use in New Zealand. Boxer Gold will be applied by ground-based methods only.

3.3. The applicant claimed that Boxer Gold's two active ingredients have different modes of action and target different sites simultaneously, improving the product's efficacy against a range of weeds. Weeds such as black nightshade compete with potato crops for nutrients, so controlling these improves crop yield and quality. Black nightshade is becoming resistant to Group C1 triazines but is fully controlled by Boxer Gold, giving farmers an alternative. The applicant explained that the potato

industry generates $130 million from exports annually, so improved crop yield and quality from weed control has an economic benefit.

3.4. The applicant explained that Boxer Gold has excellent crop safety and can be applied up to 25% crop emergence – this gives growers more flexibility in timing product application if conditions are unsuitable.

3.5. The applicant agreed with the EPA's hazard classification of and proposed controls for Boxer Gold. They noted that studies had been done on Boxer Gold itself which showed that the active ingredients together were no more hazardous than each one individually.

3.6. The applicant acknowledged that they should have directly engaged with Māori rather than rely on the EPA to circulate the application to Te Herenga. They said that they would directly supply interested parties with information for their next application.

3.7. The Committee asked the applicant about the benefits to growers and whether there was a real need for another product. The applicant replied that the main benefit is the different modes of action of Boxer Gold's active ingredients, which helps with resistance management, and allows more flexibility and choice for growers. The applicant said that growers have reported particular issues with black nightshade, which the applicant claims Boxer Gold completely controls. The Committee then asked how many growers the applicant expects would use Boxer Gold in 2021 if it were approved, and whether these growers would get better yields. The applicant did not know the expected sales volumes but thought that growers would get increased yield from using Boxer Gold.

3.8. The Committee asked whether Boxer Gold is a pre-emergence or post-emergence herbicide as it was not clear in the documents. The applicant responded that Boxer Gold should predominantly be applied pre-emergence but could be applied after planting up to 25% foliage emergence and acknowledged that this may not have been clear in the documents provided. The Committee also asked what was meant when the application referred to Boxer Gold having short residual effects but also residual control. The applicant answered that it is important for weeds to be controlled immediately after planting as then when the crop canopy is established that outcompetes the weeds. Boxer Gold enables this early weed control.

3.9. The Committee asked whether resistance mostly affected Group C herbicides. The applicant said that Group C1 triazines are the most affected and that these are heavily relied upon by growers. The Committee then asked when metribuzin would be used in tandem with Boxer Gold. The applicant replied that this could be used where field pansy and white clover are an issue – this mixture expands the possible use of Boxer Gold. The Committee commented that likely tank mixes should be assessed as part of applications.

3.10. The Committee asked whether the applicant was comfortable with the proposed labelling control addressing non-target plants. The applicant replied that they had no major concerns with the controls.

3.11. The Ngāi Tahu HSNO Committee commented that they could not find any quantitative information on Boxer Gold improving crop yield, and asked whether field trials comparing Boxer Gold to standard products had been done. The applicant responded that field studies had been done but that they did not have the data from these.

3.12. The Ngāi Tahu HSNO Committee noted that the applicant mentioned tank mixes in their presentation but that this was not in the application – this concerns the Committee.

3.13. Mary Hobbs raised a Danish report that stated that prosulfocarb is not registered for use in vegetables and fruit and that mentioned human health concerns. The applicant was not aware of the particular report but noted that several EU countries use prosulfocarb. Mary Hobbs then said that she is concerned about the cumulative effects of herbicides in both potatoes and the land. She did not feel that the application was complete and the applicant's answers had not satisfied her that Boxer Gold is safe.

3.14. There were no further questions.

EPA's presentation

3.15. Régis Lapage and Michael Berardozzi presented the EPA assessment, starting with a brief description of Boxer Gold and its proposed use pattern. They then gave an overview of the application and the three submissions received.

3.16. The hazardous properties and characteristics of prosulfocarb were presented. This active ingredient is classified 6.1D (oral), 6.5B, 6.9B (oral), 9.1A, 9.2A and 9.3C, is highly persistent in water, is low to slightly mobile in soil and may bioaccumulate in fish. The EPA classified Boxer Gold 3.1D, 6.1E (oral), 6.3B, 6.9B (oral, inhalation), 9.1A and 9.2A.

3.17. The EPA explained that the risk assessment approach focused on prosulfocarb and Boxer Gold, as S-metolachlor is already approved at higher application rates. They also took the applicant's risk assessment into account. The EPA concluded that risks to operators, re-entry workers and bystanders were below the level of concern. They reported that compliance with the HSW Act was possible and adequate for Boxer Gold, but noted WorkSafe's advice that sections 39 - 42 of the HSW Act may not have been met due to a hazardous co-formulant.

3.18. The EPA's ecotoxicity risk assessment was based on application of Boxer Gold via boom spray in either fine or coarse droplets. The EPA determined that risks to groundwater, soil organisms and pollinators were below the level of concern, but that refinement was required for aquatic organisms, sediment-dwelling organisms, non-target plants, birds, and non-target arthropods. No synergistic effect from combining the two active ingredients in Boxer Gold was found.

3.19. The EPA explained that the aquatic risk assessment refinement used spray drift curves based on Boxer Gold application by fine and coarse droplet boom spray. The refinement found that a buffer zone of 32 m (rounded to 30 m) for fine droplets and 2 m (rounded to 5 m) for coarse droplets are required for spray drift reduction for the protection of waterbodies. The EPA therefore proposed that

Boxer Gold be applied by coarse droplet boom spray with a 5 m buffer zone for downwind waterbodies. The risk from surface runoff was also considered based on a 4% slope and no crop interception. This model found that a 1 m buffer zone is needed to mitigate risks from runoff to the aquatic environment.

3.20. The EPA determined that no buffer zone is required to mitigate risks of spray drift to sediment-dwelling organisms, but that a 5 m downwind buffer zone is needed for non-target plants. Risk assessment refinement found prosulfocarb's chronic toxicity to omnivorous birds to be slightly above the level of concern. However, the EPA argued that omnivorous birds are unlikely to feed on potato foliage and that potato fields are not a usual habitat for threatened birds. Therefore, the EPA concluded that the chronic toxicity risks to threatened birds are likely to be below the level of concern. The EPA also determined that the risks of prosulfocarb to some species of in-field arthropods were above the level of concern, so proposed a control warning users that Boxer Gold may not be compatible with Integrated Pest Management (IPM).

3.21. The EPA presented the findings of the cultural risk assessment. Boxer Gold may impact mahinga kai, particularly freshwater species and valued plants. The EPA noted that Māori are highly represented in respiratory illness so may be disproportionately affected by this aspect of Boxer Gold's toxicity. They also recognised that Boxer Gold may kill some in-field arthropods. However, the EPA concluded that the proposed controls would adequately manage the risks to Māori. No issues arose concerning the Treaty of Waitangi. The EPA acknowledged their oversight in not sending the application to Te Herenga.

3.22. The EPA presented the potential benefits of Boxer Gold. They recognised that increased crop yield, resistance management and more choice would be a benefit to growers, though noted that there are currently at least 12 active ingredients available for weed control in potatoes. They caveated the discussion of benefits by noting that the Agricultural Chemicals and Veterinary Medicines group (ACVM) assesses efficacy, not the EPA.

3.23. The EPA concluded that, if appropriate controls were in place, the proposed use of Boxer Gold would result in negligible risks to human health and the environment and that it would provide some benefits to farmers. Therefore, the EPA recommended that Boxer Gold be approved with controls.

3.24. The Committee asked about the timing of public submissions and release of documents for application. The EPA replied that submissions from the public opened before the science memo was released, but that they would open after release of the science memo for future applications.

3.25. The Committee asked whether the R-isomer of metolachlor is more toxic than the S-isomer. The applicant responded that neither isomer was more toxic than the other and that the studies provided for metolachlor were often on the racemic mixture.

3.26. The Committee asked about the non-target plant label statement and whether this could be read as an implicit 'de-facto' approval for these plants. The EPA replied that they had tried to provide specific

guidance on the effects on non-target plants and that they had not intended it to be a de-facto approval.

3.27. The Committee raised the advice from WorkSafe regarding Boxer Gold's hazardous co-formulant. The EPA responded that they have limited control over this as formulation is decided by the applicant. They noted that the EPA has a risk mitigation policy while WorkSafe's policy is risk elimination. This difference is regularly discussed by the agencies, and the EPA is revising their pesticide application form to make the risk elimination policy clearer for applicants. However, the EPA acknowledged the challenge of accommodating both WorkSafe's and the EPA's policies.

3.28. Mary Hobbs asked about studies conducted using the mixture of active ingredients and whether these had shown any negative effects. The EPA replied that several studies on the mixture had been provided and that these were used to inform the toxicity endpoints. Mary Hobbs then asked whether any cumulative effects from other herbicides had been considered. The EPA responded that this is a difficult area to study as the full spray cycle for each crop is unknown. Also, the Hazardous Substances and New Organisms (HSNO) Act only allows the current application to be considered.

3.29. Mary Hobbs asked whether S-metolachlor was originally a product from Monsanto. The applicant confirmed that it was not.

3.30. Mary Hobbs asked how spray drift can be measured when farmers may not follow the controls, as this is not monitored. The EPA replied that they set controls that are understood, can be followed by users and easily enforceable. The EPA explained that compliance is a matter they take very seriously.

3.31. There were no further questions.

Presentations by submitters

Ngāi Tahu HSNO Committee

3.32. Stephanie Dijkstra from the Ngāi Tahu HSNO Committee (the Committee) began with a brief introduction to Ngāi Tahu and why they submit on EPA matters. She highlighted that Ngāi Tahu's takiwā (tribal territory) is diverse in the type of land it includes.

3.33. The Committee commented that there was a lot of information in the confidential appendix and little specific information publicly available, which made it difficult for submitters. They could not find any studies in the application that supported the applicant's claim of Boxer Gold's efficacy.

3.34. The Committee did not agree with the EPA's use of a 4% slope in their modelling of runoff as, in their experience, potato crops tend to be steeper than this. They were particularly concerned because Boxer Gold would be applied at a time of year when runoff into water was more likely, and the EPA's assessment showed Boxer Gold to be extremely toxic to the aquatic environment and highly ecotoxic to soil. The Committee worried that the substance could deplete food sources for different organisms. They noted that there is no bioaccumulation and no synergistic effect from the two active ingredients.

3.35. The Committee commented on the insufficient consultation with Māori and suggested that the EPA ensures information is sent to the Committee and other interested parties in a timely manner. They did not think that the benefits of Boxer Gold outweighed the risks, particularly to the environment, so opposed the application.

3.36. The Committee asked what would be required for the Committee to support an application. The Committee replied that they would require a clear case as to why the substance was particularly needed in New Zealand – Ngāi Tahu would only support a product with clear benefits or that replaces outmoded chemistry. For the Boxer Gold application, they would require the slope used in runoff modelling to be increased. The Committee then asked whether the information provided by the EPA was sufficient and, other than the slope, whether the Committee was satisfied with the risk assessment. The Committee replied that it is useful to have specific data for each species and that they were satisfied with the EPA's assessment.

3.37. The applicant asked whether the application's consultation document had eventually been circulated, as this addressed some of the Committee's concerns. The Committee said that it had not, but that the criticism was mostly aimed at the EPA. The EPA acknowledged that improvements to the Māori consultation and submissions process is needed. They explained that Potatoes NZ had provided information about the slope of crops, but acknowledged that the slope used in the risk assessment was not representative of all situations. The EPA said that they would re-evaluate this parameter for future applications.

3.38. There were no further questions.

Mary Hobbs, NZ Outside

3.39. Mary Hobbs began by thanking Ngāi Tahu and agreeing with their concerns regarding the slope of potato crops. She referred to another submitter's comments that potato fields in the Pukekohe region are often on hills with streams that could flush herbicides into waterways.

3.40. Mary Hobbs said that she is concerned about the continual addition of chemicals to the land and agrees with Ngāi Tahu that they should only be introduced when absolutely necessary. She spoke of the spiritual connection people have to the land and that, while people want to solve issues, they must first 'do no harm'. She would like the land to be as free of chemicals as possible and to 'learn from nature's blueprint'.

3.41. Mary Hobbs asked the EPA to look into the Danish report previously mentioned and why this determined that prosulfocarb should not be sprayed on fruits or vegetables.

3.42. The Committee commented that Mary Hobbs had expressed the issues that applicants and the EPA have in seeking to solve problems while balancing this against potential harm. They also said that the hearing was not the appropriate time for the Danish report to first be raised, but that the EPA would look into it.

3.43. The Committee had no questions but acknowledged everything that Mary Hobbs had said in her submission.

3.44. There were no further comments.

Applicant's right of reply

3.45. The applicant said that there was nothing they wished to directly comment on. They accepted the EPA's risk assessment and the proposed hazard classifications and controls. The applicant also acknowledged that the Māori consultation had not been handled well and said they would learn from this. They supported the EPA releasing the science memo before opening public submissions for future applications.

3.46. The hearing was adjourned.

4. Consideration

4.1. The application was considered by the Committee on 30 June 2020, following the decision pathway (available in Appendix B).

4.2. The following information was considered by the Committee:

- the application form and its confidential appendices, including about 500 studies
- the submissions
- the Science Memorandum
- the Staff Report
- the WorkSafe assessment report
- the Cultural Risk Assessment
- information presented at the hearing

4.3. The Committee considered that it had received sufficient information to proceed with its consideration of the application. Further comments on different aspects of this information can be found in the following sections.

Hazard classifications

4.4. The Committee adopted the hazard classifications for Boxer Gold as recommended in the Science Memorandum, based on the information provided by the applicant and on other available information as documented in the Science Memorandum. The EPA classifications differed slightly from those proposed by the applicant (see Table 1).

Table 1: Hazard classifications of Boxer Gold

Hazard	Applicant classification	EPA classification
Flammability	No	**3.1D**
Acute toxicity (oral)	6.1E	6.1E
Acute toxicity (dermal)	6.1E	**No**
Acute toxicity (inhalation)	6.1D	**Not determined**
Skin irritancy	6.3B	6.3B
Target organ or systemic toxicity	6.9B	6.9B (oral, inhalation)
Aquatic ecotoxicity	9.1A	9.1A
Soil ecotoxicity	9.2A	9.2A

Identification of controls

4.5. The suite of controls proposed by the EPA include the prescribed controls triggered by the hazard classifications of Boxer Gold, deletions and variations to the prescribed controls in accordance with section 77 of the Act, and additional controls proposed in accordance with section 77A. The Committee discussed and accepted these controls for Boxer Gold.

Risk assessment

4.6. The Committee took into account the EPA risk assessment for Boxer Gold as detailed in the Science Memorandum. The key points are summarised below.

4.7. The risk assessment has taken into account the full life cycle of the substance, including import, packaging, transport, storage, use and disposal.

4.8. The overall risk and benefit assessment:

- considered the risks posed by Boxer Gold
- determined whether the risks are outweighed by the benefits
- determined whether any variations or additions to the prescribed controls are required to manage the risks of this substance, and identified controls that may not be applicable or necessary that can, therefore, be deleted

Risks during importation, manufacture, transportation, storage and disposal

4.9. The applicant intends to import Boxer Gold packaged ready for sale. The risks associated with the importation, manufacture, transportation, storage and disposal of Boxer Gold were considered by the Committee based on the EPA risk assessment.

4.10. The Committee considered that adherence to the proposed controls and other legislative requirements would ensure that the level of risk to human health and the environment from importation, manufacture, transportation, storage and disposal of Boxer Gold would be negligible. These include the Hazardous Substances Notices regarding packaging, identification, emergency management and disposal of hazardous substances, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and New Zealand's HSW requirements.

Assessment of risks to human health

4.11. The Committee noted that the quantitative risk assessment determined that risks to operators during mixing, loading and application of Boxer Gold for each use pattern were below the level of concern with the use of PPE.

4.12. The Committee noted that the EPA assessment determined that the risks to re-entry workers and bystanders were below the level of concern.

4.13. The Committee noted that WorkSafe assessed the available information for Boxer Gold and considered that compliance with the HSW (HS) and HSW (General Risk and Workplace Management) Regulations would be adequate to reduce the risks associated with the use of this substance in the workplace. The Committee discussed WorkSafe's advice on the hazardous co-formulant, and the EPA said that this was an ongoing issue. The Committee concluded that if WorkSafe had serious concerns, they would have specified these in their report.

Assessment of risks to the environment

4.14. The Committee noted that the EPA staff had conducted a quantitative risk assessment. The risk assessment considered the effect of the proposed use of Boxer Gold on target and non-target organisms in the environment.

Aquatic organisms

4.15. The Committee noted that the EPA assessment showed non-acceptable risks to aquatic organisms. They also noted that to mitigate the risks from spray drift, additional controls requiring boom spray application, coarse droplet size and a 5 m buffer zone for downwind waterbodies were proposed by the EPA.

Sediment-dwelling organisms

4.16. The Committee noted that risks to sediment-dwelling organisms from the proposed use of Boxer Gold were identified by the EPA as potentially being above the level of concern. However, refinement showed that no buffer zone was required to mitigate risks from spray drift to these organisms when coarse droplet size is used. Therefore, the Committee did not propose any controls additional to those proposed to mitigate risks to aquatic organisms.

Earthworms and other soil organisms

4.17. The Committee noted that the EPA assessment found that both the acute and chronic risks to soil organisms from the proposed use of Boxer Gold were negligible.

Non-target plants

4.18. The Committee noted that the EPA assessment found that the risks to non-target plants from the proposed use of Boxer Gold were non-negligible. They also noted that additional controls setting a 5 m buffer zone and requiring a label statement were proposed by the EPA.

Birds

4.19. The Committee noted that the chronic risks to birds from the proposed use of Boxer Gold were identified by the EPA as potentially being non-negligible. However, refinement showed that the risks to threatened species were likely to be below the level of concern, so the Committee did not propose any conditional controls.

Pollinators and non-target arthropods

4.20. The Committee noted that the EPA assessment found that the risks to non-target arthropods from the proposed use of Boxer Gold may be non-negligible, and that the EPA had therefore proposed an additional label statement control.

Assessment of risks to Māori and their relationship to the environment

4.21. The Committee noted that the EPA staff assessed the potential effects on the relationship of Māori to the environment in accordance with sections 5(b), 6(d) and 8 of the Act. This included an assessment of the potential impacts of Boxer Gold on kaitiakitanga, and fulfilment of Treaty of Waitangi obligations.

4.22. Based on the Māori perspective report and other information provided to the Committee by the applicant and submitters, the Committee considered that with the proposed controls in place, the impact of approval of use of Boxer Gold on the relationship of Māori to the environment would be negligible, and likely to be consistent with the principles of the Treaty of Waitangi.

Assessment to risks to society, the community and the market economy

4.23. The Committee considered that the overall level of risk to society, the community and the market economy after taking into account the controls would be negligible.

New Zealand's international obligations

4.24. The Committee noted no international obligations have been identified that may be impacted by the approval of Boxer Gold.

Assessment of benefits

4.25. The applicant referred to several benefits of the substance in their application and elaborated on these at the hearing.

Increased yield

4.26. The applicant considers that Boxer Gold has shown very high levels of efficacy against major weeds in potato crops, particularly black nightshade. During the hearing, the applicant stated that weeds compete for resources with the potato crop, so controlling these increases crop yield and quality. The EPA considers that an efficacious product would be a significant benefit, but that the level of this is undetermined because ACVM assesses efficacy data.

Resistance Management

4.27. The applicant stated that black nightshade is becoming resistant to Group C1 triazine herbicides and that growers are having difficulty controlling this weed. They claimed that Boxer Gold's two active ingredients working simultaneously help manage resistance and that Boxer Gold can completely control black nightshade. The EPA considers that resistance management would be a significant benefit, but that the level of this is undetermined because ACVM assesses efficacy data.

More choice for farmers

4.28. The applicant considers that the availability of Boxer Gold would give more choice to farmers in regards to weed control, particularly for black nightshade, and that a herbicide offering dual modes of action would be highly beneficial for growers. The EPA notes that Boxer Gold contains a new active ingredient which could provide an additional tool for farmers, therefore this is considered a significant benefit.

Conclusions on the assessment of benefits

4.29. After considering the information that was presented, the Committee considered that there are potential benefits that will be derived for New Zealand by allowing the import or manufacture of Boxer Gold, though they noted that the threshold for benefits is low.

5. Controls

Prescribed controls

5.1. The hazard classifications of Boxer Gold determine a set of prescribed controls specified by the EPA Notices under section 77 of the Act. There are also requirements in the HSW (HS) Regulations. Note: the HSW (HS) Regulations requirements are not set for the substance under this approval but apply in their own right.

5.2. The prescribed controls set the baseline for how the substance must be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed, transported,

handled and used. The prescribed controls also set information requirements (eg Safety Data Sheets), signage and emergency management. These controls form the basis of the controls specified in Appendix A.

5.3. Clause 17 of the Labelling Notice requires that certain toxic or corrosive components are identified on the product label. Section 3 of Schedule 1 of the Safety Data Sheet (SDS) Notice requires certain toxic or corrosive components are identified on the SDS. Section 8 of Schedule 1 of the SDS Notice requires occupational exposure limits to be identified on the SDS. Based on the information provided by the applicant, there is at least one component of Boxer Gold that has a Workplace Exposure Value (WES) and this needs to be identified on the SDS.

Exposure limits

5.4. The Committee noted that the EPA does not propose a Tolerable Exposure Limit (TEL) for Boxer Gold, or any element or component in Boxer Gold, as exposure to this substance is not likely to result in an appreciable toxic effect to people, provided controls on use are followed. However, the Committee noted that the Acceptable Daily Exposure (ADE) and Potential Daily Exposure (PDE) shown below are proposed by the EPA as health-based exposure guidance values that can be used to inform risk assessments as well as the setting of controls, such as Maximum Residue Levels (MRLs) under the ACVM Act 1997.

5.5. The following values are provided for prosulfocarb:

- ADE = 0.005 mg/kg bw/day
- PDE (food) = 0.0035 mg/kg bw/day
- PDE (drinking water) = 0.001 mg/kg bw/day
- PDE (other) = 0.4 mg/kg bw/day

5.6. No Environmental Exposure Limit (EEL) values are proposed at this time for prosulfocarb. This is because it is not considered that, with controls in place, environmental exposure is likely to result in an appreciable ecotoxic effect based on the quantitative risk assessment.

Changes to prescribed controls

Maximum impurity

5.7. The Committee noted the recommendation to set a limit for an impurity of toxicological relevance in the active ingredient S-metolachlor used to manufacture Boxer Gold. The Committee agreed with the EPA staff recommendation to set the following impurity limit:

R-metolachlor (178961-20-1): maximum 130 g/kg

Maximum application rate

5.8. The Committee noted that the environmental assessment was based on the application rates proposed by the applicant, and therefore agreed with the EPA staff recommendation to propose a maximum application rate and number of applications. Therefore, the maximum application rate for Boxer Gold is 5 L/ha (equivalent to 4 kg prosulfocarb/ha and 0.6 kg S-metolachlor/ha) with a maximum of one application per year.

Application method

5.9. The Committee noted that the environmental risk assessment was based on the application methods specified by the applicant. In particular, the restriction to apply Boxer Gold via ground-based methods only, the restriction to a coarse droplet size and the restriction to favourable wind conditions are key factors in minimizing exposure to aquatic environments. The Committee therefore agreed with the following EPA recommendation:

- Boxer Gold can only be applied by ground-based methods.
- Boxer Gold must be applied with low boom ground-based equipment, using a coarse droplet size, as defined by the American Society of Agricultural and Biological Engineers (ASABE) Standard (S572) or the British Crop Production Council (BCPC) guideline.
- Boxer Gold must not be applied when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.

Buffer zones

5.10. The Committee noted the recommendation to set a buffer zone to mitigate the risks from spray drift. The Committee agreed with the EPA's recommendation that Boxer Gold must not be applied within 5 m of any downwind waterbody.

Additional label statements

5.11. The Committee noted the recommendation to require additional label statements to mitigate risks from runoff and spray drift to the aquatic environment and non-target plants. The Committee therefore agreed with the following EPA recommended label statements:

- *"To reduce runoff from treated areas into aquatic habitats, characteristics and conditions of the site must be considered. Site characteristics and conditions that may lead to runoff include, but are not limited to, moderate to steep slope, bare soil, and poorly draining soil (eg soils that are compacted, fine textured or low in organic matter such as clay). Avoid application of Boxer Gold when heavy rain is forecast."*
- *"**WARNING**, very toxic to some plant species. Certain plants may be damaged or killed from contact with this product. The substance should not be applied within 5 m of a downwind area containing any non-target plants".*

- *"Before application users should check with the regional authority to establish if there are wetlands, indigenous vegetation habitat areas or reserves which may contain threatened plants adjacent to the application area, in which case it is recommended to increase the buffer zone to 20 m".*

5.12. The Committee also noted the recommendation to require additional label statements to mitigate risks to non-target arthropods and limit off-target exposure. The Committee therefore agreed with the following EPA recommended label statements:

- "***WARNING**, might not be compatible with IPM*".
- *"**DO NOT** apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site."*

Review of additional controls and variations

5.13. The Committee reviewed the additional controls and variations to the prescribed controls mentioned above and considered them necessary to achieve their purpose of effective risk management of the use of Boxer Gold in New Zealand.

5.14. The full suite of controls, including variations, can be found in Appendix A of this document.

5.15. At the hearing, the applicant was given an opportunity to comment on the proposed controls as set out in the Staff Report. The applicant had no concerns with the controls, and the Committee has not made any changes to the controls recommended by the EPA.

6. Conclusion

6.1. Taking into account the assessment of the potential risks and benefits associated with Boxer Gold the Committee considered that, with all of the controls in place:

- The overall risks to human health and the environment arising from the hazardous properties and the use of Boxer Gold are negligible.
- Significant adverse impacts on the social or economic environment from the use of Boxer Gold are not anticipated.
- If Boxer Gold is applied in the proposed manner, it would likely be consistent with the principles of Te Tiriti o Waitangi/the Treaty of Waitangi. Significant impacts on Māori culture or traditional relationships with ancestral lands, water, wahi tapu, valued flora and fauna or other taonga have not been identified.
- Benefits will be derived for New Zealand by allowing the use of Boxer Gold.

7. Decision

7.1. Pursuant to section 29 of the Act, the Committee has considered this application for approval under section 28 of the Act. The Committee has considered the effects of this substance throughout its life cycle, the controls that may be imposed on this substance and the likely effects of this substance

being unavailable. The Committee has also taken into account the considerations set out in Part 2 of the Act.

7.2. The Committee was satisfied with the hazard classifications identified by the EPA in Table 1 and has applied these classifications to Boxer Gold.

7.3. The Committee considered that, with controls in place, the risks to human health and to the environment would be negligible, and the benefits associated with the release of this substance would outweigh the adverse effects. Therefore, in accordance with section 29 of the Act and clause 26 of the Hazardous Substances and New Organisms (Methodology) Order 1998, the Committee approved the application to import or manufacture Boxer Gold for release with controls.

Signed by: **Dr Kerry Laing**	**Date: 4 August 2020**
Chair, Decision Making Committee **Environmental Protection Authority**	

Appendix A: Controls applying to Boxer Gold

EPA Controls

Control code	Regulation	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances
SDS	EPA Safety Data Sheet Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for class 9 substances
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of class 9 substances
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	Qualifications required for application of class 9 pesticides

HSNO Additional Controls and Modifications to Controls

<table>
<tr><th>Code</th><th>HSNO Act</th><th>Control</th></tr>
<tr><td>Application rate</td><td>Section 77
Variation to HPC clause 50</td><td>The maximum application rate for Boxer Gold is 5 L/ha (equivalent to 4 kg prosulfocarb/ha and 0.6 kg S-metolachlor/ha) with a maximum of one application per year.</td></tr>
<tr><td>Application method</td><td>Section 77A</td><td>Boxer Gold can only be applied by ground-based methods.
Boxer Gold must be applied with low boom ground-based equipment, using a coarse droplet size, as defined by the American Society of Agricultural and Biological Engineers (ASABE) Standard (S572) or the British Crop Production Council (BCPC) guideline.
Boxer Gold must not be applied when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.</td></tr>
<tr><td>Maximum impurity</td><td>Section 77A</td><td>The following maximum limit is set for the toxicologically relevant impurity in the active ingredient S-metolachlor used to manufacture Boxer Gold:
R-metolachlor (CAS 178961-20-1): maximum 130 g/kg</td></tr>
<tr><td>Buffer zones</td><td>Section 77
Variation to HPC notice clause 51</td><td>The person in charge of the application of this substance and any person applying this substance must ensure that the substance is not applied within a specified distance of a downwind waterbody.
For this substance the following buffer zone applies, according to the relevant application method and scenario:
<table>
<tr><th>Application method</th><th>Sensitive area</th><th>Required buffer zone (m)</th></tr>
<tr><td>Ground-based</td><td>Water body</td><td>5</td></tr>
</table>
</td></tr>
<tr><td>Label</td><td>Section 77
Variation to Labelling Notice</td><td>The label must include the following statements:
• “To reduce runoff from treated areas into aquatic habitats, characteristics and conditions of the site must be considered. Site characteristics and conditions that may lead to runoff include, but are not limited to, moderate to steep slope, bare soil, and poorly draining soil (eg soils that are compacted, fine textured or low in organic matter such as clay). Avoid application of Boxer Gold when heavy rain is forecast.”
• “WARNING, very toxic to some plant species. Certain plants may be damaged or killed from contact with this product. The substance should not be applied within 5 m of a downwind area containing any non-target plants.”
• “Before application users should check with the regional authority to establish if there are wetlands, indigenous vegetation habitat areas or reserves which may contain threatened plants adjacent to the application area, in which case it is recommended to increase the buffer zone to 20 m.”
• “WARNING, might not be compatible with IPM.”</td></tr>
</table>

		• *"**DO NOT** apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site."*

HSW HS Requirements

Note: these requirements are not set for the substance under this approval but apply in their own right under the HSW Act and HSW (HS) Regulations according to the classification of the substance. They are listed here for information purposes only.

Code	Regulation	Description
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers
HSW2-2	Reg 2.5 - 2.10	Signage
HSW2-3	Reg 2.11	Safety data sheets
HSW2-4	Reg 2.12 - 2.14	Packaging
HSW3-1	Reg 3.1	Inventory
HSW3-2	Reg 3.2 - 3.3	Managing risks associated with hazardous substances
HSW4-2	Reg 4.5 - 4.6	Information, instruction, training and supervision
HSW5-1	Reg 5.2 - 5.5	Fire extinguishers
HSW5-2	Reg 5.6 - 5.13	Emergency response plans
HSW8-2	Reg 8.3 - 8.4	Requirements for public transportation of class 1 to 5 substances
HSW10-3	Reg 10.5	Requirement to segregate class 2, 3, and 4 substances
HSW10-5	Reg 10.8 - 10.20	Requirements to prevent unintended ignition of class 2.1.1, 2.1.2 and 3.1 substances
HSW10-12	Reg 10.30-10.33	Secondary containment for class 3 and 4 pooling substances
HSW11-1	Part 11	Controls relating to adverse effects of unintended ignition of class 2 and 3.1 substances
HSW13-2	Reg 13.7	Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate
HSW13-3	Reg 13.8	Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used
HSW13-8	Reg 13.17	Prohibition on use of substance in excess of tolerable exposure limit
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded
HSW16-1	Part 16	Requirements for tank wagons and transportable containers
HSW17-1	Part 17	Requirements for stationary container systems

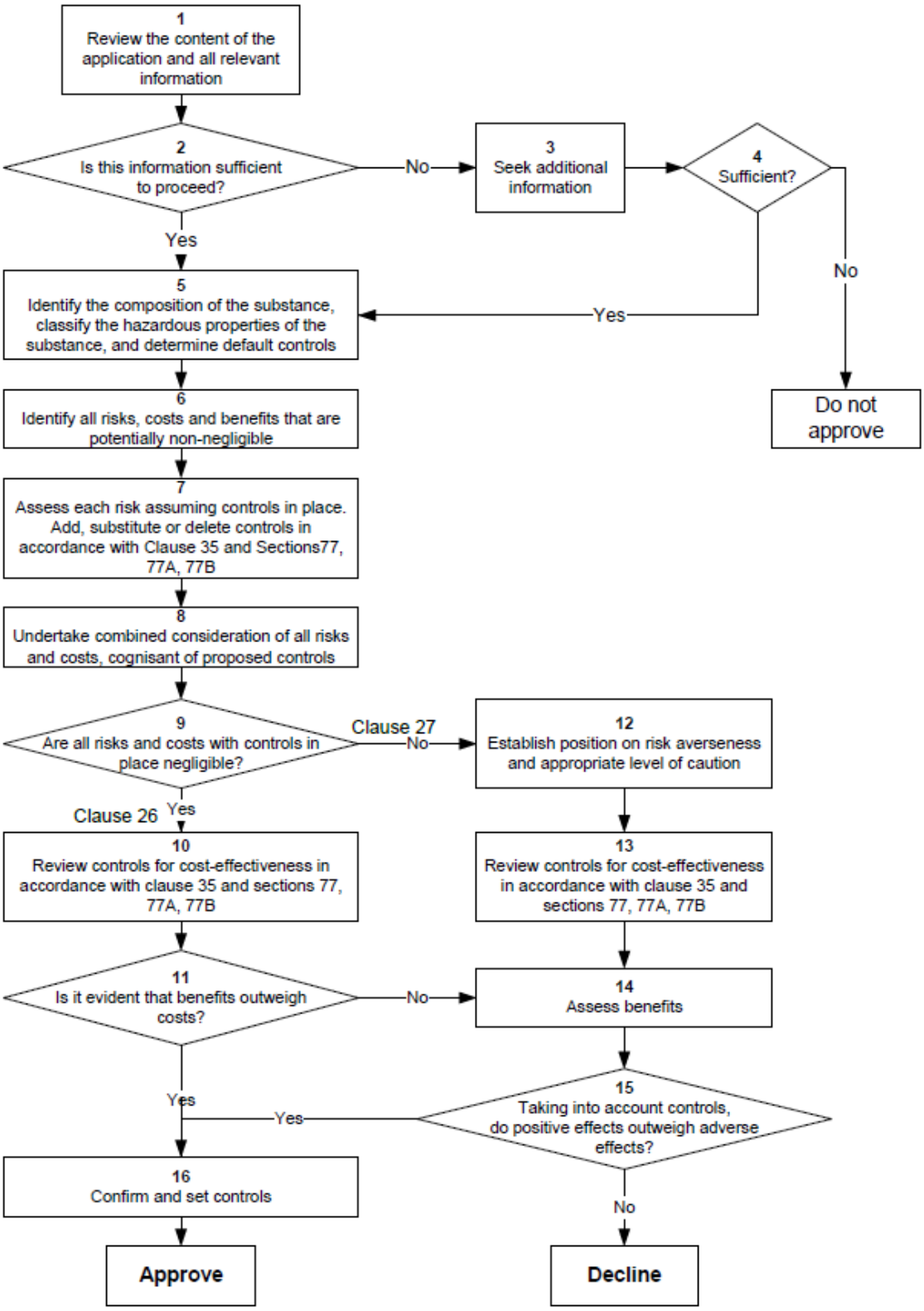
Appendix B: Decision Path

Context

This decision path describes the decision-making process for applications to import or manufacture a hazardous substance. These applications are made under section 28 of the HSNO Act and determined under section 29.

Decision path for applications to import or manufacture a hazardous substance, application made under section 28 of the Act and determined under section 29.

For proper interpretation of the decision path it is important to work through the flowchart in conjunction with the explanatory notes.



Explanatory Notes

Item 1:	**Review the content of the application and all relevant information** Review the application, the E&R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology.
Item 2:	**Is this information sufficient to proceed?** Review the information and determine whether or not there is sufficient information available to make a decision. The Methodology (clause 8) states that the information used by the HSNO decision maker in evaluating applications shall be that which is appropriate and relevant to the application. While the HSNO decision maker will consider all relevant information, its principal interest is in information which is significant to the proper consideration of the application; ie information which is "necessary and sufficient" for decision-making.
Item 3:	**(if 'no' from item 2) Seek additional information** If there is not sufficient information then additional information may need to be sought from the applicant, EPA staff or other parties/experts under section 58 of the Act (clause 23 of the Methodology).
Item 4	**Sufficient?** When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision? If the HSNO decision maker is not satisfied that it has sufficient information for consideration, then the application must be declined under section 29(1)(c).
Item 5:	**(If 'yes' from item 2 or from item 4) Identify the composition of the substance, classify the hazardous properties, and determine default controls** Identify the composition of the substance, and establish the hazard classifications for the identified substance. Determine the default controls for the specified hazardous properties using the regulations "toolbox".
Item 6:	**Identify all risks, costs and benefits that are potentially non-negligible[1]** Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these „values" are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs that might not be obviously linked to risks are direct financial costs that cannot be considered as "sunk" costs (see footnote 1). Where such costs arise and they have a market economic effect they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 11). Identification is a two-step process that scopes the range of possible effects (risks, costs and benefits).

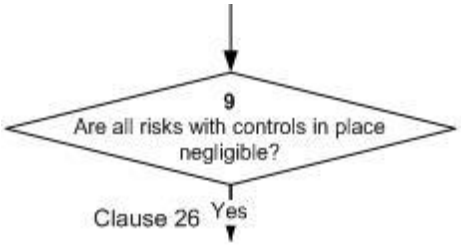
[1] Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account in weighing up adverse and positive effects. These latter types of costs are sometimes called "sunk" costs since they are incurred whether or not the application is successful.

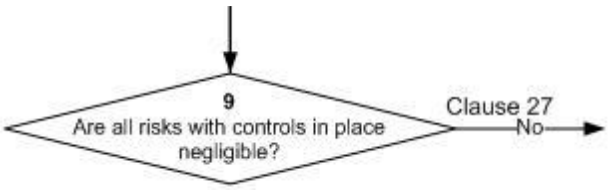
	Step 1:	Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act[2]. Consider the effects of the substance through its lifecycle (clause 11) and include the likely effects of the substance being unavailable (sections 29(1)(a)(iii) and 29(1)(b)(iii)). Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14). Consider short term and long term effects. Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.
	Step 2:	Document those risks, costs and benefits that can be readily concluded to be negligible[3], and eliminate them from further consideration. Note that where there are costs that are not associated with risks some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.
Item 7:	**Assess each risk assuming controls in place. Add, substitute or delete controls in accordance with clause 35 and sections 77, 77A and 77B of the Act.** The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. The assessment is carried out with the default controls in place. Assess each potentially non-negligible risk and cost estimating the magnitude of the effect if it should occur and the likelihood of its occurring. Where there are non-negligible financial costs that are not associated with risks then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account. The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost. This assessment includes consideration of how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and how significant the uncertainty is for the decision (clause 29(a)). Consider the HSNO decision maker's approach to risk (clause 33 of the Methodology) or how risk averse the HSNO decision maker should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls. See EPA report 'Approach to Risk' for further guidance[4].	

[2] Effects on the natural environment, effects on human health and safety, effects on Māori culture and traditions, effects on society and community, effects on the market economy.

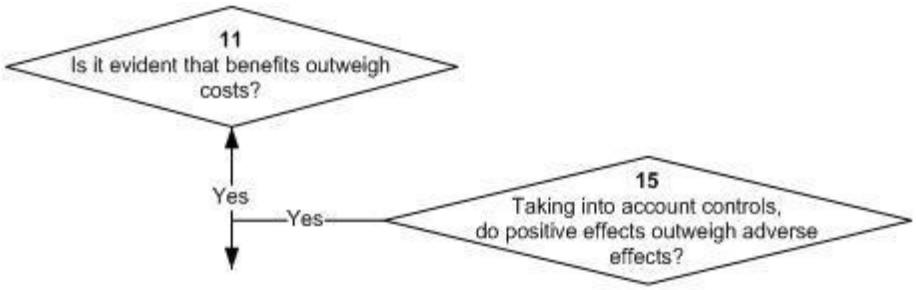
[3] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits."

[4] http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf

	Where it is clear that residual risks are non-negligible and where appropriate controls are available, add substitute or delete controls in accordance with sections 77 and 77A of the Act to reduce the residual risk to a tolerable level. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B. While clause 35 is relevant here, in terms of considering the costs and benefits of changing the controls, it has more prominence in items 10 and 13. If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.
Item 8:	**Undertake combined consideration of all risks and costs, cognisant of proposed controls** Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a “basket" of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.
Item 9:	**Are all risks with controls in place negligible?** Looking at individual risks in the context of the “basket" of risks, consider whether all of the residual risks are negligible.
Item 10:	 **(from item 9 - if ‘yes’) Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** Where all risks are negligible the decision must be made under clause 26 of the Methodology. Consider the practicality and cost-effectiveness of the proposed individual controls and exposure limits (clause 35). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.
Item 11:	**Is it evident that benefits outweigh costs?** Risks have already been determined to be negligible (item 9). In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 7. Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community. Consider whether there are any non-negligible external costs that are not associated with risks. If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of

	internal or private net benefit, and therefore total benefits outweigh total costs[5]. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the HSNO decision maker to indicate that the applicant believes the benefits to be greater than the costs. However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 14).
Item 12:	 **(if 'no' from item 9) Establish position on risk averseness and appropriate level of caution** Although "risk averseness" (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7).
Item 13:	**Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 9 and 12). Consider whether any of the non-negligible risks can be reduced by varying the controls in accordance with sections 77 and 77A of the Act, or whether there are available more cost-effective controls that achieve the same level of effectiveness (section 77A(4)(b) and clause 35(a)). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the views of the applicant (clause 35(b)), and making sure that the total benefits that result from doing so continue to outweigh the total risks and costs that result. As for item 7, if the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.
Item 14:	**(if 'no' from item 11 or in sequence from item 13) Assess benefits** Assess benefits or positive effects in terms of clause 13 of the Methodology. Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of it occurring. This assessment also includes consideration of the HSNO decision maker's approach to uncertainty or how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect.

[5] Technical Guide "Decision making" section 4.9.3. Where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the HSNO decision maker takes the act of making an application as evidence that the benefits outweigh the costs. See also Protocol Series 1 "General requirements for the Identification and Assessment of Risks, Costs, and Benefits".

	An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The HSNO decision maker will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[6]. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the HSNO decision maker may choose to be more risk averse and to place a higher weight on the risks and costs. As for risks and costs, the assessment is carried out with the default controls in place.
Item 15:	**Taking into account controls, do positive effects outweigh adverse effects?** In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7, 10 and/or 13. Where this item is taken in sequence from items 12, 13 and 14 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology. Where this item is taken in sequence from items 9, 10, 11 and 14 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.
Item 16:	 **(if 'yes' from items 11 or 15) Confirm and set controls** Controls have been considered at the earlier stages of the process (items 5, 7, 10 and/or 13). The final step in the decision-making process brings together all the proposed controls, and reviews for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.

[6] This principle derives from Protocol Series 1, and is restated in the Technical Guide "Decision making".