Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM
CONTAINMENT

Application Form: HS3 Import or Manufacture any Hazardous Substance in Containment

under section 31 of the Hazardous Substances and New Organisms Act 1996

To submit an application, please send by post to: Environmental Protection Authority, Private Bag 63002, Wellington 6140
OR email to: HSApplications@epa.govt.nz

Payment must accompany application: see our fees and charges schedule for details. Please allow 10 working days for processing.

Applicant:

Phil Lester, Te Herenga Waka - Victoria University of Wellington

Name of substance:

Experimental dsRNA for *Varroa destructor* control and to protect honey bees

APPLICANT CHECKLIST			
Mandatory sections filled out	☐	Appendices enclosed	☐
Initial fees enclosed	☐	Signed and dated	☐
Electronic copy of application emailed to EPA	☐		

Office use only

Application code:

Date received:

EPA contact:

Initial fees paid: $

Application version no.:

Important

1. You can talk to an applications advisor at the EPA, who can help you scope and prepare your application. We need all relevant information early on in the application process. Quality information up front will speed up the process.
2. This application form may be used to seek approvals for more than one hazardous substance where the substances are related – for example, a concentrated compound (active ingredient) and its related formulations, or a range of substances for similar purposes to be tested in a field trial.
3. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included in an appendix to the application form.
4. Commercially sensitive information must be collated in a separate appendix.
5. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
6. You can get more information at any time by contacting us. One of our staff members will be able to help you.

   Environmental Protection Authority
   Private Bag 63002
   Wellington
   New Zealand
   Telephone: 64 4 916 2426
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   http://www.epa.govt.nz

Section 1 – Applicant details

1.1 Name and postal address in New Zealand of the organisation making the application:

Name: Prof. Phil Lester

Address: [redacted]

Phone: [redacted]

Fax: [redacted]

1.2 The applicant's location address in New Zealand (if different from above):

Address:

1.3 Name of the contact person for the application:

This person should have sufficient knowledge to respond to queries and either have the authority to make decisions that relate to processing the application on behalf of the applicant, or have the ability to go to the appropriate authority.

Name: [redacted]

Position: [redacted]

Address: [redacted]

Phone: [redacted]

Fax: [redacted]

Email: [redacted]

Section 2 – Application type and related approvals required

This form is only for an application to import a hazardous substance into containment, or manufacture a hazardous substance in containment.

2.1 Is this application to manufacture or import a hazardous substance in containment for any of the following purposes?

Containment applications can only be made for a limited range of purposes. In particular, the substance must not be intended for commercial manufacture or sale.

Small amounts of any hazardous substance for use as an analytical standard, where approval to import or manufacture that substance has been declined?	☐ Yes	☒ No
Research on any hazardous substance to acquire information for use in assessing that substance for a HSNO approval?	☐ Yes	☒ No
Research and development on any hazardous substance?	☐ Yes	☒ No
Use in an emergency?	☐ Yes	☒ No
Formulating, relabelling, repackaging, or storing any hazardous substance for export to a destination outside New Zealand?	☐ Yes	☒ No
Other purposes?	☐ Yes	☒ No

2.2 If you answered 'yes' to one of the purposes listed above, please provide some supporting detail. If you answered 'yes' to 'other purpose', describe the purpose and explain why this purpose is appropriate to a containment application.

The parasitic mite *Varroa destructor* is the greatest threat to honey bee health both in New Zealand and around the globe. Without effective control these mites will result in the collapse and death of a hive, through a direct combination of their feeding and the transmission of viruses. Traynor et al. (2020) highlight the *Varroa* problem, stating *"worrying observations include increasing acaricide resistance in the varroa population and sinking economic treatment thresholds, suggesting that the mites or their vectored viruses are becoming more virulent"*. New forms of mite control are desperately needed.

One potential option for a next-generation method for the control of pests such as *Varroa* is the use of double-stranded RNA (ribonucleic acid; dsRNA) for RNA interference or gene silencing. RNA interference is the process by which double-stranded RNA specifically silences the expression of homologous genes through degradation of their cognate mRNA (Hammond et al. 2001). Silencing is a post-transcriptional phenomenon: it is not a genetic modification as it does not modify DNA. The treatment of eukaryoktic cells with externally produced RNA molecules,

for the purpose of inducing small interfering RNA (siRNA)-mediated gene silencing, has been reviewed (and re-reviewed) by the EPA for the purposes of the Hazardous Substances and New Organisms Act 1996. These reviews have concluded the use of dsRNA are not "*are not genetically modified organisms in accordance with section 2A(1)(d) of the HSNO Act*" (APP203395, 2021).

Garbian et al. (2012) reported that dsRNA may be effective for mite control. They found that a "*reciprocal exchange of dsRNA between bee and Varroa engendered targeted gene silencing in the latter, and resulted in an over 60% decrease in the mite population. Thus, transfer of gene-silencing-triggering molecules between this invertebrate host and its ectoparasite could lead to a conceptually novel approach to Varroa control*" (Garbian et al. 2012). Others have also found dsRNA can be effective and may even be a 'silver bullet' for *Varroa* control (Paxton 2020). In the United States, the company GreenLight Biosciences, Inc. have been developing dsRNA for *Varroa* control. They have developed an economically viable production system and delivery method.

These dsRNA sequences are produced and then added to a sugar solution or matrix, and feed to honey bees. The dsRNA is incorporated into the nectar and brood food delivered to the developing larvae in the brood cells. The varroa mite comes in contact with the dsRNA in this brood food while it hides and reproduces in the brood cells. An example of a dsRNA concentration we propose to use is as in Garbian et al. (2012). In their study, bees were fed 5 ml of 50% sucrose solution in troughs placed small mini-hives maintained in the laboratory. In their approach they used 200 mg each of five to 14 dsRNAs added to the sugar solution (Garbian et al. 2012). The use of dsRNA has now scaled up to employ large field trials in the United States previously by Bayer, and now by GreenLight Biosciences, Inc. For example, one field trial conducted by Bayer in 2016 used 2500 colonies, based in locations around the US (Masucci 2020). Additionally, GreenLight Biosciences, Inc. conducted field trials with a total of 1440 colonies in various locations in the US over the course of 2021.

We propose to feed dsRNA to bees within the laboratory but also to a small number of hives (20 -200) in the field environment. Our dsRNA delivery methods will mirror those used the GreenLight Biosciences, Inc. system as reported by Masucci (2020). None of the honey used in the trials will be used for human consumption. Our goal is to scale-up in successive trials:

- Small cage trials. Within the laboratory we would have cages containing a small number (10-50 bees) of adult bees collected from the university hives. The bees can be inoculated with Varroa mites and fed dsRNA treatments. The bees would be maintained in the cages and they would never leave the laboratory environment. At the conclusion of the experiment the bees would be killed for DNA extraction. Any remaining bees would be disposed of as per normal PC2 laboratory conditions.
- Small hive trials within the laboratory. This approach uses the protocol of Garbian et al. (2012), which had miniature hives with a queen, 250 workers, plus brood (juvenile honey bees). They are maintained in cages within the laboratory. Each cage has a small foraging arena. The miniature hive can be inoculated with Varroa mites. The bees can be fed dsRNA treatments. As per the small cage trials, the bees would be maintained in the cages and they would never leave the laboratory environment. At the conclusion of the experiment the bees would be killed for DNA extraction. Any remaining bees would be disposed of as per normal PC2 laboratory conditions. We expect to use a maximum approximately 80 mini-hives in this experiment.

- Field trials with realistic hives. Our ultimate goal is to test our dsRNA treatments on 20-200 hives placed in the field environment, in different regions of New Zealand. We'd like to perform this experiment over 2 successive summers. This would be the ultimate test of the mite control system. Virus, mite and bee populations would be monitored. Honey produced by the bees would not be sold or enter the market. Bees would not be destroyed at the end of the experiment.

2.3 Is the information in this application relevant to import, manufacture or both?

Import the substance(s) only?	☒ Yes	☐ No
Manufacture the substance(s) only?	☐ Yes	☒ No
Import and manufacture the substance(s)?	☐ Yes	☒ No
If import only, indicate whether or not manufacture is likely in New Zealand:	☐ Yes	☒ No

2.4 If the information in the application relates to manufacture of the substance(s) in New Zealand, provide information on the proposed manufacturing process and any alternatives.

We are not proposing to manufacture the dsRNA treatments within New Zealand.

2.5 If this substance(s) needs an approval under any other legislation, has an application for this approval been made?
(Optional)

Name of approval	Application made
Agricultural Compounds and Veterinary Medicines Act 1997	☐ Yes ☒ No ☐ NA
Food Act 1981	☐ Yes ☐ No ☒ NA
Medicines Act 1981	☐ Yes ☐ No ☒ NA
Chemical Weapons (Prohibition) Act 1996	☐ Yes ☐ No ☒ NA
Radiation Protection Act 1965	☐ Yes ☐ No ☒ NA
Biosecurity Act 1993	☒ Yes ☐ No ☐ NA
Resource Management Act 1991	☐ Yes ☐ No ☒ NA
Other (please specify):	

	☐ Yes ☐ No
	☐ Yes ☐ No
	☐ Yes ☐ No

Section 3 – Information on the substance(s)

Note that all information that is commercially sensitive must be attached as an appendix. The application form should be cross-referenced to the appendix but should be able to be read as a stand-alone document (which will be publicly available).

If approval is being sought for more than one hazardous substance, this section must be completed separately for each hazardous substance.

3.1 State the unequivocal identification of the substance(s).

Our dsRNA treatments will be those used in Masucci (2020). The concentrations of this dsRNA application will vary, from approximately 1 mg/mL – 10 mg/ml. The sequence targeting *Varroa* mites is currently confidential but it is as stated in the appendix. We have two sources for this dsRNA: one from RNA Greentech LLC, and the other from GreenLight Biosciences, Inc.. The GreenLight Biosciences, Inc. delivery method is a sealed plastic pouch (Figure 1) containing a sucrose solution as specified in the appendix. The CAS Registry number for the GreenLight Biosciences, Inc. dsRNA, CSF and sequence information is presented in the confidential appendix.

Figure 1. Honey bees feeding on top of a GreenLight pouch with dsRNA and sucrose syrup at the hive of beekeeper in Barwick, Georgia, USA. This hive was part of a large scale trial involving many thousands of hives across several states. A preliminary analysis of the results from this trial suggest that it was successful in reducing *Varroa* mite abundance.
Photo from www.greenlightbiosciences.com

For the RNA Greentech LLC systemthere are no additional chemical, trade names or or common names. The dsRNA we obtain from the company RNA Greentech LLC is delivered to us in distilled water and is certified as 'clear and free of foreign particles' (see the attached PDF). In addition, we will use a dsRNA for a Green fluorescent protein (GFP) as a 'positive control' for trials where dsRNA is administered. GFP is a common positive control in experiments with dsRNA for pest control (Christiaens et al. 2020).

[redacted]

3.2 Provide information on the chemical and physical properties of the substance(s).

The RNA Greentech LLC is a colourless liquid. The GreenLight Biosciences, Inc. dsRNA is a clear aqueous solutions, that is odorless at a pH between 5-7. It is not flammable nor explosive.

3.3 Provide information on the hazardous properties of the substance(s).

dsRNAs have a history of safe consumption by humans and other vertebrates as concluded by an OECD Environment, Health and Safety Publication discussing the safety of externally applied dsRNA pesticides (2020).

RNA is present in the environment and is continually consumed by organisms. GreenLight Biosciences, Inc. formulates dsRNA into a sucrose matrix made of U.S. FDA direct food substances affirmed as generally recognized as safe (U.S. Food and Drug Administration, 2021). Of relevance is a recent study in which sequences of dsRNA were fed to monarch butterfly larvae. KrishnanI et al. (2021) chronically exposed the entire monarch larval stage to common and tropical (milkweed leaves treated with concentrations of Varroa-active dsRNA that are one- and ten-fold higher than those used to treat honey bee hives. This corresponded to concentrations of 0.025–0.041 and 0.211–0.282 mg/g leaf, respectively. The Varroa mite and monarch-active dsRNA's did not cause significant differences in larval mortality, larval or pupal development, pupal weights, or adult eclosion rates when compared to negative controls.

The dsRNA and sucrose matrix is not explosive, flammable, and does not have oxidising properties.

3.4 Provide information on what will happen to the substance throughout its whole life, from its introduction into New Zealand, its uses, through to disposal.

The information provided needs to reflect the containment character of the application. It will be used in the development of exposure scenarios and the assessment of risks, and hence the specification of the containment conditions.

General handling

Victoria University of Wellington laboratories has considerable experience in testing experimental compounds operate to practices which meet the Worksafe requirements developed previously for the now surpassed Code of Practice for CRI and University Laboratories (ELCOP). Handling of substances in the field will be in accordance with the Code of Practice for the Management of Agrichemicals NZS 8409: 2004.

Importation

Experimental substances will be imported to meet the requirements of the HSNO and ACVM Acts.

Transport

Each experimental dsRNA compound and matrix will be imported fully packaged, with the compound contained in polyethylene terephthalate (PET) bottle or other suitable containers. These compounds when transported in bulk, will be packed in UN approved packaging that is suitable for the shipment to and within New Zealand. Transport workers, wharf workers will only handle the fully packaged product, comprising the outer package, inner absorbent material and the inner package containing the substance. Exposure during transport, storage and handling is only possible through the breach of this packaging. The substances will be transported from Victoria University of Wellington laboratories sites to field sites using double containment to prevent leakage or spillage from contaminating the environment. A Safety Data Sheet (if available) will accompany any transported substances and be available at all stages of product life.

Storage

Substances used to manufacture the formulations will be stored in designated and secure chemical storage areas at Victoria University of Wellington. Surplus substances and used containers shall ultimately be disposed of in a manner compliant with the Hazardous Substances (Disposal) Regulations 2001.

Manufacturing and dispensing

We will not be manufacturing and dsRNA on-site in Victoria University of Wellington laboratories.

Intended use of the substance

The substances will be applied by ground based application methods. Handling of substances in the field will be in accordance with the Code of Practice for the Management of Agrichemicals NZS 8409: 2004.

Disposal of the substance

The amount of compound prepared will be the minimum necessary for the trial. At the end of each trial, any remaining dsRNA and matrix would be recovered from the hives and reused or disposed of in Victoria University of Wellington's organic chemistry laboratory's solid chemical waste stream. Disposal options will relate to the relevant requirements of the Hazardous Substances (Disposal) Regulations 2001and standard NZS8409:2004 Management of Agrichemicals.

3.5 Provide information on the quantity of the substance proposed to be imported or manufactured.

This information is used in the development of exposure scenarios and the assessment of risks.

There are three sets of trials for which we will need quantities of dsRNA.

- Small cage trials. Within the laboratory we would have cages containing a small number (10-50 bees) of adult bees collected from the university hives. We expect to import approximately 200 mg of dsRNA from RNA Greentech LLC for this experiment.
- Small hive trials within the laboratory. This approach uses the protocol of Garbian et al. (2012), which had miniature hives with a queen, 250 workers, plus brood (juvenile honey bees). We expect to use a maximum approximately 80 mini-hives in this experiment. Each hive would be treated with between 0-4 g/L of dsRNA in a single dose, with the potential for multiple doses in a treatment plan.
- Field trials with realistic hives. Our ultimate goal is to test our dsRNA treatments on 20-200 hives placed in the field environment, in different regions of New Zealand. We'd like to perform this experiment over 2 successive summers. between 0-4 g/L of dsRNA in 500 mL pouch formulated in a sucrose matrix. 1-2 pouches would be given to a hive for 1 treatement, with the possibility of 2 treatments in a year.

Section 4 – Information on the proposed containment system

4.1 Provide information on the proposed containment system.

It is essential that good information is provided on the containment system because the adequacy of containment, in conjunction with the hazardous properties of the substance, will have a major impact on whether or not approval is given.

You will need to provide a description of the containment proposed AND information on how you intend to address the following issues (proposed controls):

- Methods for preventing the escape of the contained hazardous substance and preventing the contamination of the facility
- Methods for excluding unwanted organisms from the facility or to control organisms within the facility
- Methods for excluding unauthorised people from the facility
- Methods for preventing unintended release of the substance by experimenters
- Methods for controlling the effects of any accidental release of the substance
- Inspection and monitoring requirements of the containment facility.

A management plan may be attached as an appendix. This plan should specify the procedures for implementing the above methods for containing the substance(s), and provide details of the qualifications of the person responsible for implementing those controls.

Subtances will be stored securely as detailed above. At all times other than when the compounds are being assessed, the compounds are stored and transported in clearly labelled, robust containers, in locked Victoria University of Wellington facilities that are only accessible to experienced/authorised staff. Equipment is thoroughly washed and rinsed after each use. The formulations are manufactured in the laboratory and all treatments are placed directly in to the brood nest of the colonies. The treated varroa and honey bees will be killed at the end of the laboratory trials, although any bees in field trials will be alive at the end of the experiment. At the end of each hive trial, any remaining matrix would be recovered from the hives and reused or disposed of in Victoria University's organic chemistry laboratory's solid chemical waste stream (though a licensed disposal company). The honey frames from treated colonies will be burned after trials have been completed. No honey will be extracted from these colonies. The surplus chemicals will be disposed of by a licensed disposal company.

The spread of these products is unlikely as other animals do not enter the colonies unless the colonies are dwindling in size. We will manage the colonies so that they remain healthy. If this is not possible then the treatments will be removed from the colonies immediately.

Methods for excluding unwanted organisms from the facility or to control organisms within the facility

The honey bee colonies are routinely monitored by the researchers for signs of unwanted pests and diseases. Pesticides may be used to control these providing they do not interfere with the trial. Active and passive insect and rodent traps are present throughout the laboratory facilities. Trial sites that are at risk from grazing animals will be secured by stock proof fencing during the duration of the trial.

Methods for excluding unauthorised people from the facility

Trials with small numbers of bees and mini-hives will be carried out in Victoria University laboratories with staff-restricted access. Field trials on hives will be conducted on Victoria University research apiaries and privately-owned properties. Access to the trial site on private property will be by permission of the trial director or owner of the property. Trial site boundaries will be clearly marked and distinctly visible from outside the trial site throughout the duration of the trial. The research sites will also clearly labelled with signs that prohibit unauthorised access, identify the area as an experimental site, and state that products are not to be removed and consumed from the study site. Property owners or managers/organisations leasing or responsible for managing land where the proposed trials are to be located will be notified in advance of when treatments are to be applied and asked to inform any staff working on the property that this is a trial site.

Methods for preventing unintended release of the substance by experimenters

No treated produce shall be consumed by people or (so far as is reasonably practicable) animals or sold, offered for sale, given away, bartered or otherwise distributed unless the ACVM Group has approved this process as part of a provisional registration or research approval. In all cases, trial sites shall be chosen so as to prevent the substances entering any surface water or groundwater system and to prevent residential buildings or workplaces not related to the research being exposed to the substance. Experimental compounds will be applied under the direction of approved handler/Growsafe® accredited personnel. These personnel will be made aware of the contents and requirements of the Project Plans and controls in order to adequately manage the substances.

Methods for controlling the effects of any accidental release of the substance

Material safety data sheets are kept on file by the project leader. Spillages will be contained, prevented from entering water bodies, and be absorbed with appropriate material. This will then be placed into sealed containers for disposal at an appropriate waste disposal facility. All staff working with the substance will be advised of this procedure prior to commencement of the trial.

Inspection and monitoring requirements of the containment facility.

Application records will be kept and are available for inspection for all substances for a minimum of three years from cessation of a trial.

Section 5 – Identification and assessment of risks

In completing this section, it is important that you take account of the proposed containment system you described in Section 4. We are particularly interested in knowing about risks that may still remain with the containment system in place. You will need to consider the effects on the environment and public health, including any social effects. You should also take account of the quantity of material involved and the number of different locations that may be involved.

Complete this section as far as you can.

5.1 Identify all of the risks of the substance(s).

Include information on potentially significant, possible risks of the substance and whether or not these risks are *likely* to be significant. It is important to think about the source of the risk – ie, the way in which the risk is created (the exposure pathway) and then the consequences of exposure. Risks should be considered in relationship to:

- the sustainability of native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health (including occupational exposure)
- the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga
- the economic and related benefits to be derived from the use of the hazardous substance
- New Zealand's international obligations.

RNA is present in and around us and the environment all the time. We believe that there is very minimal risk of exposure to our dsRNA treatments. There is some degree of risk associated with unintentional exposure of people, animals and the environment. This could occur through the spillage during transport, manufacturing or application, entry of animals or unauthorised people to the trial site, or consumption of unapproved treated produce. Safe transport, storage and handling (including the use of PPE, following instructions on the SDS) and disposal of the substances, controlling access to the trial sites and the low risk from the method of application (absorbed into a matrix which is prepared in a laboratory) will mitigate this risk so it is not significant.

We maintain an active engagement and involvement with Māori interest groups regarding the use of dsRNA or RNAi for pest control, thought the National Science Challenge "Biological Heritage" programme. Examples of the output from our Māori interest work include Palmer et al. (2021). We will continue our nation-wide consultation with Iwi, and especially Māori beekeepers, regarding this research through the National Science Challenge programme. We expect that the research performed in these trials will inform that engagement.

5.2 Provide an assessment of the potential risks identified in Section 5.1.

An explicit risk assessment only needs to be provided for those risks which might be significant. The assessment should consider whether the identified risks can be adequately managed by the proposed containment system, and the substance(s) itself adequately contained.

The assessment should include the nature, probability of occurrence, and magnitude of each adverse effect. The uncertainty bounds of the information contained in the assessment should also be discussed.

Section 6 – International considerations

6.1 The EPA is interested in whether this substance (or any of its components) has been considered by any other regulatory authority in New Zealand, or by any other country. If you are aware of this, please provide details of the results of such consideration.
(Optional)

GreenLight Biosciences, Inc. are working on their an application to the Environmental Protection Agency (EPA) in the U.S. They have completed a 4 month field trial in commercial hives in the US and are in the middle of another 3 month field trial currently. This product, made through a different manufacturing process, was submitted to the US EPA by Bayer AG 2019, but was subsequently withdrawn and IP assets sold to GreenLight in 2020.

Section 7 – Miscellaneous

7.1 Provide a glossary of scientific and technical terms used in the application.

dsRNA: double stranded ribonucleic acid (RNA) is a molecule similar to DNA. An RNA strand has a backbone made of alternating sugar (ribose) and phosphate groups. More recently, some small RNAs have been found to be involved in regulating gene expression.

7.2 Provide here any other information you consider relevant to this application that is not already included.

APP203395 (2021). An application to determine whether eukaryotes treated with double-stranded RNA molecules were considered genetically modified organisms for the purposes of the Act. https://www.epa.govt.nz/database-search/hsno-application-register/view/APP203395

Christiaens, O., et al. (2020). "Double-stranded RNA technology to control insect pests: current status and challenges." Frontiers in Plant Science 11: 451.

Garbian, Y., et al. (2012). "Bidirectional transfer of RNAi between honey bee and *Varroa destructor*: *Varroa* gene silencing reduces *Varroa* population." PLoS Pathogens 8(12): e1003035.

Hammond, S. M., et al. (2001). "Post-transcriptional gene silencing by double-stranded RNA." Nature Reviews Genetics 2(2): 110-119.

Krishnan, N., et al. (2021). "Evaluating toxicity of Varroa mite (Varroa destructor)-active dsRNA to monarch butterfly (Danaus plexippus) larvae." Plos One 16(6): e0251884.

Masucci, J. D. (2020). "Developing double-stranded RNA as a new *Varroa* control product." American Bee Journal May, 2020: 1-6.

Organisation for Economic Co-operation and Decelopment. (2020). “Considerations for the Environmental Risk Assessment of the Application of Sprayed or Externally Applied ds-RNA-Based Pesticides.” OECD Environment, Health and Safety Publications Series on Pesticides, no. 104.

Palmer, S., Dearden, P.K., Mercier, O.R., King-Hunt, A. & Lester, P.J. (2021). "Gene drive and RNAi technologies: a bio-cultural review of next-generation tools for pest wasp management in New Zealand." Journal of the Royal Society of New Zealand 52: 1-18.

Traynor, K. S., et al. (2020). "*Varroa destructor:* a complex parasite, crippling honey bees worldwide." Trends in Parasitology 36(7): 592-606.

U.S. Food and Drug Administration (2021). “Substances Added to Food (formerly EAFUS)” https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FoodSubstances

Section 8 – Summary of public information

The information provided in this section may be used in the EPA’s public register of substances, required under Section 20 of the HSNO Act.

This summary information will be used to provide information for the people and agencies (eg, Ministry for the Environment, Department of Conservation, Regional Councils etc) that will be notified of the application, and for potential submitters who request information. This information will also be used to prepare the public notice of the application.

For these reasons, applicants should ensure that this summary information does not contain any commercially sensitive material.

8.1 Name of the substance(s) for the public register:

Please use a maximum of 80 characters.

Experimental dsRNA for Varroa destructor control and to protect honey bees

8.2 Purpose of the application for the public register:

This should include an abstract (in a maximum of 255 characters) giving information on the intended use of the substance and why an application is needed, based on its hazardous properties.

To import experimental formulations of double-stranded RNA (dsRNA) for the purpose of developing a slow release delivery matrix to control varroa in honey bee colonies. Formulations are considered to be hazardous substances under the HSNO Act 1996.

8.3 Use categories of the substance(s):

The EPA has adopted the system of use categories developed by the European Union, which identify various functional uses of substances. This information is pertinent to the assessment of exposure scenarios and the determination of risk, and is also useful for building up a profile of the substance. There are three sets of use categories. Within each of these, applicants should state which use categories are relevant to all intended uses of the substance(s).

1. Main category: There are four main categories.
2. Industry category: There are 16 industry categories.
3. Function/Use category: There are 55 function/use categories.

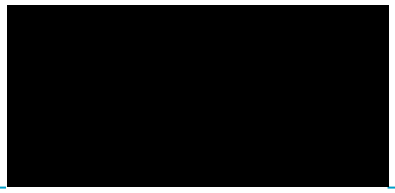
8.4 Executive summary:

In this section, the applicant should provide a summary of information contained in this application, including:

- the identification of the substance, its hazardous properties, intended uses and disposal
- an assessment of the adverse effects of the substance
- information on the proposed containment.

This is an application to import under containment, experimental formulations containing double-stranded RNA (dsRNA) for the purpose of developing a highly-targeted, species-specific miticide for honey bee protection. The intention is to conduct contained laboratory and field trials to provide information relevant for the development of

these formulations. Given the ubiquity of RNA we consider risks to be minimal, although there is potential unintentional exposure of people, animals and the environment. The containment practices proposed with this application are designed to contain the compounds and manage any hazards and risk. Our goal is to develop knowledge on both the safety and efficacy of dsRNA as a next-generation method of pest control.



15 August 2022

Signature **Date**

Appendix 1 – Commercially sensitive information