



DECISION

27 July 2020

Summary

Substance	SmartFresh Inbox
Application code	APP204020
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	AgroFresh New Zealand Limited
Purpose of the application	To import or manufacture SmartFresh Inbox for release
Date application formally received	11 June 2020
Consideration date	21 July 2020 – 27 July 2020
Considered by	The Acting General Manager ¹ of the Hazardous Substances and New Organisms group of the Environmental Protection Authority (“the EPA”)
Decision	Approved with controls
Approval code	HSR101433
Hazard classifications	9.1C

¹ The Acting General Manager of the HSNO group of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act.

1. Substance

- 1.1. SmartFresh Inbox is a sachet containing 0.14 g/kg 1-methylcyclopropene (1-MCP) as the active ingredient, in the form of a vapour releasing powder. The sachet is intended to be directly added to boxes and containers containing fruits. The sachet allows the release of 1-MCP vapour, which can extend the shelf-life of many fruits by inhibiting the effects of ethylene, to prevent or reduce premature senescence (deterioration) of fruits.

2. Process and consultation

Application receipt

- 2.1. The application was formally received on 11 June 2020 under section 28 of the Act.

Information available for consideration

- 2.2. The information available for the consideration comprised:

- the application form
- the confidential appendices to the application
- the EPA staff advice memorandum.

- 2.3. There was sufficient information to assess the application.

Public notification

- 2.4. This application was not publicly notified under section 53(2) of the Act because it was unlikely that there would be significant public interest in the application.

Notification to government departments

- 2.5. In line with section 53(4) of the Act, as the application was not publicly notified under section 53(2) of the Act, government departments were equally not notified of the application for SmartFresh Inbox.

Legislative criteria for the application

- 2.6. The application was considered under section 29 of the Act, taking into account other relevant sections of the Act, the EPA Notices, the HSW Act, the HSW (HS) Regulations and the Hazardous Substances and New Organisms (Methodology) Order 1998.

3. Hazardous properties of SmartFresh Inbox

- 3.1. The hazard classification of SmartFresh Inbox was determined by the EPA in the frame of the section 26 application APP203079 (July 2018) (Table 1).

Table 1: Hazard classification of SmartFresh Inbox

Hazard	Classification
Aquatic ecotoxicity	9.1C

4. Risk and benefit assessment

Risk assessment

- 4.1. The risk assessment has taken into account the hazardous properties of the substance, the considerations in Part 2 of the Act, the prescribed controls under the Act and the requirements under other relevant legislation such as the HSW Act, Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994.
- 4.2. The human health and environmental risks have been assessed in accordance with Section 29(1) of the Act. This assessment takes into account the full life cycle of this substance, including import and manufacture, packaging, transport, storage, use and disposal.
- 4.3. The EPA determined that there is a potential for exposure to people and the environment during the import, manufacture and use phase of SmartFresh Inbox.
- 4.4. The active ingredient, 1-MCP, is already present in various approved substances and in lower concentrations than in SmartFresh Inbox. These substances are also used for the post-harvest treatment of fruits. The risks from the use of SmartFresh Inbox are therefore not expected to be significantly higher than already approved substances.
- 4.5. The risk and benefit assessment:
 - considered the risks posed by SmartFresh Inbox,
 - determined whether the risks are outweighed by the benefits,
 - determined whether any variations, additions to or deletion of the prescribed controls are required to manage the risks of the substance.

Assessment of risks to human health

- 4.6. Exposure to SmartFresh Inbox could occur during the use of the substance when the sachets containing the vapour releasing powder are placed inside a box containing fruit. In particular, the gaseous component, 1-MCP, is released during the use of the substance.
- 4.7. Based on the toxicity studies provided by the applicant and assessed by the EPA in the frame of the section 26 formal determination (APP203079), and based on the exposure scenario associated with the use pattern of SmartFresh Inbox, it is considered that risks to human health are **negligible**.
- 4.8. Risks during other phases of the lifecycle are mitigated by the prescribed controls.

Assessment of risks to the environment

- 4.9. SmartFresh Inbox is classified as harmful in the aquatic environment (9.1C). Due to the proposed use pattern, exposure to SmartFresh Inbox to the environment during the use stage of its lifecycle is expected to be very limited. The substance could reach high concentrations in the aquatic environment in the case of accidental spillage of the substance, however this risk is mitigated by the

prescribed controls. Quantitative exposure modelling and an ecological risk assessment was not performed as environmental risks due to the proposed use pattern of this substance are deemed low.

- 4.10. It is considered that the risks to the environment arising from the ecotoxicity of SmartFresh Inbox will be mitigated to a negligible level by applying the prescribed controls to the substance, as well as an additional control that limits the substance to be used in enclosed boxes or containers for the purpose of preserving fruit.

Assessment of risks to Māori and their relationship to the environment

- 4.11. A cultural assessment has been undertaken by the EPA to consider potential impacts of the application on the economic, social, and cultural well-being of Māori, and the relationship of Māori with the environment, pursuant to sections 5(b), 6(d) and 8 of the HSNO Act. The cultural assessment includes tangible and intangible taonga, such as culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga. Key findings of the assessment are outlined below.

Impact on the relationship of Māori and their culture and traditions with their environment and taonga

- 4.12. This application is not likely to significantly affect the relationship of Māori and their culture and traditions with their environment and taonga, including culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga.

Impact on the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being

- 4.13. This application is not likely to significantly affect the ability and capacity of Māori to maintain their economic, social, and cultural well-being.

Treaty of Waitangi principles

- 4.14. The Principles of the Treaty of Waitangi have been considered in relation to this application, as summarised below.

The active protection principle: the Crown has a duty to actively protect Māori interests.

- 4.15. No issues arise.

The informed decision making principle: the Crown has a duty to make informed decisions.

- 4.16. No issues arise.

The partnership principle: to act fairly, reasonably, and in good faith.

- 4.17. No issues arise.

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

4.18. No risks to society, communities or the market economy from the approval of SmartFresh Inbox have been identified.

New Zealand's international obligations

4.19. No international obligations that may be impacted by the approval of SmartFresh Inbox have been identified.

The effects of the substance being unavailable

4.20. The likely effects of SmartFresh Inbox being unavailable have been considered. Should SmartFresh Inbox not be available, it could lead to less consumer choice.

5. Prescribed controls

5.1. The hazard classification of SmartFresh Inbox determines a set of prescribed controls, specified by the EPA Notices² under section 77 of the Act. There are also requirements in the HSW (HS) Regulations. Note: the HSW (HS) 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.

Exposure limits

5.3. Under s77B of the Act, the EPA may set a Tolerable Exposure Limit (TEL) and/or an Environmental Exposure Limit (EEL) for a substance with toxic or ecotoxic properties.

- Regulation 13.17 of the HSW (HS) Regulations prohibits the use of a class 6 substance in excess of a TEL.
- Clause 49 of the Hazardous Property Controls Notice prohibits use of a class 9 substance in excess of an EEL.

5.4. The EPA has not provided ADE (Acceptable Daily Exposure) and PDE (Potential Daily Exposure) values for any components in this substance. Therefore a TEL for SmartFresh Inbox, or any element or compound in the substance, is also not set as exposure to this substance is not likely to result in an appreciable toxic effect to people, provided controls on use are followed.

² There may also be default controls in regulations made under the Act for certain hazardous substances such as fireworks.

- 5.5. No EEL value has been set previously for the active ingredient in SmartFresh Inbox because it is considered that exposure to the substance is not likely to result in an appreciable toxic effect to the environment, provided conditions of use are followed.
- 5.6. There are no Workplace Exposure Standard (WES) nor Prescribed Exposure Standard (PES) values currently set for components of SmartFresh Inbox.

6. Changes to prescribed controls

- 6.1. The following additional HSNO controls apply to SmartFresh Inbox under section 77A of the Act, as set out in Table 2:

Table 2: Justification for the section 77A additional controls (see Appendix A for the control wordings)

Control	Justification
Use restriction	<p>As the risk assessment of the proposed substance has been based on its use in enclosed boxes or containers, the addition of the following use restriction control is applied to SmartFresh Inbox, as it is more effective than the prescribed controls with respect to their effect on the management, use and risks of the substance:</p> <p>This substance must only be applied in enclosed boxes or containers for the purpose of treatment for agricultural produce.</p>
Restriction on impurity	<p>The active ingredient in SmartFresh Inbox, 1-MCP, is associated with one toxicologically significant impurity (1-chloro-2-methylpropene and 3-chloro-2-methylpropene). When present in high enough concentrations, this impurity can cause adverse effects to people or the environment. Imposing a restriction on the maximum amount of this impurity will prevent it from occurring in concentrations sufficient to cause adverse effects to people or the environment. Accordingly, it is considered that the application of an additional control to address this concern will be more effective than the prescribed controls with respect to its effect on the management, use and risks of the substance.</p>

Assessment of changes to controls

- 6.2. The changes to the prescribed controls in the above section under sections 77A of the Act fulfil the legislative criteria.
- 6.3. These controls have been incorporated into the Appendix of this document.
- 6.4. The applicant was provided an opportunity to comment on the controls as set out in this decision and no concerns were raised.

7. Summary

- 7.1. After taking into account the prescribed controls and any variations to these controls, it was concluded that the residual level of risk of any potentially significant adverse effects, is negligible.

8. Decision

- 8.1. Pursuant to section 29 of the Act, I have considered this application for approval under section 28 of the Act. I have 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. I have also taken into account the considerations set out in Part 2 of the Act.
- 8.2. I consider that, with controls in place, the risks to human health and to the environment are negligible, and the benefits associated with the release of this substance will outweigh the adverse effects. Therefore, I consider that the application to import or manufacture SmartFresh Inbox for release is approved with controls in accordance with section 29 of the Act and clause 26 of the Hazardous Substances and New Organisms (Methodology) Order 1998.



Dr Clark Ehlers

Date: 27 July 2020

Acting General Manager, HSNO, EPA

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Appendix: Controls applying to SmartFresh Inbox

EPA Controls

Control code	EPA Notice	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

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HSNO Additional Controls and Modifications to Controls

Control Code	HSNO Act	Control
Maximum impurity	Section 77A	The following limit is set for the toxicologically relevant impurities in the active ingredient 1-MCP used to manufacture this substance: 1-chloro-2-methylpropene: maximum 0.05% 3-chloro-2-methylpropene: maximum 0.05%
Use restriction	Section 77A	This substance must only be applied in enclosed boxes or containers for the purpose of treatment for agricultural produce.

HSW Requirements

Note: these requirements are triggered by the ecotoxic properties of SmartFresh Inbox and apply under the HSNO Act.

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
HSW5-2	Reg 5.6 - 5.13	Emergency response plans
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
HSW13-14	Reg 13.30 - 33	Secondary containment requirements for class 6 and 8 pooling substances
HSW17-1	Part 17	Requirements for stationary container systems