



To: Gayle Holmes, Acting GMHSNO

Copy To: Dr Stephen Cobb, New Organisms Manager

From: [REDACTED], Principal Scientist, New Organisms

Date: 20 November 2019

Subject: Decision to notify application APP203504

Purpose of this memo

1. To decide whether application APP203504 should be publicly notified.

Background

Discretion to notify

2. Under section 53(2) of the Hazardous Substances and New Organisms (HSNO) Act, the EPA has the discretion to notify application APP203504 if it considers that there is likely to be significant public interest.
3. The purpose of public notification is to ensure that the decision-maker is informed on all relevant matters and has heard the views of those affected by the decision, including the views of the public, technical information, the effect of the decision on the public or specified groups, and any additional information the public can provide. This ensures that the decision may be made following a fully informed consideration of all relevant factors.
4. The EPA Board has delegated the decision to publicly notify applications under section 53(2) to the Chief Executive, who has subdelegated decision-making to the General Manager of Hazardous Substances and New Organisms.

Discussion

Potential for public interest

5. Some New Zealanders may be interested in this application. I have attempted to determine whether this would meet the threshold of significant public interest outlined in section 53(2) of the HSNO Act by addressing the following points.

Is the application for novel new organisms or activities?

6. Application APP203504 is from Massey University who proposes to develop low-risk genetically modified organisms in containment for the purposes of research and teaching.
7. The organism(s) in the application are:

Taxonomic name	Common name
<p>Risk Group 1 microorganisms including (but not limited to) Bacteria, Archaea, Viruses (including Bacteriophages), eukaryotic microbes (Algae, Fungi (including Yeasts), Phytoplankton, Zooplankton, Protozoa and Micro-invertebrates) that are unlikely to cause disease in humans, animals, plants, or fungi.</p>	
<p>Risk Group 2 microorganisms including (but not limited to) Bacteria, Archaea, Viruses (including Bacteriophages), eukaryotic microbes (Algae, Fungi (including Yeasts), Phytoplankton, Zooplankton, Protozoa and Micro-invertebrates) that may cause disease in humans, animals, plants, or fungi but are unlikely to be a serious hazard to laboratory personnel, the community, animals, or the environment, and have effective treatment and preventive measures with respect to any infections that they may cause, and present a limited risk of spread on infection.</p>	
<p>Animal cell lines (as Category 1 host organisms) (including immortalized and primary cell lines) from organisms within the Kingdom Animalia, Phyla Arthropoda, and Chordata. Animal cell lines may include induced pluripotent stem cell lines and embryonic stem cell lines. Animal cell lines will be established or primary cell lines are obtained from commercial sources or reputable scientific laboratories.</p>	
<p>Human cell lines (as Category 1 host organisms) (including immortalized and primary cell lines). Human cell lines may include induced pluripotent stem cells, but not human embryonic stem cell lines. Human and animal cell lines will be established or primary cell lines obtained from commercial sources, or reputable scientific/clinical laboratories. Human cell lines may include genetically modified primary cell lines imported with Massey University Human Ethics Committee approval. Consultation with appropriate iwi/hapū representatives will also be undertaken. This includes cell lines derived from individuals identified as Māori as long as consultation with and consents from individuals involved have been obtained. Consultation with appropriate iwi/hapū representatives will also be undertaken.</p>	
<p>Plant cells and tissues (as Category 1 host organisms) including protoplasts, cultured cells, and tissue from Kingdom Plantae.</p>	

Taxonomic name	Common name
Terrestrial laboratory animals (as Category 2 host organisms)	
<i>Mus musculus</i> L., 1758	Mouse.
<i>Rattus norvegicus</i> Berkenhout, 1759	Brown rat, Norway rat, laboratory rat.
<i>Rattus rattus</i> L., 1758	Black rat, ship rat.
<i>Drosophila melanogaster</i> Macquart, 1843 (syn. <i>Sophophora melanogaster</i>)	Fruit fly, vinegar fly.
<i>Caenorhabditis elegans</i> Maupas, 1900	Roundworm.
<i>Nasonia vitripennis</i> Walker 1836	Jewel wasp.
<i>Nasonia giraulti</i> Darling 1990.	Jewel wasp.
<i>Nasonia longicornis</i> Darling 1990	Jewel wasp.
<i>Strongyloides stercoralis</i> Bavay 1876	Threadworm.
<i>Gallus gallus domesticus</i> L., 1758	Chicken.
Aquatic laboratory animal (as Category 2 host organism)	
<i>Danio rerio</i> Hamilton-Buchanan, 1822	Zebrafish.
Plant genera and species (as Category 2 host organisms)	
<i>Acca</i> O.Berg, 1856	Feijoa. Taxonomic family: Myrtaceae.
<i>Actinidia</i> Lindl., 1836.	eg, Chinese gooseberry, kiwifruit. Excluding <i>A. henanensis</i>, <i>A. rubricaulis</i>. Taxonomic family: Actinidiaceae.
<i>Agathis</i> Salisb., 1807	kauri, dammara. Taxonomic family: Araucariaceae.
<i>Allium</i> L., 1753.	eg, onion, garlic. Taxonomic family: Amaryllidaceae.
<i>Amaranthus</i> L., 1753.	eg, pigweed, love-lies-bleeding. Taxonomic family: Amaranthaceae.
<i>Apium</i> L., 1753	eg, celery, celeriac. Taxonomic family: Apiaceae
<i>Arabidopsis</i> (D.C.) Heynh, 1842	eg, thale cress, arabidopsis. Taxonomic family: Brassicaceae.
<i>Arabis</i> L., 1753	rockcress. Taxonomic family: Brassicaceae.
<i>Arachis</i> L., 1753	eg, peanut, groundnut. Taxonomic family: Fabaceae.
<i>Atropa</i> L., 1753	belladonna. Taxonomic family: Solanaceae.
<i>Avena</i> L., 1753	oat. Taxonomic family: Poaceae.
<i>Bambusa</i> Schreb., 1789.	bamboo. Taxonomic family: Poaceae.

Taxonomic name	Common name
<i>Beta</i> L., 1753	eg, Silver beet, beetroot, sugar beet. Taxonomic family: Amaranthaceae.
<i>Boechnera</i> Á. Löve & D. Löve, 1976.	rockcress. Taxonomic family: Brassicaceae.
<i>Brachypodium</i> P. Beauv., 1812.	eg, stiff brome. Taxonomic family: Poaceae.
<i>Brassica</i> L., 1753.	eg, canola, cabbage, turnip, mustard. Taxonomic family: Brassicaceae.
<i>Cajanus</i> D.C., 1813.	eg, pigeon pea. Taxonomic family: Fabaceae.
<i>Camellia</i> L., 1753.	Camellia, tea. Taxonomic family: Theaceae.
<i>Capsicum</i> L., 1753.	chili peppers. Taxonomic family: Solanaceae.
<i>Carthamus</i> L., 1753.	eg, safflower. Excluding <i>C. lanatus</i> . Taxonomic family: Asteraceae.
<i>Carya</i> Nutt., 1818.	eg, hickory, pecan. Taxonomic family: Juglandaceae.
<i>Castanea</i> Mill., 1754.	eg, chestnut. Taxonomic family: Fagaceae.
<i>Chenopodium</i> L., 1753.	eg, goosefoot, quinoa. Taxonomic family: Amaranthaceae.
<i>Cicer</i> L., 1753.	eg, chickpea. Taxonomic family: Fabaceae.
<i>Citrullus</i> Schrad. ex Eckl. & Zeyh., 1836.	eg, watermelon, citron melon. Taxonomic family: Cucurbitaceae.
<i>Citrus</i> L., 1753.	orange, lemon, grapefruit. Taxonomic family: Rutaceae.
<i>Coffea</i> L., 1753.	coffee. Taxonomic family: Rubiaceae.
<i>Coix</i> L., 1753.	Chinese pearl barley; Job's tears. Taxonomic family: Poaceae.
<i>Colocasia</i> Schott, 1832.	eg, taro. Taxonomic family: Araceae.
<i>Corylus</i> L., 1753.	eg, hazel, hazelnut. Taxonomic family: Betulaceae.
<i>Cucumis</i> L., 1753.	eg, cucumber, winter melon. Taxonomic family: Cucurbitaceae.
<i>Cucurbita</i> L., 1753.	eg, pumpkin, squash. Taxonomic family: Cucurbitaceae.
<i>Daucus</i> L., 1753.	carrot. Taxonomic family: Apiaceae.
<i>Dioscorea</i> Plum., 1753.	yam. Taxonomic family: Dioscoreaceae.
<i>Drymocallis</i> Fourr. ex Rydb. 1898.	eg, cinquefoils. Taxonomic family: Rosaceae.
<i>Eleusine</i> Gaertn., 1788.	finger millet. Taxonomic family: Poaceae.
<i>Eucalyptus</i> L'Her., 1789.	gum tree. Taxonomic family: Myrtaceae.
<i>Festuca</i> L., 1753.	fescue. Taxonomic family: Poaceae.
<i>Fragaria</i> L., 1753.	strawberry. Taxonomic family: Rosaceae.

Taxonomic name	Common name
<i>Glycine</i> Willd. 1802.	eg, soybean, soya bean. Taxonomic family: Fabaceae.
<i>Helianthus</i> L., 1753.	eg, sunflower, Jerusalem artichoke. Excluding <i>H. ciliaris</i> . Taxonomic family: Asteraceae.
<i>Hordeum</i> L., 1753.	barley. Taxonomic family: Poaceae.
<i>Humulus</i> L., 1753.	eg, hops. Taxonomic family: Cannabaceae.
<i>Ipomoea</i> L., 1753.	eg, sweet potato, morning glory. Excluding <i>I. indica</i>, <i>I. caerulea</i>, <i>I. hederacea</i>, <i>I. plebia (biflora)</i>, and <i>I. tribola</i> . Taxonomic family: Convolvulaceae.
<i>Juglans</i> L., 1753.	walnut. Excluding <i>J. ailantifolia</i> . Taxonomic family: Juglandaceae.
<i>Lactuca saligna</i> L., 1753.	willowleaf lettuce, least lettuce. Taxonomic family: Asteraceae.
<i>Lactuca sativa</i> L., 1753.	Lettuce. Taxonomic family: Asteraceae.
<i>Lactuca serriola</i> L., 1756.	prickly lettuce, milk thistle. Taxonomic family: Asteraceae.
<i>Lactuca virosa</i> L., 1753.	wild lettuce, bitter lettuce, opium lettuce, poisonous lettuce, tall lettuce, great lettuce. Taxonomic family: Asteraceae.
<i>Lathyrus</i> L., 1753.	peavine, vetchling, sweet pea. Taxonomic family: Fabaceae.
<i>Leptospermum</i> J.R.Forst. & G.Forst., 1775.	tea tree. Taxonomic family: Myrtaceae.
<i>Lens</i> Mill. 1768.	lentil. Taxonomic family: Fabaceae.
<i>Linum</i> L., 1753.	flax. Taxonomic family: Linaceae.
<i>Lolium</i> L., 1753.	ryegrass. Taxonomic family: Poaceae.
<i>Lupinus</i> L., 1753.	lupin, lupine. Taxonomic family: Fabaceae.
<i>Macadamia</i> F. Muell., 1857.	Macadamia. Taxonomic family: Proteaceae.
<i>Malus</i> Mill., 1754.	apple. Taxonomic family: Rosaceae.
<i>Manihot</i> Mill. 1754.	eg, cassava. Taxonomic family: Euphorbiaceae.
<i>Medicago</i> L., 1753.	eg, lucerne, alfalfa. Taxonomic family: Fabaceae.
<i>Nicotiana</i> L., 1753.	tobacco. Taxonomic family: Solanaceae.
<i>Olea</i> L., 1753.	olive. Taxonomic family: Oleaceae.
<i>Oryza</i> L., 1753.	rice. Taxonomic family: Poaceae.
<i>Oxalis</i> L., 1753.	eg, New Zealand yam, oca. Taxonomic family: Oxalidaceae.
<i>Panicum</i> L., 1753.	broom millet. Excluding <i>P. maximum</i> and <i>P. repens</i> . Taxonomic family: Poaceae.

Taxonomic name	Common name
<i>Pastinaca</i> L., 1753.	parsnips. Taxonomic family: Apiaceae.
<i>Pennisetum glaucum</i> (L.)R.Br., 1810.	pearl millet. Taxonomic family: Poaceae.
<i>Pennisetum clandestinum</i> Hochst. ex Chiov., 1903.	kikuyu grass. Taxonomic family: Poaceae.
<i>Persea</i> Mill. 1754.	eg, avocado. Taxonomic family: Lauraceae.
<i>Petunia</i> Juss. 1803.	petunia. Taxonomic family: Solanaceae.
<i>Phaseolus</i> L., 1753.	common bean. Taxonomic family: Fabaceae.
<i>Physalis</i> L., 1753.	ground cherry, cape gooseberry. Taxonomic family: Solanaceae.
<i>Pinus</i> L., 1753.	pinus. Excluding <i>P. contorta</i> . Taxonomic family: Pinaceae.
<i>Pisum</i> L., 1753.	eg, garden pea. Taxonomic family: Fabaceae.
<i>Poa</i> L., 1753.	meadow-grass, bluegrass, tussock, speargrass. Taxonomic family: Poaceae.
<i>Prunus</i> L., 1753.	plum, cherry, nectarine, peach. Excluding <i>P. serotina</i> . Taxonomic family: Rosaceae.
<i>Raphanus</i> L., 1753.	radish. Taxonomic family: Brassicaceae.
<i>Ribes</i> L., 1753.	eg, currant, gooseberry. Taxonomic family: Grossulariaceae.
<i>Rubus</i> L., 1753.	raspberry, blackberry. Excluding <i>R. ellipticus</i> and <i>R. moluccanus</i> . Taxonomic family: Rosaceae.
<i>Salvia</i> L., 1753.	eg, mint, sage. Taxonomic family: Lamiaceae.
<i>Secale</i> L., 1753.	rye. Taxonomic family: Lamiaceae.
<i>Solanum</i> L., 1753.	potato, tomato, eggplant. Excluding <i>S. carolinense</i>, <i>S. elaeagnifolium</i>, <i>S. marginatum</i>, <i>S. mauritanium</i>, and <i>S. torvum</i> . Taxonomic family: Solanaceae.
<i>Sorghum</i> Moench, 1794.	sorghum. Excluding <i>S. halepense</i> and <i>Sorghum</i> × <i>almum</i> . Taxonomic family: Poaceae.
<i>Spinacia</i> L., 1753.	eg, spinach. Taxonomic family: Amaranthaceae.
<i>Trifolium</i> L., 1753.	clover. Taxonomic family: Fabaceae.
<i>Triticum</i> L., 1753.	wheat. Taxonomic family: Poaceae.
× <i>Triticale</i> Tscherm.-Seys. ex. Müntzing.	Triticale (wheat × rye hybrid). Taxonomic family: Poaceae.
<i>Vaccinium</i> L., 1753.	eg, blueberry, cranberry, lingonberry. Taxonomic family: Ericaceae.
<i>Vicia</i> L., 1753.	eg, broad bean, fava bean, vetch. Taxonomic family: Fabaceae.

Taxonomic name	Common name
<i>Vigna</i> Savi 1824.	eg, black-eyed bean, cowpea, mung bean. Taxonomic family: Fabaceae.
<i>Vitis</i> L., 1753.	grape. Taxonomic family: Vitaceae.
<i>Zea</i> L., 1753.	corn. Taxonomic family: Poaceae.

8. This application is similar to applications APP201859, and APP202708, granted to the University of Otago in 2015, and Auckland University in 2019, respectively, for the development in containment of low-risk genetically modified organisms for the purposes of research and teaching. Like APP203504, APP201859 and APP202708 allow the development of genetically modified risk group 1 and risk group 2 microorganisms into containment, as well as many of the same animal species under consideration in APP203504. Unlike APP201859 and APP202708, the current application considers 89 different genera of plants for importation, excluding unwanted organisms and prohibited organisms under the Biosecurity Act 1993 and/or the HSNO Act 1996.

How does this application compare to previous applications that have and have not been notified?

9. The following applications were found to be of significant public interest:
- Application NOC03005 from the Ministry of Agriculture and Forestry: to import the bacterium *Melissococcus pluton* (the causal agent of European foulbrood in introduced honey bees) for diagnostic testing purposes, including the development of new laboratory test methods and for surveillance in New Zealand.
 - Application NOC04012 from the Ministry of Agriculture and Forestry: to import strains of microorganisms that potentially causes exotic and emerging diseases of animals into containment for diagnostic and testing purposes.
 - Application GMD02028 from AgResearch Limited: to develop transgenic cattle that can express functional therapeutic foreign proteins in their milk, and to develop transgenic cattle to study gene function and genetic performance. The development involved use of human genes, and outdoor containment of genetically modified animals.
 - Application ERMA200223 from AgResearch Limited: to develop in containment genetically modified goats, sheep and cows to produce human therapeutic proteins, or with altered levels of endogenous proteins for the study of gene function, milk composition and disease resistance. These developments also involved the use of human genes and outdoor containment of genetically modified animals.
 - Application ERMA200512 from Life Clinic Hirudotherapy and Healing: to import into containment an Asian medicinal leech for use in treatments. This application was considered to have novel issues to consider as the leeches will come into direct contact with the general public and the outcome of this application if approved was likely to directly affect the business of New Zealand supplier of clinically bred medicinal leeches.

10. The applications that were not considered to meet the definition of significant public interest include the following applications:
- Various genetically modified organisms used in research
 - APP201859 and APP202708, for the development in containment of low-risk genetically modified organisms for the purposes of research and teaching. As mentioned in paragraph 7, these applications/approvals are the most similar to the present application under consideration.
 - Butterflies for display (applications NOC98008, NOC03002 and ERMA200600)
 - Giant panda (*Ailuropoda melanoleuca*) for display (application ERMA200520)
 - Medium size predator cats; fishing cat (*Prionailurus viverrinus*), caracal (*Caracal caracal*), ocelot (*Leopardus pardalis*), and margay (*Leopardus pardalis*) for display
 - Gorilla (*Gorilla gorilla*) for display
 - Brown bear (*Ursus arctos*) for display
 - Insect pests for research (all Lepidoptera species).
11. We consider that APP203504 is very similar to both APP201859 and APP202708, as well as applications/approvals for many other genetically modified organisms (many including entire genera of genetically modified plants), none of which were publicly notified.

Have any significant cultural, economic, environmental, ethical, health, international, or spiritual effects be identified?

12. Significant cultural, economic, environmental, ethical, health, international, or spiritual effects were not identified. The applicant consulted with mana whenua iwi regarding the application, and they stated that they could see no reason why the application should not proceed. The Kaupapa Kura Taiao (KKT) report for this application concluded that the application with its proposed controls, is not likely to significantly affect the ability and capacity of Māori to maintain their economic, social and cultural well-being.

Is there any other relevant information?

13. The EPA will consult with the Department of Conservation and the Ministry of Agriculture and Forestry about this application as part of routine application processing.

Overall conclusion

14. Based on the information in the application, mana whenua iwi consultation, KKT advice, and previous decisions not to publicly notify previous applications for the importation into containment of low-risk genetically modified organisms, we conclude that this application is not likely to be of significant public interest.

Recommendation

I recommend that:

- This application does not meet the threshold of significant public interest as set out in section 53(2) of the HSNO Act.

Please indicate your decision below.

“signed here”

“22 November 2019”

Date

Principal Scientist, New Organisms

New Organisms Group

Decision

I decide that application:

<input checked="" type="checkbox"/>	Will not be publicly notified as there is not likely to be significant public interest in the application.
<input type="checkbox"/>	Will not be publicly notified as there is not likely to be significant public interest in the application; however, targeted notification should be undertaken (for the reason/s specified below).
<input type="checkbox"/>	Will be publicly notified as there is likely to be significant public interest in the application (for the reason/s specified below).

Comments/Reasons



“22 November 2019”

Gayle Holmes

Date

Acting General Manager, Hazardous

Substances and New Organisms

Environmental Protection Authority