

Supplemental Materials

Relevant Hazardous Substances and New Organisms Act definitions (Hazardous Substances and New Organisms Act, 1996).

2A Meaning of term new organism

(1) A new organism is—

(a) an organism belonging to a species that was not present in New Zealand immediately before 29 July 1998:

(b) an organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation:

(c) an organism for which a containment approval has been given under this Act:

(ca) an organism for which a conditional release approval has been given:

(cb) a qualifying organism approved for release with controls:

(d) a genetically modified organism:

(e) an organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

(2) An organism is not a new organism if—

(a) the organism is not a genetically modified organism and—

(i) an approval is granted under section 35 or 38 to release an organism of the same taxonomic classification; or

(ii) the organism is a qualifying organism and an approval has been granted under section 38I to release an organism of the same taxonomic classification without controls; or

(iii) an organism of the same taxonomic classification has been prescribed as not a new organism; or

(b) the organism is a genetically modified organism and—

(i) an approval is granted under section 38 to release an organism of the same taxonomic classification with the same genetic modification;

or

(ii) the organism is a qualifying organism and an approval has been granted under section 38I to release an organism of the same taxonomic classification with the same genetic modification without controls; or

(iii) an organism of the same taxonomic classification with the same genetic modification has been prescribed as not a new organism;

or

(c) the new organism was deemed to be a new organism under section 255 and other organisms of the same taxonomic classification were lawfully present in New Zealand before the commencement of that section and in a place that was not registered as a circus or zoo under the Zoological Gardens Regulations 1977.

(2A) A new organism does not cease to be a new organism because—

- (a) it is subject to a conditional release approval; or
 - (b) it is a qualifying organism approved for release with controls; or
 - (c) it is an incidentally imported new organism.
- (3) Despite the provisions of this section, an organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970 is a new organism.
- (4) Subsection (3) does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus.

Table S1. Purpose of the application

Source	Description [‡]	Notes
<p>Application “To obtain a determination of whether an organism is a new organism” APP203395 (Trought 2018).</p>	<p>Eukaryotic cells that have been transiently transfected with <i>synthetic molecules of double stranded RNA</i> to inhibit (temporarily) the <u>activity of the complementary RNA</u>.</p>	<p>Application for eukaryotic cells (which may be tissue culture) becomes a determination for all eukaryotic organisms.</p> <p>Application for use of synthetic/artificial dsRNA molecules</p>
<p>EPA Staff Report “Determining whether eukaryotic cell lines treated with double-stranded RNA are genetically modified organisms” (EPA 2018a).</p>	<p>[the applicant] seeks a determination...on whether eukaryotic cells treated with <i>artificially synthesised dsRNA</i> to transiently suppress the expression of user-selected genes are new organisms for the purpose of the Act.</p>	<p>contrasts with determination for all dsRNA molecules of undisclosed source or size.</p> <p>Application originally limited to an activity on the mRNA target that is temporary becomes any form of expression suppression to any RNAi treatment outcome in the determination.</p>
<p>EPA Decision “Purpose of the Application” page 1 (EPA 2018b).</p>	<p>“eukaryotic cell lines that have been <i>treated with externally applied double-stranded RNA</i> molecules for the purpose of <u>inducing a transient small interfering RNA (siRNA) response</u> are new organisms.”</p>	
<p>EPA Decision section 2 (EPA 2018b).</p>	<p>“eukaryotes <i>treated with double-stranded RNA</i> molecules were considered genetically modified organisms.”</p>	
<p>[‡]Highlighted terms are inferred as homologous in the different passages.</p>		

1. Trought K. APP203395: Landcare Research Ltd2018.
<https://www.epa.govt.nz/database-search/hsno-application-register/view/APP203395>.
2. EPA. EPA staff report. Determining whether eukaryotic cell lines treated with double-stranded RNA are genetically modified organisms.: Environmental Protection Authority 2018. <https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203395/APP203395-EPA-Advice-Document-FINAL.pdf>.
3. EPA. Decision: Environmental Protection Authority2018.
<https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203395/APP203395-Decision-FINAL-.pdf>.