Supplemental Materials


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