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Environmental Protection Authority
Te Mana Rauhī Taiao

Claire Bleakley
President
GE Free New Zealand
Wellington, New Zealand

Via: president@gefree.org.nz

Private Bag 632
Wellington 6140, New Zealand

Level 10, Grant Thornton House
215 Lambton Quay
Wellington 6011, New Zealand

epa.govt.nz
+64 4 916 2426

Dear Ms Bleakley

I refer to your letter to the Environmental Protection Authority (EPA), received on 3 October 2019.

In your letter, you refer to the EPA's 2018 determination that dsRNA does not come under the jurisdiction of the Hazardous Substances and New Organisms Act 1996 (the HSNO Act) regarding a genetically modified organism (APP203395). You have asked the following questions, which have been treated as a request for information under the Official Information Act 1982 (the OIA):

1. *Has there been a reassessment of the dsRNA decision? If so, please may I have a copy of the decision?*
2. *Are there any manipulations using dsRNA the EPA consider to be genetically modified organisms under HSNO and therefore subject to regulatory oversight?*
3. *If yes, which ones?*
4. *If not why not?*
5. *Are any end products created through dsRNA in vitro manipulation considered as GMOs?*
6. *Would they be subject to approval under the HSNO Act to be commercially released?*
7. *If not why not?*
8. *Please could you give us the products that have been released using dsRNA manipulation?*

Under the HSNO Act, the EPA manages the risks to New Zealand's environment, economy, the health and safety of people, and Māori culture and traditions, from organisms that are new to New Zealand, including genetically modified organisms (GMOs). When coming to a decision about a new organism, the EPA considers the evidence and data, and seeks further information where necessary.

My response to each of your questions is provided below.

1. Has there been a reassessment of the dsRNA decision? If so, please may I have a copy of the decision?
The EPA has received new information, and the EPA's decision making committee (DMC) is now reconsidering the decision (statutory determination APP203395).

2. Are there any manipulations using dsRNA the EPA considers to be genetically modified organisms under HSNO and therefore subject to regulatory oversight?
The EPA has approved the development of genetically modified organisms using genetic constructs designed for the expression of double-stranded RNA, such as microRNA (miRNA) and small interfering RNA (siRNA). These approvals involve genetic modification of the host organism's DNA to express genes that create double-stranded RNA.

3. If yes, which ones?
Some examples of such approvals are:

- APP201315 - to develop genetically modified Escherichia coli, yeast and animal cell lines for cell-based assays and in vitro models to study the broad physiological interactions of food and food-based components with the human body
- APP202984 - to develop plasmids and replication defective viral vectors in order to transform low risk mammalian cell lines, for subsequent use in mouse models.
- APP203059 - to develop GM microorganisms, mammalian cells and primary cultures to produce recombinant proteins
- APP203262 - to develop low-risk genetically modified organisms using standard molecular biological and genome editing techniques for research purposes.
- APP203321 - to analyse the virulence of plant-pathogenic fungi by genetic modifications involving candidate pathogenicity genes in bacteria, fungi, specific host and model plants.

All of the decision documents relating to EPA approvals for genetically modified organisms are publicly available on the EPA website (at https://www.epa.govt.nz/database-search/hsno-application-register/).

The EPA's approvals aim to ensure that the work is done in approved facilities and that the genetically modified organisms do not escape. EPA approvals are often given for a wide range of potential genetic modifications directed at the examination of various traits or characteristics of an organism. This means that the EPA does not always know, at the point of approval, whether a particular genetic modification (such as for the expression of genes that create double-stranded RNA) will be performed in the future.

4. If not why not?
I hope that the following explanation answers this part of your request.

The EPA does not consider a eukaryotic cell or organism to be a new organism under the HSNO Act if it:

- does not otherwise meet the definitions of 'new organism' in section 2A of the HSNO Act,
- is not a prohibited organism as laid out in section 50(1) and Schedule 2 of the HSNO Act,
- is not an unwanted organism as defined in section 2 of the Biosecurity Act 1993, and
- has been treated with externally applied double-stranded RNA.

The EPA has not determined the GMO status of any application of dsRNA to organisms that are not covered by these provisions.

5. Are any end products created through dsRNA in vitro manipulation considered as GMOs?
The EPA does not always know, at the point of approval, whether a particular genetic modification (such as for the expression of genes that create double-stranded RNA) will be performed in the future. The EPA's approvals aim to ensure that the work is done in approved facilities and that the genetically modified organisms, if created, do not escape.
The decision documents relating to all approvals for new organisms are publicly available on the EPA website (I have provided the relevant link in my response to question 3).

6. Would they be subject to approval under the HSNO Act to be commercially released?
Organisms covered under the APP203395 determination treated with exogenous double-stranded RNA would not need to be approved by the EPA for release into the environment. This is in contrast to organisms that, for example, are covered by containment and/or development approvals, and which would need to be approved by the EPA for release.

7. If not why not?
As the organisms covered under the APP203395 determination are not considered to be new organisms, they do not require EPA approval for release into the environment (this assumes they have been treated with double-stranded RNA indoors).

8. Please could you give us the products that have been released using dsRNA manipulation?
Any organisms covered under APP203395 that may or may not have been released are not tracked by the EPA because they are not new organisms and do not require approval by the EPA. All other release approvals to date have been for medicines or veterinary medicines, and the documents relating to those approvals are available on the EPA website (please see the link provided in my response to question 3).

You have the right to seek an investigation and review of this decision by the Ombudsman. You can contact the Ombudsman on 0800 802 602, or by email at info@ombudsman.parliament.nz.

If you have any further queries, please do not hesitate to contact us via ministerials@epa.govt.nz.

Yours sincerely

Gayle Holmes
Acting General Manager Hazardous Substances and New Organisms
Environmental Protection Authority