Advisory Committee on Releases to the Environment

Advice on an application for deliberate release of a GMO for research and development purposes

Advice of the Advisory Committee on Releases to the Environment (ACRE) to the Secretary of State under S.124 of the Environmental Protection Act 1990

Details of the notification

Notifier: Rothamsted Research

Notification reference: 16/R8/01

Product: *Camelina sativa* that has been genetically modified to produce omega-3 long chain polyunsaturated fatty acids and the pigment astaxanthin in its seeds.

ACRE is satisfied that the risks to human health and the environment associated with this proposed release are extremely low. ACRE has not identified any reasons for the trial not to proceed. The trial is very similar to one previously considered by ACRE, which received Defra authorisation and was carried out in 2014/15 under very similar conditions by the same applicant. After careful consideration of the present application, ACRE suggests similar measures are put in place, namely:

1. Planting of a non-modified *Camelina sativa* pollen barrier surrounding each plot of GM camelina (to flower synchronously with the GM camelina, and of a width consistent with that previously used for GM oilseed rape).

2. Alternatively, a separation distance consistent with that used for GM oilseed rape should be maintained between the GM camelina and any wild or cultivated *Camelina* species outside of the trial site. If any of these species are found within the separation distance during the trial, they should be killed by herbicide application or hand-pulling before flowering.

3. During the trial, suitable measures should be in place to prevent seed dispersal by birds.

4. After sowing, any drilling equipment used should be thoroughly cleaned on the edge of the plot to ensure that no seeds remain on the coulters or other parts of the drill.

5. Prior to harvest, the combine to be used should be prepared to minimise any loss of small seeds through augers, sieves etc. The combine should be one designed to minimise admixture between plots and to facilitate cleaning down.

6. After harvesting, the combine should be thoroughly cleaned on the edge of the plot to ensure no seed remains.

7. Each experimental plot should be shallow cultivated in the spring following harvest (to a depth of no more than 5 cm) to stimulate germination of any volunteer seed in the seed bank.

8. Post-harvest, the presence of volunteers should be monitored during the growing season (February until October) at least monthly for a minimum of two years. Monitoring may cease a) if no volunteers are identified in the second year of monitoring or b) after the first volunteer-free year. The number of volunteers found should be reported to Defra. After counting, all volunteers should be killed by herbicide application or hand-pulling before flowering.

9. Material intended for the food/feed chain should not be grown on the site until at least the second year after the trial.

10. Waste seed and plant material (including destroyed volunteers) from the trial should be disposed of by autoclaving, incineration or deep burial at a local authority-approved landfill site using an approved contractor.

Comment

The GM camelina has been modified to produce omega-3 long chain polyunsaturated fatty acids and the pigment astaxanthin in its seeds. The applicant (Rothamsted Research) wishes to carry out the research trial in order to test the agronomic and yield performance of the GM camelina under field conditions.

ACRE have addressed a number of issues in its safety assessment, including the molecular characterisation of the material for release, an environmental risk assessment, measures that might be necessary to minimise the spread and persistence of the GMO, and any necessary monitoring requirements. To inform its decision-making, Defra consulted external assessors (including FERA) and requested that ACRE consider the information received from them, as well as addressing any scientific points raised during the period allowed for receipt of public representations which ran from 1st Feb until 19th March 2016.

Molecular characterisation

The proposed trial involves the release of three transformation events and one ‘stack’ which combines two of these events (four plant ‘lines’ in total). Two of the constructs (B7.2 and DHA2015.1) each encode seven omega-3 LC-PUFA biosynthesis genes, six of which are identical on both constructs. In construct B7.2, the seventh gene (a Δ4-desaturase) originates from *Thalassiosira pseudonana*, whereas in construct DHA2015.1, the Δ4-desaturase originates from *Ostreococcus* RCC809. All the omega-3 LC-PUFA biosynthesis genes originate either from algal, moss or fungal gene sequences, have been

codon-optimised for expression in the Cruciferae and were chemically synthesised. Each gene is under the control of a seed-specific promoter and is contained by a transcription termination sequence. Constructs B7.2 and DHA2015.1 also both contain the 'Ds-Red' red fluorescent marker protein (from reef coral *Dicosoma* sp.), under the control of the CaMV 35S promoter and nopaline synthase terminator. The third construct (ASX-A2) encodes three heterologous genes which direct the synthesis of the ketocarotenoid astaxanthin, each under the control of seed promoters. It also encodes the selectable marker gene BAR, which confers resistance to glufosinate-ammonium herbicides.

The four lines to be planted may be summarily designated thus:

1. B7.2
2. DHA2015.1
3. ASX-A2
4. B7ASX (B7.2 + ASX-A2)

ACRE notes that the material for release has been well-characterised at the molecular level and that the transgenes have been shown to be stably inherited following normal rules of Mendelian genetics over five generations. ACRE is therefore satisfied that the genetic changes are stable. The applicant had not provided details of the vector backbone or data on integration of the vector backbone into the plants genome. ACRE agreed that integration of vector backbone would not represent an environmental risk in this case, and as such concluded that sufficient information had been provided to support the risk assessment.

Environmental risk assessment

Overall, ACRE is satisfied with the information provided and the applicants assessment of the risks associated with the release. ACRE is content that the proposed release does not represent a risk to the environment or to human health.

The biology and ecology of *C. sativa*[1] suggest it has a low baseline of invasiveness and does not compete well with surrounding vegetation. The genetic modification is unlikely to alter this or confer any selective advantage. ACRE notes that the flora of the Rothamsted site has been well-characterised and that the applicant has a good knowledge of plant species present on the experimental farm.

As with invasiveness, persistence and survivability are unlikely to be altered in the GM camelina. There is some uncertainty over the baseline persistence of *C. sativa* in UK conditions, and this is reflected in the recommended monitoring measures. The applicant intends to avoid re-using experimental plots to avoid interference of volunteers in

[1] Plant and Biotechnology Risk Assessment Unit, Canadian Food Inspection Agency Ottawa, Ontario (2012). The Biology of *Camelina sativa* (L.) Crantz (Camelina). http://www.inspection.gc.ca/plants/plants-with-novel-traits/applicants/directive-94-08/biology-documents/camelina-sativa-l-/eng/1330971423348/1330971509470

subsequent experimental plots. ACRE also noted that as a small-seeded crop, camelina seeds could be dispersed via a number of routes, including birds and small mammals.

Minimising dispersal and persistence

As described above, ACRE agree that the risks to the environment and human health associated with this release are extremely low. Even in the absence of any significant risks, Defra has requested that ACRE advise on proportionate measures that could be taken to restrict the GMO to the site and duration of the trial.

ACRE considers that maintaining a separation distance consistent with that used previously for GM oilseed rape between the GM camelina and any wild or cultivated camelina species (particularly *C. sativa*, *C. alyssum* and *C. microcarpa*) outside of the trial site would be a suitable measure to minimise the likelihood of cross-hybridisation. Alternatively, the applicant could put in place a 'pollen barrier' of non-modified *C. sativa* surrounding the GM camelina, to reduce the likelihood that pollen might be transferred from the trial site. To be effective, the pollen barrier should flower at the same time as (and so should be of the same variety and be sown on the same day as) the GM camelina. To increase the evidence base for environmental risk assessment of any future proposals for wider cultivation of GM camelina, ACRE suggests that the applicants may wish to collect data relating to the rate of cross-pollination between the GM camelina and that forming the pollen barrier, if it is practicable to do so.

ACRE acknowledge that birds represent one possible route of seed dispersal, and recommend that suitable measures should be put in place to keep them out of the trial site (such as those suggested by the applicant). In addition, the small size of camelina seeds should be taken into account when selecting, checking and cleaning equipment used for sowing and harvesting. Prior to harvest, the combine should be prepared to minimise any loss of small seeds through augers, sieves etc. The combine should be one designed to minimise admixture between plots and to facilitate cleaning down. After harvest, the applicant should ensure that the combine is cleaned completely such that all seed is removed before leaving the trial site, and cleaning of the combine should take place on the edge of the newly harvested plot.

ACRE note comments from Fera on this application indicating that waste seed and plant material from the trial should be disposed of by autoclaving, incineration or deep burial at a local authority-approved landfill site using an approved contractor.

Towards minimising the persistence of material within the experimental plots, it is recommended that after harvest, the plot should be left fallow until the following spring, at which point the whole plot should be shallow cultivated to a depth of no more than 5 cm (and preferably less). This should stimulate germination of any volunteer seed.

To minimise the likelihood of any material from the trial entering the human food or animal feed chain, ACRE recommends that the trial site is not used to cultivate crops for the food/feed chain until at least the second year after the trial is completed (subject to the monitoring outlined below).

Monitoring

In order to determine whether the proposed measures are operating effectively, ACRE suggests that the applicant should carry out the following monitoring for a minimum of two years. Monitoring may cease a) if no volunteers are identified in the second year of monitoring or b) after the first volunteer-free year. Volunteers of *C. sativa* growing on experimental plots and in the surrounding area should be allowed to emerge, before being counted at least monthly (during the growing season). Data on numbers of volunteers should be provided to Defra annually. Any volunteers identified should be destroyed by herbicide application or hand-pulling before flowering.

Issues arising from public consultation

Fifteen public representations were received (see below). ACRE are only required to consider scientific aspects. It has considered comments relating to the following:

Seed dispersal by wildlife

ACRE consider that the invasiveness and persistence of the GM camelina is unlikely to be affected by the genetic modification, as is the allergenicity, toxicity and potential for harmful effects on human or animal health. As such, ACRE considers that the risks associated with the proposed release are extremely low. As requested by Defra, ACRE has recommended proportionate measures to minimise the dispersal of material from the trial site. This includes measures to minimise the likelihood of seed dispersal by the most significant potential routes, i.e. removal by birds and via equipment used on the site. ACRE advised that although it is possible that a small amount of seed might be removed from the site by wildlife such as small mammals or molluscs (as is the case in any field trial), this would not pose a risk to the environment or human health.

Pollen dispersal, outcrossing and hybridisation

ACRE agree with the applicant's assessment that the species that are most likely to be sexually compatible with *C. sativa* (including *C. sativa* itself) are unlikely to be found on the Rothamsted estate. Cross-hybridisation with less closely related Camelineae is unlikely or expected to be at a very low level, and if this were to occur, the genetic modification would not be expected to confer a selective advantage or enhance persistence in the environment. ACRE has proposed proportionate measures to minimise the likelihood of cross-hybridisation with the species it believes have the most potential to cross-hybridise based on available evidence.

Characterisation and stability of material for release

Regarding the molecular and phenotypic characterisation, ACRE consider that if expression of the transgenes in pollen (or other plant parts) were to occur, it would not represent a risk to the environment or human health, and as such did not request further information from the applicant.

The applicant has provided sufficient details of the DNA sequences that have (or could have) integrated into the plants genome, and ACRE has not identified any elements of concern. The information provided by the applicant indicates that the GM camelina for release is morphologically indistinguishable from untransformed controls, with no difference in seed set, seed size, fertility or vegetative performance detected. The applicant's characterisation of the GMOs for release and experience of handling them under glasshouse conditions strongly suggest that in the context of this trial they would be unlikely to cause adverse effects.

Unintended effects on toxicity and allergenicity

ACRE considered that the transgenes transferred to the GM camelina are unlikely to affect the toxicity and allergenicity of the camelina to humans or animals via incidental exposure, and as detailed above any significant unintended effects would likely have been detected during the crop development process. If in the future an application was made for wider commercial cultivation of this GM crop in the UK for use in the human food chain or animal feed, a more detailed assessment would be undertaken, to include consideration of unintended effects on food safety.

Food safety and future use

Food safety is outside the scope of this assessment. Material from the proposed trial is not authorised to enter the food or feed chain. The applicant has amended their application to fully reflect this and ACRE is content with that amendment. The proposed trial is for research purposes, and any future applications of the technology are outside the scope of this assessment.

ACRE is grateful for the representations submitted by members of the public and is content that all of the issues relevant to this trial have been considered during the Committee's assessment of the dossier.

6 April 2016

Public consultation representations (Total 15):

GM Freeze submitted a multi-agency response on behalf of 21 organisations. The following summary was helpfully provided:

a) There is a risk of outcrossing via seed and/or pollen dispersal and cross-hybridization.
b) The applicant has not made available the detailed results of monitoring from the previous GM camelina release mentioned above.
c) The case that this trial must take place via a deliberate release to the environment (rather than contained use) has not been made convincingly.
d) The molecular characterisation of the inserted genetic cassettes involved in this trial is incomplete.
e) Food, feed and environmental safety of the GM camelina need to be considered due to the risk of pollen or seed escape, dispersal by wildlife, human error or accidental release.
f) The applicant's argument that this release is justified on sustainability grounds does not stand up to scrutiny. The need for the products that could eventually be produced as a result is based on spurious arguments.

I wish to urge rejection of the application by the Rothamstead Institute to grow a GM modified crop at their Hertfordshire estate.

- There is no absolute certainty that cross-fertilisation will not occur, thus transferring the genes of the modified plant to the outside area.
- There is no real need for this "fish oil substitute" to be grown. Far better to concentrate on improvements and increases in the fish-farming industry itself.
- There is no certainty that the so-called protection netting will succeed and in spite of bird-scarers etc. some birds may become entangled.
- The insect-repellent netting may surely be injurious to any bees that try to enter.
- There can be no absolute certainty that all GM seed on the ground will not be picked up and dispersed by pigeons.
- There appears to be no evidence that all possible research has been done to mitigate against the undesirable spread of GM modified crops to the surrounding area.

Dear UK Government,

I am totally against this trial and think it should be unnecessary in the 21st century when we already produce enough food to feed the planet yet waste so much that people are dying of starvation. Let's focus on cutting waste and not dangerous experiments that will most likely have harmful effects on the environment and unknown effects on people's health. Please don't experiment with the planet and our health.

I would like to say that as a member of the public I am wholeheartedly AGAINST all and any GMO trial plantings.

I believe that you are not taking the risks seriously - if, or rather when, the pollen or seeds escape their supposedly secure test site, then they WILL infect everything around them. The researchers, and those who stand to profit from GMOs, know this but choose to ignore the risk.

We have no need of any GMO anything, and anyone who has done even a small amount of research and thought about the consequences knows it.

I am hoping that common sense will prevail and that GMOs will be banned, forever, everywhere. Nobody wants them now, and we don't want to leave a poisonous mess for our grandchildren either.

To Whom It May Concern

Re Camelina Sativa GMO release

There are lots of other types of camelina which it could potentially cross pollinate with. So i think it is a not good idea to go ahead with this, until we know more about safety.

We could create pesticide resistance in plants we don't want to and the owners of the patent could claim ownership of other crops as in percy schmeiser (canada) case.

Dear Sirs

I am objecting to the 'fish oil' camelina trial application as pollen and seed could escape and affect natural relatives. I am aware that the genetic engineering process always carries a risk of unexpected effects, why should we be needlessly exposed to such risks?

Furthermore I believe the research group hasn't adequately tested the potential environmental nor food safety harms that their GM plant could cause. I am also sure that growing GM oils to prop up the fish farming industry will not make it sustainable.

Do we really need such applications as the methods we employ currently already provide enough, and more importantly, safe food. We do not need these costly and potentially hazardous 'inventions'.

I have grave concerns about both of these proposed trials because:-

Any genetic engineering trial carries environmental and food safety risks. Neither of these research groups appear to have adequately tested for possible environment/food safety pollution risks.

We already have plenty of blight resistant potatoes – why do we need GM ones?!?

There is no way of preventing pollen or seeds escaping and affecting natural relatives.

If the fish farming industry cannot remain viable, then why on earth would anyone believe that production of GM oils would save it???

I understand that the potato trial will use an antibiotic resistance marker – this would be dangerous because, if it escaped, it could bond with disease-causing bacteria, thus making them antibiotic resistant.

I object to the deliberate release of genetically modified camelina for research and development purposes - the synthesis and accumulation of omega-3 long chain polyunsaturated fatty acids and astaxanthin in Camelina sativa - because:

1. Pollen and seed could escape from the trials and affect natural relatives.

2. The genetic engineering process always carries a risk of unexpected effects. The research group has not adequately tested the potential environmental nor food safety harms that their GM plants could cause.

3. Growing GM oils to prop up the fish farming industry will not make it sustainable.

I write to add my name to what must be a growing list of objectors to this GM research .

Which is not only unnecessary ,but unsafe for our surrounding environment.

Dear GM Regulation Team

Application 16/R8/01

I wish to object to this further application on the following grounds:

Pollen and seed are extremely difficult to contain and could escape to affect natural relatives

Oils derived from camelina will not help in the matter of sustaining fish stocks

There is always a risk of surprise effects in genetic manipulation: I do not believe there has been adequate testing of the possibility of either environmental or food safety harm.

I should say that I have been closely following the GM debate for two decades, including observing two meetings of the GM Science Panel back in 2003. I have yet to be convinced that genetic engineering is even necessary, let alone fool-proof. I sincerely hope this trial will not be allowed to proceed.

Dear Sirs,

I object in the strongest terms to the release of genetically modified camelina sought by Rothamsted Research.

Pollen and seeds could escape and affect natural relatives. Choice is going to be denied to all as GM contamination ruins all other crops. Those who are forcing GM on the world should be made responsible for the consequences and not allowed power without responsibility.

The genetic engineering process always carries a risk of unexpected effects. The research group has not adequately tested the potential environmental and food safety harms that these GM plants could cause - and since neither they nor the officials who support them will be made responsible for the consequences, there is little incentive to ensure damage containment is guaranteed.

Growing GM oils to prop up the fish farming industry will not make it sustainable.

As an organic gardener & one who wishes to continue to eat natural organic food, I object to open trails of GM crops.

The attempt to introduce omega 3 to camelina is fraught with risk as pollen & seed are bound to escape & affect natural relatives.

Furthermore, the genetic engineering process always carries a risk of unexpected effects which have the potential to cause environmental & dietary harm.

I object to this trial on the following grounds:

- Pollen and seed could escape from the trial and affect natural relatives.
- The genetic engineering process always carries a risk of unexpected effects. The research group has not adequately tested the potential environmental nor food safety harms that their GM plants could cause.
- Growing GM oils to prop up the fish farming industry will not make it sustainable.

As an organic gardener & one who wishes to continue to eat natural organic food, I object to open trails of GM crops. The attempt to introduce omega 3 to camelina is fraught with risk as pollen & seed are bound to escape & affect natural relatives. Furthermore, the genetic engineering process always carries a risk of unexpected effects which have the potential to cause environmental & dietary harm.

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As a group member of Garden Organic and an organic gardener myself, I wish to continue to eat natural organic food unaffected by potential contamination as a result of open trails of GM crops. The attempt to introduce omega 3 to camelina is fraught with risk as pollen & seed are bound to escape & affect natural relatives. Furthermore, the genetic engineering process always carries a risk of unexpected effects which have the potential to cause environmental & dietary harm.

I would like to register my objection to the above, I am against Genetically modified organisms, I believe them to be unsafe to the eco system and a Trojen horse for patenting and profiteering.