GM Team
Department for Environment, Food and Rural Affairs
Area 1C, Nobel House
17 Smith Square
London, SW1P 3JR

Submitted by email to gm-regulation@defra.gsi.gov.uk

17 March 2016

Dear Madam/Sir

Application from Rothamsted Research to release a genetically modified organism, reference 16/R8/01.

We are writing on behalf of GM Freeze, GeneWatch UK, GM Free Cymru, the Soil Association, Organic Growers Alliance, Mums Say No to GMOs, GM Free Dorset, Beyond GM, EcoNexus, Action Against Allergy, Sevenoaks Friends of the Earth, GM Watch, Organic Research Centre, Unicorn Grocery, the Springhead Trust, Find Your Feet, South Gloucester Friends of the Earth, White Home Farm, Whole Organic Plus, ACE Energy and Shepton Farms to request that the above application to release genetically modified *Camelina sativa* (GM), modified to synthesise and accumulate omega-3 long chain polyunsaturated fatty acids and astaxanthin, is refused.

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GM Freeze is the umbrella campaign for a moratorium on GM in food and farming in the UK. **The Soil Association** is the UK's leading membership charity campaigning for healthy, humane and sustainable food, farming and land use. **The Organic Growers Alliance** supports and represents those growers involved in commercial organic horticulture. **Mums Say No to GMOs** is a coalition of mothers and their families using consumer pressure to stop GM crops being grown and sold in the UK. **GM Free Dorset** is a grass roots campaign supported by individuals, groups, local businesses and charities that exist to promote rural sustainability. **Beyond GM** is a UK campaigning group raising the level of public understanding and engagement with issues around GMOs. **Action Against Allergy** provides information and support to those made chronically ill through different forms of allergy and those who care for them. **GM Watch** is a news and information service that aims to keep the public up to date on issues around GM crops and foods and associated pesticides. **Organic Research Centre** is the UK's leading independent research centre for the development of organic/agroecological food production and land management solutions to key global issues. **Unicorn Grocery** in Manchester has pioneered a cooperative approach to sustainable urban food supply. **Springhead Trust** is a rural, educational, sustainability charity. **Find Your Feet** helps poor rural families in Asia and Africa to grow enough food so they don't have to go hungry. **White Home Farm** in Lincolnshire grows conventional combinable crops. **ACE Energy** helps farmers to use less energy intensive methods of farming. **Shepton Farm** in Somerset grows grass/clover, arable crops and apples.

An objection was lodged with DEFRA by GM Freeze[1] on behalf of several groups to the previous application from Rothamsted Research (ref: 14/R8/01) to release *Camelina sativa* genetically modified (GM) to produce eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). This objection to the new application from Rothamsted Research to release *C. sativa* (ref 16/R8/01) reiterates and builds on the concerns expressed in 2014 with recent peer-reviewed publications.

We do not believe that this trial should go ahead at the present time. The applicant's argument that the risks associated with deliberate release are balanced by the potential benefits of producing a non-marine source of nutrition for the aquaculture industry do not hold water. This is partly due to the variety of risks and potential disbenefits associated with the release and partly because the need for the eventual products of this trial is not proven. In summary our objection cover the following points:

1 There is a risk of outcrossing via seed and/or pollen dispersal and cross-hybridization.
2 The applicant has not made available the detailed results of monitoring from the previous GM camelina release mentioned above.
3 The case that this trial must take place via a deliberate release to the environment (rather than contained use) has not been made convincingly.
4 The molecular characterisation of the inserted genetic cassettes involved in this trial is incomplete.
5 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.
6 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.

1. Risk of outcrossing via seed and/or pollen dispersal and cross-hybridization.

1.1. The risk of outcrossing via pollen dispersal was considered a serious issue with the 2014 application[2] and recent research underlines the possibility of outcrossing and hybridization with wild relatives.

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1.2. By asserting that that they will make efforts to minimise (Part A4) or mitigate (para 37) pollen and seed dispersal the applicant concedes that the escape of pollen and seed cannot be eliminated entirely, even with the intended measures such as netting and use of rows of wildtype *C. sativa* surrounding the experimental plot serving as a pollen trap. They also note that camelina dispersal by wind (para 6) is an important factor.

1.3. The applicant acknowledges the possibility of hybridization with other camelina species (eg *C. alyssum, C. microcarpa*) but reports they are not recorded in a 15 km range. However, this is still an issue of concern as "distance will not protect us; if cross-pollination can occur, it will. A bee that gets on a train could deliver its cargo of pollen to far-flung places".[3]

1.4. The applicant references Julie-Galau et al (2013)[4] (para 28) that "Whilst potential cross-hybridising species such as *Capsella bursa-pastoris* are widely distributed across the UK and commonly found in Hertfordshire, the ability of *C. sativa* and *C. bursa-pastoris* to form viable offspring has experimentally been demonstrated to be very limited".

1.5. However, although Julie-Galau et al. (2013) found that *C. sativa* and *C. bursa-pastoris* "produced a few hybrid plants, and these displayed both male and female sterility", they limit their conclusions to the study area in France, "These results suggest that the potential for pollen-mediated gene flow from future field trials in Versailles of GM camelina would be extremely limited."

1.6. Julie-Galau et al. (2013) further discuss that *C. bursa-pastoris* is an extremely variable plant with many ecotypes and possibly with multiple origins, "It is not clear to what extent these results can be generalized. ….Although this suggests that there are capsella ecotypes that are less able to cross with camelina, this also means that we cannot exclude that there may be ones with increased ability to hybridize" and conclude "If there are circumstances where gene flow from camelina to capsella is of concern, it would be appropriate to consider whether there are means to break the pathway to harm in a more definitive manner." This has not been performed for the ecotypes in the vicinity of the proposed experimental site.

1.7. Therefore, outcrossing with *C. bursa-pastoris* may be "very limited", but cannot be eliminated. This is important because it is a wild relative that is common in the vicinity of the proposed field trial. The concern is that, should outcrossing occur and a fertile hybrid result, albeit at very low frequency, this could persist in the natural environment and even introgress through natural populations of *C. bursa-pastoris*.

1.8. There is at least one case of escaped GM seed that has resulted in an ongoing inadvertent feral establishment. An experimental GM bentgrass escaped either by wind-blown seed or a failure to remove immature seed heads from the field trial at a research station in the USA in 2003 and 2005.[5] The grass has established and remains in uncultivated habitats where it has hybridised with a naturalised grass species.

1.9. Therefore, there is a possibility for pollen and/or seed escape to the wider environment and a possibility to hybridize with camelina and capsella relatives. Such a hybridization could result in the GM trait persisting, and even introgressing into natural populations. The implications of this have not been considered or quantified but could impact on biodiversity (eg if the plant was no longer palatable to foraging animals, including insects).

2. **Lack of detail in results of monitoring from previous GM camelina release**.

2.1. Rothamsted Research was granted consent for a previous release (ref 14/R8/01) covering 1 April 2014 to 31 October 2017. Numerous conditions were placed on the consent including "an assessment of the effectiveness of measures to control volunteers, including details of the number of volunteers detected each month in the trial site".[6] However, the reporting of volunteers appears to have only been carried out at a rudimentary level. If more detail has been shared with Defra it has not been placed in the public domain.

2.2. Reports submitted by the applicant for the 2014 and 2015 growing season[7] note that:

"A number of volunteers were observed in the trial site during November visits, and the trial site was sprayed with glyphosate on 23rd Nov 2015. The 50m area was seen to be free of volunteers. Monitoring of the trial site will restart on 1st Feb 2016"

"Post-trial monitoring of Year 1 of the GM Camelina trial was conducted according to plan. A number of volunteers were observed within the site, though whether these were derived from the GM line or the non-GM pollen barrier was not determined. Volunteers were destroyed by the application of glyphosate to the trial site. No volunteers were observed in the 50m area around the trial site"

"On inspection of site in November Camelina volunteers were found on site. The spread of volunteers was sporadic across the area and in places they were locally abundant with several plants growing next to each other. Therefore in some areas you had 30 plants/m2 and in other places zero. The whole trial area was sprayed with glyphosate on 23/11/15."

2.3. These reports were the only documents provided to us by Defra in response to a request for information on monitoring results but they do not state the **number** of volunteers involved. It is imperative that detailed monitoring results from previous field trials are allowed to be investigated by any interested third parties prior to any new permission to release GM camelina. If monitoring is required on a weekly or monthly basis, then it should be reported on that basis.

3. The case that a deliberate release is necessary has not been made.

3.1. The applicant has not made a strong enough case that this trial must take place via a release of GM *C. sativa* to the environment rather than through research within contained facilities. This GM plant is designed to produce bio-active molecules (EPA, DHA and astaxanthin) and many would regard it as a GM 'pharm' crop. No GM pharm crops have been commercialised anywhere in the world, and undoubtedly concerns regarding outcrossing and mix ups play a part in this. This GM *C. sativa* is a crop producing seeds/oil intended to be used as a feeding supplement in aquaculture. This is a vastly different method of production to GM commodity crops, such as soya or rape seed which require large-scale production. Therefore, there does not appear to be a reason why this crop cannot be grown in secure 'contained use' conditions, eg through carefully controlled greenhouses designed for the purpose. Indeed, one might even expect better (more reproducible) results if the plant is grown under controlled conditions.

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4. The molecular characterisation is incomplete.

4.1. Question 14 of the application requires:

"14. The following information on the sequences actually inserted or deleted:

(a) the size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced into the genetically modified plant or any carrier or foreign DNA remaining in the genetically modified plant,

(b) the size and function of the deleted region or regions,

(c) the copy number of the insert"

4.2. No evidence or statement is presented by the applicants for the copy number of the inserted cassette for each experimental line (Question 14c), nor of whether any endogenous plant DNA has been re-arranged or deleted (Question 14b) in any of the lines. This is important as the genetic cassettes are complex, with all three of the experimental lines containing more than ten individual genetic elements each, and two lines containing more than 25 elements. Fragments and rearrangements of either inserted DNA or endogenous DNA can affect food and environmental safety – and these could be important in the event of an escape.

5. Food, feed and environmental safety need to be considered.

5.1. Pollen and seeds could escape from the trial site through dispersal by wind, wildlife or machinery. Human error and mix ups could also result in accidental releases, not only to the environment but also to the human food chain or even directly to humans.[8] Therefore, some consideration needs to be made of food safety in the event of the GM camelina seed/oil being consumed by humans. Food safety to humans would have to be considered in the event of possible commercialisation of this GM crop anyway, even if it is intended solely as an animal feed, so it would be unwise to proceed without properly considering the risks in this area.

5.2. Our objection to the previous GM camelina trial[9] stated

"Furthermore the consequences and risks of the expression of either the whole set of inserted genes or only some of them in other parts of the plants, as well as the possibility that the DNA sequence contains additional regulatory elements (such as enhancers) or contains duons, should be assessed before consent is granted for environmental release. Additionally both the inserted seed promoters and the constitutive promoters may affect expression of the plant's own genes. A specific point of deliberation should also be the consequences of gene silencing, which is known to increasingly occur under environmental stress conditions and also where promoter elements have been duplicated, such as NP in event "B" and NP and CNL is event "C". [previous trial events]

"The applicant cites a scientific paper (Ruiz-Lopez *et al.*, 2013) in describing the accumulation of EPA and DHA in iteration B of the altered *C. sativa.* However that paper also reports a number of other alterations to the lipid composition of transgenic *C. sativa,* including a very pronounced decrease in the accumulation of oleic acid. The applicant fails even to acknowledge these changes or account for them in its risk assessment."

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5.3. Unfortunately, it still remains the case that there has been only rudimentary analysis of the fatty acid profile in subsequent publications[10] [11] [12] and no consideration given to possible unintended consequences of the genetic modification. The attempted genetic engineering of a novel metabolic pathway is far more ambitious than the genetic engineering in current GM crops (eg GM Roundup Ready soya, which contains four genetic elements). Therefore, there are likely to be some unintended effects. It is vital that these are actively searched for, evaluated and considered in terms of food and environmental safety as they could be important to food and environmental safety in the event of an escape.

6. **The need for GM camelina producing EPA, DHA and astaxanthin is based on spurious arguments.**

6.1. The applicant argues that a deliberate release of GM camelina producing EPA, DHA and astaxanthin is required on sustainability grounds. Principally, that people require fish containing these compounds for adequate health and nutrition and that the fish they consume are fed these compounds from marine sources which are becoming depleted by current aquaculture practices. Despite many claims to the contrary, there is no conclusive evidence of health benefit from omega-3 fatty acid supplementation and some evidence of potential harm[13].

6.2. Human nutrition is complex. As a recent Outlook article in *Nature*[14] discussed:

"Beyond simple measures of micronutrient intake, individual requirements are also influenced by a person's genetics. So far, much of the research has focused on how people process omega-3 fatty acids, chiefly DHA and eicosapentaenoic acid (EPA), which are crucial for human cognitive health.

"Omega-3 fatty acids are found primarily in oily, wild fish, such as salmon and tuna, but pasture-raised animals are also a good source. (Animals fed only soya or maize have fewer omega-3s.) In 2012, researchers discovered that most African populations, but not European populations, carried a variant of the *FADS* gene that made them more efficient at converting omega-3s in plants into a usable form, meaning that they required less from animal sources. Conversely, a 2014 paper reported that people carrying a variant of the *APOE* gene (11–17% of US individuals of European descent) that confers a greater risk of developing late-onset Alzheimer's disease, derived little benefit from eating fatty fish." There is no evidence that fish are an essential source of omega-3 fatty acids, as studies report that vegetarians have heart health that is equal to or better than non-vegetarians.[15]

6.3. Even if we accept the premise that higher EPA and DHA consumption will lead to better health, it does not follow that these fatty acids must be obtained by eating fish. Fish accumulate the compounds under consideration by consuming marine algae. Indeed, EPA, DHA and astaxanthin are all already commercially available as human food supplements derived from algae[16]. Omega 3 fatty acids (including EPA and DHA) are available from meat and dairy sources (especially those from organic or other pasture-fed livestock[17]) and humans are able to synthesise EPA and DHA from shorter chain omega 3 sources in plants. These include new plant sources, such as oil from the Ahiflower (*Buglossoides arvensis*) which has recently been launched in the UK[18] and whose omega-3 oils can be converted to EPA.

6.4. Synthetic astaxanthin is currently used in the aquaculture industry and a recent economic evaluation[19] suggested that it could be produced at a lower cost from algae using current technologies. Similarly, the potential for microalgae to be used as a feed for aquaculture has received much attention from the research community and shows potential to have a smaller resource footprint than traditional fish feed.[20]

6.5. Therefore, GM camelina is neither the only, nor in all likelihood the most economical, solution to reducing the use of fish oil as a feed in aquaculture. In contrast it possibly entails the most risk in terms of the environment and human health. Any escape of GM camelina seeds or pollen would be extremely difficult to recall and possibly irreversible. It is not worth the risk of a release.

6.6. Finally, the sustainability challenges of the aquaculture industry are many and varied. They are not limited to the supply of feed/oil but include nutrient discharges, spread of fish diseases and fish escapes. If the overall impacts of aquaculture are considered, including external environmental costs (such as impacts on marine biodiversity), it is highly unlikely that aquaculture would be regarded as economically sustainable, with or without GM camelina.

Yours faithfully

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ANNEX A Monitoring and reporting requirements in DEFRA's consent to release genetically modified organisms ref. 14/R8/01 (DEFRA 2014)

General monitoring requirements

Condition 8. The consent holder must:

(1) Inspect the entire trial site during the period of cultivation of GMO(s) at least once a week to ensure that the limitations and conditions of this consent are being met.

(2) Maintain raw data and reports of inspections of volunteers and provide this information to the Secretary of State on request as soon as possible. Maintain raw data and reports of inspections of volunteers and provide this information to the Secretary of State on request as soon as possible.

Reports

Condition 9. The holder of the consent must submit a report to the Secretary of State in the format outlined in the Annex to Commission Decision 2003/701/EC (O.J. L254, 08/10/2003, p.21) by December 1st in the first year of the trial period. Such report or reports must also include the following information:

(1) an assessment of any risks or actual or potential adverse effects to human health or the environment from the GMO(s),

(2) whether the release on that particular plot progressed as planned and if it did not:

i) what occurred;

ii) any additional measures that were taken;

iii) any additional measures that will be taken; and

iv) why these measures were taken.

Condition 10. Subject to Condition 11, the consent holder must submit a report in the format specified in the Annex to Decision 2003/701/EC to the Secretary of State on each anniversary of the date that the first report is submitted in accordance with Condition 9. This report must include the following information:

(1) an assessment of the effectiveness of measures to control volunteers, including details of the number of volunteers detected each month in the trial site,

(2) the re-evaluation of monitoring requirements, including whether or not the consent holder proposes to continue monitoring and the reasons for this decision,

(3) any additional precautions considered necessary to minimise the dispersal of the GMO(s) outside of the trial site.

Condition 11. The consent holder must continue to submit the reports referred to in Condition 10 until the Secretary of State has agreed in writing that the trial site has been controlled in accordance with Condition 6(10), and that the trial is therefore terminated.