Part B: Information about the release application to be included on the public register

B1 The name and address of the applicant

Rothamsted Research,
West Common,
Harpenden
Hertfordshire,
AL5 2JQ

B2 A general description of the genetically modified organisms in relation to which the application is being made

The organism to be released is the oilseed *Camelina sativa* (hereafter referred to as "Camelina") and we have used genetic modification to introduce into this plant the capacity to produce the omega-3 long chain polyunsaturated fatty acids (omega-3 LC-PUFAs) eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and related compounds. The synthesis of these health-beneficial fatty acids has been engineered to only occur in the seeds of the GM Camelina. Similarly, GM Camelina plants have been engineered to accumulate ketocarotenoids such as astaxanthin (ASX). Again, the synthesis and accumulation of ASX has been engineered to only occur in the seeds of the GM Camelina. In a third iteration, GM Camelina plants have been engineered to be altered in their endogenous seed composition, in terms of the fatty acids profile and oil type. This includes accumulating fatty acids that are either short chain (< than C16) or very long chain (>C22). **The variation in synthesis and accumulation of these only occur in the seeds of the GM Camelina**.

The GM Camelina plants have been engineered with the novel capability to accumulate the non-native fats and oils through the introduction of the biosynthetic genes for these fatty acids. Such genes are found in taxonomically-diverse range of organisms, predominantly marine microbes (such as microalgae and diatoms) and some oomycetes and lower plants. In a few examples, these synthetic genes are derived from other organisms (including mammals). Synthetic genes (meaning that the native DNA sequences have been codon-optimized and chemically synthesized) from such organisms have been integrated into the genome of Camelina, under the control of seed-specific promoters. Thus, the recoded sequence is different from that which it was derived, in terms of DNA sequence, and therefore can serve as a unique barcode.

B3 The location at which the genetically modified organisms are proposed to be released

We propose to carry out a maximum of 2 trials/year over a four-year period and will avoid reusing the same plots. It will be sited on the experimental farm at Rothamsted Research, Harpenden, at grid reference TL122134, and also at the experimental

farm at Rothamsted Research, Brooms Barn, at grid reference TL762655.

B4 The purpose for which the genetically modified organisms are proposed to be released (including any future use to which they are intended to be put).

The purpose of this experimental trial is to determine the performance of these different GM Camelina iterations in the field, with respect to oil composition and oil quantity for different lipids as well as other aspects of seed composition. It is also to assess any additional phenotypic and agronomic variations. Specific questions to be examined are:

Do the GM Camelina plants efficiently accumulate different omega-3 LC-PUFAs in seed oil in the field?
Do the GM Camelina plants efficiently accumulate ASX in their seeds in the field?
Do the GM Camelina plants efficiently accumulate specific alterations to their seed oil composition in the field?
Do the GM Camelina plants still accumulate total seed oil to appropriate levels?
Is there any further alteration to the lipidome of field-grown GM Camelina?
Is there any difference between the different lines in terms of agronomic performance?
Is there any advantage or disadvantage to the GM Camelina plants in terms of field-performance?
In addition, the optimal agronomic management of GM camelina will be determined.

B5 The intended dates of the release.

The exact timing of sowing of the trial will depend upon weather conditions at the time. The field trial start date will be in April/May 2024 and the plants will be harvested in Aug-Oct the same year. We intend to carry out similar experiments in 2025-27. The option of trialing a winter-sowing is also envisaged (sowing in Oct) although the preferred season is a spring sowing.

B6 The environmental risk assessment.

Of the multiple GM Camelina constructs described in this application, all direct the seed-specific expression of their transgenes and as such are indistinguishable from the non-GM equivalent except for the modified composition of their seeds, in particular by the presence of either omega-3 long chain polyunsaturated fatty acids or ASX, or through the variation of other seed oil fatty acid components. This modified composition is found only in the seeds of the GM Camelina and is absent from all other vegetative tissues (e.g. leaves, roots, stems). There are no known hazards associated with these modifications.

In all cases, the gene template organisms are not known to be pathogenic or allergenic to humans. None of the genes under investigation, or the selectable or visual marker genes, are expected to result in the synthesis of products that are harmful to humans, other organisms or the environment. Any unknown hazards

arising from the expression and ingestion of foreign proteins will not occur since the Camelina plants will not be consumed by humans.

The probability of GM Camelina seeds escaping from the trial sites or the transfer of inserted characteristics to sexually-compatible species outside the trial area is estimated as very low. Camelina seeds are moderate in size and not normally dispersed by wind. Management measures including the use of humming tape and hawk kites will be employed to mitigate the risk of seed removal by birds. There will be no compatible Camelina species grown within 750 meters from the boundary of the sites and no sexually-compatible wild relatives of *C. sativa* exist in the vicinity of the Rothamsted farms.

The risk of non-sexual, horizontal gene transfer to other species is extremely low. In the event of horizontal gene transfer to bacteria, neither the trait genes nor the marker genes would be expected to confer a selective advantage in the field environment under consideration. We estimate the likelihood of horizontal gene transfer as low and the consequences, were it to occur, as negligible. The areas proposed to be planted with GMOs is small and temporary (lasting between 4 and 5 months).

Bearing in mind its limited scope, overall risk of harm to human health or the environmental arising from this trial is assessed as very low, consistent with previous Consents (16/R8/01, 18/R8/01 and 19/R8/01) for similar traits and genes.

B7 The methods and plans for monitoring the genetically modified organisms and for responding to an emergency.

The release sites will be visited by trained laboratory personnel who are working on the project at no less than weekly intervals during the growing season of each year of the trial. Any unexpected occurrences that could potentially result in adverse environmental effects or the possibility of adverse effects on human health will be notified to the Defra GM team immediately. Should the need arise to terminate the release at any point the emergency plans detailed below will be followed.

At the end of each season, the plot will remain in stubble and monitored for volunteers during the remainder of the year and the following season. Any volunteers identified will be destroyed by appropriate non-selective herbicide treatment or removed by hand and destroyed.

Following completion of the trial the release site will remain fallow for a further season to enable easy identification of volunteers. The site will be inspected regularly, and any volunteers identified will be immediately destroyed either physical removal or by application of a systematic broad leaf herbicide.

Emergency procedures: In the unlikely event that the integrity of the site is seriously compromised, the trial will be terminated and all plants, (including GM and control Camelina plots, and any pollen barrier if used) will be destroyed using a suitable herbicide or harvesting as deemed appropriate. All harvested material will be removed from the site and disposed of appropriately, e.g. by incineration or deep

burial at a local authority-approved landfill site using an approved contractor. Transportation of waste materials will be in secure containers. The phone numbers of all key staff will be available to site security and farm.