Application for consent to release a GMO

Part A2: Data or results from any previous releases of the GMO

Give information on data or results from any previous releases of this GMO by you either inside or outside the European Community [especially the results of monitoring and the effectiveness of any risk management procedures].

This GMO has not previously been released.

Part A3: Details of previous applications for release

Give details of any previous applications to release the GMO made to the Secretary of State under the 2002 Regulations or to another Member State under the Deliberate Release Directive 2001/18/EC.

There have been no previous applications to release these GMOs. However, Rothamsted Research and the John Innes Centre have received previous consents to release GM wheat, most recently: 22/R55/01 and 21/R52/01, respectively.

Part A4: Risk assessment and a statement on risk evaluation

Summary
Environmental risks

The probability of seeds escaping from the trial site or the transfer of inserted characteristics to sexually- compatible species outside the trial area is estimated as very low. Commercial wheat varieties do not establish easily or thrive in uncultivated environments and are naturally self-pollinating with out-crossing being a rare event. Wheat seeds are relatively large and not normally dispersed by wind. Management measures including the use of gas guns and hawk kites will be employed to mitigate the risk of seed removal by birds.

Management procedures to minimise the spread of seeds or pollen will further reduce the probability of these events occurring. There will be no sexually compatible cereals grown for 20 metres from the boundary of the experimental plots and no sexually-compatible wild relatives of wheat exist in the vicinity.

Following the example of Consent 24/R57/01 and Variation of **Consent 22/R55/01** (22/05/2024), other GM crops that are the subject of separate consents or notifications may be grown simultaneously within the trial sites as long as a wheat pollen barrier of at least 3 metres width surrounding the GMOs, is sown on the same day as the GMOs, at the same sowing density as the GMOs, with a variety of similar growing characteristics (height, flowering time) within the perimeter of the plot.

If out-crossing to plants outside the trial area were to somehow occur, selection pressure to maintain the genes in the environment would not exist where conventional herbicides such as glyphosate are used to control wheat or weed species. Even if the up-regulation photosynthesis genes does occur, the chances of successful establishment of these wheat plants in unmanaged ecosystems is extremely low (Driever *et al.*, 2014).

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 selectable marker genes would be expected to confer a selective advantage in the field environment under consideration (Philips *et al.*, 2022).

The area proposed to be planted with GMOs or GMO-segregating azygous plants is small; total area is less than 1 hectare across all trial locations and traits, and temporary (trial seasons lasting between 11 and 12 months at maximum, running from 2026 to 2033 only).

Human health risks

All lines were advanced through successive generations and screened by dPCR until no hygromycin resistance gene (hptII) signal was detected (copy number 0). Where residual T-DNA–derived sequences may remain, these are therefore expected to be partial fragments that do not constitute an intact selectable marker gene and are not predicted to encode a functional hygromycin resistance protein.

Where applicable, the donor organisms of the genetic elements are not known to be pathogenic or allergenic to humans, and none of the genes under investigation, nor any residual selectable marker fragments, are expected to result in the production of products harmful to humans, other organisms, or the environment.

Any unknown hazards arising from the expression and ingestion of foreign proteins will not be realised because the wheat plants will not be consumed by humans. Thus

the overall risk of harm to human health or the environmental risk arising from this trial is assessed as very low.

Risk assessment

Conclusions on the Potential Environmental Impact from the Release or the Placing on the Market of GMOs

i. **Likelihood of the genetically modified higher plant (GMHP) becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.**

Negligible. Please see table below for detailed assessment.

ii. **Any selective advantage or disadvantage conferred to the GMHP.**

Very low. Please see table below for detailed assessment.

iii. **Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.**

Very low. Please see table below for detailed assessment.

iv. **Both Potential immediate and any delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids and pathogens (if applicable).**

Not applicable.

v. **Both Possible immediate andany delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.**

Not applicable.

vi. **Possible immediate and any delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into direct contact with, or in the vicinity of the GMHP release(s).**

Neglible. Please see table below for detailed assessment.

vii. Possible immediate and any delayed effects on animal health and consequences for the food/feed chain resulting from consumption of the GMO and any products derived from it if it is intended to be used as animal feed.

Very low. Please see table below for detailed assessment.

viii. Possible immediate and any delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

Very unlikely. Please see table below for detailed assessment.

ix. Possible immediate, or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

Negligible. Please see table below for detailed assessment.

Table 1: Detailed environmental risk assessment for the GM plant

	Step1: Potential hazards which may be caused by the characteristics of the novel plant	Step 2: Evaluation of how each hazard could be realised in the receiving environments	Step 3: Evaluation of the magnitude of harm caused by each hazard if realised	Step 4: Estimation of how likely/often each hazard will be realised as harm	Step 5: Modification of management strategies to obtain lowest possible risks from the deliberate release	Step 6: Overall estimate of risk of harm caused by the release for each hazard
a	**Increased invasiveness in natural habitats or persistence in agricultural habitats.**	Increased invasiveness may arise from intended or unintended effects of the genetic modificationthat resulted in wheat plants with a more 'weedy' habit that are better able to establish and thrive in uncultivated environments or to persist in	Wheat is an annual species that requires active management to out-compete weedier plants. Left unmanaged, wheat does not establish and survive in nature and thus has a low base line of invasiveness and persistence (Kaur, Sachan & Sharma, 2021). Even if intended or unintended effects of the genetic modification resulted in major changes in invasiveness or persistence, itis considered that this would not result in significant environmental harm for agricultural or	It is highly unlikely that intended or unintended effects of the genetic modification will result in major changes in invasiveness or persistence. If it were to occur, this hazard would be realised only if seeds or pollen possessinggenes encoding these traits were to spread from the trial site and successfully become established elsewhere. This is very unlikely as wheat pollen is relatively heavy so does not travel far, it has a short half-life	Harvested seeds will be transported from the site in sealed containers. Machinery will be cleaned thoroughly prior to removal from the site. There is a large buffer zone to minimize the spread of pollen. Surrounding the trialsite is a 20 metre area in which no sexually compatible cereals will be grown. Appropriate physical barriers and/or deterrents	Overall riskis negligible.

		agricultural habitats.	unmanaged ecosystems. Wheat is a benign plant that can be easily managed by cultivation or herbicides. The magnitude of harm if the hazard wasrealised is considered to be very small.	and there are no sexually compatible species for out-crossing for at least 20m from the trial site. Seed removal from the site will be rigorously managed. The chances of modified wheat plants establishing themselves outside the trial site are negligible.	will be employed to minimise access by large mammals and birds.	
e	**Selective advantage or disadvantage conferred to sexually compatible plant species**	Selective advantage or disadvantage may result from the intended traits (improved photosynthesis) or as a result of unintended effects of the genetic modification. Thesehazards could be realised in the receiving environment via dispersal of GM	The basal ability for commercial cereal crop varieties to survive in uncultivated environments is very low. We anticipate that the conferred traits of improved photosynthetic rates will provide only minor selective advantage compared to other factors determining a plant's ability to survive in unmanaged ecosystems.	This hazard would be realised only if seeds or pollen possessing genes encoding these traits were to spread from the trial site and successfully become established in environments were the appropriate selection pressures were present. This is very unlikely as wheat pollen is relatively heavy so does not travellong distances (Loureiro et al., 2007), it has a short half-life and there are no sexually compatible	Harvested seeds will be transported from the site in sealed containers. Machinery will be cleaned thoroughly prior to removal from the site. There is a large buffer zone to minimize the spread of pollen. Surrounding the trialsite is a 20 metre area in which no sexually compatible plants will be grown so it will be easy to see	Overall riskis very low.

		seeds from trial siteto the surrounding environment or via out-crossing to sexually-compatible species outside trial site.		species for out-crossing for at least 20m from the trial site. Seed removal from the site will be rigorously managed. Overall, the frequency of this hazard resulting in environmental harm is very low.	any cereal plants in thesurrounding area. Appropriate physical barriers and/or deterrents will be employed to minimise access by large mammals and birds.	
f	**Potential environmental impact due to interactions between the novel plant and target organisms**	This hazard could not be realised because there are no target organisms.	Not applicable.	Not applicable.	Not applicable.	No risk.
g	**Potential environmental impact due to interactions between the novel plant and non-target organisms**	Changes in the plant interactions with non-target organisms could result from the intended or unintended effects of the genetic	Wheat plants have a range of pests and fungal pathogens. Wheat also interacts with beneficial insects that attack aphid pests. If there is an impact on these non-target organisms from increased plant vigour,	Impact of this hazard on the environment would only occur if seeds or pollen from the GM plants were to spread from the trial site and become established. The measures described above that minimize the spread of	There will be a 3 m pollen barrier surrounding the trial site and there is a large buffer zone that minimises any risk. Surrounding this whole trial area no sexually	Overall risk is very low.

		modification through increased plant vigour.	the impact will be negligeable as these non-target organisms would be localized to the trial area and the crop is controlled through chemical agronomy to control these non-target organisms.	GM pollen will make the likelihood of this hazard to be considered extremely low.	compatible plants, with the exception of other GM trials, will be allowed to grow for 20 m (or 20 m from a GM plot at the JIC Church Farm, as above). Appropriate physical barriers and/or deterrents will be employed to minimise access by mammals and birds.	
h	**Potential effect on human or animal health due to the introduced genes**	By contact or ingestion of GM plant material.	The genetic modifications in all the lines are not expted to result in the synthesis of the products that are harmful to human health. The gene-modified barley have exhibited a difference in the expression pattern of a number of genes involved in the plant metabolites. None of these genes are known to be toxic or harmful to human	Some contact between the GM plants and humans or animals is expected. People operating farm machinery and scientists working in the trial site will come into physical contact with the plants. Small mammals such as mice, invertebrates and birds may alsocome into contact and/or ingest plant material.	No plant material from the trial will enter the food or animal feed chain. Appropriate physical barriers and/or deterrents will be employed to minimise access by large mammals and birds.	Overall riskis very low.

			health, nor are they known to exert any toxic or allergenic effects. Any unknown hazards with respect to human health arising from the expression and ingestion of foreign proteins will not be realised because the plants will not be consumed by humans.		Machinery will be cleaned before being removed fromthe trial site	
i	**Potential effects on biogeochemical processes (changes in soil decomposition of organic material)**	No detrimental effect on the soil is expected from the introduced genes.	Soil decomposition or any other biogeochemical process is not expected to be affected any differently due to the cultivation of GM wheat plants compared to wildtype cv Cadenza.	Any effect is expected to be comparable to that of non-GM wheat cv Cadenza under conventional agricultural practice.	Conventional agricultural practice for these type of GM trials will be followed strictly, no modifications are expected.	Overall risk is very low.
j	**Possible environmental impact due to changes in cultivation practice**	This modification may result in higher yields.	The magnitude of any changes due to changes in cultivation practice will be negligible.	The frequency that this hazard may be realised is low. The number of plants is small and will be sown for a small number of growing seasons, ending 2033 (each season lasting between 10 and 11 months).	None.	Overall risk negligible.

Part A5: Assessment of commercial or confidentiality of information contained in this application.

Identify clearly any information that is considered to be commercially confidential. A clear justification for keeping information confidential must be given.

Not applicable.

Part A6: Statement on whether detailed information on the description of the GMO and the purpose of release has been published

Make a clear statement on whether a detailed description of the GMO and the purpose of the release have been published, and the bibliographic reference for any information so published.

This is intended to assist with the protection of the applicant's intellectual property rights, which may be affected by the prior publication of certain detailed information, for example by its inclusion on the public register.

A description of the GMOs and the purpose of the release have not yet been published.

References

Driever, S.M., Lawson, T., Andralojc, P.J., Raines, C.A. & Parry, M.A.J. (2014) *Natural variation in photosynthetic capacity, growth, and yield in 64 field-grown wheat genotypes.* **Journal of Experimental Botany**, 65(17), pp. 4959–4973. Available at: https://academic.oup.com/jxb/article/65/17/4959/557658 (Accessed: 27 March 2026).

Kaur, P., Sachan, S. and Sharma, A. (2021) 'Weed competitive ability in wheat: a peek through in its functional significance, present status and future prospects', *Physiology and Molecular Biology of Plants*, 27, pp. 2165–2179. Available at: https://link.springer.com/article/10.1007/s12298-021-01079-y [link.springer.com]

Loureiro, I., Escorial, M.C., González-Andujar, J.L., García-Baudin, J.M. & Chueca, M.C. (2007) 'Wheat pollen dispersal under semiarid field conditions: potential outcrossing with *Triticum aestivum* and *Triticum turgidum*', *Euphytica*, 156, pp. 25–37. Available at: https://link.springer.com/article/10.1007/s10681-006-9345-7

Philips, J.G., Martin-Avila, E.M., Robold, A.V. & Office of the Gene Technology Regulator (2022)
Horizontal gene transfer from genetically modified plants – Regulatory considerations. **Frontiers in Bioengineering and Biotechnology**, 10. Available at: https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2022.971402/full (Accessed: 27 March 2026).