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Department for Environment, Food and Rural Affairs
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Submitted by email to gm-regulation@defra.gov.uk

11 January 2023

Dear Madam/Sir

Re: Application from Wild Bioscience Ltd to release a genetically modified organism, reference 22/R55/01 as published at https://www.gov.uk/government/publications/genetically-modified-organisms-wild-bioscience-ltd-22r5501

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We are writing on behalf of GM Freeze, Genewatch UK, GMWatch, Beyond GM, EcoNexus, the Soil Association, Organic Farmers & Growers, the Organic Research Centre, the Biodynamic Association, Sheepdrove Organic Farm, The Kindling Trust, Organic Arable, Whole Health Agriculture, WWOOF UK, the CSA Network, GM Free Dorset, GM Free Somerset, Real Seeds, The Sheffield Wheat Experiment, The Real Bread Campaign, Bread Matters Ltd, Shepton Farms, SE Essex Organic Gardeners, Heart of England Organic Group and Green Christian, to request that the above application to release genetically modified (GM) wheat is refused.

GM Freeze is the UK umbrella campaign for a responsible, fair and sustainable food system, focused on concerns about the use of genetic engineering in food and farming.

GeneWatch UK is a not-for-profit organisation which aims to ensure genetic science and technologies are used in the public interest. **GMWatch** provides the public with the latest news and comment on genetically modified (GMO) foods and crops and their associated pesticides. **Beyond GM** is an initiative educating and engaging the public to raise the level of debate around the issues of GMOs and sustainable food production in the UK. **EcoNexus** analyses and reports on new technologies that have the potential for significant negative impacts on biodiversity and ecosystems.

The Soil Association is the charity that digs deeper to transform the way we eat, farm and care for the natural environment. **Organic Farmers & Growers** were the first UK organic certification body to be approved by the Government and now certify more than half of UK organic land. **The Organic Research Centre (ORC)** is the UK's leading independent organic research organisation. **The Biodynamic Association** promotes biodynamic methods for healthy farming, forestry and gardening for planet, nature and people. **Sheepdrove Organic Farm** and award-winning eco-conference centre are committed to sustainability, conservation and education.

The Kindling Trust works with communities, farmers, health providers, activists and policymakers to create a fairer more sustainable food system for all. **Organic Arable** is a wholly organic grain business that is farmer-owned and run. **Whole Health Agriculture** is a community of farmers, health professionals and citizens who support and promote those who farm for health and vitality**.**

WWOOF UK is a membership charity which connects people wanting to learn about ecological growing and low impact lifestyles with sites across the country. **CSA Network UK** is a multi-stakeholder co-operative dedicated to promoting and supporting community supported agriculture across the UK. **GM Free Dorset** is a grass roots campaign promoting rural sustainability across the county of Dorset. **GM Free Somerset** is a grass roots campaign supported by individuals, groups, local businesses and charities that exist to promote rural sustainability.

Real Seeds provides open pollinated seed appropriate for growers producing vegetables under sustainable low input conditions. **The Sheffield Wheat Experiment** explores community-based wheat growing, processing and baking. **The Real Bread Campaign** finds and shares ways to make bread better for us, better for our communities and better for the planet. **Bread Matters Ltd** is a bread research and training organisation, run by the author of Bread Matters.

Shepton Farms are organic farmers and fruit growers. **SE Essex Organic Gardeners** is a local group of Garden Organic, supporting and working with the Soil Association and Pesticide Action Network UK. **Heart of England Organic Group** is a local group for people interested in the environment, organic growing and food, covering Coventry, Warwickshire, and the surrounding areas. **Green Christian** are inspired by their faith and work to care for Creation through prayer, living simply, public witness, campaigning and mutual encouragement.

We are of the strong opinion that this open field trial should not go ahead. The application is incomplete and the proposed field trial represents a risk without providing any public benefit. In summary, our objection covers the following points:

1. The application is incomplete and does not appear to have been prepared with due care and attention
   1.1. Key information about the intended genetic changes has not been supplied
   1.2. There is no molecular characterisation to check for unintended genetic modifications
   1.3. The application does not appear to have been prepared with due care and attention

2. The GM wheat lines contain antibiotic resistance marker genes

3. The applicant is preparing for commercialisation without subjecting their work to appropriate scrutiny

4. There is potential for escape, contamination and outcrossing

5. The GM wheat will not benefit society

1. The application is incomplete and does not appear to have been prepared with due care and attention

1.1. Key information about the intended genetic changes has not been supplied

The application (Part A1, paragraph 12) describes the novel version of PHYB used in the experimental wheat plants as "*99.8% identical to the native version, differing only by two amino acid substitutions that are also found in the natural diversity of this gene".* The applicant does not, however, describe the substitutions or where they are seen in nature. As they have chosen not to publish their work to date or submit it for peer review, we (and those tasked with deciding whether or not to approve the proposed deliberate release) are asked to simply take the applicant's word for it. This is unacceptable in any circumstances and the prevalence of wheat allergies and intolerance raise additional food safety concerns.

Genetics is not a numerical science so it is disingenuous of the applicant to describe the intended genetic changes made in terms of proportionate "sameness", particularly when they have also submitted a patent application that relies on providing evidence that the gene in use is both new and inventive.

The genome is more like an ecosystem than a code book with single point mutations capable of causing profound, often unexpected, phenotypic changes. In this instance, the inserted gene appears to also be involved in mediating flowering time[1] so it is entirely possible that the intended changes will result in additional, unexpected outcomes. These need to be thoroughly investigated and subjected to independent scrutiny before consent is given to release the GMO through an open field trial.

1.2. There is no molecular characterisation to check for unintended genetic modifications

Part A1, paragraph 14 of the application document requests *"information on the sequences actually inserted or deleted"* including details of copy number, location of insert and methods of determination. Despite stating in Part A1, paragraph 41 that "*Transgene copy number and zygosity testing was provided via quantitative (Taqman) PCR and performed by NIAB"* the applicant has chosen not to share the results of these important tests and instead simply asserts that "*all transformation events will result in a nuclear localization for the transgenes"*.

The application does not include any consideration, under paragraph 14 or elsewhere, of the potential for unintended modifications resulting from the genetic manipulation process. Unintended genetic modifications raise potential safety implications so must be investigated. The standard risk assessment practice for doing this is to perform molecular characterisations that will identify disruption to the genome but this has not been included in the application. As a result, we have no indication of where the novel genes were inserted, how stable those insertions are, or whether they have disrupted endogenous genes. Once again, the applicant is asking us to take it on trust that the only changes made are those that were intended.

1.3. The application does not appear to have been prepared with due care and attention

The risk assessment in Part A4 of the application notes several times that there are no plans to use what it describes as "kanamycin-based herbicides". Kanamycin is an antibiotic and is not listed on the University of Hertfordshire's Pesticide Properties Database[2] so these points are difficult to interpret. Further examination reveals that the relevant sections of the risk assessment table bear a remarkable resemblance to the similar table submitted by the applicant's proposed trial partner, Rothamsted Research, in their 2016 application for consent to plant experimental GM wheat in an open field trial (16/R08/01)[3]. That GMO featured a marker gene conferring tolerance to glufosinate-based herbicides so we are tempted to conclude that the applicant has run a "find and replace" command on the 2016 application text to simply replace references to one marker gene with another. This is clearly inadequate and suggests a cavalier approach to the consent application process.

The same risk assessment table recognises that "*small mammals such as mice, invertebrates and birds may also come into contact with and/or ingest plant material"* but proposes as a mitigation measure that "*physical barriers and/or deterrents will be employed to minimise access by **large mammals** and birds."* [our emphasis] We are sure that the applicant knows the difference between a large and a small mammal and is not suggesting that the use of a lockable deer-proof fence (as noted in Part A1, paragraph 16 of the application) will deter mice, voles and rabbits from the trial site. Rather, especially when considered alongside the entries relating to kanamycin noted above, we would suggest that the application has been produced without due care and attention. This raises significant concern about both the information supplied in the application (what else has been included in error or left out entirely?) and the manner in which the trial will be conducted if it is approved.

2. The GM wheat lines contain antibiotic resistance marker genes

The plasmid inserted into the GM wheat contains the *nptII* kanamycin resistance gene as a selectable marker. We highlight the comments we made, most recently, in response to an application for consent to release experimental GM potatoes (22/R29/01) which also featured the *nptII* gene:[4]

> *"Kanamycin is listed as an essential medicine for priority diseases by the United Nations World Health Organisation (WHO)[5] and concern about the future of therapeutic antibiotics is only growing among learned organisations such as the European Medicines Agency[6].*
>
> *"Globally, there is a high level of concern regarding the rise of antibiotic resistance that could render key antibiotics ineffective in treating infections in humans and animals. The UK government recently published a 20-year vision and 5-year national action plan[7] to prevent further antimicrobial resistance, which includes antibiotic resistance. The vision calls tackling antimicrobial resistance a "global priority", while the 5-year plan includes the reduction of antimicrobials in agriculture[8]. Therefore, any consent to cultivate GM plants that may contain antibiotic resistance genes, even as field trial, is not in keeping with the UK national action plan to prevent further antimicrobial resistance."*

The application for a field trial should be refused until, and unless, the applicant can demonstrate that the antibiotic resistance gene has been bred out of the experimental wheat plants.

3. The applicant is preparing for commercialisation without subjecting their work to appropriate scrutiny

The applicant, Wild Bioscience Ltd, is a private company that appears to be a "spin out" from Oxford University. Part A5 of the application asserts that "*this is privately funded research*" before noting commercial sensitivity and referencing a patent application. However, the high degree of similarity between the application documents and those submitted by the publicly-funded research institute Rothamsted Research for consent reference 16/R8/01[9] (see 1.3, above) suggests a working relationship that is significantly closer than might be understood by the description in this application (Part A1, paragraph 1) that *"The Rothamsted Farms team will carry out the trial".*

The relationship between taxpayer-funded academic research conducted for public good and the development of commercial products is a matter for political debate and will, no doubt, be dismissed as out of scope for this public consultation. What is highly relevant to the question of whether or not to authorise this trial, though, is the clear evidence that the applicant is preparing for commercialisation. In that context it is entirely unacceptable for concerns about public safety, escape and contamination to be dismissed on the grounds of scale or the intention that the products of this trial will not enter the food chain.

As we have asked in response to previous field trial applications without yet receiving an answer*: if the Advisory Committee on Releases to the Environment (ACRE) is not able to consider the future impacts of GMOs in development, just who is responsible for ensuring that any GMOs that are released do not harm our food, our farms or the natural environment?*

4. There is potential for escape, contamination and outcrossing

As we have detailed in previous objections to UK GMO wheat trials[10], wheat has escaped from field trials in the USA on three separate occasions[11] [12]. The discovery of the GM wheat, between eight and 15 years after the conclusion of the GM field trials from which it escaped, prompted some countries to halt purchasing of US wheat[13] and led to market concerns for US farmers and traders. Investigations by APHIS (United States Department of Agriculture – Animal and Plant Health Inspection Service)[14] failed to find the route of contamination in any of these cases.

As we stated in our previous objections:

> "*Together, these incidents present a worrying picture of how easy it is for GM wheat to escape from field trials and remain a GM contamination threat for many years. The uptake and expression of trialled GM traits in other wheat varieties suggests that pollen escaped from the trials. The timelines show that GM wheat trial escapees can remain either undetected or dormant for over 10 years. The impact of these incidents on US wheat trading demonstrates a considerable risk to UK farmers and processors in the event of any escape from the proposed trial.*
>
> *"As the routes of contamination from the US trials are not apparent, it is not possible to suggest mitigation measures that could have prevented the escapes. As a result, open-air field trials of GM wheat should not proceed.*

We note that ACRE, in its advice on the most recent previous GM Wheat field trial application (21/R52/01)[15], once again dismissed the relevance of the US experience because trials there were more numerous and on a larger scale than each of the individual applications made in the UK. If consent is given for this new proposed trial it will be the sixth GM wheat field trial conducted in the UK in recent years, all located in the South and East of England. It will bring the total number of trial seasons for which consent has been given to 26 (with this application covering two plantings per year for five years). This trial should not be approved until ACRE has considered the cumulative risk of escape from numerous GM wheat field trials running within relatively close proximity to each other and within the most significant wheat-growing areas of the UK.

Outcrossing to a common weed is also a concern with the proposed trial. The applicant notes (Part A1, paragraph 28) that a wild relative of wheat, *E. repens, "is common on the Rothamsted estate"* and that it *"will be controlled along with other weeds in and around the trial site using standard farm practices"* However, no details are provided as to what these "standard farm practices" involve.

The applicant states further that "*no reports of wheat x Elytrigia or Elymus spontaneous hybrids have been reported."* As we have noted in previous communications on GMO field trial applications: [16]

> *"Before the UK trials of GM oilseed rape began it was stated that cross pollination between the crop and the common arable weed charlock (Sinapsis arvensis) was impossible under field conditions. Yet during the Farm Scale Evaluations from 2000-2003 such a cross did occur. This demonstrated that rare events do occur under natural conditions."*

5. The GM wheat will not benefit society

Increased yield will not feed the hungry. World food production already far exceeds the needs of generations to come, with estimates suggesting that we already produce enough to feed the world's 2050 predicted human population peak. However, around a third of food is wasted and that which remains is not equitably distributed.

Focusing on increased yield as a response to existing inequity or an adaptation to the climate emergency risks embedding further the root causes of hunger. As stated in a new paper considering holistic climate change solutions,[17] "*It would be unfortunate if the outcome of climate change mitigation or adaptation was an atmosphere with less carbon but an Earth with all the same horrors of poverty, malnutrition, wealth and energy inequity."*

Even if one accepts the premise that increased production is desirable, the proposition that genetics is the key factor limiting current yields does not bear up under examination. The hugely varied actual yield realised by cultivating the same wheat varieties under different environmental and management practice demonstrates that there is far more to be gained by examining soil health, rotation, planting density and a range of other factors. It is also important to consider how the cultivation of GM wheat with increased yield would impact on factors such as fertiliser requirement.

We highlight the points made in our response to Rothamsted Research's 2016 application for an open field trial of wheat genetically manipulated to "improve" photosynthesis for increased yield: [18]

> *Resilience relies on diversity and researchers consider that widening the gene pool of wheat (eg by crossing with wild relatives) is an essential part of breeding new varieties for adaption to climate change[19]. By contrast, genetic engineering approaches narrow the genetic pool by focusing on existing varieties[20].*

Whilst plant breeding can provide drought or heat tolerant varieties, it is not possible to know what to plant in any given year, due to the unpredictability of the weather. Diversity (genetic, crop and landscape) can help by providing an "insurance policy" as some varieties/crops will do better than others in any given season. It can also help with disease and pest suppression and increase production[21].

Agroecological approaches, such as organic farming, place an emphasis on diversity. They encourage healthy soils, which not only enhance soil fertility but have good water holding characteristics, increasing resilience to drought. Agroecological approaches also provide benefits for biodiversity, which GM crops do not. Such approaches are urgently needed, given the current poor state of wildlife in agricultural systems[22].

In conclusion, the proposed trial represents an unacceptable risk to people, wildlife and the wider environment without providing any benefit to society. We request, therefore, that the Minister denies consent and prevents the proposed open-air field trial going ahead.

Yours faithfully

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