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Department for Environment, Food and Rural Affairs
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By email gm-regulation@defra.gsi.gov.uk

17 May 2013

Dear Sir/Madam,

Re: GM Wheat Application Rothamsted Research reference number 11/R8/01

We wish to object to the above application from Rothamsted Research to release GM wheat into the environment in Autumn 2013.

We have a number of concerns about this application that we believe are grounds for refusing the application. These are outlined below. We also have concerns about the justification for such an experiment, the lack of transparency surrounding it and the future development of this GM wheat.

As previous the application for Spring wheat this application also raises ethical questions concerning the use of synthetic cow gene, which should be subject to wider debate outside the narrow terms of a deliberate release application. The applicant states that this gene "has most similarity to that from cow (*Bos taurus*)". In the past commercial GM crops have not included genes of animal origin, and had Rothamsted taken the enzyme gene directly from a cow this would have prompted considerable debate. The fact that the gene is a synthetic copy of the cow gene does not avoid the fact that its origin is an animal, and this raises ethical questions the public has not had the opportunity to comment upon in principle.

This issue may also be raised at EU level should an application ever be made for commercial approval.

We therefore request that Ministers defer a decision on the application until there has been a public consultation on whether or not the use of synthetic animal genes should be permitted in GM crops. If there is a consensus that this use of genetic material is unacceptable, this would be grounds to refuse the application.

Apart from this, we have a number of other grounds for rejecting the application and ask Ministers to do so. These objections include:

No market for the end product

There is currently no market for GM wheat in the UK, EU or elsewhere (ABC 2011 and Canadian National Research Council 2011). Previous research into GM wheat in the UK was abandoned (BBC 2004). None of the UK's supermarkets allow GM ingredients in food.

In addition there are proven agronomic and farm habitat creation and management techniques that provide adequate control of aphid populations in Winter wheat by building populations of parasitoids and parasites in wheat fields (Powell et al 2004). These approaches also have many other benefits including: providing habitats for pollinators, other insects, farmland birds and, mammals; enhancement of the landscape; and increase soil carbon (if they become permanent features).

In addition to the lack of consumer demand for this GM wheat it is doubtful that it will gain much favour with arable farmers. A previous initiative to traditionally breed resistance to Barley Yellow Dwarf Virus into Winter wheat in the mid 2000s was abandoned because it was not deemed to be competitive compared to cost of aphicides at the time, and therefore farmers would not be prepared to buy new resistant varieties unless pesticide costs rose sharply or the products were no longer available (ADAS Consulting 2005). As a percentage of the value of the crop, aphid treatments and sprays are the same now as they were in the mid 2000s (Nix 2012 and National Association of Agricultural Contractors 2013) suggesting that expensive GM seeds would be hard to sell.

We question why Ministers should sanction spending public money on this project when it could be used on researching the other approaches to aphid control in Winter wheat based on parasitoids and predators and

improved agronomy (for example longer rotations to avoid “second” wheat crops and “green bridging of aphids” from previous stubble in to the newly germinated crop and delayed sowing).

Given these options and the market barriers to GM wheat there seems to be no justification for this trial other than a political one to demonstrate that Rothamsted is engaged in GM trials in order to secure future BBSRC funding for their GM crop research.

We do not accept that this extension of the trial into the Autumn of 2013 using public money can be justified.

Experimental Design

Rothamsted has not been open about their scientific objectives for the Autumn trial, or indeed the previous Spring trial. The application states, “*This is a research trial to assess any change in behaviour of aphids, their parasitoids or predators that result from the modified volatiles given off by these GM plants.*” However there is no further information on how this will be achieved to justify an outdoor trial at taxpayers’ expense.

The experimental design has two treatments (a high EBF emitting wheat and low EBF emitting wheat) and a control. The individual plots are separated by 9 metres of barley and two 0.5 metre buffer strips next to each treatment. From the information provided it is not clear if it will be possible to compare the effects of the different treatments given that the EBF pheromone may drift between plots and incoming aphids, predators and parasites may perceive the entire trial as one block of cereals and not several.

The trial design does not appear to allow for any study of aphid or parasitoid/predator habituation to the EBF pheromones (see below).

The lack of transparency from Rothamsted about precisely what it hopes to achieve from the trial means it is difficult to form a judgment on its scientific value or justification, but on the basis of the information available we see no reason for an outdoor trial to be approved.

More research needed on the impact of the aphid attack pheromones

A recent scientific paper on *Arabidopsis thaliana* (Kunert 2010) suggests that the genetic modification of wheat to produce the EBF pheromone could result in more complex interactions than implied by the applicant, and that there is room to doubt whether the GM wheat will have the desired effect on aphids. There is also evidence that the ecological consequences could be quite complex. The proposed GM field trial is therefore premature, and future research to address these uncertainties should be carried out in the first instance with non-GM plants naturally producing EBF. Such research should also include options for using EBF without the use of genetic modification as suggested above.

The applicant states, “The survivability of these plants in unmanaged systems may be affected by their ability to modify the behaviour of aphids and their parasitoids or predators.” (Part A paragraph 16)

One change in behaviour in aphids in the GM wheat might divert aphids in greater numbers onto neighbouring non-GM crops. This could result in use of aphicides on the non-GM crop when none would have been otherwise required because the critical aphid population, at which economic harm would have occurred, would not have been reached.

Predators and parasitoids may be drawn to the GM crop believing the presence of sesquiterpene (*E*)- β -farnesene (EBF) signifies the presence of prey. This may divert them from non-GM crops where there is a significant aphid population in need of control because the signals coming from the GM wheat may be stronger. This could result in more harm to the non-GM crop than may have been caused otherwise. This type of effect may strongly affect organic cereal farmers, who rely on natural predators and parasitoids to keep aphids under control, but may also affect any farmer who chooses not to use GM wheat.

Understanding of how aphids and their predators/parasitoids will react to EBF produced by GM wheat is very limited, and the design of the experiment proposed for Autumn 2013 does not fully address these issues or any other possible environmental impacts. There is an overwhelming case for further studies to be conducted using non-GM plants to enable the possible interactions to be studied, and these may also produce information on non-GM options for using EBF. To allow for further study of how the EBF pheromone influences the behaviour of aphids, predators and parasites and non-target organisms more research is required, and therefore the application should be rejected.

In addition to research on how EBF impacts on insect predators and parasitoids, we would also recommend that other species which rely on aphids as part of their diet, such as swifts, swallows, martins and skylarks,

should be included so that the effect of changes in aphid populations and distribution can be included.

Impacts on soil not assessed

There is no mention in the application of any potential impact on soil dwelling organisms by the release of the pheromone (eg, via the roots) or of any other genetic changes of the wheat. One of the breakdown products of EBF is said to be acetone (Part A paragraph 19), which may well impact soil organisms in the root area of the plant and change the composition of the soil food web. The application should be rejected because of this lack of data.

Presence of a glufosinate ammonium marker gene

The GM wheat has a tolerance gene conferring the ability to tolerate glufosinate ammonium-based (GA) herbicides. This would increase its survivability in environments where these herbicides are the only ones used. Its presence in a commercial variety would be undesirable (see below) and therefore the present trial should not proceed with it included.

The presence of the GA tolerance gene could be used as an agronomic trait in a commercial variety in the future to make it attractive to farmers wishing to control weeds in cereal crops. The results of the UK's Farm Scale Evaluations (FSE) clearly showed that GM herbicide tolerant Spring and Winter oilseed rape with GA tolerance had a significant impact on the flowering plant species in arable fields compared to the current herbicide regime used on conventional crops. This also would have a significant impact on numbers of arable weeds and insects, which forms a vital food resource for farmland wildlife and would harm many species (Heard et al 2003a, Heard et al 2003b and Roy et al . 2003). In addition overdependence on glufosinate ammonium for weed control in cereals could lead to the development of weed resistance in major arable weeds, leading in turn to an escalation in herbicide usage and costs, as has happened in Roundup Ready crops in the US and South America (Duke & Powles 2008 and Binimelis et al 2008).

The presence of the GA tolerance marker gene is now unnecessary, and the application should be rejected because of it.

Risk of gene transfer

Although this Autumn trial will not produce any pollen due to its early termination, it makes no sense to encourage the development of GM crops that, if commercialised, would seriously disrupt the food chain and increase costs through the need to prevent contamination of non-GM crops.

Rothamsted Research conceded in the application for the Spring trial that there is a risk of outcrossing from the GM wheat by making a number of proposals to reduce the risk to neighbouring commercial wheat crops or other experimental crops on their land. Given the long-term risk of outcrossing and co-mingling if this GM were grown commercially in the future, there is no reason to approve an application that could lead to the development of an unsustainable variety.

In their Wpring GM wheat application Rothamsted Research stated that wheat does outcross to other wheat plants at a rate "usually less than 1%" but also stated, "Under certain growing conditions individual genotypes may have out-crossing rates of up to 4-5%." If outcrossing caused a GM presence of 0.09% or over in neighbouring non-GM wheat, the crop would be required under EU Regulation 1830/2003 to be labelled as GM. An organic crop would lose its certification in the same circumstances. GM levels between zero and 0.09% may also affect the markets and price received for the contaminated crop due to the retail policies on GM ingredients, many of which require that no GM is present. Thus any GM contamination of wheat has the potential to cause considerable economic harm throughout the food web. This adds weight to the case for rejecting the current application on the grounds that it will not prove to be sustainable.

A number of studies have shown outcrossing at significant levels between different non-GM varieties, with some at over 6% (Hucl 1996) and at distances up to 42 metres (Hansen 2005). Outcrossing rates are dependent on the weather and on the variety of wheat, and without specific testing outcrossing rates should not or cannot be assumed (Hansen 2005, Hucl 1996). Rothamsted Research presents no data on the outcrossing potential of variety which has been genetically modified, Cadenza, in different environmental conditions, and therefore its true potential for outcrossing is not known. The application should be rejected because of the absence of this data.

According to the application there is a small risk that the GM wheat could outcross to relatives in the grass family, from the genera *Elytrigia* and *Elymus*. Attention should be on two species in the genus *Elytrigia* – *Elytrigia repens* (common couch) and *Elymus caninus* (bearded couch). As the former is an extremely troublesome weed in cereals and other arable crops as well as in many other crops and gardens, the

application should be refused to remove the chance of this occurring. A chance crossing between the GM wheat and a couch plant would result in glufosinate ammonium resistance developing in common couch as a consequence of the presence of the marker gene, and potentially an increased fitness due to reduced aphid attack if the trait is performing according to design.

Previous research has demonstrated that unexpected or low probability crossing events can occur in the field. For instance it was thought that crosses between the common arable weed charlock (*Sinapsis arvensis*) and oilseed rape were impossible under field conditions, and yet during the Farm Scale Evaluations from 2000-2003 such a cross did occur (Centre for Ecology and Hydrology 2005), demonstrating that rare events do occur under natural conditions. The creation of a population of glufosinate ammonium resistant couch could cause serious agronomic problems for farmers in the long-term and lead to an increased use of herbicides to control it. As the trial is not necessary, the future risk of outcrossing to wild grasses could be eliminated by rejecting the application.

If commercialised in the future there will also be risk of gene transfer via seeds being moved by mammals or birds off fields which would be impossible to prevent and provided further reason for not proceeding with this trial.

Food safety

There is no point in field testing crops that would eventually fail to get commercial approval because of problems with the safety of the crop. This point is all the more relevant because there is no market for the end product at present, and the presence of the kanamycin resistant marker genes will be highly contentious in other EU Members States.

The presence of Antibiotic Resistant Marker (ARMs) genes

The GM wheat contains two copies of a kanamycin resistance genes used as genetic markers. The EU phased out markers for antibiotic resistance which may have "adverse effects on human health and the environment" (EU Directive 2011/18 Article 4.3). Their use in trial sites was phased out in December 2008.

The European Medicines Agency (2007) commented on the use of kanamycin resistant genes in GM crops. It expressed concern that the aminoglycosides group of antibiotics, which includes kanamycin, could become more important in the future if antibiotic resistance to other groups of antibiotics increases. It pointed out that kanamycin is currently used to treat bacterial infections, including tuberculosis (TB), in cases where other antibiotics fail due to the development resistance in the pathogens. Kanamycin is already in clinical use. There is a risk that the kanamycin gene could horizontally transfer into harmful bacteria rendering the pathogenic microorganisms resistant to this group of antibiotics and reducing the options for successful antibiotic treatment of serious illnesses and infections. The risk for horizontal gene transfer is greatly enhanced due to the extensive presence of bacterial sequence homologies and the origin of replication sequences, as also acknowledged by the applicant. The presence of the kanamycin resistant gene is grounds to reject the application based on future risk to the viability of the aminoglycosides group of antibiotics.

Impacts from the genetic modification events

The applicant states:

- "We have not analysed the position or the structure of the insertion nor sequenced the flanking genomic DNA." (part A paragraph 14)
- "We have not specifically investigated genetic or phenotypic stability of these lines." (Part A paragraph 17)
- "There appears to be no published toxicity or allergenicity data for EBF but at the levels expected to be generated by these plants and because they will not enter the food or feed chains, we consider the potential toxic or harmful effects to be negligible." (Part A paragraph 19)

Despite the substantial lack of data the applicant is happy to pronounce the GM wheat safe for human consumption. There is little point in proceeding with a deliberate release before establishing whether or not it is safe for consumption by people or animals.

The applicants provide no information on any impacts caused by the genetic modification of the two GM wheat events, for instance the effect on the gene expression of the wheat's own genes. Wheat is known to cause intolerance problems in many people (in the UK 25,000 people suffer from Coeliac disease, gluten intolerance (BMA 1990)), some with serious health consequences, such as wheat-dependent exercise-induced anaphylaxis.

As wheat can have a significant health impact on a minority of people any potential changes to the composition, expression or shape of normal proteins arising from the GM events should be investigated before field trials are permitted.

Unpredicted effects

The applicant states, "Except for the emission of EBF, all aspects of the phenotype of events 2803R6P1 and 2812R9P1 including morphology, pollination and seed-set **appear** to be identical to non-transgenic control wheat plants." (Part A paragraph 16)

This statement and the statement in paragraph 19 are purely assumption based and ignore the body of scientific research and evidence regarding the presence of unpredicted effects due to the genetic engineering of a plant.

For example it is well recognised that the insertion of genes and genetic sequences via genetic engineering commonly leads to mutations in the plant, in particular when using particle bombardment. It is also widely recognised that the interaction of the inserted genes with each other or with the plant's own genes can give rise to unpredicted effects of both qualitative and quantitative nature, including antagonistic, additive or synergistic effects. These effects and their consequences cannot be predicted from the gene sequence inserted into the plant but require a thorough investigation, including feeding trials.

No data on toxicology and allergenicity

As mentioned above the applicant states, "There appears to be no published toxicity or allergenicity data for EBF but at the levels expected to be generated by these plants and because they will not enter the food or feed chains, we consider the potential toxic or harmful effects to be negligible" (Part A paragraph 19).

Although this trial will produce no grains, the presence of GM seeds increases the risk of contamination due to accidental co-mingling on site. This has already occurred on a number of occasions around the world when experimental traits have been found in non-GM commercial crops. For instance in the US Bayer's experimental test crops of LL601 rice led to this unapproved GM trait entering the food chain (USDA undated) in 2006 as a contaminant in non-GM exports from the US to many countries around the world. This led to import bans, very significant financial losses for the US rice industry and a series of court actions (GM Freeze 2010). No food safety risk assessment for the LL601 trait was available at the time of the contamination. The contamination was not detected in commercial rice crops until five years after the experimental trials were completed in 2001.

Similarities between the LL601 case and the GM wheat trials at Rothamsted Research are obvious. The lack of any food safety data or risk assessment of the GM wheat could cause similar problems if any remaining GM seed were to contaminate non-GM wheat seed lots which eventually were used for commercial production.

The concerns about food safety set out above should lead to the application being refused.

We request that you inform Ministers of the reasons we believe that this application should be rejected. There is no justification for proceeding with trials of GM wheat or using £1.28 million of public money given the need for a public consultation on the use of synthetic animal genes and the lack of market and scientific uncertainties about this particular genetic modification. The planned expenditure should be re-allocated to non-GM solutions to aphids in cereal crops.

Yours sincerely,



Pete Riley
Campaign Director

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