GM Team
Department for Environment, Food and Rural Affairs
Area 1C, Nobel House
17 Smith Square
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Submitted by email to gm-regulation@defra.gsi.gov.uk

17 March 2016

Dear Madam/Sir

Application from the Sainsbury Laboratory to release a genetically modified organism, reference 16/R29/01.

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, Shepton Farms and Garden Organic to request that the above application to release genetically modified (GM) potatoes modified to resist late blight (*Phytophthora infestans)* 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. **Garden Organic** (formerly known as the Henry Doubleday Research Association) is the UK's leading organic growing charity.

We do not believe that this trial should go ahead at the present time. The knowledge gained from this trial will be very limited as genetic resistance has been established in controlled conditions and the trial period is not long enough to assess the potatoes' long term resistance as blight mutates. Given the danger of contamination, the potential for food safety risks should the potatoes ever enter the food chain and the very serious hazard of antibiotic resistance out-crossing, the potential benefits do not outweigh the clear risks and disbenefits. In summary our objection covers the following points:

1 There is no market for GM potatoes for sale to consumers or the potato processing industry.
2 There is no need for a GM solution as conventionally-bred blight-resistant potato varieties already exist.
3 The single R genes genetically engineered into each variation in this trial are likely to be overcome as late blight mutates.
4 There is a risk of contamination via cross pollination, true seed and groundkeepers/volunteers.
5 There has been no assessment of potential food safety risks caused by unexpected genetic alterations, unintended consequences of planned genetic alterations or altered allergenicity of GM proteins.
6 Antibiotic-resistance marker genes have been used.

1. No market for GM potatoes

1.1. All major UK supermarkets have a policy of not stocking GM produce for human consumption. This has been the case for nearly two decades, and there are no indications from the major retailers (based on our regular interactions with them) that they would alter their policy in the case of GM potatoes resistant to late blight. None of the major potato product manufacturers have indicated a willingness to use GM potatoes or to label their crisps, oven chips or other potato based products as GM as required by EU regulations (Regulation (EC) No 1830/2003).

1.2. We therefore conclude that the public money being invested in late blight research should be redirected to conventional breeding research focusing on marker assisted selection (see below).

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2. No need for GM late blight resistant potatoes

2.1. Late blight, *Phytophthora infestans,* is a major disease in UK ware potato production and considerable effort has been put into a range of conventional solutions. These include selective breeding to introduce genetic resistance that will prevent crop infection; organic and inorganic fungicide treatments for infected crops; planting cultivar mixtures[1] to reduce the severity of the disease; and phytosanitary measures, such as controlling infection from out grade piles and volunteers. The development of conventionally-bred varieties with genetic resistance to late blight has made progress and a number of varieties with good resistance in foliage and tubers are already on the market.

2.2. Resistance to late blight is assessed as part of National List and Variety Trials in the UK. Varietal resistance is scored between 1 and 9 with 9 being the most resistant. The Potato Council's variety database[2] lists 22 out of all 254 varieties (8.7%) with resistance to late blight in foliage above score 6 including early, second early, early main crop and main crop varieties. For tuber resistance, 51 varieties (20%) score 6 and above. One second early variety, Athlete, scores 9 for tuber and 9 for foliage resistance. Four varieties score nine for tuber resistance and 8 score above 7 for both tubers and foliage. This shows that there are already a range of resistance genes in the gene pool available for conventional breeding. The Sarpo varieties (Sarpo Mira, Axona, Shona and Una bred by the Sarvari Research Trust[3]) have consistently high scores for late blight resistance in foliage and good scores for tuber resistance.

2.3. In contrast to those described above, the potato variety genetically modified by the Sainsbury Laboratory in application 16/R29/01, Maris Piper, scores 5 for tuber and 4 for foliage resistance. It would be illogical to produce a variety with good foliage resistance but poor tuber resistance but it is unclear from the application for the proposed release and from the previous release of GM potatoes by the Sainsbury Laboratory[4] whether the research extends to tuber resistance as well as foliage resistance. Defra should seek clarification from the applicants as to whether tubers are included as this may change the nature of the consent issued to include a period of storage of the harvested tubers.

2.4. Late blight constantly evolves to overcome resistance (R) genes (see below). However, the genetic resistance in Sarpo mira (genes from which have been used by the applicants to genetically modify Maris Piper in 16/R29/01) has been investigated because it has endured over a long period of time without being overcome by newly evolved strains of late blight. This research found[5] that Sarpo Mira contains "a pyramid of at least five different R genes that confer both qualitative and quantitative resistance to late blight". The researchers concluded that they have identified "the molecular markers and effector assays to breed the five resistance genes and improve the agronomic traits of 'Sarpo Mira'. In addition, in the future, the approach of combining qualitative R genes with quantitative ones should be given more consideration in late blight resistance breeding."

2.5. The rapid development of Marker Assisted Selection (MAS) has enabled conventional plant breeders to introduce beneficial traits for yield, quality and resistance to abiotic and biotic stresses into new varieties much quicker than was the case previously. The use of MAS also offers the opportunity to avoid undesirable traits. Potato breeders are well placed to utilise this approach:

> "the potato map is one of the most highly saturated maps with different molecular markers, and it therefore provides extensive opportunities for optimal use of DNA analysis for MAS."[6]

2.6. Markers in potatoes include R genes and markers for the gene Rp1l, which confers resistance to *Phytophthora infestans,* were first reported in 2001. In addition, Quantitative Trait Loci (QTL) (identifying regions of the genome that may contain genes involved in the expression of the quantitative trait) have also been mapped for late blight resistance. QTL for many other traits have already been mapped including yield, tuber number, tuber weight, dormancy, chip colour, starch content and glycoalkaloid content. Techniques such as cleaved amplified polymorphic sequences (CAPS) and sequence characterised amplified regions (SCAR) markers can be used for the selection of qualitative traits such as R genes for late blight. MAS is also useful in selecting for backcrossing to increase the efficiency of wild genome reduction in following generations.

2.7. We believe that MAS offers a quicker, and less risky, means than GM to the development of new potato varieties that combine resistance to late blight and many other problematic pests and diseases, with desirable quality traits. The current GM research programme at the Sainsbury Laboratory has failed to deliver any variety into the UK market despite more than a decade of research. The lack of public support and demand for GM potatoes from UK retailers and processors suggests that the GM approach should be abandoned and replaced with a publicly funded breeding programme based on MAS targeting important traits such as resistance to late blight and potato cyst nematodes (PCN). This programme should also be linked with research and development into agronomic techniques to reduce potato pest and disease problems (there are 600 identified in the UK) and develop sustainable production techniques.

3. Single R genes will not protect as blight mutates

3.1. As indicated in 2.4, above, robust resistance to late blight in Sarpo mira depends on "a pyramid of at least five different R genes that confer both qualitative and quantitative resistance to late blight"[7]. This does not appear to be what is intended in the proposed GM trials at the Sainsbury Laboratory in which six single resistance genes will be genetically engineered into the variety Maris Piper to produce six different transgenic versions.

3.2. The pathogen causing late blight exists as a large population containing much genetic variation, particularly in relation to virulence against blight resistant potatoes. It mutates frequently and many existing strains of the pathogen contain various combinations of virulence genes. In recent decades these have evolved further through sexual reproduction and in 2008 the scores for foliar late blight resistance of a number of varieties were amended in response to their poorer than expected performance against a new genotype, 13_A2[8] (known as Pink 13). A GM blight–resistant potato that contains resistance genes matching only one of these virulence combinations is an essentially short term solution as it will only be a matter of time before spores of the matching pathogen strain land on the resistant potato plants and overcome them. Individual varieties may last longer than others, and could indeed survive this time-limited trial unscathed, because the matching virulence is not readily available. However, the selection of a rare mutant or of a recombinant from sexual reproduction which brings two or more rare virulence genes together, is inevitable.

3.3. We request that Defra asks the Sainsbury Laboratory for a realistic assessment of how effective adding one resistance gene per transgenic version is likely to be against a rapidly changing pathogen in the context of commercial production. We could see nothing in the application to suggest that the GM potatoes proposed for this trial will be any more effective against blight than conventionally bred varieties which have, so far, stood up reasonably well. Nor was there information on whether the genetically engineered resistance genes provide tuber or foliar resistance, or both, in Maris Piper.

4. Contamination

4.1. The proposed Sainsbury Laboratory trial uses Maris Piper potatoes, which are well known to flower frequently[9], produce many berries[10] and produce large numbers of small tubers[11] that can generate volunteers or groundkeepers. Maris Piper has, therefore, the capacity to distribute GM traits via pollen movement, true seed and groundkeepers/volunteers.

4.2. The contamination of non-GM potatoes with the presence of GM would make it illegal for that crop to be placed on the market in the absence of a marketing consent under EC Regulation 1829/2003 for the GM strain. Even if marketing consent had been granted, contamination beyond the minimum threshold would mean that potatoes planted and grown as non-GM would require labelling under EC Regulation 1830/2003. Such contamination, or even the threat of contamination, could damage affected growers and the many smaller scale potato product manufacturers financially, especially if contamination undermined their brand and reputation as purveyors of quality products. There is, therefore, a paramount need to prevent contamination of non-GM potatoes in both the trial and if GM late blight resistant potatoes based on Maris Piper were ever granted commercial approval.

4.3. The applicants claim that pollen movement from flowering GM Maris Piper will be minimal by wind and by bumblebees. The application makes no reference to other possible insect pollinators, in particular the pollen beetle (*Meligethes aeneus)* which is capable of carrying pollen over longer distances. We do not believe that the trial should go ahead unless the potential for cross pollination by insect groups other than honey bees and bumblebees is fully assessed.

4.4. In addition, true seed produced by Maris Piper could remain dormant in the soil. It is reported that soil dormancy can be as long as ten years for true potato seed[12]. In a previous application for consent for potatoes in the Netherlands[13] it was stated "[b]otanical seeds of potato ('true potato seed') can survive frost periods". The formation of GM seeds in non-GM commercial and domestic potatoes could result in contamination of future crops.

4.5. Groundkeepers (plants growing from potato tubers remaining in the ground after harvest) in broadleaf crops sown after potatoes, such as oilseed rape, beet or another non-GM potato crop, are particularly difficult to see and control. The numbers of small tubers remaining in the soil after harvesting can be as many as 300,000 per hectare (more than were sown in the first place)[14] and it is known that Maris Piper is prone to produce smaller tubers that can be missed during harvest.

4.6. The applicant claims that groundkeepers are killed by exposure to short periods of temperatures below zero (2 hours of exposure to -1.9^{o}C). However, this is based on laboratory research[15] rather than monitoring real conditions in fields where potatoes had previously been grown. Climate change predictions include warmer and wetter winters for the UK[16], borne out by the weather experienced in winter 2015/16. Long periods (50 hours or more[17]) of prolonged frosts that penetrate well into top soil could become less common, increasing the chances of GM groundkeepers surviving, sprouting in following crops and producing more tubers. Snow cover insulating soil from frost could also affect groundkeeper survival.

4.7. The problems of volunteer and groundkeeper control would be significantly greater if commercial growing were ever approved. Post-harvest control of volunteers/groundkeepers would be a major operation especially if soil conditions at harvest led to many small tubers being missed and remaining in the soil. The difficulties in preventing and controlling the presence of groundkeepers was amply illustrated by research in Scotland[18] (where winters are generally colder than England):

After harvest c124000, tubers/ha of cvs. Redskin and Majestic remained in a field at the Scottish Horticultural Research Institute (SHRI). Of these about one fifth were on the surface, the remainder being buried in the top 20 cm of soil. Surveys of fields which had recently been planted with potatoes indicated that large numbers of groundkeepers can survive through many years of cereal monoculture. On average, the number of daughter tubers per volunteer plant was greater than one and their average size remained constant. Winter soil temperatures are apparently not low enough in this part of Scotland to kill a high proportion of the buried tubers. The sharp fall in the numbers of volunteer plants noted on two occasions was tentatively related to the growing the year before of more open crops such as raspberry and vegetables which are usually repeatedly weeded at the SHRI.

4.8. A further potential source of contamination is the movement of tubers. Tubers (especially small ones) could be removed from the trial site by wild animals, mainly rodents such as brown rats (*Rattus norvegicus*). They could also be removed in machinery and on vehicle wheels. The applicants have not set out sufficient measures to prevent these possibilities from occurring.

5. Food safety

5.1. Unexpected genetic alterations, unintended consequences of planned genetic alterations and altered allergenicity all raise safety issues that the applicant has not dealt with to the level we believe is required by a proper risk assessment. Consequently, we do not believe the trial should proceed until these points have been sufficiently addressed. We see no point in proceeding with research on certain aspects of how the GM potatoes interact with the environment if they have characteristics that may render them unsafe for human consumption. We request, therefore, that the application be refused until such time as safety data becomes available.

5.2. Genetic modification processes, both the actual insertion and the tissue culture processes, have the potential to produce significant unintended and unexpected effects through transformation induced mutations (which can lead to disruptions or sequence alterations of genes), novel interactions, up- or down-regulating of the plant's indigenous genes or the activation of sequences previously not utilized by the plant, especially when a number of genes are inserted together.[19] [20] The applicant has not provided any evidence to show they have looked for unexpected events in the GM potatoes and has failed to address the possible food safety aspects of the genetically modified potatoes arising from other unexpected outcomes of the genetic engineering events.

5.3. There are at least two examples where experimental GM potatoes produced entirely unpredicted outcomes. The first was a potato modified to have low levels of the NAD-malic enzyme. This modification had the surprising effect of increasing the potatoes' starch content - an outcome the research team was unable to explain[21]. This indicates that at least two biochemical pathways were affected by the GM event. The second example comes from Germany when an attempt to introduce a yeast gene to increase starch content had the opposite effect and several unexpected compounds were formed by the disruption caused to the metabolism[22].

5.4. Research published in 1999 on GM potatoes[23] modified to produce an insect toxin raised safety concerns about the GM variety used in feeding trials. It suggested a link between feeding GM potatoes and damage to the immune system and growth rates of rats. This research provoked much scientific controversy[24] at the time, but no follow up research has ever been carried out.

5.5. Research in Australia found altered allergenicity in a protein when genetically engineered from its parent bean into peas[25]. We believe that before development of these GM potatoes progresses any further, well designed allergenicity tests should be carried out on all the novel proteins present.

6. Antibiotic resistance gene nptII

6.1. We are very concerned and somewhat surprised that the Sainsbury Laboratory has chosen to continue to use the antibiotic resistance gene *nptII* (conferring resistance to the antibiotic kanamycin) as a marker gene in three of the transgenic potatoes in their application. We consider that this aspect alone is adequate grounds for the Secretary of State to refuse the application to release pSLJ21152, pSJL24466 and pSJL24468 due to the risk of horizontal transfer into pathogenic bacteria.

6.2. However low the probability of this occurring, we consider that it is a totally unnecessary risk at a time when antimicrobial resistance around the world is reaching levels which threaten public health. Since the applicant's previous application to release transgenic potatoes in 2010, that also included the nptII marker gene, concern about the increase in antibiotic resistant pathogens has increased greatly (for example WHO's World Antibiotic Awareness Week in 2015[26]). The World Health Organisation describes it as "so serious that it threatens the achievements of modern medicine. A post-antibiotic era - in which common infections and minor injuries can kill - far from being an apocalyptic fantasy, is instead a very real possibility for the 21st century"[27].

6.3. The European Medicines Agency commented on the use of kanamycin resistant genes in GM crops in 2007 [28]. They emphasised the fact that kanamycin was already being used to fight antibiotic resistant TB:

Aminoglycosides such as kanamycin are currently recommended for treatment in multidrug resistant tuberculosis (MDR-TB). Drug resistance in TB is part of the explanation for the resurgence of TB. WHO estimates that eight million people get TB every year…. In Estonia, Kanamycin was very recently introduced in the TB program (personal communication).

6.4. They were critical of the European Food safety Agency's opinion that neomycin and kanamycin are of "minor therapeutic importance".

The terms "infrequent use" and "limited indications" cannot be equated with "minor therapeutic importance". The use may remain infrequent, but the importance of use of neomycin/kanamycin for decolonisation/decontamination may well increase as a consequence of increasing problems with multiresistant or panresistant (ESBL producing) gram-negatives and of multiresistant staphylococci.

6.5. The fact that that the three other GM varieties in the application 16/R29/01 do not use the nptII gene clearly demonstrates that the use of antibiotic resistance markers is unnecessary. Concerns about the presence of antibiotic resistance marker genes in GM crops were raised as long ago as 1996 when the presence of ampicillin resistant gene in Bt176 maize[29] was questioned by the Advisory Committee on Novel Foods and Processes. We urge the Secretary of State to convert this concern into action in the light of the very real threats posed by antibiotic resistant bacteria and prohibit the testing of GM crops containing antibiotic resistance marker genes.

7. Conditions of consent

7.1. We have made what we believe is a compelling case for rejecting this application. However, if Defra decides to grant consent to the applicant it is essential that the trial is conducted in such a way as to minimise the potential impact on neighbouring farmers and growers as well as the wider environment. We therefore request the following conditions be placed on any consent given in order to minimise adverse impacts on the environment and the risk of contamination:

7.2. Neighbouring farmers should be consulted before the application is processed to ascertain their planting intentions in the period covered by the trial.

7.3. No other potatoes should be grown on the site at the John Inness Centre for the duration of the trial.

7.4. All potatoes in the trial should be destroyed on site regardless of whether they are GM or not and should not be removed from the site.

7.5. A prohibition on future potato crops on the same land for 10 years.

7.6. A requirement to monitor and control groundkeepers for 8 years or until none have appeared for two years.

7.7. A requirement to remove flowers prior to pollination.

7.8. A separation distance of 1.5 km between the trial and the nearest non-GM potato crop including allotments or gardens.

Yours faithfully

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