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Submitted by email to [gm-regulation@defra.gov.uk](mailto:gm-regulation@defra.gov.uk)

29 April 2022

Dear Madam/Sir

**Re: Application from the Sainsbury Laboratory to release a genetically modified organism, reference 22/R29/01 as published at <https://www.gov.uk/government/publications/genetically-modified-organisms-the-sainsbury-laboratory-22r2901>**

We are writing on behalf GM Freeze, GeneWatch UK, GMWatch, Beyond GM, EcoNexus, The Soil Association, Organic Farmers & Growers, The Organic Research Centre (ORC), Garden Organic, Sheepdrove Organic Farm, The Kindling Trust, Real Seeds, Shepton Farms, WWOOF UK, GM Free Somerset, GM Free Dorset, GM Free Cymru, Genetic Engineering Network, Agri-Activism UK, Green Christian, Springhead Trust, Sustainable Dorset, SE Essex Organic Gardeners, Avon Organic, Norfolk Organic Group, Heart of England Organic Group, Brighton CSA – Fork and Dig It CIC, and OrganicLea to request that the above application to release genetically modified (GM) potato is refused.

**GM Freeze** is the umbrella campaign for a moratorium on GM in food and farming in the UK.

**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. **Garden Organic** (formerly known as the Henry Doubleday Research Association) is the UK's leading organic growing charity with over 20,000 members throughout the UK and abroad.

**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. **Real Seeds** provides open pollinated seed appropriate for growers producing vegetables under sustainable low input conditions. **Shepton Farms** are organic farmers and fruit growers. **WWOOF UK** is a membership charity which connects people wanting to learn about ecological growing and low impact lifestyles with sites across the country.

**GM Free Somerset** is a grass roots campaign supported by individuals, groups, local businesses and charities that exist to promote rural sustainability. **GM Free Dorset** is a grass roots campaign promoting rural sustainability across the county of Dorset. **GM Free Cymru** is the community pressure group campaigning to keep Wales free of genetically modified crops. **Genetic Engineering Network** facilitates the exchange of information between groups and campaigners. **Agri-Activism UK** is a network of people who campaign for cleaner, healthier and more sustainable agricultural and food systems.

**Green Christian** are inspired by their faith and work to care for Creation through prayer, living simply, public witness, campaigning and mutual encouragement. The **Springhead Trust** promotes environmental education, sustainability, organic agriculture and local performing arts. **Sustainable Dorset** is a central hub for sustainable and resilient activity across the county, with the aim of raising awareness and increasing interest and involvement in sustainability.

**SE Essex Organic Gardeners** is a local group of Garden Organic, supporting and working with the Soil Association and Pesticide Action Network UK. **Avon Organic Group** promote organic growing to their members and the local area by organising talks on all aspects of organic gardening. **Norfolk Organic Group** promotes the organic movement in Norfolk by encouraging people to grow organically and to use resources sustainably. **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.

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**Brighton Community Supported Agriculture – Fork and Dig It CIC** is a community food growing project committed to organic principles. **OrganicLea** is a workers' cooperative growing food on London's edge in the Lea Valley, producing and distributing food and plants locally while inspiring and supporting others to do the same.

We do not believe that this trial should go ahead. Key information is missing, the potential for unintended impacts has not been properly assessed and some of the intended GM traits are potentially harmful. In summary, our objection covers the following points:

1. Key information required to properly assess the proposed trial has not been provided.
  - 1.1. The results of previous trials have been withheld from scrutiny.
  - 1.2. The GM plants have not been fully characterised.
2. The genetic manipulation that has taken place has not been adequately analysed or assessed for unplanned changes or unintended effects.
  - 2.1. The GMO lines to be trialled feature stacked traits that may interact in novel and unexpected ways.
  - 2.2. The environmental and health risks associated with the RNAi module have not been properly explored.
3. Some of the intended GM traits may damage the environment and/or human health.
  - 3.1. The GM potatoes may include an antibiotic resistance gene.
  - 3.2. The GM potatoes contain herbicide tolerance genes.
  - 3.3. The "tuber quality" traits raise concerns about food quality and the promotion of unhealthy diets.
4. Containment of the GM potatoes cannot be guaranteed.

## **1. Key information required to properly assess the proposed trial has not been provided**

### **1.1. The results of previous trials have been withheld from scrutiny**

The applicant has been growing genetically modified potatoes in open field trials continuously since 2016 and refers several times in this application to the previous releases of lines containing several of the same, or very similar, constructs to those included in this application. For example:

- In Part A1, paragraph 13: *"The effectiveness of this stack of [Rpi] genes was repeatedly confirmed in the past field trials under consents 17/R29/01 and 19/R29/01."*
- In Part A1, paragraph 14 (a): *"It is worth noting that lines transformed with SLJ25057 have already been tested in the field in Norwich and Cambridge under consents 17/R29/01 and 19/R29/01. Field trials took place in the summers of 2017-2021 and further details on the characterisation of such lines have been submitted to APHA as part of the corresponding release reports."*
- In Part A1, paragraph 18: *"The same Rpi gene stack has been extensively trialled in releases under consents 17/R29/01 and 19/R29/01, and it's expected to perform equally well in the new release."*

However, the results of six years of field trials under multiple different consents (beginning with the more basic 16/R29/01), have not been made available for peer review or public scrutiny as the applicant notes:

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- In Part A1, paragraph 9: *“The modifications made to the transgenic potatoes referred to in this application are not expected to affect any of these characteristics (as initially confirmed in trials 17/R29/01 and 19/R29/01; Witek AI, unpublished).”*
- In Part A1, paragraph 13: *“The results so far repeatedly confirmed the expected effect of the silencing module on the tubers, which have significantly reduced both discolouration upon bruising and accumulation of reducing sugars (Witek AI, unpublished).”*
- In Part A6: *“None of the transgenic lines proposed for release in this application have been the subject of any publication.”*

Under Part A2, when asked to provide data or results from previous releases, the applicant simply states that *“As expected, they showed full resistance against late blight and had yield indistinguishable from relevant non-transgenic varieties. Monitoring during the release did not uncover any unexpected event or hazard and risk management procedures in place where (sic) deemed appropriate.”*

Given the applicant’s habit of pursuing GMO release consents that overlap with existing projects, it is particularly concerning that they have chosen not to publish their results or submit them to peer review. We raise a number of concerns below that are exacerbated by the absence of publicly accessible, and properly scrutinised, scientific analysis of the field trials already conducted as part of the applicant’s work on GM potatoes.

## 1.2. The GM plants have not been fully characterised

We highlighted in our submission to the public consultation on the applicant’s most recent previous linked field trial application (19/29/01)<sup>1</sup> our concerns about missing information regarding copy numbers of inserts and the integration (or not) of backbone DNA (from the inserted plasmid). Once again, The Sainsbury Laboratory has chosen not to provide the information specifically requested in Part A1, paragraph 14 which requests detailed information on **the sequences actually inserted or deleted**. Instead, the applicant responds under point (a) that *“Sequences outside the T-DNA are not expected to integrate; however, this may still happen in some instances”* and under point (c) that *“insert copy numbers in all transgenic lines is expected to be low”*.

We note the Advisory Committee on Releases to the Environment (ACRE)’s dismissal of these concerns<sup>2</sup> and the committee’s view that full characterisation is *“not linked to a specific risk of harm”* but it is simply not possible to be certain that the intended genetic modifications are all that has occurred unless the GM potatoes are fully sequenced.

Detailed analysis is always important before a genetically manipulated plant is released. In this case the integration (or otherwise) of the backbone DNA is of particular importance due to the presence of an antibiotic resistance marker gene (see 3.1, below). The inclusion of genes intended to identify plants that have integrated the backbone DNA through phenotypic changes does not assist in the scrutiny of the applicant’s safety claims as they have failed to publish the results of previous trials that also employed this approach (see 1.1, above).

It is completely unacceptable to continue asking ACRE, the Minister, and the public, to simply take the GM developers’ word for it that the only genetic changes that have occurred are those that were intended.

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## 2. The genetic manipulation that has taken place has not been adequately analysed or assessed for unplanned changes or unintended effects

### 2.1 The GMO lines to be trialled feature stacked traits that may interact in novel and unexpected ways

The GM potatoes have been modified with a complex mix of genetic changes intended to achieve multiple, unrelated traits encompassing resistance to late blight, potato cyst nematode and potato virus as well the silencing of genes involved in browning on bruising and reducing sugar production under cold storage. As we highlighted in our responses to the applicant's closely related previous GM potato field trials in 2017<sup>3</sup> and 2019<sup>4</sup>:

*“Genetic modification is promoted to the public as the straightforward insertion of individual genes conferring simple traits. The complexity of this proposed trial reveals a more worrying step towards a ‘transgenic treadmill’ where an increasing number of genes and traits are inserted into a single GM crop. The mixing of pest resistance with ‘designer’ traits focused on ‘tuber quality’ takes us a significant step towards the production of very complex GMOs where numerous novel compounds are produced at once. This considerably increases the potential for unexpected interactions between both genes and compounds produced, with implications for food, feed and environmental safety.”*

Commenting on the applicant's previous field trial applications (17/R29/01 and 19/R29/01), ACRE stated, identically in each case<sup>5</sup>, that it had *“considered the potential for the different gene products or traits to interact and could not identify a plausible scientific hypothesis that would lead to harm.”*

However, the key issue here is that the combination of genetic alterations is entirely novel so it is not possible to judge how these will interact on a molecular, epigenetic or phenotypic basis without detailed experimental data. The applicant states (Part A4) that *“no harmful properties are expected to emerge when the above-mentioned genes and traits are combined”* but as they have not published any peer-reviewed scientific papers on the ongoing trials or made such data public in other ways (see 1.1, above) no such judgement can be made, and it must be assumed that interactions are both possible and unpredictable.

These GM potatoes should not be grown in an open field until detailed experimental data has been independently analysed to examine any interactions between the varied genetic changes and the traits they generate.

### 2.2 The environmental and health risks associated with the RNAi module have not been properly explored

Three of the four potato lines that the applicant wishes to grow in open field trials (SLJ25057, SLJ25566, SLJ25586) contain a gene silencing module targeting the *Ppo* and *Vinv* genes. We detailed our concerns about the safety of RNAi-based GM crops in responses to the applicant's previous linked potato field trial applications<sup>6</sup> and once again wish to stress that there are significant gaps in scientific knowledge of the extent and nature of potential adverse impacts of these genetic changes. Double-stranded RNA (dsRNA) and/or short interfering RNA (siRNA) may create unpredictable off-target effects by silencing non-target genes within the GM plant itself. Gene silencing in non-target organisms could occur following ingestion and processing of dsRNA to siRNA<sup>7</sup>. Indeed, human consumption of the potatoes could lead to silencing of our own genes via uptake and processing of dsRNA to siRNA in the gastro-intestinal tract.

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We note ACRE's view<sup>8</sup> that "*Studies reporting the uptake and function of small RNAs are controversial in the scientific community*" and the applicant's reference to a 2015 study (referenced in the Part A2 as Liu et al, 2015) to conclude (in Part A2, point vi) that "*No toxic or allergenic potential is therefore expected and nucleic acids (such as the endogenous RNA and DNA molecules of plants) are readily degraded by human digestive fluids*".

However, an accumulating number of (largely more recent) studies suggest the survival of ingested RNA is a real possibility that should be seriously considered. These include a 2014 study on honeysuckle-encoded microRNA to treat influenza A viruses<sup>9</sup>; a 2017 study that revealed "*a major mechanism underlying the absorption of dietary microRNAs*"<sup>10</sup> and a 2018 study that found "*some dietary [small]RNA may be more digestively stable*"<sup>11</sup>. Even more recently, a 2021 study highlights different factors that may mediate RNA survival<sup>12</sup>, while a 2022 paper examines the possibility of regulating the expression of human genes by exogenous bovine RNA<sup>13</sup>.

The GM potato field trial should be refused on the grounds that the risk assessment is incomplete as it does not consider the impact of the RNAi-manipulated GM plants on non-target organisms.

### **3 Some of the intended GM traits may damage the environment and/or human health**

#### **3.1 The GM potatoes may include an antibiotic resistance gene**

As with previous linked GM potato field trials, the vector backbone sequence includes a marker gene, *nptII* that confers resistance to the kanamycin family of antibiotics. We note the applicant's intention to counter-select plants where the backbone has been integrated but are unconvinced by their assertion (Part A4, Risk Assessment, point ii) that "*no detrimental effect is expected*" in the event of backbone integration because the antibiotic resistance gene "*is only used for bacterial selection*".

Kanamycin is listed as an essential medicine for priority diseases by the United Nations World Health Organisation (WHO)<sup>14</sup> and concern about the future of therapeutic antibiotics is only growing among learned organisations such as the European Medicines Agency<sup>15</sup>. As detailed in our response to the applicant's most recent linked GM potato field trial application (19/R29/01)<sup>16</sup>:

*"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<sup>17</sup> 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<sup>18</sup>. 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."*

It is unacceptable for another round of field trials to proceed without explicit confirmation that the plants to be grown do not include genes conferring antibiotic resistance.

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### 3.2 The GM potatoes contain herbicide tolerance genes

The GM potatoes will be tolerant to certain herbicides. Part B2 of the application states that *“all the transgenic plants proposed for release in this application also contain the CSR gene which confers resistance to some herbicides (sulfonylureas and imidazolinones). This trait will be used only for the in vitro selection of transgenic lines during tissue culture and these plants remain sensitive to other herbicides.”*

We would like to highlight relevant comments that we made in response to the applicant’s most recent linked field trial application (19/R29/01)<sup>19</sup>:

*“Although the herbicide tolerance is intended for the selection of transformed lines, there is no guarantee that it will be used only for this purpose in the event of any future commercialisation as several pesticides in this family are approved for use in the EU<sup>20</sup>. The use of this herbicide tolerance trait could have a significant effect on biodiversity by reducing plants available to wildlife, as shown in the UK Field Scale evaluations for oilseed rape<sup>21</sup>. Even for field trial purposes, no GM crops with herbicide tolerance traits should be introduced to the environment.”*

We are concerned by ACRE’s repeated assertion that such concerns are out of scope, as in its comments on consent 19/R29/01<sup>22</sup>:

*“Some of the representations raise concerns about the commercial cultivation of these GM potatoes, for example whether farmers might use sulfonylurea and imidazolinone herbicides. If these GM potatoes were notified for commercial cultivation in the future, such concerns would be considered. ACRE is required to advise on the risks posed by this particular trial and agrees that these herbicides should not be used on the trial site.”*

The UK Government is now responsible for deciding which GMOs may be cultivated in England and the perceived potential benefits of GM blight resistant potatoes are frequently quoted in political discussion about GMO regulation. We respectfully suggest, therefore, that it is time for ACRE, or another suitably qualified body, to begin considering all the potential impacts of this and other GMO development projects, including the presence of herbicide tolerance genes.

### 3.3 The “tuber quality” traits raise concerns about food quality and the promotion of unhealthy diets

If the GM plants included in the proposed trial proceed to commercial release, the so-called “tuber quality” traits will support further industrialisation of the food chain and a potential reduction in food quality.

In Part A1, paragraph 13, the applicant reports that *“The results so far repeatedly confirmed the expected effect of the silencing module on the tubers, which have significantly reduced both discolouration upon bruising and accumulation of reducing sugars (Witek AI, unpublished).”* This unpublished observation, which has not been subjected to peer review, nonetheless acknowledges that silencing of the *Ppo* gene prevents **browning** rather than **bruising**. This masks, rather than prevents, damage to bruised cells meaning that those processing the potatoes – and the consumers who buy the products created from them – will be unable to identify and remove damaged tissue.

Considering the trait focused on reducing cold-induced sweetening, we highlighted the following section of our response to the applicant’s most recent previous linked GM potato field trial application (19/R29/01)<sup>23</sup>:

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*The silencing of the Vinv gene is intended to prevent blackening upon high temperature cooking following cold storage. ... It is not necessary for potatoes to be kept in cold storage if they are used within a few weeks of harvesting and changes that facilitate long cold storage will only encourage a practice that increases the environmental footprint of food production (through the highly resource intensive practices of refrigeration and active cooling). Furthermore, as we stated in comments on the applicant's previous GM potato trial application,<sup>24</sup> while consumers are advised<sup>25</sup> to reduce intake of acrylamide (contained in the browning colour of foods cooked at high temperatures) the most beneficial way for them to do so is to eat less fried starchy food. The chips and crisps likely to be produced from non-browning potatoes will still be high in fat and frequently laden with salt. The marketing of end products from this kind of potato as a "healthy" alternative will undermine more holistic public health messages encouraging people to eat a balanced diet low in fried and processed foods. The net result of these potatoes - should they ever come to market - is, therefore, unlikely to be beneficial to public health.*

Leading cancer charity Cancer Research UK goes further. Dismissing any requirement to avoid acrylamide as a "cancer myth", their website states<sup>26</sup> that "Good quality studies have not shown that acrylamide from food causes cancer in humans" and "Your overall diet (what you eat day to day) is more important than individual foods for reducing your cancer risk."

We note comments in ACRE's advice on previous iterations of the proposed field trial that food safety, consumer benefits and the suitability of the proposed crops for addressing the agronomic and health challenges facing society are out of scope for its assessment of proposed field trials. However, significant levels of public funding are being ploughed into this research project, and the UK Government is now responsible for assessing and authorising all environmental GMO releases in England. In this context it is simply unacceptable for ACRE to continue kicking key questions about the environmental, health, social and ethical impacts of GM crops into the metaphorical long grass.

#### **4 Containment of the GM potatoes cannot be guaranteed**

We note that the applicant has taken on board criticism of its previous field trial applications and proposes a post-trial monitoring period of four years (rather than the previously proposed three). However, none of the measures proposed to limit pollen-mediated gene flow or to identify and destroy groundkeepers can guarantee that the GM potatoes will be contained. Indeed, as ACRE notes in its advice on trial consent 19/R29/01<sup>27</sup> "Monitoring of previous releases of potatoes has revealed that groundkeepers may persist for several years after the initial release." Human error is also a key factor and has resulted in GM contamination of potatoes in the EU (Sweden) as a result of 'co-mingling'<sup>28</sup>.

The potential for GM potatoes to remain undetected in the soil beyond the monitoring period, and for escape or gene flow via other means during the trial itself, is a compounding factor that increases the importance of the other concerns that we raise in this submission.

In conclusion, the proposed trial represents an unacceptable risk. The absence of key information, combined with the potential for harm through intended and unintended genetic changes means that the trial will be of no net benefit to society. We request, therefore, that the Minister denies consent and prevents this open-air field trial going ahead.

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Yours faithfully

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Julian Turner Secretary <b>Norfolk Organic Group</b>	Ross Taylor Secretary <b>Heart of England Organic Group</b>	Julia McKay Coordinator <b>Brighton CSA - Fork and Dig It CIC</b>	Brian Kelly Director <b>OrganicLea</b>

## References

<sup>1</sup> GM Freeze et al. 2019. Multi-agency response to potato trial 19/29/01 [https://www.gmfreeze.org/wp-content/uploads/2019/04/multi-agency-response-to-GM-potato-trial-19\\_R29\\_01.pdf](https://www.gmfreeze.org/wp-content/uploads/2019/04/multi-agency-response-to-GM-potato-trial-19_R29_01.pdf)

<sup>2</sup> ACRE updated 2019. Acre advice on an application for deliberate release of a GMO for research and development purposes (19/R29/01) [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/813149/19r2901-acre-advice.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/813149/19r2901-acre-advice.pdf)

<sup>3</sup> GM Freeze et al. 2017. Multi-agency response to potato trial 17/R29/01. [https://www.gmfreeze.org/wp-content/uploads/2017/04/Multi\\_agency\\_response\\_to\\_GM\\_potato\\_trial\\_application\\_17\\_R29\\_01.pdf](https://www.gmfreeze.org/wp-content/uploads/2017/04/Multi_agency_response_to_GM_potato_trial_application_17_R29_01.pdf)

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<sup>4</sup> GM Freeze et al. 2019. Multi-agency response to potato trial 19/29/01 [https://www.gmfreeze.org/wp-content/uploads/2019/04/multi-agency-response-to-GM-potato-trial-19\\_R29\\_01.pdf](https://www.gmfreeze.org/wp-content/uploads/2019/04/multi-agency-response-to-GM-potato-trial-19_R29_01.pdf)

<sup>5</sup> ACRE, updated 2019. ACRE advice: potato plant trial <https://www.gov.uk/government/publications/acre-advice-potato-plant-trial>

linking to:

ACRE advice on GM potato plants (17/R29/01) <https://www.gov.uk/government/publications/acre-advice-application-for-a-trial-of-gm-potato-17r2901>

and

Acre advice on GM potato plants (19/R29/01)

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/813149/19r2901-acre-advice.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/813149/19r2901-acre-advice.pdf)

<sup>6</sup> GM Freeze et al. 2017. Multi-agency response to potato trial 17/R29/01. [https://www.gmfreeze.org/wp-content/uploads/2017/04/Multi\\_agency\\_response\\_to\\_GM\\_potato\\_trial\\_application\\_17\\_R29\\_01.pdf](https://www.gmfreeze.org/wp-content/uploads/2017/04/Multi_agency_response_to_GM_potato_trial_application_17_R29_01.pdf)

And

GM Freeze et al. 2019. Multi-agency response to potato trial 19/29/01 [https://www.gmfreeze.org/wp-content/uploads/2019/04/multi-agency-response-to-GM-potato-trial-19\\_R29\\_01.pdf](https://www.gmfreeze.org/wp-content/uploads/2019/04/multi-agency-response-to-GM-potato-trial-19_R29_01.pdf)

<sup>7</sup> See, for example:

Parker, K.M., Barragán Borrero, V., van Leeuwen, D.M., Lever, M.A., Mateescu, B. & Sander, M. 2019. Environmental fate of RNA interference pesticides: adsorption and degradation of double-stranded RNA molecules in agricultural soils. *Environmental Science & Technology* 53: 3027-3036;

Roberts, A.F., Devos, Y., Lemgo, G.N.Y. & Zhou, X. 2015. Biosafety research for non-target organism risk assessment of RNAi-based GE plants. *Frontiers in Plant Science* 6: 958. <https://doi.org/10.3389/fpls.2015.00958>;

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