GeneWatch UK response to the FSA consultation on applications for nine genetically modified organisms for food and feed uses

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GeneWatch UK opposes the applications for nine genetically modified (GM) organisms (maize) for food and feed uses[1], as outlined below. In all cases, the risk assessment is inadequate to establish safety, proposals for monitoring are inadequate, and other legitimate factors (lack of labelling of GM-fed meat and dairy products, concerns regarding adverse environmental impacts in the countries where GM crops are grown, and concerns regarding the patenting of seeds) should lead to refusal of the import authorisations for these GM crops.

1. Response to RP476 consultation: MIR604 maize (renewal)

Syngenta's MIR604 maize (Unique Identifier: SYN-IR6Ø4-5) is a Bt crop, which expresses the cry3A gene from Bacillus thuringiensis (Bt) coding for a Bt-toxin (Cry3A), which aims to confer resistance to western corn rootworm (*Diabrotica virgifera virgifera*), northern corn rootworm (*D. longicornis barberi*) and other related coleopteran species. It also expresses the phosphomannose isomerase (PMI) gene from the bacterium *Escherichia coli* which allows the plant to use mannose as a carbon source through production of the PMI protein and is used as a selectable marker.

1.1 Do you have any concerns on the safety of the products/events which have not been considered below with respect to the intended consumers, stakeholders or impacts?

Yes, because the EFSA risk assessment is inadequate to establish safety.

The proposed approval relies on the risk assessment by the European Food Safety Authority (EFSA) in EFSA Journal No.5846 (2019) (assessment of genetically modified maize MIR604 for renewal authorisation).[2] Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary. A comprehensive critique of the EFSA risk assessment has been published by TestBiotech (including relevant scientific references).[3] In particular, we note that:

- The integration of the additional DNA was performed by using *Agrobacterium tumefaciens* in two different lines of maize and the final event was derived from stacking (crossing). Since MIR604 has to be considered to be a stacked event derived from crossing two distinct lines of maize, data have to be requested on the parental plants. In the absence of such data, the market authorisation and the renewal application for the maize does not fulfil the standards required.
- The available data indicate that gene expression is dependent on the varietal background and might also be influenced by site specific conditions. Therefore, EFSA should have requested more recent data on gene expression, taking into account a larger number of varieties and a broad range of environmental conditions.
- The material derived from the plants should have been assessed by using '-omics' techniques to investigate changes in the gene activity of the transgene and the plant genome, as well as changes in metabolic pathways and the emergence of unintended biologically active gene products.
- The data presented do not represent expected agricultural practices or the different meteorological and agronomic conditions under which the crop is to be grown and thus no final conclusions can be drawn on the safety of the plants.

- The toxicological risk assessment originally performed by EFSA has some substantial weaknesses: the Bt proteins used in the original risk assessment exhibited a different structure and biological activity compared to those produced in the plants. Furthermore, a sub-chronic feeding study performed with MIR604 for the original risk assessment showed some significant findings. There is insufficient study of effects after long-term exposure to various dosages of the relevant Bt proteins.
- The Bt toxin Cry3A has not been subjected to detailed analysis regarding potential immunological effects. Potential allergenicity of the combination of the two enzymes (Cry3A and PMI) also requires further investigation.
- Fully evaluated methods should be published that allow the Bt concentration in the maize to be measured by independent scientists, as is the case for other plant protection compounds used in food and feed production. This is necessary to make sure that the environment as well as human and animals coming into contact with the material (for example, via dust, consumption or manure) are not exposed to higher quantities of Bt toxins than described in the application.

Since the risk assessment is inadequate to establish safety, the application should be refused.

1.2 Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual GMOs, and if in favour of authorisation, the terms on which the GMOs are authorised (as outlined in the FSA/FSS opinions)?

Since the risk assessment is inadequate to establish safety, the application should be refused. Other legitimate factors also support the refusal of the application (see below).

As noted by TestBiotech, if approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption.[4] Thus, the monitoring report should, at very least, contain detailed information on: i) actual volumes of the GM products imported; ii) the ports and silos where shipments of the GM products were unloaded; iii) the processing plants to which the GM products were transferred; iv) the amount of the GM products used on farms for feed; and v) transport routes of the GM products. Environmental monitoring should be run in regions where viable material of the GM products, such as kernels, are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of viable material (such as kernels) all receiving environments need to be monitored. Furthermore, environmental exposure through organic waste material, by-products, sewage or faeces containing GM products during or after the production process, and during or after human or animal consumption, should be part of the monitoring procedure.

1.3 Are there any other factors that should be considered by Ministers that have not been highlighted?

Other legitimate factors in ministerial decisions may include political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Such legitimate factors should include:

- Lack of labelling of GM-fed meat and dairy products, which would allow consumers to choose whether or not to consume such products.[5]
- Concerns regarding the environmental impacts of Bt GM crops in the countries where they are grown.[6]

- The existence of patents on GM seeds which grant excessive monopoly rights to multinational companies and prohibit seed saving and sharing.

These factors should lead to refusal of the application.

1.4 Do you have any other feedback?

The literature review conducted by the applicant is far from comprehensive. The FSA/FSS should take steps to ensure a systematic review of the relevant literature is conducted for all applications.

2. Response to RP526 consultation: MZIR098 maize (new application)

Syngenta's maize MZIR098 (Unique Identifier: SYN-ØØØ98-3) is an herbicide tolerant (HT) crop) which has been genetically modified to be tolerant to the herbicide glufosinate ammonium (glufosinate) and is also a Bt crop, genetically modified with the aim of protecting it against coleopteran pests, particularly western corn rootworm (*Diabrotica virgifera virgifera*), northern corn rootworm (*D. berberi*), and Mexican corn rootworm (*D. vigifera zeae*). Maize MZIR098 was produced by Syngenta to express the following proteins:

- synthetic Bt toxin eCry3.1Ab (fusion of modified Cry3A (mCry3A) gene and a synthetic Cry1Ab),
- synthetic Bt toxin mCry3A (plant codon optimised Cry3A),
- PAT conferring resistance to the active herbicide ingredient, glufosinate ammonium.

2.1 Do you have any concerns on the safety of the products/events which have not been considered below with respect to the intended consumers, stakeholders or impacts?

Yes, because the EFSA risk assessment is inadequate to establish safety.

The proposed approval relies on the risk assessment by the European Food Safety Authority (EFSA) in EFSA Journal No.6171 (2020) (assessment of genetically modified maize MZIR098 for food and feed uses).[7] A comprehensive critique of the EFSA risk assessment has been published by TestBiotech (including relevant scientific references).[8] In particular, we note that:

- The data provided on gene expression do not represent the conditions in which the plants may be grown. Experiments under controlled and defined conditions should have been performed to gather sufficiently reliable data on gene expression and functional genetic stability. This would have to include exposure of the plants to all biotic or abiotic stressors which are relevant but which might have been absent in the field trials. The generation of these data should have taken all relevant patterns of herbicide application and the application of the complementary herbicides as well as various genetic backgrounds into account.
- The complementary herbicide, glufosinate, was not used in the high doses that may be expected in the case of increasing weed resistance, which would lead to higher residues.
- There were several significant findings on differences in composition, which should
- have been investigated in more detail and under the full range of expected agricultural and bioclimatic conditions, including various genetic backgrounds. These investigations should also include so-called 'omics' (transcriptomics, proteomics, metabolomics). Further, an analysis for many important maize constituents is missing.
- There is a general lack of peer reviewed data on toxicology in regard to the newly synthesized Bt toxins produced by MZIR098. Only very few Bt toxins (especially

Cry1Ab) have been investigated in detail in regard to their exact mode of action, and there is no data on the Bt toxins produced in the maize.
- Maize produces protease inhibitors, which can delay the degradation of the Bt toxins and enhance their toxicity in a synergistic way, synergistic effects between eCry3.1Ab and mCry3A cannot be excluded, and spraying with the complementary herbicide may also enhance toxicity of the Bt proteins, yet these potential synergistic effects were not assessed.
- As yet, only two Bt toxins (Cry1Ac and Cry1Ab) have been tested in detail for their possible effects on the immune system. However, EFSA did not request the applicant to provide experimental data on the allergenic or immunogenic potential of mCry3A and eCry3.1Ab.

Since this crop combines Bt and herbicide tolerant traits, combinatorial effects (or potential mixed toxicity) emerging from simultaneous exposure to a fixed combination of potential stressors, emerging from GM plants at the stage of consumption, need to be assessed in far more detail.[9]

Further, there are important gaps in the overall risk assessment of all herbicide tolerant (HT) GM plants by EFSA.[10] In particular, test samples from field trials, used in EFSA's risk assessment processes, are sprayed with much lower rates of herbicides compared to current agricultural practices. Thus, HT GM plants with unknown concentrations of herbicide residues may be imported from countries with weaker herbicide regulations than the UK. In addition, potential combinatorial effects of the expected mixtures of herbicide residues are not investigated and long-term effects of the consumption of products and their impact on the immune system, the endocrine system and the gut microbiome escape the risk assessment completely or to a large extent.

Since the risk assessment is inadequate to establish safety, the application should be refused.

2.2 Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual GMOs, and if in favour of authorisation, the terms on which the GMOs are authorised (as outlined in the FSA/FSS opinions)?

Since the risk assessment is inadequate to establish safety, the application should be refused. Other legitimate factors also support the refusal of the application (see below).

As noted by TestBiotech, if approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption.[11] Thus, the monitoring report should, at very least, contain detailed information on: i) actual volumes of the GM products imported; ii) the ports and silos where shipments of the GM products were unloaded; iii) the processing plants to which the GM products were transferred; iv) the amount of the GM products used on farms for feed; and v) transport routes of the GM products. Environmental monitoring should be run in regions where viable material of the GM products, such as kernels, are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of viable material (such as kernels) all receiving environments need to be monitored. Furthermore, environmental exposure through organic waste material, by-products, sewage or faeces containing GM products during or after the production process, and during or after human or animal consumption, should be part of the monitoring procedure.

2.3 Are there any other factors that should be considered by Ministers that have not been highlighted?

Other legitimate factors in ministerial decisions may include political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Such legitimate factors should include:

- Lack of labelling of GM-fed meat and dairy products, which would allow consumers to choose whether or not to consume such products.[12]
- Concerns regarding the environmental impacts of Bt GM crops in the countries where they are grown.[13]
- Concerns regarding the environmental impacts of HT GM crops in the countries where they are grown, including potential adverse effects on biodiversity and human health of the blanket spraying of these crops with herbicides.
- The existence of patents on GM seeds which grant excessive monopoly rights to multinational companies and prohibit seed saving and sharing.

These factors should lead to refusal of the application.

2.4 Do you have any other feedback?

The literature review conducted by the applicant is far from comprehensive. The FSA/FSS should take steps to ensure a systematic review of the relevant literature is conducted for all applications.

3. Response to RP535 consultation: MON 87427 × MON 89034 × MIR162 × NK603 maize and its sub-combinations (new application)

Monsanto's (now Bayer's) stacked GM maize MON 87427 × MON 89034 × MIR162 × NK603 is produced by crossing GM maize plants containing MON 87427, MON 89034, MIR162 and NK603 using traditional breeding methods. Therefore, this product inherited the traits as present in the parental lines, glyphosate-tolerance (from MON 87427 and NK603) and insect-protection (Bt) (from MON 89034 and MIR162). The stacked maize line was obtained through the traditional cross breeding of the parental organisms MON 87427 × MON 89034 × MIR162 × NK603 (Unique Identifier: MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-ØØ6Ø3-6). The line inherited genes that express cry1A.105, cry2Ab2, vip3Aa19 and cp4epsps. The expression of these genes confer glyphosate herbicide tolerance and resistance to Lepidoptera and Coleoptera. The sub-combinations in this context refers to any two or three combinations of the four genetic modification insertions: MON 87427, MON 89034, MIR162, NK603; to the genetically modified crop.

3.1 Do you have any concerns on the safety of the products/events which have not been considered below with respect to the intended consumers, stakeholders or impacts?

Yes, because the EFSA risk assessment is inadequate to establish safety.

The proposed approval relies on the risk assessment by the European Food Safety Authority (EFSA) in EFSA Journal No.5734 (2019) (assessment of genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and sub-combinations, for food and feed uses).[14]

A comprehensive critique of the EFSA risk assessment has been published by TestBiotech (including relevant scientific references).[15] In particular, we note that:

- Uncertainties remain about other biologically active substances arising from the method of genetic engineering and the newly introduced gene constructs.

- Robust data should have been presented to assess whether metabolic changes with relevance to biosafety occur in the stacked maize.
- The data presented do not adequately represent the conditions in which the plants are grown. The plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather reliable data on gene expression and functional genetic stability. In addition, EFSA should have requested the applicant to submit data from field trials with the highest dosage of glyphosate that can be tolerated by the plants, including repeated spraying. Higher applications of the herbicide will not only lead to a higher burden of residues in the harvest, but may also influence the expression of the transgenes or other genome activities in the plants.
- The material derived from the plants should have been assessed by using "-omics" techniques to investigate changes in the gene activity of the transgene and the plants genome, as well as changes in metabolic pathways and the emergence of unintended biological active gene products.
- EFSA should have requested additional data from several varieties, including those cultivated in South America, to examine how the gene constructs interact with the genetic background of the plants.
- There were many significant changes especially in the composition of the plants, but no toxicology testing of the whole stacked plant (feeding study) was requested. It should be taken into account that in processed products, such as maize gluten, toxins show a much higher concentration. There does not appear to be any sub-chronic or chronic feeding study performed with whole food and feed derived from the stacked maize.
- There is a need to study effects after long-term exposure to various dosages of the Bt toxins, including in combination with material sprayed with the complementary herbicides.
- Without detailed assessment of herbicide residues, no conclusion can be drawn on the safety of the imported products. Such assessments should take account of evidence that commercially traded formulations of glyphosate, such as Roundup, can be more toxic than glyphosate itself.
- Potential adverse effects that result from combinatorial exposure of various potential stressors need specification, and their assessment needs to be prioritised.
- The EFSA assessment of the stacked maize does not fulfil the requirements for assessing allergenicity of the source of the transgene.
- As yet, only two Bt toxins (Cry1Ac and Cry1Ab) have been tested for their possible effects on the immune system; none of the toxins produced in the maize were investigated in this regard in empirical research.
- No method for identification of the stacked trait has been made available. Based on the information available, it will not be possible to distinguish the stacked event from a mixture of single parental events or stacked events that overlap with the actual stack.

Since this crop combines Bt and herbicide tolerant traits, combinatorial effects (or potential mixed toxicity) emerging from simultaneous exposure to a fixed combination of potential stressors, emerging from GM plants at the stage of consumption, need to be assessed in far more detail.[16]

Further, there are important gaps in the overall risk assessment of all herbicide tolerant (HT) GM plants by EFSA.[17] In particular, test samples from field trials, used in EFSA's risk assessment processes, are sprayed with much lower rates of herbicides compared to current agricultural practices. Thus, HT GM plants with unknown concentrations of herbicide residues may be imported from countries with weaker herbicide regulations than the UK. In addition, potential combinatorial effects of the expected mixtures of herbicide

residues are not investigated and long-term effects of the consumption of products and their impact on the immune system, the endocrine system and the gut microbiome escape the risk assessment completely or to a large extent.

Since the risk assessment is inadequate to establish safety, the application should be refused.

3.2 Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual GMOs, and if in favour of authorisation, the terms on which the GMOs are authorised (as outlined in the FSA/FSS opinions)?

Since the risk assessment is inadequate to establish safety, the application should be refused.

As noted by TestBiotech, if approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption.[18] This requires a method for identification of the stacked event to be made available. The monitoring report should at very least contain detailed information on:
i) actual volumes of the GM products imported,
ii) the ports and silos where shipments of the GM products were unloaded,
iii) the processing plants to which the GM products were transferred,
iv) the quantity of the GM products used on farms for feed, and
v) transport routes of the GM products.
Environmental monitoring should be run in regions where viable material of the GE products such as kernels are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of viable material (such as kernels) all receiving environments and environmental exposure need to be monitored.

3.3 Are there any other factors that should be considered by Ministers that have not been highlighted?

Other legitimate factors in ministerial decisions may include political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Such legitimate factors should include:

- Lack of labelling of GM-fed meat and dairy products, which would allow consumers to choose whether or not to consume such products.[19]
- Concerns regarding the environmental impacts of Bt GM crops in the countries where they are grown.[20]
- Concerns regarding the environmental impacts of HT GM crops in the countries where they are grown, including potential adverse effects on biodiversity and human health of the blanket spraying of these crops with herbicides.
- The existence of patents on GM seeds which grant excessive monopoly rights to multinational companies and prohibit seed saving and sharing.

These factors should lead to refusal of the application.

3.4 Do you have any other feedback?

The literature review conducted by the applicant is far from comprehensive. The FSA/FSS should take steps to ensure a systematic review of the relevant literature is conducted for all applications.

4. RP606 – MON 87427 × MON 89034 × MIR162 × MON 87411 maize and its sub-combinations (new application)

Monsanto's (now Bayer's) stacked GM maize MON 87427 × MON 89034 × MIR162 × MON 87411 (Unique Identifier: MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9) is produced by crossing maize plants containing MON 87427, MON 89034, MIR162 and MON 87411 using traditional breeding methods. Therefore, this product inherited the GM traits as present in the parental lines, glyphosate-tolerance (from MON 87427 and MON 87411) and insect-protection (Bt) (from MON 89034, MIR162 and MON 87411). The line inherited genes that express cry1A.105, cry2Ab2, vip3Aa19 and cp4epsps. The expression of these genes confer glyphosate herbicide tolerance and resistance to *Lepidoptera* and *Coleoptera*. The line also contains a suppression cassette that expresses an inverted repeat sequence that results in the formation of a double-stranded RNA (dsRNA) transcript containing a 240 bp fragment of the WCR Snf7 gene (DvSnf7) and is designed to match the sequence of western corn rootworm (WCR). The sub-combinations in this context refers to any two or three combinations of the four genetic modification insertions line MON 87427, MON 89034, MIR162, MON 87411 to the genetically modified crop.

4.1 Do you have any concerns on the safety of the products/events which have not been considered below with respect to the intended consumers, stakeholders or impacts?

Yes, because the EFSA risk assessment is inadequate to establish safety.

The proposed approval relies on the risk assessment by the European Food Safety Authority (EFSA) in EFSA Journal No.5848 (2019) (assessment of genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and sub-combinations, for food and feed uses).[21]

A comprehensive critique of the EFSA risk assessment has been published by TestBiotech (including relevant scientific references).[22] In particular, we note that:

- EFSA should have requested much more detailed investigation into potential biologically active gene products and changes in metabolic pathways.
- The data presented do not represent the conditions in which the plants are grown and no specific data were requested or used for detailed comparison to assess the genome x environment interactions.
- The plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather reliable data on gene expression and functional genetic stability.
- EFSA should have requested the applicant to submit data from field trials with the highest dosage of glyphosate that can be tolerated by the plants, including repeated spraying.
- Further research is needed to make reliable predictions in regard to dsRNA effects in mammals and EFSA did not assess additional unintended gene products, such as other unintended dsRNA, that can emerge from the insertion of the transgenes.
- No detailed was made of the extent to which the modification of the Bt protein Cry3Bb1 could change its biological characteristics.
- The plants should have been subjected to a much broader range of defined environmental conditions and stressors in order to gather reliable data on gene expression and functional genetic stability. The same investigations should be performed in regard to dsRNA produced in the maize.
- EFSA should have requested the applicant to submit data from field trials with the highest dosage of the complementary herbicides that can be tolerated by the plants,

including repeated spraying. Taking into account the specific characteristics of the stacked maize, only the application of high and repeated dosages of glyphosate-based herbicides should have been regarded as representative of expected agricultural practices.

- The material derived from the plants should have been assessed by using 'Omics-techniques' to investigate changes in the gene activity of the transgene and the plants genome, as well as changes in metabolic pathways and the emergence of unintended biological active gene products.
- The molecular characterisation of the dsRNA as produced in the plants does not allow an assessment of its non-target across kingdom effects and the concentration of the toxin the plants cannot be determined.
- EFSA should have requested additional data from several varieties, including those cultivated in South America, to examine how the gene constructs interact with the genetic background of the plants.
- Despite numerous open questions regarding potential health impacts (due to the combination of Bt toxins and the additional dsRNA), there appears to be no sub-chronic or chronic feeding study performed with whole food and feed derived from the stacked maize.
- In regard to herbicide-resistant plants, specific assessment of residues from spraying with complementary herbicides must be considered to be a prerequisite for granting authorisation. Further attention should be paid to the specific toxicity of the metabolites of the pesticide active ingredients that might occur specifically in the stacked event. EFSA should have requested the company to submit data from field trials with the highest dosage of the complementary herbicides that can be tolerated by the plants, including repeated spraying. The material derived from those plants should have been assessed in regard to organ toxicity, immune system responses and reproductive toxicity, also taking combinatorial effects with other plant components into account.
- EFSA did not request the applicant to provide data to verify whether the source of the transgene is allergenic. It should be noted that the immune system responses caused by the allergens in the soybeans might be considerably enhanced by the adjuvant effects of the Bt toxins.
- As yet, only two Bt toxins (Cry1Ac and Cry1Ab) have been tested for their possible effects on the immune system; none of the toxins produced in the maize were investigated in this regard in empirical research.
- No method for identification of the stacked event has been made available. Based on the information available, it will not be possible to distinguish the stacked event from a mixture of single parental events or stacked events that overlap with the actual stack.

Since this crop combines Bt and herbicide tolerant traits, combinatorial effects (or potential mixed toxicity) emerging from simultaneous exposure to a fixed combination of potential stressors, emerging from GM plants at the stage of consumption, need to be assessed in far more detail.[23]

Further, there are important gaps in the overall risk assessment of all herbicide tolerant (HT) GM plants by EFSA.[24] In particular, test samples from field trials, used in EFSA's risk assessment processes, are sprayed with much lower rates of herbicides compared to current agricultural practices. Thus, HT GM plants with unknown concentrations of herbicide residues may be imported from countries with weaker herbicide regulations than the UK. In addition, potential combinatorial effects of the expected mixtures of herbicide residues are not investigated and long-term effects of the consumption of products and their impact on the immune system, the endocrine system and the gut microbiome escape the risk assessment completely or to a large extent.

Since the risk assessment is inadequate to establish safety, the application should be refused.

4.2 Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual GMOs, and if in favour of authorisation, the terms on which the GMOs are authorised (as outlined in the FSA/FSS opinions)?

Since the risk assessment is inadequate to establish safety, the application should be refused.

As noted by TestBiotech, if approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption. [25] This requires a method for identification of the stacked event to be made available. The monitoring report should at very least contain detailed information on:
i) actual volumes of the GM products imported,
ii) the ports and silos where shipments of the GM products were unloaded,
iii) the processing plants to which the GM products were transferred,
iv) the quantity of the GM products used on farms for feed, and
v) transport routes of the GM products.
Environmental monitoring should be run in regions where viable material of the GE products such as kernels are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of viable material (such as kernels) all receiving environments and environmental exposure need to be monitored.

4.3 Are there any other factors that should be considered by Ministers that have not been highlighted?

Other legitimate factors in ministerial decisions may include political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Such legitimate factors should include:

- Lack of labelling of GM-fed meat and dairy products, which would allow consumers to choose whether or not to consume such products.[26]
- Concerns regarding the environmental impacts of Bt GM crops in the countries where they are grown.[27]
- Concerns regarding the environmental impacts of HT GM crops in the countries where they are grown, including potential adverse effects on biodiversity and human health of the blanket spraying of these crops with herbicides.
- The existence of patents on GM seeds which grant excessive monopoly rights to multinational companies and prohibit seed saving and sharing.

These factors should lead to refusal of the application.

4.4 Do you have any other feedback?

The literature review conducted by the applicant is far from comprehensive. The FSA/FSS should take steps to ensure a systematic review of the relevant literature is conducted for all applications.

5. Response to RP607 consultation: MON 87751 × MON 87701 × MON 87708 × MON 89788 soybean (new application)

Monsanto's (now Bayer's) 'Glycine max' GM soybean is a four-event stack produced via conventional crossing, consisting of cry lepidopteran resistance (MON 87551, MON 87701), dicamba and glyphosate tolerance (MON 87708) and glyphosate tolerance (MON 89788). The stacked soybean line MON 87751 × MON 87701 × MON 87708 × MON 89788 (Unique Identifier: MON-87751-7 x MON-877Ø1-2 x MON-877Ø8-9 x MON-89788-1) was obtained through the traditional cross breading of each of the parental organisms to produce a soybean that expresses each of dicamba monooxygenase, Cry1Ac, Cry2Ab2, Cry1A.105 and EPSPS genes. The expression of these genes is expected to confer resistance to Lepidoptera and tolerance to dicamba and glyphosate herbicide.

5.1 Do you have any concerns on the safety of the products/events which have not been considered below with respect to the intended consumers, stakeholders or impacts?

Yes, because the EFSA risk assessment is inadequate to establish safety.

The proposed approval relies on the risk assessment by the European Food Safety Authority (EFSA) in EFSA Journal No.5847 (2019) (assessment of genetically modified soybean MON 87751 × MON 87701 × MON 87708 × MON 89788 for food and feed uses).[28]

A comprehensive critique of the EFSA risk assessment has been published by TestBiotech (including relevant scientific references).[29] In particular, we note that:

- EFSA should have requested much more detailed investigation into potential biologically active gene products, position effects and changes in metabolic pathways.
- The data presented do not represent the conditions in which the plants will be grown. The plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather reliable data on gene expression and functional genetic stability and on plant composition and phenotypical characteristics.
- The amount of glyphosate used in the field trials was much lower than is typically used by farmers growing GM glyphosate-tolerant crops today. Higher applications of herbicides will not only lead to a higher burden of residues in the harvest, but may also influence the expression of the transgenes or other genome activities in the plants. EFSA should have requested the applicant to submit data from field trials with the highest dosage of the complementary herbicides that can be tolerated by the plants, including repeated spraying and the application of each of the relevant herbicides alone and in combination.
- The material derived from the plants should have been assessed by using 'Omics-techniques' to investigate changes in the gene activity of the transgene and the plants genome, as well as changes in metabolic pathways and the emergence of unintended biological active gene products.
- Plant composition and gene expression can be influenced by the process of stacking and the resulting overall genomic background of the stacked event. Therefore, EFSA should have requested data from the parental plants to be grown in parallel as well as additional data from several varieties, including those cultivated in South America.
- The material derived from the plants should have been assessed by using 'Omics-techniques' to investigate changes in the gene activity of the transgene and the plants genome, as well as changes in metabolic pathways and the emergence of unintended biological active gene products.
- The data show a much lower number of significant findings in the plant composition and the phenotypical characteristics if the plants were sprayed with the complementary herbicides, indicating that metabolic pathways might have been

impacted by the application of the complementary herbicide. This should have been investigated in more detail.

- Toxicology testing of the whole stacked plant (feeding study) was not requested.
- The analysis of the toxicity data for glyphosate and dicamba indicate a higher toxicity if the two herbicides are combined. EFSA should have requested data on the combined toxicity of the residues from spraying with the complementary herbicides.
- EFSA should have requested the company to submit data from field trials with the highest dosage of the complementary herbicides that can be tolerated by the plants, including repeated spraying. The material derived from those plants should have been assessed in regard to organ toxicity, immune system responses and reproductive toxicity, also taking combinatorial effects with other plant components into account. These investigations should take into account that commercially traded formulations of glyphosate, such as Roundup, can be more toxic than glyphosate itself, due to the presence of additives. Furthermore, attention should be paid to the specific toxicity of the metabolites in the active ingredients of the pesticide that might occur specifically in the stacked event.
- Despite numerous open questions regarding potential health impacts (including regarding the various Bt toxins, as well as the herbicide applications), we are not aware of a single sub-chronic or chronic feeding study performed with whole food and feed derived from the stacked soybean.
- The EFSA opinion does not fulfil the requirements for assessment of potential synergistic or antagonistic effects resulting from the combination of the transformation events in regard to toxicology.
- EFSA did not request the applicant to provide data to verify whether the source of the transgene is allergenic.
- No method for identification of the stacked trait has been made available. Based on the information that is available, it will not be possible to distinguish the stacked event from a mixture of single parental events or stacked events that overlap with the actual stack.

Since this crop combines Bt and herbicide tolerant traits, combinatorial effects (or potential mixed toxicity) emerging from simultaneous exposure to a fixed combination of potential stressors, emerging from GM plants at the stage of consumption, need to be assessed in far more detail.[30]

Further, there are important gaps in the overall risk assessment of all herbicide tolerant (HT) GM plants by EFSA.[31] In particular, test samples from field trials, used in EFSA's risk assessment processes, are sprayed with much lower rates of herbicides compared to current agricultural practices. Thus, HT GM plants with unknown concentrations of herbicide residues may be imported from countries with weaker herbicide regulations than the UK. In addition, potential combinatorial effects of the expected mixtures of herbicide residues are not investigated and long-term effects of the consumption of products and their impact on the immune system, the endocrine system and the gut microbiome escape the risk assessment completely or to a large extent.

Since the risk assessment is inadequate to establish safety, the application should be refused.

5.2 Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual GMOs, and if in favour of authorisation, the terms on which the GMOs are authorised (as outlined in the FSA/FSS opinions)?

Since the risk assessment is inadequate to establish safety, the application should be refused.

As noted by TestBiotech, if approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption. [32] This requires a method for identification of the stacked event to be made available. The monitoring report should at very least contain detailed information on:
i) actual volumes of the GM products imported,
ii) the ports and silos where shipments of the GM products were unloaded,
iii) the processing plants to which the GM products were transferred,
iv) the quantity of the GM products used on farms for feed, and
v) transport routes of the GM products.
Environmental monitoring should be run in regions where viable material of the GE products such as kernels are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of viable material (such as kernels) all receiving environments and environmental exposure need to be monitored.

5.3 Are there any other factors that should be considered by Ministers that have not been highlighted?

Other legitimate factors in ministerial decisions may include political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Such legitimate factors should include:

- Lack of labelling of GM-fed meat and dairy products, which would allow consumers to choose whether or not to consume such products.[33]
- Concerns regarding the environmental impacts of Bt GM crops in the countries where they are grown.[34]
- Concerns regarding the environmental impacts of HT GM crops in the countries where they are grown, including potential adverse effects on human health of the blanket spraying of these crops with herbicides.
- The existence of patents on GM seeds which grant excessive monopoly rights to multinational companies and prohibit seed saving and sharing.

These factors should lead to refusal of the application.

5.4 Do you have any other feedback?

The literature review conducted by the applicant is far from comprehensive. The FSA/FSS should take steps to ensure a systematic review of the relevant literature is conducted for all applications.

6. Response to RP620: Bt11 maize (renewal)

Syngenta's Bt11 maize (Unique Identifier: *SYN-BT Ø11-1*) is an insect-resistant and herbicide tolerant maize produced by inserting the cry1Ab gene from *Bacillus thuringiensis subsp. kurstaki* to confer resistance to the European corn borer (*Ostrinia nubilalis*), and the phosphinothricin N-acetyltransferase (PAT) encoding gene from *Streptomyces viridochromogenes* to confer tolerance to phosphinothricin (PPT) herbicide, specifically glufosinate ammonium.

6.1 Do you have any concerns on the safety of the products/events which have not been considered below with respect to the intended consumers,

stakeholders or impacts?

Yes, because the EFSA risk assessment is inadequate to establish safety.

The proposed approval relies on the risk assessment by the European Food Safety Authority (EFSA) in EFSA Journal No.6347 (2021) (assessment of genetically modified maize Bt11 for renewal authorisation).[35] Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Bt11 produces the insecticidal protein Cry1Ab and is resistant to glufosinate.

As far as we are aware, a comprehensive critique of the EFSA risk assessment for Bt11 has not been published, but many of the points made for the other GM crops considered in this consultation remain relevant.

Since this crop combines Bt and herbicide tolerant traits, combinatorial effects (or potential mixed toxicity) emerging from simultaneous exposure to a fixed combination of potential stressors, emerging from GM plants at the stage of consumption, need to be assessed in far more detail.[36]

Further, there are important gaps in the overall risk assessment of all herbicide tolerant (HT) GM plants by EFSA.[37] In particular, test samples from field trials, used in EFSA's risk assessment processes, are sprayed with much lower rates of herbicides compared to current agricultural practices. Thus, HT GM plants with unknown concentrations of herbicide residues may be imported from countries with weaker herbicide regulations than the UK. In addition, potential combinatorial effects of the expected mixtures of herbicide residues are not investigated and long-term effects of the consumption of products and their impact on the immune system, the endocrine system and the gut microbiome escape the risk assessment completely or to a large extent.

Since the risk assessment is inadequate to establish safety, the application should be refused.

6.2 Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual GMOs, and if in favour of authorisation, the terms on which the GMOs are authorised (as outlined in the FSA/FSS opinions)?

Since the risk assessment is inadequate to establish safety, the application should be refused.

If approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption. The monitoring report should at very least contain detailed information on:
i) actual volumes of the GM products imported,
ii) the ports and silos where shipments of the GM products were unloaded,
iii) the processing plants to which the GM products were transferred,
iv) the quantity of the GM products used on farms for feed, and
v) transport routes of the GM products.
Environmental monitoring should be run in regions where viable material of the GE products such as kernels are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of viable material (such as kernels) all receiving environments and environmental exposure need to be monitored.

6.3 Are there any other factors that should be considered by Ministers that have not been highlighted?

Other legitimate factors in ministerial decisions may include political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Such legitimate factors should include:

- Lack of labelling of GM-fed meat and dairy products, which would allow consumers to choose whether or not to consume such products.[38]
- Concerns regarding the environmental impacts of Bt GM crops in the countries where they are grown.[39]
- Concerns regarding the environmental impacts of HT GM crops in the countries where they are grown, including potential adverse effects on biodiversity and human health of the blanket spraying of these crops with herbicides.
- The existence of patents on GM seeds which grant excessive monopoly rights to multinational companies and prohibit seed saving and sharing.

These factors should lead to refusal of the application.

6.4 Do you have any other feedback?

The literature review conducted by the applicant is far from comprehensive. The FSA/FSS should take steps to ensure a systematic review of the relevant literature is conducted for all applications.

7. Response to RP714 consultation: MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and its sub-combinations (new application)

The five-event stack GM maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 (Unique Identifier: *MON-87427-7* × *MON-8746Ø-4* × *MON-89Ø34-3* × *SYN-IR162-4* × *MON-ØØ6Ø3-6*) was produced by conventional crossing to combine five single maize events: MON 87427 (expressing the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein); MON 87460 (expressing the cold shock protein B (CSPB) and neomycin phosphotransferase II protein (NPTII)); MON 89034 (expressing the Cry1A.105 and Cry2Ab2 proteins); MIR162 (expressing the Vip3Aa20 and phosphomannose isomerase (PMI) proteins)); and NK603 (expressing the CP4 EPSPS protein and the variant CP4 EPSPS L214P) to confer resistance to certain lepidopteran pests and tolerance to drought and glyphosate-containing herbicides. The sub-combinations in this context refers to any two, three or four combinations of the five genetic modification insertions: MON 87427, MON 87460, MON 89034, MIR162, NK603; to the genetically modified crop.

7.1 Do you have any concerns on the safety of the products/events which have not been considered below with respect to the intended consumers, stakeholders or impacts?

Yes, because the EFSA risk assessment is inadequate to establish safety.

The proposed approval relies on the risk assessment by the European Food Safety Authority (EFSA) in EFSA Journal No.5774 (2019) (assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and sub-combinations, for food and feed uses).[40]

A comprehensive critique of the EFSA risk assessment has been published by TestBiotech (including relevant scientific references).[41] In particular, we note that:

- EFSA should have requested much more detailed investigation into potential biologically active gene products and changes in metabolic pathways.
- The data presented do not represent the conditions in which the plants are grown: the field trials were not conducted in all relevant regions where the maize will be cultivated, and no extreme weather conditions were taken into account; the field trials did not take current agricultural management practices into account (especially regarding herbicide spraying); only one transgenic variety was included in the field trials.
- No specific data were requested or used for detailed comparison to assess genome x environment interactions.
- Higher applications of the herbicide will not only lead to a higher burden of residues in the harvest, but may also influence the expression of the transgenes or other genome activities in the plants. EFSA should have requested the applicant to submit data from field trials with the highest dosage of glyphosate that can be tolerated by the plants, including repeated spraying.
- The stacked maize inherits the antibiotic resistant marker nptII that renders resistance to clinically important antibiotics, such as neomycin and kanamycin, which are of therapeutic relevance. The risk of transfer of antibiotic resistance from GM plants to bacteria is a risk that should be avoided.
- The available data strongly indicate gene expression of several of the newly introduced genes is likely to depend on, or be influenced by, stacking, varietal background, the spraying of the herbicide or environmental conditions such as drought. Therefore, the plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather reliable data on gene expression and functional genetic stability.
- The material derived from the plants should have been assessed by using omics techniques to investigate changes in the gene activity of the transgene and the plants genome, as well as changes in metabolic pathways and the emergence of unintended biological active gene products.
- Therefore, to assess changes in plant composition and biological characteristics, the plants should have been grown under conditions of severe drought, with and without irrigation, with and without application of the complementary herbicide, and also in comparison with more moderately severe climate conditions. Moreover, the plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather reliable data.
- Glyphosate was only sprayed at an early stage of vegetation and at compatively low dosages. Taking into account the specific characteristics of the stacked maize, only the application of high and repeated dosages of glyphosate should have been regarded as representative for expected agricultural practices.
- EFSA should have requested additional data from several varieties, including those cultivated in South America, to examine how the gene constructs interact with the genetic background of the plants.
- The plant material should have been assessed by using omics techniques to investigate changes in plant composition or agronomic characteristics in more detail.
- More than half of the parameters measured in regard to agronomic characteristics and plant composition were significantly different. Despite these findings, no toxicity testing of the whole stacked plant (feeding study) was requested.
- Only very few Bt toxins (especially Cry1Ab) have been investigated in more detail in regard to their exact mode of action, and there is no data on the Bt toxins produced in the maize.
- Without detailed assessment of herbicide residues on the crop, no conclusion can be drawn on the safety of the imported products: due to specific agricultural practices in

the cultivation of these herbicide resistant GM plants, there are, for example, specific patterns of applications, exposure, occurrence of specific metabolites and emergence of combinatorial effects that require special attention. Account should be taken of evidence that commercially traded formulations of glyphosate, such as Roundup, can be more toxic than glyphosate itself.

- EFSA should have requested the company to submit data from field trials with the highest dosage of the complementary herbicides that can be tolerated by the plants, including repeated spraying. The material derived from those plants should have been assessed in regard to organ toxicity, immune system responses and reproductive toxicity, also taking combinatorial effects with other plant components into account. Further attention should be paid to the specific toxicity of the metabolites of the pesticide active ingredients that might occur specifically in the stacked event.
- Despite all the open questions regarding potential health impacts, we are not aware of a single sub-chronic or chronic feeding study performed with whole food and feed derived from the stacked maize.
- EFSA did not request the applicant to provide data to verify whether the source of the transgene is allergenic. Furthermore, several studies indicating that immune responses such as adjuvanticity in mammals are triggered by Bt toxins should be considered in this context.
- There is specific cause for concern that the maize or gluten is likely to be fed together with soybeans that naturally produce enzymes, which can substantially delay the degradation of Bt toxins in the gut.
- As yet, only two Bt toxins (Cry1Ac and Cry1Ab) have been tested for their possible effects on the immune system; none of the toxins produced in the maize were investigated in this regard in empirical research.
- EFSA has admitted that only “limited experimental evidence” is available to conclude the safety of Bt toxins in regard to immune system reactions and has accepted the need for more detailed testing.
- No method for identification of the stacked event has made available. Based on the information available, it will not be possible to distinguish the stacked event from a mixture of single parental events or stacked events that overlap with the actual stack.

Since this crop combines Bt and herbicide tolerant traits, combinatorial effects (or potential mixed toxicity) emerging from simultaneous exposure to a fixed combination of potential stressors, emerging from GM plants at the stage of consumption, need to be assessed in far more detail.[42]

Further, there are important gaps in the overall risk assessment of all herbicide tolerant (HT) GM plants by EFSA.[43] In particular, test samples from field trials, used in EFSA’s risk assessment processes, are sprayed with much lower rates of herbicides compared to current agricultural practices. Thus, HT GM plants with unknown concentrations of herbicide residues may be imported from countries with weaker herbicide regulations than the UK. In addition, potential combinatorial effects of the expected mixtures of herbicide residues are not investigated and long-term effects of the consumption of products and their impact on the immune system, the endocrine system and the gut microbiome escape the risk assessment completely or to a large extent.

Since the risk assessment is inadequate to establish safety, the application should be refused.

7.2 Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual GMOs, and if in favour of authorisation, the terms on which the GMOs are authorised (as outlined in the

FSA/FSS opinions)?

Since the risk assessment is inadequate to establish safety, the application should be refused.

As TestBiotech has noted, if approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption. [44] This requires a method for identification of the stacked event to be made available. The monitoring report should at very least contain detailed information on:
i) actual volumes of the GM products imported,
ii) the ports and silos where shipments of the GM products were unloaded,
iii) the processing plants to which the GM products were transferred,
iv) the quantity of the GM products used on farms for feed, and
v) transport routes of the GM products.
Environmental monitoring should be run in regions where viable material of the GE products such as kernels are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of viable material (such as kernels) all receiving environments and environmental exposure need to be monitored.

7.3 Are there any other factors that should be considered by Ministers that have not been highlighted?

Other legitimate factors in ministerial decisions may include political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Such legitimate factors should include:

- Lack of labelling of GM-fed meat and dairy products, which would allow consumers to choose whether or not to consume such products.[45]
- Concerns regarding the environmental impacts of Bt GM crops in the countries where they are grown.[46]
- Concerns regarding the environmental impacts of HT GM crops in the countries where they are grown, including potential adverse effects on biodiversity and human health of the blanket spraying of these crops with herbicides.
- The existence of patents on GM seeds which grant excessive monopoly rights to multinational companies and prohibit seed saving and sharing.

These factors should lead to refusal of the application.

7.4 Do you have any other feedback?

The literature review conducted by the applicant is far from comprehensive. The FSA/FSS should take steps to ensure a systematic review of the relevant literature is conducted for all applications.

8. Response to RP715 consultation: MON 88017 maize (renewal)

Monsanto's (now Bayer's) GM maize line MON88017 (Unique Identifier: MON-88Ø17-3) was produced using recombinant-DNA techniques to express the cry3Bb1 gene encoding a Coleopteran-specific insecticidal protein from Bacillus thuringiensis (Bt) (subsp. kumamotoensis) to seek to to control infestation with corn root worm, and the cp4 epsps gene from the soil bacterium Agrobacterium ssp. strain CP4, to convey tolerance to glyphosate-based herbicides.

8.1 Do you have any concerns on the safety of the products/events which have not been considered below with respect to the intended consumers, stakeholders or impacts?

Yes, because the EFSA risk assessment is inadequate to establish safety.

The proposed approval relies on the risk assessment by the European Food Safety Authority (EFSA) in EFSA Journal No.6008 (2020) (assessment of genetically modified maize MON 88017 for renewal authorisation).[47] Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

A comprehensive critique of the EFSA risk assessment has been published by TestBiotech (including relevant scientific references).[48] In particular, we note that:

- EFSA should have requested a much more detailed investigation into potential biologically active gene products and changes in metabolic pathways.
- The data presented do not represent the conditions in which the plants are grown.
- The plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather specific and reliable data on gene expression and functional genetic stability.
- EFSA should have requested the applicant to submit more recent data from field trials, also taking into account the highest dosage of glyphosate that can be tolerated by the plants, including repeated spraying.
- No detailed examination was undertaken regarding the extent to which the modification of the Bt protein Cry3Bb1 will change its biological characteristics.
- EFSA also did not request a detailed analysis based on so-called 'omics' (transcriptomics, metabolomics, proteomics) to investigate changes in the overall metabolism in the plants.
- EFSA should have requested the applicant to submit data from more recent field trials, also taking into account the highest dosage of the complementary herbicides that can be tolerated by the plants, including repeated spraying.
- No data are presented in the renewal assessment regarding currently applied agricultural practices and changes in meteorological and agronomic conditions under which the crop is to be grown. The plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather reliable data.
- EFSA should have requested the applicant to submit data from field trials, also taking into account the highest dosage of the complementary herbicides that can be tolerated by the plants, including repeated spraying. Only the application of high and repeated dosages of glyphosate should have been regarded as representative for expected agricultural practices.
- Compositional analysis assessed by EFSA in 2009 revealed a range of statistically significant differences in the composition of maize MON88017 and its non-GM comparator. Therefore, EFSA should have requested further tests for the current application, for example, including repeated spraying with higher herbicide dosages and exposure to a much wider range of environmental conditions, also taking more extreme drought conditions into account. Furthermore, the plant material should have been assessed by using 'omics-techniques' to investigate changes in plant composition or agronomic characteristics in more detail.
- Without detailed assessment of herbicide residues, no conclusion can be drawn on the safety of the imported products: due to specific agricultural practices in the cultivation of these herbicide resistant GM plants, there are, for example, specific patterns of applications, exposure, occurrence of specific metabolites and emergence of combinatorial effects that require special attention. This must take

account of evidence that commercially traded formulations of glyphosate, such as Roundup, can be more toxic than glyphosate itself.

- EFSA should have requested the company to submit data from field trials with the highest dosage of glyphosate that can be tolerated by the plants, including repeated spraying. The material derived from those plants should have been assessed in regard to organ toxicity, immune system responses and reproductive toxicity, also taking combinatorial effects with other plant components into account. The potential impact on the intestinal microbiome should also be considered.
- The material derived from the plants should have been assessed in regard to organ toxicity, immune responses and reproductive toxicity, also taking combinatorial effects with other plants components into account.
- EFSA opinions on MON88017 contain only limited information regarding the assessment of allergenicity.
- As yet, only two Bt toxins (Cry1Ac and Cry1Ab) have been tested for their possible effects on the immune system. While the applicant provided some data on Cry3Bb1 in regard to celiac disease, other diseases associated with symptoms of chronic inflammation were not considered at all.

Since this crop combines Bt and herbicide tolerant traits, combinatorial effects (or potential mixed toxicity) emerging from simultaneous exposure to a fixed combination of potential stressors, emerging from GM plants at the stage of consumption, need to be assessed in far more detail.[49]

Further, there are important gaps in the overall risk assessment of all herbicide tolerant (HT) GM plants by EFSA.[50] In particular, test samples from field trials, used in EFSA's risk assessment processes, are sprayed with much lower rates of herbicides compared to current agricultural practices. Thus, HT GM plants with unknown concentrations of herbicide residues may be imported from countries with weaker herbicide regulations than the UK. In addition, potential combinatorial effects of the expected mixtures of herbicide residues are not investigated and long-term effects of the consumption of products and their impact on the immune system, the endocrine system and the gut microbiome escape the risk assessment completely or to a large extent.

Since the risk assessment is inadequate to establish safety, the application should be refused.

8.2 Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual GMOs, and if in favour of authorisation, the terms on which the GMOs are authorised (as outlined in the FSA/FSS opinions)?

Since the risk assessment is inadequate to establish safety, the application should be refused.

As TestBiotech has noted, if approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption.[51] The monitoring report should at very least contain detailed information on:
i) actual volumes of the GM products imported,
ii) the ports and silos where shipments of the GM products were unloaded,
iii) the processing plants to which the GM products were transferred,
iv) the quantity of the GM products used on farms for feed, and
v) transport routes of the GM products.

Environmental monitoring should be run in regions where viable material of the GE products such as kernels are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of viable material (such as kernels) all receiving environments and environmental exposure need to be monitored.

8.3 Are there any other factors that should be considered by Ministers that have not been highlighted?

Other legitimate factors in ministerial decisions may include political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Such legitimate factors should include:

- Lack of labelling of GM-fed meat and dairy products, which would allow consumers to choose whether or not to consume such products.[52]
- Concerns regarding the environmental impacts of Bt GM crops in the countries where they are grown.[53]
- Concerns regarding the environmental impacts of HT GM crops in the countries where they are grown, including potential adverse effects on biodiversity and human health of the blanket spraying of these crops with herbicides.
- The existence of patents on GM seeds which grant excessive monopoly rights to multinational companies and prohibit seed saving and sharing.

These factors should lead to refusal of the application.

8.4 Do you have any other feedback?

The literature review conducted by the applicant is far from comprehensive. The FSA/FSS should take steps to ensure a systematic review of the relevant literature is conducted for all applications.

9. Response to RP716 consultation: MON 89034 maize (renewal)

Monsanto's (now Bayer's) GM maize line MON 89034 (Unique Identifier: *MON-89Ø34-3*) expresses two Bt-toxins encoded by the genes cry1A.105 and cry2Ab2 from *Bacillus thuringiensis* that confer resistance against certain lepidopteran pests such as fall armyworm (*Spodoptera sp.*), black cutworm (*Agrotis ipsilon*), European corn borer (*Ostrinia nubilalis*) and the corn earworm (*Helicoverpa zea*).

9.1 Do you have any concerns on the safety of the products/events which have not been considered below with respect to the intended consumers, stakeholders or impacts?

Yes, because the EFSA risk assessment is inadequate to establish safety.

The proposed approval relies on the risk assessment by the European Food Safety Authority (EFSA) in EFSA Journal No.5845 (2019) (assessment of genetically modified maize MON 89034 for renewal authorisation).[54] Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

We note that TestBiotech has warned that in maize 89034 (used for crossing in the stacked event) a highly synthetic Bt toxin is produced.[55] This toxin is a combination of Cry1Ac, Cry1F and Cry1Ab.There is no native form of this combined protein, so its risks cannot be compared with the ones from native Bt toxins used before. In this case, synergistic effects,

selectivity and toxicity have to assessed comprehensively to exclude risks for human health and farm animals.

Since the risk assessment is inadequate to establish safety, the application should be refused.

9.2 Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual GMOs, and if in favour of authorisation, the terms on which the GMOs are authorised (as outlined in the FSA/FSS opinions)?

Since the risk assessment is inadequate to establish safety, the application should be refused.

As noted above for the other applications, if approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption.

9.3 Are there any other factors that should be considered by Ministers that have not been highlighted?

Other legitimate factors in ministerial decisions may include political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Such legitimate factors should include:

- Lack of labelling of GM-fed meat and dairy products, which would allow consumers to choose whether or not to consume such products.[56]
- Concerns regarding the environmental impacts of Bt GM crops in the countries where they are grown.[57]
- The existence of patents on GM seeds which grant excessive monopoly rights to multinational companies and prohibit seed saving and sharing.

These factors should lead to refusal of the application.

9.4 Do you have any other feedback?

The literature review conducted by the applicant is far from comprehensive. The FSA/FSS should take steps to ensure a systematic review of the relevant literature is conducted for all applications.

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