FSS Board Update on Genome Editing

1 Purpose of the paper

1.1 The purpose of this paper is for information and to provide the Board with an overview of the subject of genome editing in light of last year's Defra consultation[1], the subsequent UK Government (UKG) response and its potential impact on the future regulatory framework for food and feed across the UK.

1.2 The Defra consultation, which covers England only, outlined a view that organisms produced by genome editing or other genetic technologies should not be regulated as genetically modified organisms if they could have been produced by traditional breeding methods. In its response to the consultation in September 2021, the UKG outlined their plans to enable the use of genome editing technologies for plants in the first instance and review the regulatory definitions of a Genetically Modified Organism (GMO).

1.3 The proposed changes would have an immediate impact on the Food Standards Agency (FSA) as amending the definition of a GMO would also affect the way in which these types of food and animal feed products are regulated.

1.4 The paper outlines the FSS regulatory responsibility in this area, the potential impacts any change to the regulatory framework in England will have in Scotland and how FSS plan to engage with the FSA, Scottish Government (SG) and Ministers. This is to ensure devolved interests are adequately represented when it comes to developing potential regulatory frameworks for authorising genome edited products and allows FSS to understand the implications for Scotland as consumer protection, awareness and education remain a priority for FSS.

1.5 The Board is asked to:

- **Note** the update on potential legislative change in England should the definition of GMOs exclude organisms that have genetic changes that could have been achieved through traditional breeding or which could occur naturally.

- **Note** the intention to explore gaps in our understanding of consumer awareness and attitudes relating to GM and genome editing in Scotland, and social research that may be needed to inform the discussion around any potential change to the regulatory framework in England and/or the rest of GB.

[1] https://consult.defra.gov.uk/agri-food-chain-directorate/the-regulation-of-genetic-technologies/

- **Discuss and agree** the extent to which FSS officials should engage with the FSA when it comes to informing the development of a regulatory framework for genome edited products, in the event of legislative change in England.

- **Discuss and agree** how the Board wish to update Ministers on FSS planned involvement in this work at a GB level.

2 Strategic aims

2.1 This work supports FSS Strategic Outcome 1 (Food is Safe and Authentic) and Strategic Outcome 4 (Consumers are empowered to make positive choices about food).

Background

2.2 Genome editing is considered a method of genetic modification under the definitions currently laid down in Directive 2001/18([2]) on the deliberate release into the environment of GMOs. This is the definition which is used in Regulation 1829/2003 on Genetically Modified Food and Feed[3] (which has now become retained EU law) which outlines the requirements that need to be met when it comes to authorising and assessing the safety of any genetically modified food and feed intended to be placed on the market in order to protect human and animal health. Enforcement provisions for these requirements are contained within The Genetically Modified Animal Feed (Scotland) Regulations 2004 and The Genetically Modified Food (Scotland) Regulations 2004.

2.3 When the current legislation was developed in Europe, there was a clear boundary between genetically modified and conventional crops, and mutagenesis (i.e. deliberately exposing a crop to radiation or chemicals to alter its DNA) was specifically exempted from the regulations because it had been used safely for decades. However, the emergence of new breeding techniques such as genome editing has blurred that boundary. With new breeding techniques, crops can be improved without the addition of foreign DNA, instead producing improved crops which are often within the natural variation of the plant (i.e. the change could have arisen through conventional cross breeding from sexually compatible parents).

2.4 On the 25th July 2018 the Court of Justice of the European Union ("the Court") ruled that organisms produced by directed mutagenesis (which includes genome editing) should be considered genetically modified organisms within the meaning of the Directive, and that they are not captured by the exemption applied to the products of random mutagenesis.

2.5 Currently the policy responsibility for Directive 2001/18 sits with Scottish Government however retained Regulation (EC) No 1829/2003 on genetically modified food and

[2] EUR-Lex - 32001L0018 - EN - EUR-Lex (europa.eu)
[3] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance) (legislation.gov.uk)

feed sits with FSS and applies the same definition of genetic modification. In broad terms, the use of genome editing – e.g. in crops and cultivation – falls under the remit of SG until the product becomes food or feed or part of a food or feed product, at which point regulatory responsibility transfers to FSS.

Under these rules, any product placed on the market that consists of a genetically modified organism, or any food or feed produced from a genetically modified organism, must be assessed by FSS and the FSA as part of the GB Regulated Products application service. This authorisation includes mandatory pre-market safety assessment undertaken by the Advisory Committee on Novel Foods and Processes (ACNFP) based on science and evidence. Following a public consultation, FSS and the FSA then present a recommendation to Ministers, which includes other relevant factors such as consumer choice and economic impact. Once authorised, any product consisting of or containing a genetically modified organism must be traceable and labelled (however there are some exemptions e.g. enzymes used to produce cheese).

2.6 As noted above, the EU legislation controlling the use of genetically modified organisms was retained in the UK at the end of the transition period. The retained legislation requires that all genome edited organisms are classified as GMOs. Defra's view is that organisms produced by genome editing or other genetic technologies should not be regulated as GMOs if they could have been produced by traditional breeding methods. In January 2021, Defra launched a consultation on the implications of addressing this and changing the definition in England. In September 2021, the UKG issued its formal response[4] to the Defra consultation on genetic technologies regulation. The response set out how it intended to enable the use of genome edited technologies on plants, where changes could have occurred naturally or could have been a result of traditional breeding methods. It also outlined the next steps the UKG intended to take including using existing powers to lay a Statutory Instrument (SI) to allow genome editing of plants at the research and development stage and, most notably, the intention to bring forward primary legislation in England to amend the regulatory definitions of a GMO to exclude organisms that have genetic changes that could have been achieved through traditional breeding or which could occur naturally. The SI in relation to genome edited crop field trials was laid before Parliament on 20 January and was debated on the 2 March[5].

2.7 The FSA is responsible for advising Ministers in England, Wales and Northern Ireland on the authorisation of GM food and feed. The planned changes to amend the definition in England of GMOs to exclude products achieved through new breeding techniques including genome editing would have immediate impacts on the FSA. If these changes are made in England, genome edited products could no longer be regulated under existing GM food and feed legislation in England, and, as things stand, would need to be covered by existing regulated product regimes (i.e. novel foods legislation for genome edited food and animal feed legislation for

[4] https://www.gov.uk/government/consultations/genetic-technologies-regulation/outcome/genetic-technologies-regulation-government-response
[5] Draft Genetically Modified Organisms (Deliberate Relea - Hansard - UK Parliament

genome edited feed). As the definition would not be amended in Scotland or Wales, genome edited products would continue to be regulated under current legislation, creating regulatory divergence within GB.

2.8 FSS's responsibility is to ensure the safety of food and feed, including those produced using genetic modification and genome editing techniques. The regulation of food and feed produced using genome editing is currently being considered through the risk analysis process. Although we do not yet know what the outcome of this process will be, as an independent science led regulator we agree with the advice provided by ACNFP that it would be appropriate to develop a robust risk assessment process for genome edited food which is distinct from the existing approach used for GMOs.

3 Discussion

What is genetic modification?

3.1 Genetic modification (GM) typically refers to the insertion of DNA from one organism into another to introduce a desired trait (characteristic) such as herbicide tolerance or pest resistance. The genes which introduce these traits generally come from bacteria, and may be introduced along with other functional pieces of DNA (for example to "turn on" the gene) from bacteria or viruses in what is known as a cassette. Traditional methods of genetic modification cannot control where in the host genome (complete set of DNA) the cassette is introduced, and genetic screening of the modified organism is required to ensure the site of insertion does not disrupt other parts of the genome. In the USA, genetic modification is generally referred to as genetic engineering and shortened to GE. Additional information on GM technologies is contained within Annex A.

What is genome editing?

3.2 Genome, or gene, editing[6] refers to the modification of a genome at a **precise location** known to control a specific trait. A common assumption is that genome editing is undertaken without the introduction of foreign DNA, however genome editing techniques can include a number of applications, from changing a single DNA letter to inserting a gene that could have been cross bred conventionally, to inserting a stretch of foreign DNA. The precision of the modifications made through genome editing is in contrast to GM where the site of insertion cannot be controlled.

3.3 Genome editing techniques are amongst a range of breeding techniques (collectively known as novel genomic techniques or new breeding techniques – see Annex A) which have been developed since the 2001 EU definition of a GMO. Although the 2018 Court of Justice of the European Union ruling stated that products of genome editing come under the definition of a GMO, there is broad agreement that the

[6] As online searches for GE are likely to recover pages dealing with genetic engineering (synonymous with GM in the USA), to avoid public confusion it is advisable not to use the abbreviation GE to represent genome editing in public-facing documents.

current definition of a GMO cannot adequately be applied to the range of breeding techniques now available to scientists. Additionally, there are no laboratory testing methods which are capable of distinguishing between changes that have been made through the use of genome editing techniques which do not involve the introduction of foreign DNA, or by conventional plant breeding methods. This causes difficulties with regard to the differentiation between food or feed produced using these methods, and therefore the regulation of such products would be challenging.

3.4 Recognising the difficulty this causes, both Defra and the EU are considering adapting their regulatory approaches so that certain applications of genome editing can be removed from the definition of a GMO and regulated in a different way.

3.5 Defra has specified that their proposed revised legislation only applies to organisms where genome editing makes changes that "could have arisen naturally". However, what is "natural" is difficult to define in a scientifically robust way. For example, the sweet potato genome is known to contain a fragment of bacterial DNA which is thought to have been naturally introduced several thousand years ago.

3.6 In contrast, the EU policy initiative examining the future regulation of plants produced using these techniques refers to "plants obtained by targeted mutagenesis and cisgenesis[7]", as these refer to two types of changes to the genome which do not involve the introduction of foreign DNA.

Impact of the proposed changes to the definition in England

3.7 As set out in para 2.6, if legislative changes were made in England, it would have an immediate impact for the FSA and mean that genome edited products would need to be regulated by other regulatory regimes. At its September 21 Board meeting[8], the FSA considered the implications of the proposed changes to the definition and what that would mean for the future regulation of genome edited products in England. The FSA are of the opinion that there is a clear case for updating the regulatory framework to reflect new scientific and technological advances in genome editing, and that the existing regulatory regimes for novel foods and animal feed would not be suitable for regulation of genome edited products.

3.8 As part of its consideration of the impact the potential change in the definition of GMO would have on the legislative framework, the FSA have outlined 5 key principles which should underpin any future regulation of genome edited products – **safety**; **transparency**; **proportionality**; **traceability** and; **building consumer confidence**. Two potential regulatory options were also outlined to the FSA Board for consideration. The options proposed either a new genetic technologies food and feed framework, capturing genome editing products excluded from the GMO

[7] Targeted mutagenesis and cisgenesis are defined by the European Commission as follows: Targeted mutagenesis: An umbrella term used to describe newer techniques of mutagenesis that induce mutation(s) in selected target locations of the genome without insertion of genetic material. Cisgenesis: Insertion of foreign genetic material (e.g. a gene) into a recipient organism from a donor that is sexually compatible (crossable). The foreign genetic material is introduced without modifications or rearrangements.
[8] FSA 21-09-06 - Genome Editing (food.gov.uk)

framework if the definition is changed or; a refresh of the current GM food and feed framework, potentially creating a tiered system of assessment for products created by a spectrum of genetic technologies. The FSA Board supported reshaping regulation and the first approach outlined above was the favoured option, recognising the need to adapt to future developments.

Assessing the safety of genome edited products

3.9 The Advisory Committee for Novel Foods and Processes (ACNFP) are the committee currently responsible for assessing the safety of novel or GM food and feed on behalf of GB and they responded to the Defra consultation by way of letter. In their response, the Committee recognised the many benefits this type of technology can bring, but they recommended that a scientifically robust safety assessment should continue to be performed for all novel foods produced using genome editing technologies, even in cases where the full current safety/risk assessment process required for a GMO product may not be considered appropriate. In cases where outcomes from the use of genome editing can be demonstrated to be the same as those that could be obtained from traditional breeding, an appropriate risk assessment process should be established to ensure consumer safety.

3.10 They consider that a proportionate case by case risk assessment approach could and should be employed for all genome edited foods at least in the early years of the adoption of this transformative technology. This could be based on that currently undertaken for novel foods. However, the exact process will need some modification to adequately assess the safety of genome edited foods.

3.11 They also recognised that there are several non-safety areas where issues may be raised by a change in the regulation of some genome edited products. These include a ‘rush-to-market', animal welfare, transparency and traceability and consumer awareness.

Impact of the proposed changes to the definition in Scotland

3.12 Any new or adapted regulatory approach developed by the FSA, without similar legislative changes being made in Scotland (or Wales), would result in regulatory divergence and may have implications for the UK internal market as genome edited food and feed products authorised and produced in England could legally be sold in Scotland, although SG are still trying to understand ways to avoid this . This is because genome edited food and feed products, intended for placing on the market, could be submitted to the FSA for approval via the GB regulated products approval service through a new, or amended, process to assess their safety. This would result in Ministers in England taking decisions on the approval of genome edited food and feed products with little or no involvement from FSS as the independent Scottish food safety authority or Ministers in Scotland.

3.13 Businesses could choose to submit dual applications to both the FSA and FSS through the GB regulated products approval service. This would present challenges on a number of fronts. If dual applications were made, the ACNFP would have to consider the safety assessment under different regulatory regimes (e.g. potential new regime in England and existing regimes in Scotland and Wales). Whilst this approach would ensure FSS involvement in the assessment of safety and provision of recommendations to the Minister, it would be done so through the existing regulatory regime. What this may mean in practice is businesses will choose to submit one application to the FSA for consideration under any new regime in England and place reliance on approval there ensuring products can be sold legally in Scotland.

3.14 FSS could work with the FSA to develop a new regulatory model for approving genome edited food and feed that would ensure consistency across GB. How this could be achieved would require further thought given there are no plans to amend the definition of GMO's in Scotland. In a broad sense, FSS officials agree with the principles outlined in the September FSA Board paper, particularly around traceability and transparency and what this would mean for consumers in terms of labelling for example. FSS involvement would ensure devolved views and the interests of Scottish consumers are factored into both the development of any new regulatory regime and any subsequent decisions that may be sought on the approval of genome edited food and feed products intended to be placed on the market. This approach would align with the recent FSA Board discussion where it agreed that FSA officials should continue to work closely with the devolved nations to try and achieve a GB wide approach for regulating genome edited products.

3.15 FSS engagement in this work at a GB level would be consistent with the principles of four country working as outlined in the provisional Food and Feed Safety and Hygiene (FFSH) UK Common Framework. Any review of the regulatory framework for GM and genome edited food or feed would also fall within scope of the FFSH framework which is underpinned by the UK risk analysis process.

3.16 FSS also has a statutory duty to represent the other interests of consumers in relation to food and supports consumer choice whilst recognising that some people will want to choose not to buy or eat genetically modified or genome edited food, however carefully they have been assessed for safety. FSS also share the FSA views around consumer attitudes and agree that education and information in this space will be important due to low levels of awareness and knowledge. The difference between GMO and new genomic technologies is something that many consumers do not understand and it is key that FSS play an active role in educating consumers when it comes to these emerging technologies and the part they may play in the future of the food chain. Scottish consumer attitudes towards the availability of GM food and other products such as chlorinated chicken, was highlighted as one of consumers main concerns in our 2020 Brexit ScotPulse survey findings.

3.17 Alongside the need for increased levels of dialogue with the public, FSS is actively considering how we enhance our understanding of consumer attitudes around GM

and genome edited food and feed as regardless of whether any new regulatory framework is adopted in Scotland, it would be possible that genome edited products would be placed on the market in Scotland should the changes outlined in this paper occur in England.

3.18 A proposed programme of work is therefore being developed by the FSS Social Science team to gather additional evidence on consumer attitudes and awareness of GM and genome editing to inform the discussion around any potential change to the regulatory framework in England and/or the rest of GB. This work would also underpin the development of a communication and engagement plan, if these changes take effect, to ensure FSS can inform, educate and support consumers in Scotland to understand how such changes would impact them.

Engagement with Scottish Government

3.19 Since the Defra consultation was launched in January 2021, FSS officials have proactively engaged with officials in SG to discuss the impact any legislative change would have in Scotland given the policy and regulatory responsibility for GM is shared between both organisations and the Scottish Government has had a long-standing opposition to the cultivation of GM crops. The difficulty that exists is the difference between cultivation in Scotland which is clearly within the scope of Ministers to decide versus the possibility of GE ingredients being used on food production in Scotland which the Internal Market Act facilitates. FSS officials will continue to engage with SG officials on future developments for potential new or adapted regulatory regimes for approving genome edited food and feed products, given the policy lead for a definition of a GMO lies with SG and this will have a bearing on whether a different regulatory regime could be implemented in Scotland.

3.20 FSS have also discussed this issue and our plans for engagement and consumer research with the SG's Constitutional and UK Relations (CUKR) team who agree that this would be in scope of the provision UK Common Frameworks and is part of FSS's role when it comes to providing independent food and feed safety advice to Scottish Ministers.

3.21 The Food Standards Scotland Statement of Performance Functions, as approved by Scottish Ministers, outlines that FSS works independently of industry and the SG. Some of our key functions include the development of food and feed policy and to advise Ministers on these matters. As the independent food safety authority for Scotland, we look to protect consumers through leading the development and delivery of proportionate and risk-based regulation. Given the likely development of a new regulatory framework in England, it is important that as Scotland's food safety regulator, FSS work closely with the FSA so that suitable advice on the implications for Scotland can be provided to Ministers.

3.22 It would therefore be the Executive's intention to provide an update to the Minister, following the Board discussion, on our plans to commission consumer research in Scotland and to engage with the FSA on the development of any new regulatory regime for the approval of genome edited products in England. This would, as a minimum, ensure devolved views and impacts are understood, and inform

subsequent FSS advice/opinion on whether a similar course of action should be considered for Scotland. It will be important to highlight that any FSS involvement at this stage would focus on food and feed safety matters and consumer interests, which would then inform our subsequent advice to Ministers.

Europe

3.23 Under the SG policy to align with EU law when it is in Scotland's interests to do so, FSS will be expected to have considered developments in EU food and feed law and the impact of divergence, including any changes to the requirements on GMOs and underpinning scientific evidence, in making risk management recommendations. This issue is now on our EU Food Law tracker and FSS officials will be monitoring developments and will prioritise advice to Ministers accordingly.

3.24 After the 2018 ruling, the Commission was requested to submit "a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law" as it became evident that new scientific knowledge and recent technical developments have made Directive 2001/18[9] on the deliberate release into the environment of genetically modified organisms is no longer fit for purpose. Moreover, the GMO Directive gives rise to more general problems, in particular with regard to the definition of genetically modified organisms in the context of naturally occurring mutations, safety considerations, as well as detection and identification.

3.25 The Commission have launched an initiative which will propose a legal framework for plants obtained by targeted mutagenesis and cisgenesis and for their food and feed products. It is based on the findings of the Commission study on new genomic techniques[10].

3.26 The aim is to have proportionate regulatory oversight to maintain a high level of protection for human and animal health and the environment and a public consultation is planned for the second quarter of 2022 with Commission adoption planned for the second quarter of 2023[11].

4 Identification of risks and issues

UK Internal Market Act

4.1 As mentioned in para 3.12, due to the Internal Market Act, this potential change will have implications for Scotland. Whilst not an immediate issue given the time it would take to bring forward legislation in England and to develop any new or adapted regulatory regime for authorising genome edited food and feed products, and noting SG are still considering legal options, it would not be possible to prevent the sale of genome edited food and feed products authorised and produced in England, being

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32001L0018&qid=1610617002703
[10] EC study on new genomic techniques (europa.eu)
[11] Legislation for plants produced by certain new genomic techniques (europa.eu)

sold elsewhere in Great Britain, irrespective of the regulatory regimes in place in any of the devolved nations.

FSS Strategic Risk

4.2 The FSS Strategic Risk Register includes a draft risk for consideration at the next Audit and Risk Committee to reflect the need to ensure regulation in Scotland keeps pace with new products and any emerging technologies used in food and feed production. The risk considers the potential for divergent regulatory frameworks across the UK (and in this case, potentially the EU) caused by FSS's inability to adapt and develop suitable regulatory frameworks that keep pace with, and take account of changes in technology which will result in lack of clarity for consumers, industry and other stakeholders.

4.3 The Board also considered its risk appetite when it comes to policy or regulatory change in August 2020. It confirmed that the Board was open to policy/regulatory approaches that have the potential to produce the best outcomes in evidence-based Scottish-specific circumstances. FSS involvement in the FSA work to review the impact of potential legislative change would mitigate this risk from being fully realised.

5 Conclusion/Recommendations

5.1 Clearly, the way genome editing in food is regulated is currently being assessed through the risk analysis process, and while ultimately Ministers decide on the risk management options, from our independent science and evidence based approach on food safety we are content with the recommendations of the ACNFP on the approach that should be applied. FSA take the same view.

5.2 Regardless of whether the regulatory framework was to change in England only, it will be important for FSS to be involved in the work being taken forward by the FSA to plan for potential legislative change and the need to review the current and future processes for regulating GM and genome edited food and feed. As the independent food safety authority for Scotland, it is FSS's role to be actively engaged in this work, which is within the scope of the UK FFSH common framework, to ensure devolved considerations are part of the process and we understand the impact in Scotland. This will also ensure that any recommendations that may present the case for having a consistent approach in GB, are taken to Scottish Ministers with our full involvement and importantly that we can ensure consumers in Scotland are aware of changes with regards to GM, genome editing and what that means for them going forward.

The Board is asked to:

- **Note** the update on potential legislative change in England should the definition of GMOs exclude organisms that have genetic changes that could have been achieved through traditional breeding or which could occur naturally.

- **Note** the intention to explore gaps in our understanding of consumer awareness and attitudes relating to GM and genome editing in Scotland, and social research that may be needed to inform the discussion around any potential change to the regulatory framework in England and/or the rest of GB.

- **Discuss and agree** the extent to which FSS officials should engage with the FSA when it comes to informing the development of a regulatory framework for genome edited products, in the event of legislative change in England.

- **Discuss and agree** how the Board wish to update Ministers on FSS planned involvement in this work at a GB level.

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16 March 2022

Annex A

Plant breeding methods not considered GM under current regulations – conventional plant breeding

Since the dawn of agriculture humans have sought to improve the crops they grow. From increasing yield to improving their tolerance to different environmental conditions, this is the science of plant breeding.

Cross breeding

Photos: I. Griffiths, IBERS, Aberystwyth

Cross breeding is where plants are crossed to produce offspring with desirable characteristics. This can be time-consuming as multiple cycles of selection are required to produce offspring with only the desired traits.

In these pictures there are two oat varieties, one with disease resistance, the other with high yield. They are being crossed aiming to produce a line with both disease resistance and high yield.

Speed breeding allows modern breeders to use controlled-environment growth chambers to achieve up to 6 generations per year instead of 2-3 under normal glasshouse conditions, cutting the time to produce a new variety.

Genetic approaches

The traits an organism displays are controlled by its genome, the DNA sequence present in every cell.

Plant breeders in the 1950s discovered that treating plants with radiation or chemicals caused mutations, increasing the genetic variation. Most mutated plants were unable to grow or had unwanted traits, but scientists could identify the few mutated plants which displayed useful novel traits and breed from these.
This is known as **mutagenesis**, and thousands of plant varieties have been produced in this way.

As the understanding of genetics has improved, plant breeders have been able to use this knowledge to speed up breeding, for example:

Marker assisted selection allows traits to be linked to specific pieces of DNA. This allows breeders to choose which plants and offspring use in their breeding programme, speeding up the breeding process.

Genomic selection allows breeders to estimate the combined effect of many different pieces of DNA from across the genome using advanced markers and statistical analysis.

Genetic modification

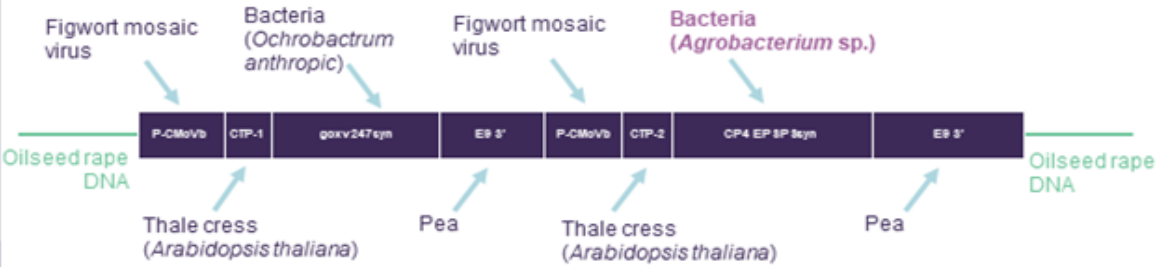
Genetic modification emerged in the 1980s as a method for introducing desired traits (characteristics) into plants, animals or microbes.

Genetic modification of plants involves introducing foreign genetic material to introduce a desired trait. This foreign material may be from one or more sources e.g. virus, bacteria, plant or animal.

Because of the technology available at the time, scientists could not control where in the genome the piece of foreign DNA was introduced and had to make the modification many times to identify a plant where the introduced DNA did not impact on an essential section of the plant's own DNA.

Most varieties of genetically modified crop available on the market are either herbicide tolerant or insect resistant, both these traits are based on pieces of DNA isolated from bacterial species.

Roundup ready oilseed rape



This is an example of the DNA fragment added into a GM crop. This diagram shows the cassette, or assembled DNA fragment, inserted into the oilseed rape genome to produce a variety which is tolerant of the weed killer Roundup (glyphosate).
It contains DNA from 2 plant species, one virus and 2 bacterial species.
The gene for herbicide tolerance comes from the bacteria *Agrobacterium*. The other pieces of DNA are functional, for example turning the gene on.

YieldGuard maize

Photo: Jan Samanek, Phytosanitary Administration, Bugwood.org

The only GM crop ever commercialised for cultivation in the EU is YieldGuard maize which was approved in 1998.
It contains a bacterial gene which gives resistance to the insect pest European corn borer.
Additionally, it contains DNA from a virus and from maize.
This variety was expected to also have herbicide tolerance, but the trait was lost during the imprecise development process.
In 2020 2 EU Member States cultivated small areas of this maize (98,152 ha in Spain and 4,216 ha in Portugal).

New breeding techniques

New breeding techniques (NBTs) or novel genomic techniques (NGTs) are umbrella terms used to group techniques which have been developed since the EU definition of a GMO was written in 2001. They blur the boundary between what could be considered GM or conventional breeding.
Some examples of these techniques are given below: