Contribution ID: 4d5d6cb7-bf2d-4fb7-bcfa-e47a4fe99ef0
Date: 14/05/2020 17:17:54

Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council

Fields marked with * are mandatory.

Questionnaire on new genomic techniques to contribute to the study requested by the Council

Discussed and finalised in the Ad-hoc Stakeholder meeting on 10 February 2020

Background

The Council has requested [1] the Commission to submit, by 30 April 2021, “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” (*i.e.* Directive 2001/18/EC, Regulation (EC) 1829/2003, Regulation (EC) 1830/2003 and Directive 2009/41/EC).

To respond to this Council’s request, the Commission is collecting contributions from the stakeholders through the questionnaire below. The study covers all new genomic techniques that have been developed after 2001.

Instructions

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques that are capable of altering the genetic material of an organism and which have emerged or have been developed since 2001 [2].

Unless specified otherwise, the term “NGT-products” used in the questionnaire covers plants, animals, micro-organisms and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research.

Please substantiate your replies with explanations, data and source of information as well as with practical examples, whenever possible. If a reply to a specific question only applies to specific NGTs/organisms, please indicate this in the reply.

Please indicate which information should be treated as confidential in order to protect the commercial interests of a natural or legal person. Personal data, if any, will be protected pursuant to Regulation (EU) 2018/1725 [3].

[1] Council Decision (EU) 2019/1904, OJ L 293 14.11.2019, p. 103-104, https://eur-lex.europa.eu/eli/dec/2019/1904/oj
[2] Examples of techniques include: 1) Genome editing techniques such as CRISPR, TALEN, Zinc-finger nucleases, mega nucleases techniques, prime editing etc. These techniques can lead to mutagenesis and some of them also to cisgenesis, intragenesis or transgenesis. 2) Mutagenesis techniques such as oligonucleotide directed mutagenesis (ODM). 3) Epigenetic techniques such RdDM. Conversely, techniques already in use prior to 2001, such as Agrobacterium mediated techniques or gene gun, are not considered NGTs.
[3] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

Guidelines

Please note that the survey accepts a maximum of 5000 characters (with spaces) per reply field. You might be able to type more than 5000 characters, but then the text will not be accepted when you submit the questionnaire. You will also receive a warning message in red colour below the affected field.

You have the option to upload supporting documentation in the end of each section. You can upload multiple files, up to the size of 1 MB. However, note that any uploaded document cannot substitute your replies, which must still be given in a complete manner within the reply fields allocated for each question.

You can share the link from the invitation email with another colleague if you want to split the filling-out process or contribute from different locations; however, remember that all contributions feed into the same single questionnaire.

You can save the draft questionnaire and edit it before the final submission.

You can find additional information and help here: https://ec.europa.eu/eusurvey/home/helpparticipants

Participants have until 15 May 2020 (close of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

Please provide the full name and acronym of the EU-level association that you are representing, as well as your Transparency Registry number (if you are registered)

If the name of the association is not in English, please provide an English translation in a parenthesis

Starch Europe

Please mention the sectors of activity/fields of interest of your association

Starch Europe is the association which represents the interests of the EU starch industry both at European and international level. Its membership comprises 27 EU starch producing companies, together representing more than 95% of the EU starch industry, and in associate membership, 7 national starch industry associations.

If applicable, please indicate which member associations (national or EU-level), or individual companies /other entities have contributed to this questionnaire

If applicable, indicate if all the replies refer to a specific technique or a specific organism

A - Implementation and enforcement of the GMO legislation with regard to new genomic techniques (NGTs)

*** 1. Are your members developing, using, or planning to use NGTs/NGT-products?**

- (x) Yes
- ( ) No
- ( ) Not applicable

* Please provide details

Starch Europe members do their utmost to guarantee that the ingredients they supply meet their customers' expectations, which is to be supplied with non-GM ingredients. Typically, testing procedures are in place on all the raw materials coming into their plants to guarantee they are non-GM. There can be cross contamination hence the importance of tolerance levels (EU legislation allows unintentional presence below 0.9% of authorized GM content to be exempted from GMO labelling). Regardless the fact that our members believe NGTs provide a valuable potential to our industry, our members are now concerned because NGTs cannot be traced, hence the testing procedures cannot guarantee that they have not been used. For the same reason, raw material suppliers cannot ensure they are providing non-GMO (conventional) material, according to the Directive 2001/18/EC currently in force, or demonstrate the absence of NGTs.
In the context of the Green Deal objectives, and notably the increased pressure on pesticide use, this technology, if permitted, could be extremely helpful. Whereas the above reflects the situation for the majority of our members, some of them work closely with farmers in cooperatives, whom they provide with seeds, on which they would like to be allowed to use these helpful techniques. we understand CRISP Cas is being specifically researched for the potential of providing potatoes in which the production of amylose was eliminated so only amylopectin starch with high stability is produced Please note that Starch Europe approach to GMOs is reflected by the statement that can be found here

*** 2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?**

- ( ) Yes

- ◉ No
- ○ Not applicable

* Please explain why not

Please read answer to question one. In addition, though, should NGT crops be commercialised outside the EU in coming years, it is to be envisaged that companies would include these crops and materials produced from them in their usual GMO traceability and control systems. Bearing in mind, of course, that today, testing for presence of NGT material as part of these traceability systems is not an option. In addition to the information provided in answering to question one above, please note that our members have monitoring plans to detect the content of unintentional GM material in their materials. These controls are performed by Polymerase Chain Reaction (PCR) based on the GMOs authorized in Europe (this does not includes NGTs). From analytical perspectives, the detection of NGTs-derived products being unclear, these monitoring plans are not adapted to such products. Therefore, our answer is ‘NO for the moment’ because it is difficult to detect them through analysis. To be able to do it, we ask the European Commission to clarify how to detect NGTs-products.

* 2 bis. Have you encountered any challenges?

- ◉ Yes
- ○ No

* Please provide details

Please see answers to questions one and two

*** 3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?**

- ◉ Yes
- ○ No
- ○ Not applicable

* Please provide details

YES, please see answer under question one. Considering the reluctance of consumers regarding GMOs, our members provide conventionally derived food products to their customers. If NGTs-derived products are considered to be GMOs and require such labelling, our members will not be able to accept raw materials derived from NGTs (traceability may exist but no control capabilities are able to identify them as said as answer to question one).

*** 4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products?**

- ○ Yes
- ◉ No
- ○ Not applicable

* 4 bis. Are you aware of any challenges encountered?

- ○ Yes
- ◉ No

*

5. Are your members taking specific measures to comply with the GMO legislation as regards organisms obtained by NGTs?

Please also see question 8 specifically on labelling

- ( ) Yes
- (•) No
- ( ) Not applicable

* Please explain why not

This survey refers to EU only, and can only be answered by Starch Europe in relation to the EU situation. Hence, there are not supposed to be any commercial organisms obtained by NGTs on the market. However, considering the difficulty also for our raw material suppliers to provide information on the use of NGTs and the fact that our members cannot detect NGTs products through analysis, they are not fully comfortable regarding the GMO legislation as regards NGTs-derived products. Indeed, our suppliers face the same difficulty caused by the absence of a detection method. Furthermore, there is also lack of clarity at this time regarding which organisms produced by NGTs are included within the GMO legislation, and which ones are not. Note also answer to Q6 below. As far as research/developments activities are concerned, as described in answer one, they are carried out in line with current GMO-legislation.

* 5 bis. What challenges have you encountered?

see answer to question 5

* **6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation?**

- ( ) Yes
- (•) No
- ( ) Not applicable

* What challenges have you encountered?

? NO. Support from the European Authorities would need to translate in clarifying outstanding aspects such as the definitions of ‘conventionally used mutagenesis techniques’ and of ‘newer’ mutagenesis techniques’. Also, given the lack of a method to identify NGTs derived products, guidance would be welcome on how the Institutions advice Starch Europe members to operate. Please also see answers to question 7.
As concerns the development activities described under point one, we understand that good support has been received from local authorities.

* **7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products?**

- (•) Yes
- ( ) No
- ( ) Not applicable

* Please describe the traceability strategy, including details on the required financial, human resources and technical expertise

Our members have experience on traceability for approved GM products, as well as for many products that meets a pre-determined set of specifications, with paper trails, agreements, auditing and controls throughout analytical approaches. These tools could be used to trace NGT products too. However these tools may be insufficient: the analytical approach is not possible today for NGTs-derived products, given the absence of a method and of an applicable threshold for detection, making compliance controls hard to implement.

* **8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?**

- ○ Yes
- ● No
- ○ Not applicable

* Please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise

see answer to question 5

* What best practices can you share?

See answer to question 5

* Please explain why not

Please see answer to question 7: no analytical approach exists and therefore, only strategies available are paper trails, agreements, auditing, which however have obvious limitations, due to the lack of a method and a threshold. At this point in time, there are no commercialised NGT crops (maize, wheat, peas and potatoes), confirmed as such, that will be subject to EU GMO labelling obligations, hence no specific measures are currently required.

* 8 bis. What challenges have you encountered?

See answer to third bullet point

* **9. Do you have other experience or knowledge that you can share on the application of the GMO legislation, including experimental releases (such as field trials or clinical trials), concerning NGTs/NGT-products ?**

- ● Yes
- ○ No
- ○ Not applicable

* Please describe for the:

- ☑ Agri-food sector
- ☐ Industrial sector
- ☐ Medicinal sector

Agri-food sector

Starch Europe members comply with the EU GMO legal regime. However, for those NGTs that are to be considered as GM, as a consequence of the ECJ mutagenesis ruling, the lack of a method to detect them, makes labelling obligations extremely complicated to be complied with, except where there has been clear traceability throughout the supply chain of a bulk crop or bulk crop material that is known to be an NGT at origin. The above is correct as regards producers buying raw materials for starch production. For producers doing contract production, including providing seed potato, the conclusion is that, if the framework within which NGTs are covered is the EU GMO regime, then production will not be possible due to cost of approval and labelling demands that will be hardly balanced with value creation.

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

The maximum file size is 1 MB

B - Information on research on NGTs/NGT-products

* **10. Are your members carrying out NGT-related research in your sector?**

- (x) Yes
- ( ) No
- ( ) Not applicable

* Please specify including subject, type of research, resources allocated, research location

YES – please see answer under point one. In general, current regulatory framework does not encourage research. Nevertheless, concerning the activity reported with answer one, we understand the following research is being carried out:

reduction of use of pesticides during cultivation of the crop (on the field).

reduced climate impact due to less processing of finished products. Through the use of NGTs, NGTs, the product keeps more of its functionalities and less processing is needed (starch with stable amylopectin).

reduction of anti-nutritional components in ready made products. Through the use of NGT we can eliminate anti-nutritional components in the plant. Anti-nutritional components prevent the extracted products from being used for food. (glycoalkaloids in potatoes).

* **11. Are you aware of other NGT-related research in your sector?**

- (x) Yes
- ( ) No
- ( ) Not applicable

* Please specify

There are several research projects running with public funding in a number of countries among which is Sweden. Due to commercial interests involved, the Secretariat of Starch Europe does not hold any specific information.

* **12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling on mutagenesis?**

Court of Justice ruling: Case C-528/16 http://curia.europa.eu/juris/documents.jsf?num=C-528/16

- (x) Yes
- ( ) No
- ( )

Not applicable

* Please describe

The current EU regulatory framework is a disincentive to support the development of NGTs in Europe even where such crops may have potential benefits in relation to food security, environment or nutrition.

*** 13. Could NGT-related research bring benefits/opportunities to your sector/field of interest?**

- (x) Yes
- ( ) No
- ( ) Not applicable

* Please provide concrete examples/data

. Please see answer to question 16

*** 14. Is NGT-related research facing challenges in your sector/field of interest?**

- (x) Yes
- ( ) No
- ( ) Not applicable

* Please provide concrete examples/data

As indicated previously, in light of current legislation development is not encouraged in the EU. This also hinders research

*** 15. Have you identified any NGT-related research needs/gaps?**

- (x) Yes
- ( ) No
- ( ) Not applicable

* Please specify which needs/gaps, explain the reasoning and how these needs/gaps could be addressed

Given the current situation with increasing population, climate change and the need to develop biodiversity it is essential that the agricultural and forestry sector are allowed to use modern technology to develop the crops we then process. NGTs are an essential part of this toolbox where we can support traditional breeding with the possibility to change specific properties in plants.

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

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C - Information on potential opportunities and benefits of NGTs/NGT-products

*** 16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest?**

(x) Yes
( ) No

* Please describe and provide concrete examples/data

As most Food Business Operators, Starch Europe members face an increasing demand for high-quality food, feed and bio-based goods using limited resources while producing less emissions. However, it is also one of the sectors already suffering from climate change and more extreme weather conditions as a consequence of the impact on the agricultural sector. The challenging goals of the European Green Deal and of one of its key components, the Farm to Fork Strategy, can only be achieved if the food chain is part of the solution to adapt to and to mitigate climate change. NGTs could be a much needed way to protect harvests and animals from pests and diseases and to improve the sustainability of the food system. Also, the IPCC report on climate change underscores the need for further breeding innovation to mitigate its effects such as resistance to water and heat stress and resistance to changing pest and disease risks. In addition, a very clear example is the breeding of crops with tetraploid genomes. On this type of crop the only realistic way of changing specific properties is NGTs, as the likelihood of having traditional mutagenesis working on all four genomes is more or less nonexistent or extremely time consuming (information relevant in particular for potatoes). The Secretariat cannot receive any detailed information on this based on commercial interests /competition and confidentiality law. Hence, it cannot provide more concrete examples than what responded under question one.
As most Food Business Operators, Starch Europe members face an increasing demand for high-quality food, feed and bio-based goods using limited resources while producing less emissions. However, it is also one of the sectors already suffering from climate change and more extreme weather conditions as a consequence of the impact on the agricultural sector. The challenging goals of the European Green Deal and of one of its key components, the Farm to Fork Strategy, can only be achieved if the food chain is part of the solution to adapt to and to mitigate climate change. NGTs could be a much needed way to protect harvests and animals from pests and diseases and to improve the sustainability of the food system. Also, the IPCC report on climate change underscores the need for further breeding innovation to mitigate its effects such as resistance to water and heat stress and resistance to changing pest and disease risks. In addition, a very clear example is the breeding of crops with tetraploid genomes. On this type of crop the only realistic way of changing specific properties is NGTs, as the likelihood of having traditional mutagenesis working on all four genomes is more or less nonexistent or extremely time consuming (information relevant in particular for potatoes). The Secretariat cannot receive any detailed information on this based on commercial interests /competition and confidentiality law. Hence, it cannot provide more concrete examples than what responded under question one.

* Are these benefits/opportunities specific to NGTs/NGT-products?

(x) Yes
( ) No

* Please explain

to the best of our knowledge

*

17. Could NGTs/NGT-products bring benefits/opportunities to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits?

- [x] Yes
- [ ] No

* Please describe and provide concrete examples/data

It is expected that the technology will provide significant advantages. Given the unfavourable situation in the EU, the only concrete examples are those deriving from the US/Canadian experience, which suggest that NGTs may significantly improve breeding. Amongst the benefits is the fight against late blight in Potato through NGTs - see attached study
Also, based on the knowledge our experts have of the existing technology, Starch Europe identified the following potential benefits for the EU potato starch industry:
Lower use of pesticides: 75% of pesticides would not need to be used;
Lower waste of tubers during storage: 5% of the harvest could be saved;
Increased yield of starch per ha: The content of starch in potatoes could increase of up to 20% ;
Better resistance to climate change: reduce by 5% harvest loss due to climate events;
Lower content level of glycoalkaloids: The content of glycoalkaloids in starch potatoes could be totally eradicated.

* Under which conditions do you consider this would be the case?

•�To be successful in bringing these benefits, an interconnected agricultural food supply chain must work together to develop and implement new approaches to the regulation of agricultural biotechnology that assures consumers and governments of the safety of the food supply, earns the trust and acceptance of consumers, and sets up coherent regulatory frameworks globally. In the context of the EU's Green Deal and Farm to Fork Strategy, this can only be achieved through a supportive policy which is truly holistic, co-ordinated, harmonised, co-owned, inclusive and based on science. This policy must be continuously evaluated against its objectives and should include incentives for both consumers and businesses

* Are these benefits/opportunities specific to NGTs/NGT-products?

- [x] Yes
- [ ] No

* Please explain

to the best of our knowledge

* **18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products?**

- [x] Yes
- [ ] No

* Please describe and provide concrete examples/data

If regulated according to the GMO-directive, there are no opportunities for any business in the EU to market crops developed by the technology. Given a situation where NGTs are regulated as crops developed by traditional breeding methods, it opens up big opportunities for SME/small scale operators to go into the market with NGT-products. A risk assessment on those types of changes will also be rather easy to do. Nevertheless, an assessment of NGTs must be flexible, applied on a case-by-case basis, and proportionate to the risk and the specific modification brought to the variety. The new situation will be that traditional breeding companies will be able to offer new varieties to all their customers as opposed to the situation we have had for many years where only large companies can afford to use GM-technology.

*** 19. Do you see benefits/opportunities from patenting or accessing patented NGTs/NGT-products?**

- (x) Yes
- ( ) No

* Please describe and provide concrete examples/data

NGT- products developed will normally be covered by existing legislation on breeders' rights. The discussion about the possibility to make patents on this technology and GMO has been ongoing for a long time. The basic reason for our very old system with patents is that especially small entrepreneurs should be able to put substantial investments into new developments and have a chance to get financial return on the investment. Larger companies normally have access to a larger market and thus are less dependent on patents. Limitations on the possibility to patent will reduce development efforts especially among SME/small scale operators. If there is a worry about access to new development this could be handled by compulsory licensing.

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

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fe6f9800-78f8-406d-99f2-591af2f76463/Starch_Europe_policy_on_GMO_for_food_and_feed_sector_.pdf

D - Information on potential challenges and concerns on NGTs/NGT-products

*** 20. Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest?**

- (x) Yes
- ( ) No

* Please describe and provide concrete examples/data

A situation where EU is regulating NGTs according to the GMO-directive while other parts of the world are not, will create a big challenge for the EU market. If European producers do not have access to NGTs – in case the EU would regulate NGTs according to the GM directive - they will be in a competitive disadvantage compared to other markets as they will not be able to benefit from the advantages of NGTs. This will create also a challenge in international trade, given the lack of detection methods, and could lead to importing NGTs without being able to detect

* Are these challenges/concerns specific to NGTs/NGT-products?

- ( ) Yes
- (x) No

* Please explain why not

A situation where the EU is regulating NGTs products in the same way as products from conventional breeding will not be problematic to our sector if the limitation on NGTs is that mutagenesis is exempted from the regulation if no new DNA is added to the cell. In that case the method produces the same products as old mutagenesis technology with less effort and in shorter time.

* **21. Could NGTs/NGT-products raise challenges/concerns for society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic challenges?**

- ○ Yes
- ◉ No

* Please explain why not

We believe that genetic engineering (including gene editing) is an important innovation for production agriculture and its applications have and will continue to show the potential to enable improvements in farmer livelihoods, sustainability, animal health and welfare, and the resilience of global agricultural supply chains. Interconnected agricultural food supply chain stakeholders must work together to develop and implement new approaches to the regulation of agricultural biotechnology that ensures consumers and governments of the safety of the food supply, earns the trust and acceptance of consumers, and set up coherent regulatory frameworks globally. Should NGTs not be regulated as GMOs, new plant varieties would anyway need to be tested and approved according to DUS in order to be sold on the market. However, were NGTs to be labelled, they would be virtually impossible to market because consumers would not accept them.

* **22. Do you see particular challenges for SMEs/small scale operators to access markets with their NGTs /NGT-products?**

- ◉ Yes
- ○ No

* Please explain and provide concrete examples and data

With the existing GMO legislation a general concern is that the provisions of the legislation cannot be fulfilled as there are no analytical methods to differentiate the plant/product. More specific for SMEs/small scale operators the cost is not realistic. Finally, the possibility for EU countries to oppose makes development extremely insecure. At the same time, if NGTs are exempted from the GMO legislation, SME/small scale operators will be able to access the market.

* **23. Do you see challenges/concerns from patenting or accessing patented NGTs/NGT-products?**

- ◉ Yes
- ○ No

* Please describe and provide concrete examples/data

see answer to question 19 above

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

The maximum file size is 1 MB

E - Safety of NGTs/NGT-products

*** 24. What is your view on the safety of NGTs/NGT-products? Please substantiate your reply**

From Starch Europe’s perspective, we believe that an assurance of safety for foods resulting from NGT is critical to build trust with consumers, governments, and our customers. Since NGTs can create a spectrum of changes from single nucleotides to the creation of new metabolic pathways, risk assessment frameworks for NGTs must be flexible and the degree of oversight commensurate with the risk

*** 25. Do you have specific safety considerations on NGTs/NGT-products?**

- (x) Yes
- ( ) No

* Please explain

Idem as above

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

The maximum file size is 1 MB

F - Ethical aspects of NGTs/NGT-products

*** 26. What is your view on ethical aspects related to NGTs/NGT-products? Please substantiate your reply**

The ethical aspects of NGT-products in general could be considered the same as for products developed by other plant breeding techniques.

*** 27. Do you have specific ethical considerations on NGTs/NGT-products?**

- (x) Yes
- ( ) No

* Please explain

see answer to question 24

Please upload any supporting documentation for this section here

The maximum file size is 1 MB

G - Consumers' right for information/freedom of choice

*** 28. What is your view on the labelling of NGT-products? Please substantiate your reply**

Starch Europe is in favour of consumers receiving the information they request and are entitled to. As concerns the labelling of NGTs, we believe that labelling would amount to a quasi-ban, due to the current negative public opinion perception of NGTs. Random mutagenesis and other traditional methods can induce many or few changes, derived products are not labeled because they are considered to be safe. It could be the same for NGTs. the Commission decides to label the products which have undergone a significant genome change. in this case, this rule should apply to all methods of genome modification -> as soon as a major change is induced in the genome, the variety is labeled (regardless of whether the method is traditional or new).We believe labelling of NGTs will only be possible if it would be supported by public campaigns that would create consumers’ understanding of their benefits and thus create public acceptance of their use

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

The maximum file size is 1 MB

H - Final question

*** 29. Do you have other comments you would like to make?**

- ◯ Yes
- ◉ No

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

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Contact

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Potato Research (2008) 51:47–57
DOI 10.1007/s11540-008-9089-y

Societal Costs of Late Blight in Potato and Prospects of Durable Resistance Through Cisgenic Modification

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Received: 19 October 2007 / Accepted: 21 April 2008 /
Published online: 28 June 2008

Abstract In the European Union almost 6 Mha of potatoes are grown representing a value of close to €6,000,000,000. Late blight caused by *Phytophthora infestans* causes annual losses (costs of control and damage) estimated at more than €1,000,000,000. Chemical control is under pressure as late blight becomes increasingly aggressive and there is societal resistance against the use of environmentally unfriendly chemicals. Breeding programmes have not been able to markedly increase the level of resistance of current potato varieties. New scientific approaches may yield genetically modified marker-free potato varieties (either trans- and/or cisgenic, the latter signifying the use of indigenous resistance genes) as improved variants of currently used varieties showing far greater levels of resistance. There are strong scientific investments needed to develop such improved varieties but these varieties will have great economic and environmental impact. Here we present an approach, based on (cisgenic) resistance genes that will enhance the impact. It consists of five themes: the detection of *R*-genes in the wild potato gene pool and their function related to the various aspects in the infection route and reproduction of the late blight causing pathogen; cloning of natural *R*-genes and transforming cassettes of single or multiple (cisgenic) *R*-genes into existing varieties with proven adaptation to improve their value for consumers; selection of true to the wild type and resistant genotypes with similar qualities as the original variety; spatial and temporal resistance management research of late blight of the cisgenic genetically modified (GM) varieties that contain different cassettes of *R*-genes to avoid breaking of resistance and reduce build-up of epidemics; communication and interaction with all relevant stakeholders in society and transparency in what research is doing. One of the main challenges is to explain

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the different nature and possible biological improvement and legislative repercussions of cisgenic GM-crops in comparison with transgenic GM-crops. It is important to realize that the present EU Directive 2001/18/EC on GM crops does not make a difference between trans- and cisgenes. These rules were developed when only transgenic GM plants were around. We present a case arguing for an updating and refinement of these rules in order to place cisgenic GM-crops in another class of GM-plants as has been done in the past with (induced) mutation breeding and the use of protoplast fusion between crossable species.

Keywords Cisgenesis · Cloning · Communication · Late blight · *Phytophthora infestans* · Potato · Resistance management · Selection · Transformation

Introduction

The most important disease in potato - the second most important arable crop (after wheat) in Europe - is late blight caused by a fungus-like microorganism (oomycete) with the scientific name *Phytophthora infestans*. The potato originates from the Andes in South America and in the beginning was grown in Europe in absence of this disease. When finally the disease struck in Europe, it led to famine, especially in Ireland. Initially the yields of potato decreased drastically but towards the end of the 19th century the disease was controlled with “Bordeaux mixture”, an environmentally very unfriendly crop protection agent consisting of copper sulfate and calcium hydroxide. Since mid-20th century chemical products based on manganese and tin became available and later also systemic products were developed. To prevent damage, growers in North and West Europe have to apply these chemical substances almost weekly. Besides the high costs incurred, the chemicals pollute the environment and give potato a bad image. In central and eastern Europe and in developing countries the crops are treated chemically much less frequently but here yields are much lower. A potato late blight resistant potato in terms of the triple P concept and principles would considerably reduce costs in regions with intensive potato production and would increase yields in areas with more extensive cultivation (Profit), would make production more environmentally friendly (Planet) and would reduce exposure to chemicals, would improve the image of arable farming and would enhance food security in developing countries (People).

Applying new scientific knowledge brings resistant potato varieties within reach. The concept of durable resistance combined with strategic resistance management in an integrated cropping system will have a major global impact. Wageningen Plant Sciences carries out a major research effort aimed at obtaining genetically modified potatoes to accelerate the solution of the late blight problem either using transgenes, but more preferably using innovative genetic modification with cisgenes (Jacobsen and Schouten 2007). Cisgenes are defined as natural indigenous potato genes or those from crossable species that are or can be used in current breeding programmes with which potato can make natural crosses. We aim at a proof of principle of an integrated resistance approach for the benefit of the industry (breeding firms and farmers) and the environment (much less spraying of plant protection chemicals). Acceleration occurs through a Genetic Modification (GM) approach by incorporation of only cisgenes from wild species (stacking them in currently grown varieties) rather than stacking during classical introgression breeding with *R*-gene containing wild species. In this GM-approach at least 15 years are saved as backcrossing and selection programmes to get rid of the linkage drag (introduction of unwanted properties) are not required. The major bottle neck at the moment for this approach is the detection and isolation of useful *R*-genes.

The proof of principle of the development of a *Phytophthora* resistant cisgenic potato variety may be a convincing way to breach the public ban on GM-crops and possibly also to contribute to the next version of the Directive 2001/18/EC which is streamlining the introduction into the environment of GM-plants and the release of GM-varieties. The approach involves in potato only the use of cisgenic *R*-genes in the absence of antibiotic resistance genes as selection marker.

The objectives of a European wide cooperative research and development project are to show the perspectives of a GM technique which distinguishes itself from the current transgenic one to arrive at a durable resistance strategy that will save the environment, reduce costs of production, increase yields and have a strong economic, ecological and scientific impact as desired in the Lisbon agenda (Lisbon Strategy 2004). There is a need not only for Europe but also for developing countries to make GM affordable and worthwhile in crops other than maize and soya bean, and to search how to arrive at a special classification of such cisgenic GM-crops.

The aim of this paper is to show the relevance of combating a major disease in arable farming in Europe, to highlight the scientific perspectives of innovative research that may reduce that problem significantly by the cisgenic resistance approach and to indicate its impact on the people, planet and profit aspects.

Economic Importance of Potato and Late Blight

Data for the calculations below were taken from databases of the Netherlands Potato Organization (NAO 2007), EUROstat (n.d.), FAOstat (n.d.) and KWIN (De Wolf and van der Klooster 2006). The latter contains all costs of operations in arable farming in the Netherlands. The most important commodity in the EU-25 by far is cereals (52 Mha grown per year) of which slightly less than half consists of wheat. Other cereals are barley, oats, rye and rice. Potatoes are grown on almost 2 Mha, comparable to sugar beet (2.2 Mha). Average sugarbeet yields are almost twice that of potato. So the total production of sugar beet is also double. Yet the value of the two crops is about equal as farmers receive roughly €50 per Mg for sugar beet against €100 per Mg for potato. This means that the total value of the 60 million Mg potato crop in the EU is about M€6,000, comparable to the sugar beet crop and about 1/5th of the €31 billion value of the wheat crop (at €250 per Mg).

Major potato producing countries with more than 1.5 million Mg of potatoes harvested are Belgium, Germany, Spain France, Italy, the Netherlands, Poland and the United Kingdom. The importance of the crop can vary considerably per country as e.g. Malta, with a small population, grows less than 1000 ha but a major proportion is exported as valuable early potato to northern Europe. To estimate the economic importance of the disease the Netherlands are taken as a case and some extrapolation will be derived from those figures.

Table 1 Potato production data in the Netherlands in rounded figures (NAO 2007)

Type	Area (ha)	Yield (Mg/ha)	Production Million Mg	Price (€/Mg)	Value (M€)
Ware	75 000	50	3.75	100	375
Seed	40 000	38	1.52	200	304
Starch	50 000	43	2.15	50	108
Total	165 000	45	7.42	-	787

The total area of 165 000 ha with a yield of 45 Mg/ha yields an amount of potatoes of 7.9 million Mg that represents an average value of about M€790 (Table 1). Applying fungicides is associated with costs of the chemical and the costs of applying them (machines, labour, and energy). The number of sprays varies between 10 and 16 per season. Seed potatoes receive fewer sprays as they are harvested prematurely but the chemicals used there are more costly per kg. Growers tend to alternate systemic fungicides with contact fungicides to avoid build up of resistance of the disease against the chemicals. Tables 2 and 3 show the most frequently used chemicals and their costs.

The cost of the 1,424 Mg chemicals applied on 165 000 ha in the Netherlands this way are calculated at M€61.1 per year. The costs of applying on average 15 times per season (machinery, labour and fuel) are calculated (KWIN, De Wolf and van der Klooster 2006) at €330 per hectare (M€54.4 national). This means that costs of control (chemical + application) amount to M€115.5 for the country per year.

Potato late blight not only leads to costs of control but also to costs due to losses. Incidental premature harvest and immediate delivery to the market due to bad storability in ware potato are estimated (once in 5 years on 10% of the area leading to 5% loss of value) to represent a value of M€1.4. Spraying machines leave tracks in the fields and locally damage the crop reducing yields by 3%. As crops are partly also sprayed because of other pests and diseases (especially seed potato crops) 1% of losses in the ware crop and starch crops and 0% of losses in the seed crops is attributed to the tracks representing a value of M€4.8.

In the Netherlands organic production of seed potatoes takes place on 350 ha and production of ware potatoes on 1050 ha with average yields of 27 and 29 Mg/ha, respectively whereas conventional yields are 38 and 50 Mg/ha. In total, organic production on 1400 ha yields 25,900 Mg less than it would have in a conventional situation. Assuming that half of the yield loss is due to late blight and assuming a farm gate price of €250/Mg leads to a loss of M€3.2. Adding up all losses incurred from late blight in the Netherlands leads to a figure of M€9.4. Added to the M€115.5 for control totals the costs of late blight in the Netherlands at M€124.9, which is 15.8% of total farm gate price (Table 1).

Conservatively applying 15% costs to the EU level, losses in the EU are estimated at M€900 (15% of M€6,000). In some countries in central Europe the costs of

Table 2 Most frequently used chemicals to control late blight and their costs per unit and per hectare (De Wolf and van der Klooster 2006)

Active ingredient	Trademark	Price in €
cymoxanil + mancozeb	Curzate	10.80 per kg
cymoxanil + famoxadone	Tanos	43.20 per kg
fluazinam	Shirlan	67.10 per l

Table 3 Amount and costs of late blight control chemicals per ha (De Wolf and van der Klooster 2006)

	Amount (kg/ha)	Costs (€/ha)
Ware potato	9	350
Seed potato	8	450
Starch potato	9	300
Average	9	370

application may be less as growers do not control or only a few times but here losses due to the occurrence of the disease are considerable. This is one of the main reasons of the low yields per ha in countries like Lithuania, Latvia, Poland and Slovakia that are about one third of yields in countries such as Denmark, Germany and the Netherlands. Globally 20 Mha of potato are grown with an average yield of 16 Mg/ha with a value of about M€32,000. A percentage of 15 of this represents a value of M €4800 as a very conservative loss annually caused by late blight. A late blight free potato would increase income and food security - with special impact on people in developing countries - where losses would decrease strongly and where the fourth commodity (after wheat, rice and maize) would increase even more rapidly than it does at present.

Environmental Aspects

Energy wise it costs about 25 GJ to grow one ha of potato. The application of 1 kg of fungicide per ha costs 40 MJ (energy content) and 2 l of diesel (×55 MJ per l indirect costs such as the costs of making the machinery included) makes it 150 MJ per spray. If crops are sprayed 15 times total energy costs are 2.25 GJ which represents 9% of the total energy costs of potato production. (All data from KWIN, De Wolf and van der Klooster 2006).

Other environmental costs are Environmental Pressure Points as, e.g., calculated by the Netherlands Centre for Agriculture and Environment (CLM). The Netherlands Committee for the Admission of Crop Protection Agents (CTB) uses these norms for groundwater and surface water in their admission procedures. There is some environmental pressure from fungicides used in controlling late blight, especially the effect of mancozeb on groundwater, but this is only a fraction of pressure from a treatment with herbicides against weeds or insecticides against pests. The effect of fungicides on human health is also much less than that of herbicides and especially insecticides according to the “Safety Information Sheets” that chemical companies have to establish following EU directives (taken from the websites of companies such as DuPont (mancozeb) and Syngenta (fluazinam)). The active ingredients can cause some damage (irritation of skin or eyes) but are not very toxic with LD_{50} values between 2000 and 5000 mg/kg whereas, e.g., insecticides are much more toxic with LD_{50} values below 100 mg/kg.

Employment

In the Netherlands potatoes are grown by 2,200 seed potato growers, 7,000 ware crop growers and 2,500 farmers who produce starch potatoes (NAO 2007). The whole potato sector - from farm gate onwards - adds value: there are over 50 export and breeding companies, over a dozen large processing factories that process 3.2 million Mg of potato into deep frozen French fries, crisps and chilled products and into starch for food and non-food uses. The total consumer value of fresh and processed potato in the Netherlands is estimated at over three billion Euros: four times the farm gate price. In the rest of Europe this is somewhat less (less seed and processing) but the 6 billion Euro farm gate price at the consumer level will represent a value of over 15 billion Euros.

Durable Resistance Against Phytophthora (DuRPh)

Breeding for resistance against late blight proved not very successful over the last 100 years. The most important source of resistance was introgressed early to mid 20th century from the wild potato species *Solanum demissum* by interspecific crosses and successive backcrosses with cultivated potato and simultaneous selection for resistance. However, all 11 major resistance genes (*R*) in due course were overcome by virulence of the disease. Mainly four of these *R*-genes have been used in varieties as single resistance gene or in combination. To combat late blight is to get involved in the struggle between the virulence genes of *Phytophthora* and the defence genes of *Solanum*. The oomycete contains avirulence genes that produce a protein that when recognised by a cell in the resistant plant triggers it to kill itself. The result is a hypersensitivity reaction that makes it impossible for late blight to infect the plant. Late blight, however, always introduced pathotypes with absence or mutated avirulence genes so that the variety did not recognise the germinating spore at cellular level so that it became susceptible.

Given the economic, social and environmental implication of late blight and the fact that conventional breeding is not able to enhance resistance, Wageningen University and Research Centre in the Netherlands started an ambitious programme in 2005 that will run for 10 years. The research programme aims at considerably reducing the costs of late blight and involves some principles that may influence positively the application of GM-food crops: continue the use of existing successful varieties but improved by cisgenic *R*-gene modification:

- only ‘free’ (without breeders rights) potato varieties are used that have proven to be safe and are adapted to growing conditions in Europe and elsewhere and that are known by consumers and processors;
- the cisgenic modifications are only carried out with single or low numbers of natural indigenous *R*-genes directly isolated from wild potato species that can be crossed with *Solanum tuberosum* following conventional techniques in potato breeding;
- the transformation will only be carried out with cisgenes without selection markers such as resistance against herbicides or antibiotics.

The initiative aims at showing the proof of principle of this approach, not at the creation and exploitation of commercial varieties. Once the principle is proven commercial companies will develop varieties for their benefit.

Therefore, in the programme but also in other, matching, projects, *R*-genes are identified, isolated from the genome of wild species and transferred (single or combined in sets of varying composition) to some ‘free’ varieties. The resulting genotypes are screened for resistance to late blight, their agricultural, processing and consumer characteristics are tested and they are screened for (desired) resemblance to the original variety. We expect that resistance management needs continuous attention, not only during the research phase but also once new resistant varieties become operational. To learn of factors that affect public acceptance of a cisgenic late blight resistant potato variety, resources (funding and scientists’ time) are allocated to listening and communication with the general public.

The five themes needed to achieve the aims are briefly outlined below.

Theme “Cloning”

Before the start of the programme, a limited set of *R*-genes was cloned (van der Vossen et al. 2003, 2005), which were freely available for research but not for commercial application. It is planned that in this programme 4-6 additional *R*-genes from other wild species, e.g., *S. berthaultii, S. pinnatisectum* and *S. chacoense* will be isolated (2nd generation genes). In this way, together with other matching projects, a set of 11-13 *R*-genes will eventually become available for the design of novel *R*-gene cassettes which will be transferred to several different potato varieties (see theme “Transformation”). These GM varieties will subsequently be used in the subsequent themes. The additional set of *R*-genes will be cloned through candidate gene and map-based cloning approaches which include the following steps:

- Creation of segregating populations for late blight resistance to detect major genes;
- Determination of the resistance spectrum and genetic basis of late blight resistance in *Solanum* genotypes previously identified as harbouring late blight resistance;
- Development and identification of molecular markers genetically highly linked to the *R*-loci of interest;
- Generation of physical maps of the *R*-loci using large genomic DNA insert libraries (BAC libraries);
- Functional characterization of *R*-gene candidates present on BAC clones that span the *R*-loci through complementation analysis.

In the meantime (mid 2007), at least 6 *R*-genes from different wild species have been isolated in other projects which are not only based on map based cloning, but also on allele mining. New developments in the field of effector research of *Phytophthora* are influencing the quick isolation of *R*-genes by allele mining. It means that based on this research interspecific homologues of *R*-genes can be recognized and isolated more easily and that the *R*-genes have to be divided into different classes. Members of the same class, with a similar resistance spectrum, can be found in different species. This throws also another light on the classical resistance breeding with *R*-genes. For a durable resistance the cloned *R*-genes, preferably belonging to different classes, are used for cisgenic transformation of potato varieties in the proof of principle experiments.

Theme “Transformation”

The goal of this theme is to transform a set of potato varieties with *R*-gene cassettes carrying varying numbers and different combinations of cloned *R*-genes. These

GM-varieties are ultimately used in the theme "Resistance Management" to study the effect of *R*-gene pyramiding and mixed cultivation on the epidemiology of *Phytophthora* outbreaks in the field. For the development of the cisgenesis concept, various *R*-gene cassettes are transferred to the selected potato varieties using the cloned indigenous *R*-genes combined with marker free transformation technology. The marker free technology is based on an efficient transformation protocol so that a sufficient number of transformed regenerants can be selected without using antibiotic or herbicide resistance selection markers in the vector (de Vetten et al. 2003; Heeres et al. 1997, 2002).

The following steps are of importance:

- Analysis and optimization of transformation efficiencies of a selected set of potato varieties;
- Development of single and multiple *R*-gene cassettes using different sets and 'generations' of *R*-genes;
- Classic and marker free transformation of three different potato varieties with *R*-gene cassettes carrying different combinations of *R*-genes by using optimized *Agrobacterium tumefaciens* mediated transformation protocols;
- About 50-100 independent transformants per transformation event are grown from callus on inoculated explants and subjected to a functional, phenotypic and molecular analysis before being handed over to research within the theme 'Selection".

Theme "Selection"

The activities in this theme are aimed at the selection of potato transformants that express the new late blight resistance gene(s) correctly and have no discrepancies from the wild type due to the transformation event or to somaclonal variation arising from the callus stage in the transformation procedure (Dale and McPartlan 1992; Kaniewski and Thomas 1999). Plant selection on resistance and morphology starts in vitro in the growth chamber, and is continued in the greenhouse, the gauze house and in the field in the years thereafter. A number of selected plants in the first field experiment will be characterized molecularly in order to level up the field experiment into a next stage for larger experiments. For stacking of *R*-genes it is important to investigate possibilities for testing their biological activity one by one against *Phytophthora*. For stacking of genes without available virulent isolates, the availability of *Avr*-genes with their HR reaction is a great help. It is important to know before-hand whether the *R*-genes of interest do have the potential to be more durable. Investigations with diverse isolates of *Phytophthora* will therefore be crucial.

One of the aims in this theme is also the creation of flexible varieties. We assume that even when a number of (new) *R*-genes are stacked in current varieties, the risk remains that late blight may overcome this barrier. Whenever this will occur we should have GM-lines available with a new set of potentially more durable resistance genes to replace the first ones. Temporal and spatial variation in the composition of the set is part of the approach. The selected plant material is used in the theme "Resistance management".

Theme "Resistance Management"

Transformation of a potato cultivar using different cassettes of resistance genes allows diversification of resistance within and between fields, without agronomical disadvantages, to avoid or delay adaptation of the *P. infestans* population to this new resistance. A combination of simulation and field experiments is used to select the most effective options for spatial and temporal diversification of resistance. Model tools, available from adjacent research within the Netherlands Umbrella Plan Phytophthora, allow simulation of *P. infestans* epidemics in space and time under a wide array of scenarios including variation in spatial scale, level of resistance, maturity type, climate and late blight management strategy. Models are used as a selection tool to identify potentially efficient options for diversification of resistance in space and time. Selected strategies will then be evaluated in multiple year field experiments for their capability to reduce infection risk and epidemic development of potato late blight (Skelsey et al. 2005).

Additionally, monitoring of the current Dutch *P. infestans* population has revealed very complex virulence spectra for currently employed *R*-genes. The current Dutch *P. infestans* population is also being monitored for virulence for new resistance genes, to be introduced as transformation material. We annually monitor the *P. infestans* population for presence and frequency of virulence against new resistance genes.

Theme "Communication and Interaction"

Communication and interaction with all relevant stakeholders in the Netherlands, transparency about what research is doing and explanation of the nature of the GM crops (cisgenic and marker free) aimed at acceptance of genetically modified cisgenic potatoes by the majority of consumers are needed. The ultimate goal is that stakeholders receive all relevant information about pros and cons of the development of a cisgenic *Phytophthora* resistant potato, in such a way that they are able to develop their own opinion about this innovation. Similar approaches have been developed with respect to stakeholders' attitude in the Netherlands concerning transgenic herbicide resistant crops (Lotz et al. 1999) and the way Dutch stakeholders have agreed on measures to prevent inadvertent admixture of genetically modified organisms with products from conventional and organic farming (Van de Wiel and Lotz 2006).

First we identify relevant stakeholder groups. With these groups and in interaction with the European Commission and researchers, themes are selected that are worked out in, e.g., workshops. A first set of proposed themes consists of the present societal costs of *Phytophthora* (in terms of people, planet, profit), the development of varieties with cisgenes, marker-free constructs, compared to varieties from traditional breeding, field experiments, preconditions and results, implementation into crop protection strategies, non-food applications versus food application. Stakeholders include breeding companies (field trials, acceptability), representatives of growers (resistance and cropping strategies), representatives of organic growers (acceptability of approach), processing industry regarding use of GM potatoes, consumer organizations, water authorities (costs of cleaning impurities), NGOs and policymakers (regulation and legislation).

Prospects

Flexible Varieties

Many potato varieties were bred dozens of years ago and some are almost one hundred years old, e.g., varieties Bintje in the Netherlands and Russet Burbank in the USA. Apparently it is very difficult to improve taste and processing quality of ware potatoes. The approach chosen will allow the insertion of genes in existing varieties thereby maintaining the desired quality but adding an important trait: sustainable resistance to late blight. The technique allows breeders to insert different combinations of genes in different varieties and even to diversify in space and time. Theoretically different farms could have a different set of resistance genes or a field could have a mixture of plants with different sets of genes. This should considerably reduce the chance of breaking resistance and if it does it would strongly reduce the spread of the disease because of a slower production of spores and of a reduced rate of infection. To further reduce the chance of resistance breaking, every few years newly discovered *R*-genes could be inserted replacing the old ones, thus continually staying one step ahead of the pathogen. The cost of such a breeding programme with cisgenic insertions would only be a fraction of the total costs associated with late blight exceeding 100 M€ per annum in the Netherlands alone. Aspects that need attention are the protection of intellectual property, registration of cisgenic improved varieties resulting in, e.g., new 'Désirées' and 'Spuntas' with enhanced resistance but for the rest indistinguishable from the original 'wildype'.

Acceptance, Legislation and Deregulation

National legislation regarding GM varies from country to country. There is a request and a positive attitude within several factions important in the potato chain of the European Union to warrant less stringent oversight for cisgenic plants, and that legislators differentiate cisgenic from transgenic plants. Transgenic plants contain genes from plants or other species that could not be introduced through introgression (crossing). Cisgenic plants contain indigenous genes from crossable species. The GM-directive 2001/18/EC in the European Union has not made a difference between the two types of GMOs discussed here. Cisgenes with their native promoters introduced into a potato variety do not introduce new phenotypic traits into a species as they were there already. They do not introduce new fitness traits so putatively will not influence the environment nor the risks in food or feed in another way than with traditional breeding. Cisgenesis may even be safer than conventional breeding because it prevents introduction of genes via linkage drag which could lead to all kinds of unwanted traits (e.g., increase glycoalkaloid content to a higher level than allowed in the regulations for breeder's rights). Results of research projects such as DuRPh on durable resistance through gene stacking should help national and EU legislators in establishing rules and regulations that are properly targeted at societal needs.

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Association des Amidonniers et Féculiers

AAF POLICY ON GMOs FOR THE FOOD & FEED SECTOR

Regulations 1829/2003/EC and 1830/200/EC[1] on GMOs have been published in the Official Journal on 18 October 2003 and entered into force on April 19th, 2004.

This legislation defines rules for the placing on the market and labelling of GMOs and food and feed products derived from GMOs. It also defines the rules for traceability of GMOs as well as of food and feed products derived from GMOs.

Biotechnology in general is interesting as it introduces new possibilities (reduction of pesticides, mycotoxins, water and soil pollution etc). However, it is clear that most of the European consumers do not accept GMOs for food use and that, as a consequence, the European starch industry will continue to require that food ingredients and additives to rely upon conventional[2] supply.

Therefore, the AAF will **continue to respond to current customer demands for conventional products in compliance with EU law as long as consumers refuse GMOs for food use.**

So far, the AAF succeeded to satisfy the demand of consumers for conventional ingredients for the food and drink industry.

Addendum I - Traceability

The AAF has always supported the European Commission's initiative to put into place a compulsory system for traceability in general[3], and for GM raw materials in particular[4], with a clear definition of the responsibilities of each operator of the food and feed chain.
The traceability is a step by step approach where each operator of the food chain is responsible for the traceability of its supply and of its sales ("from whom to whom" traceability approach). As a result, each operator is individually responsible for the attainment of an adventitious presence as low as technically achievable.

[1] Regulation (EC) n°1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.
Regulation (EC) n°1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

[2] By "conventional" products, the AAF, in line with several European institutions who used this term at many occasions means the products to which the GMO traceability/labelling obligations do not apply. The AAF recommends that manufacturers do not use terms such as "traditional" or "GMO-free" as there is no clear definition of what this means, and it is likely to be very difficult to achieve - and substantiate - in any commercially complex food product. There is no EU legislation covering the use of the term "GM free" on food labels.

[3] The traceability of conventional maize products is not part of the GM legislation, but is legally required, as from January 2005, under Regulation 178/2002/EC of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matter of food safety. Article 3.15 of this Regulation defines traceability as the "*ability to trace and follow a food, feed, food producing animal or substance… through all stages of production, processing and distribution*".

[4] The traceability of GMOs and GM derived products is defined in the Regulation 1830/2003/EC of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Article 3.3 of this Regulation defines the traceability of GMOs as "*the ability to trace GMOs and products produced from GMOs, at all stages of their placing on the market, through the production and distribution chains*".

Association des Amidonniers et Féculiers

The starch industry put into place, on a voluntary basis, Quality Management Systems such as ISO 9000, including internal operational traceability, well before 1999. All the procedures related to the procurement of conventional maize were further integrated in these systems to ensure that no GM maize enters the manufacturing of our products:

a) There must be adequate measures at all stages of the supply chain, including transport; these must be transparent and documented. For example: seed producers → growers → collectors (who generally also handle the drying) → brokers and traders → procurement departments of the starch producers → maize starch plant.

AAF members have been able to comply with the requests of their customers for conventional ingredients and will continue to do so.

Addendum II - AAF Policy on GM Potato

The Addendum takes into consideration the fact that a new GM variety of starch potato has been approved for cultivation in the EU for the exclusive use in non-food and feed applications. AAF members are committed to provide non-GM potato starch products and ingredients when their customers so require.

The AAF fully trusts that the EFSA and the Commission will have adopted adequate safety measures to avoid any adventitious presence in crops of new GM varieties. It is confident as well that the Commission and Member States will make sure that such measures will be fully implemented.

Nonetheless, the AAF wants to confirm its policy on GMOs and in particular

1. Its determination to serve the demand of its customers;

2. Its firm support of traceability systems.

The AAF trusts indeed that all partners in the chain will take all necessary measures (safety measures, segregation systems, monitoring, etc…) to avoid any possible commingling.

Issued in May 2006
Amended in October 2011