Consumer vote

Results of the BfR Consumer Conference "Genome Editing in the Field of Nutrition and Human Health" 2019

Consumer vote on the use of genome editing in the field of nutrition and human health, from 30 September 2019

1 Introduction

As the consumer group was made up of a diverse range of people, the views expressed are accordingly heterogeneous. The assessments and opinions expressed in this vote were shared by varying numbers of individuals within the group, even when this is not indicated. Even when the words "we" and "us" are used, this does not literally mean the entire group.

First, a few introductory points need to be discussed:

Genome editing (GE) is a complex subject and cannot be dealt with in its entirety in the short period of time available. As consumer group, we agree that in light of climate change and massive loss of biodiversity, humanity is presented with some major challenges. Just as there is no single cause, there is also not just one all-encompassing solution. The majority of our group believes that our way of life and economic system must become more sustainable as a whole. This also includes agriculture. Remodelling agriculture to make it more sustainable is one of society's more pressing tasks.

However, it is important that no new technology obfuscates or thwarts the necessity for society to become more sustainable. For this reason, new approval criteria should be established for all new products, regardless of technology. The Norwegian approval process could serve as a guide for this, for example. As long as the effects of a product on sustainability, health, the climate, species diversity, animal welfare and other things are considered during the approval process, we believe that GE has some potential to make improvements in this area.

When assessing the new genetic engineering techniques which are summarised under the term "genome editing", there are greatly diverging opinions in our consumer group. We are of the view that in these cases, it is not the technology that should be assessed, but the final product. Neither the existing mutagenesis breeding nor breeding with genome editing technology are dangerous per se. Certainly, mutagenesis breeding has also led to critical applications. If genome editing is associated with more sustainability in an overall concept, we believe that the technology can be used sensibly.

The group is aware that no technology is 100 % safe and mistakes can always occur. The principle of precaution should direct all decisions and actions.

No method is good or bad per se. Genome editing is a tool which must be handled responsibly. Rules are needed for this. Maintaining diversity and protecting the environment and soil should always be considered.

Alternatives to genetic engineering are also not necessarily less risky; the use of pesticides also affects many beneficial insects. Classic mutagenesis creates thousands of unwanted modifications in the genome.

Genome editing methods should be considered in a nuanced way. Products must be inspected for risks instead of assessing the process as such. It must be clarified whether the final product of genome editing technology really falls under the Genetic Engineering Law. Point mutations can also occur in natural ways. It is not possible to verify the application of

genome editing, except when foreign genes are introduced. Techniques must be developed to verify the use of genome editing.

To date, there are no methods allowing the safe application of genome editing directly in humans. Only the ex vivo treatment of cells works so far.

Basic research on the opportunities and risks of using genome editing must also be funded and carried out by the state. Public funding should go towards protecting humans, animals and the environment. The aim of research is to improve life and make it easier, not to make profit. Funding for genome editing applications must be checked critically and reduced if necessary.

Patent holders must document the procedure, and supply, verify and publish verification methods.

There is an almost general consensus that it is practical and necessary to spread successful cultivation methods and techniques from ecological agriculture into conventional agriculture as well. There is also an almost general consensus in the view that use of classic genetic engineering has promoted the industrialisation of agriculture. Moreover, herbicide resistances (rapeseed/soya) and toxin production (Bt corn/Bt cotton) have ultimately led to a rise in pesticide use, due to increased resistances. Besides these negative uses of classic genetic engineering, a majority of us find the transfer of foreign genes to be ethically questionable.

The cross-applicational demands of the group are:

- Maintaining a principle of precaution
- Freedom of choice for consumers
- Freedom of information and transparency
- Priority of social aspects over economic interests
- Patent law reform: no patent protection for living beings
- Liability for unexpected damage caused by the manufacturer
- Labelling genetically modified foods, even when animal feed has been genetically modified (e.g. for milk and meat)

2 General

Opportunities

Creating a better understanding of gene interactions and recombination effects

New freedoms arising from compensation opportunities

Risks

Unintended genetic engineering modifications ("off-target mutations" and epigenetic modifications) which cannot be recognised with applied genome analysis methods or clinical examinations, and which would only be detectable through their long-term effects.

Verifiability remains a major challenge.

The removal of freedom of not having to make a choice.

Abuse of the technology for biohacking/bioterrorism

Demands

A societal consensus must be found on the use of genetic engineering/genome editing. Politics must not decide alone. Promises of salvation and demonisation are both misleading and useless. We demand factual and honest information. Transparency is needed.

Interventions in genes by humans are still genetic engineering, even if they are no different from natural mutations. International regulations and monitoring are needed here. A moratorium on gene drive applications must be declared.

Improved protection against illegal manipulations and better legislation with appropriate punishments are required. The use of genetic engineering and genome edition needs a clear legal framework to ensure that it is only carried out by appropriately qualified people. This should be implemented throughout the EU or on a global scale.

More funds should be made available for independent research on the risks of genome editing procedures.

There is a lack of clear commitment from the government towards the principle of precaution. This must apply for the entire EU and the government should advocate for it.

Current reporting in the media is mainly positive. This should be neutral in general and also with regard to assessment. We demand better, factual and comprehensive information for the general public.

A revision of this consumer vote in a final meeting is desirable.

The ECJ has made it clear that genome editing should be classified as a genetic engineering procedure, and associated products should be liable under the Genetic Engineering Law accordingly. Some consumers feel there is a lack of a clear statement from the government showing they accept the verdict and therefore reject unregulated release. This must also be represented on a European level. To avoid fraud, a monitoring strategy to improve control should be drawn up by independent experts.

There is a lack of a committee independent from the industry, which is equally filled with NGO representatives and which decides on awards for agricultural subsidies with regards to the needs of sustainable and socially balanced agriculture.

Organic farming needs more funding. The services it provides to the system should be considered in this regard. Funding should include research and teaching. Research grants for

non-sustainable developments should be diverted towards developing, testing and spreading organic farming.

Urgent changes are needed in the field of patent law: patents which block the breeding of new varieties in organic farming, such as "absolute product protection", must not be granted and patents which have already been granted must be declared invalid. The demand "no patents on living beings" must be reformed to end its dependence on patent applicants.

For approval processes to ensure controllability, it must be possible to identify a genetically modified, patented plant or its seeds. The patent applicant should therefore be required to document the intervention performed in the genome, and publicise and verify a detection procedure. This will then enable authorities to detect cases of fraud or uncontrolled propagation - even to other species - and apply penalties accordingly.

Genetically modified organisms must be tagged even if they do not demonstrate any easily detectable differences to conventional organisms.

The question of liability for unexpected damages must be legally regulated in accordance with the costs-by-cause principle. Any applied methods leading to failures and therefore representing a risk must be reported and made internationally known. This should help to ensure strict product liability.

The use of genome editing must be regulated and controllable. The development of regulations for it must be transparent, and the authors must be made known. Reports and decisions in this regard must be published. It must be ensured that freedom of choice is the governing principle and continues to be so.

Research which is partly or fully funded by taxes must be published.

A costs-by-cause principle with strict product liability is demanded, in particular when using genome editing in association with nanotechnology. This applies both to protecting the lives and health of humans, and fixing and compensating for damages, e.g. for organic farmers.

Some participants demanded a clear labelling of products which were manufactured using genetic engineering methods. Further, some participants of the consumer group also demand that the use of genome editing be prohibited if other, non-damaging procedures are already in use.

Compatibility with the environment on release must be testable and adhered to in order to prevent resistances, as well as protecting the lives of non-livestock.

The importation of organisms which were bred using genome editing must be regulated. Prohibited release and illegal import must be met with penalties, which must be determined in the German Criminal Code.

The following demands concern approval procedures for food and animal feed:

- Independent research
- Assessments should not be based on studies that the company has carried out itself.
- Universal guidelines about proof and studies to be produced
- Universal guidelines about performing animal feed trials
- Risk assessment must be adapted to meet the challenges of genome editing, e.g. from the food and animal feed sector: feeding trials of 90 days on rats are too short.
- Long-term feeding trials should be performed even after approval.
- A re-evaluation should take place one year after approval.
- Consider general ecological effects appropriately, and also test thoroughly

An objective analysis of opportunities and risks should be performed, so that only modifications and mechanisms which provide societal, climate or other benefits that outweigh the risks are approved.

Companies' business models should be regulated when there is a benefit in doing so from a general social perspective.

There are no long-term studies as the technology is relatively new. Therefore, a regular evaluation must take place, and the exchange of experiences and side effects must be facilitated. The public (consumers) must also be involved in this in order to appraise the current state of research.

The use of genome editing is not inevitable. It is linked to insufficient knowledge and error-prone technology. This subjects the population to unpredictable dangers. Insolvency-proof, developer-funded provisions for compensation are a prerequisite for using genome editing.

The work of national and international ethics committees must be supported and strengthened.

The results of breeding through genome editing, like those of breeding through other methods, present a potential risk to humans and the environment. This risk appears to depend greatly on the modifications made. It is therefore not a question of assessing the technological basis. Tests on a case-by-case basis must be established / maintained at a product level.

Genome editing has been controversially discussed by experts and consumers. State-financed educational and information material should take this into account. For example, information material can be developed and distributed inter-departmentally(BMU/BMBF).

NGOs must be given access to funds and information to monitor and question general development as well as special developments.

It should be the state's task to inform consumers about groundbreaking scientific advances such as genome editing, e.g. via a state scientific magazine or social media.

Genome editing is a second choice. We cannot endanger centuries of evolution with economically motivated developments, out of responsibility for generations to come. Genetic engineering, including genome editing, should only be used if the results cannot be achieved by changing the circumstances or using existing alternatives.

Opinions among the group are divided on the subject of different regulations for transgenic and non-transgenic modifications, and equating point mutation by means of genome editing with conventional mutagenesis;

- some consumers believe that a clear distinction should be made in the Genetic Engineering Law between the use of foreign DNA and the use of GE for generating point mutations. The latter should be equated with the use of mutagenesis.
- By contrast, some consumers demand an examination of the question whether dealing with organisms from point mutation can be equated with those from mutagenesis.
- Some consumers see a clear distinction between point mutations which have resulted from or been produced by genome editing, conventional breeding or conventional genetic engineering.

Public research must keep up with privately financed research.

Standardisation of the legal patchwork as a long-term global aim.

Questions about possible ecological effects and the our ability to undo them must be an elementary part of the approval procedure.

Researchers and scientists should create a public international database in which all GE projects are recorded, and are therefore accessible.

3 Humans

Opportunities

The responsible use of genome editing can offer individuals the opportunity to avoid an existing or expected illness or impairment, and therefore have the perspective for a full life.

Genome editing can offer a new experimental therapeutic approach for fatal diseases, for example, as an alternative to chemotherapy. In future, research may also lead to the cure for formerly incurable hereditary diseases.

Developing individual therapies for humans.

Risks

The use of genome editing may trigger autoimmune reactions in patients.

There is a risk that individualised therapies may only be accessible to a wealthy minority.

Using genome editing in the germ line can increase the pressure for optimisation the individual is confronted with. Societal pressure on parents who choose to have a disabled child despite the availability of treatment opportunities may increase in future. The problem of making a decision on a "life worth living" may arise.

Demands

Human self-determination is the priority. Humans have the right to decide to have children with an impairment if they so wish. Society must fulfil its duty of care. Stigmatisation of any kind contradicts a free, self-determined life.

The regulations of the Embryo Protection Law must also apply to genome editing in future. Interventions in the germ line cannot be made; patents in this field should be unlawful.

Internationally binding regulations should be established with regards to germ line interventions. The government should be involved in developing these regulations.

Only somatic therapies should be approved, but no optimisations. It must not be possible to patent modifications to human genes.

Data security and protection must be observed in all instances.

In general, research and the use of genome editing in humans should only occur in the context of secure, fact-based risk assessment. A risk-benefit appraisal should be carried out for each patient before use. Higher risks may be taken in cases of diseases with terminal prognoses. Patients and relatives must be fully informed about opportunities and risks, and their comprehension must be ensured. Doubts must be communicated.

Health insurances should pay for the costs of curing rare hereditary diseases, so that use of the technology is not only accessible to the wealthy.

One consumer believes the use of genome editing in human cells to be fundamentally wrong, because it is not possible to draw a line between curing and optimisation.

4 Animals

Opportunities

Some of the consumer group see the use of genome editing for animal husbandry as an opportunity to increase animal welfare.

Livestock breeds may become resistant to pathogens through the use of GE. This may in turn lower mass deaths and reduce the use of medication.

By improving breeding, fewer animals must be kept and slaughtered.

Animal characteristics which have died out could be reintroduced.

Rare species may be protected through resistance to epidemics.

Risks

The future effects of genetic modification are difficult to estimate and cannot be reversed.

There is the danger of an unchecked spread to animals that have not been genetically modified.

There are risks resulting from monopolisation and the subsequent dependence on individual suppliers, and increased costs arising from patenting.

Species diversity may decrease.

For some of the consumer group, it is doubtful whether the use of genome editing may not rather exacerbate the problem of factory farming and high meat consumption.

Demands

When introducing new breeding procedures, these must also be tested from animal welfare and climate protection perspectives. A comprehensive, state-supervised risk-benefit analysis is needed.

There are concerns as to whether transgenic livestock really are necessary. The use of genetic engineering is secondary to changes in animal husbandry conditions. This must be taken into account for approval processes. Issues of animal protection must also be checked for when approving classically bred breeds.

A risk assessment of complex systems resulting from genome editing must be carried out. This is especially required for new varieties and/or breeds which emerge as a result of a large number of genetic modifications.

Rare species should not be protected through the use of genome editing. Instead, their genetic material should be stored in databases.

There should be a moratorium on gene drives, also with regards to locally restricted experimental releases beyond closed experimental laboratories. Genetic modifications, especially gene drives for organisms in open nature, should be prohibited. Unregulated interference with ecosystems must be ruled out.

Animals should not exclusively be used as "bioreactors" for humans if alternative technologies are available.

Some of the consumer group demand that breeding animals as organ donors for humans should be completely banned. Creating chimeras should be ruled out.

Some of the consumer group demand a ban on genetically modified animal feed in animal husbandry.

5 Plants

Opportunities

The problem of feeding the growing global population can be addressed by increasing yields. Increased resource efficiency with regards to the use of land is possible, including recultivating degraded soils, water consumption and the use of fertilisers, as well as a reduced use of pesticides.

Genome editing offers opportunities to maintain genetic diversity, e.g. by crossing back to wild varieties or with the help of the offspring of wild plants.

By using genome editing in the breeding of crop plants, breeding procedures will become significantly faster and may react more efficiently to new demands with regards to the climate, soil or yield.

Genome editing can contribute to climate protection by reducing food waste through longer shelf lives, greater yields per surface area, or by optimising photosynthesis.

Genome editing should be considered a problem-solving tool, e.g. for nutrition composition or for yields, and for adapting to changing environmental conditions.

Risks

An unchecked propagation of genetically modified organisms (GMOs) must be anticipated, as they have a fitness advantage over natural plants. This may cause unwanted effects on the environment, e.g. by interbreeding with other crops or wild plants. Unregulated spread of pesticide and herbicide resistances may occur.

The characteristics of plants may change so much that they are less suitable for consumption, e.g. due to selicycalate and solanine content, higher allergenic potential etc.

New invasive species which destabilise local ecosystems may emerge from the introduction of transgenic plants.

Patent laws and species protection may lead to a monopoly of seed producers. Small farms may no longer be able to afford new varieties under such circumstances.

Demands

Gene drives for wild species should not be considered unless methods are available to isolate areas. There should be a general ban on key species.

Some participants demand that due to the principle of precaution, genome editing with point mutations should be exempt from the Genetic Engineering Law and Ordinance. Other genome editing procedures should definitely be identified as GMO.

We demand that DNA sequence modifications be documented. In those cases where differentiation between genome editing and mutagenesis is not possible, the product should be assessed and not the production technique. A distinction must be made between the genome editing procedure and the assessment thereof. The risk assessment must also take effects on the environment into account (e.g. on food chains, pollinators, symbionts and microbiomes). In general, risk assessments should be invested in.

Whole genome sequencing should be set as the standard for inspecting genome modifications. As verifiability is not feasible without further DNA modifications, we demand detailed patents for specific modifications. Means of avoiding or exposing fraud cases should be found, e.g. if a GE plant has not been declared as such.

Breeding cultivated plants is an important task for ecologising the agricultural system. Such breeding can be carried out using genome editing and other methods. As well as genome editing systems, funding should also comprehensively promote other innovative research approaches, such as participative and ecological breeding.

The future focus of plant breeding should be on promoting research and development of organic farming and ecological agriculture methods in development aid, to increase yield performance in the long term.

Breeding costs money. Systems which enable the financing of breeding work through property rights must be fostered. However, licensing costs must also be appropriate. Variety rights appear to regulate these well and must therefore be maintained.

Establishing an approval procedure which assesses the influence on sustainability, species diversity, feeding a growing global population, soil quality, animal welfare, climate etc. as well as risk assessment. Civil society should be involved in these approval processes as well as independent scientists, e.g. through NGOs. The principle of precaution must always be applied here. Universities and minor seed producers must be supported if the costs for this approval process are too high. The approval of varieties from natural breeding must also check for ecological and other risks.

It must be ensured that universities and minor seed producers also have the opportunity to develop and be given market approval for new products. Patent and variety laws may need to be adapted for this. The dominant position of a few corporations on the market must be broken through.

It must be guaranteed that farmers can breed and reproduce their own seeds, and are not forced to depend on corporations, and that regionally adapted varieties must also be developed for small markets in developing countries. Informal seed trade in Africa must remain possible. More funds should be made available for ecological agriculture projects for development aid.

There should be no patent protection for naturally occuring characteristics, only variety protection. Patents should not include entire features as this may also affect conventional breeds with this feature.

The costs-by-cause principle must apply for the use of GMOs. The costs for separating the flow of goods and other contamination prevention measures must be covered by the producers and users of genetically modified organisms. The cost-by-cause principle must allow for organic farms to be protected and/or compensated.

We demand an environmental compatibility investigation to be extended to include second order problems, e.g. pesticide resistances, an increased use of pesticides, a reduction in biodiversity and a reduction in humus. Greater promotion of organic farming - including greater promotion of research in this area - is needed, as is a holistic investigation of benefits

to the ecosystem, to take into account soil cultivation – it is to be prevented that high crop yields are prioritised and soils become increasingly deficient in nutrients.

Some participants demand freedom of choice for those who do not want to consume genetically modified foods, for example by means of a certificate for seeds without genome editing and/or "old genetic engineering". Some participants demand that a "no genetic engineering" label should not be given to products resulting from mutagenesis. The database records for companies "acknowledging" their products for the sake of transparency and traceability should be published. No markers should be contained in the genome of the final product.

Some consumers demand that no cultivation and/or release of transgenic plants should occur.

Appendix 1 - Consumer Conference information

Principal agency:	German Federal Institute for Risk Assessment (BfR)
Contractor:	BIOCOM AG
Closing conference:	28 to 30 September 2019

The BfR Consumer Conference “Genome Editing in the Field of Nutrition and Human Health” aimed to gather nuanced viewpoints from informed consumers on the application of genome editing in the form of a consumer vote.

For this purpose, a group of 20 interested consumers were invited to attend two preliminary weekends on 10-11/08/2019 and 31/08 - 01/09/2019, on which they had a chance to get to know each other and received an easily comprehensible introduction to the scientific, technological and societal aspects of genome editing.

The entire Consumer Conference was run by an external service provider. The BfR was not actively involved in the moderation, discussion and preparation of the consumer vote. The information material used by the participants to familiarise themselves with the subject of genome editing was initially compiled by the BfR's own specialists in biology and communication sciences and then weighted by the external service provider using didactically meaningful criteria. As the third supervisory body, a scientific advisory panel was set up, which consisted of experts from technological impact assessment, social research and risk management. As members of the scientific advisory panel, Prof. Dr. Eng. Detlef Bartsch (Head of the Genetic Engineering Department at the Federal Office of Consumer Protection and Food Safety), Univ.-Prof. Dr. Stefan Böschen (Head of the Institute for Technology and Society at RWTH Aachen University) and Dr. Eng. Arnold Sauter (Deputy Head of the Office of Technology Assessment at the German Bundestag) monitored the Consumer Conference. The advisory panel examined the information materials with a view to balancing the presentation of risks and benefits and the scientific rigour of the explanations and illustrations.

At the end of the second preparatory weekend of the Consumer Conference, the consumer group put together questions which were posed to selected experts at the expert hearing on the third weekend of the Consumer Conference. The 13 specialists invited to the expert hearing were also selected by the consumer group from a list of 32 available experts on the second preparatory weekend.

Following the expert hearing, the consumer group composed the vote, which was presented to representatives from the fields of politics, science, industry and civil society as the central result of the consumer conference at the conference’s closing event.

Appendix 2 - The consumer group

The consumer group consisted of 20 citizens: ten women and ten men. Five of the participants were aged under 31, four were aged 31-40, three were aged 41-50, four were aged 51-60 and another four were aged over 60. Each of the occupational status categories, e.g. in school / higher education, in full or part-time employment, pensioner / early retiree, parental leave / housewife / househusband, and currently unemployed, as well as persons indicating “Other” as their occupational status category, were all represented in the participant group.

The BfR Consumer Conference "Genome Editing in the Field of Nutrition and Human Health" was publicly advertised on the website of the German Federal Institute for Risk Assessment and declarations of interest from consumers with no professional interests in participation were invited. Consumers were made aware of the event by means of flyers and posters placed in public institutions, and via social media.

The German Federal Institute for Risk Assessment received 147 valid declarations of interest in participating from consumers. Profiles which were socio-demographically similar were identified among these applicants, from which a subsequent random selection was performed. The deciding factors for these groupings were the sex, age category and occupational status of the interested consumers. Whenever a selected applicant declined the invitation to participate, another person was selected randomly from the same group of similar applications. The aim of the selection process was to invite a group of consumers as heterogeneous as possible with regards to their social demographics in order to include a variety of opinions, thoughts, socio-political demands, and hopes and fears.

Appendix 3 - The experts involved

The following 13 persons were selected from a list of 32 experts:

Professor Jens Boch	Leibniz University Hannover Institute of Plant Genetics
Dr Margret Engelhard	German Federal Agency for Nature Conservation (BfN)
Professor Boris Fehse	University Medical Center Hamburg-Eppendorf Department of Stem Cell Transplantation, Research Department Cell and Gene Therapy
Dr Ralf Kühn	Max Delbrück Center for Molecular Medicine
Professor Stephan Meyer	*Technical University* of *Applied Sciences Wildau*
Professor Urs Niggli	Research Institute of Organic Agriculture (FiBL)
Christof Potthof	Gen-ethisches Netzwerk e.V.
Professor Ortwin Renn	IASS Potsdam, Institute for Advanced Sustainability Studies e.V.
Professor Stefan Schillberg	Fraunhofer Institute for Molecular Biology and Applied Ecology IME
Professor Gerd Seibold	Technical University of Denmark Department of Biotechnology and Biomedicine (DTU Bioengineering)
Daniela Wannemacher	German Federation for the Environment and Nature Conservation (BUND)
Professor Ernst A. Wimmer	Georg-August University of Göttingen Johann-Friedrich-Blumenbach Institute for Zoology and Anthropology
Dr Hans Zillmann	Martin Luther University of Halle-Wittenberg Philosophy seminar