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Member State 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

endorsed in the Joint Working Group of GMO competent authorities on new genomic techniques on 15 January 2020

Introduction

With this questionnaire the Commission is collecting contributions from Member States competent authorities to respond to the Council's request[1] for "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). The scope of the study goes beyond new mutagenesis techniques, as there are other new techniques, for which the Council seeks clarification. Therefore, the study covers all new genomic techniques, which have been developed after 2001.

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques, which are capable to alter 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-organims and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research. GMO competent authorities are invited to seek input from other competent authorities when appropriate.

The questionnaire is meant to provide information primarily, but not exclusively, at national level. 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 a specific NGT, please indicate this in the reply. With regard to agri-food applications, replies may include considerations on specific sectors, such as the organic sector.

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

Instructions

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 30 April 2020 (closure of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

* Which Member State are you representing?

Bulgaria

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

* **1. Have you been consulted by companies/organisations/research institutes for regulatory advice or another issue on products developed or to be developed by NGTs ?**

- ○ Yes
- ◉ No

* **2. Have you taken specific measures (other than inspection) related to the application of the GMO legislation to NGT-products?**

- ○ Yes
- ◉ No

* Please explain why not

All organisms that have been genetically modified are within the scope of the Bulgarian GMO legislation, incl. those developed using NGTs.

* 2 bis. Have you encountered any challenges or limitations, including administrative burden or costs?

- ◉ Yes
- ○ No

* Please describe

In most cases, the detection and identification of organisms developed with NGTs would be very difficult or practically impossible. Quantification of the modifications will be even more difficult. At present, Bulgaria has no practical experience in detection, identification and quantification of organisms whose genomes have undergone minimal changes, especially when those changes are identical to mutations and polymorphisms present in nature. We expect that the methods of analysis will not be sufficiently informative about how the genetic alteration has occurred and that will lead to difficulties in the detection and identification. It would be possible to identify definitely minimal genetic changes introduced with the help of NGTs only when the applicant has provided information about them with registration documents under Commission Implementing Regulation (EU) No 503/2013 on applications for authorization of genetically modified food and feed (the applicant is required to submit methods of detection, identification and quantification).

* How could these challenges or limitations be overcome?

It would be useful if one or more centralized laboratories are set up within the EU for detection and identification of those GMOs developed with the help of NGTs that are particularly challenging or expensive. This way, the necessity for each Member State to set up and equip its own expensive laboratory that will perform a relatively small number of analyses will be avoided.
It should also be carefully considered whether organisms developed using NGTs, which are virtually identical to naturally occurring counterparts or to those created by other techniques should be classified as GMOs. This could necessitate changes in EU legislation.

*

3. Have you adapted your inspection practices to cover all NGT-products and to ensure the enforcement of traceability requirements?

- ○ Yes
- ◉ No

* Please explain why not

Bulgarian authorities have not adapted their inspection practices since there are no harmonized sampling strategy and methods for the detection, identification and quantification of those modifications. The way samples are collected and stored should allow for their retrospective analysis, if needed.

* 3 bis. Have you encountered challenges or limitations, including administrative burden or costs?

- ◉ Yes
- ○ No

* Please describe

We do not currently know what actual needs for inspections of products are and will be, incl. for the inspections of organisms developed with NGTs. Also, depending on the methods to be used for detection, identification and quantification of those products and organisms, it may be necessary to adapt or completely alter the methods for sampling and analysis and for documentation checks.

* How could these challenges or limitations be overcome?

It will be useful to harmonize, within the EU, the documentary requirements and sampling and analytical methods related to the control and traceability of organisms and products developed using NGTs.

* **4. Do you have experience or information on traceability strategies, which could be used for tracing NGT-products?**

- ○ Yes
- ◉ No

* 4 bis. Have you encountered any challenges or limitations, including administrative burden or costs?

- ◉ Yes
- ○ No

* Please describe

We are not currently aware about any products, incl. organisms developed using NGTs that are produced or authorized within the EU. If that happens, the traceability requirements for GMOs and GM products will have to be followed. If the products are manufactured in third countries, they may not be classified as GM and, consequently, their traceability may be difficult.

* How could these challenges or limitations be overcome?

It would be useful if the study includes analysis of product labelling and traceability practices, incl. for organisms developed using NGTs in the countries from which is most likely import into EU to take place.

* **5. What other experience can you share on the application of the GMO legislation, including experimental releases (such as field trials and clinical trials), concerning NGT-products in the:**

- [x] **Agri-food sector?**
- [x] **Industrial sector?**
- [x] **Medicinal sector?**

Agri-food sector

So far, environmental releases, in the field of agri-food industry, of organisms or other products developed using NGTs have not taken place in Bulgaria.

Industrial sector

So far, environmental releases, for industrial purposes, of organisms or other products developed using NGTs have not taken place in Bulgaria.

Medicinal sector

So far, environmental releases, incl. clinical trials, of organisms or other products developed using NGTs have not taken place in Bulgaria.

* **6. Have plant varieties obtained by NGTs been registered in national catalogues?**

- ○ Yes
- ◉ No

* **7. Do you require specific information in national catalogue when registering plant varieties obtained by NGTs?**

- ○ Yes
- ◉ No

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B - Information on research and innovation

* **8. Have you supported with national funding programmes NGT-related research projects/programs (ongoing or finalised in the last 5 years), including on identification or traceability?**

- ○ Yes
- ◉ No

* 8 bis. Please highlight the potential challenges encountered when supporting/funding NGT-related research and any consequences from these challenges.

The National Science Fund at the Ministry of Education and Science has not funded research projects or scientific programs in the last 5 years (ongoing or finalised during this period) related to NGTs studies. Projects or programs focused on identification or tracking of objects and phenomena related to NGTs have not been funded either. In 2017, three such projects had been submitted and evaluated (two in the Expert Commission in Medicine and one in the Expert Commission in Agrarian Sciences), but all three did not receive the required scores and were not funded.

*** 9. How do you see NGT-related research evolving?**

Bulgaria expects that because of the ECJ ruling the administrative burden on research and development institutions that conduct research in the field of NGTs will increase, as they will have to comply with and enforce the rather stringent requirements of European GMO legislation. This will further decrease the attractiveness of EU and its Member States as a place to conduct such cutting-edge research.
At the same time, NGTs are extremely valuable for gene modification and will play increasing role when the mechanism of human diseases are studied in cell cultures and animal models. Their utility and applicability in the field of monogeneous and complex human genetic diseases is yet to be fully evaluated. The NGTs are expected to be developed further and to find more applications in the creation of plants, animals and microorganisms with improved characteristics.
We expect that research projects related to performance evaluation, long-term effects on organisms and environment, ethical issues related to application in a number of fields, especially on humans, will be initiated in near future.
NGT studies will require the creation of technology platforms, multidisciplinary teams and expensive equipment, as well as development of capacities to use those technologies. That could be possible in the coming years when Centers of Excellence and Centers of Competence will be established in Bulgaria.

*** 10. Have you identified any NGT-related research needs from private or public entities?**

- ○ Yes
- ◉ No

*** 11. Could NGT-related research bring opportunities/benefits to science, to society and to the agri-food, medicinal or industrial sector?**

- ◉ Yes
- ○ No

* Please provide concrete examples/data

NGTs include a number of very promising technologies that can be of great benefit to the society, research and the economic sectors listed.
In healthcare, NGTs can provide opportunities for targeted and individualized therapies, as well as for treatment of hereditary diseases that affect multiple genes and parts of the chromosomes.
With regard to the environment, NGTs can be used to create GMOs that are much closer to natural analogues and thus have much lower negative environmental impact. Using NGTs, it will be possible to develop organisms that can eliminate contaminants in situ. That can be done either by reengineering existing metabolic pathways or by creating entirely new ones. Another area of potential interest is the gene drives that can be used to eliminate invasive alien species and vectors of infectious diseases.
The potential benefits of NGTs research would be in all of the above areas. For example, in the field of science, platforms and teams will be set up to work on issues of public concern and contribute to better quality of life and higher economic standards. In terms of healthcare, they are important for the development not only of personalized medicine, but also of global problems related to the control and prevention of

infectious diseases, neoplasias, antimicrobial resistance, etc. The environmental challenge is the accumulation of huge amounts of waste, some of which would be recycled and included in so-called circular economy with the participation of genetically constructed microorganisms - bacteria, fungi, etc. by genetic engineering methodology. Equally applicable are these techniques in the production of high-yield and high-quality varieties of plants and animal species that are resistant to disease, stress, and other adverse environmental factors.
The NGTs provides means for very specific and faster mutagenesis in a large number of animals, plants and microorganism. This will allow better and deeper understanding of the genetics, molecular and cellular biology of those species. In addition, they will allow faster and more effective development, laboratory screening and testing of new species, products, vaccines, gene therapy and therefore will give opportunities for research and development in fields such as human health, crop production, animal husbandry, among others.

* **12. Could NGT-related research bring challenges/concerns to science, to society and to the agri-food, medicinal or industrial sector?**

- (●) Yes
- ( ) No

* Please provide concrete examples/data

Despite the perspectives of using NGTs, experience with them is limited. Therefore, the potential risks to human health and the environment are difficult to assess.
Interference with the human genome can have unpredictable consequences for human evolution and development. Sometimes it is difficult to differentiate between therapy and improvements and that problem will be even more serious with NGTs.
With regard to the environment, there is still very little experience with the use of organisms developed using NGTs, incl. those that have been developed using synthetic biology and gene drives. Due to the complexity of ecological interactions, it is very difficult to assess in advance the impact of those organisms on biodiversity and ecosystems.
Research into NGT and the knowledge and products gained are not only a scientific challenge, but also a subject of public concern and attention. They are possible and applicable in all the above sectors (agriculture, medicine, industry) and the scaling process - from laboratory technology to semi-industrial or industrial technology poses certain risks to humans, animals and the environment. It is therefore necessary to comply with all the requirements of National and European legislation, including the requirements referred to genetic studies, the specific rules and regulations.
The NGTs also raises new challenges related to moral and ethical issues when they are applied for human use, especially when the research involves germ line cells and embryos.
As many of the NGTs are relatively novel, the long-term impact of products or new species created with those technologies on the environment, biodiversity, and human health are hard to be estimated due to insufficient data.

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C - Information on public dialogues and national surveys

* **13. Have you or other institutions/bodies/entities organised national dialogues concerning NGTs?**

- ○ Yes
- ◉ No

* **14. Have you or other institutions/bodies/entities organised national surveys, which assessed public opinion on NGTs?**

- ○ 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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D Information on ethical aspects

* **15. Have any national bodies or expert groups discussed or issued opinion on the ethical aspects of NGTs?**

- ○ Yes
- ◉ No

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E - Information on opportunities and benefits from the use of NGTs and NGT-products

* **16. Could the use of NGTs and NGT-products bring opportunities/benefits to the agri-food, medicinal or industrial sector?**

- ◉ Yes
- ○ No

* Please provide concrete examples/data

NGTs include a number of very promising technologies that can be of great benefit to different economic sectors.
In healthcare, NGTs can provide opportunities for targeted and individualized therapies, as well as for treatment of hereditary diseases that affect multiple genes and parts of the chromosomes.
With regard to the environment, NGTs can be used to create GMOs that are much closer to natural analogues and thus have lower negative environmental impact. Using NGTs, it will be possible to develop organisms that can eliminate contaminants in situ. That can be done either by reengineering existing

metabolic pathways or by creating entirely new ones. Another area of potential interest are the gene drives which can be used to eliminate invasive alien species and vectors of infectious diseases.
All that should create new business opportunities in the innovative economic sectors.

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

- (●) Yes
- ( ) No

* Please provide concrete examples/data

It is difficult to identify the specific products and procedures that will be developed using NGTs, especially in the medium to long term. At present, it is clear that these techniques allow more precise manipulation of genomes of many different species, incl. humans. This will allow creation of new therapies, incl. targeted and individualized therapies, as well as for treatment of hereditary diseases that affect multiple genes and parts of the chromosomes. It can be expected that in the near future most of the live vaccines will be developed using total genome synthesis of the respective viruses and bacteria, which will reduce the number of non-target mutations and hence increase their safety. Some techniques, such as gene drives and techniques for sterile insects (as well as for other organisms) can be used to reduce or eliminate populations of disease vectors and invasive alien species. The editing of genes and genomes of agricultural plants and animals will allow faster and more efficient introduction and selection of desired characteristics, e.g. for increased yields, resistance to pathogens, drought, etc.
Synthetic biology (which not necessarily uses NGTs) also has big potential to make a positive contribution to society. In general, the main developments are related to the creation of biological macromolecules with entirely new properties, incl. ones not found in nature; creating new metabolic and signalling pathways in the cell; creation of organisms containing new components (amino acids, nucleotides, etc.); creation of minimal cells and viruses; development of new ecosystem engineering techniques. Each of these areas has huge potential and specific examples from the past two years can be presented for every area.

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

In order to maximise the social and economic benefits of the NGTs while minimizing the associated risks it is important that the regulatory regime must be adapted to the specific technical aspects of those technologies. It should not be too burdensome, and the assessment and management of risks should be primarily aimed to those that pose greatest danger to human health and environment.

* **18. Do you see particular opportunities for SMEs on the market access to NGTs?**

- (●) Yes
- ( ) No

* Please explain under which conditions

NGTs provide a number of business opportunities, including for SMEs. The SMEs founded to commercialize the results of basic research with the participation of academic institutions or individual scientists have particular potential. However, the success of such SMEs will depends on their ability to meet EU regulatory requirements that are too burdensome and to have access to the necessary initial funding.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

At the core of the patent system and of the granting of patents is the promotion of innovation and technological progress by protecting those who have made investments. In the pharmaceutical sector, and in particular with regard to biotechnology and biomedicine involving the application of NGTs, the overall cost of innovation is very high and obtaining monopoly rights for a fixed period provides fair compensation for the invested financial resources and the used research capacity. That provides opportunity for return on investments and efforts made, as well as probability to generate profit. In addition, monopoly rights with patent protection, in principle, have stimulate those involved in research and the potential investors of capital to provide new and/or improved products and technologies, incl. medicines. Such developments are expected to improve the overall medical capabilities aiming to preserve and extend human life and improve its quality.
This way, patent protection for innovative solutions is considered a key factor in providing research and development incentives, with protection leading to a competitive advantage. The patenting of biotechnological inventions, in particular those in the field of biomedicine, is of paramount importance for universities and research institutions, as patents are a major asset for attracting investment.

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F - Information on potential challenges and concerns of NGT products

*** 20. Could the use of NGTs and NGT-products raise challenges/concerns for the agri-food, medicinal or industrial sector?**

- (●) Yes
- ( ) No

* Please provide concrete examples/data

Despite the prospects of using NGTs, experience with them is limited. Therefore, the potential risks to human health and the environment are more difficult to assess.
Interference with the human genome can have unpredictable consequences for human evolution and development. Sometimes it is difficult to differentiate between therapy and improvementc and that problem will be even more serious with NGTs.
With regard to the environment, there is still little experience with the use of organisms developed using NGTs, incl. those that have been developed using synthetic biology and gene drives. Due to the complexity of ecological interactions, it is difficult to assess in advance the impact of these organisms on biodiversity and ecosystems.
All that together with the regulatory requirements to be met could create difficulties for the industry and could reduce the attractiveness of developments in the area and their commercialization.

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

- (●) Yes
- ( ) No

* Please provide concrete examples/data

It is difficult to identify the specific products and procedures that will be developed using NGTs, especially in the medium to long term. A typical example are the organisms carrying synthetic gene drives that have not yet been released into the environment, so their impact is unknown and can only be estimated on the basis of models. Interference with the human genome can have unpredictable consequences for human evolution and development. Sometimes it is difficult to differentiate between therapy and improvement and that problem will be even more serious with NGTs. Those uncertainties, together with potentially significant risks, are example of the challenges that NGTs pose. Similar risks exist for agriculture, plant and animal health. It is not yet clear what the effects of NGTs will be on existing economic sectors and the related social and economic consequences.
It should be noted that such challenges and concerns are not unique to NGTs, but are typical of any new technologies that have potential to cause technological revolution. Examples in the past are chemical technologies and synthesis, nuclear technology, electronics. Currently, similar challenges are associated with the use of nanomaterials and artificial intelligence.

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

In order to minimize the risks and challenges associated with NGTs risks it is important that the regulatory regime should be flexible enough to adapt to the novel information that will be gained with the wider use of those technology. The regulation should not be too burdensome in areas where the risks are minimal or negligible and are effectively managed nor should be to rigid as not to able to adapt when new risks and challenges emerge in a given area.

* **22. Do you see particular challenges for SMEs on market access to NGTs?**

- (●) Yes
- ( ) No

* Please explain under which conditions

The existing regulatory requirements for GMOs, as well as the lack of long-term experience with NGTs, can significantly increase the risks and costs associated with the commercialization and marketing of the products developed using NGTs. This would put SMEs with less access to financial and human resources at a relative disadvantage compared to large companies.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

The main commonly held concerns regarding patenting of products developed with the help of NGTs are related to the possible establishment of temporary monopolies, charging higher prices for products and the

related limitation of the ability to respond to public health emergencies, creating more favourable conditions for the large pharmaceutical companies while limiting the opportunities for other market players, such as SME.
It should also be noted that the EU and Member States are significantly lagging behind other countries (which are key competitors) in patenting of techniques and products developed using some NGTs. Gene editing is a documented example of this trend (Worldwide CRISPR patent landscape shows strong geographical biases; Martin-Laffon, Kuntz and Ricroch, Nature Biotechnology 37 (6), 613-620). There is no reason to believe that the situation is different for other key technologies. In this regard, we believe that the EC study should also include examination of the EU's position vis-à-vis other countries and regions regarding NGTs patents.

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G - Final question

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

- (●) Yes
- ( ) No

Please provide your comments here

1. The definition of mutagenesis is a critical issue. No such definition is provided either in Directive 2001/18 /EC or in Directive 2009/41/EC. The Court's judgment on Case C-528/16 does not provide an explicit definition, but it is clear that mutagenesis is understood quite broadly.
A definition of mutation is present in Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, according to which “A mutation means a permanent change in the amount or structure of the genetic material in a cell. The term ‘mutation’ applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including specific base pair changes and chromosomal translocations).” Therefore, mutagenesis would be every process that leads to permanent change(s) in the amount or structure of the genetic material in a cell.
Considering that the question of the definition of mutagenesis, in the context of EU GMO legislation, is critically important in determining the scope and the exclusions of that legislation, the study should clarify the issue and, if necessary, propose appropriate legislative changes.
2. The judgment on Case C-528/16 is in the context of Directive 2001/18/EC, with Directive 2009/41/EC not being considered. Furthermore, Directive 2009/41/EC does not directly refer to Directive 2001/18/EC. Therefore, the definition of GMOs under Directive 2001/18/EC and the definition of GMMs under Directive 2009/41/EC are very similar but independent of each other. More important are the differences in techniques that are excluded from the scope of the two Directives.
Crucial for the judgment on Case C-528/16 is Recital 17 of Directive 2001/18/EC on whose basis the Court has decided that “Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex IB to that directive and in the light of recital 17 thereof, must be interpreted as meaning that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive.“
Key difference between the two Directives is that there is no recital in Directive 2009/41/EC that corresponds

to Recital 17. Thus, in the context of the judgment on Case C-528/16, all microorganisms obtained through mutagenesis should be excluded from the scope of Directive 2009/41/EC, and not only those obtained through techniques/methods, which have conventionally been used in a number of applications and have a long safety record. This together with a broad interpretation of the definition of mutagenesis, could lead to the conclusion that all GMMs are excluded from the scope of that Directive. The co-legislators clearly did not intend such a conclusion, but the issue should be thoroughly considered and clarified in the study. Further clarifications are also needed regarding the scope and application of the exclusion of self-cloning under Directive 2009/41/EC.
3. Authorizations for the deliberate release of GMOs under Part B of Directive 2001/18/EC are granted by the national competent authorities of the country where the application has been submitted. Although there is an established mechanism for the exchange of information and coordination, but the process can be improved when the release is take place in more than one MS. A harmonized electronic process for submission and evaluation of applications for deliberate release of GMOs into the environment, similar to the one planned for clinical trials, could be useful and effective.
4. Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use introduces a harmonized electronic process for the submission and evaluation of clinical trials that will take place in several MS. At the same time, when a trial involves a product containing GMOs, it will be necessary to obtain individual authorization (or other form of consent) in each individual MS (under Directive 2001/18/EC or under Directive 2009/41/EC, as there are differences between MS practices). Although there is an ongoing process of harmonization between MS, it should be examined whether establishing common mechanism (in the GMO part) for clinical trials of medicinal products containing GMOs would be beneficial.
5. Regarding the contained use of GMOs, Directive 2009/41/EC covers only GM microorganisms (GMMs). The technological developments have significantly increased the repertoire of genetic modifications that can be introduced into organisms different from microorganisms. Some modifications can have serious and potentially irreversible negative consequences to the environment if released accidentally. Gene drives, as well as some other possible developments in synthetic biology, are such examples. It could be useful to explore the possibility of harmonizing the conditions for contained use of the GMOs other than GMMs.

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