Contribution ID: 168fe372-d97c-4a29-9368-63b39a60b200
Date: 15/05/2020 13:29:46

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

POLLINIS

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

Research and programmes focusing on wild pollinators/Apis mellifera; trying to modify current agricultural management strategies to protect pollinators; making citizens aware of issues on protection of pollinators /Apis mellifera (including work related to pesticides, NGTs, agricultural landscapes)

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

1. SICAMM Holland-Marleen Boerjan and Alan Forskitt; 2.University of Galway - NIU Galway Ireland - Keith A. Browne (Researcher in Molecular Evolution in honey bees); 3. Division of Apiculture - Hellenic Agricultural Organization "DEMETER" Greece - Fani Hatjina; 4. APIMONDIA -Bee Health Scientific Commission Greece - Fani Hatjina; 5. Norsk Brunbiesenter Norway - Anja Laupstad Vatland (Prosjektleder); 6. OGM Dangers France - Hervé Le Meur; 7. Wild Bees Project France - Rosa Maria Licon Luna; 8. Norsk Brunbielag Norway: Lars Andreas Kirkerud (Biology of honeybees, morphometrics); 9. Friends of the Earth Malta - Alexei Pace; 10. Faculty of Ecological Agriculture, University Educons from Sremska Kamenica Serbia - Slađan Rašić; 11. Aurelia Stiftung Germany - Johann Lütje Schwienhorst and Jan Hellberg; 12. Asociación de Apicultores de Gran Canaria, ApiGranca Spain - Antonio Quesada Quesada.

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

Gene drive (e.g. Prime editing, daisy, CRISPR-Cas9) techniques, pollinators/Apis mellifera

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?**
  - ○ Yes
  - ◉ No
  - ○ Not applicable

* Please explain why not

No, the sustainability of NGT has not been yet adequately or sufficiently evaluated and therefore using products or organisms that have not been assessed in regards to environmental and health, or social impacts are not supported by POLLINIS (including SICAMM, University of Galway - NIU Galway, Division of Apiculture- Hellenic Agricultural Organization "DEMETER", APIMONDIA Bee Health Scientific Commission, Norsk Brunbiesenter, OGM Dangers, Wild Bees Project, Norsk Brunbielag, Friends of the Earth, University Educons from Sremska Kamenica ,Aurelia Stiftung and Asociación de Apicultores de Gran Canaria, ApiGranca).

* **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

N/A

* 2 bis. Have you encountered any challenges?

- ○ Yes
- ◉ No

* **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

There have been two labs who have successfully constructed Apis mellifera, two labs have made advances to construct a GD honey bee: (Kohno, Suenami et al. 2016, Hu, Zhang et al. 2019).

Supporters of NGT propose creating a GD honey bee to solve the problem of their decline and to maintain and increase pollination. The idea is to generate a more resilient strain of honeybee that would survive better the effects of pesticides, viruses, parasites and diseases. Some call this version of bee a “pesticide/disease /pest-proof bee”, “bulletproof bee” (GMWATCH 2018).

A team at the Science and Technology department in the University of Missouri have also used synthetic biology techniques for honey bees (Foster and Pummill 2011). Assuming that removing some honey bee pathogens would diminish the incidence of colony collapse disorder. Using this approach, they propose to engineer a microbe to produce fumagillin, which would enable farmers to control pathogens, mainly nosema ceranae.

Honey bee health work by (Grozinger and Robinson 2015, Grozinger and Zayed 2020). These two papers explain ways to develop genomic approaches to control bee parasites and pathogens, especially targeting genetic sequences in pathogens and parasites; identifying factors that improve resilience which can be incorporated into management practices by beekeepers. Grozinger and Zayed 2020 particularly speak about future research to increase resilience of the honey bee through genetic manipulation (RNAi and CRISPR-Cas9 based on genome editing) of genes differently regulated in response to stressors varroa (Maori, Paldi et al. 2009) and nosema ceranae (Li, Evans et al. 2016).

Patent – through the gut – bees can assimilate neonics better “A method and system for the treatment of honey bees (Apis mellifera), bats, and butterflies protects them from various life threatening conditions, including Colony Collapse Disorder, white nose syndrome, etc. and in particular, provides honey bees, bats and butterflies with the ability to assimilate and degrade neonicotinoids.” Link: https://patents.google.com /patent/US20190022151A1/en
Patent - Optimal gene – special light farmers can use to activate the gene (ETC Group 2019) (US2016 /0310754A1)
Link:http://www.etcgroup.org/sites/www.etcgroup.org/files/files/etc_hbf_forcing_the_farm_web.pdf

In addition to proposing GD honey bees or pollinators for helping with agricultural output, including honey production, there is an upward trend of research on genome editing systems for conservation to address biodiversity loss. Particularly, these genomic techniques are tools to help solve the problem of the decline of pollinators: replacement, or improvement (the same with respect to gene drive) - to help protect the species.

There are current emerging trends to modify populations in the wild, facilitated by advances in gene editing techniques, particularly gene drives (Piaggio, Segelbacher et al. 2017).

Up to date, there has been no release in the wild. This is verified by S. Kyriakides, Commissioner (2019-2024) for Health and Food Safety for the European Commission. She writes in a response to a parliamentary question (n°791/2020) of Mazaly Aguilar on 10 February 2020 and replied on 6 April 2020 concerning the release of gene drive organisms (Kryriakides 2020). Commissioner Kryriakides writes:

a. In the EU, all genetically modified organisms (GMOs) released into the environment need to be authorised according to Directive 2001/18/EC and have to undergo a thorough assessment of all identified risks in accordance with the abovementioned Directive and European Food Safety Authority guidance. This obligation is equally applicable to the release of GMOs engineered with gene drives.
b. The Commission is not aware of any evidence supporting the concern that GMOs engineered with gene drives can be released into the environment without permission. The Member States are responsible for the implementation and proper enforcement of the EU legislation, including controls aimed at verifying that no unauthorised GMO is released into the environment. In the event of an unauthorised release, Directive 2001/18/EC obliges Member States to take all necessary measures to terminate the release, initiate remedial action if needed, and inform the public, the Commission and the other Member States.
c. To date, no application for authorisation of deliberate releases of GMOs engineered with gene drives has been made in the EU.

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

- ○ Yes
- ○ No
- ◉ Not applicable

*** 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

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

- ○ Yes
- ○ No
- ◉ Not applicable

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

- ○ Yes
- ○ No
- ◉ Not applicable

*** 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

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

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B - Information on research on NGTs/NGT-products

* **10. Are your members carrying out NGT-related research in your sector?**
  - Yes
  - No
  - Not applicable

* **11. Are you aware of other NGT-related research in your sector?**
  - Yes
  - No
  - Not applicable

* Please specify

Some related research on NGT (in addition to those written in question 3) are related to pest control strategy. For example, one of the biggest pests in agriculture is the monarch butterfly (Karageorgi, Groen et al. 2019). Researchers have proposed gene drive insects as a tool for an area-wide pest control strategy. As such, there is extensive literature on the economic benefits of area-wide sterile insect technique (SIT) programmes with limited research on potential risks and complications to the environment of such gene drive insects (e.g. Baltzegar, J., et al. 2018)

* **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

- Yes
- No
- Not applicable

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

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

There are no perceived benefits to our sector/field of interest. However, we want to emphasise that because existing research primarily focuses on how to improve and further apply NGT techniques, the research must refocus efforts to:

- Develop a better risk assessment, based on the precautionary principle.

In the Draft opinion by EFSA on "evaluation of existing EFSA guidelines for their adequacy for the molecular characterization and environmental risk assessment of genetically modified insects with synthetically engineered gene drives" (2020), EFSA falls short providing sufficient information for risk managers to adequately assess specific risks and how to deal with the actual risk when released. Indeed, the very nature of a risk assessor is a scientific endeavor and the risk managers are supposed to take care of the goals of society (Vareman 2010). Even if risk assessors are the science behind the evaluation, stating the risk is merely not enough because risk managers must be informed of science and what it actually means, especially the consequences of risks when released, especially un-intended risks. How are risk managers supposed to implement action if they don't completely understand the "what", "how" and "then what" of the risk? This is especially true where there is uncertainty (already proposing a risk assessment implies that there is uncertainty). A decision must be made where uncertainty lies simultaneously with understanding scientific values, these decisions become the concern of policy makers – risk managers (Vareman 2010).

- Understand how to conduct "ecological confinement" when considering field release when most researchers agree that this itself is very challenging (Akbari, Bellen et al. 2015). We could further argue that despite no known current field release of NGT organisms outside of the laboratory, there could be accidental releases – those mosquitos or flies escaping confinement for example. Although there are reports of trying to safely confine GD experiments in the laboratory (Akbari, Bellen et al. 2015), there is a risk of escape through accidents or outside intervention. Theoretically scientists are able to reverse gene drives by releasing another GD canceling out the original (Esvelt, Church et al. 17 July 2014); they further argue that:
only populations that have the sequence targeted by CRISPR can be altered by a drive, potentially allowing us to target subpopulations with unique sequences. This also means that deliberately altering the sequences needed by another drive can provide protection against it, allowing us to immunize populations against specific drives and their associated changes (Esvelt, Church et al. 17 July 2014).

- Understand better how to conduct post market environmental monitoring.

- Understand more rigorously potential risks and unknown risks: unintended effects of genome editing systems and include both unintended on- and off-target effects such as mutations, chromosomal recombination events, high-frequency production of aberrant protein products and multiple integration event and the possibility of unintended transgenic organisms; and (the effects of NGTs related to population dynamics, resistance, fitness and wider ecological interactions).

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please provide concrete examples/data

There is currently limited research on how to understand better NGTs when applied to organisms and its effects on the environment; and even less emphasis on application of the precautionary principle. Instead, most of the research is motivated by the interests of how to use this technology and increasingly how to improve it. Scientific research versus profit and the move to patenting living things (by State interests) is a conflict that already exists with many of our scientists sitting on expert panels and those making decisions on how NGTs will materialise. In fact, there exists examples of a precarious proximity between EFSA GMO panelists and their direct and/or indirect financial conflict of interest with the agribusiness and food industries (Testbiotech; CEO).

Moreover, there is a limited understanding of the NGT risks on organisms released in the environment. For example, the very nature of gene drive organisms is to spread and persist. This raises many issues for any application of gene drive to pollinators, including honey bees. One of the ways to identify risk is through the ecosystem services (ES). This ES approach is increasingly contested and encounters multifaceted objections (Schröter et al. 2014). This approach is particularly unadapted to NGT given that these techniques when applied to organisms can impact various components of biodiversity which are difficult to identify and measure. It is even more difficult to identify the numerous risks to organisms and overall functioning of the environment, especially because of its interconnectedness and complexity. For these reasons, and considering that GDMIs could disrupt ecosystem balance, we argue that NGT-related research faces numerous challenges.

By their very nature, NGTs present several risks for human and animal health as well as the environment. These techniques lead to a change in scale in terms of the number of species that can potentially be targeted and of the geographical spectrum in which these mutations can take place. Currently, there is very little data on GD systems (ENSSER 2019). They argue that current evaluations on GD systems are based on the assumption that genes will “behave” and “perform” as they are supposed to (Champer, Buchman et al. 2016).

This underfunding of such risk research is in contradiction with the precautionary approach, as well as a neutral and objective approach to science to enable a better development of a “fit for purpose” risk assessment. As imposed by the GMO-directive 2001/18: “Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs” (article 4(1) first sentence); and it further writes: “Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted” (recital 21).

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

- (●) Yes
- ( ) No
- ( ) Not applicable

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

There are numerous gaps and needs in NGT-related research, especially when applied to NGT-related issues of agriculture, beekeeping and conservation.

1. An inadequate risk assessment on the release of NGT organisms

In the European Union, the current environmental risk assessment on deliberate release of GMOs under revision considers techniques based on the Mendelian inheritance regarding genetic inheritance - creating organisms that cannot reproduce their genetic modification on their own. However, since the GMO directive 2001/18, biotechnologies have considerably evolved and this regulatory framework does not adequately assess risks of field release of NGT organisms in the environnement. This is due to an important difference between GMO and NGT organisms: one cannot distinguish organisms and products born from natural mutation, or from NGT. Hence, the very essence of characteristics of NGTs contradicts the current GMO's risk assessment in place in the EU.

Considering that by nature, NGTs constitute an unprecedented threat to our ecosystems as they have the capacity to autonomously propagate and modify entire species genomes outside of human control, it is crucial to establish an adequate risk assessment until any field release of NGT organisms is considered.

2. Insufficient application of the precautionary principle

Any potential safe deployment of this technology are based on assumptions and not experimental evidence: on the contrary, recent research has found that genomic editing can result in numerous unexpected, unpredictable and undesirable outcomes, even at the intended gene editing site (Kosicki, Tomberg et al. 2018, ENSSER 2019, Tuladhar, Yeu et al. 2019).

The precautionary approach stresses that one must take careful measures where there is a lack of scientific evidence. Till more data are available, precautionary measures should preclude any deliberate release of gene drive pollinators/honey bees.

3. A limited understanding of unknown risks and consequences to the wider functioning of the ecosystem

Considering this point of such field release of genomic edited organisms, experts also have drawn attention to research in the lab and would thus be pertinent to honey bees or pollinators. For example, there are currently no national or international rules on contained use of GDOs (Sirinathsinghji 2020). Noble et al. (2018) and others argue that conditions in the lab must be extremely strict because of their potential to spread and persist if during the release they escape (Akbari, Bellen et al. 2015). Confinement strategies need to be multiple, including molecular, ecological, reproductive and physical measures (Akbari, Bellen et al. 2015). Sirinathsinghji (2020) argues that some GDOs have the same characteristics as pathogens and as pathogens require strict measures because of spread, persistence, irreversibility and, with population suppression methods, lethal traits (Simon, Otto et al. 2018).

Understanding better the unpredictability, irreversibility and consequences of horizontal gene transfer when gene drive organisms released into the wild. Since there is limited research done on the risks of NGTs to the environment, the current situation seemingly overestimates the perceived potential and benefits of NGTs.

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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?**

- ○ Yes
- ◉ No

* Please explain why not

No, the sustainability of NGT has not been yet evaluated adequately or sufficiently and therefore using products or organisms that have not been assessed in regards to environmental and health, or social impacts are not supported by POLLINIS (including SICAMM, University of Galway - NIU Galway, Division of Apiculture- Hellenic Agricultural Organization "DEMETER", APIMONDIA Bee Health Scientific Commission, Norsk Brunbiesenter, OGM Dangers, Wild Bees Project, Norsk Brunbielag, Friends of the Earth, University Educons from Sremska Kamenica, Aurelia Stiftung and Asociación de Apicultores de Gran Canaria, ApiGranca).

Supporters of NGT propose to create a gene drive (GD) honey bee to solve the problem of their decline and to maintain and increase pollination, including to sustain honey production. The idea is to generate a more resilient strain of honey bee that would survive better the effects of pesticides, viruses, parasites and diseases. Some call this version of bee a “pesticide-proof bee”, “bulletproof bee” (Warner 2019).

Beyond the attractiveness of using new technologies to control the free pollination service and given the disappearance of pollinators, the issue of genetic forcing applied to bees to make them more resistant to pesticides and viruses is disputed by many prominent pollinator specialists. Even Martin Beye, who developed a GD honey bee argued that the purpose of their work was to understand the genetic basis for bee behaviour and health. It was never to build a pesticide-resistant bee (Schulte, Theilenberg et al. 2014). In an interview with the Guardian newspaper, Beye stated: we need to move to farming practices that don’t harm bees. They should be working on that. Not on manipulating bees” (Warner 2018).

Gene drive honey bees are not a solution to the decline of honey bees. It is a way to not change the conventional agricultural system. Creating GD honey bees does not address the real causes of honey bee decline but rather it is a way to maintain the current use of pesticides and agricultural landscape. Studies are focused on understanding what kind of buffers can be developed to protect honey bees from the dangerous effects of pesticides in the current agricultural landscape instead of fixing the problem. This approach tends to normalise the use of pesticides and the obsession to increase agricultural output and thus, honey bees must be made stronger and more resilient to confront pesticides, keep pollinating and produce honey. There are indeed alternatives to this approach.

As an alternative to pesticides and using NGTs on pollinators, instead there is a need to make changes to meet the needs of the pollinators, especially honey bees. To keep pollinators healthy, they need surroundings with varied types of flowers and other plants. (Ricigliano 2019).

The search for a super-bee is one of the tools that will be offered to beekeepers to accomplish high productivity and be more resilient to the dangerous effects of pesticides. These super-bees can only be developed in the labs if the State encourages research, financial aid and regulation. Subsequently, leading to a more vicious path of patent authorisation and ultimately guaranteeing a stronghold of considerable importance to actors already committed to this path. Bees should not be patented and thus be held in the hands of large businesses when for centuries they have been wild and available to beekeepers around the globe.

For these “super bees”, “pesticides-resistant bees”, the issue of patents is of prime importance. Since these genomic edited organisms are industrial responses to the problems posed by the industrial agricultural model, they already carry major strategic stakes for agribusiness players: it is a way of "changing everything to change nothing". This is a common point for all gene drives applied to agriculture.

*

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?

- ○ Yes
- ◉ No

* Please explain why not

No, we do not believe that NGTs/NGT-products will bring benefits/opportunities to society.
Supporters of NGT propose creating a gene drive (GD) honeybee to solve the problem of their decline and to maintain and increase pollination. The idea is to generate a more resilient strain of honeybee that would survive better the effects of pesticides, viruses, parasites and diseases. Some call this version of bee a "pesticide-proof bee", "bulletproof bee" (Warner 2018).
Indeed, the possibility of creating bees pesticide-resistant domestic products appears to be one of the main applications of GD bees. The process of gene editing does not reflect the reality in which we live. Gene editing, as many technological fixes, only fixes one variable within a complex system. These new techniques make it possible to maintain the conventional agricultural system in place without tackling the causes of the problem, with uncertain and dangerous consequences for nature and food security.

Moreover, the application of NGT on pollinators/honey bees maintains the power imbalances between funding and experts. For example, there are also reports of Defense Advanced Research Projects Agency (DARPA) and funding Monsanto's "Secret Military Study", which uncovers a secretive JASON group of military advisors who produced a classified study on gene drives that proposes solutions for overcoming problems of releasing GD into the wild and what might be realisable in the next ten years related to GD and its agricultural applications (Hammond 2017).

Also, issues of power imbalances affect social implications related to patents and should be at the center of attention when talking about NGTs. For example, beginning with seeds, analysing how big companies gained power over seeds preventing farmers from cross breeding would be useful to understand companies developing genetically engineered animals or plants. In the end, even though there was broad agreement within the EU that seed companies had unfair advantages over the farmers and increased dependencies to the food chain, patents on crops came. Now, these patents and licenses are in the hands of a few companies. The same story repeats itself with new gene editing techniques where these techniques are highly contested and again in the hands of a very few.

While honey bees and pollination until now have remained beyond the reach of agro-industry, the use of NGTs on pollinators/honey bees opens the door to the privatisation of living organisms through the development of patented genomic edited bees to further the interest of agriculture and/or beekeeping. Indeed, as mentioned above, the creation of genetically modified bees resistant to pesticides is perfectly in line with the economic model of the agro-industry, which holds the entire agricultural market by selling pesticides against pests and patented seeds to farmers. In this context, farmers are bound by the contracts they have signed with agro-industry producers since they have to buy back the seeds in perpetuity because they cannot develop their own (Warner 2018). By not addressing the causes of the disappearance of pollinators, the main interest of the holders of these technologies is to develop new products for sale to farmers who will be able to benefit from them (Rowe 2019).

The preference of these processes and frameworks is for science-based knowledge and technical risk assessments without addressing adequately ethical and societal implications. Let's step back and broaden the discussion beyond the usual three main camps: decision makers and politicians who write, implement and influence regulations and laws on GD (who may or may not have any direct contact with GD); scientific experts understanding the ABCs of GD who might have direct and indirect contact with GD); and then those

scholars who study questions on science and its effects on society on the other (who might have direct connect with GD). Citizens must be aware of the consequences of gene drives on their lives and they must be involved in these important discussions.

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

- ○ Yes
- ◉ No

* Please explain why not

N/A

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

- ○ Yes
- ◉ No

* Please explain why not

No, we do not see any benefit or opportunity from patenting or accessing patented NGTs/NGT-products.

While honey bees and pollination until now have remained beyond the reach of agro-industry, the use of NGTs on bees opens the door to the privatisation of living organisms through the development of patented genetically modified bees of interest to agriculture and/or beekeeping.
For example, the creation of genetically modified bees resistant to pesticides using NGTs is in line with the economic model of the agro-industry, which holds the entire agricultural market by selling pesticides against pests and patented seeds to farmers. In this context, farmers are bound by the contracts they have signed with agro-industry producers since they have to buy back the seeds in perpetuity because they cannot develop their own (Warner 2018).

It should also be noted that researchers Al Dahhan and Westenberg have recently proposed to address Colony Collapse Disorder by using synthetic biology to develop honey bees that are free from certain pathogens such as Nosema ceranae (IUCN assessment report on synthetic biology and biodiversity conservation, 2019, pp.103-104). When these NGTs applications will be developed, it is likely that they will be submitted for patent applications.

As written see below, in the US - where gene drive organisms are not regulated as they are not considered genetically modified - patents on gene drive pollinators have been submitted and approved:
For example, Elwha LLC submitted a patent for registration to the US Patent and Trademark Office (USPTO), which aims to use genetic forcing to control field pollination by genetically modified bees whose optical genes have been modified. If commercialised, these genetically engineered bees would allow patent holders to control pollination to the extent that the possession of light beams specific to the activation of optical genes introduced by genetic forcing would allow genetically modified bees to be directed to specific crops. By not addressing the causes of the disappearance of pollinators, the main interest of the holders of these technologies is to develop new products for sale to rich farmers who will be able to benefit from them (Rowe 2019).

Another example, USPTO granted an application in February 2020 for a patent on the development of a CRISPR application to provide honey bees (Apis mellifera), bats, and butterflies with “the ability to assimilate

and degrade neonicotinoids". To do so, they intend "to insert desired genes into microbes that inhabit the honey bee gut". This patent is valid in the United States until 2035 (https://patents.google.com/patent /US20190022151A1/en).

Issues of power imbalance affect social implications related to patents and should be at the center of attention when talking about NGTs. For example, regarding seeds, analysing how big companies gained power over seeds preventing farmers from cross breeding would be useful to understand companies developing genetically engineered animals or plants. In the end, even though there was broad agreement within the EU that seed companies had unfair advantages over the farmers and increased dependencies to the food chain, patents on crops came. Now, this story of patents and licenses are already in the hands of a few companies. The same story repeats itself with NGTs where these techniques are highly contested and again in the hands of a very few.

Just like farmers have been prevented from reusing seeds from a year-to-year basis without paying a fee to seed patenting companies, the development of NGT pollinators or NGT pollinator-products which access will be restricted to patents and amount to patenting life.
We strongly believe that honey bees as well as other pollinators, as part of biodiversity's common patrimony, must remain outside of the scope of NGTs applications and their patenting processes.

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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?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Yes, NGTs and NGT-products raise challenges and concerns for our sector:
1. Risks:
The very nature of GDOs is to spread and persist. Understanding the full extent of the release of GDOs in the wild is limited. Unpredictability - the principle of GD is to completely alter the odds of the rules of inheritance to almost 100% in sexually reproducing organisms; GD will eventually preferentially pass on the gene until an entire generation possesses it.

As studies have shown that evolved resistance can arise through various mutational mechanisms that would be selected for if the drive reduces fitness (Sarkar 2018, Bull June 2016, Noble, Olejarz et al. 2017). It depends on how the drive behaves on a molecular level, how it mutates? – intentionally and unintentionally – and "potentially constantly adding to the genetics alterations or modification of the population in a way that most likely cannot be predicted" (p.100) (ENSSER 2019).

Moreover, the drive could go as expected and still have extremely unknown ramifications: to where

geographically they will go since technically, for pollinators there are no borders when flying. There is therefore a significant risk of unbalanced ecosystems and/or promoting the undesirable development of other species to eradicate whole species at risk, affecting other non-target species causing their extinction. The potential use of GDO raises even more serious problems related to the risk of transboundary contamination of agricultural systems around the world (p.10577) (Webber, Raghu et al. 2015, Esvelt, Smidler et al. 2014, Noble, Olejarz et al. 2017).

Linked to unknown consequences for the wider functioning of the ecosystem and non-target wild organisms, Noble et al. (2018) argue that GD technologies can become highly invasive and might have grave consequences (caused by potential drive resistance within a population that could be irreversible). There are currently no tools or mechanisms for undoing the GD once in the wild – in other words, no way to reverse or restore a living system back to what it was (ENSSER 2019). The potential power of drive "to eliminate or modify means that there is no room for errors in the technology or for unintended effects on the target species or the ecosystem into which it is released" (p.58) (ENSSER 2019).

Other examples of challenges to the actual technique and its consequences are related to horizontal gene transfer. Gene drive accelerates the possibility of horizontal gene transfer; there are studies showing this in the development of Wolbachia-based biocontrol techniques (Agren and Clark 2018). Broadly this possibility is the transfer of a GD to another species or even humans, which leads to unpredictable non-target effects to environment and unintentional spread of the GD construct contaminating non-target organisms (p.105) (NASEM 2016). Courtier-Orgogozo (2019) argues that we do not know the rate of horizontal gene transfer of GD constructs but we know that: risk of hybridisation is high but involves a few species and they have to be closely related to the GD; the risk of transfer is relatively low but it involves many more potential species, which would be more difficult to understand and tackle (Courtier-Orgogozo, Danchin et al. 2019).

Based on the number of uncertainties, moving forward with GD pollinators would completely disregard the precautionary principle. In its communication on the precautionary principle.

2. Patents:

The issue of patents is at the center of attention when talking about NGT. While honey bees and pollination until now have remained beyond the reach of agro-industry, the use of genetic forcing on honey bees and other pollinators opens the door to the privatisation of living organisms through the development of patented genetically modified bees of interest to agriculture and/or beekeeping. Indeed, as mentioned above, the creation of genetically modified bees resistant to pesticides is perfectly in line with the economic model of the agro-industry, which holds the entire agricultural market by selling pesticides against pests and patented seeds to farmers. In this context, farmers are bound by the contracts they have signed with agro-industry producers since they have to buy back the seeds in perpetuity because they cannot develop their own (Warner 2018). By not addressing the causes of the disappearance of pollinators, the main interest of the holders of these technologies is to develop new products for sale to farmers who will be able to benefit from them (Rowe 2019).

The unknown risks raise too many concerns for our sector and the regulation of patents on living things with only a few individuals to potentially hold the rights to GD honey bee/pollinator patents creates an imbalance of power for certain stakeholders.

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

- (●) Yes
- ( ) No

* Please explain

The very nature of gene drive organisms is to spread and persist (different than that of GMOs). This raises many issues for any application of gene drive to pollinators, including honey bees. By their very nature, NGTs present several risks for human and animal health as well as the environment. These techniques lead to a change in scale in terms of the number of species that can potentially be targeted and of the geographical spectrum in which these mutations can take place. Currently, there is very little data on GD systems (ENSSER 2019). They argue that current evaluations on GD systems are based on the assumption that genes will “behave” and “perform” as they are supposed to (Champer, Buchman et al. 2016).

* **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 describe and provide concrete examples/data

Environment
Supporters of NGT propose creating a gene drive (GD) honey bee to solve the problem of their decline and to maintain and increase pollination. The idea is to generate a more resilient strain of honeybee that would survive better the effects of pesticides, viruses, parasites and diseases. Some call this version of bee a “pesticide-proof bee”, “bulletproof bee” (Warner 2018).

Indeed, this process of gene editing does not reflect the reality in which we live. Gene editing, as many technological fixes, only fixes one variable within a complex system. These new techniques make it possible to maintain the conventional agricultural system in place without tackling the causes of the problem, with uncertain and dangerous consequences for nature and food security.
Unknown risks are unknown (many risks discussed in question 20), especially with respect to pollinator field release where such applications of NGT could disrupt functioning of ecosystems and biochemical pathways within organisms. Also we know that once released, those organisms cannot be retrieved.

Consumer
Patents should be at the center of attention when talking about NGTs. For example, beginning with seeds, analysing how big companies gained power over seeds preventing farmers from cross breeding would be useful to understand companies developing genetically engineered animals or plants. In the end, even though there was broad agreement within the EU that seed companies had unfair advantages over the farmers and increased dependencies to the food chain, patents on crops came. Now, these patents and licenses are already in the hands of a few companies. The same story repeats itself with new gene editing techniques where these techniques are highly contested and again in the hands of a very few.

While honey bees and pollination until now have remained beyond the reach of agro-industry, the use of genetic forcing on bees opens the door to the privatisation of living organisms through the development of patented GMO bees of interest to agriculture and/or beekeeping. Indeed, as mentioned above, the creation of GMO bees resistant to pesticides is perfectly in line with the economic model of the agro-industry, which holds the entire agricultural market by selling pesticides against pests and patented seeds to farmers. In this context, farmers are bound by the contracts they have signed with agro-industry producers since they have to buy back the seeds in perpetuity because they cannot develop their own (Warner 2018). By not addressing the causes of the disappearance of pollinators, the main interest of the holders of these technologies is to develop new products for sale to rich farmers who will be able to benefit from them (Rowe

2019).

Society

Power imbalances exist between funding and experts. For example, there are also reports of Defense Advanced Research Projects Agency (DARPA) and funding Monsanto's "Secret Military Study", which uncovers a secretive JASON group of military advisors who produced a classified study on gene drives that proposes solutions for overcoming problems of releasing gene drive into the wild and what might be realisable in the next ten years related to GD and its agricultural applications (Hammond 2017).

Citizens must be aware of the consequences of gene drives on their lives and they must be involved in these important discussions (especially concerning the adoption of a precautionary approach regarding GD pollinators potentially released into the wild).

Humans and animal
By their very nature, NGTs present several risks for human and animal health as well as the environment. These techniques lead to a change in scale in terms of the number of species that can potentially be targeted and of the geographical spectrum in which these mutations can take place. Currently, there is very little data on GD systems (ENSSER 2019). They argue that current evaluations on GD systems are based on the assumption that genes will "behave" and "perform" as they are supposed to (Champer, Buchman et al. 2016).

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

We believe if NGT-related organisms were released outside of the lab any of these issues would be the case.

Moreover, research on NGT on organisms inside the lab needs to be further investigated. There are currently no national or international rules on contained use of GDOs (Sirinathsinghji 2020). Noble et al. (2018) and others argue that conditions in the lab must be extremely strict because of their potential to spread and persist if during the release they escape (Akbari, Bellen et al. 2015). Confinement strategies need to be multiple, including molecular, ecological, reproductive and physical measures (Akbari, Bellen et al. 2015). Sirinathsinghji (2020) argues that some GDOs have the same characteristics as pathogens and as pathogens require strict measures because of spread, persistence, irreversibility and, with population suppression methods, lethal traits (Simon, Otto et al. 2018).

* Are these challenges/concerns specific to NGTs/products obtained by NGTs?

- (●) Yes
- ( ) No

* Please explain

The very nature of gene drive organisms is to spread and persist (different than that of GMOs). This raises many issues for any application of gene drive to pollinators, including honey bees. By their very nature, NGTs present several risks for human and animal health as well as the environment. These techniques lead to a change in scale in terms of the number of species that can potentially be targeted and of the geographical spectrum in which these mutations can take place. Currently, there is very little data on GD systems (ENSSER 2019). They argue that current evaluations on GD systems are based on the assumption that genes will "behave" and "perform" as they are supposed to (Champer, Buchman et al. 2016).

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

- ○ Yes
- ◉ No

* Please explain why not

N/A to us

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

- ◉ Yes
- ○ No

* Please describe and provide concrete examples/data

We see major challenges when patenting or accessing patented NGTs/NGT-products:
While honey bees and pollination until now have remained beyond the reach of agro-industry, the use of NGTs on bees opens the door to the privatisation of living organisms through the development of patented genetically modified bees of interest to agriculture and/or beekeeping.
For example, the creation of genetically modified bees resistant to pesticides using NGTs is in line with the economic model of the agro-industry, which holds the entire agricultural market by selling pesticides against pests and patented seeds to farmers. In this context, farmers are bound by the contracts they have signed with agro-industry producers since they have to buy back the seeds in perpetuity because they cannot develop their own (Warner 2018).

It should also be noted that researchers Al Dahhan and Westenberg have recently proposed to address Colony Collapse Disorder by using synthetic biology to develop honey bees that are free from certain pathogens such as Nosema ceranae (IUCN assessment report on synthetic biology and biodiversity conservation, 2019, pp.103-104). When these NGTs applications will be developed, it is likely that they will be submitted for patent applications.

As written below, in the US - where gene drive organisms are not regulated as they are not considered genetically modified - patents on gene drive pollinators have been submitted and approved:

For example, Elwha LLC submitted a patent for registration to the US Patent and Trademark Office (USPTO), which aims to use genetic forcing to control field pollination by genetically modified bees whose optical genes have been modified. If commercialised, these genetically engineered bees would allow patent holders to control pollination to the extent that the possession of light beams specific to the activation of optical genes introduced by genetic forcing would allow genetically modified bees to be directed to specific crops. By not addressing the causes of the disappearance of pollinators, the main interest of the holders of these technologies is to develop new products for sale to rich farmers who will be able to benefit from them (Rowe 2019).

Another example, USPTO granted an application in February 2020 for a patent on the development of a CRISPR application to provide honey bees (Apis mellifera), bats, and butterflies with “the ability to assimilate and degrade neonicotinoids”. To do so, they intend “to insert desired genes into microbes that inhabit the honey bee gut”. This patent is valid in the United States until 2035 (https://patents.google.com/patent /US20190022151A1/en).
Issues of power imbalance affect social implications related to patents and should be at the center of

attention when talking about NGTs. For example, regarding seeds, analysing how big companies gained power over seeds preventing farmers from cross breeding would be useful to understand companies developing genetically engineered animals or plants. In the end, even though there was broad agreement within the EU that seed companies had unfair advantages over the farmers and increased dependencies to the food chain, patents on crops came. Now, this story of patents and licenses are already in the hands of a few companies. The same story repeats itself with NGTs where these techniques are highly contested and again in the hands of a very few.

Just like farmers have been prevented from reusing seeds from a year-to-year basis without paying a fee to seed patenting companies, the development of NGT pollinators or NGT pollinator-products which access will be restricted to patents and amount to patenting life.

We strongly believe that honey bees as well as other pollinators, as part of biodiversity's common patrimony, must remain outside of the scope of NGTs applications and their patenting processes.

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E - Safety of NGTs/NGT-products

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

We believe that assessing the actual risk of NGTs/NGT-products cannot be done. Safety is linked to issues of risks and uncertainties of research on NGT and potentially released gene drive pollinators. As we have said in question 20, the very nature of GDOs is to spread and persist. This raises many issues for any application of gene drive (GD) to pollinators, including honey bees.

One of the ways to identify risk is through the ecosystem services (ES). This ES approach is increasingly contested and encounters multifaceted objections (Schröter et al. 2014). This approach is particularly unadapted to genetically modified organisms given that the latter can impact various components of biodiversity which are difficult to identify and measure, or do not have immediate value as ES but play an important role in ecosystem functioning and biodiversity conservation. It is even more difficult to identify the numerous risks to organisms and overall functioning of the environment, especially because of its interconnectedness and complexity. For these reasons, and considering that GDOs could disrupt ecosystem balance, we argue that NGT-related research faces numerous challenges, including its unpredictability, evolved resistance, unknown ramifications (both geographically where for pollinators, there are no borders when flying.

There is therefore a significant risk of unbalanced ecosystems and/or promoting the undesirable development of other species to eradicate whole species at risk, affecting other non-target species causing their extinction. The potential use of GDO raises even more serious problems related to the risk of transboundary contamination of agricultural systems around the world; they write: for CRISPR- Cas9 GD, this putative silver bullet technology could become a global conservation threat" (p.10577) (Webber, Raghu et al. 2015). Even those who have created these techniques, they understand that this possible intentional

spread might go beyond a target geographic area into the native population. This potential global spread of synthetic biological products could affect population genetics generally (Esvelt, Smidler et al. 2014, Noble, Olejarz et al. 2017). Moreover, risks of outcrossing to other species through horizontal gene transfer increase the unknowns are manifold.

Based on the number of uncertainties of risk to organisms, including non-target organisms, moving forward with GDMIs completely disregards the precautionary principle. The Commission underlines: "recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty"(summary, point 4, 3rd para. p.3).

In other words, since we cannot adequately evaluate the risk, there needs to be further assessment on actual unknown risks related to safety of the environment and human health before any field release.

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

- (●) Yes
- ( ) No

* Please explain

There are many specific safety concerns for NGT pollinators.

Bees, both managed honey bees and wild bees, occupy the same environment. Not only are managed honey bees situated in open fields - essentially out in the wild but they are also often in close proximity to other wild bee populations. Numerous interactions occur between managed and wild bees in the overall workings of the ecosystem, especially at shared floral resources but managed populations interact with flower resources, where other pollinators visit. As a result, safety is linked to issues of field release of NGT organisms. Understanding the full extent of the release of GDOs in the wild is limited. As we have said, there are many unknown risks of any field release of NBT-related applications.

Unpredictability and possible evolving resistance (Sarkar 2018, Bull June 2016, Noble, Olejarz et al. June 2016) can potentially lead to a wide range of unknown and unpredictable outcomes. In this case, it depends on how the drive behaves on a molecular level, how it mutates – intentionally and unintentionally – and "potentially constantly adding to the genetic alterations or modification of the population in a way that most likely cannot be predicted" (p.100) (ENSSER 2019). This resistance applied to honey bees/pollinators would be dangerous since they play a role within the ecosystems and they have existing relationships with each other and their floral resources.

Relevant to the pollinator sector, a honey bee colony where there could be several thousand of honey bees living and interacting together is a good example of a complex system . In fact, for many of our organisations, their hives are composed of Apis mellifera and these particular bees are known to have colonies based on "social behaviour patterns" (Winston 1987). As noted by Rivère et al. (2018), "social organisation depends on the multiple interactions (e.g. pheromones, nutrition, communication) occurring between specialised individuals (i.e. forager, nurse, builder, etc.) of different casts and ages. From these interactions, complex phenomena thus emerge at the system-level (the colony) allowing its self-regulation and self-adaptation" (pg.1). As honey bee colonies are seen as complex systems in themselves, the uncertainties of effects of applying NGT to them could incur further unknown risks.

Moreover, the drive could go as expected and still have extremely unknown ramifications: to where geographically they will go since technically, for pollinators there are no borders when flying. There is

therefore a significant risk of unbalanced ecosystems and/or promoting the undesirable development of other species to eradicate whole species at risk, affecting other non-target species causing their extinction.

Linked to unknown consequences for the wider functioning of the ecosystem and non-target wild organisms, Noble et al. (2019) argue that GD technologies can become highly invasive and might have grave consequences (caused by potential drive resistance within a population that could be irreversible). There are currently no tools or mechanisms for undoing the GD once in the wild – in other words, no way to reverse or restore a living system back to what it was (ENSSER 2019).

The potential power of drive "to eliminate or modify means that there is no room for errors in the technology or for unintended effects on the target species or the ecosystem", as well as the honey bee's own complex system, into which it is released (p.58) (ENSSER 2019). This "ecological confinement" is too risky.

Other examples of challenges to the actual technique and its consequences are related to horizontal gene transfer; there are studies showing this in the development of Wolbachia-based biocontrol techniques (Agren and Clark 2018). Broadly this possibility is the transfer of a GD to another species or even humans, which leads to unpredictable non-target effects to environment and unintentional spread of the GD construct contaminating non-target organisms (p.105) (NASEM 2016). Courtier-Orgogozo (2019) argues that we do not know the rate of horizontal gene transfer of GD constructs but we know that: risk of hybridisation is high but involves a few species and they have to be closely related to the GD; the risk of transfer is relatively low but it involves many more potential species, which would be more difficult to understand and tackle (Courtier-Orgogozo, Danchin et al. 2019).

Any potential safe deployment of NGT-related technology are based on assumptions and not experimental evidence: on the contrary, recent research has found that genomic editing can result in numerous unexpected, unpredictable and undesirable outcomes, even at the intended gene editing site (Kosicki, Tomberg et al. 2018, ENSSER 2019, Tuladhar, Yeu et al. 2019).

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F - Ethical aspects of NGTs/NGT-products

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

New genomic techniques, including CRISPR-related to engineer gene drives have offered supposed solutions to solve society's major problems, including combating malaria, or eradicating unwanted pests in agriculture. New genomic techniques advance and change rapidly and its applications closely follow thereafter. Most commenters agree that GD technologies could affect all aspects of society, ranging from agriculture, environmental conservation to human health. Even more, most people engaged in these discussions agree that there are questions about potential and unknown harms and ramifications of GD technologies to humans and the environment.

These technical advances, however, outpace policy and regulatory discussions (Oye, Esvelt et al. 2014).

Current international, regional and national governmental agencies are working to understand better the existing scientific knowledge, frameworks, policies and risk assessment guidelines related to gene editing processes (NASEM 2016, ENSSER 2019, IUCN 2019). These agencies work mostly at a level of regulatory decision-making bringing in scientific experts to discuss the nuts and bolts of GD and trying to develop better risk assessments.

In the absence of widely deliberative accepted guidelines on NGT, however, there is a direct omission of informed and inclusive discussion in these formal processes among citizens and those beyond experts of biotechnology and gene drive.
Mainly experts on gene drive or decision-makers, often with little input from those external to biotechnology expertise and citizens, hold the power. Moreover, there is limited understanding on how public engagement should feed into governance and a lack of consensus about best practices in this regard (p.7) (NASEM 2016).

There are also funding imbalances - those who fund NGTs usually have a great influence in what kind of research is done and thus benefits a certain pool of actors and not others). Moreover, these imbalances also affect regulatory frameworks, especially on who participates in such frameworks and who influences those voices are the ones heard and determine the decisions taken up. As well, issues of power imbalance affect social implications related to patents and should be at the centre of attention when talking about NGTs. For example, beginning with seeds, analysing how big companies gained power over seeds preventing farmers from cross breeding would be useful to understand companies developing genetically engineered animals or plants. In the end, even though there was broad agreement within the EU that seed companies had unfair advantages over the farmers and increased dependencies to the food chain, patents on crops came. Now, this story of patents and licenses are already in the hands of a few companies. The same story repeats itself with new gene editing techniques where these techniques are highly contested and again in the hands of a very few. POLLINIS and all organisation participating in this consultation (i.e. SICAMM, University of Galway - NIU Galway, Division of Apiculture- Hellenic Agricultural Organization "DEMETER", APIMONDIA Bee Health Scientific Commission, Norsk Brunbiesenter, OGM Dangers, Wild Bees Project, Norsk Brunbielag, Friends of the Earth, University Educons from Sremska Kamenica Aurelia Stiftung and, Asociación de Apicultores de Gran Canaria, ApiGranca). strongly disagree with the process of patenting living organisms.

While honeybees and pollinators had remained beyond the reach of agro-industry, the use of genetic forcing on bees opens the door to the privatisation of living organisms through the development of patented GMO bees of interest to agriculture and/or beekeeping. Indeed, as mentioned above, the creation of GMO bees resistant to pesticides is perfectly in line with the economic model of the agro-industry, which holds the entire agricultural market by selling pesticides against pests and patented seeds to farmers. In this context, farmers are bound by the contracts they have signed with agro-industry producers since they have to buy back the seeds in perpetuity because they cannot develop their own (Warner 2018).

The preference of these processes and frameworks is for science-based knowledge and technical risk assessments without addressing adequately ethical and societal implications. It is critical to broaden the discussion beyond the usual three main camps: decision makers and politicians who write, implement and influence regulations and laws on NGT (who may or may not have any direct contact with GD); scientific experts understanding the ABCs of NGT who might have direct and indirect contact with GD); and then those scholars who study questions on science and its effects on society on the other (who might have direct connect with GD). Citizens must be aware of the consequences of NGT on their lives and they must be involved in these important decision-making processes.

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

- (●) Yes

No

* Please explain

The gene editing systems encompassing NGT have offered supposed solutions to solve society's major problems, including maintaining and increasing the output of the current agricultural system. New genomic techniques advance and change rapidly and its applications closely follow thereafter. Most commenters agree that NGT could affect all aspects of society, ranging from agriculture, environmental conservation to human health. Even more, most people engaged in these discussions agree that there are questions about potential and unknown harms and ramifications of NGT to humans and the environment.

In the absence of widely deliberative accepted guidelines, however, there is a direct omission of informed and inclusive discussion in these formal processes among citizens and those beyond experts of biotechnology and gene drive. For example, the process of IUCN members commenting on 075 IUCN Principles on Synthetic Biology and Biodiversity offer fora to engage in diverse public participation, but none of these processes use more open inclusive processes to include a broader public.

Despite having a stakeholder consultation as a part of this current process, there has been no involvement of a broader group of citizens or any awareness of NGT-related issues for citizens and its consequences on their way of life. Indeed the possible effects NGT-related applications are so extensive that we will all be affected (including human and animal health and the environment). In fact, even if you assume that some NGOs, government bodies, have some understanding of the awareness, wants and needs of citizens, the stakeholder consultation currently conducted by the Commission is still a process limited to citizens with a relatively good knowledge on NGT-related issues, and perhaps even in the Commission's processes, especially representatives of NGOs and those experts of biotechnology and gene drive disciplines.

Those experts on gene drive or decision-makers, often with little input from those external to biotechnology expertise and citizens, hold the power. Moreover, there is limited understanding on how public engagement should feed into governance and a lack of consensus about best practices in this regard (p.7) (NASEM 2016).

We believe that there are issues of power imbalances that affect social implications related to patents and should be at the centre of attention when talking about NGTs. For example, beginning with seeds, analysing how big companies gained power over seeds preventing farmers from cross breeding would be useful to understand companies developing genetically engineered animals or plants. In the end, even though there was broad agreement within the EU that seed companies had unfair advantages over the farmers and increased dependencies to the food chain, patents on crops came. Now, this story of patents and licenses are already in the hands of a few companies. The same story repeats itself with new gene editing techniques where these techniques are highly contested and again in the hands of a very few.

For the moment, honeybees and pollination have remained beyond the reach of agro-industry, the use of genetic forcing on bees opens the door to the privatisation of living organisms through the development of patented NGT bees of interest to agriculture and/or beekeeping. Indeed, as mentioned above, the creation of NGT bees resistant to pesticides is perfectly in line with the economic model of the agro-industry, which holds the entire agricultural market by selling pesticides against pests and patented seeds to farmers. In this context, farmers are bound by the contracts they have signed with agro-industry producers since they have to buy back the seeds in perpetuity because they cannot develop their own (Warner 2018).

The preference of these processes is for science-based knowledge and technical risk assessments without addressing adequately ethical and societal implications. POLLINIS and the organisations represented in this consultation (i.e. SICAMM, University of Galway - NIU Galway, Division of Apiculture- Hellenic Agricultural

Organization "DEMETER", APIMONDIA Bee Health Scientific Commission, Norsk Brunbiesenter, OGM Dangers, Wild Bees Project, Norsk Brunbielag, Friends of the Earth, University Educons from Sremska Kamenica, Aurelia Stiftung and Asociación de Apicultores de Gran Canaria, ApiGranca) believe that these processes must ensure that all citizens are aware of how NGT techniques could affect their way of living in their environment, so that they are able to effectively participate in a public consultation and eventually have the knowledge to choose and state their opinions.

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G - Consumers' right for information/freedom of choice

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

N/A

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H - Final question

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

- (●) Yes
- ( ) No

Please provide your comments here

As a general statement, we are against the deliberate release of NGT-related application to honey bees /pollinators, such as GD pollinators is a practice without precedent nor history of safe use. There is no guarantee that this will result in predictable outcomes. There is insufficient data to prove that this will be safe. Till more data are available, the precautionary principle would preclude any deliberate release of NGTs into the wild.

We would stress that, at present, suggestions of a potential safe deployment of this technology are based on assumptions and not experimental evidence. On the contrary, recent research has found that gene editing can result in numerous unexpected, unpredictable and undesirable outcomes, even at the intended gene editing site (see Kosicki, M. et al., 2019; Tuladhar et al., 2019; ENSSER Statement, 2019).

We urge the Commission to keep in mind the call for a moratorium on gene drive field tests as the deployment of GD pollinators might lead to undesired side effects on organisms and overall functioning of ecosystems.

Although we are indeed optimistic that we, with other national organisations, have been accepted to be part of this survey, we still believe there is further room for the Commission to broaden its public consultation. As the Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Emerging on Newly Identified Health Risks (SCENIHR) and Scientific Committee on Consumer Safety (SCCS) – one of the documents cited as a previous EU initiative on new biotechnology techniques argues that any governance framework must include:
horizontal scanning coupled to assessment of risks and benefits in an iterative, multi-level and multi-actor process. The process involves interaction with relevant actors from society, including industry, science, NGOs, citizens ad takes their interests and values into account" (p.15) (Renn, Klinke et al. 2011, van Asselt and Renn 2011) (Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) et al. 2015).

Hence, we (POLLINIS and the 12 organisations represented in this consultation - SICAMM, University of Galway - NIU Galway, Division of Apiculture- Hellenic Agricultural Organization "DEMETER", APIMONDIA Bee Health Scientific Commission, Norsk Brunbiesenter, OGM Dangers, Wild Bees Project, Norsk Brunbielag, Friends of the Earth, University Educons from Sremska Kamenica, Aurelia Stiftung and Asociación de Apicultores de Gran Canaria, ApiGranca encourage the Commission to involve citizens at a deeper level during such consultations. We strongly argue using pesticides and applying NGTs on pollinators are far from being a sustainable solution. Instead, we must work towards protecting pollinators.

To conclude, let's ask the question differently: what necessary measures should be taken to protect pollinators?

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