

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

B a c k g r o u n d

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 / E C) .

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 a f t e r 2 0 0 1 .

I n s t r u c t i o n s

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

[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 as 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

European Consumer Organisation (BEUC)

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

Consumer rights, Food, Financial Services, Digital Rights, Sustainability

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

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

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

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

- Yes
- No
- Not applicable

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

- Yes
- No
- Not applicable

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

- Yes
- No
- Not applicable

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

- Yes
- No
- Not applicable

* Please provide details

For consumers, the unintentional use of NGTs poses important risks as consumers want to know whether the food they purchase has been produced using genetic engineering. The labelling of products produced using such technologies is central to ensuring consumers right to know and freedom of choice (please see question 28 for more details). Current EU legislation on genetically modified organisms, which NGTs are subject to as stated by the ECJ, requires NGTs to undergo an approval procedure with corresponding traceability and labelling obligations. Therefore, an unintended use of NGTs would not be permitted. It is therefore important that further research is undertaken on detection methods for these technologies.

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

- Yes
 No

* Please provide details

Please see above.

*** 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

* 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

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

- Yes
- No
- Not applicable

* 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

We expect more research on the traceability of possible effects on health and the environment of NGT-products. There are an increasing number of countries which approve new genetic engineering without a risk assessment for the health and the environment (e.g. USA, Canada, Russia, Australia). Thus, marketable NGT-products are entering the market in these countries without a risk assessment, traceability and labelling. This means that agricultural systems that deliberately do not use genetic engineering in their production (organic farming, GMO-free production) cannot be protected from unintentional contamination. We therefore recommend that research into the detection of genetic modification should be strengthened. In our opinion, consumers should not be restricted in their freedom of choice.

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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 describe and provide concrete examples/data

Please see response to question 17.

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

- Yes
 No

* Please explain why not

The challenges posed by improving the sustainability of the food system are multi-factorial. The development and use of NGTs, even if employed in order to help tackle such issues, will not be sufficient to answer the multitude of problems faced by it which are seen by consumers as key societal concerns and for which rather a paradigm shift will be required.

A citizens' dialogue undertaken by the UK consumer organisation, Which? and a UK governmental agency to discuss views on food systems has shown that consumers (who participated in the study), when discussing a range of potential solutions to address challenges related to environmental externalities of our food systems, clearly supported those that were low-tech, natural or focused on behaviour change. When it comes to hi-tech solutions, consumers think that they should only be considered if independent organisations have ensured that they are safe and if there were no low-tech alternatives which would be publicly acceptable and achieve similar outcomes.

* **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 describe and provide concrete examples/data

Consumers may perceive future NGTs which are used for purposes which genuinely contribute to societal benefits and sustainability in a more positive light. Nevertheless, this does not however negate the demand from consumers for such products to remain subject to labelling requirements to allow for freedom of choice. Please see the response to question 21 for further elaboration on this.

Consumer research undertaken by authorities in Germany found that while consumers could potentially see benefits of genome editing for the improvement of agriculture to respond to real societal concerns, the possible disadvantages raised by consumers were many including concerns regarding; who benefits financially from them, the unknown impacts, a lack of traceability jeopardising the freedom of choice as well as ethical concerns.

The UK citizens' dialogue reported similar responses from participants who, although they did not reject biotechnology completely, they wanted reassurances that it would be used for the 'right' reasons (i.e. to support sustainable food production rather than drive profit). They also wanted assurances that unforeseen consequences were properly monitored, including any possible risk to public health or biodiversity. Participants also mentioned that that supporting one application may pave the way for other less acceptable and less ethical applications.

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

Please see above.

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

Yes
 No

- * Please explain why not

Please see above.

- * **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

The extensive costs required to invest in the research needed to develop genetically modified products including from new genomic techniques would be prohibitive for most SMEs. Moreover, the eventual patents for organisms produced using these methods, risks accelerating the concentration of the seed industry.

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

Yes
 No

- * Please explain why not

The biotechnology sector is already intensely concentrated. Investment from such companies towards NGTs and the subsequent patents on NGT products further risks affecting the variety of seeds available to the disadvantage of other approaches such as traditional breeding.

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

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b19193b3-7260-4e88-927a-27733ad15c02/food-system-challenges---public-dialogue-on-food-system-challenges-and-possible-solutions-445299.pdf

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

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

- Yes
 No

* Please describe and provide concrete examples/data

Consumers are increasingly interested in the methods of production of the foods they purchase and consume. The questioning of the legal status of NGTs – despite the ECJ's judgement that they are to be considered as GMOs – raises concern as it threatens consumers' ability and right to make informed food choices.

In the latest Eurobarometer poll on Food Safety in the EU (2019), over a quarter of consumers (27%) ranked 'genetically modified ingredients in food or drinks' as one of their top five concerns. Some have interpreted this finding as a shift in consumer attitudes towards GMOs since 2010 – when the previous Eurobarometer poll was conducted (as in 2010, 66% of Europeans replied they were worried about GMOs). Yet, the two surveys are not directly comparable, as they differ in the way the questions were phrased. In the 2010 poll, consumers were asked, for a series of possible risks (incl. the presence of GMOs in food and drinks), to what extent they felt worried (or not) about these. But in 2019, consumers were asked to pick their five top food safety concerns out of a long list of issues. Unsurprisingly, EU consumers feel less concerned about GMOs than they are over antibiotics in meat, pesticides or food additives for instance, because the presence of genetically modified ingredients in food products remains at a very low level on the EU market thanks to current legislation. Many Europeans (incl. the French Ecology Minister) mistakenly believe that GMOs are prohibited in the EU (which is largely the case for cultivation, but not for marketing and food and feed use). The 2019 Eurobarometer poll also found that only 21% of respondents had even heard of genome editing. Given that its use in the EU is at a very nascent stage, it is not surprising that a very small (4%) proportion of consumers listed it as one of their top five concerns out of all others they may have for the food they consume. Nevertheless, it is clear that as the issue becomes more prominent and widely debated, consumer awareness and concern about the use of these techniques are likely to increase in parallel.

Indeed, a study recently undertaken in Austria on consumer attitudes to genetic modification in general and NGTs in particular found that a strong majority (85.2%) of those surveyed believed that freedom from genetic engineering is an important aspect when shopping, reiterating the importance of maintaining consumer choice on this issue. Moreover, 84.1% of respondents want NGT products to be controlled as strictly as previous genetic engineering and 69.3% said that they do not want to see NGT products on the market. The importance of labelling of NGTs was also underlined in the report with 85.6% of respondents stating that these techniques should be labelled as genetic engineering. 94% said that they wanted their authorities to work at an EU level to ensure that NGTs are regulated as strictly as current GMOs.

In Germany, the results of consumer research in 2017 found that genome editing in the food sector was largely rejected by participants who clearly perceived genome editing, irrespective of the legal classification, as a form of genetic engineering. In the food sector, the disadvantages outweigh the advantages in the opinion of the participants. They clearly demanded a labelling obligation for foods produced with the help of genome editing. They also expected its strict regulation by the responsible authorities.

Any potential future exemptions for NGTs from having to comply with the traceability and labelling requirements set out in the GMO Regulations (1829/2003 and 1830/2003) also risks damaging the integrity of the organic sector. At a time when consumers are increasingly concerned by the impacts of certain aspects of conventional farming, the purchasing of organic food has significantly increased. As NGTs and GMOs are prohibited from the organic food supply chain, it is important that traceability and labelling requirements are fulfilled for NGTs to ensure that producers are not limited in their choice of farming methods and consumers are subsequently still able to make a choice between organic and conventionally produced food products.

Furthermore, 'GMO-free' labels are well-established in many countries. In 2017, 75 companies from 10 countries - Europe-wide - will have achieved a total turnover of 144.2 billion euros with GMO-free production. In Austria, 3500 products bear the GMO-free label while the entire poultry, egg and milk sectors are GMO-free. As mentioned above, traceability and labelling requirements must be fulfilled for NGTs so that GMO-free labelled products may continue to be offered to consumers.

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

- Yes
- No

* Please explain

Please see above for details.

*** 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

Methods of food production and the acceptability thereof is an area of increasing importance for today's consumers when they make their food choices.

A citizens' dialogue undertaken by the UK consumer organisation, Which? and a UK governmental agency to discuss views on food systems has shown that consumers (who participated in the study), when discussing a range of potential solutions to address challenges related to environmental externalities of our food systems, clearly supported those that were low-tech, natural or focused on behaviour change. When it comes to hi-tech solutions, consumers think that they should only be considered if independent organisations have ensured that they are safe and if there were no low-tech alternatives which would be publicly acceptable and achieve similar outcomes.

Experience with genetic modification to date has shown a predominance in herbicide and insect resistance for use in industrial crops such as soy, corn, rapeseed and cotton. At a time when there is an increased focus on fundamentally changing the food system to tackle societal concerns such as climate change, there may be legitimate concerns amongst consumers that new genomic techniques are not sufficient to tackle these key issues and a more significant paradigm shift will be required to meet the challenges. Moreover, while it remains to be seen which NGTs eventually make it to market, their use in producing herbicide and insect resistant crops could be perceived negatively by consumers. Indeed, in Europe, the presence of pesticide residues in foods is one of the top concerns listed by consumers .

In the debate on new genomic techniques, the potential benefits of such technologies to contribute to tackling some of society's key concerns such as pesticide use or climate-resistant plants are often put forward. However, the question arises which positive effects for consumers can actually be deduced from some of the current applications. For example, apples or mushrooms, whose cut surfaces do not turn brown, are in reality not a benefit for consumers. Indeed it could rather mislead consumers into believing that such products are fresher than they actually are.

A recent survey (<https://www.bioteknologiradet.no/filarkiv/2020/04/Rapport-holdninger-til-genredigering.pdf>) in Norway found that consumers' attitudes towards the use of gene editing depended on the purpose for which they were employed and most consumers are negative about using gene editing for purposes that are not perceived to be of significant benefit to society or which may impact animal welfare negatively, such as changing the appearance of animal and plant products or enhancing production traits in livestock.

The afore-mentioned UK citizens' dialogue found that whilst not all consumers may completely reject biotechnology in general, they wanted reassurances that its use was for the right reasons (to support sustainable food production rather than profit). It was also underlined that it was important for consumers that unforeseen consequences were properly monitored, including any possible risk to public health or biodiversity. A key concern throughout this discussion was that biotechnology was concerned less with food sustainability and more about corporate profit. Many participants were very cynical about the motives of the agro-chemical and seed firms. These challenges/concerns are not specific to NGTs/NGT products since consumer awareness of NGTs/NGT products is very low so far.

Economic Concerns

The consumption of organically produced food has been increasing significantly in recent years. The proportion of products labelled as GMO-free has also been rising for years.

There is a risk of higher costs for consumers who consciously choose non-GM and organic products.

Organic farming and "GMO-free production" would require elaborate separation systems in seed and feed to avoid unintentional contamination. The costs of this would most likely be reflected in the product price. It is possible that, in case of deregulation, due to the lack of traceability of NGT products, they would no longer be able to offer their products GMO-free.

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

Please see above.

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

Yes

No

- * Please explain why not

These concerns can also be relevant for genetic engineering in general, not just NGTs (for which awareness is very low currently).

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

Yes

No

- * Please explain and provide concrete examples and data

The extensive costs required to invest in the research needed to develop genetically modified products including from new genomic techniques would be prohibitive for most SMEs. Moreover, the eventual patents for organisms produced using these methods, risks accelerating the concentration of the seed industry which could in turn threaten consumer choice.

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

Yes

No

- * Please describe and provide concrete examples/data

The biotechnology sector is already intensely concentrated. Investment from such companies towards NGTs and the subsequent patents on NGT products further risks affecting the variety of seeds available to the disadvantage of other approaches such as traditional breeding.

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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**

Organisms produced with new genomic techniques do not have a long history of safe use and may exhibit properties which may pose risks to human health and the environment. It is important to take a precautionary approach with such products, whose premature release into the environment or use for food and feed purposes, without a risk assessment, can have irretrievable impacts, which is of special concern should the NGT produce off-target effects.

Risks to human health that could potentially be associated with NGTs and NGT products in the absence of appropriate regulations include for instance the presence of toxins, allergens or altered nutrients in food derived from crops and animals obtained from NGTs.

Because of their short history of use, it is extremely challenging to correctly appreciate the breadth of the potential safety risks associated with NGTs and NGT products. For instance, in the US, the Food and Drug Administration found unintended antibiotic resistance genes in 'gene-edited' dehorned cattle. It is likely that, as the use of NGTs develops, new risks will be uncovered. This makes a precautionary approach to the use of these techniques all the more necessary.

Just like all other GMOs, it is therefore vital that products obtained from NGTs are required to undergo a thorough risk assessment which considers the risks to the environment, animal welfare and human health before they can be placed on the market for food and/or feed use.

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

- Yes
 No

* Please explain

Please see response to Question 24.

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

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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**

There are some concerns with NGTs with regard to animal welfare. This includes for instance a high failure rate for genetically engineered mammals, often leading to many aborted, dead or deformed embryos; animal suffering as a result of the new genetically engineered trait (some animals are too heavy to walk easily, or over-produce milk); increased disease susceptibility for herds/flocks as a result of greater genetic uniformity. New genomic techniques could exacerbate these concerns as they may strive to push animals even further beyond their physiological limits.

Yet, support for the welfare of farm animals is very high among Europeans, as shown by a 2016 Eurobarometer poll on animal welfare, which found that 94% of EU citizens consider that protecting the welfare of farm animals is important. A parallel can be drawn with animal cloning for food production. The 2010 Eurobarometer on biotechnology found that 67% of Europeans saw cloning as totally unacceptable for food production and that 69% agreed cloning would risk treating animals as commodities. It is more than probable that a survey on consumer attitudes towards the application of NGTs to farm animal breeding would obtain very similar findings.

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

- Yes
 No

* Please explain

Please see response to Question 26.

Please upload any supporting documentation for this section here

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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**

BEUC has always strongly advocated for genetically modified organisms and food/feed produced therefrom to be subject to strict traceability and labelling requirements, as per the current EU legislation, to allow consumers a choice between such products and those which are produced conventionally. Discussion of and consumer concern with highly technical processes in food production go beyond safety-related concerns.

Environmental concerns such as worries for the impact on biodiversity, as well as ethical and socio-economic concerns are also prominent features in any debate on genetic modification. It is imperative therefore that consumers are equipped with the information, clearly displayed on the label, as to whether a certain food product has been produced using genetic modification techniques so that they are able to make an informed decision. As genetic modification is an important concern for many consumers it is essential that this information is not relegated as 'additional information' provided electronically through, for example, QR codes but is placed on the label where consumers can use this information at the point of purchase.

As mentioned previously, consumer research recently undertaken in Austria underlined the importance consumers attach to the freedom to opt for foods not produced with genetic engineering methods. Correspondingly, the importance of labelling NGTs was underlined with 85.6% of respondents stating that they wanted these techniques to be labelled as genetic engineering and 94% said that they wanted their authorities to work at an EU level to ensure that NGTs are regulated as strictly as current GMOs.

Moreover, the possibility for consumers to be able to opt for products bearing a 'GMO-free' label is also crucial to allow freedom of choice. 83% of respondents to another study said that GMO-free production was important to them.

The right to choose also requires non-GM supplies of crops and animals to be maintained and GM products to be labelled as such. As already mentioned, all over Europe non-GM production are increasing. It is very important for consumers, that these non-GM supplies will be able to stay on the market and can offer their products to the consumers so their demand for non-GM food will be guaranteed.

Even when consumers are presented with a positive appraisal of new genomic techniques, as was the case in a recent Norwegian survey undertaken by the Biotechnology Council, consumers still felt it necessary for products produced with these techniques to be labelled.

A recent consumer focus group conference in Germany found that of importance to participants when discussing this issue were: maintaining a principle of precaution, freedom of choice for consumers, freedom of information and transparency, priority of social aspects over economic interests, no patenting of living beings, liability for unexpected damage by the manufacturers, and labelling.

Previous consumer research undertaken by German authorities in 2017 found that participants in a consumer focus group on the issue felt that, once genome editing had been explained to them that it was genetic engineering because of the human intervention. The claim that genome editing could be considered as a natural process was even felt to be more like a 'deliberate deception'. The labelling of NGTs was held to be a prerequisite for an informed decision.

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H - Final question

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

- Yes
 No

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Contact

SANTE-NGT-STUDY@ec.europa.eu