

Minutes of first ISSG on Study on New Genomic Techniques

3 December 2019

DG SANTE presented the background of the study and the Council request on New Genomic Techniques. DG SANTE also shared the draft outline of the study, which will need further adaptation when work progresses, and the working methods and provided clarification responding to questions raised by the other services.

The discussion was very constructive and the ISSG agreed on the following:

- To respond to the Council's request, the scope of the study must go beyond new mutagenesis techniques, as there are other new techniques, for which the Council seeks clarification. Therefore, the study should cover all new techniques, which have been developed after 2001. For the questions to be sent to Member States and stakeholders, terminology/definitions need to be included so that the scope is clear.
- Services agreed to contribute to the issues identified in the draft outline.
- Working methods and timeline were agreed: in-house COM study based on Member States' and stakeholders' contributions (targeted consultation), complemented by expert contributions from the JRC¹, other services, EURL/ENGL and EFSA. Seven ISSG meetings are planned between December 2019 and December 2020. The draft study should be ready at ISSG level by mid-December 2020, to leave time for conclusions, next steps and political validation.
- Services will contribute to the list of stakeholders (by 6/12) and to the questions to Member States (by 11/12) and to stakeholders (by 18/12).
- Meeting with Member States (GMO competent authorities) is planned for 15 January and an ad-hoc stakeholder meeting for 13 February.
- A single webpage on the study will be created by DG SANTE to provide information to the public. Other services can provide useful links that can be included on this webpage.
- Transparent communication among DGs on the topic will be pursued, including on communication with stakeholders.

SANTE invited services to nominate one contact person in order to have a single coordinated contribution to the study from each DG. Functional mailbox should be used for communication with SANTE: SANTE-NGT-STUDY@ec.europa.eu

Next ISSG meeting on 4 February 2020.

These minutes have been agreed by all the participants.

Documents in the Annex:

Agenda
Background document
Draft outline of the study
List of participants

¹ Agreement on JRC contribution to be confirmed at Directors' level by 11.12.2019

Study on New Genomic Techniques
1st meeting of the Interservice Steering Group

3 December 2019 10.00-11.30
DG SANTE, Rue Froissart 101
meeting room F101-00/33, video link to JRC-Geel

Draft Agenda

1. Background on the study - Council Decision 2019/1094
2. Draft outline of the study
3. Working methods
 - a. Timeline and ISSG meetings
 - b. Targeted stakeholder consultation
 - c. Contribution from other DGs
 - i. Relevant stakeholders
 - ii. Research
 - iii. Patents
 - iv. State-of-the-art of new genomic techniques
 - v. Market applications
 - vi. Future scientific and technological developments
 - d. SANTE webpage
4. AOB

Background for the first meeting of ISSG – Study on new genomic techniques

CJEU ruling on mutagenesis

Directive 2001/18/EC on the deliberate release into the environment of GMOs contains an exemption applicable to “mutagenesis techniques”. The Court of Justice’s preliminary ruling (Case C-528/16) concluded that only organisms obtained by techniques of mutagenesis, conventionally used in a number of applications and with a long safety record, are exempted. Therefore, the GMO legislation is applicable to organisms obtained by mutagenesis techniques as well as to other genomic techniques, which have emerged after the adoption of Directive 2001/18/EC.

Request of the Council under Article 241 TFEU

The Council Decision, based on Article 241 TFEU, was adopted on 8 November. The Council requests the Commission to submit

- a study, by 30 April 2021, regarding the status of new genomic techniques under Union law and in light of the Court of Justice’s judgment;
- a proposal (accompanied by an impact assessment), if appropriate in view of the outcomes of the study, or otherwise to inform the Council on other measures required as a follow-up to the study.

The Council considers that a study is necessary to clarify the situation and justifies the request by noting that although the ruling brought legal clarity, it raises practical questions, which have consequences for the national competent authorities, industry, in particular in the plant breeding sector, research and beyond.

Terminology

- **New Genomic Techniques (NGTs)**: techniques, which are capable to alter, regulate the expression or synthesise genetic material and which have emerged or have been developed since 2001. Examples include CRISPR-techniques, Talen, prime editing etc.

The timeline for the ISSG work

- 1st meeting – 3 December 2019 – kick-off meeting
- 2nd meeting – 4 February 2020
- 3rd meeting – 2 April 2020
- 4th meeting – 4 June 2020
- 5th meeting – 3 September 2020
- 6th meeting – 5 November 2020
- 7th meeting – 15 December 2020 – final comments from ISSG on the study

Draft outline to be adapted

- 1. Background**
 - a. Council Decision – request to clarify the situation of new genomic techniques (NGTs)
 - b. Overview of NGTs under GMO legislation and linkages with other sectors
- 2. Implementation and enforcement of the legislation with regard to NGTs - based on stakeholders' contributions**
 - a. State of play by Member States (including on detection, traceability, official controls and required resources, experimental releases, links with other legislation²)
 - b. State of play by operators (including provision of detection methods as part of authorisation, traceability methods and labelling)
- 3. Analysis of the status of NGTs (based on stakeholders' contributions and expert opinions) regarding**
 - a. State-of-the-art on scientific and technological developments in NGTs
 - b. Overview of safety/risk profiles of different techniques (EFSA) and other contributions on safety
 - c. Ethics including EGE opinion
 - d. Research
 - e. Business model
 - f. Innovation and competitiveness
 - g. Opportunities and potential benefits
 - h. Trade and regulations on NGTs in 3rd countries
- 4. Outlook**
 - a. Market applications (current and near-market)
 - b. Trends in research
 - c. Future scientific and technological developments in NGTs
- 5. Conclusions in light of the analysis and outlook**
- 6. Next steps**

Annex

- Table on techniques
- Terminology
- EFSA opinion
- ENGL report
- EGE opinion
- Research-related statistics
- Overview of 3rd countries' regulations on NGTs

² Such as pharma, seeds

Participants 1st ISSG on New Genomic Techniques

DG	Name
SJ	[REDACTED]
AGRI	[REDACTED]
JRC	[REDACTED] [REDACTED] [REDACTED] (via videolink)
MARE	[REDACTED]
TRADE	[REDACTED]
GROW	[REDACTED]
RTD	[REDACTED]
SANTE	[REDACTED] [REDACTED]
SG	[REDACTED] (excused)
ENV	<i>Not present</i>
CLIMA	<i>Not present</i>