Ministry of Environment
and Food of Denmark
The Danish
Agricultural Agency

New Genomic Techniques – current status and on-going activities in the EU and Denmark

DanSeed Symposium 2020

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Content of the presentation

1) **Very short background on new genomic techniques and their regulation in the EU**

2) **What has happened since last year's presentation at DanSeed -**

   - At EU-level?
   - At Danish level?

3) **Next steps:**

   - In the EU
   - In DK

A continuing story…
New genomic techniques and their regulation in the EU

1990: Directive 90/220/EEC on deliberate release of GMOs

2001: Directive 2001/18/EC on deliberate release of GMOs, repealing Directive 90/220/EEC

2001-2009: Consolidation of EU's GMO-legislation: food/feed, traceability and labelling, contained use

2007: Commission establishes New Techniques Working Group, it reports unofficially in 2012

2011: Joint Research Center report on New Plant Breeding Techniques

2016: France request European Court of Justice (ECJ) to rule on new mutagenesis techniques

2018: ECJ-ruling: New mutagenesis techniques are *not* exempted from the provisions of the GMO-regulation

What has happened since last year's DanSeed -

at EU-level?

ENGL-report on detection of food and feed plant products obtained by new mutagenesis techniques

Detection of GMOs is a key concept in EU's current regulation because of:

1. The regulation's requirements on traceability and labelling in market authorisations

- Cover all authorised GMOs and food and feed products containing GMOs,
- *Applicants* shall ensure that an application for marketing of a GMO includes a detection, identification and quantification method.

2. The regulation's requirements on inspections and market control

- *Competent authorities* shall organise inspections and control to ensure compliance with the GMO-legislation as regards authorised and non-authorised GMOs.

3. The regulation's requirements on non-authorised GMOs

- No *import or use* of non-authorised GMOs (zero-tolerance applies).

ENGL-report on detection, some key conclusions

For applicants:
"..it is questionable if event specific identification and quantitative detection methods can be developed readily for all genome-edited plants."

For Competent Authorities (and importers!):
"..it is highly improbable for enforcement laboratories to be able to detect the presence of unauthorised genome-edited plant products in food or feed entering the EU market without prior information on the altered DNA sequences."

"..market control will fail to detect unknown genome-edited plant products"

Applicants, Competent Authorities, and importers will not be able to comply with current EU-regulation as regards new mutagenesis techniques!

Council Decision (EU) 2019/1905 of 8 November 2019 on new genomic techniques

The Council requests the Commission:

- to submit a study by 30 April 2021,
- in light of the European Court of Justice's decision,
- regarding the status of New Genomic Techniques under Union law,
- and if appropriate in view of the outcomes of the study, to submit a proposal,
- accompanied by an impact assessment,
- or otherwise to inform the Council on other follow-up measures.

Questionnaire from the Commmission to Member States on New Genomic Techniques

1) Covers plant, animals, microorganisms and derived food and feed products obtained through all types of NGTs

2) Defines New Genomic Techniques as *”techniques capable of altering the genetic material of an organism and developed since 2001”*

3) Contains 24 questions on New Genomic Techniques relating to i.a.:

   - Potential benefits or challenges for individual sectors and society,
   - Implementation of legislation (inspection etc),
   - Experience with traceablility strategies,
   - Research: benefits or challenges for sectors, science or society.

Questionnaire from the Commission to Member States, *continued*

- The Danish Ministry of Environment and Food will reply for DK at the latest 30 April 2020 following consultations with other ministries and stakeholders

- At a joint meeting of the GMO-committees, DK recommended the Commission to focus their study first on new mutagenesis techniques used in plants and microorganisms,

- ..and as a second step to address other techniques and organisms.

Other activities initiated by the Commission

1) Another questionnaire issued to **European Stakeholders**

2) **European Food Safety Authority** (EFSA) will prepare an overview on risk assessment of plants developed through NGTs. Will issue scientific opinions on Site Directed Nucleases 1 and -2 and on Oligonucleotide Directed Mutagenesis (ODM) by the end of October 2020

3) **Joint Research Cente**r will provide an overview on state of the art, market applications and expected future developments of NGTs

4) **European Network of GMO-laboratories** (ENGL) continue to work on detection, including of microorganisms obtained by new mutagenesis techniques

5) **European Group of Ethics** work on gene editing, expected to report in April/May 2020

6) Presentations from **Member States (DK, DE)** on public involvement at the joint meeting of the GMO-committees 15 January 2020

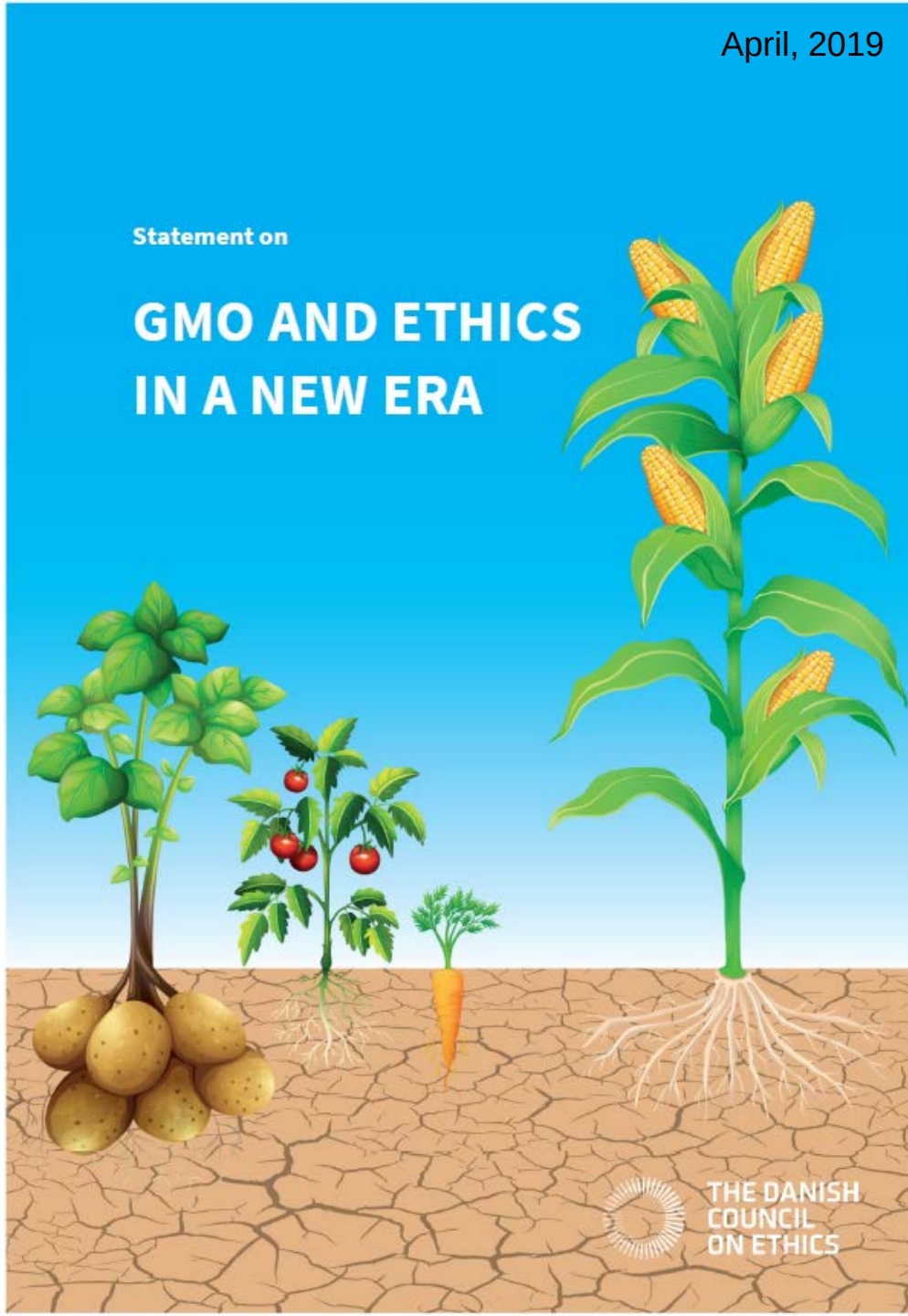
What has happened since last year's DanSeed -

at Danish level?

The Danish Council on Ethics: Time for a new beginning

The Council's overall recommendation:

"It is ethically problematic to reject GMO varieties if they can help alleviate or solve significant problems and there are no good arguments for rejecting them"



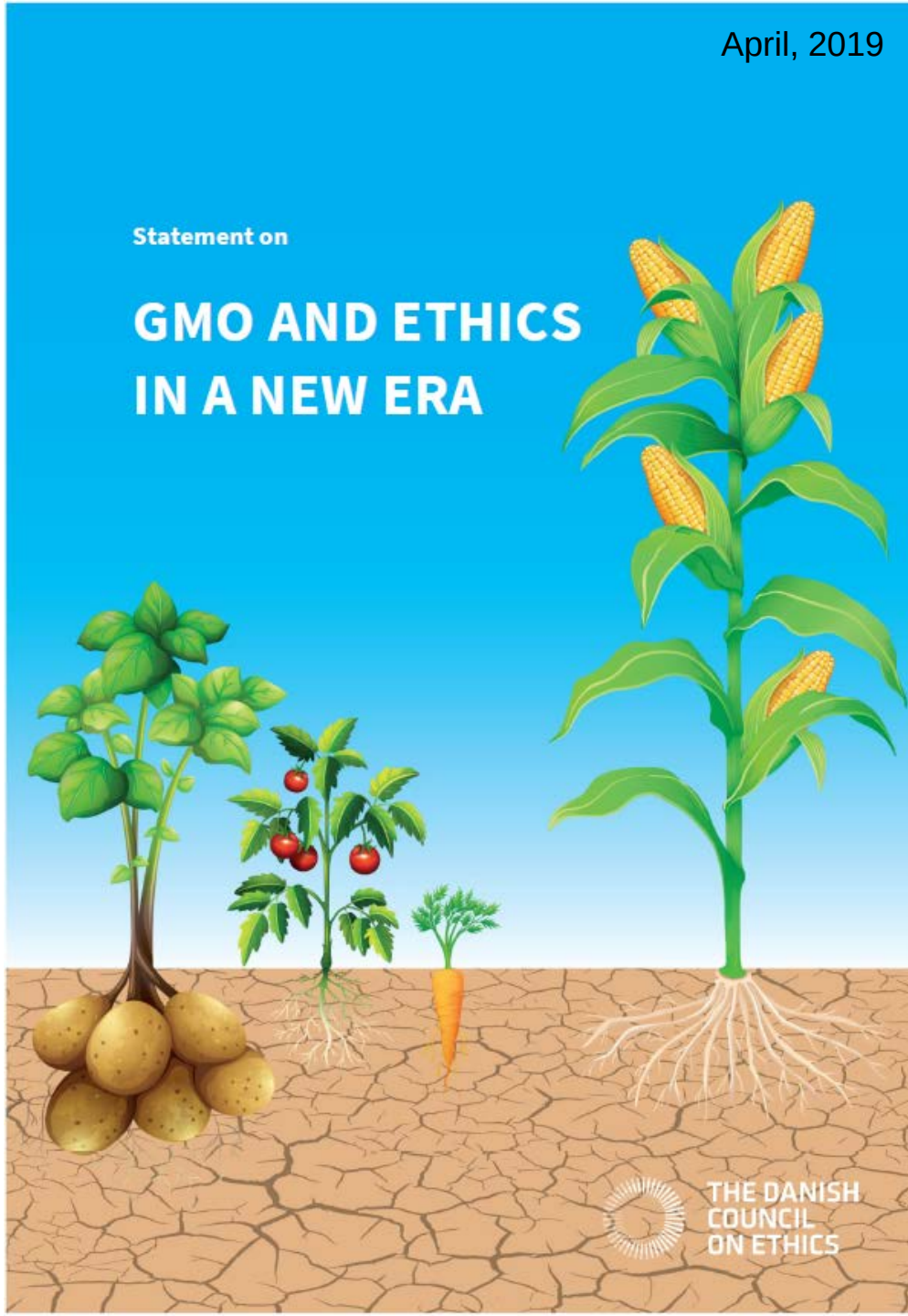
A large majority of the Council members find that:

“Not all GMOs should be prohibited solely because of the process, gene technology, used to produce them”

“Some GMO types are compatible with both the absence of particular risks and respect for nature's own processes. GMOs such as these should not be rejected or obstructed by subjecting them to risk assessment requirements that are not imposed on similar new varieties developed by conventional means.”

“Denmark should work towards changing the authorisation procedures to a product-based system …thus moving away from a process-based system”

April, 2019



Some activities at Danish Ministerial and Parliamentary level

- Bilateral contacts with various stakeholders i.a. from the agricultural and industrial sectors
- Letters to the ministers from NOAH, Greeenpeace et al. on new genomic tecniques and the need to implement the decision of the European Court of Justice
- Appearance (*Danish: Foretræde*) from Novozymes before the Parliament's Enviroment and Food Committee. Subject: New genomic techniques and the regulatory situation in the EU (*13 November 2019*).
- Consultation (*Danish: Samråd*) on new genomic techniques in the Parliament's Enviroment and Food Committee (*11 December 2019*)

New Genomic Techniques: Next steps

At EU-level:

- Technical discussions to continue at joint working group meetings in June and October 2020

At national level in DK:

- Expected public hearing in Parliament (spring 2020)
- Government and Parliament to decide on a Danish position on the regulation of new mutagenesis techniques

Current status at policy level:

Thank you for your attention!