

## News and Current Developments

- ECJ Ruling and GMO-free Labelling: Objection or not?
- Gen Drives: New Regulation in Germany
- Ornamental Plant Monitoring in Hesse

## ECJ Ruling and GMO-free Labelling: Objection or not?

- In 2008, the German legislator passed a national regulation for food products to be labelled as “**Ohne Gentechnik**”.
  - The German term “Ohne Gentechnik” is not an exact translation of the English term “**GMO-free**”. It has been chosen to reflect precisely the legal definition of a food substance that is produced without genetically engineered material and meets certain criteria in terms of feeding animals etc..
  - The label is a success story: More than 700 companies use the label for more than 13.000 food products, achieving a total turnover exceeding 7,7 billion euros in 2018.
- **ECJ ruling 25.07.18**: organisms obtained by mutagenesis constitute GMOs within the scope of the Directive 2001/18/EC, but are excluded from its application – **new legal situation for the GMO-free label?**

## ECJ Ruling and GMO-free Labelling: Objection or not?

- German pro-GMO initiative „Forum Grüne Vernunft e.V.“ (FGV, „forum for green common sense“): Using the GMO-free label for products originating from conventional mutagenesis is no longer legally permissible and constitutes an act of **illegal consumer deception**.
  - Intimidation of German consumer protection authorities and food retail companies: FGV has asked companies such as ALDI, Edeka, Lidl and Rewe to **restrict the use of the label** to products known to be bred without conventional mutagenesis by **July 1st, 2019**.
  - Otherwise FGV threatens to file charges on suspicion of „commercial fraud“ if labelling products originating from conventional mutagenesis as GMO-free is continued.
- Legal opinions by law office GGSC and Food Federation Germany e.V. (former BLL): **No chance of success!**

## ECJ Ruling and GMO-free Labelling: Objection or not?

- Products of conventional mutagenesis are **GMOs according to Directive 2001/18/EC**, but **not** according to Regulations (EC) 1829/2003 (GM food and feed), 1830/2003 (traceability and labelling) and 834/2007 (organic production).
- In these regulations, the **exclusion of conventional mutagenesis is part of the legal definition of the term „GMO“** – in contrast to the legal definition in Directive 2001/18/EC.
- Therefore, the use of the GMO-free label remains legally permissible, even if misinterpretation by consumers is possible. The **use of a legal regulation** adopted by the German legislator – the „Ohne Gentechnik-Kennzeichnung“ **can not be misleading in a legal sense.** (Even if there are individual opinions quoted in the literature classifying the regulation as „legally authorized consumer deception“).

## ECJ Ruling and GMO-free Labelling: Objection or not?

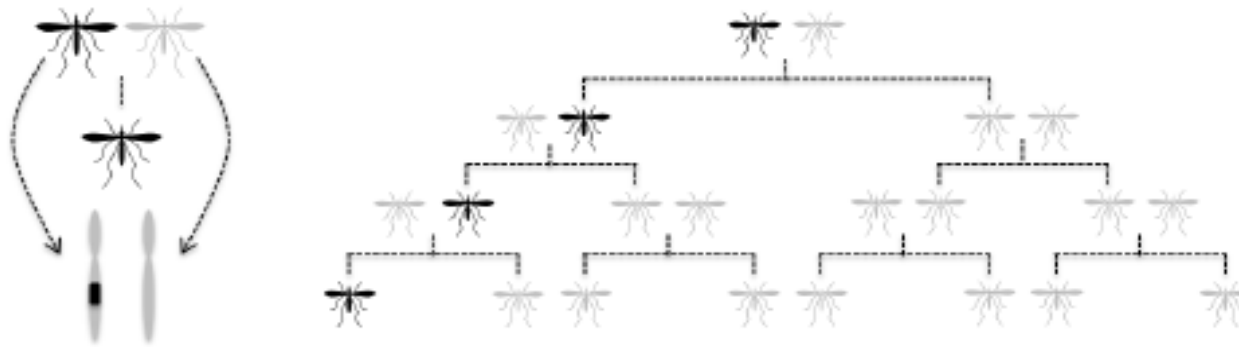
- Against this background, the **GMO-free regions remain GMO-free**. This has also been questioned by the FGV in a letter to all German network members. No answer was given by Hesse.
  - The German federal ministry **BMEL has not yet adopted a formal position** in this matter. In its answer to a brief parliamentary enquiry put by the liberal Free Democratic Party (FDP), BMEL just refers to the competence of the federal Länder when enforcing the national GMO-free labelling regulation. BMEL will, however, monitor the further application of the regulation subsequent to the ECJ ruling.
- As expected, food retail companies did not delist products with the supposedly „misleading“ label by July 1st. FGV has **reported to the competent public prosecution offices** due to „strong suspicion of commercial fraud“. Decisions are not expected in the near future. In a second step, FGV has also **threatened to report employees** of competent authorities.

## Legal Definition “GMO” in the EU

- **Directive 2001/18/EC:** “For the purposes of this Directive ... genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.”
- **Regulation (EC) 1829/2003:** “For the purposes of this Regulation, ‘genetically modified organism’ or ‘GMO’ means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC.”
- **Regulation (EC) 834/2007:** „For the purposes of this Regulation, the following definitions shall apply: the definition of ‘Genetically modified organism (GMO)’ is that given in Directive 2001/18/EC ... and which is not obtained through the techniques of genetic modifications listed in Annex I.B of that Directive.”

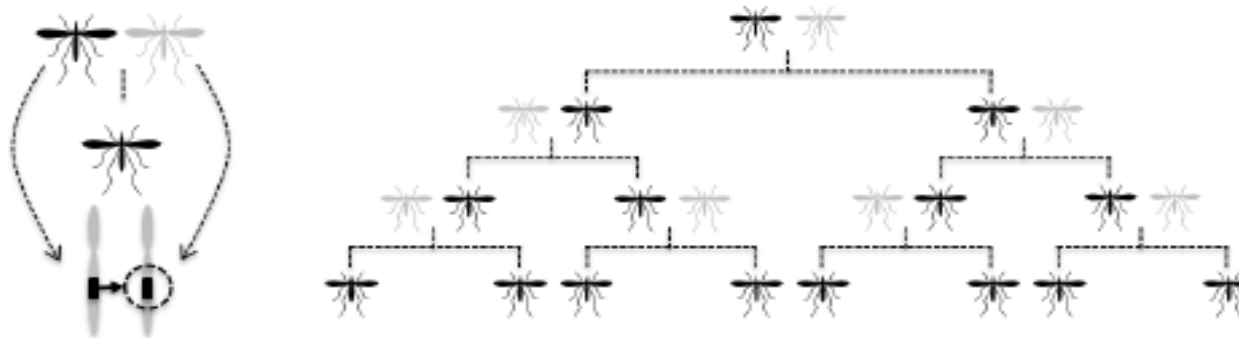
# Gen Drives: New Regulation in Germany

## Normal genetic (mendelian) inheritance



Genetic mutation is inherited from one parent and transmitted to half of offspring.

## Gene drive inheritance



<http://www.biotechnologiradet.no/filarkiv/2017/02/Statement-on-gene-drives.pdf>

## Background

**Mendel's Laws:**  
In sexually reproducing organisms, offspring has a 50 % chance to inherit given traits from its parents.

**Gene drive:**  
Biased inheritance of a given trait to all offspring that spreads rapidly and possibly irreversibly in the entire population.

## Gen Drives: New Regulation in Germany

- The amended version of the German „Genetic Engineering Safety Regulation“ (Gentechnik-Sicherheitsverordnung) - which applies to the contained use of GMOs - has been announced on August 15th, 2019, and will enter into force on March 1st, 2021.
- For the first time, **special regulations for gene drive experiments** will enter into force in Germany. So far, there have only been recommendations by the „Central Committee on Biological Safety“ (ZKBS).
- Genetic engineering activities are classified into four safety levels depending on the risks for human health and the environment. According to the new regulation, **gene drive experiments fundamentally have to be assigned to class 3**, i.e. a regular **authorisation procedure** has to take place (in contrast to the notification procedure required for safety level 1 and 2).
- Depending on the results of the risk assessment, downgrading is possible.



## Gen Drives: New Regulation in Germany

- Gene drive experiments are subject to **prior approval** by the competent authority before activities are allowed to start in the lab (as it would be the case of a notification in safety level 1 and 2),
- Experiments are **not considered comparable** to each other as in the case of safety level 2 activities; i.e. case-by-case risk assessment by the ZKBS is carried out and available **before** starting lab activities
- Importance of the new regulation is emphasized by a **resolution of the Federal Council** being based on the Berlin Declaration adopted by the Network at their joint 9<sup>th</sup> European Conference in September 2018:  
*“... The federal Länder organized in the European Network of GMO-free regions have therefore already stated in their Berlin Declaration of September 7, 2018 "the strongest reservations concerning the release of so called "gene drive" applications" and have called for "all necessary measures to prevent the introduction of gene drives into our environment" ....”*

## Ornamental Plant Monitoring in Hesse

- In April 2017, the Finnish competent authority informed about **unauthorised GM petunia** with untypical orange flower colour.
- Almost 70 GM petunia varieties were identified on the German market (> 100 in the EU); more than 300 retailers were checked and identified plant material had to be destroyed.
- The „Working Group of the Federal Länder on Genetic Engineering“ (LAG) adopted a **guideline for the control of ornamental plants** with regard to genetic modifications. Key element of ornamental plant monitoring is the sampling and analysis of petunia cuttings on a random basis at the bottlenecks of import into the EU, i.e. airports.
- **Largest port of entry** in Germany is the **Rhein-Main-Airport Frankfurt am Main**.

## Ornamental Plant Monitoring in Hesse

- During the import season November 2017 to March 2018, **273 petunia cuttings** were collected at the Rhein-Main-Airport and analysed for genetic modifications. **All results were negative.** Results for further 73 samples collected in other federal Länder were also negative.
- Import season 2018/2019: Results for **101 petunia cuttings** at the Rhein-Main-Airport were **negative.** Monitoring was extended to the analysis of **43 carnation cuttings**; results were also **negative.**
- In 2019, **one GM petunia** was detected in Germany. All plant material was destroyed.

## Ornamental Plant Monitoring in Hesse

- Further activities:
  - **Continue** sampling of **petunia and carnation** cuttings.
  - **Extend spectrum of ornamental plants** to be monitored on the basis of literature research. Genetic modifications with standard promoters and terminators are described for the genera *Pelargonium*, *Begonia*, *Chrysanthemum*, *Orchidacea*, *Rosa* and *Lilium*; i.e. routine screening procedures should be possible. Except for the latter two, these are also imported in larger amounts at the Rhein-Main-Airport.
  - Have a closer look at **tomato seeds** especially from China. There have been suspicions of unauthorised genetic modifications in the past, but few samples have been analysed so far (with negative results).