

Management Board  
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# EFSA GMO PANEL

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Chair of the Panel on Genetically Modified Organisms

# WHAT IS THE ROLE OF PANEL?

- Works primarily on GM plants but also micro-organisms and animals
- Scientific advice on:
  - Molecular characterization
  - Food and Feed safety
  - Comparative assessment
  - Environmental risk assessment



# PANEL MAIN ACTIVITIES: 1. APPLICATIONS

- Import and processing (I&P) application. No applications for cultivation



Maize



Soybean



Cotton



Oil seed rape



Sugar beat

Single and stack events

**Classical applications:** herbicide tolerant and/or insect resistant crops

**Recent applications:** complex metabolic traits ( $\omega$ 3 fatty acid), yield enhancement traits, plant sterility and plant architectural changes



# PANEL MAIN ACTIVITIES: 1. APPLICATIONS



Draft Opinion



Discussion  
for possible  
adoption



EFSA  
Scientific Opinion

GMO Unit

WG on molecular characterisation

WG on food and feed safety

WG on comparative analysis and ERA

Cross-cutting WG

GMO Panel



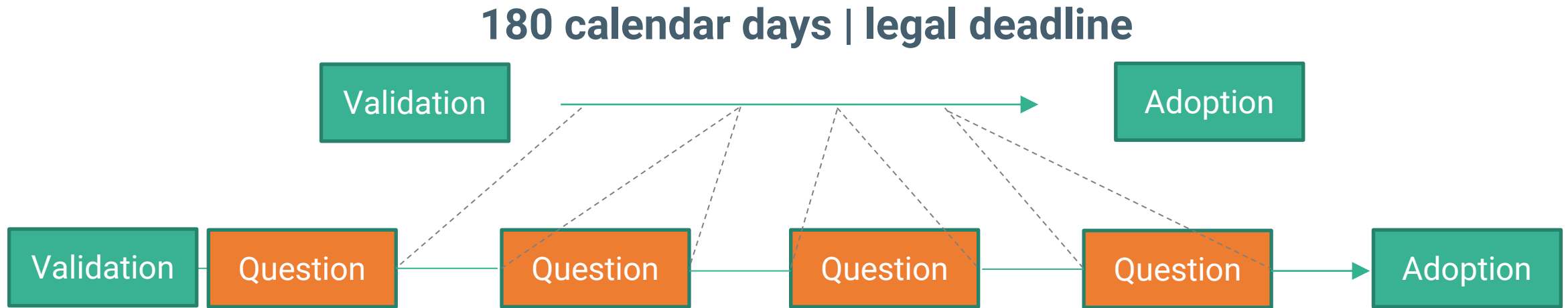
Public  
comments



MSs comment on the  
confidential dossier



# PANEL MAIN ACTIVITIES: 1. APPLICATIONS



- >1000 effective days from validation to adoption including time for answering EFSA's questions
- Average for EFSA risk assessment in 2022 and 2023 was <180 days
- Average number of stop-of-the-clock was 11 (2019-2023)
- Currently there are 23 questions under RA (no questions on delay)



## PANEL MAIN ACTIVITIES: 2. GENERIC MANDATES

### From EC:

- GM Microorganisms (GMM) New Genomic Techniques (NGTs) – DL June 2024
- GM Animals (GMA) NGTs – DL June 2025
- Post Market Environmental Monitoring for the cultivation of **maize MON 810** – DL July 2024

### Self-tasked:

- Risk assessment of **protein safety** in applications – DL end 2024



## PANEL MAIN ACTIVITIES: 2. MANDATES / EC

- **GMMicroorganisms-NGT** (public consultation is ongoing)
  - Living **GMM-NGT** might be released in the next years. To be ready for the first application
  - **2011 guidelines for GMM are still applicable** even if there are needs for updates in certain areas
- **GMAanimals-NGT**
  - Not many experts in this field at the EU level exist. **A WG has been established**
  - An opportunity to **verify the adequacy of 2012 and 2013 GMA** guidelines for RA applied to NGT
- **PMEM MON810**
  - EFSA acquired experience useful to **improve PMEM plans for cultivation** applications





## PANEL MAIN ACTIVITIES: 2. MANDATES / SELF-TASKED

- Assessment of protein toxicity and allergenicity is regulated by Reg. (EU) 503/2013
- In the recent application **the assessment is increasingly challenging**
  - higher number of proteins to be tested that in some cases are also difficult to test
- EFSA gained experience in more complex recent applications
- To **develop complementary/alternative testing strategies** towards *in-silico* and *in-vitro* testing (new approach methodologies NAMs)
- Public consultation in June/July 2024 - Publication expected by end of 2024





## PANEL MAIN ACTIVITIES: 3. TECHNICAL NOTES

- Complement the applicable guidelines
- Provide requirements and recommendations
- Useful to rapidly take on board the latest developments in RA



### Ongoing activity (self-tasked):

Update of the 2018 EFSA Technical Note for **DNA sequencing** quality in plants

### Examples of finalised notes:

2019 and 2022 – on human and animal dietary exposure

2019 – on literature search and review

2018 – on the DNA sequencing quality



# CHALLENGES AND OPPORTUNITIES OF THE GMO PANEL

- A high number (18) of already authorised GM events needs to be **renewed in 2024** and 8 new applications are expected
- The risk assessment of GMO application is increasingly challenging – **Currently developing complementary/alternative testing strategies**
- NGTs: GMO Panel past opinions assessed adequacy of current GMO guidelines and **recommended updates on guideline requirements that are not fully applicable** (e.g. due to the lack of a *transgene*) – **Basis for new guidelines**
- EFSA and the GMO Scientific Network are establishing a sub-group of MSs experts to contribute on **EFSA future activities on NGT guidelines** – **Strengthen collaboration with MSs**

