Farm to Fork Strategy and Contaminants Regulation affecting Flour Millers

European Flour Millers Congress
7 June 2024

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The European Green Deal (EGD)

Farm to Fork Strategy (F2F) action plan: 27 actions

New legislative proposals

Revision of current legislation

Non legislative such as Code of conduct, action plans

Sustainable Use of Plant Protection Products Regulation (SUR) proposal

- **The initiative in a nutshell:**
  - Regulation – directly binding and uniformly applicable to all Member States
  - Legally binding targets: 50% reduction in the use and risk of chemical pesticides and use of more hazardous by 2030 - in line with the F2F and Biodiversity strategies
  - Streamlined National Action Plans (NAPs) and annual reporting that support the legally binding targets
  - Environmentally friendly pest control ensuring all farmers practice Integrated Pest Management (IPM) in which chemical pesticides are used only as a last resort
- **Commission proposal adopted on 22 June 2022**
  - European Parliament rejected the proposal on 22 November 2023
  - Discussions in Council remained difficult
  - Commission announced withdrawal of the proposal on 6 February 2024

Increasing availability of plant protection products containing biological active substances

New Regulations and guidance documents on MO

- ❑ Guidance document on Metabolites of Concern (Oct 2020)
- ❑ Guidance document on AMR (May 2021)
- ❑ Four implementing Regulations (applicable as from Nov 2022)

Two Communications from the European Commission

- ❑ List recommended test methods/ guidance documents
- ❑ Support dossier-preparation
- ❑ Not legally binding
- ❑ Endorsed in March 2023
- ❑ Additional database of useful guidance documents

Explanatory notes + dRR

- ❑ Support understanding of the new EU Reg
- ❑ Support dossier-preparation
- ❑ Harmonise risk assessment and risk management
- ❑ Not legally binding
- ❑ Endorsed at PAFF October

Others

- ❑ IUCLID
- ❑ New test methods (OECD)
- ❑ Consensus documents on MO species
- ❑ Background level on MO species

Completed/available

On-going

New EU rules on plant and forest reproductive material

5 July 2023 - Commission adopted two legislative proposals: one on the production and marketing of plant reproductive material and one on the production and marketing of forest reproductive material in the Union

- **The revision seeks to:**
  - increase clarity and coherence of the legal framework;
  - enable the uptake of new scientific and technical developments and in particular, innovative production processes, bio-molecular techniques and digital solutions;
  - ensure availability of PRM/FRM suitable for future challenges;
  - support the conservation and sustainable use of plant and forest genetic resources;
  - harmonise the framework for official controls on PRM/FRM;
  - improve coherence of the PRM/FRM legislation with the plant health legislation.
- **Ordinary legislative process is now ongoing**

EU food waste reduction targets

Legislative proposal adopted by the Commission on 5 July 2023

Part of the revision of the Waste Framework Directive (+textile waste)

On-going negotiations with the European Parliament and the Council of the EU

Reduction of nutrient losses

- **What are the problems:**
  - Inefficient and excessive use of fertilisers is a major source of pollution with negative effects on drinking water, eco-systems, air quality and human health.
  - Up to half of the nitrogen applied in agriculture is not taken up by plants but is lost to the environment.
  - This leads to higher production and use of fertilisers and additional costs for farmers.
- **Objective of the Farm-to-Fork Strategy:**
  - Reducing nutrient losses from agriculture with 50 % by 2030, while maintaining the fertility of soils, expected to result in 20 % less fertiliser use.
- **Possible actions**
  - Implementing and enforcing the relevant environmental and climate legislation in full.
    - Losses can be reduced by more efficient use of fertilisers, targeted mitigation measures, alternative methods to increase soil fertility and changes in dietary habits.
  - The Commission is developing an integrated nutrient management action plan (INMAP) to address nutrient pollution at source.
- **Where we are in the process:** Public consultation on the INMAP took place in 2022 - no date for adoption fixed yet

Commission proposal on plants obtained by certain new genomic techniques (NGTs)

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#EUGreenDeal

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WHAT ARE NEW GENOMIC TECHNIQUES?

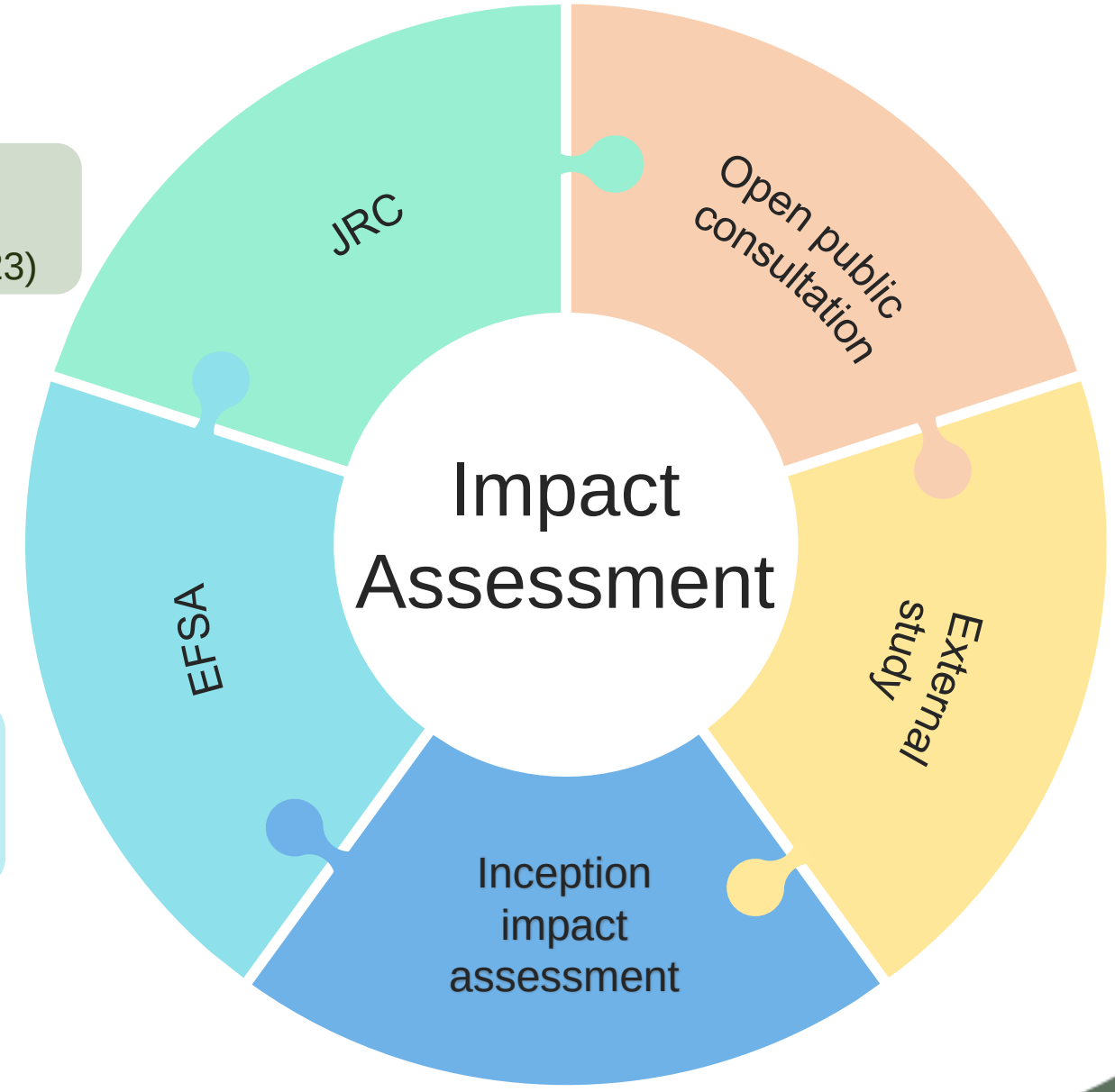
NGTs
are techniques
of genetic modification
that can help breed new plant
varieties faster, and with higher
precision than conventional breeding
techniques.
NGTs can produce a wide diversity
of plant products. These plants may
have only small changes that might
also occur in nature or through
conventional breeding or they
may have more complex
modifications.

Objectives of the proposal

- High level of protection of health and environment
- Developments to contribute to sustainability and climate adaptation in a wide range of plant species, especially for the agri-food system
- Opportunities for research and innovation, including for SMEs

Evidence

- ✓ Two 2021 reports
- ✓ Case studies (2023)
- ✓ EURL,ENGL (2019, 2023)



Two fact-finding studies on official controls in Member States

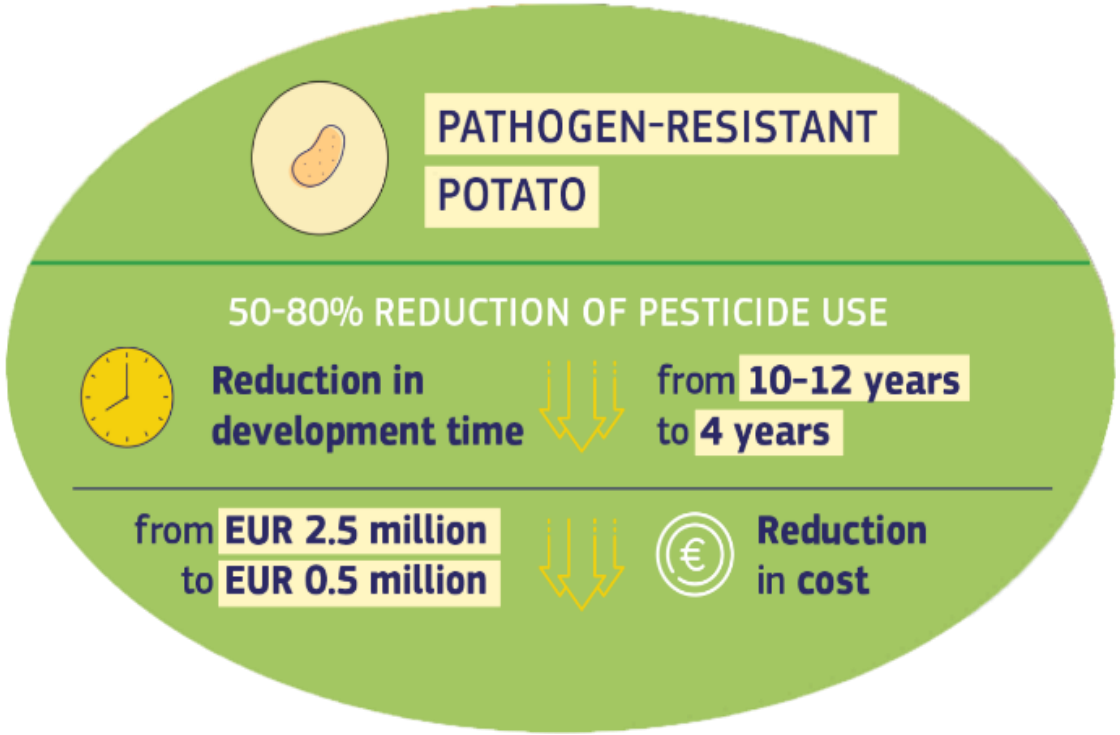
- ✓ Opinions on NGTs
- ✓ Statement on risk assessment criteria

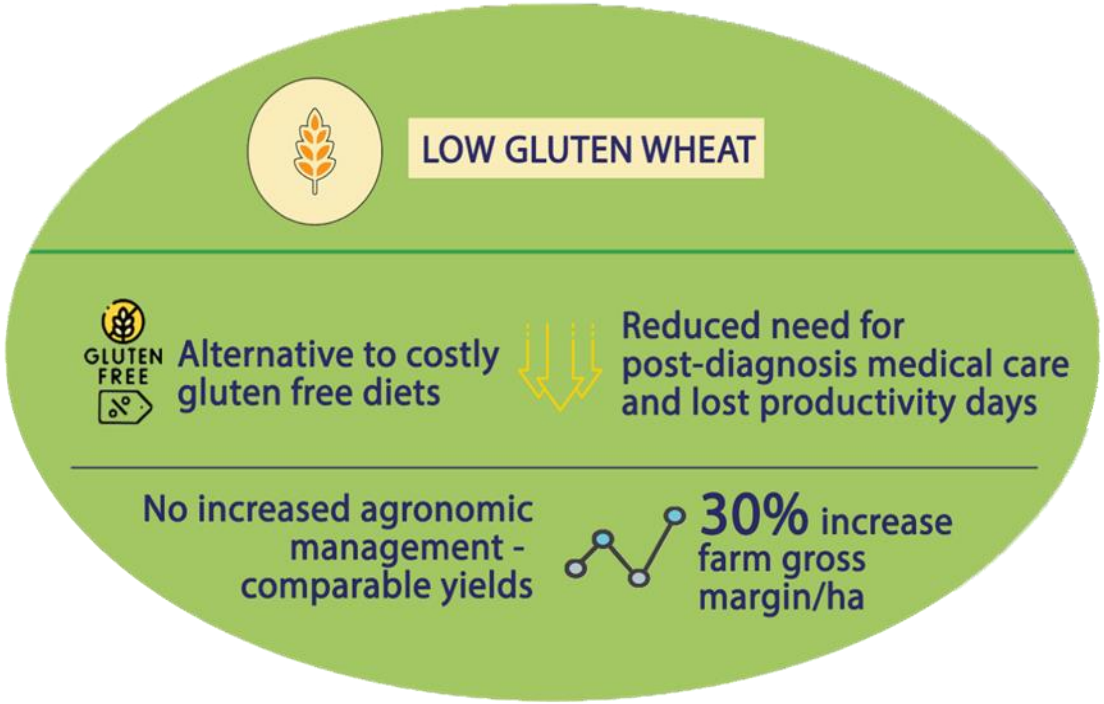
- ✓ Targeted interviews
- ✓ Targeted survey
- ✓ Focus groups
- ✓ Desk research
- ✓ Case studies

Safety

- ✓ Variety of different products with different safety profiles.
- ✓ No specific hazard associated to these techniques.
- ✓ Similar products obtained by different techniques are not expected to present significantly different risks.
- ✓ Lesser amounts of risk assessment data on a case-by-case basis.
- ✓ Potential for reduced unintended effects.

Examples of NGT plants – JRC case studies





Category 1 – NGT plants equivalent to conventional

- Verification procedure based on objective criteria
- Subject to the rules applicable to conventionally bred plants
- Seeds labelled as NGT
- Information available in a public database and variety catalogues

Category 2 – NGT plants not equivalent to conventional

- Authorisation procedure with adapted risk assessment and detection method requirements
- Traceability and labelling as GMO.
  Voluntary statement on purpose of modification
- Regulatory incentives for NGT plants with desirable traits
- Mandatory coexistence measures

Monitoring and reporting

Prohibition in organic production

Legislative process – State of play

- Requires agreement of European Parliament and Council (qualified majority of Member States)
  - EP: 1st reading amendments adopted on 24 April 2024
  - Council: discussions ongoing
- Non-binding opinions:
  - European Economic and Social Committee (25 October 2023)
  - Committee of the Regions (17 April 2024)
- Numerous national parliaments have submitted comments (under Protocol No 2 to TFEU)

Legal framework for regulating contaminants in the cereal chain

- Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food and General Food Law (Regulation (EC) 178/2002)

- Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food
  - Establishment of maximum levels

Requirements and principles for regulating contaminants in food

- high level of human health protection – all food placed on the market must be safe
- obligatory consultation of EFSA
- free movement in internal EU market
- international standards (Codex) to be taken into account
- contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)

Regulating contaminants in the EU

- EFSA scientific opinion: assessment of the (human) health risks related to the presence of a contaminant in food → is the basis for the management measures i.e. when a (potential) health risk is identified, regulatory measures are taken to ensure a high level of human health protection.

- Management measures are targeted at the foods/food groups significantly contributing to the exposure at foods with frequent findings of high levels of a certain contaminant

  → Given the high proportion of cereals/cereal products in a human diet: cereals are frequently identified as significantly contributing to the exposure

  → For contaminants for which EFSA has identified a (potential) health concern, cereals and cereal products are frequently among the foods to be regulated.

Regulating contaminants in the EU

- Other legitimate factors considered (not exhaustive)
  - Feasibility / achievability by applying good practices (*regional differences in the EU, impacts from climate change*)
  - Balance risks of contaminants – benefits of consumption of certain foods (health risk – health benefit considerations) (*cereals : in particular relevant for whole grain, whole meal products, bran products: beneficial from nutrition point of view – in many cases higher levels of contaminants)*
  - Analytical achievability/feasibility by routine methods of analysis to ensure effective enforcement

Maximum levels for cereals /cereal products

- Because of importance of cereals and cereal products in human diet, maximum levels established for many contaminants in cereals and cereal products
  - Mycotoxins: aflatoxins, ochratoxin A, deoxynivalenol, zearalenone, fumonisins (maize), ergot alkaloids
  - Plant toxins: tropane alkaloids
  - Metals: lead, cadmium, arsenic (rice), *nickel*
  - Other: melamine, perchlorate

As Low As Reasonably Achievable (ALARA) and cumulative effect

Feasibility / achievability by applying good practices

→ typically the 95th percentile of the occurrence data available in the EFSA database is considered to be feasible (95 % of the production compliant) while it is considered that the remaining 5 % should be able to comply by applying good practices or doing extra efforts as regards good practices

Concern:

→ through cumulative effect of the 95th percentile approach for each contaminant → (much) lower percentile compliant for all regulated contaminants ? **Not necessarily - next slide**

Cumulative effect of multiple ‘As Low As Reasonably Achievable (ALARA)’

Cumulative effect of the 95th percentile approach –example of mycotoxins

- simulation done by VGMS (German cereal milling association) on 206 samples in the years 2016-2020 on deoxynivalenol, T2-HT2 toxin and ergot alkaloids resulted in non-compliances from 7,3 % to 13,9 % with average 11,4 % non-compliance;
- simulation done by UK Flour Millers on 528 samples in the years 2013-2021 on deoxynivalenol, zearalenone, T2-HT2 and ergot alkaloids resulted in non-compliances from 9,3 % to 20 % with average of 15,1 %;
- simulation done by the European Commission on data from the EFSA database in the years 2012-2019
  - 1512 samples on deoxynivalenol, zearalenone and fumonisins resulted in a cumulative non-compliance of 6,6% (while the non-compliance for deoxynivalenol alone was 4,7 %)

  and
  - 455 samples on deoxynivalenol, zearalenone, fumonisin and T-2-HT-2 toxin resulted in a cumulative non-compliance of 9,7 % (while the non-compliance for deoxynivalenol alone was 6,6 %)

Specific case: regulating mycotoxins in cereals

Challenges

- Year-to-year variation
- Geographical variation
- Increased prevalence due to climate change / extreme weather conditions

Year to year variation and geographical variation taken into account in the setting of maximum levels –see next slide (**depending of availability of data**)

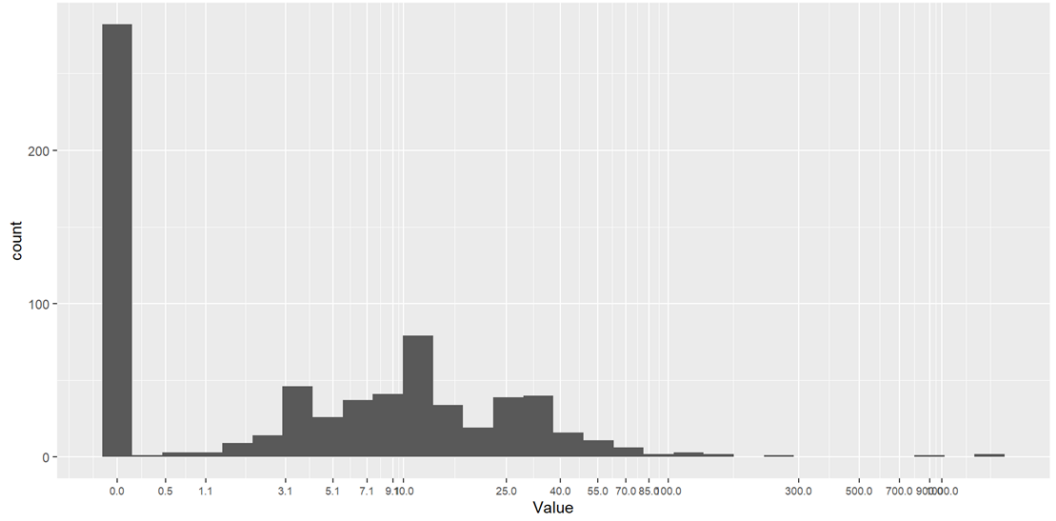
→ Share of industry data on occurrence of mycotoxins in cereals/cereal products in the EFSA database is low: Importance for stakeholder organisations to do extra efforts to submit more data to the EFSA database to enable a better taking into account of year-to-year and regional variation.

The specific case of regulating mycotoxins in cereals

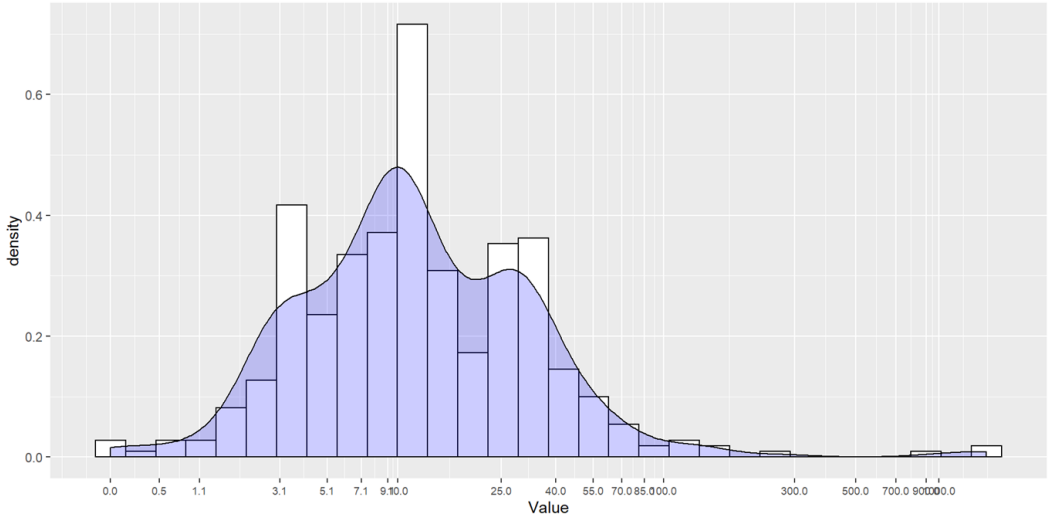
Year to year variation and geographical variation: is reflected in the non-normal distribution of occurrence data

Example of data on sum of T-2 and HT-2 toxin in oat milling products (717 results of which 438 quantified results) –

Histogram of all results



Histogram/density of quantified results



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Specific case of regulating mycotoxins in cereals – climate change

Are mitigation / prevention measures able to address the increasing prevalence / occurrence of mycotoxins due to climate change / extreme weather conditions ?

- Availability of mitigation tools: more mitigation tools are available as the consequence of research → but further research needed
- Effectiveness of certain mitigation tools not yet proven in all production conditions
- Although certain mitigation tools are available and effective, mitigation tools are not always applied on a large scale
- Consequences of EU Green Deal in particular Farm to Fork Strategy and Strategy on Biodiversity on the application and availability of prevention / mitigation tools (reduction of pesticides, grass borders of fields as source of ergot contamination, ploughing effective prevention measure for deoxynivalenol versus minimum/zero tillage against erosion).
- Application of remediation measures (advanced sorting techniques, …)

Concerns of stakeholders are taken into account when regulating contaminants

Targeted stakeholder consultations on draft MLs → comments are examined in detail with Member States and when justified, levels are adapted (increased).

Stakeholder forums on specific contaminants: opportunity to share concerns and discussion with EC and Member States

- → Maximum level of deoxynivalenol in wheat bran to be reconsidered (following new occurrence data previously not provided – highlighting the importance of submitting timely all available occurrence data by stakeholder organisations to EFSA)
- → Postponement of the application of the maximum level for nickel in cereals with one year
- → Specific case of ergot and ergot alkaloids (next slide)

Concerns of stakeholders are taken into account when regulating contaminants

Specific case of ergot alkaloids

Detailed examination of the information provided by stakeholders at the ergot alkaloid forum on 13 October 2023 → the lower maximum levels foreseen to become applicable as from 1 July 2024 are not yet achievable for

- ergot sclerotia in unprocessed rye grains and for
- ergot alkaloids in milling products of wheat (with an ash content lower than 900 mg/100 g dry matter), rye milling products and rye placed on the market for the final consumer

because of an increase in the prevalence of ergot sclerotia and ergot alkaloids in cereals due to climatic conditions.

It is therefore foreseen to defer the application of the lower maximum levels:

- for ergot sclerotia in unprocessed rye grains for 1 year and
- for ergot alkaloids in milling products of wheat (with an ash content lower than 900 mg/100 g dry matter), rye milling products and rye placed on the market for the final consumer for 4 years.

Draft Regulation to be adopted and published second half of June 2024

What to expect in the coming months

Transition period ahead of the next Commission

- Commission will focus on:
  - Conclusion of files currently in negotiations (eg: PRM, NGTs, FW)
  - Implementation of existing + soon to be finalised new legislation
  - Evaluations (eg: FCM legislation)
- Report resulting from the Strategic dialogue on the future of agriculture available by September

Thank you for your attention !

For further information:
https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en
https://food.ec.europa.eu/plants/pesticides/sustainable-use-pesticides_en
https://food.ec.europa.eu/plants/pesticides/micro-organisms_en
https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en
https://food.ec.europa.eu/safety/chemical-safety/contaminants_en

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