Identification of known / unknown classical GMO and NGT products / reference materials

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What we stand for: Clear mission

„AGES stands for protecting the health of humans, animals, plants and soil and for food security.“

Agency

Organisation and legal basis

Owner

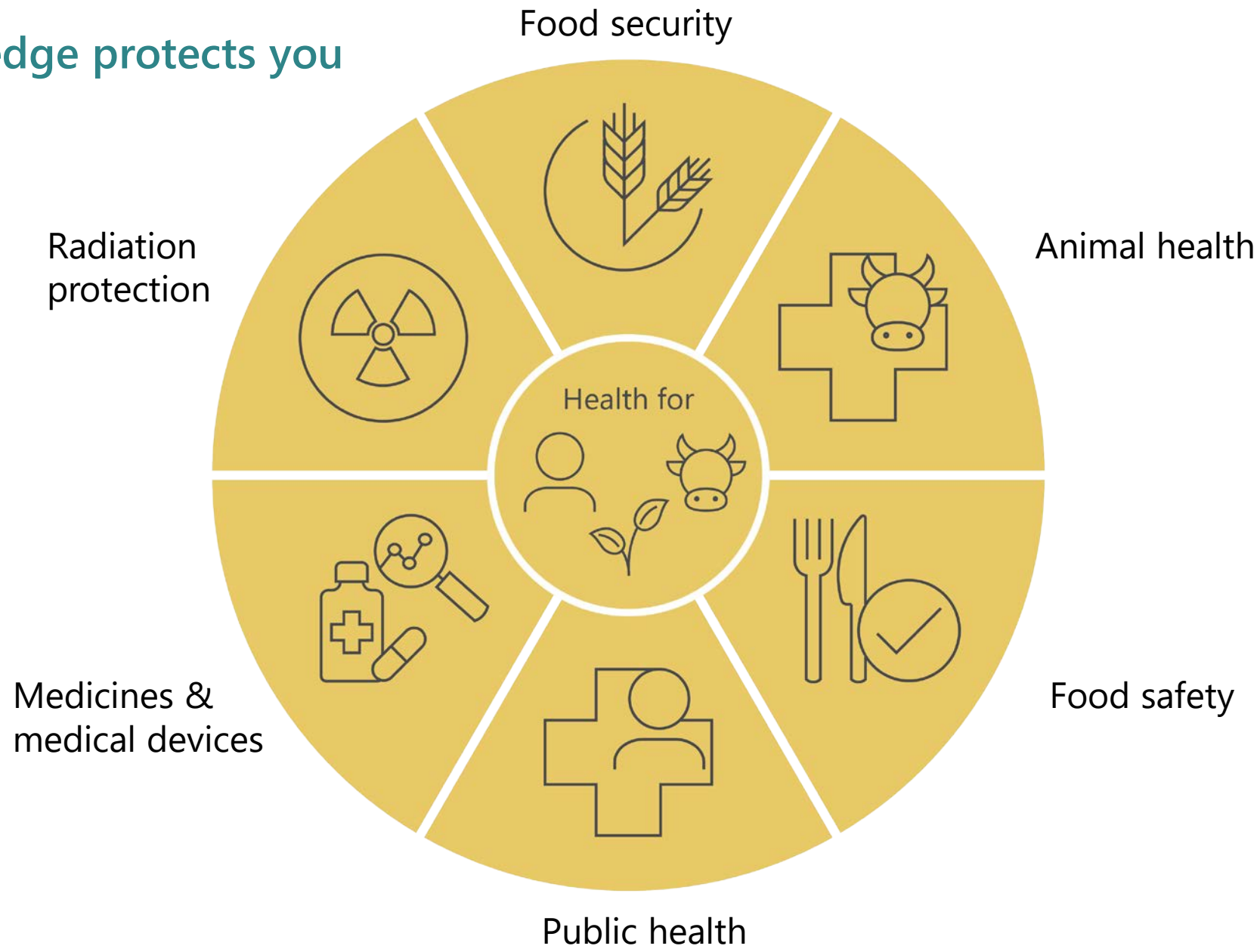
Republic of Austria
represented by
BMSGPK and BML

Legal Basis

Health and Food
Safety Act
(GESG)

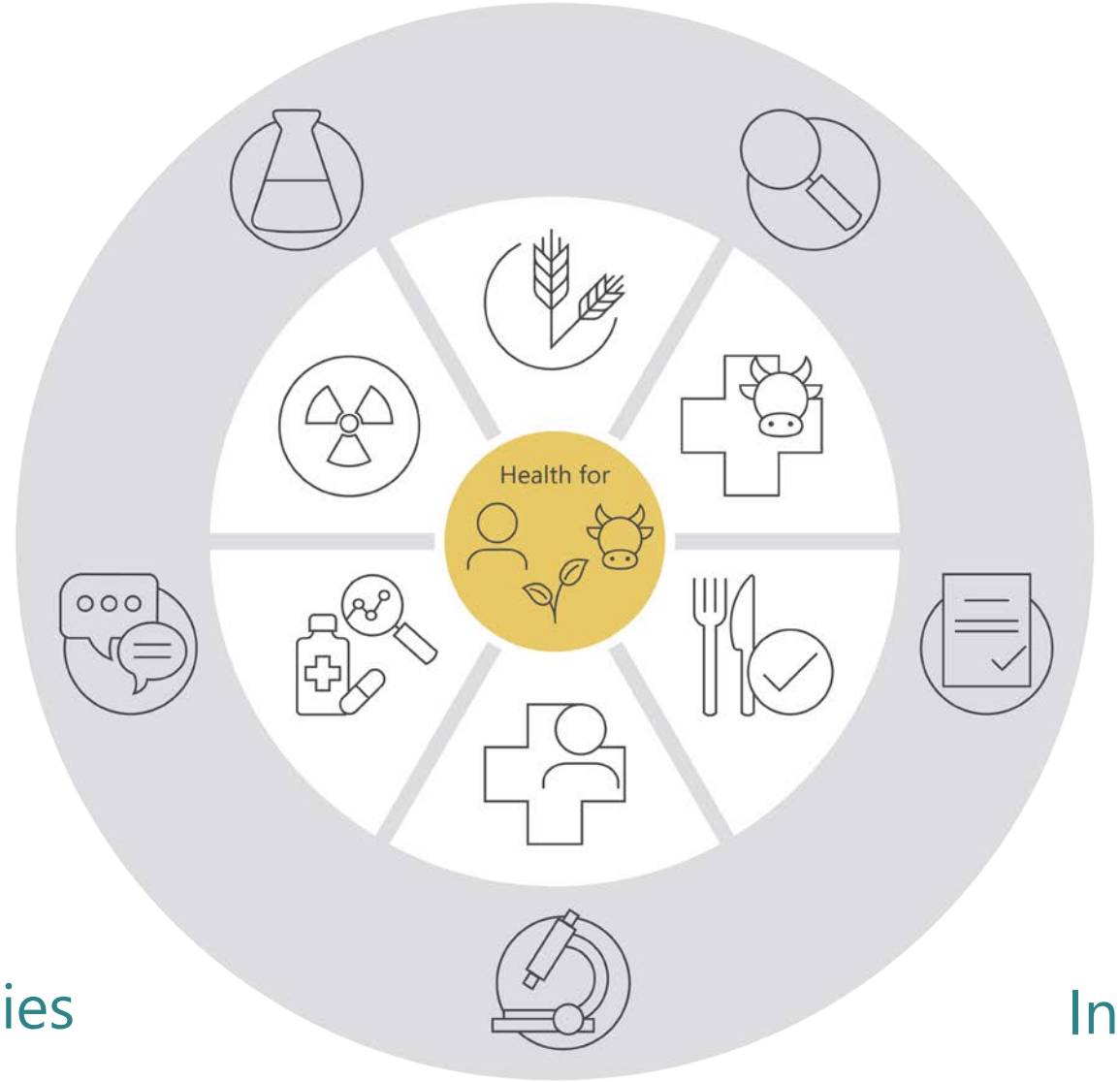
AGES cycle

Our knowledge protects you



Health for humans, animals & plants

Our responsibility



Authorities

Industry

Consumers & patients

AGES AND GMO/NGT

Central interface: Implementation, consultation, working groups

- Food safety, food security, risk assessment
  - GMO monitoring and surveillance including planning; variety and seed testing: applications for authorization
- European and Austrian legal framework
  - We implement the legal requirements
- Research and development: Prepare for the challenges
  - Studies
  - Science-based assessments
  - Scientific and technical policy advice

- Challenges
  - Scientific developments and political decisions
  - Expectations of the society (consumers, stakeholders, economic operators, etc.)

CURRENT SITUATION: KEY CONSIDERATIONS

GMO Traceability: Consumer expectation?

- Clear specifications are important and necessary
  - certainty and safety – operators and consumers, environment
- Legal certainty and definition of the legal framework
  - implementation!
- Health and safety for humans, animals, environment
  - monitoring of known and unknown GMOs
- Economic considerations - Traceability
  - facilitate the international trade of genome-edited products
  - organic, GMO -free
  - “free from" labels require the possibility of analytical control

- Austria: Status of organic farming, GMO-free products

INFORMATION AND MATERIAL ARE PROVIDED

Obligations according to the current EU regulatory framework

- Description of detection and identification techniques for the genetically modified plant
  - information on the genetic modification: details of nucleotide sequences or other type of information which is necessary to identify the GMO product and its progeny
  - propose appropriate methods for sampling, identification and detection
  - experimental data demonstrating the specificity of the methodology
- Transmission of samples of the GMO, control samples (reference material)
- Methods of sampling and detection are validated by the EURL GMFF

„DETECTION“ HAS TWO ASPECTS

Usually no differentiation made in the case of “classical” GMOs

- Detection
  - demonstrates the presence of a particular genetic or phenotypic modification by analytical means
  - qualitative – which GMO?
  - quantitative – how much of the GMO? → correct labelling (admixtures)
- Identification
  - clear assignment to a specific plant or product and to a specific developer
  - typically by event-specific detection
  - assignment of a detection result to specific plant, product, developer

TRANSGENIC PLANTS/“CLASSICAL“ GMOs

Detection, identification and quantification possible

- Random insertion of transgenic sequences
  - unique sequences at the junction between inserted transgenes and plant genomic sequences
  - sufficient evidence for identification of a GMO
  - event-specific methods are commonly used to detect and to identify a GM plant
- Screening may be possible
  - typical transgenic elements: promoters, terminators, others
  - unknown GMOs
- Multi-level approach applied
- Applicant needs to provide material and method

CHALLENGES IN IDENTIFICATION

According to the current state of knowledge and technology

- Prior information is always needed
  - information on the modified sequence and the site in the genome
  - information-based investigations, use of traceability systems
- Detection of very small changes in the genome (SNVs)
  - possible if the mutation is known
  - may be technically challenging
  - does not show what has caused the modification/mutation
  - no information about the applied technique (if applicable)
- Availability of reference material
  - method development

IDENTIFICATION OF NGT PLANTS AND PRODUCTS

Feasibility: Some aspects require specific attention and effort

- SDN-1 and SDN-2
  - detection is possible if site is known
  - the sequence at the specific site is likely to show no difference to traditionally mutated ones
  - case-by-case investigation in combination with detection results
    - multiple mutations
    - specific traits
    - no “classical” screening-elements → patterns?
- SDN-3
  - detection is possible if site is known
  - can be a transgene, linkage regions are established, event-specific method possible
  - combination of SDN-3 with a cisgene can be challenging

WHAT IS IMPORTANT FOR CONTROL ACTIVITIES?

Technical view and socio-economic dimension

- Technical considerations
  - detection of very small changes (SNVs) is possible with (adapted) PCR-based methods
    - advantages of PCR-based methods are available equipment and expertise
  - consideration of necessary limits of detection and quantification
  - identification case-by-case: combined results, multiple changes, probability
  - currently no proof of the type of technique used possible

- Management decisions
  - international database for plants and methods
  - international exchange of information
  - research on genomic alterations after genome editing
  - decision on cost-benefit/risk-benefit

CONSTRAINTS

Methods, technical requirements, policy

- Methodology
  - method development
  - availability of information
  - sequence reference database
- Availability of reference material
  - challenge quantification
- Technical prerequisites
  - equipment, staff, expertise
    - standard detection methods: PCR-based
    - other possibilities, e.g. sequencing
- Policy
  - decisions related to the regulatory framework - requirements

REMAINING CHALLENGES

Method development is possible under certain conditions

- Internationally different legal requirements
- Prerequisites for method development for the detection of genome-edited plants
  - sufficient and appropriate information about the modification(s)
- Access to reference material
- Prerequisites for identification of genome-edited plants
  - uniqueness of the specific sequence change(s) and/or
  - sufficiently reliable and clearly assignable data
  - combinatorial consideration of results of analytical detection and other available data

OPPORTUNITIES

An anticipatory detection and identification network

- Diverse sources of information may feed into a process to identify a genome-edited product
  - may also aid detection and identification strategies
- Cooperation of competent authorities, governmental agencies, researchers and companies/developers
  - key element - voluntary disclosure of information by developers and authorities
  - support information exchange
- Making use of best practice examples
  - governance of food products, stewardship programs, governance networks, etc.
  - existing databases (Biosafety Clearing House, EUginius)

FUNDING AND FURTHER READING

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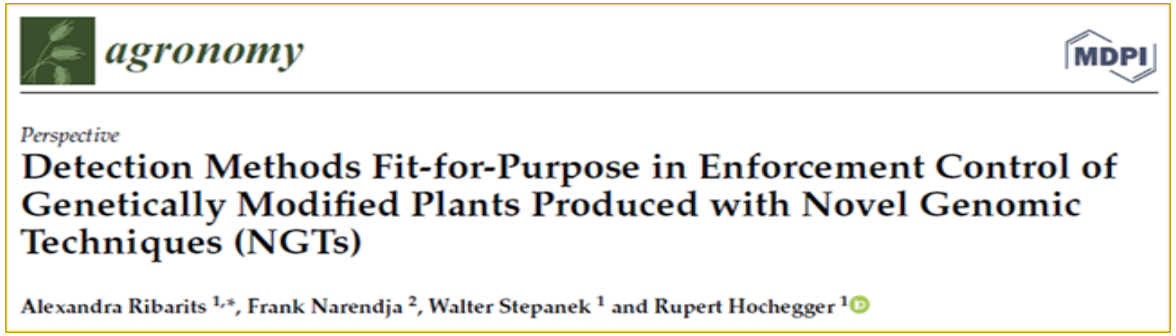
Project report (in German): https://www.bfn.de/publikationen/bfn-schriften/bfn-schriften-622-analyse-von-nachweismethoden-fuer-genomeditierte-und



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