Objective, general principles and methodology for food safety assessment of genetically modified organisms

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Risk Assessment is a systematic process of evaluating the potential risks that may be involved in a projected activity or undertaking.

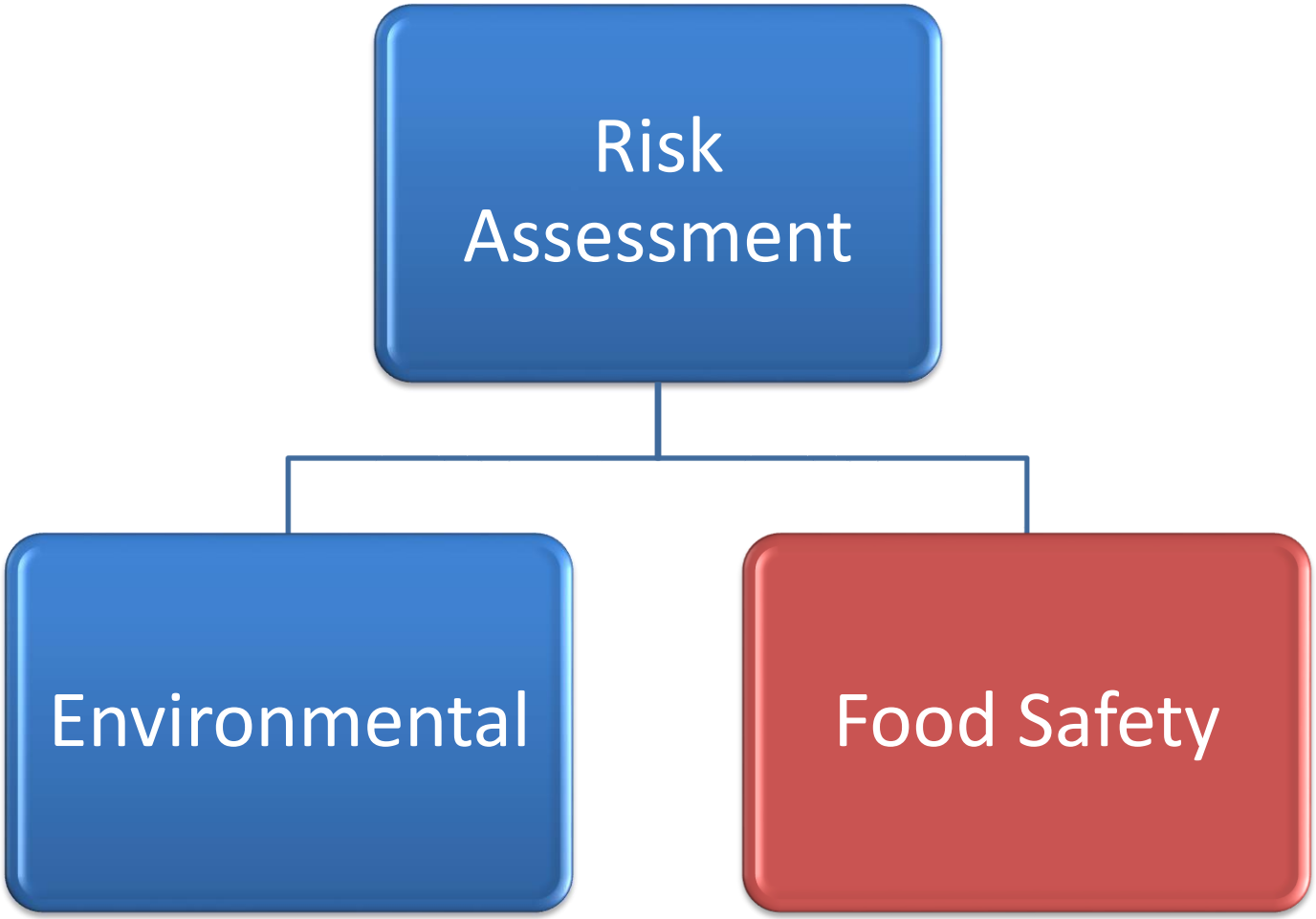
It is a concept that has a long tradition in regulating human activities with the aim to minimise or avoid risk to human health and the environment.

Biosafety System aims to prevent, manage, minimize or eliminate hazards to human health among others

Therefore, Risk Assessment is a core component of Biosafety System

Article 10 of the CPB provides that decisions be taken in accordance with Article 15, which provides for Risk Assessment

Food Safety Assessment (FSA)



Food safety

Food safety is reasonable certainty of no harm resulting from food consumption under anticipated condition

There is no absolute safety…

Objectives of FSA

The objective of Risk Assessment is to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health. (CPB - Article 15)

Safety assessment aims to conclude as to whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. (CAC/GL 44-2003)

- Therefore, the goal is to provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used and/or eaten according to its intended use.
- Definition of the novel food for a well-informed and appropriate decision

Principles of FSA

Science based

- Scientifically sound and transparent
- Conclusions – independently verifiable by relevant experts
- Guided interpretation

Case-by-Case

- Required information varies (nature & level of detail) from case to case
  - GMO concerned, intended use and consumer population

Comparative

- Risk consideration should be in the context of risks posed by the conventional counterpart

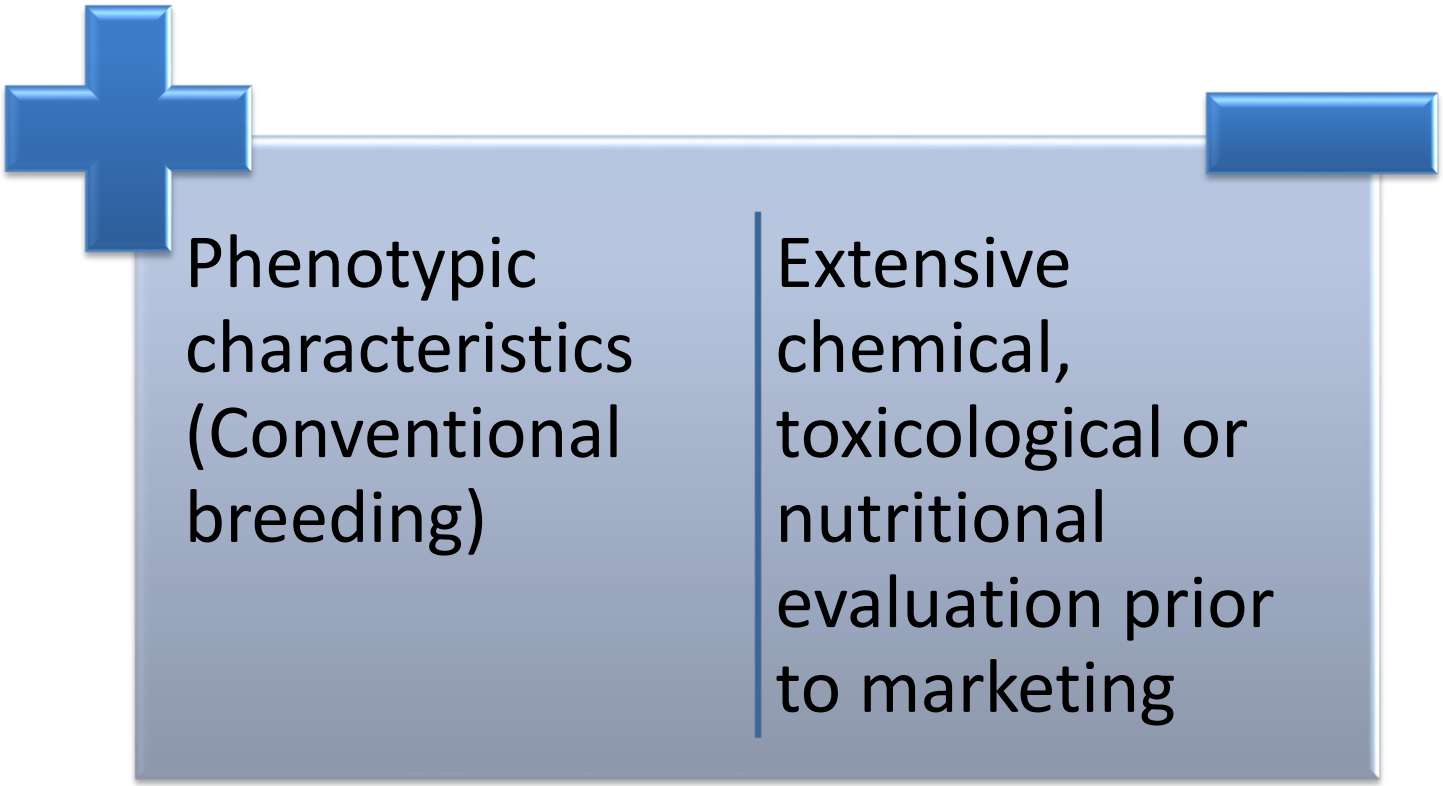
Principles of FSA

History of safe use

- Confirmation of safety of the traditional food and/or conventional counterpart with compositional data and from experience of continued use in the customary diet of a significant number of people

Substantial equivalence

Conventional breeding/Wild species



Food derived from animal of known and acceptable health status are generally considered suitable for human consumption

- The Codex principles of risk analysis (particularly for risk assessment – Hazard identification, Hazard characterization, Exposure assessment and Risk characterization)
  - primarily intended for discrete chemical entities (food additives, pesticide residues, specific chemical or microbial contaminant) that have identifiable hazards and risks
  - not intended for whole foods as such
- Complete characterization of all risk associated with food is rare

- More focused approach is required for whole food (comparative approach)
- The comparative approach is based on the concept of '**SUBSTANTIAL EQUIVALENCE (SE)**'

Substantial equivalence embodies the idea that existing organisms used as food, or as a source of food, can be used as the basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new. (OECD)

- SE is a multidisciplinary approach for safety assessment
- It takes into account both intended and unintended changes
- It is not a safety assessment in itself
- It represents a starting point for safety assessment relative to its conventional counterpart
- It aids in the identification of potential food safety and nutritional issues
- Outcome does not imply absolute safety

Methodology for FSA:

- Identification of hazard (i.e. a compound or agent that has the potential to produce harm);
- Evaluation of the likelihood of harm resulting from exposure to the hazardous compound or agent;
- Evaluation of the likelihood that exposure to the hazard would occur;
- Estimation of the overall risk of any harm that may be realized;

Methodology for FSA…

- Recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
- Where there is uncertainty regarding the level of risk: further information or appropriate risk management strategies and/or monitoring

Framework of FSA
(CAC/GL 68-2008)

- Description of the rDNA animal
- Description of the recipient animal & its use as/for food (production)
- Description of the donor organism
- Description of the genetic modification(s)

Description of the production methods for the initial rDNA animal & the production processes for rDNA animal ultimately used as/for food (production)

Characterization of the genetic modification(s) in the rDNA animal ultimately used as/for food (production)

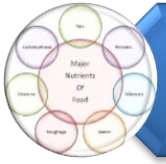
Safety assessment

Other considerations **(Unintended effects)**

Safety Assessment

Health status of the rDNA animal

Expressed substances (non-nucleic acid)



Compositional analyses of key components

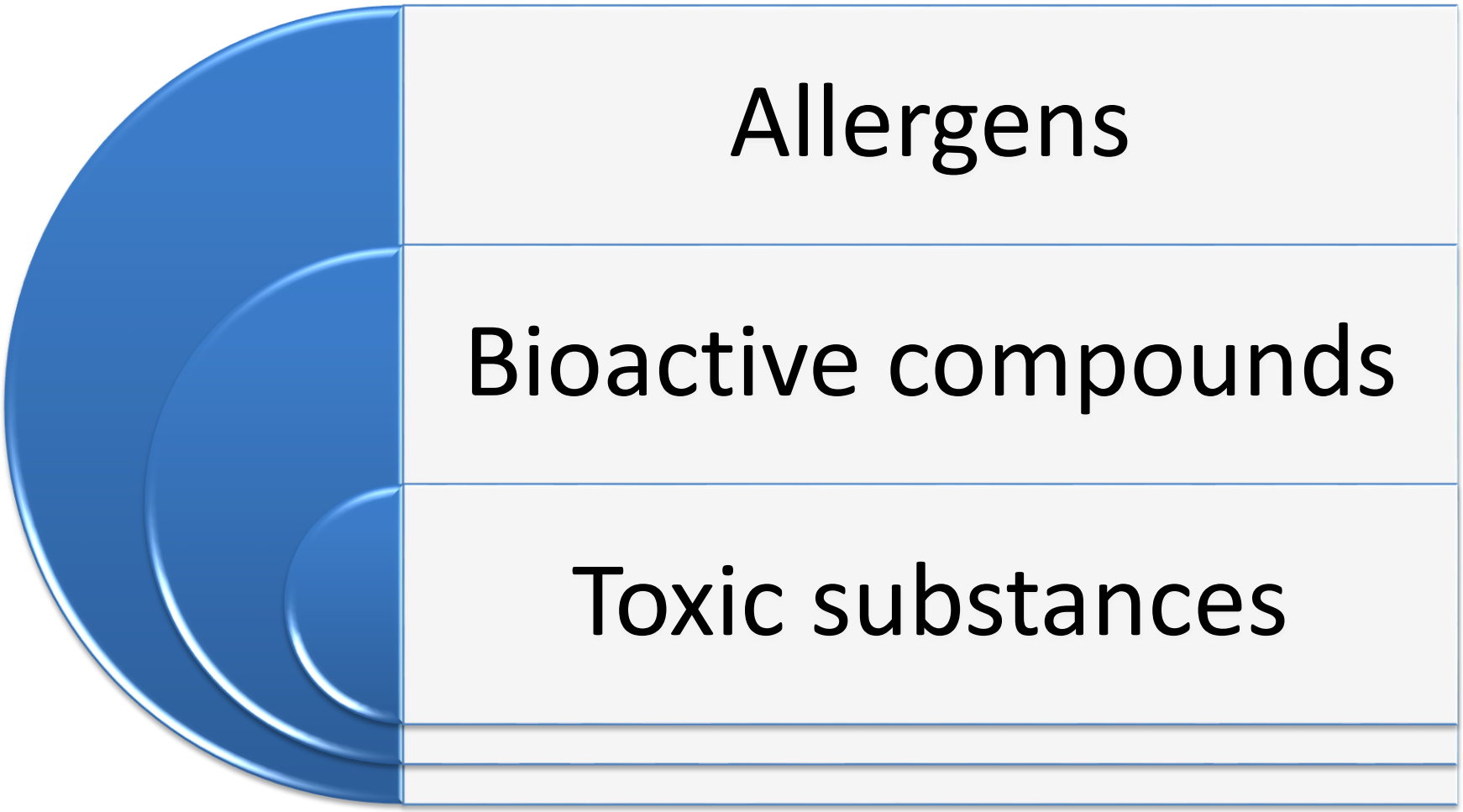
Food storage and processing

Intended nutritional modification

- Source of the protein
- AA sequence homology
- Pepsin resistance
- Specific serum screeining
- Other considerations

Allergenicity

Food safety hazards



AquAdvantage Salmon

- GE Atlantic salmon
- Intended for faster growth
- Intended for use as food

Are there any differences between food from AquAdvantage salmon and other Atlantic salmon that pose a food consumption risk?

Hazard identification & characterization

Direct effects

- Food consumption risks resulting from the expression of the inserted construct (Chinook salmon GH)
- Toxicological testing of potential hazards on case-by-case basis - Allergic assessment of proteins new to food (potential allergenicity of Chinook GH)

Effect on hormones associated with increased GH expression and/or growth???

Finding & conclusion I

- No statistical difference between the hormones in GE & non-GE salmon
- Fish GH not active at the mammalian GH receptor

Neither GH nor selected hormones of the somatotropic axis are different in AquAdvantage salmon and the non-GE atlantic salmon

Finding & Conclusion II

- Transfer of a gene from an allergenic source can present a new risk to individuals allergic to source
- No homology with known allergenic sequence

No new allergenic risk posed by Chinook GH

Direct effects: Conclusion

- No biologically relevant changes in levels of somatotropic axis hormones

- No new allergenic risk posed by Chinook salmon GH in AquAdvantage salmon

Hazard identification & characterization

Indirect effects

- Food consumption risks as a result of the rDNA contruct or its gene product perturbing the physiology of the animal (nutritional deficiency, increased allergenicity)

- Comprehensive compositional analysis
- Allergenicity of salmon

Indirect effects: Conclusion

- No biologically relevant differences in composition of AquAdvantage salmon

- No biologically relevant differences in allergenicity of AquAdvantage salmon

Food safety conclusion

Are there any differences between food from AquAdvantage salmon and other Atlantic salmon that pose a food consumption risk?

AquAdvantage salmon is Atlantic salmon.

Food from AquAdvantage salmon is as safe as food from other Atlantic salmon.

Concerns on unintended effects…

- Comparable database not as readily available for food animals as for plant species
- There is limitation in the information provided by targeted compositional analysis
- Validated unbiased profiling methodologies (currently being developed) may help address this limitation
- Emerging tools and resources including omics-based technologies are being assessed and viewed as possible means of identifying potential unintended effects not tested by targeted approaches

- Clinical and epidemiological studies are useful for anticipating and detecting adverse effects, identifying health outcomes, and assessing exposures
- As at 2010: >130 RP, 25years, >500 IRG
- Post marketing surveillance is another approach to identify unanticipated adverse health consequences from the introduction of GE food, however,
  - There must be adequate traceability system in the food production chain
  - Possibility to identify consumers with exposure to that product and whose health status can then be monitored (intermingling – crops)
  - Consumers are often exposed to ingredients derived from GE crops/animals rather than the whole food

Concluding thoughts…

End point of the assessment process is to conclude that **GM food is as safe as its conventional counterpart**

Absolute safety is an UNACHIEVABLE goal

At best, the *absence of harm (when used under anticipated conditions) can be demonstrated*

Visit us @ www.nepad-abne.net

Comments & Questions
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Thank you

References

- Cartagena Protocol on Biosafety (CPB)
- Codex Alimentarius Commission Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (CAC/GL 68-2008)
- Codex Alimentarius Commission Principles for the Risk Analysis of Foods derived from Modern Biotechnology (CAC/GL 44-2003)
- US FDA Food Safety Assessment on Animal Biotechnology – AquAdvantage salmon (Archived document).