Sampling in GM food and feed safety assessment

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European Food Safety Authority

www.efsa.europa.eu
**FOODS/FEED RISK ANALYSIS**

1) Hazard identification (identification of possible effect)
2) Hazard characterization (nature and severity of the effect)
3) Exposure assessment (likely intake/exposure to the effect)
4) Risk characterization (probability of occurrence of effect)
5) Risk management (decision-making process for release on the market)

*Sampling is central to collect test material to address 1, 2, 3*

*Inadequate sampling may lead to wrong risk characterization*
REALITY IS: TOO LITTLE ATTENTION TO SAMPLING

- Little attention paid to sampling issues in foods/feed risk assessment
- Most effort devoted to reduce analytical errors

**Why?**

*Because it is easier!*

![Diagram showing the relationship between lot, sample, analysis, and total error, with sampling and analytical errors highlighted.](image-url)
LARGE DIVERSITY OF FOODS/FEED PRODUCTS

How to ensure representative sampling for all types of materials??
1. **Hazard identification**: normally comparative approach to identify differences between samples and control.

   *If the samples not representative, identification of potential risk is not reliable*

2. **Hazard characterization**: different approaches depending on the nature of the hazard.

   *If the samples not representative, characterization of potential risk is not reliable*
3. **Exposure:** to quantify the likely intake/exposure of human and animals to the foods/feed.

   **no exposure = no risk**

   ✓ Specific segments of the population may be more sensitive (infants/elderly)

   ✓ Specific groups expected to have higher exposure (operators)

   **Difficult task:**

   clear need for further development of sampling strategies ensuring representativeness of population exposure patterns
The challenge is to characterize heterogeneity patterns to ensure fit-for-purpose sampling strategies!
Sampling protocols currently used in food/feed safety rely on distributional assumptions

Assumptions are rarely (if ever) verified

Heterogeneity patterns are ignored

Representativeness is not documented

Risk estimates are not reliably quantified!
the distributional heterogeneity is **not** a constant characteristic, but a *transient* phenomenon, changing its pattern and magnitude every time an attempt is made to characterize or quantify it.

That’s why distributional assumptions are dangerous and lead to wrong safety assessment conclusions.
GOAL

“Development and harmonization of reliable sampling approaches for generation of data supporting GM plants risk assessment”

Timeframe:
- 24 months (ends in April 2016)

Deliverables:
- 3 intermediate reports
- 1 Final document

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THE STANDARDS ON REPRESENTATIVE SAMPLING

2013: the first EU sampling standard fully based on the Theory of Sampling - TOS!

2004 and 2006: Sampling Recommendations explicitly addressing representativity!

www.ds.dk
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2015: SPECIAL SESSION ON J. AOAC

A first attempt to bring the theory of sampling and foods/feed safety assessment together!
EFSA CONTRACT

SERVICE CONTRACT

TITLE – Development and harmonisation of reliable sampling approaches for generation of data supporting GM plants risk assessment

CONTRACT NUMBER – OC/EFSA/GMO/2013/04 – CT 01
THREE REPORTS

- **Report 1**: on the specific sampling needs for GM plants risk assessment according to the risk assessment strategy described in the EFSA GMO Panel Guidance Document and the Implementing Regulation 503/2013

- **Report 2**: Inventory of scientifically reliable existing sampling strategies and report on their applicability to GM plants risk assessment

- **Report 3**: Delivery of a sampling strategy for the various GM plants RA steps, as described in the EFSA GMO Panel Guidance Document and the Implementing Regulation 503/2013

The final document (spring 2016) will include the 3 reports
CONCLUSIONS

• Central is the sampling necessary to collect material for:
  ✓ Hazard identification
  ✓ Hazard characterization
  ✓ Exposure assessment

• So far the crucial role of sampling has either not been explicitly addressed or, worst, addressed wrongly relying on unverified distributional assumptions.

• Characterization of heterogeneity is necessary to ensure representative sampling

• Representative sampling will result into reliable risk estimates upon which correct risk management decisions can be based
Thank you very much!