



Directorate-General for Health & Consumers

Conclusions – Regulatory outlook on mycotoxins in feed and food - Challenges

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Aflatoxin – conclusions – follow-up

- Transparency in the chain – Sharing information - Early warning system
- Representative sampling – major importance
 - Guidance for application Regulation (EU) 691/2013 sampling feed
 - Guidance for application Regulation (EC) 401/2006 as updated – sampling food
- Sampling procedures
 - EN/ISO 24333:2009
 - GAFTA 124 Sampling rules
 - ...
 - Sampling /analysis /reporting of data in chain and towards competent authorities
- Managing heterogeneity of analytical results → guidance document

T-2 and HT-2 toxin

- Guidance document for implementation of Commission Recommendation 2013/165/EU
 - * Outcome UK stakeholder group
 - * issues (not exhaustive): LOQ, reporting to EFSA, repetitive findings
- * Guidance level of 0,05 mg/kg for cat feed



Current issues at EU level as regards sampling and analysis for mycotoxins

Issues within the context of this mycotoxin forum

- Sampling of large lots for mycotoxins – food
- Validation requirements and performance criteria for screening methods for the determination (quantitative / qualitative) of mycotoxins (food)
- Changes to performance criteria for T-2 and HT-toxin (food)

Current and future challenges/ perspectives

- Ensure an appropriate follow-up from risk management on new EFSA opinions in the pipeline:
 - Sterigmatocystin (opinion available)
 - Nivalenol (opinion available)
 - Enniatins
 - Beauvericin
 - Diacetoxyscirpenol
 - Moniliformin

New requests to EFSA

- Masked/hidden/bound/glycosylated mycotoxins and metabolites : scientific challenges (analytical/toxicological) – challenges for prevention -- regulatory challenges
 - Request from European Commission to EFSA for risk assessment
- Deoxynivalenol (including 3-AcDON and 15-AcDON)
 - Request from European Commission to EFSA for risk assessment

New requests to EFSA

DON Comprehensive

The scientific opinion should, inter alia, comprise the:

- a) evaluation of the toxicity of deoxynivalenol, metabolites of deoxynivalenol and masked deoxynivalenol for animals and humans, considering all relevant adverse acute and chronic health effects;
- b) assessment of the co-occurrence of deoxynivalenol with metabolites of deoxynivalenol and masked deoxynivalenol in food and feed;
- c) estimation of the dietary exposure (chronic and acute dietary exposure) of the EU population to deoxynivalenol, metabolites of deoxynivalenol and masked deoxynivalenol including the consumption patterns of specific (vulnerable) groups of the population (e.g. high consumers, children, people following a specific diet, etc);

New requests to EFSA DON Comprehensive

The scientific opinion should, inter alia, comprise the:

d) estimation of the exposure of the different animal species to deoxynivalenol, metabolites of deoxynivalenol and masked deoxynivalenol from feed;

e) assessment of the acute and chronic human health risks for the EU population including for specific (vulnerable) groups of the population as the consequence of the estimated dietary exposure;

f) assessment of the animal health risks for the different animal species as the consequence of the estimated exposure from animal feed.



New requests to EFSA - DON specific (following discussions at Codex Alimentarius)

The scientific opinion on risks to human health related to a possible increase of the maximum level of deoxynivalenol for flour, semolina, meal and flakes derived from wheat, maize or barley from 750 $\mu\text{g}/\text{kg}$ to 1000 $\mu\text{g}/\text{kg}$, with the understanding that the maximum level for bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals remain at the level of 500 $\mu\text{g}/\text{kg}$.

New requests to EFSA

Metabolites and masked toxins

A scientific opinion on the risks to animal and human health related to the presence of metabolites and the masked or bound forms of fumonisins, zearalenone, T-2 and HT-2 toxin and nivalenol in food and feed.

The scientific opinion should, inter alia, comprise the:

- a) evaluation of the toxicity of the metabolites and masked or bound forms of these mycotoxins for animals and humans and this compared to the toxicity parent mycotoxins
- b) assessment of the co-occurrence of the metabolites and masked or bound forms of these mycotoxins in food and feed.
- c) estimation of the dietary exposure of the EU population to the metabolites and masked or bound forms of these mycotoxins including the consumption patterns of specific (vulnerable) groups of the population (e.g. high consumers, children, people following a specific diet, etc) and this compared to the dietary exposure to the parent mycotoxins.

New requests to EFSA

Metabolites and masked toxins

A scientific opinion on the risks to animal and human health related to the presence of metabolites and the masked or bound forms of fumonisins, zearalenone, T-2 and HT-2 toxin and nivalenol in food and feed.

The scientific opinion should, inter alia, comprise the:

d) estimation of the exposure of the different animal species to the metabolites and the masked or bound forms of these mycotoxins from feed and this compared to exposure to the parent mycotoxins.

e) assessment of the human health risks for the EU population including for specific (vulnerable) groups of the population as the consequence of the estimated dietary exposure to the metabolites and masked or bound forms of these mycotoxins and the parent mycotoxins.

f) assessment of the animal health risks for the different animal species as the consequence of the estimated exposure from animal feed to the metabolites and masked or bound forms of these mycotoxins and the parent mycotoxins.

Findings of other mycotoxins

- penitrem A (mainly feed - food (?)) – *Penicillium*
- cyclopiazonic acid (food/feed) - *Penicillium*
- mycophenolic acid - *Penicillium*
- roquefortine (A,B) C - *Penicillium*
- emodin - *Aspergillus*
- penicillic acid – *Penicillium*
- Fusarenon-X – *Fusarium*
- Fusarin C - *Fusarium*
- ...

From a risk management point of view: need for prioritisation → role of research to put findings in a right context

Current and future challenges as a consequence of changing weather conditions

- Tension between MLs based on the application of prevention measures versus changing climate/weather conditions and year to year variation
- Increasing prevalence of aflatoxins in Europe (increased levels of aflatoxins in the South-(East) of Europe in 2012 – 2013)
- ...