

Food Safety – Risk Assessment and Risk Management at a European Level

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SELAMAT Seminar – 24th April 2006



Outline of Talk

- Introduction
- Risk Analysis
 - Risk Assessment – EFSA
 - Risk Management – DG Health and Consumer Protection
- Role of EFSA
 - Examples of Scientific Opinions
- Role of DG Health and Consumer Protection
 - Examples of Risk Management Actions
- Conclusions



Food Safety in Europe

- Media driven food scares – BSE, dioxins, nitrofurans, Sudan I, benzene
- Lack of public confidence in the safety of food
- Conflict between producer and consumer interests
- Lack of good traceability systems



Separation of Responsibilities

Agriculture Departments historically represented food producers and consumers

From 2000 onwards – new Food Authorities established representing consumers interests

e.g.

- UK Food Standards Agency
- FSAI established in Ireland
- AFSSA established in France



Definition of Risk Analysis

A process consisting of three components

- Risk Assessment
- Risk Management
- Risk Communication



EU established an Independent European Food Agency in 2002

European Food Safety Authority (EFSA)
Based in Parma (Italy) from 2005



Undertakes Risk Assessment and Risk Communication

NOT

Risk Management



EFSA has six main tasks:-

- Provides independent scientific advice on food safety issues
- Advises on technical issues to underpin policy and legislation
- Collects and analyses data on dietary exposure
- Identifies emerging food safety risks
- Supports European Commission in case of crisis
- Communicates to the General Public



EFSA has 4 primary components:-

- Management Board
(14 members + Commission)
- Executive Director + staff (250)
- Advisory Forum (25 members)
- Scientific Committee + Panels



Scientific Committee

Composition

- Chairs of the 8 Scientific Panels
- 6 scientists not members of the EFSA Panels

Role

- General co-ordination, interface with Panels
- Questions involving several Panels
- Questions out of the scope of any of the Panels



Eight Scientific Panels

- Food additives, flavourings, processing aids and materials in contact with food (AFC)
- Additives and products or substances used in animal feed (FEEDAP)
- Plant health, plant protection products and their residues (PPR)
- Genetically modified organisms (GMO)
- Dietetic products, nutrition and allergies (NDA)
- Biological hazards (BIOHAZ)
- Contaminants in the food chain (CONTAM)
- Animal health and welfare (AHAW)



Panel on Contaminants in the Food Chain [CONTAM]

The Panel on contaminants in the food chain deals with questions on contaminants in food and feed, associated areas and undesirable substances such as natural toxicants, mycotoxins and residues on non authorised substances not covered by another Panel



SANCO requests Opinion from EFSA

(deadline proposed)



Terms of Reference



EFSA Panel sets up Working Group (WG)



WG Chair from Panel plus co-opted members



Opinion drafted by WG



Opinion considered by Panel and adopted (after revision)



Opinion published in EFSA journal on website



Six requests from SANCO on mycotoxins in animal feed



- Aflatoxin B1- February 2004
- Deoxynivalenol – June 2004
- Zearalenone – July 2004
- Ochratoxin A – Sept 2004
- Ergot alkaloids – April 2005
- Fumonosins B1 and B2 – June 2005



Terms of reference for consideration of *Fusarium* toxins, OTA and ergot alkaloids in animal feed



- Determine daily exposure level for different species above which signs of toxicity can be observed
- Identify most sensitive animal species
- Determine transfer/carry over levels to animal products (human foods)
- Identify feed materials which are a source of contamination
- Assess contribution of different feed materials to overall animal exposure



Most sensitive animal species



- **DON** shows toxic effects in all animal species – pigs particularly susceptible
- Pigs are the most sensitive species to **ZON** followed by sheep with poultry least sensitive to hormonal effects
- Pigs most sensitive species to **OTA** but chickens also sensitive. Ruminants less sensitive than monogastric animals
- Limited data on sensitivity to **ergot** and complexity of mixtures (adverse effects with pigs)
- Horses and pigs are sensitive to **fumonisin** (also ducks, turkeys, fish)



Carry-over from feed to animal products



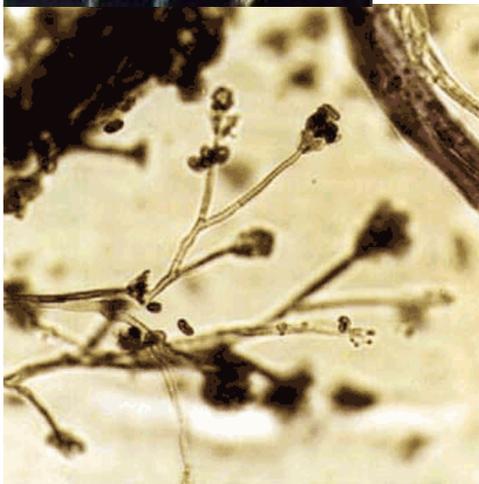
- DON rapidly metabolised – carry-over very low
- Limited tissue disposition of ZON but low transmission into milk and eggs
- Transfer of OTA into blood, kidney, liver and muscle
- Limited and incomplete data on ergot transfer but no evidence of accumulation in edible tissues
- Transfer of fumonisins into edible tissues including milk and eggs is limited

Feed materials which are a source of contamination – DON

- DON levels vary year-to-year with climate, season, geographic conditions, agronomic practice e.g. fungicide use etc
- Levels range from $\mu\text{g}/\text{kg}$ to tens of mg/kg
- Confounding factor - DON invariably co-occurs with other trichothecenes and ZON



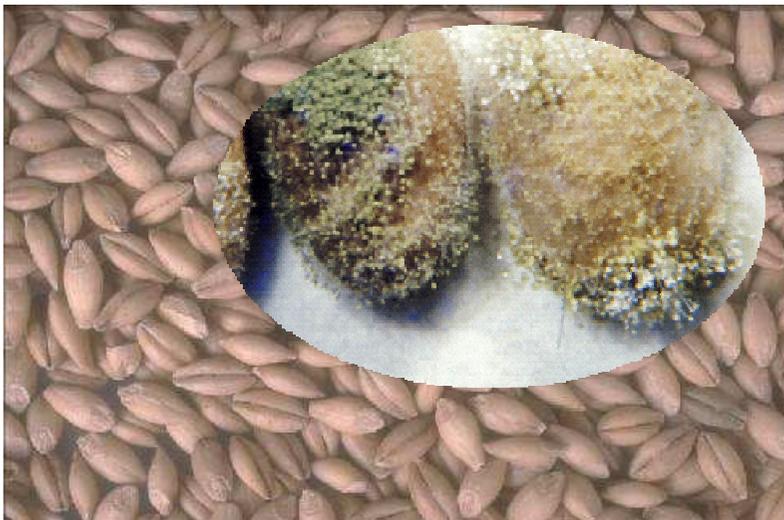
Feed materials which are a source of contamination – ZON



- ZON levels vary year-to-year with climate, season, geographic conditions, agronomic practice e.g. fungicide use etc
- Levels range from $\mu\text{g}/\text{kg}$ to tens of mg/kg
- Confounding factor - ZON invariably co-occurs with Fusarium toxins

Feed materials which are a source of contamination – OTA

- Maize, wheat, rye, oats, and barley principal sources
- Post-harvest formation
- Heterogeneous contamination – high variability



Feed materials which are a source of contamination – Ergot alkaloids



- Rye and other grains/grasses are principal sources
- Control of exposure to non-feed sources difficult (grasses)
- Variability in alkaloid pattern between fungal source and in relation to host plant



Feed materials which are a source of contamination – Fumonisin

- Predominantly maize and maize-based products contaminated
- Maize invariably contaminated frequently at mg/kg levels
- Little data on feed *per se*
- Confounding factors - fumonisins invariably co-occur with other *Fusarium* toxins



Conclusions – exposure

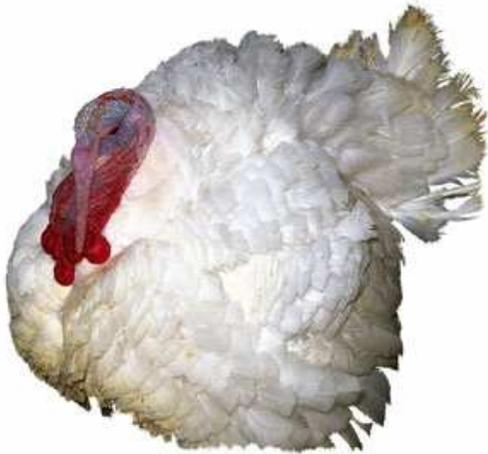
- Data inadequate to make good estimates of animal exposure from feed
- Human exposure to *Fusarium* toxins from cereal sources far exceeds levels from transfer to animal products



- Only in the case of ochratoxin A do animal products contribute equivalent amounts to other sources of exposure



Conclusions – occurrence data



- Lack of data on mycotoxin contamination in animal feed
- Most data is for cereals where end-use is not specified – assumptions may not be valid that contamination levels for grain destined for human consumption equivalent to that for feed
- Analytical methods have not been validated for feeds *per se*
- Human exposure to *Fusarium* toxins from cereal sources far exceeds levels from transfer to animal products



Need for more information



- Variability of ergot alkaloid patterns needs to be established in European feed materials
- Ergot alkaloid standards need to be established
- Significance of 'bound' fumonisins needs to be determined



Risk Management

Risk management is the process of weighing:

- risk assessment and other factors
- policy alternatives
- promotion of fair trade practices

If needed, selecting appropriate prevention and control options



Risk Management Elements

- Risk Evaluation
- Risk Management Option assessment
- Implementation and management of decisions
- Monitoring and review



DG Health and Consumer Protection (SANCO)



- Responsible for Food Safety Risk Management
- Regulations and Directives in hygiene and food safety
- Food Control Harmonisation
 - Rapid Alert System (RAFFS)
 - Reference Laboratory network (CRLs)



Conclusions

- Transparent and science-based risk assessment in Europe – EFSA
- Consultative risk management process – SANCO + Member States
- Consumer confidence in food safety is being slowly restored
- Systems are in place to better identify future emerging risks

