

# European Community policy contaminants in foodstuffs



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# Council Regulation 315/93



- Regulatory framework :

Council Regulation (EEC) N) 315/93 of 8 February 1993 laying down Community procedures for contaminants in food

(this Regulation does not apply to contaminants which are the subject of more specific Community rules, such as pesticide residues, veterinary drug residues, ...)

# Regulation 315/93

## Definition contaminant



- contaminant means any substance not intentionally added to food which is present in such food as a result of the production, manufacture, processing preparation treatment, packing packaging transport or holding of such food or as a result of environmental contamination

# Regulation 315/93 Provisions



- **General provision:**
  - **food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market**
- **Good practice:**
  - **contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)**

# Regulation 315/93 Provisions



- When necessary for protecting public health maximum levels shall established for specific contaminants --> Procedure for setting maximum levels. This can also include a reference to the sampling and analysis methods to be used.
- Obligatory consultation of the European Food Safety Authority(EFSA) Panel on contaminants in the food chain before provisions having effect upon public health shall be adopted.

# Regulation 315/93 Provisions



- safeguard clause: as consequence of new information or reassessment of existing information --> suspicion of constituting a health risk although complying EU legislation
- internal market: no restriction on placing on the market for foods complying with EU legislation for reasons relating to their contaminant content

# Regulation 315/93 Provisions



- national measures
  - possibility to maintain national measures in case they were adopted before 1993 and insofar they are not overruled by EC-legislation
  - necessity to adopt new national legislation
- National measures new EC Member States
- notification procedure for new national legislation -- under Regulation 315/93 or 1998/34 (technical standards and regulations)
- competent Standing Committee: Standing Committee on the Food Chain and Animal Health.

# Strategy - establishment of maximum levels



- Scientific risk assessment: assessment of the risks related to the presence of a contaminant in foodstuffs / establishment of a tolerable intake --> is the basis for the measures to be taken
- exposure assessment: human exposure (average and 95 percentile) assessed against tolerable intake. Particular attention to vulnerable groups of population, high level consumers, ...

# Strategy - establishment of maximum levels



- Determination of foods/food groups significantly contributing to the exposure
- Occurrence data of the contaminant in the various food/food groups
- Setting a maximum level following the ALARA principle (As Low As Reasonably Achievable). The degree of severity of the application of this principle depends on the relation exposure - tolerable intake

# Strategy - instruments to reduce/prevent presence



- EC-Measures to reduce the contaminant level in food are determined on a case by case basis (dependent of the nature of the contaminant), are divergent and can be a combination of several approaches into one strategy.
- Prevention of major importance
- Instruments: maximum levels, action levels, target levels, source-directed measures, code of practices, encouraging GAP, GMP, ...
- maximum levels are at EC level always combined with sampling provisions and requirements for the methods of analysis

## Strategy - sampling



- Adequate sampling procedure is of crucial importance for estimating lot average levels in case contaminants are heterogeneously distributed throughout a lot (as is the case for aflatoxins, ochratoxin A,...) and is therefore in these cases an essential component in the development of any maximum level
- exporter's risk/producer's risk against importer's risk/consumer's risk: EU policy is that a sampling procedure must be practicable and must minimise the consumer's risk without rendering trade impossible

# Strategy - method of analysis



- Performance criteria based approach.
  - **Advantage: does not avoid making use of technological progress and newest technologies and laboratories can use the analytical method most appropriate for their facilities**
  - **includes parameters such as detection limit, repeatability, coefficient of variation, reproducibility recovery for various levels**

# Contaminants regulated / to be regulated under 315/93



- **Nitrates**
- **Mycotoxins**: aflatoxins, ochratoxin A, patulin, Fusarium-toxins (zearalenone, fumonisins, trichothecenes: Deoxynivalenol, *T-2* and *HT-2* toxin), ergot alkaloids, ...
- **Heavy metals**: lead, cadmium, mercury, arsenic, methylmercury...
- **Other industrial (processing) and environmental contaminants**: 3-MCPD, dioxins, dioxin-like PCBs, inorganic tin, PAH, non-dioxin-like PCBs, acrylamide, BFRs, PFOS, tributyltin (TBT), iodine, furan, ethylcarbamate, ...
- **Inherent plant toxins**: pyrrolizidine alkaloids, solanine ...

# Risk management options used – to be used



- **Maximum levels:** aflatoxins, ochratoxin A, lead, cadmium, 3-MCPD, inorganic tin
- **Maximum levels with regional derogations:** nitrates, dioxins
- **Maximum levels combined with code of practice for prevention and reduction:** patulin, Fusarium-toxins
- **Comprehensive strategy (feed and food) comprising of a combination of maximum levels, action levels, target levels and source-directed measures:** dioxins

# Risk management options used – to be used



- **Maximum levels with data collection: PAH, dioxins**
- **Maximum levels combined with dietary advice: mercury**
- **Dietary advice: ????? (OTC/TBT)**
- **Tools for reduction of presence: acrylamide**

# Community legislation in application of 315/93



- **Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs.**
  - Maximum level does apply to edible part
  - For dried, diluted, processed or compound foodstuffs: concentration/dilution factor, relative proportion (exception aflatoxins) apply also to products used as food ingredient
  - prohibition of mixing contaminated-non contaminated consignments and prohibition of detoxification by chemical treatment (mycotoxins)

# Maximum levels Nitrates



- **Nitrates:** maximum levels for fresh spinach, preserved, deep-frozen or frozen spinach and fresh lettuce and iceberg type lettuces ranging from 2000 to 4500 ppm
  - different levels for different periods of the year, and for protected and open-grown lettuce
  - possibility for derogation for local production/local consumption
  - application of **Good Agricultural Practice (GAP)** to reduce nitrate levels / monitoring
- For baby foods and processed cereal based foods for infants and young children: 200 ppm

# Maximum levels Aflatoxins



- **Aflatoxins (B1, total, M1):**
  - groundnuts, nuts and dried fruit
    - for direct human consumption or as food ingredient: 2.0 µg/kg for AFB1 and 4.0 µg/kg AFTOT
    - to be subjected for sorting or other physical treatment: nuts and dried fruit : 5.0 µg/kg AFB1 and 10.0 AFTOT and for groundnuts: 8.0 µg/kg AFB1 and 15.0 ppb AFTOT
  - cereals
    - raw cereals and cereal/cereal products for direct human consumption or food ingredient with the exception of raw maize: 2.0 µg/kg for AFB1 and 4.0 µg/kg AFTOT
    - raw maize: 5.0 µg/kg for AFB1 and 10.0 µg/kg AFTOT

# Maximum levels Aflatoxins



- Milk: 0.05 µg/kg aflatoxin M1
- Spices : 5.0 µg/kg AFB1 and 10.0 µg/kg AFTOT
  - *Capsicum* (chillies, chilli powder, cayenne, paprika) *Piper* (black and white pepper), *Myristica fragrans* (nutmeg) *Zingiber officinale* (ginger) and *Curcuma longa* (turmeric)
- Baby foods, processed cereal-based foods and dietary foods for special medical purposes for infants and young children : 0.10 µg/kg AFB1 (on dry matter)
- Infant formulae and follow-on formulae, including infant milk and follow-on milk: 0.025 µg/kg AFM1 → recital: international ring trial to verify if a level of 0.01 µg/kg AFM1 can be reliably determined, in view of considering the reduction of the maximum level.

# Maximum levels Ochratoxin A



- **Ochratoxin A:**

- raw cereal grains (including rice and buckwheat): 5.0  $\mu\text{g}/\text{kg}$
- all products derived from cereals (including processed cereal products and cereal grains intended for direct human consumption): 3.0  $\mu\text{g}/\text{kg}$
- dried vine fruit (currants, raisins and sultanas): 10.0  $\mu\text{g}/\text{kg}$
- Baby foods, processed cereal-based foods and dietary foods for special medical purposes for infants and young children : 0.50  $\mu\text{g}/\text{kg}$  (on dry matter)

# Maximum levels Ochratoxin A



- **Ochratoxin A (cont'd) :**
  - **Roasted coffee beans and ground roasted coffee except soluble coffee: 5.0 µg/kg**
  - **Soluble coffee (instant coffee): 10.0 µg/kg**
  - **Wine (red, white and rosé) and other wine and/or grape must based beverages: 2.0 µg/kg**
  - **Grape juice, grape juice ingredients in other beverages, including grape nectar and concentrated grape juice as reconstituted 2.0 µg/kg**
  - **Grape must and concentrated grape must as reconstituted intended for direct human consumption: 2.0 µg/kg**

# Ochratoxin A

## Future steps



- SCF opinion of 17 September 1998 → basis for the abovementioned measures
- EU research project on the mechanisms of OTA induced carcinogenicity finished spring 2005
- EFSA has been requested to update the scientific opinion from SCF in light of these and other new research results
- Based on this updated risk assessment, a review of the OTA measures is foreseen by 30 June 2006 in particular
  - **Revision of the ML in dried vine fruit and grape juice in view of a reduction**
  - **Consideration of setting an ML in green coffee, dried fruit other than dried vine fruit, beer, cocoa and cocoa products, liqueur wines, meat and meat products, spices and liquorice**

# Maximum levels Patulin - food



- fruit juices (in particular apple juice), fruit nectar, fruit juice ingredients in other beverages and concentrated fruit juice after reconstitution as instructed by the manufacturer: 50 µg/kg
- spirit drinks, cider and other fermented drinks derived from apples or containing apple juice: 50 µg/kg
- solid apple products , including apple compote and apple puree intended for direct consumption: 25 µg/kg
- apple juice and solid apple products, including apple compote, apple puree for infants and young children and other baby food other than processed cereal-based foods: 10 µg/kg

# Maximum levels Patulin - food



- **Recommendation (2003/598/EC) on code of practice for the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages with a lower target level for patulin in apple juice of 25 µg/kg defined**
  - Review of the maximum level of 50 µg/kg with a view to reducing them to take account of the progress in scientific and technological knowledge and the implementation of the abovementioned Code.

# Provisions

## *Fusarium*-toxins - Food



- Deoxynivalenol, zearalenone, fumonisins B1 & B2 and T-2 & HT-2 toxin
- For the purpose of the application of the MLs for *Fusarium*-toxins, rice is not included in “cereals” and “cereal products”
- Mixing non-complying products with complying products is prohibited and also chemical decontamination is prohibited
- Measures applicable from 1/07/2006
- No maximum levels for nivalenol, 3-AC-DON, 15-AC-DON
- Unprocessed: marketed for first stage processing
- First-stage processing: any physical or thermal treatment , other than drying, of or on the grain (cleaning and sorting not considered as first stage processing)
- Review of provisions foreseen by 1 July 2008

# Maximum levels - Food *Fusarium*-toxins – DON



- Deoxynivalenol (DON)
  - unprocessed cereals with the exception of durum wheat, oats and maize: 1250 µg/kg
  - Unprocessed durum wheat and oats: 1750 µg/kg
  - Unprocessed maize: for the time being no ML – eventually 1750 µg/kg applicable from 01/07/2007 onwards if no maximum level has been established in the meantime
  - Cereal Flour, including maize flour, maize grits and maize meal 750 µg/kg
  - Bread, pastries, biscuits, cereal snacks and breakfast cereals: 500 µg/kg
  - Pasta (dry) 750 µg/kg
  - Processed cereal based food for infants and young children and ingredients for the manufacture of these products: 200 µg/kg

# Maximum levels - food

## *Fusarium*-toxins - ZEA



- Zearalenone

- unprocessed cereals with the exception of unprocessed maize: 100 µg/kg
- unprocessed maize: for the time being no ML – eventually 200 µg/kg applicable from 01/07/2007 onwards if no maximum level has been established
- Cereal Flour, except maize flour: 75 µg/kg
- Maize flour, maize meal maize grits and refined maize oil: for the time being no ML – eventually 200 µg/kg applicable from 01/07/2007 onwards if no maximum level has been established in the meantime

# Maximum levels - food

## *Fusarium*-toxins - ZEA



- Bread, pastries, biscuits : 50 µg/kg
- Maize snacks and maize based breakfast cereals: for the time being no ML – eventually 50 µg/kg applicable from 01/07/2007 onwards if no maximum level has been established in the meantime
- Other cereal snacks and breakfast cereals: 50 µg/kg
- Processed maize based food for infants and young children and ingredients for the manufacture of these products: for the time being no ML – eventually 20 µg/kg applicable from 01/07/2007 onwards if no maximum level has been established in the meantime
- Other processed cereal based food for infants and young children and ingredients for the manufacture of these products: 20 µg/kg

# Maximum levels - Food *Fusarium*-toxins – FB1 + FB2



- Fumonisin B1 + B2
  - No maximum level established for the time being – if no specific level is fixed before 1 October 2007, the following levels will apply:
    - unprocessed maize: 2000 µg/kg
    - Maize grits, maize meal, maize flour and refined maize semolina: 1000 µg/kg
    - maize based food for infants and young children and baby food: 200 µg/kg (on dry matter basis)
    - Other maize based foods for direct human consumption: 400 µg/kg

# Maximum levels - Food

## *Fusarium*-toxins: T-2 + HT-2



- T-2 + HT-2 toxin
  - Reliable occurrence data very limited
  - Occurs in particular in oats
  - No internationally validated methods of analysis
  - For the time being no ML proposed
  - Foreseen to, if appropriate, to establish maximum levels for T-2 and HT-2 toxin by 01/07/2007

# Recommendation Prevention *Fusarium*-toxins



- Draft Recommendation on the prevention and reduction of *Fusarium* – toxins in cereals and cereal products
  - Risk factors to be considered for inclusion in Good Agricultural Practices (GAP)
  - Contamination by *Fusarium*-toxins of cereals can be imputed to multiple factors
  - integrated approach addressing in a reasoned way all possible risk factors taking into account the local situation

# Maximum levels Lead



- **Lead - products of animal origin / fish**
  - cows milk: 0.02 ppm
  - infant formulae /follow-on formulae 0.02 ppm
  - meat of bovine animals, sheep, pig and poultry 0.1 ppm
  - edible offal of cattle, sheep, pig and poultry 0.5 ppm
  - muscle meat
    - fish 0.2 ppm
    - seabream, eel, grey mullet, grunt ,horse mackerel, sardine, sardinops, spotted seabass and wedge sole 0.1 ppm
  - crustaceans 0.5 ppm
  - bivalve molluscs 1.5 ppm
  - Cephalopods(without viscera) 1.0 ppm

# Maximum levels Lead



- **Lead - products of plant origin**
  - **cereals, legumes and pulses** **0.2 ppm**
  - **vegetables** **0.1 ppm**
    - **except Brassica, leafy vegetables and cultivated fungi** **0.3 ppm**
  - **fruits** **0.1 ppm**
    - **except berries and small fruits** **0.2 ppm**
  - **fats and oils including milk fat** **0.1 ppm**
  - **fruit juices** **0.05 ppm**
  - **wines (from 2001 harvest onwards)** **0.2 ppm**

# Maximum levels Cadmium



- **Cadmium: products of animal origin / fish**
  - meat of bovine animals, sheep, pig and poultry **0.05 ppm**
  - Horse meat **0.2 ppm**
  - liver of cattle, sheep, pig and poultry **0.5 ppm**
  - kidney of cattle, sheep, pig and poultry **1.0 ppm**
  - muscle meat of
    - fish **0.05 ppm**
    - anchovy, bonito, seabream, eel, grey mullet, horse mackerel, luvar, sardine, sardinops, tuna and wedge sole **0.1 ppm**
    - Swordfish **0.3 ppm**
  - crustaceans **0.5 ppm**
  - bivalve molluscs **1.5 ppm**
  - Cephalopods (without viscera) **1.0 ppm**

# Maximum levels Cadmium



- **Cadmium: products of plant origin**
  - cereals excluding bran germ, wheat grain and rice **0.1 ppm**
  - bran, germ wheat grain and rice **0.2 ppm**
  - soybeans **0.2 ppm**
  - vegetables and fruits **0.05 ppm**
    - leafy vegetables, fresh herbs, celeriac and cultivated fungi **0.2 ppm**
    - stem vegetables, root vegetables and potatoes, excluding celeriac **0.1 ppm**

# Maximum levels Mercury and 3-MCPD



- Mercury
  - fishery products except several species 0.5 ppm
  - several species 1.0 ppm
  - Dietary advice as regards consumption of swordfish, shark, marlin and pike by woman in child bearing age and children  
[http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/information\\_note\\_mercury-fish\\_12-05-04.pdf](http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/information_note_mercury-fish_12-05-04.pdf)
- 3 - MCPD
  - hydrolysed vegetable protein (40 % DM) 0.02 ppm
  - soy sauce (40 % DM) 0.02 ppm

# EU strategy on dioxins



- **Comprehensive set of measures to limit the the presence of dioxins in environment, feed and food**
- **Environment measures are addressed in Commission Communication COM (2001) 593 of 24/10/2001**
- **Measures in feed and food consist of three pillars**
  - maximum levels
  - action levels
  - target levels

# Dioxins - first pillar: Maximum levels



- for regulatory control
- highly contaminated products are not allowed to be put on the market or have to be withdrawn from the market.
- transparent
- ensuring uniform application of legislation across the EU
- established at a strict but feasible level

## Dioxins: Second pillar Action levels



- early warning tool for competent authorities and operators
- triggering action on identification of sources and pathways of contamination
- pro-active approach to reduce the presence of dioxins in food and feed
- interaction with environmental measures

# Dioxins Third pillar Target levels



- target levels indicate the levels to be achieved over time in feed and food in order to ultimately bring human exposure for the majority of the EU population down to or below the TWI for dioxins, furans and dioxin-like PCBs.

# Legislation Dioxins



- maximum levels and action levels established and applicable since July 2002 only for PCDD/F
- requirements as regards sampling and methods of analysis (screening and confirmatory purposes)
- active approach to establish a comprehensive database on the presence of dioxin-like PCBs.

# Legislation Dioxins



- in addition to control programs for the presence of dioxins in feed and food (targeted control), also specific monitoring programmes on background levels of dioxins and dioxin-like PCBs in feed and food have been established (time trends)
- inclusion of dioxin-like PCBs in the maximum levels was foreseen (together with establishment of specific action levels for dioxin-like PCBs) by the end of 2004.

# Maximum levels Food Com. Regulation 466/2001



- all levels are on fat basis , with the exception of levels for fish (muscle meat of fish on fresh weight basis)
- levels for PCDD/F applicable since 1 July 2002
- levels are not applicable for food products containing less than 1 % fat (except for fish and fish products)
- All levels are expressed as pg WHO-PCDD/F-TEQ/g (fat or fresh weight)
- upperbound levels (non quantified congeners equal to limit of quantification)

# Current Max. Levels (PCDD/F) Food – Reg. (EC) 466/2001



- **meat and meat products originating from**
  - Ruminants (bovines, sheep) 3 pg/g fat
  - Poultry and farmed game 2 pg/g fat
  - Pigs 1 pg/g fat
- **liver and derived products from terrestrial animals**  
6 pg/g fat
- **fish and fishery products and products thereof**
  - muscle meat 4 pg/g product
    - Where fish are intended to be eaten whole, the maximum level shall apply to the whole fish
    - Applies to crustaceans excluding the brown meat of crab and to cephalopods without viscera

# Current Max. Levels (PCDD/F) Food Reg. (EC) 466/2001



- **milk and milk products** **3 pg/g fat**
- **hen eggs and egg products**  
(including free range eggs) **3 pg/g fat**
- **oils and fats**
  - **fat from ruminants** **3 pg/g fat**
  - **fat from poultry** **2 pg/g fat**
  - **fat from pigs** **1 pg/g fat**
  - **mixed animal fat** **2 pg/g fat**
  - **vegetable oils and fats** **0.75 pg/g fat**
  - **fish oil for human consumption** **2 pg/g fat**

## Action levels: feed - food Recomm. 2002/201/EC



- action levels also only for PCDD/F for the time being
- levels at roughly 2/3 of maximum levels
- food: action level also for fruits vegetables and cereals (0.4 ng/kg)
- exceeding of action level - report to Commission and other Member States: results identification sources: mutual exchange of information

# Dioxin-like PCBs (DL-PCBs)



- Discussions within the EU ongoing since Spring 2004
- Dioxins/furans different sources of contamination than dioxin-like PCBs → data indicate no fixed ratio in the presence of dioxins /furans and dioxin-like PCBs
- Establishment of new total WHO-TEQ maximum levels (PCDD + PCDF + DL-PCB) by Commission Regulation No 199/2006 of 3 February 2006. These new maximum levels are applicable as from November 2006 onwards all maximum levels are expressed as pg WHO-PCDD/F-DLPCB-TEQ/g (fat or fresh weight)
- Current dioxin levels remain in application for a transitional period.
- Different sources of contamination → separate action levels for dioxins/furans and dioxin-like PCBs.

# Total TEQ values FOOD (PCDD + PCDF + DL-PCB)



- **meat and meat products originating from**
  - Ruminants (bovines, sheep) 4.5 pg/g fat
  - Poultry and farmed game 4.0 pg/g fat
  - Pigs 1.5 pg/g fat
- **liver and derived products from terrestrial animals**  
12,0 pg/g fat
- **fish and fishery products and products thereof**
  - muscle meat 8,0 pg/g fresh weight
    - Where fish are intended to be eaten whole, the maximum level shall apply to the whole fish
  - muscle meat of eel 12 pg/g fresh weight

# Total TEQ values FOOD (PCDD + PCDF + DL-PCB)



- **milk and milk products** 6,0 pg/g fat
- **hen eggs and egg products** 6,0 pg/g fat  
(including free range eggs)
- **oils and fats**
  - fat from ruminants 4.5 pg/g fat
  - fat from poultry 4.0 pg/g fat
  - fat from pigs 1.5 pg/g fat
  - mixed animal fat 3.0 pg/g fat
  - vegetable oils and fats 1.5 pg/g fat
  - marine oil for human consumption 10,0 pg/g fat

# Maximum levels FOOD

## Specific provisions



- As regards marine oil, efforts have to be done by the operators to increase the capacity to remove effectively dioxins, furans and dioxin-like PCBs from marine oil. Legislation provides that all maximum levels for dioxins and dioxin-like PCBs have to be reviewed before 31 December 2008 with the aim of significantly reducing of the maximum levels. As regards marine oil, this significant lower level shall be determined based on the technical possibilities of the most effective decontamination procedure.
- Increased monitoring on presence of PCDD/F and DL PCBs in food for infants and young children

# Maximum levels FOOD

## Specific provisions



- Temporary derogation for Finland and Sweden is replaced by a temporary derogation ending 31 December 2011 for six fish species: salmon (*Salmo salar*), herring (*Clupea harengus*), river lamprey, trout (*Salmo trutta*), char (*Salvelinus spp*) and roe of vendace (*Coregonus albula*).
- Possibility for Estonia (already foreseen in Accession Treaty) and Latvia and Lithuania to have the same derogation as Finland and Sweden under the same conditions. Evidence that these conditions are fulfilled still to be provided.

# Revision of maximum levels Dioxins - FOOD



- Revision of the maximum levels by 31 December 2008 with the aim of significantly reducing the maximum levels for the sum of dioxins and dioxin-like PCBs
- The existing maximum levels for dioxins (PCDD/F) remain applicable for a temporary period of time. Food must comply during this temporary period simultaneously with maximum levels for PCDD/F and with the maximum levels for the sum of PCDD/F and DL-PCBs. The deletion of the separate maximum level for PCDD/F will be considered by 31 December 2008
- Setting of target levels postponed to 31 December 2008

# Maximum levels Inorganic Tin



- Regulation 242/2004 of 12 February 2004
  - **canned foods other than beverages: 200 mg/kg**
  - **canned beverages, including fruit juices and vegetable juices : 100 mg/kg**
  - **canned foods (baby foods, processed cereal based foods, infant formulae and follow-on formulae including infant milk and follow-on milk, dietary foods for special medical purposes) for infants and young children, excluding dried and powdered products: 50 mg/kg (on the product as sold)**

# Polycyclic aromatic hydrocarbons (PAH)



- Scientific Committee for Food opinion - December 2002: number of PAH are genotoxic carcinogens
- Benzo(a) pyrene (B(a)P) can be used as a marker for the occurrence and effect of carcinogenic PAH → further monitoring will provide information on the suitability of B(a)P as a marker
- Contamination through direct heating/drying processes (combustion gases in direct contact with the product intended to be dried/heated) and contamination through environmental pollution
- Decontamination possible of oils through active carbon
- Review of maximum levels for PAH in the listed foods by 1 April 2007, taking into account progress on the knowledge on the occurrence of benzo(a)pyrene and other carcinogenic PAH in food

# Maximum levels PAH – B(a)P



- Maximum levels for benzo(a) pyrene
  - oils and fats intended for direct human consumption or use as an ingredient in foods (exc. cocoa butter) 2.0 µg/kg
  - Foods for infants and young children: 1.0 µg/kg
  - smoked meats and smoked meat products: 5.0 µg/kg
  - Muscle meat of smoked fish and smoked fishery products: 5.0 µg/kg
  - Muscle meat of fish other than smoked fish 2.0 µg/kg
  - Crustaceans, cephalopods other than smoked 5.0 µg/kg
  - Bivalve molluscs 10.0 µg/kg

# Polycyclic aromatic hydrocarbons (PAH)



- Commission Recommendation on further investigations on PAH in food as regards
  - the suitability of B(a)P as a marker. Monitoring of the occurrence of 15 PAH highlighted by the SCF as being carcinogenic
  - Alternative heating/drying/smoking processes to lower contamination by PAH
  - Presence of PAH in cocoa butter
  - Environmental sources of PAH in food

# ACRYLAMIDE



- Note of the acrylamide workshop October 2003
- Information on ways to lower the levels of acrylamide formed in food
  - **details of approaches found to lower the levels of acrylamide in food – cut potato products, cereal products, coffee**
  - **Recommendations to food producers and processors, to retailers and to caterers**
- [http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/acryl\\_guidance.pdf](http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/acryl_guidance.pdf)

# Sampling and methods of analysis - aflatoxins



- **Directive 1998/53 - Sampling - aflatoxins**
  - nuts, groundnuts, dried fruit and cereals: 100 incremental samples / 30 kg aggregate samples / to be divided in 3 subsamples rejection and acceptance criteria:
    - for direct human consumption: all three subsamples to be in compliance with maximum level
    - to be subjected to sorting or physical treatment: average of subsamples/aggregate sample to be in compliance with maximum level
  - derived products/spices : 10 kg samples
  - milk: specific provisions

# Sampling and methods of analysis - aflatoxins



- **Directive 1998/53 - Methods of analysis - aflatoxins**
  - **sample preparation:**
    - complete sample to be ground until complete homogenisation
    - levels apply to edible part --> edible part to be homogenised or if nut with shell is homogenised: calculation of the analytical result on the edible part
  - **performance criteria: recovery, repeatability, reproducibility**

# Sampling and methods of analysis - ochratoxin A



- **Directive 2002/26 - Sampling - Methods of analysis ochratoxin A**
  - **cereals, derived cereal products and dried vine fruit: 100 incremental samples / 10 kg samples**
  - **acceptance - rejection criteria: average of aggregate sample to comply with maximum levels**
  - **for the rest: equivalent provisions as for aflatoxins**

# Sampling and methods of analysis - patulin



- **Directive 2003/78/EC - Sampling - Methods of analysis patulin**
  - **3 - 10 incremental samples / 1 kg samples**
  - **duplicate analysis in case first result is less than 20 % below or above the maximum level and calculate the mean.**

# Sampling and methods of analysis - heavy metals



- **Directive 2001/22** - Sampling - Methods of analysis: lead, cadmium, mercury and 3-MCPD
  - 3 - 10 incremental samples / 1 kg samples
  - compliance with a lot on the basis of the mean of two independent analysis
  - performance criteria for methods of analysis for heavy metals: LOD (1/10), LOQ (1/5), precision (Horrat  $r$  and  $R < 1.5$ ), recovery (80-120 %)
  - performance criteria for methods of analysis 3-MCPD: recovery (75-110 %) LOQ: 10 ppb

# Sampling and methods of analysis - dioxins



- **Directive 2002/69 - Dioxins**
  - **sampling: 3 - 10 incremental samples / 1 kg samples**
  - **screening method combined with confirmatory method**
  - **screening method**
    - **detect presence dioxins, furans /DL PCBs at level of interest (less than 30 % - 40 % below or exceeding)**
    - **high sample throughput**
    - **very low rate of false negatives**

# Sampling and methods of analysis - dioxins



- level of dioxins/furans/DL PCBs of positive samples from screening must be confirmed/ determined by confirmatory method
- criteria to be complied with on total TEQ:
  - screening methods (S): false negative rate < 1 % and CV < 30 %
  - confirmatory methods (C): Trueness: +/- 20 % and CV < 15%
- control of recovery individual congeners:  
60-120 % (C) or 30- 140 % (S)
  - exception for congeners contributing less than 10 % to total TEQ (PCDD/F)

# Sampling and methods of analysis - tin



- **Directive 2004/16 - Sampling - Methods of analysis - tin**
  - 1 - 5 incremental samples (cans) – in case suspicion individual cans exceed ML → further investigations
  - performance criteria for methods of analysis for tin: LOD (< 5mg/kg), LOQ (<10 mg/kg), precision (Horrat r and R < 1.5), recovery (80-105 %)
  - performance criteria – uncertainty function approach to assess suitability of the method to be used – formula for maximum standard uncertainty

# Sampling and methods of analysis - PAH



- **Directive 2005/10/EC - Sampling - Methods of analysis – PAH**
  - **3 - 10 incremental samples of 100 g (aggregate sample of minimum 300 g)**
  - **performance criteria for methods of analysis for tin: LOD ( $< 0.3 \mu\text{g}/\text{kg}$ ), LOQ ( $< 0.9 \mu\text{g}/\text{kg}$ ), precision (Horrat  $r$  and  $R < 1.5$ ), recovery (50-120 %)**
  - **performance criteria – uncertainty function approach to assess suitability of the method to be used – formula for maximum standard uncertainty**

# Sampling and methods of analysis - *Fusarium*-toxins



- Sampling and analysis official control (2005/38/EC)
  - Similar provisions as for ochratoxin A
  - cereals, derived cereal products : 100 incremental samples of 100 gram /10 kg samples
  - acceptance - rejection criteria: average of aggregate sample to comply with maximum levels
  - For T-2 and HT-2: uncertainty function approach to assess suitability of the method to be used
  - Reporting and interpretation of results

# REPORTING OF ANALYTICAL RESULTS



- Corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported
- Analytical result to be reported as  $x \pm U$  whereby  $x$  is the analytical result and  $U$  the expanded measurement uncertainty
- Expanded measurement uncertainty, using a coverage factor of 2, which gives a confidence interval of approx. 95 %
- For dioxins, alternatively the approach by establishing the decision limit  $CC\alpha$  (according to Commission Decision 657/2002/EC) can be used
- Detailed report on relationship analytical results, measurement uncertainty and recovery:  
[http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/report-sampling\\_analysis\\_2004\\_en.pdf](http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf)

# INTERPRETATION OF ANALYTICAL RESULTS



- A consignment is considered as non-compliant if analytical result, corrected for recovery exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty

## Specific existing safeguard measures



- In addition to the setting of maximum levels --> in some cases appropriate to take additional measures to protect public health
  - aflatoxins- pistachio's - Iran
  - aflatoxins- peanuts - Egypt
  - aflatoxins- hazelnuts, dried figs, pistachio's - Turkey
  - aflatoxins - peanuts - China
  - aflatoxins - Brazil nuts in shell - Brazil

# Specific existing safeguard measures



- Provisions
  - (temporarily suspension of import - currently not in application)
  - Health certificate, control at export (100 %)
  - Limited validity of health certificate (case of pistachios's from Iran)
  - Control at import (100 % - specific frequency 10-20 %) import only via designated points of import
  - Fate of non complying consignment (Brazil nuts in shell from Brazil)
  - Other provisions : splitting of consignment, costs of control, ...

# Current – very recent activities on contaminants in food



- **simplification and improve readability of legislation:** consolidation and recast of existing legislation in particular the 466/2001 (maximum levels, has been 18 times amended since 2001),
- **merging of the sampling directives for mycotoxins into one sampling Regulation** (Commission Regulation (EC) No 401/206 of 23 February 2006 laying down the sampling methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs – OJ L 70, 9.3.2006, p. 12),
- **merging all safeguard measures as regards aflatoxins in to one Commission Decision (ongoing)**

# Current – very recent activities on contaminants in food



- **provide additional guidance to competent authorities to ensure harmonised application of EU legislation throughout the EU:**
  - **guidance note for competent authorities for the control of compliance with EU-legislation on aflatoxins (available on SANCO-website)**
  - **guidance note on sampling of large lots (static/dynamic) of cereals for mycotoxins as well developing an screening approach to control a large number of lots in short time.**

# Current - Future discussions (non exhaustive list)



- Discussion on a number of contaminants in view of future regulatory measures to reduce the presence in food (not necessarily leading to the setting of maximum levels)
  - **Agricultural contaminants:** ochratoxin A (extension of current MLs), Fusarium-toxins (T-2 and HT-2 toxin), ergot alkaloids,
  - **Environmental contaminants:** non-dioxin-like PCBs, arsenic, methylmercury, brominated flame retardants (BFRs), perfluoro-octane sulphonates (PFOS), tributyltin (TBT), iodine
  - **Processing/industrial contaminants:** acrylamide, furan, ethylcarbamate, ...
  - **Inherent plant toxins:** solanine, pyrrolizidine alkaloids