Prohibition of substances and control of residues

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DG SANTE E.2.

Prohibition of substances and controls of residues: outline

- *Directive 96/22/EC – "hormone ban"*
- *Decision 99/879/EC – "bovine somatropine ban"*
- *Regulation 37/2010 – MRLs and prohibited subst.*
- *Directive 96/23/EC & Decision 97/747/EC – "residue monitoring"*
- *Decision 2011/163/EC – "third country list"*
- *Decision 98/179/EC – "official sampling"*
- *Decision 2002/657/EC – "analytical methods & interpretation of results"*
- *Decision 2005/34/EC & Regulation 470/2009 – "reference points for action"*
- *EU reference laboratories Regulation 882/2004 and Reg. 2017/625.*

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Directive 96/22/EC "hormone ban"

- *Based on consumer risk*
- *Applicable to all food producing animals*
- *Limits the use of specific substances with growth promoting properties to specific therapeutic and zootechnical treatments under detailed conditions*
- *All other placing on the market, holding and administering of such substances is prohibited, as is the holding and trading of treated animals and derived animal products.*

Dir. 96/22/EC: substances

- *Prohibited substances:*
  - **Thyrostatic substances**
  - **Stilbenes, stilbene derivatives, their salts and esters**
  - **Oestradiol 17β and its ester-like derivatives**
- *Prohibited substances with derogations:*
  - **Beta-agonists**
- *Provisionally prohibited substances:*
  - **Substances having oestrogenic (other than oestradiol 17β and its ester-like derivatives), androgenic or gestagenic action**

Dir. 96/22/EC: conditions for therapeutic and zootechnical use

- *Only by veterinarian or under veterinary supervision and responsibility*
- *Only use of authorised products*
- *Only specific forms of treatment (e.g. no implants)*
- *Only for individual animals (except aquaculture)*
- *Obligatory registration (type of treatment, type of product, date of treatment, identity of the animals)*

Dir. 96/22/EC: poss. therapeutic use

- *Only possible for prohibited substances with derogations and provisionally prohibited substances*
- *Testosterone and progesterone and derivatives*
  - **Treatment of fertility problem (including termination of unwanted gestation)**
- *Beta-agonists*
  - **Cows: tocolysis**
  - **Horses: respiratory problems, navicular disease and laminitis, tocolysis**
- *Allyl-trenbolone*
  - **Horses: tocolysis**

Dir. 96/22/EC: poss. zootechnical use

- *Substances having oestrogenic (other than oestradiol 17β and its ester-like derivatives), androgenic or gestagenic action*
  - **Synchronising oestrus**
  - **Preparing donors and recipients for the implantation of embryos**
  - **Sex inversion in aquaculture animals (< 3 m age)**

Dir. 96/22/EC: third country imports

- *Imports only possible when "affording guarantees at least equivalent"*

Decision 1999/879/EC: "BST ban"

- *Prohibits the placing on the market of bovine somatotropin (BST) for and its administration to dairy cows.*

- *Based on animal welfare:*
  - **Risk of clinical mastitis ↗**
  - **Duration of treatment of mastitis ↗**
  - **Incidence of foot and leg disorders ↗**
  - **Poss. severe reactions at injection site**

Regulation (EU) No 37/2010

- *Table 1: classification of authorised pharmacologically active substances as regards their maximum residue limits (MRLs)*

- *Table 2: prohibited substances e.g.*
  - **Chloramphenicol**
  - **Metronidazole**
  - **Nitrofurans**

Directive 96/23/EC "residue monitoring directive"

- *Annual NRMP (national residue monitoring plans)*
- *Targeted sampling: aimed to detect residues and substances*
- *Suspect sampling: follow-up samples following non-compliant findings in targeted sample*
- *Covers live animals, their excrements, body fluids and tissues, animal products, animal feed and drinking water.*
- *Substances covered:*
  - **Group A: substances with anabolic effect and prohibited substances**
  - **Group B: authorised veterinary medicinal products and contaminants**

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Dir. 96/23/EC: the NRMP

- *Obligatory sampling frequencies, both at the farm and in slaughterhouses*
- *Annual approval exercise*
  - **Submission plan < 31 March**
  - **Commission evaluated the plans on conformity with the Directive**
  - **Approval through Standing Committee**
- *Sampling & analysis*
  - **Official control laboratories (NRL and EU RL network)**
- *Results*
  - **Submission results to COM and EFSA by 30 June**
  - **Commission informs Standing Committee**
  - **Annual Communication to EP and Council**

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Residue monitoring: animal species

- *Directive 96/23/EC*
  - **Bovine, porcine, ovine, caprine and equine animals**
  - **Broiler chickens, spent hens, turkeys, other poultry**
  - **Aquaculture products**
- *Decision 97/747/EC*
  - **Milk (bovine & other species)**
  - **Eggs (hen & other species)**
  - **Rabbit meat & meat of wild and farmed game**
  - **Honey**

Dir. 96/23/EC: substances & requirements

RESIDUE OR SUBSTANCE GROUP TO BE DETECTED BY TYPE OF ANIMAL, THEIR FEEDINGSTUFFS, INCLUDING DRINKING WATER, AND PRIMARY ANIMAL PRODUCTS

Type of animal, feeding-stuffs or animal products Substance groups	Bovine, ovine, caprine, porcine, equine animals	Poultry	Aqua-culture animals	Milk	Eggs	Rabbit meat and the meat of wild (*) game and farmed game	Honey
A 1	X	X	X			X	
2	X	X				X	
3	X	X	X			X	
4	X	X				X	
5	X	X				X	
6	X	X	X	X	X	X	
B 1	X	X	X	X	X	X	X
2a	X	X	X	X		X	
b	X	X			X	X	
c	X	X				X	X
d	X						
e	X	X		X		X	
f							
3a	X	X	X	X	X	X	X
b	X			X			X
c	X	X	X	X		X	X
d	X	X	X	X			
e			X				
f							

(*) Only chemical elements are relevant where wild game is concerned.

ANNEX I

GROUP A — **Substances having anabolic effect and unauthorized substances**

(1) Stilbenes, stilbene derivatives, and their salts and esters

(2) Antithyroid agents

(3) Steroids

(4) Resorcylic acid lactones including zeranol

(5) Beta-agonists

(6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990

GROUP B — **Veterinary drugs** ([1]) **and contaminants**

(1) Antibacterial substances, including sulphonomides, quinolones

(2) Other veterinary drugs

(a) Anthelmintics

(b) Anticoccidials, including nitroimidazoles

(c) Carbamates and pyrethroids

(d) Sedatives

(e) Non-steroidal anti-inflammatory drugs (NSAIDs)

(f) Other pharmacologically active substances

(3) Other substances and environmental contaminants

(a) Organochlorine compounds including PcBs

(b) Organophosphorus compounds

(d) Chemical elements

(d) Mycotoxins

(e) Dyes

(f) Others

Dir. 96/23/EC: enforcement measures

- *Targeted sampling → non-compliance → suspect sampling*
- *Very specific enforcement measures in the event of an infringement*
  - **Investigation, blocking of farm, slaughtering, imposing cost of analysis on the operator**

Dir. 96/23/EC: third countries

- *Basis for third countries list*
- *Guarantees at least equivalent*
- *Plans to be submitted to Commission for approval*

Decision 2011/163/EC: "third country list"

- *Third countries only need approval for the commodities they wish to export to the EU*

ovine/caprine species, aquaculture and eggs	all species and products except horses, rabbits and farmed game

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Decision 98/179/EC – official sampling

- *Laboratories must*
  - **be approved & accredited**
  - **participate regularly and successfully in adequate proficiency testing schemes organised by the national or European Union reference laboratories**
- *Sampling must*
  - **be unforeseen, unexpected and effected at no fixed time and on no particular day of the week**
  - **be spread over the whole year (particular seasons)**
  - **take into account all available information**

Decision 2002/657/EC – analytical methods & interpretation of results

- *Official samples: analyse using methods that are*
  - **documented in test instructions (preferably ISO 78-2 standard on methods of chemical analysis)**
  - **validated against the performance criteria**

    Decision limit (CC α): limit at and above which it can be concluded with an error probability of α that a sample is non-compliant

    Detection capability (CC β): smallest content of the substance that may be detected, identified and / or quantified in a sample with an error probability of β
  - **subject to quality control according to Chapter 5.9 of ISO 17025**
- *Interpretation of results → definition of non-compliant result of analysis*

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Decision 2002/657/EC – analytical methods & interpretation of results

- *Test against*
  - **Authorised substances:**
    MRL – maximum residue limit (Reg. 37/2010)
    Cascade MRL – (Reg. 2018/470)
  - **Prohibited or unauthorised substances**
    Zero tolerance (CC alpha)
    MRPL – minimum required performance limit (2002/657/EC)

Minimum required performance limits

Substance and/or metabolite	Matrixes	MRPL
Chloramphenicol	Meat Eggs Milk Urine Aquaculture products Honey	0,3 µg/kg
Medroxyprogesterone acetate	Pig kidney fat	1 µg/kg
Nitrofuran metabolites: — furazolidone — furaltadone — nitrofurantoin — nitrofurazone	Poultry meat Aquaculture products	1 µg/kg for all
Sum of malachite green and leuco-malachite green	Meat of aquaculture products	2 µg/kg

Decision 2005/34/EC: Reference points for action "RPAs"

- MRPLs of Dec. 2002/657 are to be used as reference points for action
- Residues at or above RPA ➔ food is non-compliant
- Applies to **imported consignments** of products of animal origin
- Via a gentlemens' agreement among MS also applied to EU production
- Applies regardless whether analytical tests are carried out routinely, under reinforced checks procedures or under a safeguard measure
- RPA apply ***irrespective of the matrix tested***

EU Reference Laboratories:

- *Regulation (EC) 882/2004*
  - Groups A (1), (2), (3) and (4), B (2)(d) and B (3)(d): RIKILT – Institute for Food Safety, part of Wageningen UR - Wageningen – The Netherlands
  - Groups B (1) and B (3)(e) and carbadox and olaquindox: ANSES – Laboratoire de Fougères – France
  - Groups A (5) and B (2)(a), (b), (e): Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) - Berlin - Germany
  - Group B(3)(d): Technical University Denmark-Copenhagen – Denmark
- *Regulation (EU) 2017/625*
  - Tasks and obligations of EU Reference Laboratories

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- *Thank you for your attention*

- *Questions?*

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