



Veterinary drug residue controls for import
into EU for animal products
(EU policy, requirements)

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Scope of presentation

- Background
- Requirements for third countries exporting food into the EU
- SPS and equivalence
- Key components for a residues plan
- Further sources of information



Background (1)

- Detailed EU legislation in the veterinary field lays down the conditions that apply to the imports of live animals and products of animal origin from third countries.
- The responsibility for this area is within the domain of the Health & Consumer Protection Directorate-General (DG SANCO).

Background (2)



The legislation of the European Union in this field is fully harmonised and the main relevant legislation is listed in the Annex of:



General guidance on EU import and transit rules for sea, air and animal products from third countries

http://ec.europa.eu/food/food/chemical_safety/residues/third_countries_en.htm



http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol5_en.htm

Background (3)



- This legislation imposes a series of health and supervisory requirements, designed to ensure that imported animals and products meet standards at least equivalent to those required for production in, and trade between Member States

Background (4)



- A detailed description of the sequence of individual steps and actions to be followed where a third country seeks approval is given in Section 7.
- In most cases, an on-the-spot inspection by the Food and Veterinary Office (FVO) is required before approval can be considered.



Producing food for the EU market



- Every country wishing to export food of animal origin to the EU must satisfy certain animal health, public health, veterinary certification and residues requirements.
 - Appear on 'lists of authorised third countries'
 - Entire country or region
 - Authorised commodities
 - Approved establishments
 - Use of model certificates
 - Food produced in accordance with EU rules
- NOT ON RESIDUES LIST = NO EXPORTS


Why does the EU require residues controls in food both from Member States and trading partners?



because...



- Legislative requirement in EU
- Public health - food safety
- Political - consumer confidence
- To detect and prevent abuse of drugs
- To facilitate trade in animals and animal products
- Equivalent standards expected from the EU's trading partners


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SPS - equivalence

- Art. 4.1.
 - Members shall accept SPS measures of other Members as equivalent.... if the exporting Member **objectively demonstrates** ... that its measures **achieve the importing Member's appropriate level of SPS protection**


EU Food Law (Regulation (EC) No 178/2002)


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- Equivalence enshrined in Community Food Law
- Article 11 of 178/2002: Food and feed imported to the Community shall **comply** with the relevant requirements of food law or conditions recognised by the Community to be **at least equivalent** with requirements contained therein

Food shall not be placed on the market if it is unsafe

Community legislation on monitoring of residues and contaminants in food of animal origin (1)


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- With regard to residues of veterinary medicines, and some pesticides (dual use substances and organophosphates) and contaminants (heavy metals) in food of animal origin, there is specific Community legislation in place
- **Council Directive 96/23/EC** lays out the requirements that must be met in relation to the planning and execution of national residue control plans for live animals and products of animal origin

Community legislation on monitoring of residues and contaminants in food of animal origin (2)



The principal objective of Council Directive 96/23/EC is to:

- Detect illegal use of substances in animal production and the misuse of authorised veterinary medicinal products and
- To ensure the implementation of appropriate actions to minimise recurrence of all such residues in food of animal origin.
- To identify causes of residues in foods

Community legislation on monitoring of residues and contaminants in food of animal origin (3)



- Consignments of food of animal origin imported into the European Union from third countries, are liable to be taken by the Member States Competent Authorities at Border Inspection Posts (point of entry into the EU) and tested for residues

Community legislation on monitoring of residues and contaminants in food of animal origin (4)



- Consignments of food which contain:
 - Residues in excess of Community Maximum Residue Limits - MRLs - (for veterinary medicines),
 - Maximum Residue Levels - MRLs - (for pesticides) and
 - Maximum Limits - MLs - (for contaminants e.g. heavy metals, dioxins etc), or contain residues of substances which do not have a Community MRL or ML

may not be legally placed on the EU market and will be rejected

Residue monitoring: requirements sought from third countries wishing to export food to the EU (1)



Trading partners should demonstrate their control system complies with EU requirements: The key points are:

1. Article 4 of Council Directive 96/23/EC specifies *inter alia* that there must be a centrally co-ordinated residue monitoring plan in place

and

Residue monitoring: requirements sought from third countries wishing to export food to the EU (2)



2. Article 7 (indent 1) of Council Directive 96/23/EC requires a description of the legislation governing the authorisation, distribution and use of veterinary medicinal products;
3. Article 7 (indent 6) of Council Directive 96/23/EC states that the number of samples taken should be in accordance with the sampling levels and frequencies laid down in Annex IV to that Directive; (see also [Commission Decision 97/747/EC](#))

Residue monitoring: requirements sought from third countries wishing to export food to the EU (3)



4. Article 11 (2) of Council Directive 96/22/EC prohibits Member States from importing from third countries:
 - animals (and/or products derived there from) to which stilbenes and thyrostats have been administered under *any* circumstances,
 - animals (and/or products derived there from) to which certain steroid hormones and beta-agonists have been administered for *growth promotion purposes*.

What food is tested for residues?



- Food of animal origin
- Laid down in Community law
 - Council Directive 96/23/EC
 - Member States test domestic and imported



For third countries.....



- An approved residues control plan is a prerequisite for export of food of animal origin to the EU.
- Approved countries are listed in Commission Decision 2004/432/EC (which is regularly updated)
 - (the last update was [Commission Decision 2009/800/EC](#))
- Plans must be submitted to the Commission and approved annually

Third countries: Residue plans



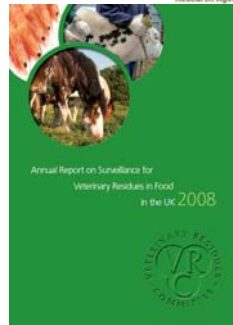
- Must offer equivalent guarantees to those provided for in Community Legislation
- FVO has established uniform procedures and protocols for the assessment of all residue control plans

Further information (1)



Veterinary residue monitoring in the UK

- www.vet-residues-committee.gov.uk/
- www.vmd.gov.uk



Further information (2)



- Community requirements – animal health, public health, certification:
http://ec.europa.eu/food/international/trade/index_en.htm
- SANCO 'third country residues' web page:
http://ec.europa.eu/food/food/chemicalsafety/residues/third_countries_en.htm
- E-mail:
SANCO-TCRESIDUEPLANS@ec.europa.eu
