Residue Monitoring Plans – EU expectations from trading partners

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IAEA International Symposium on Food Safety and Quality,
Vienna, 10 to 13 November 2014
Residue monitoring in food (of animal origin) – why?
• Legislative requirement in EU
  • Council Directive 96/23/EC (food of animal origin)
• Public health – consumer protection
• To detect and prevent misuse and illegal use of veterinary medicines and EU-banned substances (EU ‘philosophy’ – hormone driven)
• To facilitate trade in animals and animal products – required from trading partners
• Safe food
Making sure food is safe in the EU

- Residue control system
  - Border inspection posts in the EU Member States
  - Residue testing laboratories
  - Residue Surveillance (Monitoring Plan)
  - Licensing and controls on use of veterinary medicines

Desk study
On-the-spot FVO scrutiny
Residues in food - role of the FVO

Compliance vs Equivalence

EU Member States
Legislation must be followed

Third countries
Other approaches acceptable provided the same end result is achieved
Article 4 of SPS Agreement
Residues in food - role of the FVO

(1) Audits -

Controls on residues in food producing animals and the use of veterinary medicinal products
Residues in food - role of the FVO

Audits cover three main issues:

**Residue monitoring plan (RMP)**
- Structure / implementation / supervision / follow-up of non-compliant results – role of the **competent authority**

**Laboratories**
- Accreditation, methods, validation, quality control

**Availability & use of veterinary medicines and feed additives and official controls thereof**
- Risk assessment on use patterns in production sectors, likelihood of residues, consumer exposure
Residues audits: 4 questions

(1) Is there a system of control?
- Residues and contaminants
- Authorisation, distribution and use of veterinary medicines
- Laboratories
- Enforcement

(2) Can it work?
- Adequate resources
- Clear roles, responsibilities and staff instructions
Residues audits: 4 questions

(3) Does it work? &
(4) If not, why not?
Residues in food - role of the FVO

(2) Evaluation of residue monitoring plans (RMPs)
Third countries’ RMPs

• Must be submitted **annually** along with results from the previous year to the Commission (FVO) *(same for Member States)*

• Must offer **equivalent** guarantees to those provided for in EU Legislation
Equivalence of third countries’ RMPs
Equivalent guarantees – consider (1):

- **Numbers** of samples and **sampling strategy**
- Method of **sampling** – targeted (directed) or random
- Animal **population** to be tested
- **Substance groups** that *must* be sampled
- Scope of testing – **which analytes** and the risk?
- Authorisation and placing on the market of **veterinary medicines**
- **Matrices** (materials) to be tested and **regulatory limits**
- **Laboratories** – method validation/accreditation
Planning: Codex vs Directive 96/23/EC

Codex Alimentarius (Volume 3, 1995) CAC/GL 71-2009

- **Sampling is random** (unbiased) & statistically based
- **Selection** of substances: should be risk-based
- Assumes **homogeneity** in animal population
- 300 samples should detect 1% violation prevalence with 95% confidence interval
- (Partially) used by some trading partners.....
Planning: Codex vs Directive 96/23/EC

Codex Alimentarius (Volume 3, 1995) CAC/GL 71-2009

but.....

• **Homogeneity** in an animal population – Is this a correct assumption when dealing with illegal treatment? What *is* the population?

• **Risk-based selection** of substances
  • Laboratory capacity
  • Disease and production system will dictate use
  • Controls (or lack of!) may also influence use of veterinary medicines – licensed & unauthorised
Planning: Codex vs Directive 96/23/EC

Directive 96/23/EC

- **Targeted** (directed) testing, prescriptive – proportion of national* production + **suspect testing** (as a result of a non-compliant result)
  - Can be segregated production in third country
  - Selection of animals from production sectors likely
to have received treatment
  - e.g. cull cows and veal calves are more likely to have received
  treatment with antibiotics rather than finishing steers
Planning: Codex vs Directive 96/23/EC

Directive 96/23/EC

• Has **mandatory** substance groups – aims to detect *illegal* use
• Compulsory on-farm (live animal) sampling for growth promoting substances
• Little scope for risk-based sampling
• *Can* result in higher sample numbers vs. Codex Alimentarius
Implementation: Sampling

- Must be **official**
- Must guarantee analytical and legal **validity** – sealing, identification, packaging, temperature
- Must allow trace back in event of a non-compliant result and allow the **competent authority** to carry out a follow-up investigation
Equivalent guarantees – consider (2):

- **Numbers** of samples and **sampling strategy**
- Method of **sampling** – targeted or random
- Animal **population** to be tested
- **Substance groups** that must be sampled
- Scope of testing – **which analytes**, risk?
- Authorisation and placing on the market of **veterinary medicines**
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Implementation: matrices tested?

Laid down in Directive 96/23/EC

Food of animal origin (**MRLs apply**) + non-edible materials – urine/blood etc
Residues of authorised medicines

**Edible tissues** tested – muscle, liver kidney - *sometimes urine is screened* – can predict tissue level

**EU Maximum (Residue) Limits/Levels (MRLs) apply**

Table 1 of the Annex to Regulation (EU) 37/2010 (Pharmacologically active substances)

Regulation (EC) No 396/2005 (Pesticides)

Regulation (EC) No 1881/2006 (Contaminants)

*Third countries expected to meet EU MRLs/MLs (for product intended for export to the EU)*
Residues of unauthorised substances

**Most appropriate matrix tested**

*fluids of excretion, hair, retina, blood*

Aim to **maximise likelihood** of detection

No EU MRLs apply

Results in excess of the CC-alpha (Decision Limit) of the chemical confirmatory method are non-compliant (violative)

*These must be followed up and investigated by the competent authority*
Equivalent guarantees – consider (3):

- **Numbers** of samples and **sampling strategy**
- Method of **sampling** – targeted or random
- Animal **population** to be tested
- **Substance groups** that must be sampled
- Scope of testing – **which analytes**, risk?
- Authorisation and placing on the market of **veterinary medicines**
- **Matrices** (materials) to be tested and **regulatory limits**
- **Laboratories** – method validation/accreditation
Substances tested in EU


• **Group A**
  - A1 stilbenes
  - A2 thyrostats
  - A3 steroids
  - A4 zeranol
  - A5 beta-agonists
  - A6 Table 2 of Annex to Reg. (EU) No 37/2010

• **Group B**
  - B1 antimicrobials
  - B2a anthelmintic agents
  - B2b coccidiostats
  - B2c carbamates/pyrethroids
  - B2d sedatives
  - B2e NSAIDs
  - B2f others e.g. corticoids
  - B3a OCs, PCBs, dioxins
  - B3b organophosphates
  - B3c heavy metals
  - B3d mycotoxins
  - B3e dyes
Substances tested in third countries

Group A
- A1 stilbenes
- A2 thyrostats
- A3 steroids
- A4 zeranol
- A5 beta-agonists
- A6 Table 2 of Annex to Reg. (EU) No 37/2010

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Substances tested in third countries


**Group A**
- A1 stilbenes
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**Group B**
- B1 antimicrobials
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- B3b organophosphates
- B3c heavy metals
- B3d mycotoxins
- B3e dyes

Mainly ‘Essential’
Some ‘Essential’, Most ‘Desirable’
Equivalent guarantees – consider (4):

- **Numbers** of samples and **sampling strategy**
- Method of **sampling** – targeted or random
- Animal **population** to be tested
- **Substance groups** that must be sampled
- Scope of testing – **which analytes**, risk?
- Authorisation and placing on the market of **veterinary medicines**
- **Matrices** (materials) to be tested and **regulatory limits**
- **Laboratories** – method validation/accreditation
Third countries: Laboratories

• No specific requirement in EU law for third country residue laboratories to be **accredited** to ISO 17025
  – *But, if not, can equivalence be guaranteed?*

• Methods must be **validated** (fit for purpose) & capable of meeting EU maximum limits
  – *Otherwise certification requirements can not be met*
Third countries: Laboratories

- Third country laboratories are **not** obliged to validate methods according to EU rules (Commission Decision 2002/657/EC) but...

  - **Must** have **validated methods** demonstrating ‘fitness for purpose’
  - Checked on-the-spot by FVO
Equivalent guarantees – consider (5):

- **Numbers** of samples and **sampling strategy**
- Method of **sampling** – targeted or random
- Animal **population** to be tested
- **Substance groups** that must be sampled
- Scope of testing – **which analytes**, risk?
- Authorisation and placing on the market of **veterinary medicinal products (VMPs)**
- **Matrices** (materials) to be tested and **regulatory limits**
- **Laboratories** – method validation/accreditation
Authorisation and use of VMPs: EU

Directive 2001/82/EC

- **Labelling** rules
- Withdrawal periods
- **Record keeping** by farmer, veterinarian, pharmacy & wholesaler
- **Veterinary prescriptions**
- **Checks** by the authorities
Countries cannot rely solely on laboratory testing if controls on the distribution and use of veterinary medicines are not adequate
Authorisation and use of VMPs – posters from this conference

Assessment of antimicrobial usage and sulfonamide residues in chicken eggs in Dar es Salaam, Tanzania

Ezekiel P. Mubito, Francis Shahada, Martin E. Kimanya and Joram J. Buza 1*

1 School of Life Science and Bio Engineering, Nelson Mandela African Institution of Science and Technology, Arusha Tanzania

- All farmers are aware of drugs withdrawal period but there is no compliance
- Farmers are unaware of detrimental effects associated with antibiotic residues to human health
- HPLC results revealed that, all samples contained sulfadiazine residues while 59.4% contained sulfamethazine
- About 30% of residues exceeding MRL were sulfadiazine residues whereas none of sulfamethazine detected above MRL

Conclusions

1. Failure to observe antibiotics withdrawal periods by poultry farmers in Dar es Salaam, and poor enforcement of law contribute to expose consumers to products containing Sufa drugs residues above tolerable limits.
2. Consulted efforts between government institutions and all stakeholders are needed to bring awareness on public health implications associated with drug residues in poultry products.
Authorisation and use of VMPs – posters from this conference

Risk of exposure to marketed milk with Chloramphenicol drug residues in Senegal

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Conclusion

The use of veterinary drugs in food produced by animals plays an important role in intensive dairy producers. The veterinary drugs protect the animal against diseases but may also be found in food if they are not used wisely. The consequences of the presence of these residues for consumers can lead to serious sanitary damages.

This study is not representative of the general situation; however, these results are alarming and highlight a misuse of antibiotics in dairy farms in Senegal. To better assess the risks associated with the consumption of locally produced milk in Senegal, we strongly recommend further studies of all levels of the dairy industry.
ANTIBIOTIC RESIDUES DETECTED IN PROCESSED AND RAW MILK SAMPLES FROM VARIOUS DAIRY HOLDINGS IN BOTSWANA
T. Tswiio

Botswana National Veterinary Laboratory, Gaborone-Botswana

RESULTS AND DISCUSSION
A total of 32 (26.2%) milk samples screened positive for sulphonamides mostly from the processed milk samples.

The prevalence rate of sulphonamides antibiotic residues is as expected since the antibiotic is widely available as an over the counter drug in Livestock Advisory Centers distributed country wide. Farmers readily use this antibiotic to treat their livestock for various ailments and the dairy industry in particular must remain vigilant in observing withdrawal periods of drugs as directed by manufacturers. Presence of drug residues in livestock products such as milk pose a great danger to public health as they contribute to resistance of bacteria to novel drugs used in the treatment of human diseases. Morobe et. al. (2009) found that 33% of milk samples from dairy processors around Gaborone carried Listeria monocytogenes resistant to at least two antimicrobials, sulphur based drugs being one of them.
Summary

• Residue monitoring – one (of many) components of a food control system

• Sampling and testing – should be risk-based and fit for purpose and results should show a high level of compliance with good agricultural and good veterinary practice

• Enforcement / sanctions and controls on use of medicines – essential if system is to work
Further information

• EU legislation:
  • http://eur-lex.europa.eu/homepage.html
  • SANCO ‘third country residues’ web page:
    • http://ec.europa.eu/food/food/chemicalsafety/residues/third_countries_en.htm
  • Validation of analytical methods:
    • http://ec.europa.eu/food/food/chemicalsafety/residues/lab_analysis_en.htm
• FVO homepage:
  • http://ec.europa.eu/food/fvo/index_en.cfm
Thank you for your attention

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