Residue Monitoring Plans – EU expectations from trading partners

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Health and Consumers

Residue monitoring in food (of animal origin) – why?

Health and Consumers

- **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**

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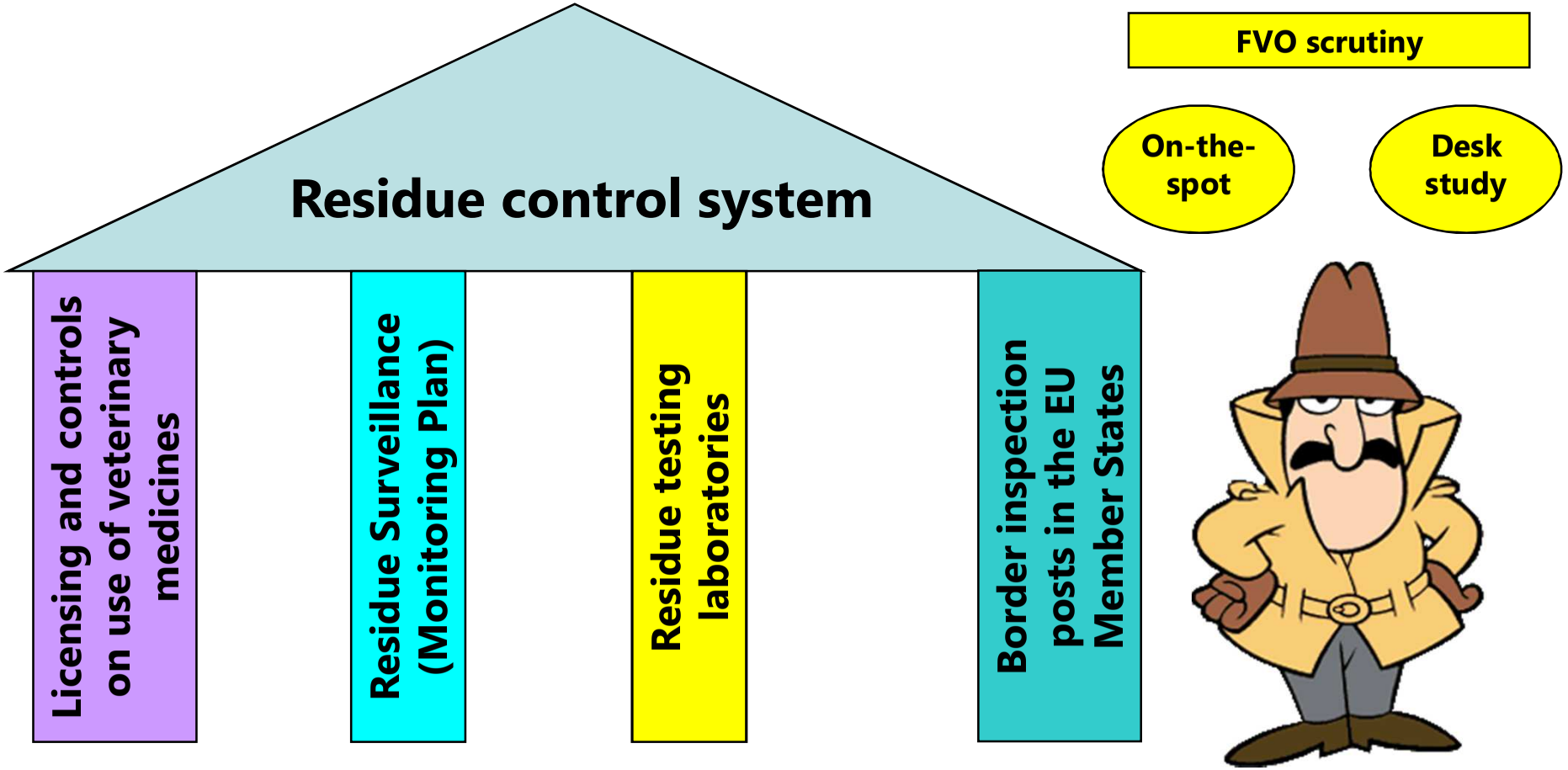
Making sure food is safe in the EU



Health and Consumers

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**

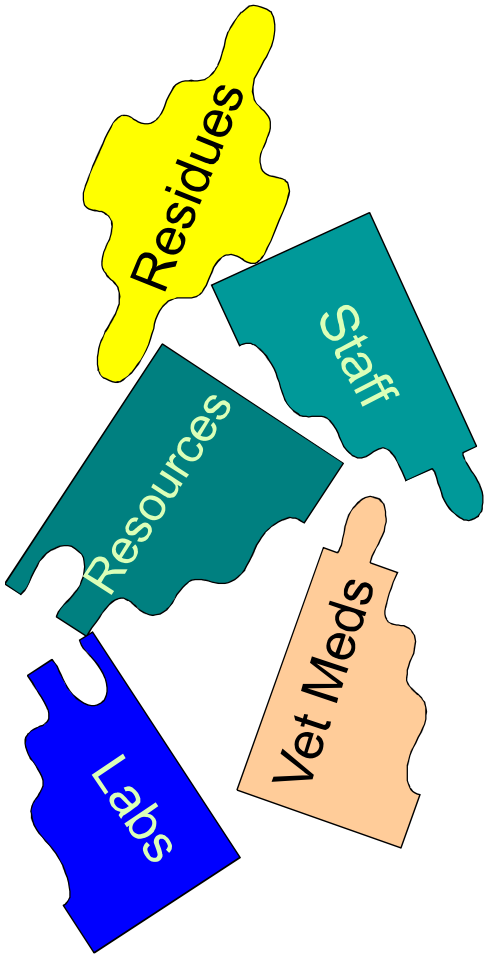
Laboratories

- **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**

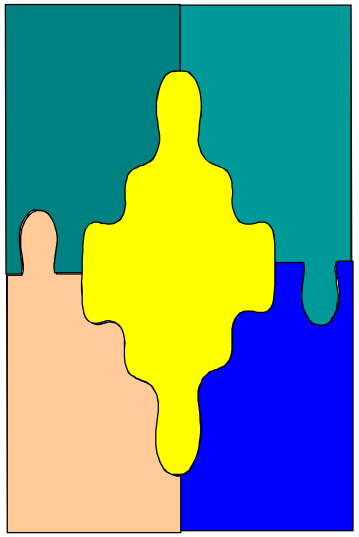
(2) Can it work?

- **Adequate resources**
- **Clear roles, responsibilities and staff instructions**

Residues audits: 4 questions

(3) Does it work? &

(4) If not, why not?



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Residues in food - role of the FVO

(2) Evaluation of residue monitoring plans (RMPs)

REGULATORY PROGRAMME FOR CONTROL OF RESIDUES IN FOOD

COUNTRY	Wonderland	DATE	24-janv-07	For official use 50
YEAR OF PLAN IMPLEMENTATION	2007			
ANIMAL SPECIES / PRODUCT	AQUACULTURE FIN FISH			
National PRODUCTION DATA - in TONNES (referring to the previous year)	10000	EU EXPORT DATA in TONNES (referring to the previous year)	5000	
PRODUCTION DATA in TONNES for calculation of SAMPLE NUMBERS. (referring to previous year's production)	5000	See instruction sheet, note 4. If a split system is in place for exports to the EU, actual export data may be entered in this cell. If there is no split system, and farmed FINFISH from ALL FARMS are eligible for export to the EU, national production data must be entered in this cell.		
NUMBER OF SAMPLES †	ACCORDING TO EU REQUIREMENTS	ACCORDING TO CODEX ALIMENTARIUS	OTHER	
MINIMUM #	50			
PLAN				

GROUP OF SUBSTANCES TO BE MONITORED		NUMBER OF SAMPLES MIN	NUMBER OF SAMPLES PLAN	COMPOUND or MARKER RESIDUE	MATRIX ANALYSED	SCREENING METHOD	CONFIRMATORY METHOD	SCREEN.METH. DETECTION LIMIT [µg/kg]	CONFIR.METH. DETECTION LIMIT [µg/kg]	DECISION LIMIT [µg/kg]	LABORATORY
A1	STILBENES	6	6	Diethylstilbestrol	Muscle	GC-MS	GC-MS	0,5	Same as for screening	Any confirmed	Laboratory B
				Dienestrol	Muscle	GC-MS	GC-MS	0,5	Same as for screening	Any confirmed	Laboratory B
				Hexestrol	Muscle	GC-MS	GC-MS	0,5	Same as for screening	Any confirmed	Laboratory B
A3	STEROIDS (WITH ANDROGENIC, ESTROGENIC OR PROGESTAGENIC ACTIVITY)	6	6	17-beta-estradiol	Muscle	GC-MS	GC-MS	0,5	Same as for screening	Any confirmed	Laboratory B
				17-beta-19-nortestosterone	Muscle	GC-MS	GC-MS	1,3	Same as for screening	Any confirmed	Laboratory B
				17-beta-testosterone	Muscle	GC-MS	GC-MS	1,2	Same as for screening	Any confirmed	Laboratory B
				trenbolone	Muscle	GC-MS	GC-MS	1,1	Same as for screening	Any confirmed	Laboratory B
				boldesterone	Muscle	GC-MS	GC-MS	1	Same as for screening	Any confirmed	Laboratory B
				norethandrolone	Muscle	GC-MS	GC-MS	0,5	Same as for screening	Any confirmed	Laboratory B
				methyltestosterone	Muscle	GC-MS	GC-MS	1,3	Same as for screening	Any confirmed	Laboratory B
				chlormadinone	Muscle	GC-MS	GC-MS	1	Same as for screening	Any confirmed	Laboratory B
				medroxyprogesterone	Muscle	GC-MS	GC-MS	0,6	Same as for screening	Any confirmed	Laboratory B
				megestrol	Muscle	GC-MS	GC-MS	0,6	Same as for screening	Any confirmed	Laboratory B
A6	Chloramphenicol + Nitrofurane+ Nitroimidazoles	6	6								
	CHLORAMPHENICOL		6	Chloramphenicol	Muscle	EIA	GC-MS-NCI	0,2	0,25	0,3	Laboratory A
	NITROFURANS										
	Nitrofurantoin metabolite		6	AHD	Muscle	LC-MS-MS	LC-MS-MS	0,5	Same as for screening	1	Laboratory B
	Furaltadone metabolite			AMOZ	Muscle	LC-MS-MS	LC-MS-MS	0,4	Same as for screening	1	Laboratory B
	Furazolidone metabolite			AOZ	Muscle	LC-MS-MS	LC-MS-MS	0,3	Same as for screening	1	Laboratory B
	Nitrofurazone metabolite			SEM	Muscle	LC-MS-MS	LC-MS-MS	0,5	Same as for screening	1	Laboratory B
	NITROIMIDAZOLES										

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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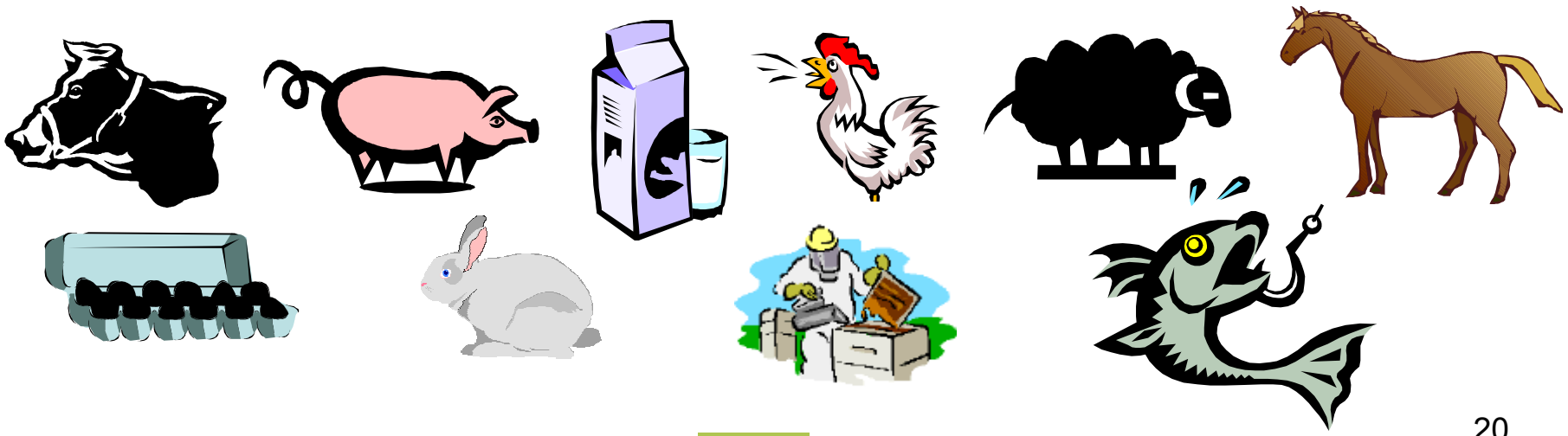
Implementation: matrices tested?

Laid down in Directive 96/23/EC

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



Residues of authorised medicines

<u>Edible tissues</u> 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

<u>Most appropriate matrix</u> 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

Annex I to Council Directive 96/23/EC

- *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

Annex I to Council Directive 96/23/EC

Group A

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

"Essential" Mainly

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

Annex I to Council Directive 96/23/EC

Group A

- A1 stilbenes
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'Essential' Mainly

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- B2e NSAIDs
- B2f others e.g. corticoids
- B3a OCs, PCBs, dioxins
- B3b organophosphates
- B3c heavy metals
- B3d mycotoxins
- B3e dyes

'Essential' most Some

'Highly 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 <u>not</u> obliged to validate methods according to EU rules (Commission Decision 2002/657/EC) but…
- <u>Must</u> 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

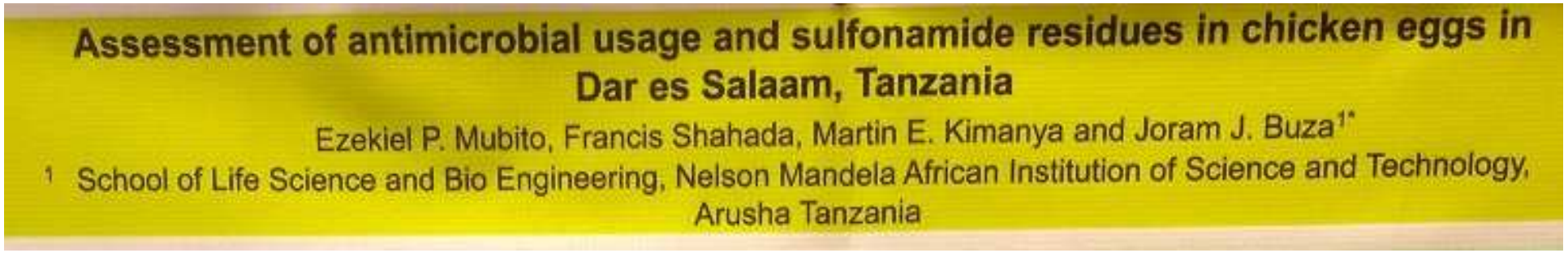
Authorisation and use of VMPs: EU

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

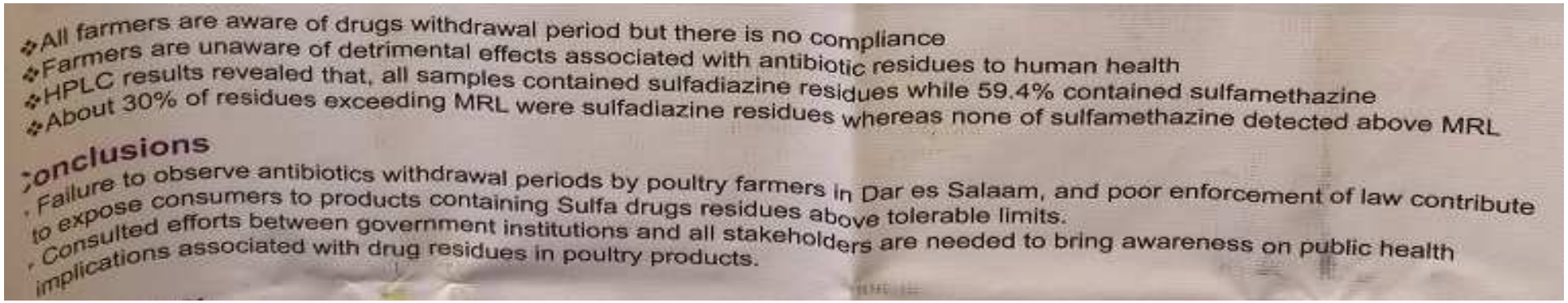
Authorisation and use of VMPs – posters from this conference



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

- 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 Sulfa drugs residues above tolerable limits.
- Consulted efforts between government institutions and all stakeholders are needed to bring awareness on public health implications associated with drug residues in poultry products.

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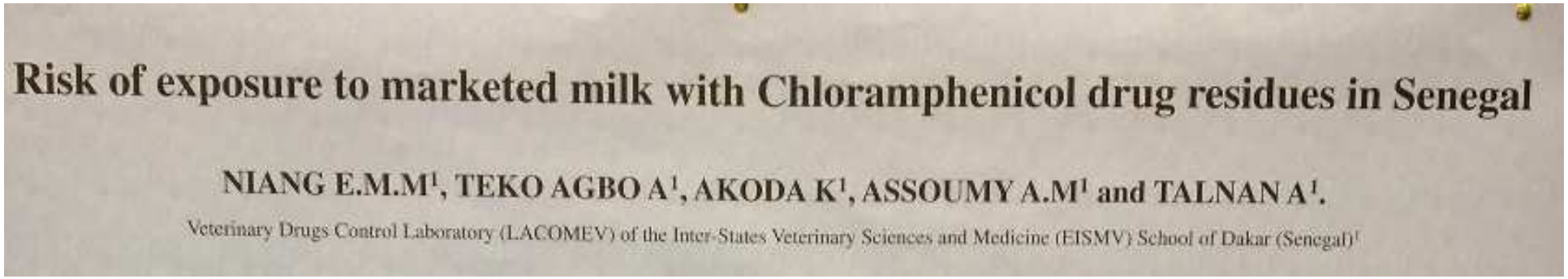
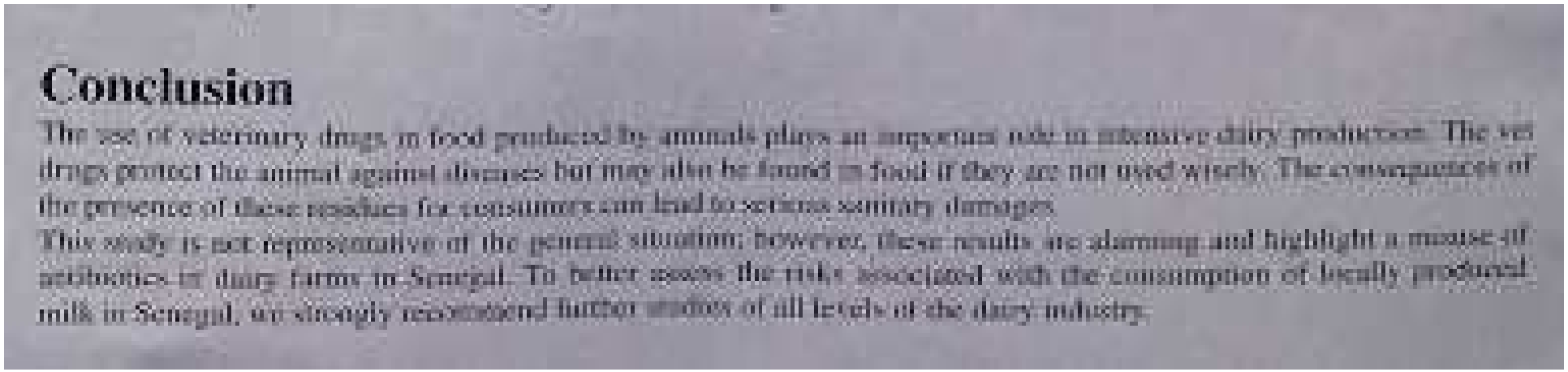
Authorisation and use of VMPs – posters from this conference



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

NIANG E.M.M[1], TEKO AGBO A[1], AKODA K[1], ASSOUMY A.M[1] and TALNAN A[1].

Veterinary Drugs Control Laboratory (LACOMEV) of the Inter-States Veterinary Sciences and Medicine (EISMV) School of Dakar (Senegal)[1]



Conclusion

The use of veterinary drugs in food produced by animals plays an important role in intensive dairy production. The vet 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

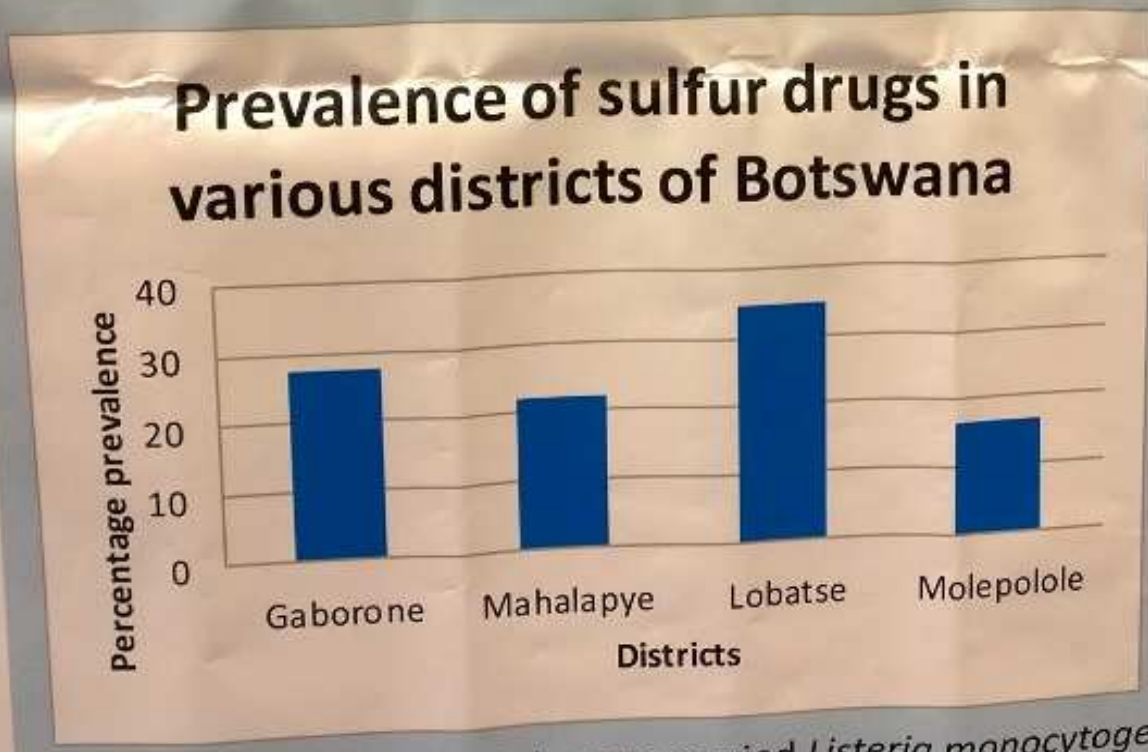
T. Tswiio[1]

[1]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 sulfonamides 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 heath 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

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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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