

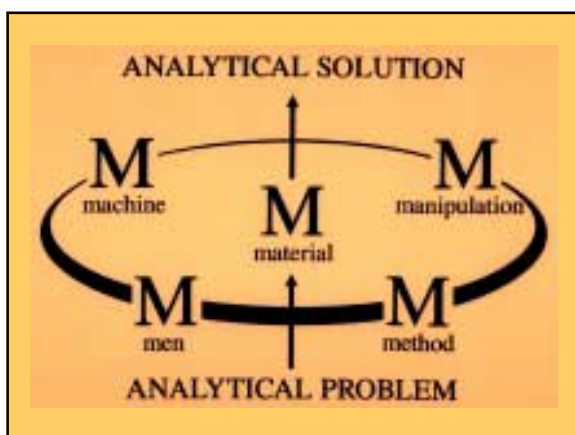
**MONSTER ACCEPTATIE
en
het
RECHT**

Rainer W. Stephany Eurachem – NL
Bilthoven 9 november 2005

Any opinions, conclusions and recommendations expressed in this presentation are those of your speaker

and

do not necessarily reflect the official views of the European Commission, the RIVM, the Utrecht University or any other Authority referred to.



Verboden gebruik van
“groeihormonen” in de Europese Unie

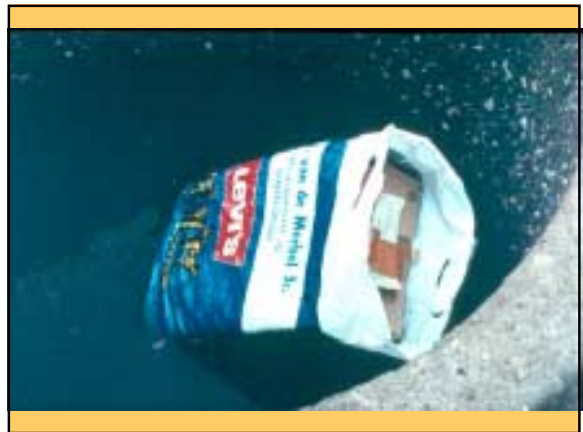
AD 19-2-02

**Paters
zien af van
aanklacht
tegen
Stephany**

vervolg van pagina 1

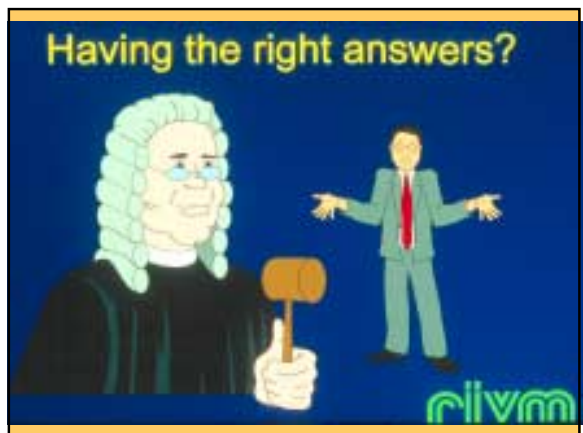
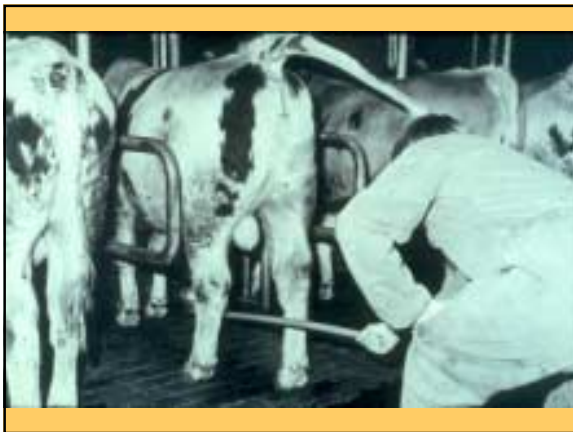
De Arnhemse advocaten
van de notaris Barends

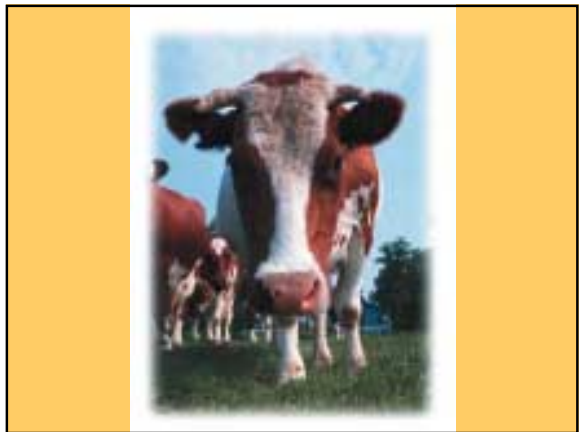
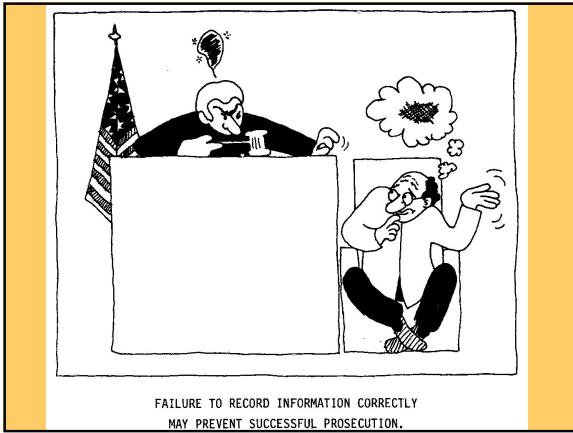


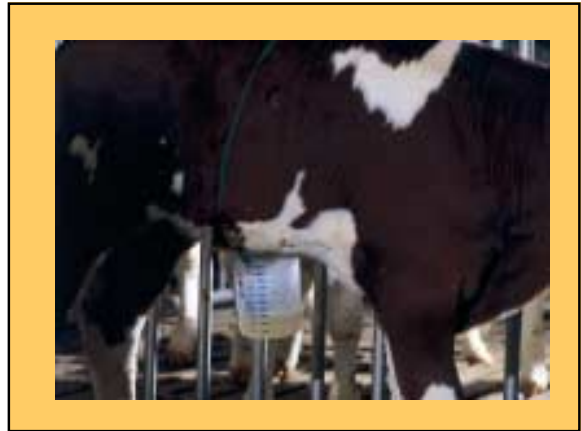




rivm







Method validation

The process of proving that an analytical method is fit for its intended purpose

The purpose is defined by the user of the test result

Valid test result

A test result that has been proven to be fit for its intended purpose

The fitness is judged by the user of the test result and is underpinned by criteria set by the laboratory

Purpose

A test result might be intended for the purpose of

- Protecting health
- Protecting trade
- Academic studies
 - Forensics
- Misleading competitors
- Production quality control
- ... and many other fair and unfair purposes

Probability

is related to the identification or the confirmation of the identity of a molecule or a microbe in a sample

Very few efforts to describe the **(un)reliability** of a laboratory test result in food inspection are focussed on the performance of

qualitative methods

True qualitative methods

identify or confirm the identity of a molecule or a microbe in a sample

on the basis of **criteria for identifiers**

Pseudo qualitative methods

are quantitative methods with a final **binary classification** of the test result.

Methods in relation to the purpose of the test result



> Screening methods

- "no" false compliant results

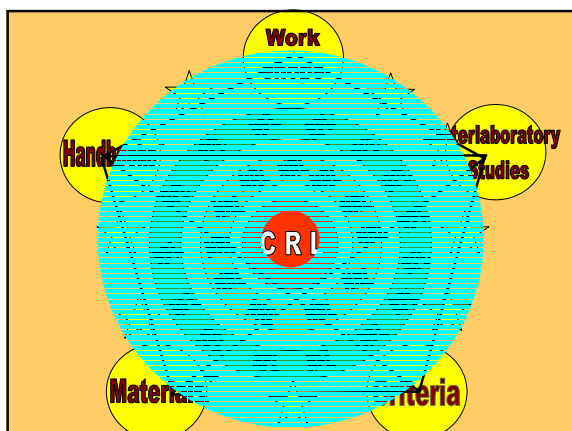
> Confirmatory methods

- reliable identification
- reliable quantification (*if applicable*)
- "no" false non-compliant results

> Arbitration ("reference") methods

- confirmatory methods with improved validation status

(not longer defined in 2002/657/EC)

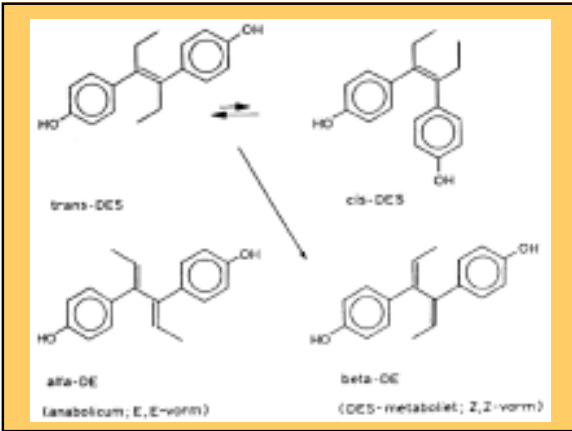


Primary objectives of the CRLs

> Last but not least:

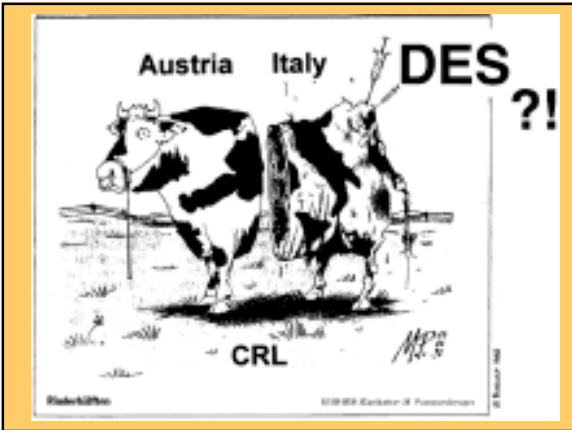
ARBITRATION ANALYSES

Diethylstilbestrol
=
DES



RIVM - CRL for RESIDUES ARBITRATION in INTERNATIONAL "DES in BEEF" DISPUTES

Year	1996 Jan.	1998 Aug.	1999 Jul.
Accuser	Bulgaria	Italy	Swits'd
Accused	Australia	Austria	USA
"DES" (ppb)	< 0,3	>> 1	~ 1 ?
Samples	2	18	10 ?
Weight (gram)	< 10	30	15
DNA test	No	Yes	No
Confirmed	Yes/No	No	No
Trade ban	Yes	Yes	Yes
Rapid alert	No	Yes	Yes
Costs / Damage >>	M\$ 0.5	€ 1	M\$ 0.5



DER STANDARD
Montag, 17. August 1998, Seite 15
Wirtschaft

Trotz negativer Proben beharrt Italien weiter auf Importstopp.

Holland soll Hormonstreit klären

Prammer glaubt an "verfälschte" Ergebnisse - Kein Schadenersatz für Bauern

Wies - Die ferschenen Holländer in Bithoves sollen des Italienisch-Österreichischen Hormonstreit endgültig klären. Am Dienstag oder Mittwoch dieser Woche werden die Italiener haargenau jene Fleischstücke nach Holland schicken, bei denen sie Hormonspuren gefunden haben.

EU MRPL's are performance criteria for laboratories who test for the presence of residues of "A" (zero tolerance) substances

MRPL's are quality bench marks (QBM's)

targetting fitness-for-purpose

Confirmation

To make sure that the test result is true
"beyond reasonable doubt"

- Is the residue detected indeed present?
- Does the mass content exceed any action level ?

(not applicable for "zero tolerance" residues)

However, since January 2005 MRPL values are accepted by the Commission as "Reference Points of Action"

Specificity of a test method

=

Σ **Selectivity of all steps in the test method**



SPECLOG - the Specificity Log

An underpinning documentation tool to demonstrate the reliability of a claim for specificity, confirmation and/or identification for a regulatory test result for residues of veterinary drugs in food and food related materials.

The SPECLOG is a suitable basis to develop adequate criteria for methods

Up to the present for the analyte in the **SPECLOG** the following different sub-databases are considered

1. data from the chemistry used in the extraction and clean-up procedure
2. data from the subsequent chromatography
3. data from the detecting spectroscopy or electrochemistry
4. data from the "blank" reagents

SPECLOG (continued)

5. data from the "blank" samples
6. data from library searches for potential interferences or matches
7. data and arguments why potential interferences in practice do not or likely will not interfere
8. whatever other data of interest or importance, like choice of sample matrix, sampling and transport / storage history and other explicit quality control data

SPECLOG (continued)

9. last but not least failure history and jurisprudence

RESIDUE POSITIVES AND LEGAL BOTTLE NECKS !

A vital question from EU regulatory residue laboratories to lawyers

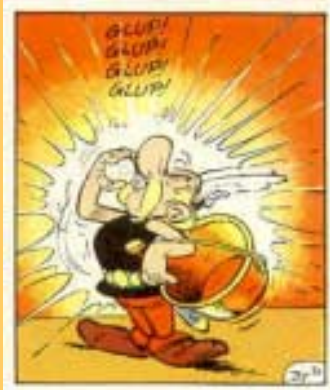
What is an acceptable reliability of the result of a **qualitative** analyses in case of the detection of an illegal "hormone" residue expressed as a probability equivalent to the legal term "beyond any reasonable doubt" ?

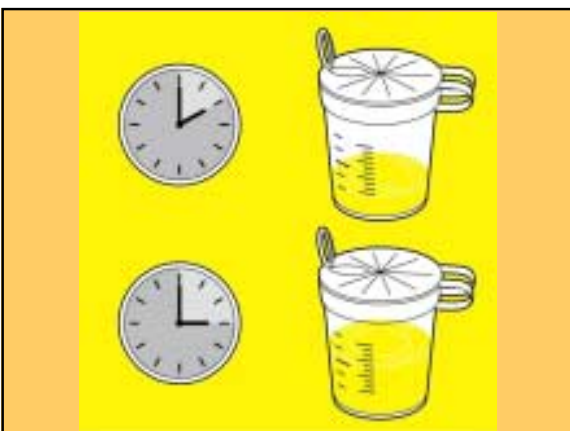
Should such a probability be e.g. 95 %, 99%, 99,9% or 99,99%?

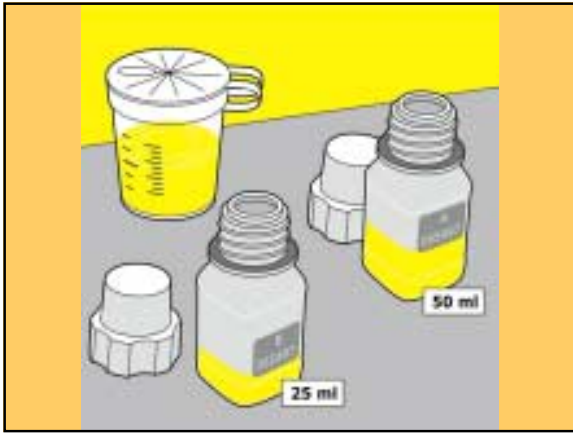
Review of the very rare jurisprudence in Court Cases indicates that for international arbitration

(in case of dispute about illegal hormone residue findings)

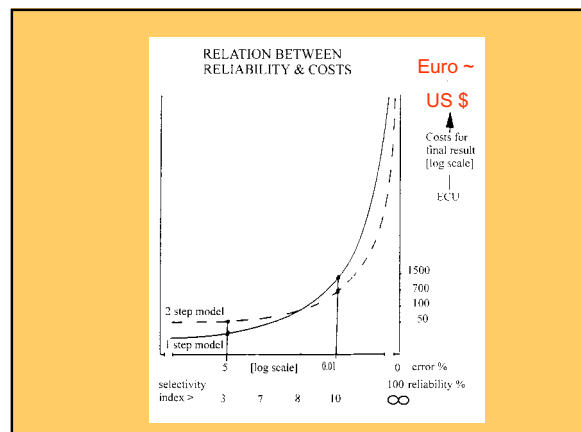
apparently a reliability not less than 99,99% is adequate.











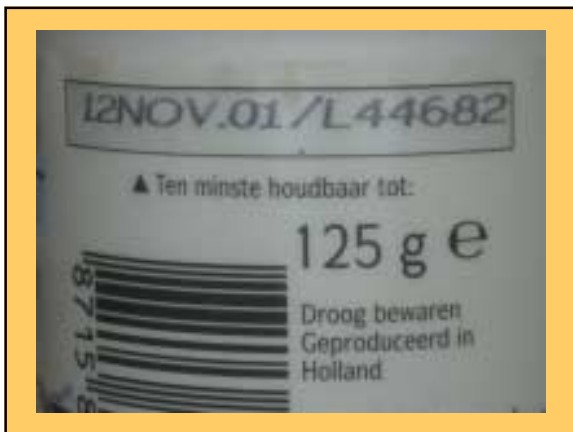
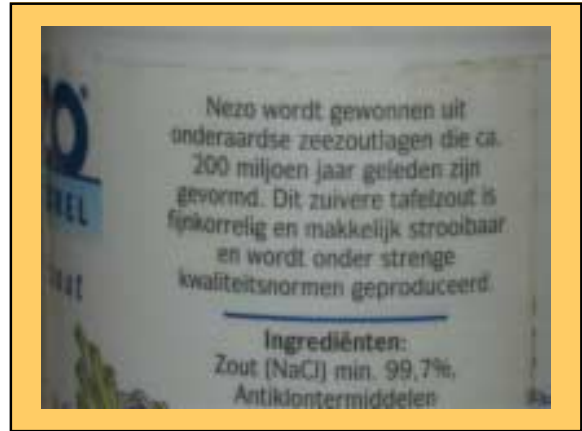
Internationale regels of eisen voor monsters en / of monsterneming zijn (bv EU of CODEX)

- omvang van de monsters is functie van onderzoeksmethode
- aantal monsters en waarschijnlijkheid voor het vinden van een *kwantitatieve* overtreding is een functie van het voorkomen van "fouten" in de onderzoekspopulatie
- voorzorgen te nemen voor behoud van representatieve status bij nemen, opslag, transport en handelen en bewaren in het lab
- opleidingseisen aan persoon die het monster neemt

Echter sommige middelen zijn bij consumptiedieren zowel dierbehandelingsmiddelen als "pesticiden" en dat geeft een probleem omdat de regels voor beide groepen verschillend zijn

... want regels of eisen aan het nemen van monsters zijn punten die in conflictsituaties alle aandacht krijgen van "juristen" van beide zijden

Hierover vindt bij het RIVM nu een CODEX overleg plaats van internationale deskundigen



Met dank aan

- **SKV** – Stichting Kwaliteitsgarantie Vleeskalveren
- **NeCeDo** – Nederlands Centrum voor Dopingvraagstukken
- **WADA** – World Anti-Doping Agency
- **Drs Marco Jonker** – ARO documentalist
- **Igno Stephany** – zoon & fotograaf