Export Requirements Challenges for third countries to attend Russia and European Union Requirements with respect of certain veterinary drug residues in animal products

International Symposium on Food Safety and Quality: Applications of Nuclear and Related Techniques

November 10 to 13 , 2014

Alfredo M. Montes Niño and Rodrigo H. M.M. Granja, Laboratório Microbioticos Campinas, SP - Brazil

Escalating Trade Dispute, Russia Bans Turkey Over Ractopamine Residues

By Helena Bottemiller | February 8, 2013

Ractopamine Banned in China, Russia, Taipei, Taiwan, Malaysia,the European Union &150 other countries!

by Laura Croft on January 7, 2013 at 7:43 PM
Posted In: CALL TO ACTION, GMO, HEALTH, WORLD ALERT

Senators Urge U.S. Trade Rep to Resolve Russian Ractopamine Ban

By Helena Bottemiller | February 20, 2013

Are US and EU Heading for Trade War over Ractopamine?

29 October 2012

GLOBAL - The EU and US could be heading for another trade war, similar to the one it had over the use of growth hormones in beef cattle, writes Chris Harris.

European ministers uphold EU ractopamine ban

By Alan Osborn , 25-Oct-2012
Last updated on 25-Oct-2012 at 12:21 GMT

U.S. and Russia Spar Over Ractopamine in Pork and Beef

By Helena Bottemiller | December 18, 2012

July 24, 2013

Ractopamine in beef threatens Brazil's export relationships

With at least eight major export markets currently prohibiting its use, Brazil's beef processing industry are growing increasingly concerned that the misuse of ractopamine for cattle fattening may threaten the industry's current and future export sales.

09 de junho de 2014 • 17h35 • atualizado às 17h42

Rússia suspeita de ractopamina em carne suína da BRF

Abatedouros são suspeitos de infringir padrões veterinários

Codex Adopts Ractopamine Limits for Beef and Pork

Contentious 69-67 vote on key trade issue pits United States against China and the EU

By Helena Bottemiller | July 6, 2012

- A tight victory for countries such as USA, Brazil and Canada
- A defeat to European Union and China
  - represents 70% of world swine meat production

Ractopamine- Codex Limits

Species	Tissue	MRL (µg/kg)
Bovine	Muscle	10
Bovine	Liver	40
Bovine	Kidney	90
Bovine	Fat	10
Porcine	Muscle	10
Porcine	Liver	40
Porcine	Kidney	90
Porcine	Fat & skin	10

Ractopamine

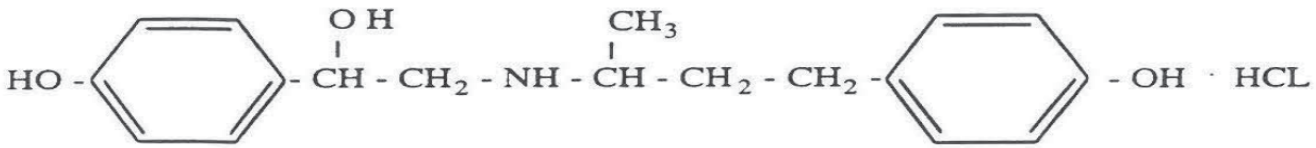
Chemical Name (ractopamine hydrochloride): Benzenemethanol, 4-hydroxy-α-[[[3-(4-hydroxyphenyl)-1-methylpropyl]amino]methyl]-, hydrochloride

CAS Registry Number: 90274-24-1

Molecular Formula: $C_{18}H_{23}O_3N \cdot HCl$

Molecular Weight: 337.8

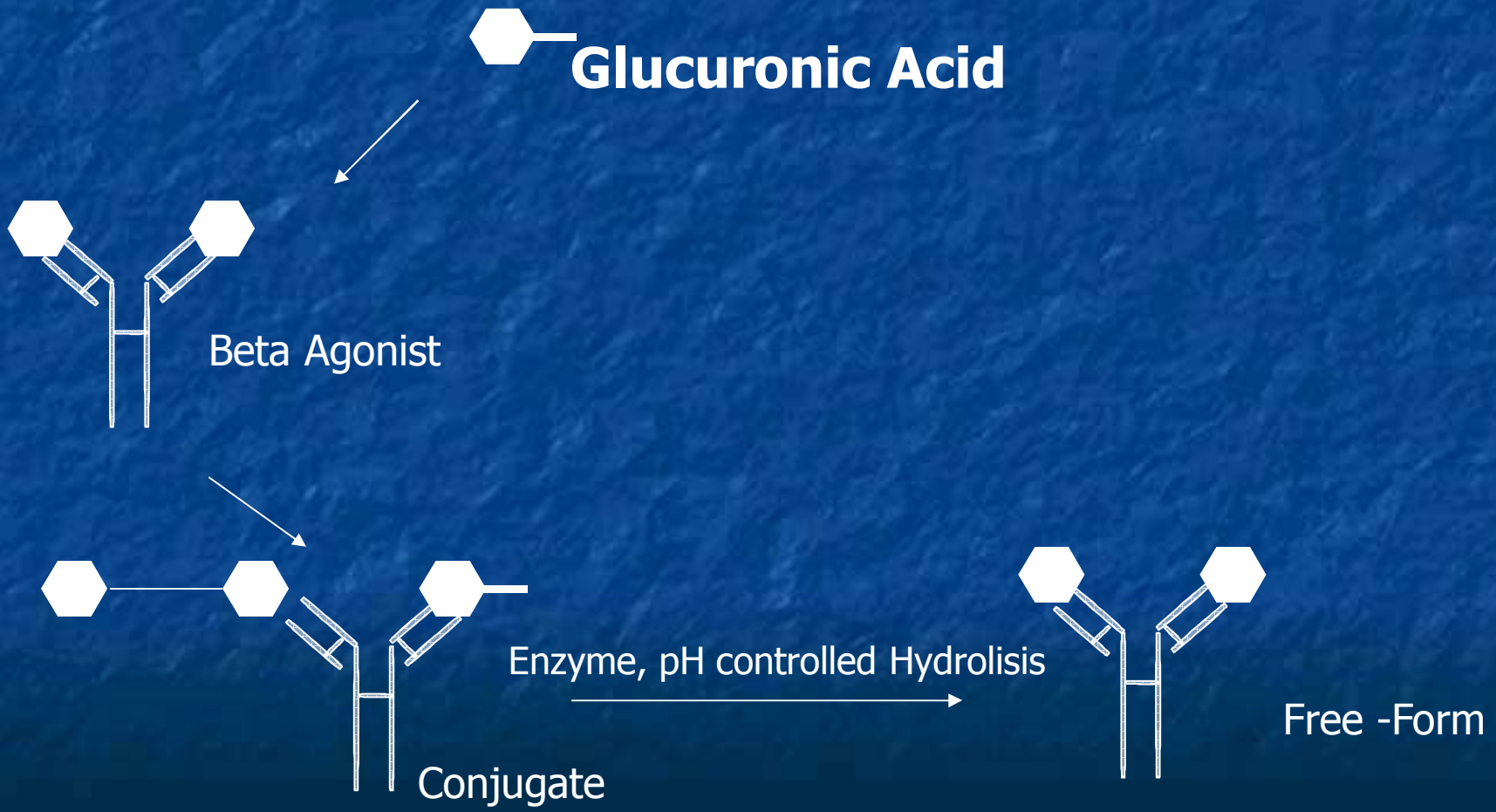
Structural Formula:



MIXTURE OF ALL STEREOISOMERS RR, SS, RS, SR

- Ractopamine is a type 1 Beta- Agonist
- Different of other Beta Agonists such as Clenbuterol and other Anilinic type 2 Beta-Agonists
- Conjugation in tissues
- Increase porcentage of lean meat and decreses carcass fat
- 45% of Swines in the US has been administrated by any form of ractopanine

Type 1 Beta-Agonist Conjugation



Legislation

- European Union Hormone and Beta Agonist Ban

23. 5. 96 EN Official Journal of the European Communities No L 125/3

COUNCIL DIRECTIVE 96/22/EC

of 29 April 1996

concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC

Legislation

- EU Council Directive 96/22/EC
  - Strong Legislation
  - Apply to Member States
  - Applied to third countries as well
    - Split system
      - Ensure Animals not treated at any stage in ife.
      - If so, not eligible for export to EU (and Russia)

Prohibited Substances

Pharmacologically active substance	
Aristolochia spp. and preparations thereof	MRL cannot be established
Chloramphenicol	MRL cannot be established
Chloroform	MRL cannot be established
Chlorpromazine	MRL cannot be established
Colchicine	MRL cannot be established
Dapsone	MRL cannot be established
Dimetridazole	MRL cannot be established
Metronidazole	MRL cannot be established
Nitrofurans (including furazolidone)	MRL cannot be established
Ronidazole	MRL cannot be established

Prohibited Substances

- EU and Russia - Ilegal act if use them
- 3rd countries may use
- Residues should not be present
- Minimum Required Performance Limit (MRPL)...or better...LEVEL
- Reference Point of Action (RPA)
  - Hormones, Beta-Agonists and Thyreostats

Prohibited Substances

- Rapid Alert System for FOODS and FEEDS (RASFF)
  - If found in concentrations above MRPL/RPA (*)
    - Product Rejection
    - Product Recall
    - Product Destruction
    - Protective Measures
      - Intensive Testing
      - Country Delisting


09 de junho de 2014 • 17h35 • atualizado às 17h42

Rússia suspeita de ractopamina em carne suína da BRF

Abatedouros são suspeitos de infringir padrões veterinários

(*) Kennedy at. Al.

Recommended Concentrations

CRL GUIDANCE PAPER (7 December 2007)

CRLs VIEW ON STATE OF THE ART ANALYTICAL METHODS FOR NATIONAL RESIDUE CONTROL PLANS

The following is the Community Reference Laboratories' (CRLs) view on state of the art analytical methods for national residue control plans established in accordance with Council Directive 96/23/EC. The purpose of this technical guidance is to improve and harmonise the performance of analytical methods used for those substances for which maximum residue limits (MRLs) have not been established according to Council Regulation (EC) No 2377/90. Thus substances with MRLs are generally not listed in this guidance paper.

NO LEGAL BASIS!

Ractopamine Situation

- NO MRPL, NO RPA
- But..with a reccomended concentration
  - EU 1 ppb for liver, muscle and kidney
  - Russia 0.1 in muscle. Is this a good tisssue to IN HOUSE control?
- Not a LIMIT – but a TARGET
- Labs should go lower than that to offer better warranties to their costumers
- Microbioticos – LQ of 0.05 ppb in muscle
- Any detected amount – NON COMPLIANT!

Split Systems

- Project Plan
- Evidence and outcomes
- Not easy
- Segregation needed
  - "Magic" procedures to remove traces for line production - carryover
- Remember: Treatment at any stage of life is banned – residues not present

Carry - over

- No Economic viable "Magic" solution
  - Use of Calcarium (bad choice)
  - Use of Nano Particles – could work but very expensive
  - average of 2% Carry-Over. (*)

(*) Kennedy at. Al.

Tissues

- Lung- Highest concentration – dificult to handle from slaughterhause sampling to laboratory
- Urine- Ease on handling
- Liver or Kidney- Are these exportable?
- Muscle- Exported product.
  - Too risky
    - Sampling
    - Detection /Quantification capabilities of laboratories

Tissues

- Mith or Fact:
  - "...If Urine less than 1 ppb – Muscle OK..."
  - Should be....but concrete scientific evidence needed.
    - Microbioticos Validated method with an LOQ of 0.17 ppb
  - Lung,Liver and Kindey less than 1 ppb should avoid problems in muscle (*)
    - Regulatory Tissues

(*) Kennedy at. Al.

Solution

- Use a laboratory capable to detect and quantify ractopamine at the lower level possible in the market
  - Cooperation with European Reference Laboratories
  - Techniques Used.
    - Screenning Methods
    - LC-MS/MS methods

Screenning Methods

- According to *Elliott et. Al.:*
  - *"....Screening methods should be capable to provide a strong evidence of the presence of the molecule in the sample..."*
  - Commercial kits declare a LOD similar to recommended concentration
    - But does this means that the kit is capable to detect the declared LOD with 95% or 99% confidence (false negatives)?
    - Costs of those kits in Developing countries, taxes, delays, the same problem ever....

Confirmatory Methods

- Capable to detect lower levels compared to Screening methos LOD
- Costs- Laboratories can offer confirmatory test at a lower cost compared to screening tests performed at slaughterplants
  - Education of Slaughter Plants Quality Assurance employees.
  - No margin for non accurate interpretation or ....non scientific basis solutions.
    - IS ABOUT NA EXACT SCIENCE WE ARE TALKING ABOUT!

Conclusions

- Third Countries should implement a zero tolerance plan on ractopamine if willing to export to Russia
- Muscle should be monitored in every consignment to Russia and EU.
- Laboratories with lowest quantification limits in the market should be used. This limit should be as low as the destination market laboratory
- The use of screening tests should be very detailed evaluated in terms of costs and risks
- Educational programmes for decision makers at meat industry should be taken into consideration
  - Go to where the problem is and solve it, and not only actions to "try to clear" the container from customs and see what happens.