

Case Study Latin America

Barbara Cordeiro

Coordinator of Veterinary Products Inspection - MAPA



5th Global Animal Health Conference and Workshop 2016

Improved Market Access for Authorised Veterinary Medicines – The Asian Perspective

Organising Committee:

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Protecting Livestock – Improving Human Lives


International Federation of Animal Health


Health for Animals
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DEVELOP
INNOVATE
ADVANCE



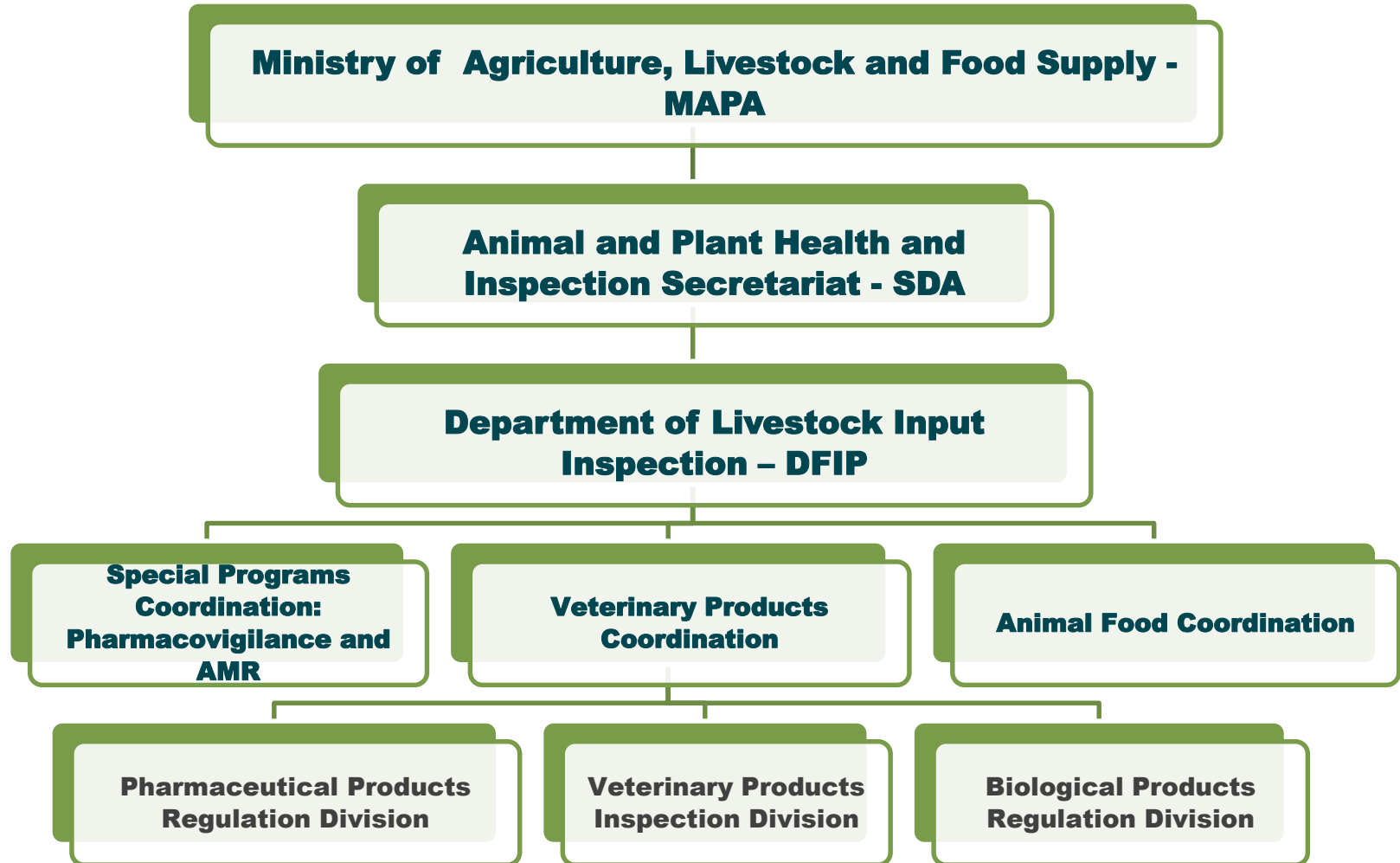
Brazil – General Characteristics



- ▶ The largest country in South America - **8.515.767,049 km²**
- ▶ Federal Republic composed by twenty-six states and one Federal District.
- ▶ The **MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY – MAPA** and other government Departments are located in Brasilia - Brazil Federal Capital.



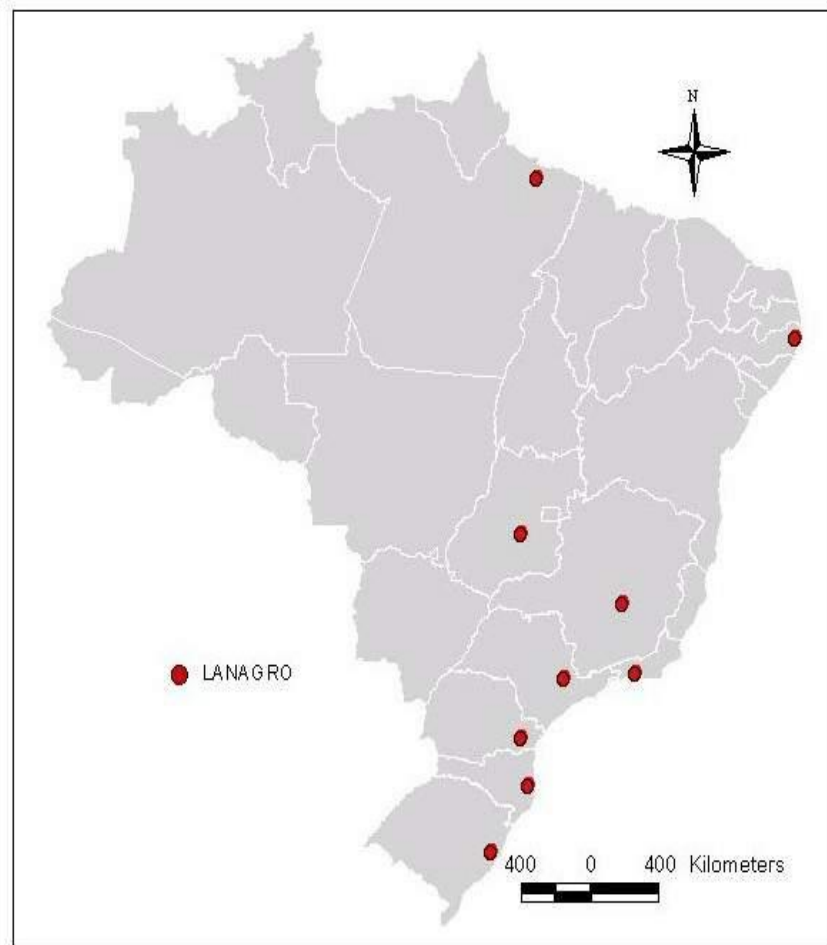
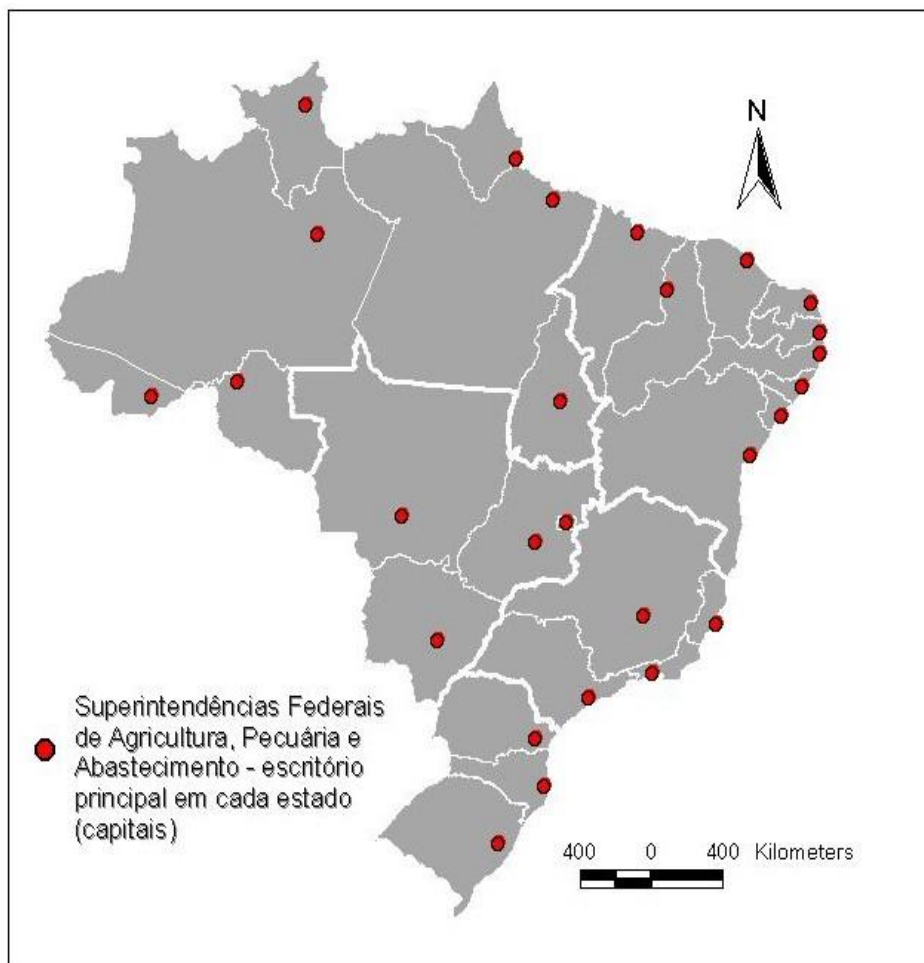
Regulatory Framework





Decentralized Unities:

Federal Superintendencies of Agriculture, Livestock and Food Supply – SFA and Nacional Laboratories - LANAGROS





MARKET CHARACTERISTICS

Decree nº 5.053 of April 22, 2004 :

“All establishments that manufacture, handle, pack, label, control the quality, store, sell, distribute, import and export veterinary medicines must be registered in MAPA;”

“All veterinary products must be registered in MAPA;”

- Registered products: more than 10.000.
- Registered firms:



Regulatory Framework difficulties:

- ▶ Harmonization among the states – many states with different characteristics;
- ▶ Number of auditors in the central Department;
- ▶ Bureaucracy;
- ▶ Standard procedures;
- ▶ Regulatory timeframes;
- ▶ Legislation;
- ▶ Specialist expertise;
- ▶ Transparency;
- ▶ Large number of application;



Initiatives adopted

- ▶ Updating legislation based on international references like VICH and CAMEVET;
- ▶ Eliminating unnecessary administrative burden: not requiring application for all simple changes with no impact on safety and efficacy;
- ▶ Increasing the number of auditors available to analyze application: involving auditors of decentralized Unities – Superintendence in the States ;
- ▶ Creating standard procedures for analysis: guidelines and SOPs based on international references like VICH and CAMEVET;
- ▶ Investment in auditors qualification: periodic training with impartial expertise from academia;



Initiatives adopted

- ▶ Reinforcement for inspection activities: creating a new Division dedicated to coordinate audits;
- ▶ Regulation proposal to prioritize analysis of innovative products;
- ▶ Reinforcement surveillance of products: creating a new Coordination Department dedicated to pharmacovigilance;
- ▶ Intensive participation in international forum and meetings like VICH and CAMEVET;
- ▶ Implementation of Electronic system to analyse register requests: public reports;
- ▶ Interacting with the applicant.

Benefits reached and expected



- ▶ Increased regulatory convergence between countries or regions: more access to animal health products;
- ▶ Predictable shorter regulatory timeframes;
- ▶ Reduction of unnecessary application;
- ▶ Efficient regulation for industry and regulators;
- ▶ Stimulation of innovative veterinary medicines in the trade;
- ▶ Regulators more qualified and supported by impartial expertise from academia;
- ▶ Transparency through the public reports from electronic system.



Challenges

Regulatory harmonization is essential, but to increase the convergence is necessary:

- ▶ Take account of particular issues among the countries:
 - Different natural characteristics: climatic zones, microorganisms, parasites and breeds- guidelines needs to have requirements that consider these differences.
 - Different technical and regulatory level.
- ▶ Stimulate and intensify the participation of more countries during the elaboration of guides and regulations;
- ▶ Political agreements to implement the guides and regulations;



Thank you!!!

barbara.cordeiro@agricultura.gov.br

dpf.cpv@agricultura.gov.br

dpb.cpv@agricultura.gov.br

+55 61 3218-2704