

International Workshop Feed Risk Assessment – Chemical Safety

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Activities in Feed Safety at FDA

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Food and Drug Administration

CVM's Vision
Excellence.Innovation.Leadership



CVM's Mission
Protecting Human and Animal Health

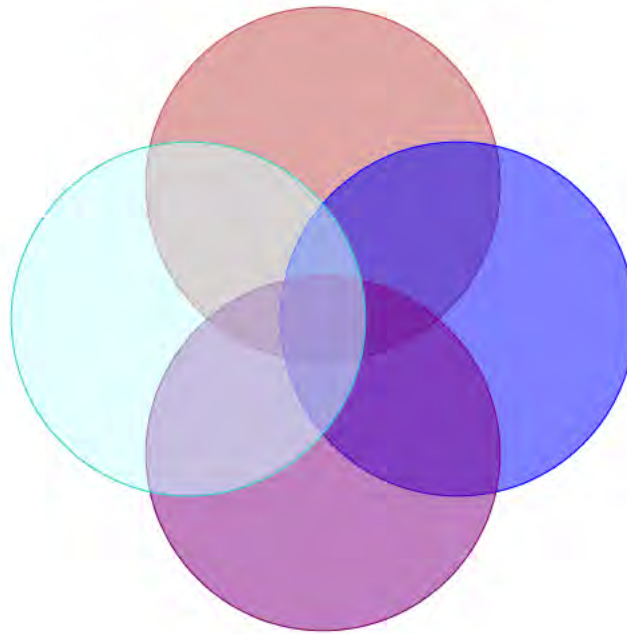
Topics

- Recent Food Safety Modernization Act (**FSMA**) activities
- Activities through partnerships
- **Animal Feed Safety System (AFSS)** activities – continuing project

Main Themes of the FSMA Legislation

Prevention

Enhanced
Partnerships



Inspections,
Compliance,
and Response

Import Safety

Food Safety Modernization Act

Title I

- **Improving Capacity to Prevent Food Safety Problems**
 - Registration of facilities
 - Hazard analysis and risk-based preventive controls
 - Performance standards
 - Building domestic capacity
 - Sanitary transportation of food
 - Plus 11 other sections...

Hazards Analysis and Risk-based Preventive Controls (Sect. 103)

- ID reasonably foreseeable hazards (biological, chemical, physical, and radiological hazards)
- ID and implement preventive controls
- Monitor effectiveness of the preventive controls

Hazard Analysis (cont'd)

- Take corrective action if the controls are not properly implemented
 - Reduce likelihood of future implementation failure
 - All affected food is evaluated for safety, and
 - All affected food is prevented from entering into commerce if it cannot be assured that the food is not adulterated or misbranded

Hazard Analysis (cont'd)

- Records kept for at least 2 years documenting the monitoring process
- Written plan and documentation of the process used to ID hazards and preventive controls
- Re-analysis required, whichever is earlier
 - If a significant change in activities conducted
 - Within every 3 years

Performance Standards (Sect. 104)

Most significant contaminants

The Secretary shall ... not less frequently than every 2 years, review and evaluate relevant health data and other relevant information, including from toxicological and epidemiological studies and analyses, current Good Manufacturing Practices issued by the Secretary relating to food, and relevant recommendations of relevant advisory committees, including the Food Advisory Committee, to determine the most significant foodborne contaminants.

Performance Standards (cont'd)

What FDA is doing to comply

- CFSAN and CVM working with a contractor
- Developing a ranking tool
- Challenges
 - differences in amounts, types of data for animals vs. humans
 - differences in amounts, types of data for microbial vs. chemical contaminants
 - many bacteria of concern in human food vs. mainly Salmonella in animal food

Food Safety Modernization Act

Title II

- **Improving Capacity to Detect and Respond to Food Safety Problems**
 - Targeting of inspection resources
 - Mandatory recall authority
 - Improving the training of State, local, territorial, and tribal food safety officials
 - Enhancing the reportable food registry
 - Plus 8 additional sections ...

Targeting Inspection Resources

(Sect 201)

- The Secretary shall identify high-risk facilities
 - Known risks of the food produced
 - Compliance history of firm
 - Effectiveness of hazard Id and safety plan
- Increase frequency of inspections of all firms
 - Inspect high-risk firms every 3 years
 - Non-high risk firms every 7 years
- Inspect foreign firms
- Rely on Federal, State, or Local inspectors

Targeting Inspection Resources

What CVM is doing to comply

- Developing a risk algorithm joining two previously separate feed-related inspectional programs for comprehensive feed safety coverage
 - BSE Compliance Program
 - Focused on processing and transporting of prohibited protein
 - Medicated Feed Compliance Program
 - Focused on the safety aspects of handling and blending medicated articles into feed
- Add other firms not covered under the two previous programs

Examples of Partnerships

- Partnership for Food Protection
 - Working to develop an early warning system for animal feed similar to the PETNet system
 - Subgroups developing shared work assignments
- Association of American of Feed Control Officials
 - Development of model regulations and policies
 - Provide a forum for regulators and industry to discuss and resolve feed regulatory issues
- Veterinary Laboratory Response Network (VetLRN) of veterinary diagnostic laboratories

Animal Feed Safety System (AFSS)

- Who? FDA CVM Office of Surveillance and Compliance has the lead
 - Members from Division of Animal Feeds
 - Division of Compliance
 - Communications Staff
 - Member of an Office of Regulatory Affairs District Office
 - Commissioned State Inspectors
- When? On-going. Initiated in 2003.
- What? Multi-faceted approach/components

Example Components of AFSS

Components of AFSS pre-dated FSMA but some have been working on projects that align with FSMA

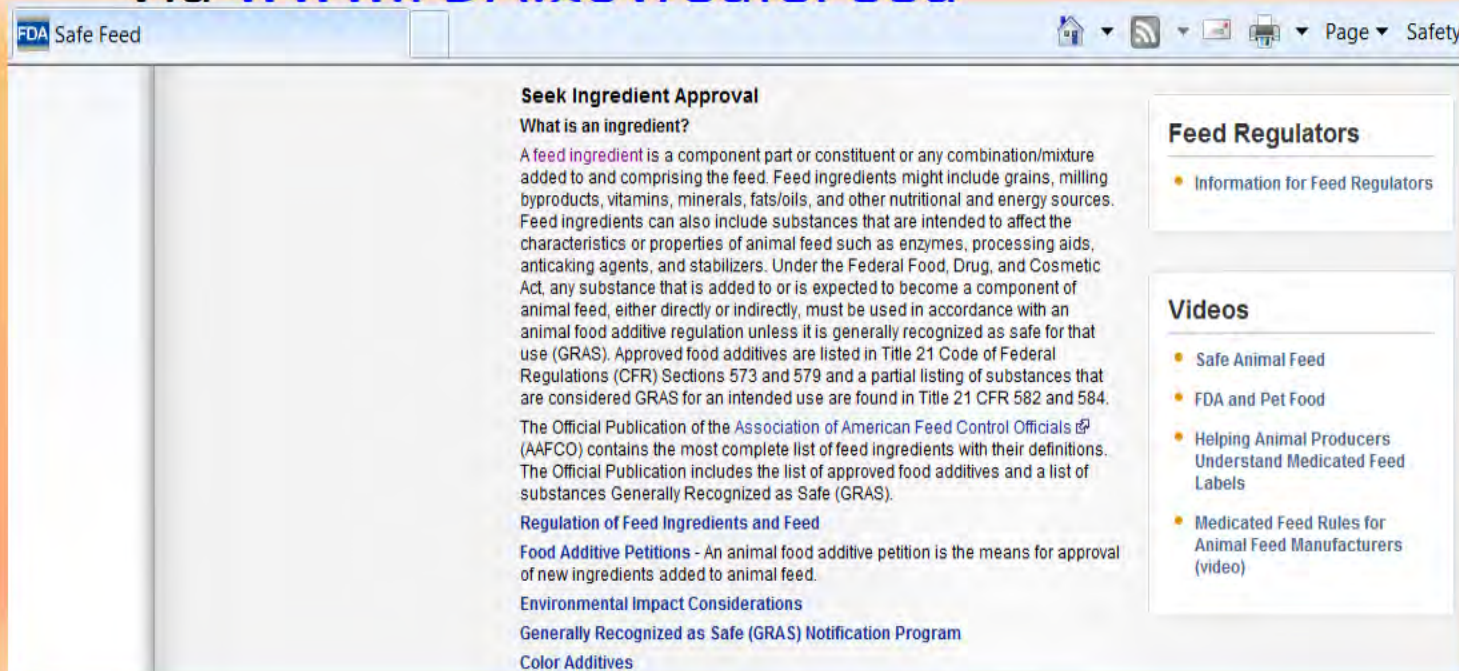
- Ingredients and the Approval Process (pilot GRAS program)
- Good Manufacturing Practices for the Production, Storage, and Distribution of Safe Feed Ingredients and Mixed Feed (drafting guidance)
- Reporting of Unsafe Feed [Safety Reporting Portal and Pet Event Tracking Network (PETNet)]
- Regulatory Oversight (working on implementation of the Sanitary Food Transportation Act)

Education and Outreach Component of AFSS

Education through various media

– Booths at Animal Society meetings and at Future Farmers of America

– Via www.FDA.gov/SafeFeed



The screenshot shows the FDA Safe Feed website. The main content area is titled "Seek Ingredient Approval" and includes a section "What is an ingredient?" with a detailed definition of a feed ingredient. Below this, there are links for "Regulation of Feed Ingredients and Feed Additive Petitions", "Environmental Impact Considerations", "Generally Recognized as Safe (GRAS) Notification Program", and "Color Additives". On the right side, there are two sidebar sections: "Feed Regulators" with a link for "Information for Feed Regulators", and "Videos" with a list of video titles including "Safe Animal Feed", "FDA and Pet Food", "Helping Animal Producers Understand Medicated Feed Labels", and "Medicated Feed Rules for Animal Feed Manufacturers (video)".

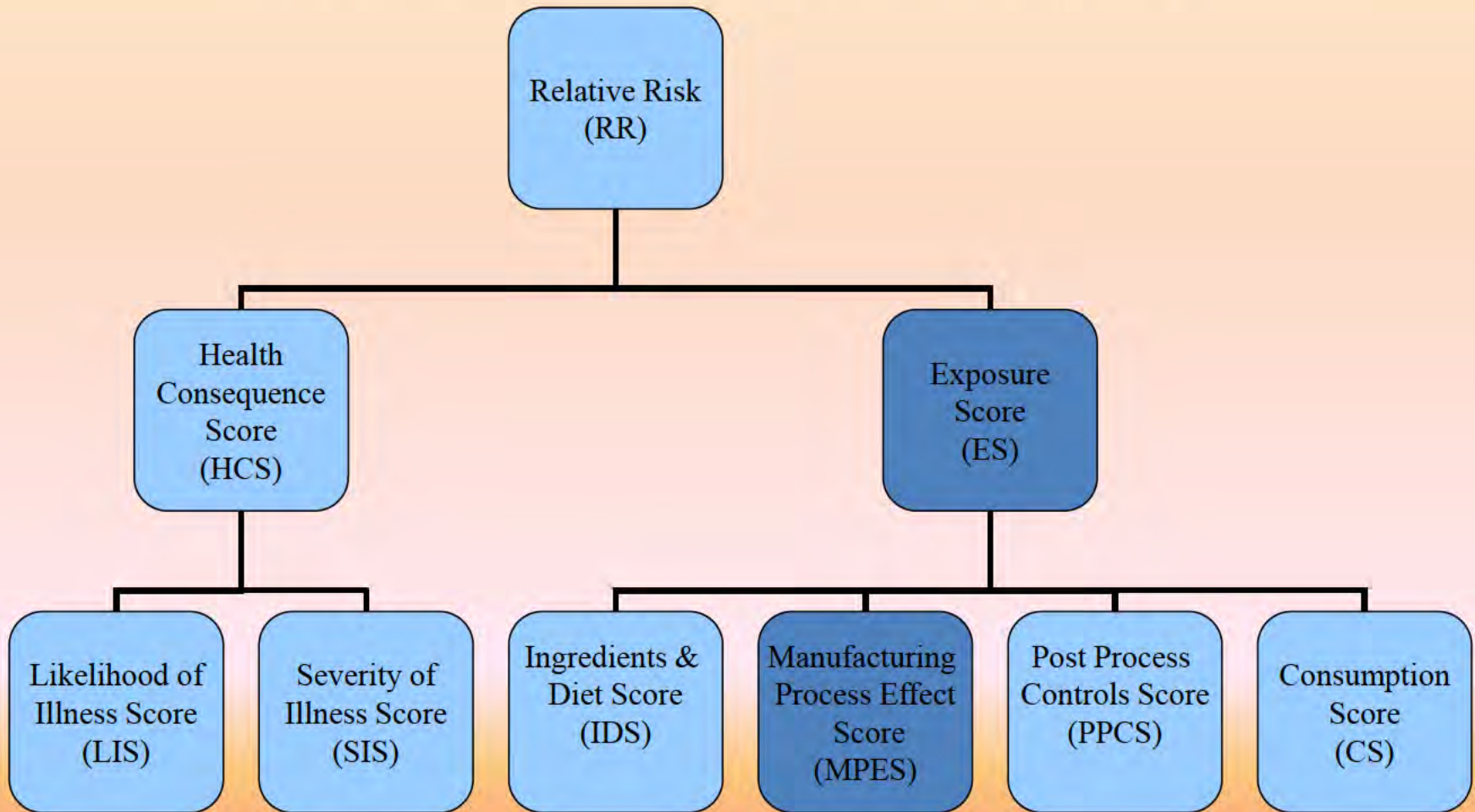
New videos on medicated feed!



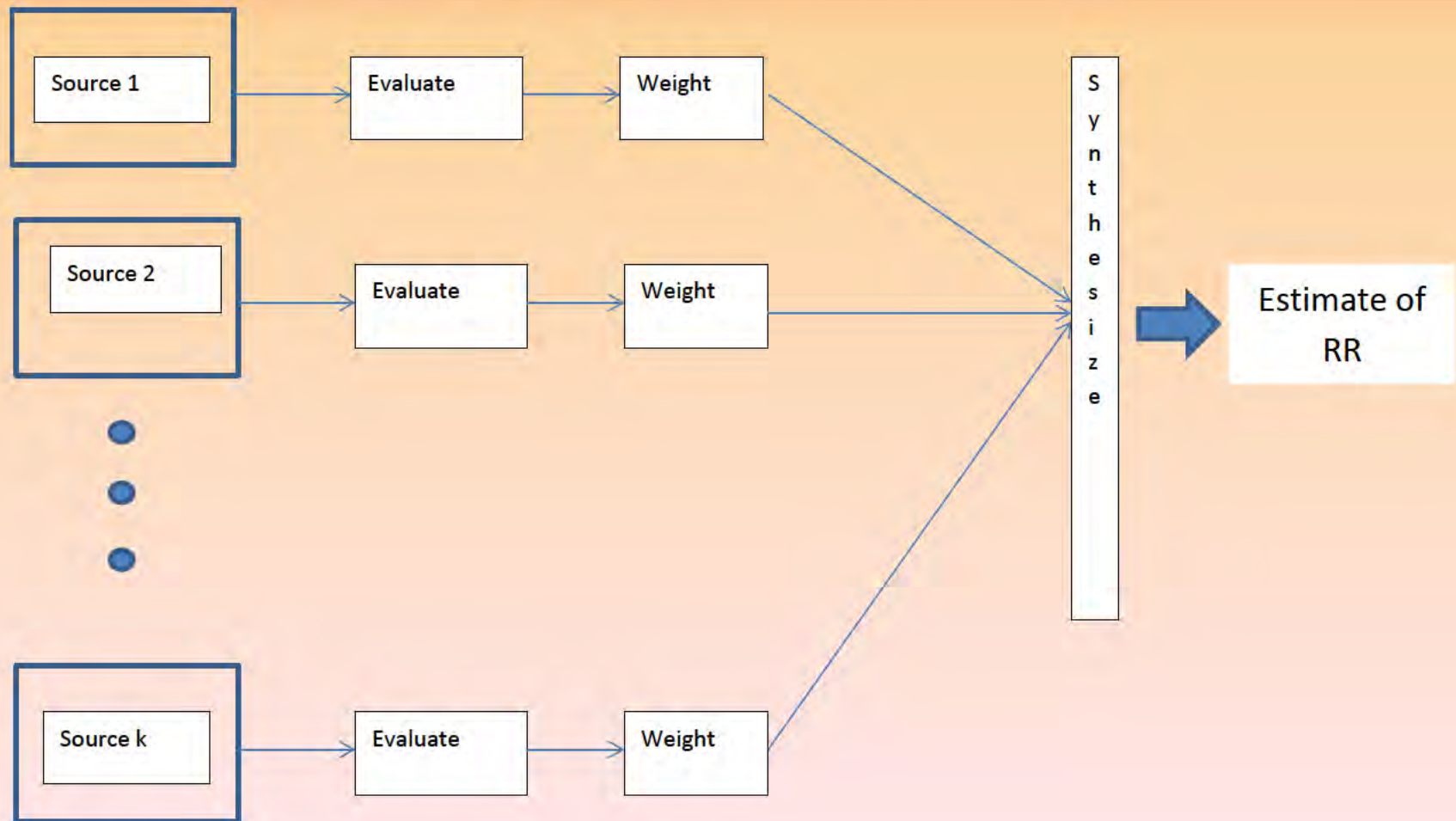
Risk Ranking Support for the AFSS

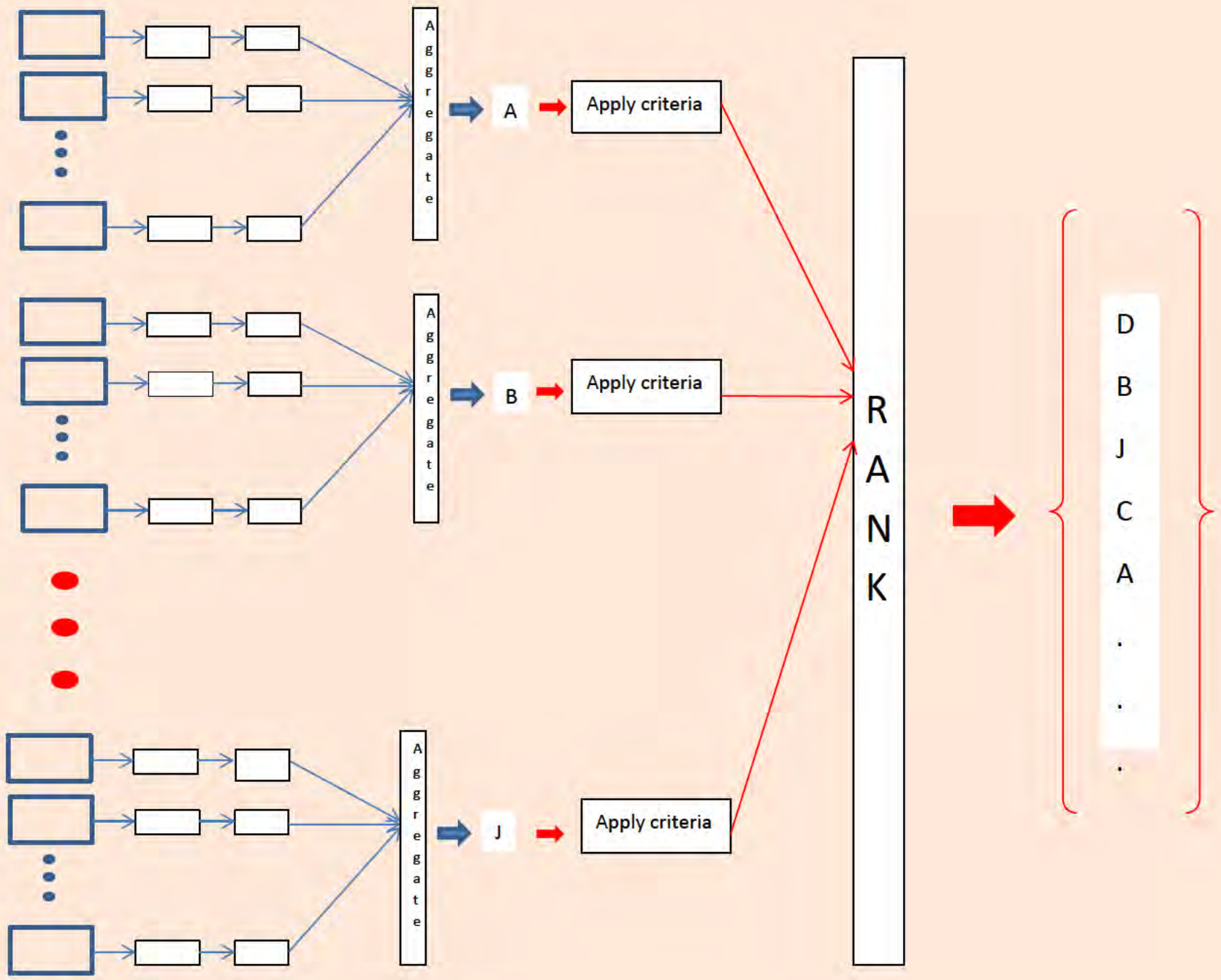
- Ranking of hazards in feed.
- Within species.
 - ✓ Human health one ranking,
 - ✓ Individual animal species separate rankings.
- Chemical hazards considered (currently)
 - Prototype developed in swine several years ago
 - ORISE Fellow working on poultry
 - **Presenting at the SRA meeting in Baltimore, Dec, 2013**

Relative Risk Model



Estimate RR, meta-analysis

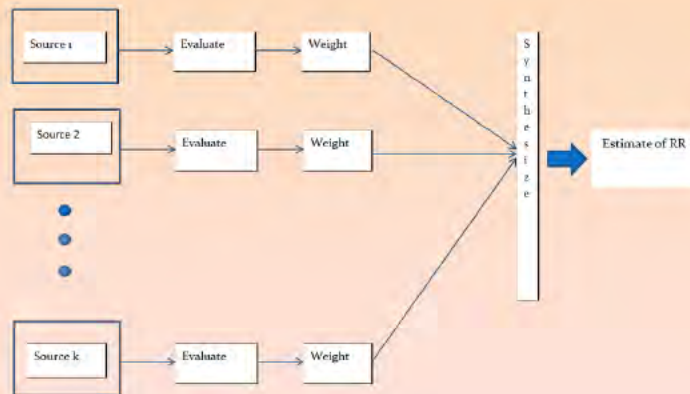




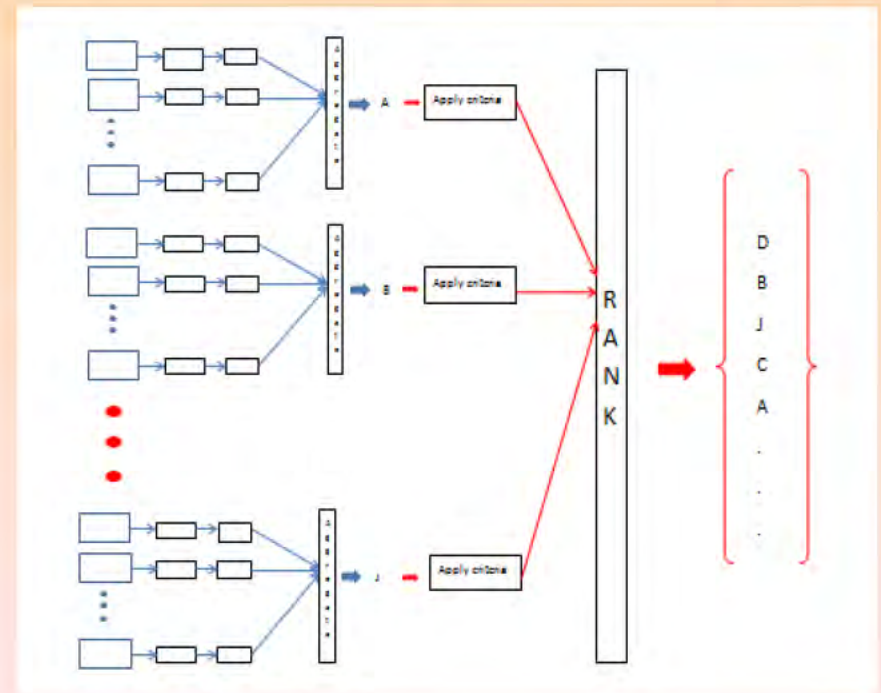
Side by Side Comparison

Is risk-ranking meta-meta analysis?

- Meta Analysis



- Risk Ranking



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Thank you !

Dank u

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merci

grazie

danke