



Relevance of Data Quality in Risk Assessment of Chemical Residues in Food of Animal Origin

Eric S. Mitema

Joint FAO/IAEA Satellite Workshop on Application of Quality Assurance and Control in Analytical Laboratories to Address Food Safety and Quality”, VIC 14 th. Nov. 2014, Vienna Austria



Edible tissues or products from food animals



Drugs can be retained in these edible tissues

Food animal

Edible by products/s

- | | |
|---------------|---|
| * Cattle | Muscle, liver, kidneys, fat, milk and offal |
| * Sheep/goats | Muscle, fat, liver, offal and milk |
| * Chicken | Meat, eggs |
| * Pig | Muscle, fat, liver |
| * Salmon | Muscle |



Public health risks from chemical/drug residues



- * 1. Anaphylaxis/food allergies
- * 2. Reproductive disorders e.g. birth malformation, genotoxicity
- * 3. Development of antimicrobial resistance (AMR) through food chain,
- * 4. Long term effects – e.g. carcinogenesis



Risk Assessment



- Fundamental rule includes:
 1. Problem formulation
 2. Hazard and exposure identification
 3. Assessment exercise



What criteria are useful in endpoint conclusions in risk assessment?



- * **Considerations**
- * -Endpoint may vary between risk assessors/reviewers
- * -An endpoint is like extrapolating “No Observed Effect Level” (NOEL) (expressed as mg/kg body weight) to assist in establishing an ADI and eventually MRL of a veterinary drug residue
- * - “**Influential**” information on endpoint must be truly credible
- * -Influential information can be defined as an element of assessment used to set a critical limit or value that defines the degree of risk
- * - All influential data must be “**Reliable**” and “**Relevant**”
- * - The study must identify Data Quality Objective (DQO) for the endpoint to be useful



What criteria are useful in endpoint conclusions in risk assessment?



- * Why then do conclusions vary between scientists or risk assessments on a given situation?
- * ***Often, it is because the quality standards for data***
- * ***reliability and relevance vary between assessment***



What criteria are useful in endpoint conclusions in risk assessment?



Reliability of a study

- * - The study employed in risk assessment is reliable if it has adequate quality factors necessary to support conclusions
- * - Studies done using **Guidelines** and **Good Laboratory Practices (GLP)** meet the standard of “best available”
- * - “**Usefulness**” of data in risk assessment is dependent on its quality and quantity
- * - If aspects of quality or reliability are lost the qualification or credibility of any study as influential diminishes



What criteria are useful in endpoint conclusions in risk assessment? cont..



- * **Assessment end point/data quality:**
 - * Depends on – conceptual model selected for assessment
 - * - How totality of the data are used in the process
- Assessment endpoint should be extrapolated by all stakeholders like sponsors, assessors and regulatory authorities



What criteria are useful in endpoint conclusions in risk assessment? cont..



Relevance of a study

- * **Data Quality objectives:** DQOs are qualitative and quantitative statements that define the type, quality and quantity of data necessary to support defensive risk management decision making
- * DQO are used to develop an effective study plan which eliminates collection or generation of data that is inconsequential to decision making
- * GLP compliant studies fulfill the intent of DQO since they exist as a suite of data intentionally developed to serve a specific risk management process
- * DQO consist of the following steps: - statement of the problem and the decision to be made, identifying inputs to the decision (data quality and quantity for risk assessment), developing a decision rule and optimizing the design for data collection



Specific criteria useful in endpoint conclusions in risk assessment



1. “Usefulness” and relevance of a study

A study selected in risk assessment is considered useful if it meets most of the set criteria listed below:

- * Study endpoint relates to assessment endpoint
- * Study endpoint can be detected under field conditions
- * Testing method matches expected environmental profile
- * Exposure route is relevant
- * Study duration matches expected exposure
- * Physico-chemical features accounted for during study design
- * Disclosure of all information sources



Specific criteria useful in endpoint conclusions in risk assessment



Usefulness and relevance of a study cont..

- * Appropriate study design utilized by all standards
- * Study ready to be subjected to peer review and regulatory process
- * Study is conducted under accepted Guidelines

2. Transparency of parameters

- * Study meets all quality and reporting criteria
- * Test procedures are clearly documented
- * Animals used are properly identified, acclimatized, fed standard feed/s, and properly housed
- * Physico-chemical parameters conducive to stable test population
- * Measurements, test levels and additives completely documented and verified



Specific criteria useful in endpoint conclusions in risk assessment



3. Quantity of data

- * Number of animals used is adequate to support statistical analysis
- * Appropriateness of animal model used for specific risk assessment
- * Number of replicates give adequate statistical basis
- * Study endpoint relates to available suite of data
- * Effective concentration within the range of other endpoint
- * Known referenced procedures and methods are employed

4. Consistency of results

- * Study has been consistently replicated
- * Endpoints are consistent with other data
- * Variations from other studies are properly understood and explained

* Collaborating data available



Specific criteria useful in endpoint conclusions in risk assessment



5. Information integrity

- * Study was conducted in a secure place (e.g. competent laboratory)
- * GLP were followed and a certificate issued where necessary
- * Full identities of authors including their qualifications, affiliations and sponsoring organisations are available
- * Data are archived, secure and available for verification



Conclusions



- * 1. Data quality depends on reliability and relevance of the selected study to support robust risk assessment
- * 2. Data used in the study should be able to withstand peer review, be published and ranked
- * 3. Data quality influences endpoint in risk assessment decision making process



Thank you



Q & A