Separation Between Risk Assessment and Risk Management

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- Concept of separation born in the USA in the mid 1970s, when US FDA and EPA began adopting systematic methods for assessing human health risks to carcinogenic
- 1980s increasing role of Risk Assessment as a basis for regulatory decisions
- Separation conceptualized by National Research Council in “Red Book” recommending a clear cut separation between 2 steps of risk analysis.

Rationale

Attempt to achieve highest possible scientific integrity of Risk Assessment process and avoid as much as possible political pressures that would undermine scientific credibility and conclusions

Recognition at **international level** through Joint FAO/WHO Food Standards Programme.

Statement of the Codex Alimentarius Commission "*There should be a functional separation of risk assessment and risk management, while recognising that some interactions are essential*".

Highlighted in the context of WTO disputes where EU has not been able to affirm its views on plausible risks.

- BUT as highlighted in NRC Red Book, this separation should not be at the expenses of proper interface between Risk Assessment and Risk Management. Such interface is "*essential for the proper interpretation of risk estimates and the evaluation of risk management options*".
- Risk of disjunction between assessment and regulatory agendas.

- As written by legal scholar "*When science, technology and public policy intersect, different attitudes, perspectives and rules of argument come into sharp conflict*".
- Hence the importance of enhancing dialogue, communication and interaction in order to reach sound and effective Risk Management decisions:
- The assessors must understand the manager's questions and both parties must acknowledge any constraints which may impact on the risk assessment.
- Strengths and limitations of the assessment must be communicated appropriately so that Risk Managers can properly understand the results.

Institutional separation reflected in EU General Food Law

- Article 3§11 of Regulation 178/2002 defines Risk Assessment as a "*scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization*".

- In turn, Risk Management is defined under §12 as "*a process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors and, if need be, selecting appropriate prevention and control options*".