



European Food Safety Authority

Risk Assessment to Risk Management – Terminology of Risk Assessment

EFSA Project on Risk Assessment Terminology

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Protection Products and their Residues

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- Background - How did we get to here?
- Aims of the collaborative terminology project
- DG SANCO funded study 2007
- EFSA funded study 2010
- The way forward



- Risk analysis paradigm – risk assessment, risk management and risk communication
- Key principles – clear, easily understood, transparent, unambiguous
- Harmonised terminology to describe similar risks - communication is critical

Background Documents

- EU Scientific Steering Committee – harmonisation of risk assessment procedures (2000)
http://ec.europa/food/fs/sc/ssc/out82_en.pdf
- Updated opinion and report (2003)
http://ec.europa/food/fs/sc/ssc/out355_en.pdf
- International Programme on Chemical Safety (IPCS) (2004)
<http://www.who.int/ipcs/methods/harmonisation/areas/ipcsterminologyparts1and2.pdf>
- European Food Safety Authority (EFSA)
 - Transparency GD procedural aspects (2006)
 - Transparency RA (2009)<http://efsa.europa.eu/en/scdocs/353.htm> and <http://...../1051.htm>



Up to date activities

- Chairs of the EU Scientific Committees and Panels responsible for risk assessment in Europe (2005-2010)
- European Workshops
- Transatlantic Risk Assessment Dialogue (2008)
- Global Risk Assessment Dialogue
- 1st International Conference on Risk Assessment (Brussels 2008)
- Collaborative Project on evaluating uncertainty, weighing scientific evidence and using the appropriate terminology in risk assessment

Collaborative transatlantic project

Evaluating uncertainty, weighing scientific evidence and **using the appropriate terminology in risk assessment.**

Aims

To exchange information on current ways to express the various dimensions of risk and to characterise risks in quantitative or qualitative terms, to make an assessment of problems posed and identify and recommend best practice.

Comparative review of risk terminology for DG SANCO

A comparative review of terminology and expressions used by the three non-food scientific committees established by Commission decision 2004/210/EC and by their predecessors established by Commission decision 97/579/EC

- Central Science Laboratory (CSL), DEFRA, UK Nov 2007
- Hart, Roelofs, Hardy and Macleod
- http://ec.europa.eu/health/ph_risk/documents/risk_rd01-en.pdf

Scientific Committee on Consumer Products (SCCP)

Cosmetic products and ingredients, toys, textiles, clothing, personal care products, domestic products e.g. detergents.

Scientific Committee on Health and Environmental Risks (SCHER)

Pollutants in environmental media and other biological and physical factors or changing physical conditions which may impact health and the environment (air quality, waters, waste and soils).

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

Antimicrobial resistance, new technologies, physical hazards, tissue engineering, blood products, fertility reduction, cancer of endocrine organs, synergic and cumulative effects, methodologies for new risks.

CSL report on terminology for DG SANCO

Objective

- Comparative review of terms and expressions used by CSTE, SCCNFP, SCCP, SCENIHR, SCHER, and SCMPMD

Purpose

- Assist current committees to identify best practice in the expression of complex ideas used in risk assessment

Scope

- Concluding sections of 100 example opinions
- Specified types of terms and expressions

Qualitative expression of uncertainty

ambivalent, appear, approximately, arbitrary, believe, borderline, cannot be assumed, cannot be excluded, considered, could, disagreement, estimated, expected, few/most, in general, incorrect, increasing evidence, indicate, likelihood, **may** (46), might, not detected/detectable, not established, open questions, outlier, perhaps, possible, potential, probably, prone to, reasonable, seem, should not, some, suggest, suspected, theoretically, **uncertain** (20) unclear, under- or overestimate, unexplained, unknown, variable

Main conclusions and recommendations

- Wide variety of verbal terms currently used
- Harmonisation unlikely to improve communication
- When quantitative estimates available, use them
- When the assessment depends on expert opinion, try expressing it quantitatively
- Adopt a systematic approach to uncertainty
- Avoid implying risk management judgements
- Explore new approaches with case studies?

EFSA's Scientific Work

- General requests for scientific opinions and advice
- Risk assessment of regulated substances and products
- Monitoring and assessing specific biological risk factors for human health and animal diseases
- Improving European risk assessment approaches and methodology



**EFSA'S CORE
VALUES:
OPENNESS AND
TRANSPARENCY,
INDEPENDENCE,
SCIENTIFIC
EXCELLENCE AND
RESPONSIVENESS**

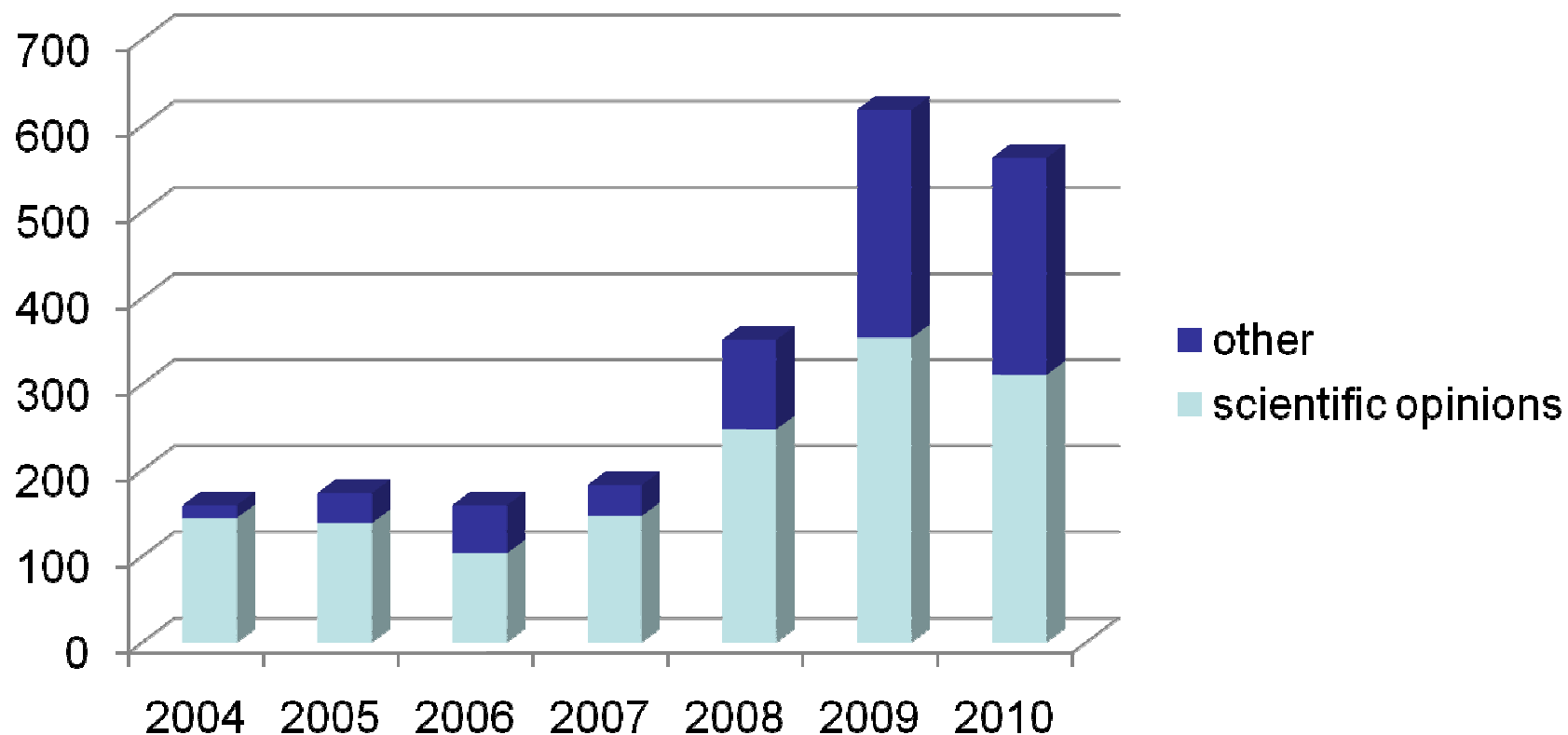
SC and the 10 Scientific Panels

- Food additives and nutrient sources added to food (ANS)
- Food contact materials, enzymes, flavourings and processing aids (CEF)
- Additives and products in animal feed (FEEDAP)
- Plant Protection Products and their Residues (PPR)
- Genetically modified organisms (GMO)
- Plant Health (PH)
- Dietetic products, nutrition and allergies (NDA)
- Biological hazards (BIOHAZ)
- Contaminants in the food chain (CONTAM)
- Animal Health and Welfare (AHAW)
- Scientific Committee (SC)

EFSA Annual scientific outputs

EFSA Journal

(<http://www.efsa.europa.eu/en/efsajournal.htm>)



Comparative review of terminology for EFSA (2010)

Report on terminology in risk assessments performed by the Scientific Panels and Scientific Committee of EFSA

- Food and Environment Research Agency (Fera),
DEFRA, UK December 2010
- Flari and Wilkinson
- www.efsa.europa.eu

Objective

Comparative review of terminology used to communicate risk, uncertainty, benefit and efficacy, in opinions published by the Scientific Committee and Scientific Panels of EFSA:

- to identify any particular patterns
- to identify similarities and/or differences between Panels
- to make recommendations for harmonising and ameliorating the communication of risk and/or uncertainty in the published opinions

Methods

- Examined abstract, summary, concluding sections and conclusions of 219 opinions published in 2008, 2009 and early 2010 (ca. 20% of total published)
- Built searchable database to archive and analyse the relevant opinion sections and the identified quantitative and qualitative descriptors

- Online searchers principally access summaries
- Identified quantitative and qualitative descriptors
- Subjective interpretation - specialised artificial intelligence software not used

Key word analysis of “descriptors”

- Expressing possibility or probability
- Expressing magnitude or characterising
- Expressing inability or difficulty to assess or evaluate
- Facilitating comparison of expressions
- Expressing frequency
- Indicating a change in the assessment
- Driving yes or no (...certainty)
- Expressing agreement or disagreement
- Contributing to characterisation but not included in any of the above

Fera Report 2010 - Results

Table 4: Count of qualitative and quantitative descriptors of benefit, or efficacy, or risk and/or uncertainty identified in the EFSA documents reviewed. Descriptors could have been employed more than once in the reviewed documents. Frequency of the most common ones is shown per primary category and per panel in tables cited below.

Descriptor primarily categorised as:	Count of descriptors identified	AHAW	ANS	BIOHAZ	CEF	CONTAM	FEEDAP	GMO	NDA	PLH	PPR	SC
Benefit - Qualitative	97	2	2	2		1	1		89			
Benefit - Quantitative	0											
Efficacy - Qualitative	93	5		7	2		38	35		2		4
Efficacy - Quantitative	1						1					
Risk - Qualitative	2161	340	194	201	151	248	210	238	44	394	65	76
Risk - Quantitative	252	2	128	2	18	60	11		9	3	16	3
Uncertainty-Qualitative	1120	190	96	136	93	164	82	11	94	129	69	56
Uncertainty-Quantitative	68		22	2	18	16	5	1	1	1	2	
Total	3792	539	442	350	282	489	348	285	237	529	152	139

Qualitative descriptors to characterise risk (>20x)

low, high, safe, very low, moderate,
unlikely adverse effects/unlikely to have any
adverse effects,
no safety concern(s), negligible , higher,
increases/increased/increasing/would increase,
as safe as

(Table 6)

- Identified a wide range of verbal expressions
- Most commonly employed descriptors appeared to be specific to each scientific panel/committee
- Only small number of quantitative descriptors of benefit, efficacy, risk or uncertainty (331/3888)
- Employing quantitative measures if these are already part of an assessment can improve communication (reduce ambiguity)
- Recommend inclusion of glossary of the qualitative terms used in each opinion and indicate boundaries for each term

The way forward for EFSA

- EFSA cross panel working group has been set up to evaluate the contractor report, analyse the results and identify lessons/best practice for improving harmonisation across EFSA to improve consistency, transparency and reduce ambiguity of communicating risk assessment.
- Target for Scientific Committee to adopt opinion by the end of 2011 after public consultation

Questions for EFSA to consider

- What is the context of the risk assessment and the different sectoral legislative constraints (wording) that frame the questions/mandates?
- How to improve the clarity of the language to express levels of risk and uncertainty?
- How to improve the continuity of the message through the risk assessment?
- How to avoid changing the message through unintentional drafting variations through the opinion?
- How to avoid terms that imply risk management judgements?

More questions for EFSA to consider

- Should uncertainties be described in quantitative terms rather than qualitative? Is this possible in all sectors?
- Recognise that some Panels are dealing with questions where it is especially difficult to define quantitative metrics (e.g. pain and suffering)?
- Uncertainties should be dealt with in separate section?
- How to present conflicting or contrasting evidences clearly?
- Expressions should be accompanied by clear statement or summary of the evidences on which they are based?
- To what extent is harmonisation desirable and/or achievable?

The collaborative way forward

- Planned publication of EFSA opinion (end 2011)
- Exchange and discuss with transatlantic/global partners to develop best practice and recommendations for increased harmonisation of risk assessment terminology.
- Joint workshop (2012)
- 3rd International Conference on Risk Assessment (2013)



Thank you for your attention

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