



Sharing information among the Scientific Committees and Panels

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Panels of Community bodies involved in Risk Assessment
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Background

- Earlier requests of agencies (EFSA, EMEA) for access to scientific data
 - Increase in such requests expected
 - Need to establish common principles of cooperation to ensure
 - scientific quality (completeness & soundness)
 - against possible divergence of opinions
 - that data provider's interests are respected
- ➔ Ongoing Topic at Meeting of Chairs (MoC)



Sharing information – Initiatives (1)

- EMEA - Reflection Paper on Cooperation
 - For identification and management of potential conflict over scientific opinions
 - Discussed at 1st MoC
 - Agreement at 2nd MoC:
 - EMEA-reflection paper to be finalized
 - Each body concerned to prepare (and share) own draft
 - Endorsement of SANCO Reflection Paper by non-food SCs in March 2007
- Lists of activities for possible cooperation (EMEA, SANCO C7/SCs)



Sharing information – Initiatives (2)

- Common Guidelines on sharing scientific data between EU RA bodies
 - Developed as outcome of 1st MoC
 - Based on EMEA reflection paper
 - First draft proposed by SANCO C7 at 2nd Meeting of Secretariats (MoS)
 - Circulation/Revision between 2nd and 3rd MoC
 - Further Discussion at 3rd MoS
 - Agreement on Draft following 3rd MoC
 - Final Draft of 7 July 2008



Guidelines – Scope & Objective (1)

- Exchange data/dossiers when needed (on ad-hoc, on-request basis)
- Facilitate identification and exchange of relevant publicly available data
- Address need to exchange relevant confidential (potentially diverse) data provided by third party



Guidelines – Scope & Objective (2)

- Need for exchange: assessment of 1 substance by 2 bodies, e.g.
 - opinion 1 final, opinion 2: conclusions differ
 - evaluations of 1 substance for different uses
- Highlight responsibilities of Secretariat
- Highlight the safeguards of legitimate interests of third parties
- Do not concern exchange with third countries, MS



Principles for applying guidelines

- Commitment of EU bodies
- Responsibility of EU bodies to facilitate data exchange
- Obligation to safeguard legitimate interests of third parties
 - Comply with personal data protection
 - No use of data for benefit of another applicant
- SC/panels have identified mutual interest
- Need to respect current legislation (e.g. confidentiality, access to docs)



Procedure (1)

- Chairs: initiative (via secretariats)
- Secretariat:
 - Contact point, facilitate exchange
 - Ensure compliance with data protection and confidentiality
- Members: committed to confidentiality
- Request: as specific as possible



Procedure (2)

- EU bodies: agree on modalities before exchange (return/destruction)
- Submitters of dossiers/requests will be consulted on exchange
- Exchange to be done under condition of **strict confidentiality**
- All specific rules on confidentiality apply (SANCO SC, agencies)



Current situation / next steps

- Comments of the Commission Legal Service received: reply to be sent
- All relevant EU bodies:
 - Guidelines to be published on website
 - Implementation