

29 *General*

- 30 • EFSA opinions must have a high degree of transparency with regard to the data, methods
31 of analysis and assumptions that are used in the risk assessment process.
- 32 • Transparency is needed in all parts of the risk assessment.
- 33 • A transparent risk assessment should be understandable and as far as possible
34 reproducible.
- 35 • Where possible, harmonised assessment terminology should be used, preferably based on
36 internationally accepted terminology.
- 37 • The procedure by which a risk assessment is completed needs to be based on accepted
38 standards of best practice.
- 39 • When circumstances require that a scientific assessment is provided within a limited time
40 period (e.g. in a crisis situation), the effect of this on the uncertainty of the response
41 should be clearly explained, and options and timescales for reducing that uncertainty
42 should be described.

43 *Scope and objectives*

- 44 • The scope and objectives of the risk assessment should be carefully considered and
45 documented, and if necessary, clarified with the originator of the request before the
46 commencement of the risk assessment.

47 *Data and data sources*

- 48 • A risk assessment requires a comprehensive description of the observations and the
49 experimental and/or environmental conditions under which the data were generated.
- 50 • The sources of all data used for the assessment, including unpublished data and personal
51 communications, must be identified and the data critically evaluated to determine their
52 quality and relevance to the assessment. These should be reflected in the relative weight
53 given to them in the assessment and taken into account in the overall evaluation of
54 uncertainty.
- 55 • If data bases, data banks and information systems are used to undertake literature data
56 surveys relevant for EFSA's activities, the identity of the data bases, data banks and
57 information systems used, should be documented along with the key search terms and
58 strategies applied and time period covered.

59 *Inclusion and exclusion of data*

- 60 • All the data and information available for the assessment are evaluated but only those
61 judged to be relevant should be used as the basis for risk assessment.
- 62 • The inclusion/exclusion criteria applied to the data should be clearly explained and
63 described within the risk assessment. If data are excluded, this should be stated clearly in
64 the opinion along with the rationale for their exclusion (e.g. poor quality).

65 *Confidential data*

- 66 • The requirements in the 2005 Decision of the EFSA's Management Board apply to
67 transparency and confidentiality of data. The approach taken is that the maximum amount
68 of information linked to EFSA's activities shall be disclosed or made accessible to the
69 public, and that only the essential minimum should be kept confidential where this is
70 justified.

71 *Assumptions*

- 72 • All assumptions should be documented and fully explained. Where alternative
73 assumptions could reasonably have been chosen, this is a form of uncertainty and should
74 be documented and evaluated together with other uncertainties (see below).

75 *Assessment*

- 76 • In qualitative assessments, conclusions are expressed in narrative argument. In
77 quantitative assessments conclusions are based, at least partly, on calculations or
78 mathematical models. In both cases, transparency requires that every element of the
79 reasoning, calculation or mathematical modelling should be communicated and justified
80 in such a way that it can be understood by others.
- 81 • Whenever mathematical models are used, it should be described whether, by what means
82 and to what extent they have been validated or evaluated, e.g. comparison with
83 independent data or review by independent experts.

84 *Variability and uncertainties*

- 85 • There may be differences in risk due to variability among individuals, populations,
86 species or ecosystems. It is important to identify and describe the most influential
87 contributors to variability in risk, preferably by statistical analysis of the underlying data.
88 However, the relevance of statistical differences interpreted in the absence of an
89 understanding of the biological process has always to be assessed with caution.
- 90 • Although it may be impossible to identify all the uncertainties, each opinions should
91 describe the types of uncertainties encountered and considered during the different risk
92 assessment steps, and indicate their relative importance and their influence on the
93 assessment outcome.

- 94 • Expression of uncertainty or variability in risk estimates may be qualitative or
95 quantitative, but should be quantified to the extent that is scientifically achievable.
- 96 • Where factors are used to account for uncertainty, an explanation of their basis and their
97 appropriateness or a reference to documents where that information may be found should
98 be included
- 99 • Where point estimates are used for variable or uncertain quantities, justification for the
100 values chosen and assessment of their influence on the assessment should be included

101 *Conclusions of a scientific opinion*

- 102 • Conclusions should address the terms of reference, should reflect the scope and objectives
103 of the risk assessment and provide a clear characterisation of the risk under consideration.
104 All key scientific information underpinning the assessment should be outlined including
105 uncertainties and data gaps;
- 106 • Conclusions should be based only on data previously described in the opinion;
- 107 • The reasoning leading to the conclusions should be clearly described. Where applicable,
108 the degree of consistency with risk assessments by other bodies should also be stated.

109 *Opinions issued by bodies/committee other than EFSA*

- 110 • Risk assessments may be performed on the same compound, agent or topic by different
111 risk assessment bodies at national, European or international level. Such opinions should
112 be considered by EFSA's Scientific Committee or Panels. Their relevance to EFSA's own
113 risk assessment should be evaluated provided that a comprehensive description of all data,
114 processes and methods is available and therefore fulfils the same quality criteria as
115 applied to opinions expressed by EFSA.
- 116 • The same data set may, however, not be appropriate in a different context. Therefore, the
117 terms of references need to be checked carefully before considering whether an opinion
118 expressed by another international body can be used by EFSA's Scientific Committee or
119 Panels.
- 120 • In case of diverging opinions, the procedure foreseen in Article 30 of Regulation (EC) No
121 178/2002 should be followed closely to identify and possibly to resolve diverging
122 scientific opinion.

123 **Key words: transparency, risk assessment, data sources, exclusion of data, confidential**
124 **data, assumptions, variability, uncertainty.**

125

126

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153 **BACKGROUND**

154 The need to increase consumer confidence in the assessment of risks and safety of food
155 (hereafter referred to as risk assessment) and to ensure a clear separation between risk
156 assessment and risk management in particular were two of the main reasons for establishing
157 the European Food Safety Authority (EFSA). The EFSA Founding Regulation (EC 178/2002)
158 states that risk assessments should be undertaken in an independent, objective and transparent
159 manner on the basis of the available scientific information and data. As the advice provided
160 by EFSA underpins the decision making in the food and feed sector, risk managers and
161 consumers need to understand the procedure through which the risks have been assessed and
162 the validity and limitations of the outcome and the associated implications.

163 A clear formulation of the scientific request to EFSA in the form of detailed ‘terms of
164 reference’ is an important step that must be taken before a risk assessment can be carried out.

165 Comprehensive and reliable exposure-effect data are rarely available. Therefore, risk
166 assessment is often confronted with incomplete data generated in experimental systems
167 including laboratory animals, *in vitro* and *in silico* approaches or data from case reports and
168 epidemiological studies in human beings and animals. The information generated in this
169 manner has to be combined with available human or animal exposure data in order to estimate
170 the risk. Inherent in such an assessment is the involvement of varying degrees of uncertainty,
171 for example uncertainties related to extrapolation from test animals to human beings or from
172 test on one species to another one, exposure duration, gaps and deficiencies in the database.
173 Therefore, it is important that the strengths and limitations of the data used and of the
174 conclusions reached are well explained. In addition, the risk assessment should describe the
175 underlying assumptions and uncertainties explaining the inclusion criteria as well as
176 exclusion-criteria for specific data sets.

177 **TERMS OF REFERENCE**

178 The Scientific Committee was requested by the European Food Safety Authority to provide
179 guidance on relevant information to be included in EFSA’s opinions to ensure the
180 transparency of the risk assessments carried out by EFSA’s Scientific Committee and Panels.
181 Such guidance should result in:

- 182 • process-related considerations, e.g. appropriate stakeholder involvement prior to and
183 during the risk assessment, handling, justification or explanation of minority opinion;
184 • consistent and harmonised documentation;
185 • a sufficiently detailed description of the strengths, robustness and limitations of the data
186 used for the risk assessment;
187 • a clear description of the underlying assumptions and uncertainties to provide the
188 reasoning for decisions;
189 • a list of criteria for inclusion or exclusion of available scientific information for a given
190 risk assessment, e.g. criteria for selection of pivotal studies and data;

- 191 • structured and stepwise progression through hazard and risk assessment, e.g. science-
192 based decisions for the need of additional studies based on previous studies in a stepwise
193 approach, resulting in an optimal set of toxicity tests (conceptual framework with decision
194 points).
195

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198 the Scientific Committee “Transparency in risk assessment – scientific aspects” for the
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203 **ASSESSMENT**204 **1. Introduction**

205 The EU general food law (EC 178/2002) establishes the rights of consumers to safe food and
206 accurate and reliable information. The European Community has chosen a high level of health
207 protection. It is important to ensure that consumers, other stakeholders and trading partners
208 have confidence in the decision making processes underpinning food law, its scientific basis
209 and the structure and independence of the institutions protecting health and other interests.
210 Regulation (EC) No 178/2002 of the European Parliament and Council established the
211 European Food Safety Authority (EFSA) to be an independent source of scientific advice and
212 scientific and technical support for the Community's legislation and policies in all fields
213 which have a direct or indirect impact on food and feed safety including human and animal
214 nutrition, animal health and welfare, plant protection and plant health. Within its mandate,
215 EFSA carries out a wide range of risk assessments, safety assessments, risk-benefit
216 assessments dealing with human and animal nutrition, animal health and welfare, plant health
217 and the environment. Hereafter in this document, for convenience the term risk assessment is
218 used to cover all these activities. The risk assessments carried out by EFSA should be
219 undertaken in an independent, objective and transparent manner on the basis of the available
220 scientific information, data and understanding. In addition, EFSA also has to ensure that the
221 public and interested parties receive reliable, objective, clear and unambiguous information in
222 the fields within its mission. While EFSA's role is to undertake scientific risk assessments
223 and to communicate their outcome, it is the role of the European Commission and Member
224 States to manage the risk, based on EFSA's assessment and other considerations, e.g.
225 technical, social, ethical and economic considerations.

226 In general, risk assessment follows the accepted methodology consisting of: (i) hazard
227 identification; (ii) hazard characterisation; (iii) exposure assessment; and (iv) risk
228 characterisation (FAO/WHO, 1995; FAO/WHO, 1997; Codex Alimentarius Commission,
229 2003; European Commission, Scientific Steering Committee, 2003). For human and animal
230 nutrition, animal health and welfare, plant health and the environment, the assessment
231 concepts are similar in principle but terminology and specific procedures may differ.

232 The Scientific Committee was requested by the European Food Safety Authority to provide
233 guidance on relevant information to be included in EFSA's opinions to ensure the
234 transparency of the risk assessments carried out by EFSA's Scientific Committee and Panels.
235 In 2006 the Scientific Committee published a guidance document addressing the procedural
236 issues that are considered beneficial to improve such transparency (EFSA, 2006b). The
237 current document focuses on the scientific issues related to transparency in the risk
238 assessment carried out by EFSA's Scientific Committee and Panels. This document deals
239 with general principles including data sources, criteria for inclusion/exclusion of data,
240 confidentiality of data, assumptions, variability and uncertainties.

241 It is intended that more specific transparency measures implemented in areas covered by
242 individual Panels should be drawn together into a follow up document.

243 **2. Need for transparency**

244 EFSA opinions must have a high degree of transparency with regard to the data, methods and
245 assumptions that are used in the risk assessment process. This is enshrined as a central pillar
246 in EFSA's founding regulation (EC No 178/2002).

247 Transparency is needed in all parts of risk assessments, including:

- 248 1) the objective and scope of the risk assessment
- 249 2) the source, nature and quality of the data, detailed methods, explicit assumptions,
250 variabilities, identified uncertainties and their significance for the outcome
- 251 3) the output and conclusions of the risk assessment.

252

253 A transparent risk assessment should be understandable and as far as possible reproducible.
254 Where possible, harmonised assessment terminology should be used, preferably based on
255 internationally accepted terminology, e.g. IPCS risk assessment terminology (WHO, 2004).
256 EFSA should also contribute, where appropriate, to ongoing international efforts to further
257 establish harmonised terminology.

258 Transparency in risk assessment contributes to:

- 259 • meeting the legitimate needs of stakeholders to understand the basis for risk
260 assessment;
- 261 • allowing an informed debate on scientific issues;
- 262 • providing a framework in which consumers can have confidence;

263

264 To achieve this, the risk assessment procedure by which an opinion is reached needs to be
265 based on scientifically accepted standards of best practice. It is therefore important that
266 existing European/international guidance documents on how to conduct risk assessment, for
267 example those of the WHO, OIE, IPPC, OECD and Codex Alimentarius are taken into
268 account. EFSA has also established guidance documents in various areas. Guidance and
269 guidelines are available for applicants on the data requirements and on the contents of
270 dossiers for assessments carried out by EFSA in the regulatory framework for the
271 authorisation of substances. A list of current guidance documents, guidelines and working
272 documents developed or in use by EFSA is available on the EFSA website. In addition, there
273 are a number of specific methodological guidelines available such as Good Laboratory
274 Practice and toxicity testing methods, e.g. OECD/EU guidelines.

275 The Codex Working Principles for Risk Analysis state that "Constraints, uncertainties and
276 assumptions having an impact on the risk assessment should be explicitly considered at each
277 step in the risk assessment and documented in a transparent manner. Expression of

278 uncertainty or variability in risk estimates may be qualitative or quantitative, but should be
279 quantified to the extent that is scientifically achievable” (Codex, 2008). The Scientific
280 Committee endorses this principle.

281 **3. General measures to provide transparency**

282 **3.1. Scope and objectives**

283 The scope and objectives of the risk assessment should be carefully considered, and if
284 necessary, clarified with the originator of the request before the commencement of the risk
285 assessment. Any questions that arise in the course of the assessment regarding the objective
286 and scope of the projected opinion or report require immediately to be addressed so as to
287 ensure the relevance of the final document.

288 Every risk assessment report or opinion should clearly communicate the following elements:

- 289 1. The context of the assessment;
- 290 2. The scope and the objectives of the risk assessment including the agent or activity
291 assessed, the hazard(s), population(s) and scenario(s) considered including exposure,
292 and the rationale for any limitations in scope;
- 293 3. The identification of any established risk assessment guidelines, data quality criteria,
294 default assumptions, decision criteria etc. that exist for the problem in hand, and
295 documentation and justification of any deviations from such standards where they
296 exist;
- 297 4. The methods used to identify relevant data and other information, including the scope
298 and criteria of literature searches.
- 299 5. Any minority opinion within the Panel conducting the assessment should be attributed
300 to their authors with their supporting arguments (EFSA, 2006b).
- 301 6. Opinions should contain a glossary of technical terms and abbreviations, or refer to an
302 accessible existing glossary if needed.

303 **3.2. Data and data sources**

305 A risk assessment requires a comprehensive description of the observations and the
306 experimental and/or environmental conditions under which the data were generated. The
307 scientific findings and other data come from sources including:

- 308 • peer-reviewed scientific papers;
- 309 • documents from national or international bodies such as reports of national monitoring
310 programmes and surveys;
- 311 • data submitted by applicants supporting authorisation requests, generated in
312 accordance with relevant guidelines and/or regulations.
- 313 • personal communications where appropriate

314

315 The sources of all data used for the assessment, including unpublished data and personal
316 communications, must be identified.

317 Limitations in the availability, relevance and quality of data used introduce uncertainties into
318 the assessment and its outcome. Therefore data from all sources should be critically evaluated
319 to determine their quality and relevance to the assessment. This should be reflected in the
320 relative weight given to them in the assessment and taken into account in the overall
321 evaluation of uncertainty.

322 There are many existing and continuously evolving data bases, data banks and information
323 systems used to undertake literature surveys relevant for EFSA's activities. Transparency
324 requires that the identity of the data bases, data banks and information systems used, should
325 be documented along with the key search terms and strategies applied and time period
326 covered.

327 When circumstances require that a scientific assessment is provided within a limited time
328 period (e.g. in a crisis situation), the effect of this on the uncertainty of the response should be
329 clearly explained, and options and timescales for reducing that uncertainty should be
330 described. EFSA has developed guidelines to address this issue (EFSA, 2007a; EFSA,
331 2007c).

332 **3.3. Inclusion and exclusion of data**

333 All the data and information available for the assessment are evaluated but only those judged
334 to be relevant should be used as the basis for risk assessment.

335 Data of less than ideal quality should not be disregarded completely, as they may contain
336 information important for the assessment. Instead, their implications should be considered,
337 while taking into account the increased uncertainty caused by their reduce quality.

338 The criteria for inclusion/exclusion of data should be clearly explained and described within
339 the risk assessment. If data are excluded, this should be stated clearly in the opinion along
340 with the rationale for their exclusion (e.g. poor quality).

341 The following aspects should be considered in making decisions to include or exclude
342 individual data sets:

- 343 • study design and power (e.g. robust statistical design);
- 344 • data quality (e.g. complying to GLP, study conducted to international agreed
345 guidelines);
- 346 • relevance of the study for answering the specific question (e.g. exposure assessment of
347 (sub)populations, geographical regions);
- 348 • adequacy of data sets (e.g. coverage of endpoints, sensitivity, specificity, appropriate
349 statistical treatment of data);
- 350 • data sources (e.g. peer reviewed scientific literature, scientific reports, data bases and
351 data banks, meeting abstracts).

352 **3.4. Confidential data**

353 EFSA's Management Board has adopted a decision (EFSA MB 10.03.2005) concerning
354 implementing measures of transparency and confidentiality requirements and they are
355 applicable to all activities undertaken by EFSA. The confidentiality of data has been also
356 addressed in the EFSA guidance on procedural aspects related to transparency in risk
357 assessment (EFSA, 2006b).

358 The balance between transparency and confidentiality is determined by the principle that the
359 maximum amount of information linked to EFSA's activities shall be disclosed or made
360 accessible to the public, and that only the essential minimum should be kept confidential
361 where this is justified. Several regulations give the European Commission the exclusive
362 competence to accept/reject confidentiality claims of third parties. In these cases EFSA is
363 bound by the outcome of such decisions by the European Commission.

364 When EFSA receives a request for access to documents, it should process that request in
365 accordance with the procedures and the principles laid down in Regulation (EC) No
366 1049/2001 and in Article 41 of the Regulation (EC) No 178/2002.

367 **3.5. Assumptions**

368 Every risk assessment contains assumptions. Obvious examples of assumptions include
369 default values (e.g. for body weight) or extrapolation factors (e.g. from animals to humans).
370 Assumptions are also often implied when using data: e.g. it is frequently assumed that a
371 sample of data (e.g. concentrations measured in a sample of food items) is representative of a
372 larger population. When calculations or mathematical models are used, the form of those
373 calculations or models implies assumptions about the way that different input parameters
374 jointly relate to the output: for example, when using a particular dose-response model it is
375 assumed that this expresses the relation between dose and response more appropriately than
376 other dose-response models that could have been chosen.

377 Transparency requires that all assumptions should be documented and fully explained. Where
378 alternative assumptions could reasonably have been chosen, this is a form of uncertainty and
379 should be documented and evaluated together with other uncertainties (see below).
380 Uncertainty regarding assumptions can be evaluated by repeating the assessment with
381 alternative assumptions and then examining their impact on the assessment outcome.

382 **3.6. Assessment**

383 Assessment is the process through which data and assumptions are used to reach conclusions
384 about risk.

385 In qualitative assessments, conclusions are expressed in narrative argument. In quantitative
386 assessments conclusions are based, at least partly, on calculations or mathematical models. In
387 both cases, transparency requires that every element of the reasoning, calculation or

388 mathematical modelling should be communicated and justified in such a way that it can be
389 understood by others. In many cases, the assessment follows an established approach, in
390 which case it may be sufficient to provide a brief description and a reference to other
391 documents where details on the approach are available. In other cases, a full description
392 should be given.

393 In qualitative risk assessments, long paragraphs of narrative text can be difficult for readers to
394 assimilate and comprehend; it may be more effective to present successive steps in the logical
395 argument as a series of bullet points. Alternatively, at the end of a long argument, it may be
396 useful to summarise the main elements. At stages in the assessment where several alternative
397 lines of reasoning could be considered, these should be stated and the relative weight given to
398 each should be described and justified. Where there is reasonable uncertainty about which
399 line of reasoning should be preferred, the assessors should consider how each alternative
400 would affect the outcome of the assessment, and communicate this as part of the evaluation of
401 uncertainty in the assessment.

402 In quantitative assessments, the calculations or mathematical models should be explained in
403 such a way that their purpose and rationale can be followed by general readers. In addition,
404 sufficient detailed information should be provided to enable others with appropriate expertise
405 to check that the calculations or model are appropriate; if it is lengthy or complex, this
406 information may be provided as an appendix or annex accompanying the opinion.

407 Except when a mathematical model is very simple, it will be helpful to readers if a graphical
408 depiction of it is provided, e.g. in the form of a flow chart. The structure of the model (choice
409 of parameters and how they are combined) should be explained and justified. Where
410 alternative calculations or model structures could reasonably be considered, the impact of this
411 on the outcome of the assessment should be explored as part of the evaluation of uncertainty
412 in the assessment.

413 Whenever mathematical models are used, it should be described whether, by what means and
414 to what extent they have been validated or evaluated, e.g. comparison with independent data
415 or review by independent experts.

416 **3.7. Variability**

417 Whereas variability in experimental systems is generally small, natural variability in
418 individuals, populations and systems is generally larger. Sources of natural variability
419 include:

- 420 • physiological status (e.g. gender, age, pregnancy and nutritional status, physical
421 activity);
- 422 • lifestyle (e.g. dietary habits, smoking, alcohol consumption);
- 423 • environmental conditions (e.g. occupational exposures, climate, farming conditions);

- 424 • genetic factors (e.g. the wide genetic diversity in many of the enzymes involved in the
425 metabolism of xenobiotics; genetic variability of repair systems; genetic variability in
426 receptor levels and affinities; variability of development rate of insects in response to
427 temperature; variability in virulence of pathogens).
- 428 • Diseases (e.g. obesity, diabetes mellitus, and liver- kidney or cardiovascular diseases).
429

430 Some of the sources of variability (e.g. genetic factors) will act throughout the lifespan of an
431 individual, whereas others (e.g. nutrition, age, lifestyles, exposure and diseases) will vary
432 during an individual's life. Hence, there may be differences in risk due to variability among
433 individuals, populations, species or ecosystems. It is important to identify and describe the
434 most influential contributors to variability in risk, preferably by statistical analysis of the
435 underlying data. However, the relevance of statistical differences interpreted in the absence of
436 an understanding of the biological process has always to be assessed with caution.

437

438 **3.8. Uncertainties**

439 Uncertainties may arise from limitations in the database, e.g. limited exposure data, gaps in
440 the effect database, the limitation of the test systems and endpoints selected, inadequacy of
441 study designs and the uncertainties in extrapolating between species. Measurement
442 uncertainties may also occur. Uncertainties may be reduced by undertaking additional studies.
443 Although it may be impossible to identify all the uncertainties, opinions should describe the
444 types of uncertainties encountered and considered during the different risk assessment steps,
445 and indicate their relative importance and their influence on the assessment outcome.

446 When uncertainty factors are used, an explanation of their basis and a justification of their
447 appropriateness need to be provided, or a reference to documents where that information may
448 be found should be included. Where point estimates are used for variable or uncertain
449 quantities, justification for the values chosen and assessment of their influence on the
450 assessment should be included.

451

452 In 2006, the Scientific Committee has published guidance on a tiered approach for achieving
453 this within the context of dietary exposure assessment (EFSA, 2006a). Initially all relevant
454 uncertainties may be analysed qualitatively using a tabular approach and, in many cases, this
455 may be sufficient (e.g. EFSA, 2006c). If needed, those uncertainties that appear to be critical
456 to the outcome may then be analysed deterministically or probabilistically (EFSA, 2007b).
457 This approach has been used by the PPR Panel (e.g. EFSA, 2006c), by the CONTAM Panel
458 (e.g. EFSA, 2008c), by AHAW Panel (e.g. EFSA 2006d, 2007d, 2007e) and is equally
459 applicable to toxicological assessments (e.g. EFSA, 2008a) and ecological risk assessments
460 (e.g. EFSA, 2008b).

461 Probabilistic approaches may be useful to quantify some of the uncertainties. When such
462 approaches are used, the outcome of the risk assessment should be characterized by reporting

463 a distribution of the risk estimates. However, use of quantitative methods does not take away
464 the need for a qualitative evaluation of the remaining uncertainties.

465 **3.9. Conclusion of a scientific opinion**

466 The conclusion of a scientific opinion should address the terms of reference, should reflect the
467 scope and objectives of the risk assessment and provide a clear characterisation of the risk
468 under consideration. It should be based only on data previously already described in the
469 opinion. All key scientific information, including uncertainties and data gaps, underpinning
470 the assessment should be outlined. The reasoning leading to the conclusions should be clearly
471 described. When applicable, the degree of consistency with risk assessments by other bodies
472 should also be described (see chapter 4).

473

474 **4. Opinions issued by bodies/committees other than EFSA**

475 **4.1. Opinions expressed by international bodies/committees**

476 Risk assessments may be performed on the same compound, agent or topic by different risk
477 assessment bodies on an international level (e.g. JECFA and JMPR), or on an EU level (e.g.
478 by sister committees of the DG Health and Consumers, EMEA, ECHA and DG Employment).

479 Such opinions should be considered by EFSA's Scientific Committee or Panels. Their
480 relevance to EFSA's own risk assessment should be evaluated provided that a comprehensive
481 description of all data, processes and methods is available and therefore fulfils the same
482 quality, criteria as applied to opinions expressed by EFSA.

483 The nature of the question answered by an opinion and the data base used to answer the
484 question, are of paramount importance. An individual data set may be appropriate for
485 performing a specific risk assessment to answer a particular question. The same data set may,
486 however, not be appropriate in a different context. In the area of chemical risk assessment, the
487 data on the toxic potential of a chemical compound in mammals (used for the hazard
488 characterisation of that chemical) can frequently be used for different risk assessments, while
489 human exposure assessments may often differ widely depending on the context. Examples are
490 the exposure of the general population versus exposure to the same chemical compound from
491 the workplace, or specific exposures scenarios within the EU population versus international
492 exposure scenarios. Therefore, the terms of reference need to be checked carefully before
493 considering an opinion expressed by another international body is to be used by EFSA's
494 Scientific Committee or Panels.

495 The following important information needs to be clearly evident in the opinion:

- 496 • clear statement on the nature of the question to be answered
- 497 • comprehensive description of the data used
- 498 • comprehensive description of the processes and methods used in the assessment

499

500 Based on this information, a qualified decision can be taken on whether an opinion of an
501 international body may be fully or partially used by EFSA's Scientific Committee or a Panel.
502 In any case, an update of such an opinion with data which may have become available since
503 its publishing needs to be considered.

504 **4.2. Opinions expressed by national bodies/committee**

505 Opinions expressed by national authorities often focus on national situations and may also
506 contain risk management elements. However, in principle the same criteria as outlined in
507 Section 4.1, also apply to opinions expressed by national authorities.

508 **4.3. Diverging opinions**

509 Diverging opinions on the same topic expressed by different risk assessment bodies are
510 difficult to be interpreted by risk managers. In general, such diverging opinions should be
511 avoided as far as possible. In that respect, the EFSA Scientific Committee and Panels should
512 respect the procedure foreseen in Article 30 of Regulation (EC) No 178/2002 precisely to
513 identify and possibly to resolve diverging scientific opinions. That procedure *inter alia*
514 foresees that, in case the diverging views between assessment bodies persist and cannot be
515 resolved, EFSA and the other body should prepare a joint document clarifying the contentious
516 scientific issue identifying the relevant uncertainties in the data.

517 **CONCLUSIONS AND RECOMMENDATIONS**

518 The Scientific Committee considers the following general principles of scientific transparency
519 as essential in every risk assessment.

520 *General*

- 521 • EFSA opinions must have a high degree of transparency with regard to the data, methods
522 of analysis and assumptions that are used in the risk assessment process.
- 523 • Transparency is needed in all parts of the risk assessment.
- 524 • A transparent risk assessment should be understandable and as far as possible
525 reproducible.
- 526 • Where possible, harmonised assessment terminology should be used, preferably based on
527 internationally accepted terminology.
- 528 • The procedure by which a risk assessment is completed needs to be based on accepted
529 standards of best practice.
- 530 • When circumstances require that a scientific assessment is provided within a limited time
531 period (e.g. in a crisis situation), the effect of this on the uncertainty of the response
532 should be clearly explained, and options and timescales for reducing that uncertainty
533 should be described.

534 *Scope and objectives*

- 535 • The scope and objectives of the risk assessment should be carefully considered and
536 documented, and if necessary, clarified with the originator of the request before the
537 commencement of the risk assessment.

538 *Data and data sources*

- 539 • A risk assessment requires a comprehensive description of the observations and the
540 experimental and/or environmental conditions under which the data were generated.
- 541 • The sources of all data used for the assessment, including unpublished data and personal
542 communications, must be identified and the data critically evaluated to determine their
543 quality and relevance to the assessment. This should be reflected in the relative weight
544 given to them in the assessment and taken into account in the overall evaluation of
545 uncertainty.
- 546 • If data bases, data banks and information systems are used to undertake literature data
547 surveys relevant for EFSA's activities, the identity of the data bases, data banks and

548 information systems used, should be documented along with the key search terms and
549 strategies applied and time period covered.

550 *Inclusion and exclusion of data*

- 551 • All the data and information available for the assessment are evaluated but only those
552 judged to be relevant should be used as the basis for risk assessment.
- 553 • The inclusion/exclusion criteria applied to the data should be clearly explained and
554 described within the risk assessment. If data are excluded, this should be stated clearly in
555 the opinion along with the rationale for their exclusion (e.g. poor quality).

556 *Confidential data*

- 557 • The requirements in the 2005 Decision of the EFSA's Management Board apply to
558 transparency and confidentiality of data. The approach taken is that the maximum amount
559 of information linked to EFSA's activities shall be disclosed or made accessible to the
560 public, and that only the essential minimum should be kept confidential where this is
561 justified.

562 *Assumptions*

- 563 • All assumptions should be documented and fully explained. Where alternative
564 assumptions could reasonably have been chosen, this is a form of uncertainty and should
565 be documented and evaluated together with other uncertainties (see below).

566 *Assessment*

- 567 • In qualitative assessments, conclusions are expressed in narrative argument. In
568 quantitative assessments conclusions are based, at least partly, on calculations or
569 mathematical models. In both cases, transparency requires that every element of the
570 reasoning, calculation or mathematical modelling should be communicated and justified
571 in such a way that it can be understood by others.
- 572 • Whenever mathematical models are used, it should be described whether, by what means
573 and to what extent they have been validated or evaluated, e.g. comparison with
574 independent data or review by independent experts.

575 *Variability and uncertainties*

- 576 • There may be differences in risk due to variability among individuals, populations,
577 species or ecosystems. It is important to identify and describe the most influential
578 contributors to variability in risk, preferably by statistical analysis of the underlying data.
579 However, the relevance of statistical differences interpreted in the absence of an
580 understanding of the biological process has always to be assessed with caution.

- 581 • Although it may be impossible to identify all the uncertainties, each opinions should
582 describe the types of uncertainties encountered and considered during the different risk
583 assessment steps, and indicate their relative importance and their influence on the
584 assessment outcome.
- 585 • Expression of uncertainty or variability in risk estimates may be qualitative or
586 quantitative, but should be quantified to the extent that is scientifically achievable.
- 587 • Where factors are used to account for uncertainty, an explanation of their basis and their
588 appropriateness or a reference to documents where that information may be found should
589 be included
- 590 • Where point estimates are used for variable or uncertain quantities, justification for the
591 values chosen and assessment of their influence on the assessment should be included

592 *Conclusions of a scientific opinion*

- 593 • Conclusions should address the terms of references, should reflect the scope and
594 objectives of the risk assessment and provide a clear characterisation of the risk under
595 consideration, including the degree of scientific uncertainty. All key scientific information
596 underpinning the assessment should be outlined including uncertainties and data gaps;
- 597 • Conclusions should be based only on data previously described in the opinion;
- 598 • The reasoning leading to the conclusions should be clearly described. Where applicable,
599 the degree of consistency with risk assessments by other bodies should also be stated.

600 *Opinions issued by bodies/committee other than EFSA*

- 601 • Risk assessments may be performed on the same compound, agent or topic by different
602 risk assessment bodies at national, European or international level. Such opinions should
603 be considered by EFSA's Scientific Committee or Panels. Their relevance to EFSA's own
604 risk assessment should be evaluated provided that a comprehensive description of all data,
605 processes and methods is available and therefore fulfils the same quality criteria as
606 applied to opinions expressed by EFSA.
- 607 • The same data set may, however, not be appropriate in a different context. Therefore, the
608 terms of references need to be checked carefully before considering whether an opinion
609 expressed by another international body can be used by EFSA's Scientific Committee or
610 Panels.
- 611 • In case of diverging opinions, the procedure foreseen in Article 30 of Regulation (EC) No
612 178/2002 should be followed closely to identify and possibly to resolve diverging
613 scientific opinion.

614

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687 **GLOSSARY / ABBREVIATIONS**

688

689 **CODEX:** Codex Alimentarius Commission

690 **EC:** European Commission

691 **ECHA:** European CHEmicals Agency

692 **EFSA:** European Food Safety Authority

693 **EMA:** European Medicines Agency

694 **EU:** European Union

695 **FAO:** Food and Agricultural Organization of the United Nations

696 **GLP:** Good Laboratory Practice

697 **IPCS:** International Programme on Chemical Safety

698 **IPPC:** International Plant Protection Convention

699 **JECFA:** Joint FAO/WHO Committee on Food Additives

700 **JMPR:** Joint FAO/WHO Meeting on Pesticide Residues

701 **OECD:** Organisation for Economic Co-operation and Development

702 **OIE:** World Organisation for Animal Health

703 **SCCP:** Scientific Committee on Consumer Products

704 **SCF:** Scientific Committee on Food

705 **SCHER:** Scientific Committee on Health and Environmental Risks

706 **WHO:** World Health Organization

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