

Advisory Forum Recommended Good Practice: substantive divergence over scientific issues (Article 30 (4))

1. Introduction

Regulation (EC) 178/2002¹ sets out provisions in Article 30 relating to diverging scientific opinions, with obligations on EFSA to maintain vigilance in order to identify potential sources of divergence at an early stage and for EFSA and Member State (MS) bodies to cooperate in circumstances where divergence occurs. Specifically, Article 30(4) states obligations for EFSA and MS in cases of substantive divergence over scientific issues (see Annex 1).

In addition, the Advisory Forum has a role in ensuring cooperation in these circumstances by virtue of Article 27 (4b).

2. Scope

These guidelines describe the actions to be taken by EFSA in cooperating with a national body to resolve divergence or prepare a joint document as described in Article 30 (4).

4. Substantive divergence (Article 30 (4))

4.1 Diverging scientific opinions can arise at any stage of development of a scientific output prepared by EFSA and a national body in parallel. In addition, there is the possibility that either EFSA or the national body will commence work on developing a new opinion relating to an issue where there is already a published opinion.

4.2 As soon as it becomes evident there is likely to be substantive divergence over a scientific issue, the Head of the relevant Units in EFSA and the national body should ensure that their line management

¹ *OJ L 31, 1.2.2002, p. 1-24*

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

is made aware of the situation leading to divergence without delay. The AF member of the MS and the respective European Commission services should also be informed.

4.3 If not already available, a request for any missing information and data relating to the relevant opinion should be made. The information should be provided without delay in the spirit of cooperation and the *Declaration of Intent* (signed at the 18th EFSA Advisory Forum meeting in Berne, 29 September 2006) and in meeting the obligation of Article 30 of Regulation (EC) 178/2002. EFSA will share with the national body all relevant supporting data and documents without prejudice to requirements regarding data protection and confidentiality.

4.4 A scientific meeting (physical or by telephone/web conference) should be convened and held involving appropriate experts and staff from both parties. Where relevant, the European Commission may be invited as an observer.

EFSA and the national body will discuss and agree on appropriate expertise and number of experts and staff to attend the meeting. The meeting will be co-chaired by a senior representative of EFSA and the concerned national body. The purpose of the meeting will be to review the scope and progress of both the EFSA and MS draft or already adopted opinions to discuss the areas of divergence.

Where possible, all relevant documents for discussion at the meeting should be made available by both parties to each other two weeks before the meeting.

4.5 The outcome of the meeting will be the production of a joint document (which may take the form of detailed meeting minutes agreed by both parties) as described in Article 30 (4). The document shall reflect the main discussions and conclusions of the meeting, and if the divergence of views cannot be resolved, the document shall clearly identify the areas of the divergence and the justification. The document should be completed with as little delay as possible after the meeting. Additional meetings (physical or virtual) can be arranged as necessary, but in a time frame intended to minimise any delay in concluding the document.

4.6 Once the document is agreed between the parties, it will be published on EFSA's website and the web site of the national body, along with the final Opinions.

5. List

5.1 EFSA will maintain a list of all matters that have been subject to Article 30(4) procedures.

Annex 1: Article 30 (4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Article 30

Diverging scientific opinions

4. Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.