



NOTE FOR THE ADVISORY FORUM

**UPDATE ON THE PROGRESS OF THE SCIENTIFIC COMMITTEE
WITH REGARD TO THE WORK
ON THE SAFETY ASSESSMENT OF BOTANICALS**

1. The EFSA Scientific Committee adopted a discussion paper on botanicals and botanical preparations widely used as food supplements and related products in June 2004. In this paper, the Committee expressed concerns about quality and safety issues of botanicals and botanical preparations that have become widely available to consumers through several distribution channels in the EU. As the market volume and the variety of products expand, so does the need for a better characterization of the range of botanicals and botanical preparations present on the market, and for harmonizing the risk assessment and consumer information approaches for these products.
2. EFSA drew the attention of the Advisory Forum to these concerns at its meeting of 1st October 2004. In order to have a clearer picture about the extent of the issue, EFSA invited the Advisory Forum members to complete a questionnaire on the information available in their countries and any related national initiatives.
3. In August 2005 EFSA gave to the Scientific Committee a mandate on botanicals and botanicals preparation which comprised three main questions: 1) the analysis of the information provided by 25 countries in response to the questionnaire sent to the Advisory Forum; 2) the preparation of a guidance document on how to assess the safety of botanicals and botanical preparations to be used in food and feed; and 3) the establishment of a list of main categories of botanical and botanical preparations and the prioritization of the products to be considered for a safety assessment.
4. The Scientific Committee established a working group who met five times since September 2005. The working group issued a proposal for a way forward, which is

Note on the progress of the SC on its work on the safety assessment of botanicals and botanical preparations

likely to be endorsed by the Scientific Committee at its next plenary meeting on 31 May-1st June 2006.

5. EFSA would like to share the result of the questionnaire as well as the approach proposed by the Scientific Committee Working Group with the Advisory Forum at the meeting on 19 May 2006. The proposal addresses the following:

The Working Group focused its work on botanicals and botanical preparations used as food supplements, although the approach chosen is, in principle applicable to other uses in food and feed.

Botanicals and botanicals preparation for which an adequate body of knowledge with regard to their safety and use is available could benefit from a Qualified Presumption of Safety (QPS).

Botanicals and botanical preparations which could not be granted a QPS status would go through a more thorough safety assessment, for which further guidance will be developed.

An *ad hoc* approach will be developed for the safety assessment of botanical and botanical preparations which contain substances with medicinal properties.

Two lists are being compiled: 1) a list of botanicals known not to be used a food supplements unless evidence is provided on the absence or compliance with maximum levels of specific substances known to be toxic or addictive or psychotropic or otherwise undesirable; 2) a list of botanicals whose possible use as food supplements should be dependent on restrictions because they are known to also have a medicinal use. These lists would be used a tool to define priorities and should be periodically updated by EFSA.

6. Assuming that the approach would be endorsed by the Scientific Committee the Working Group will focus on the following activities in the coming months: the development of criteria for granting a QPS status to botanicals and botanical preparations, the development of a QPS list applying these criteria, the completion of the two lists of plants showing toxicological concern and medicinal properties, the development of criteria for the botanicals and botanical preparations to be assessed in priority, the development of a method for the safety assessment of botanicals and botanical preparations which would not be granted a QPS status, the establishment of specific requirements for botanicals and botanical preparations containing medicinal substances, the possible application of the overall approach in the feed area.