



***UPDATE ON SAFETY EVALUATION OF BOTANICAL
INGREDIENTS FOR FOOD SUPPLEMENTS***

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A MAJOR AND HIGHLY COMPLEX TASK

- **Providing guidance on how to ensure safety of botanicals and botanical preparations used in food supplements has been a major and highly complex work for the EFSA's Scientific Committee and experts from Member States participating in such an undertaking.**

MOTIVATIONS OF THE WORK CARRIED OUT BY EFSA ON BOTANICALS INGREDIENTS OF F.S.

The work carried out by EFSA in this sector has been motivated by the:

- the recognition of the physiological/nutritional value of food supplements consisting of botanicals and botanical preparations able to provide a number of useful naturally-occurring active substances present in such products; and
- the lack of harmonization among M.S. in the ways they regulate this sector.

CONSIDERABLE LACK OF HARMONIZATION IN MEMBER STATES

- **An overview, published in mid 2007 by AESGP, clearly showed, according to documents officially published by the competent Authorities in 20 EU Member States plus Croatia and Switzerland, that, out of about 1900 herbal species, several hundreds botanical species are: (i) prohibited from use in some M.S. and not regulated in other; or (ii) allowed for use in some M.S., prohibited in other M.S. and not regulated in other M.S.; or (iii) allowed for use in some M.S. and not regulated in other M.S.**

THE MAIN OBJECTIVE OF THE EFSA WORK ON BOTANICAL INGREDIENTS

The main objective of the EFSA guidance document is, in response to the encouragement received from M.S., to assist in avoiding, through proper selection of botanical species, of plant parts and other means such as selective extraction procedures and *ad hoc* treatments, exposure of consumers, through food supplements, to undesirable substance(s) often largely naturally-occurring in botanicals and botanical preparations and to promote harmonization of the internal market.

THE EFSA GUIDANCE APPROACH IS A SUBSTANTIAL HELP TO ENSURE SAFETY OF BOTANICAL FOOD SUPPLEMENTS

- **The safety guidance approach worked out by EFSA is based on the long term history of safe use with no reported adverse effects and no significant increase of human exposure as long as no substances of concern are known to be present. Therefore, for botanical ingredients for which such conditions apply, this safety guidance approach does not impose any new burden on the operators of the food chain in this sector.**

THE GUIDANCE DOCUMENT

- The guidance document for safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements includes: (i) Data requirements for the assessment; (ii) Science-based framework for the assessment; (iii) Criteria for priority setting; and (iv) the Compendium.
- The ESCO Report provides examples how to apply the safety assessment approach proposed by EFSA.

THE COMPENDIUM

- The Compendium is intended to flag botanicals or part of botanicals containing naturally substances of concern for human health (e.g. toxic, addictive or psychotropic). More than 1000 genus, species and varieties are listed and documented. It.
- The presence of a substance of concern in a given botanical product does not mean necessarily that this substance will also be present at levels of concern in the food supplement. Therefore, this information in itself is not prejudicial of the possible use.
- Therefore, the Compendium in itself does not imply any judgment on whether listed botanicals are suitable or not suitable for applications in food supplements.

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- **Absence among the more than 1000 species listed in the Compendium of a botanical species for which an evidence of long term use exists, implies no detection so far of any substance(s) or data of concern and provides for a much stronger presumption of safety.**
- **As many as about 650 botanical species which, according to the above-mentioned AESGP Publication, are used in one or more EU M.S., plus Croatia and Switzerland, in food supplements are not mentioned at all in the EFSA Compendium and are, therefore, confirmed not to have any specific reasons for concern according to such criterion.**

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- **The listing in the Compendium of a specific botanical species implies the possible presence in it of one or more carcinogenic substances or toxic substances at subacute levels, with the consequence that the long term use without reports on adverse effect cannot be any more considered sufficient in its own to ensure safety as the health impact of such substances could be extremely difficult to detect in the absence of *ad hoc* epidemiological investigations.**

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- **In such a case, it is obviously necessary either avoid the use of the botanical part or to develop, where possible, a rationale for use indicating why the data reported in the Compendium are not relevant for the safety of the specific product, This may depend e.g. on the use of botanical part devoid of the specific substance of concern or of extraction methodology preventing the carry over of the substance of concern).**

- **As many as about 260 botanical species which, according to the above-mentioned AESGP Publication, are used in one or more EU M.S. in food supplements, are also included in the Compendium. The corresponding products are the ones that would need to be examined to ensure that the reason for concern reported in the compendium does not apply to them.**

- **As many as about 750 botanical species, which, according to the above-mentioned AESGP Publication, are not used in any in food supplements in the EU M.S. plus Croatia and Switzerland, are included in the Compendium, thus providing an explanation of why they are not used.**

- **Finally, there about 250 botanical species which, according the ASGP Document are currently not used in food supplements in any E.U. Member States or Croatia and Switzer-land, and are not currently included in the Compendium.**
- **It is unclear whether this is due to lack of benefits, to lack of data or reasons for concern not explored yet by the Compendium or to any other reasons.**

- **IN CONCLUSION, of the above-mentioned 1900 botanical species listed in the 2007 AEGSP Publication:**
- **About 40% are reported not to have use as food supplements and are also listed in the EFSA's Compendium;**
- **About 33% are reported to have uses as food supplements and are not reported in the EFSA's Compendium;**
- **About 14% are reported to have uses as food supplements and are also reported in the EFSA's Compendium:**
- **About 13% are reported not to have food use and are not mentioned in the EFSA's Compendium .**

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For botanicals for which it is impossible to establish a recognized presumption of safety, the EFSA guidance document adopted by EFSA SC introduces also a framework for assessing their safety, including the types of additional testing that would be most useful.

THE RECENT WORKSHOP IN ATHENS (24 NOVEMBER 2009)(Recommendations not finalized yet).

- **The EFSA Guidance Document and its Compendium should be used by all those who are responsible for the safety of botanical food supplements:**
- **The presentation of the Compendium should be improved to avoid misunderstandings and misuses;**
- **A reasonable and effective way forward should be found to collaborate more with stakeholders;**
- **Possible role of the Plant-LIBRA European Project in taking a key role in a series of follow up actions.**