Our Reading of the Plant Decree

The plants decree has been published July 17th, 2014 «laying down the list of plants, other than mushrooms, authorized in food supplements and their conditions of use». You'll find here below a reading of the publication - especially annexes II et III

The plant decree was published on July 17, 2014 in the official journal, laying down the list of plants, other than mushrooms, authorized in food supplements and their conditions of use. Its implementation is January 2015, 1st. The list of fungi, and probably essential oils, will be the subject of further publication.

This decree includes 14 articles, describing the terms used and the applications, and 3 annexes.

This text is intended for all players acting in the production, processing and distribution of food supplements. It refers to the other decrees of this sector, such as the European Directive 2002/46 / EC and its amendments, including national decrees (2006/352, 1170/2009). It gives the list of plants authorized on the market and / or mutual recognition by Article 16.

Annex I

Annex I lists the 540 authorized plants (at the date of June 2014), with :

Their scientific name and family : synonyms exist in several cases . If necessary, you can also visit the website www.theplantlist.org

Their vernacular name

The part(s) used

The substances to be monitored : it is not necessarily substances to be absent or undetectable, but substances that the decree specifically request to be checked.

The restrictions of use: mainly specific labeling warnings (child, pregnant women), sometimes about the process.

Annex II

Annex II contains information that may be provided by operators in the sector in order to understand the preparation. As such, a model was proposed by Synadiet and Food Supplements Europe. This model is split into several parts. There is no obligation to complete each field, as indeed it's just a model-form :

Plant (ie. Raw Material)

Plant Description : Scientific name, vernacular name, family, existing monograph, risk of falsification (by another similar plant for example)

Culture method (geographical origin, method of cultivation, specific agreements, licensing, 338/97) and collection (collected plant parts , mechanical or manual cleaning, drying)

Parts of the plant used and its identification (controls, markers, purity)

Production process (starting from the plant)

Geographical location of the process (unit), manufacturer, preparation before process (grinding, separation, ...)

Description of the extraction process from the raw material (ex. if it is extracted from an oleoresin, it is necessary to mention the process from the plant): solvent (concentration and quality) for extraction, purification, and any other step (elimination of compounds or hazardous compounds).

Other information related to the process, definition of a batch, size

Plant preparation (ex. Plant extract for BECARRE Natural)

Name , PER (Plant Extract Ratio: final ratio after extraction and before any other addition and the initial amount of extracted plant - dry /dry if it is a dry extract), DER (Drug Extract Ratio: ratio between the final ratio of the preparation and the initial amount, so after addition any additives or carrier ...). A product without carrier shows a PER = DER. Sometimes indicated, the NER is the native ratio

Full composition (in %, with the nature and purpose of each component, purity criteria additives - 231/2012)

Standardization (markers, actives) with a detailed method of analysis (validated / internal validation) and the standard used as a reference

Substances to be monitored : with reference to Annex I or any other molecule needing to be monitored

Impurities (eg 2009/32), contaminants, bacteriological controls, other controls, see ... 1881/2006, 629/2008, 1259/2011, etc

Statements, other data : nutritional data, GMO (1829 and 1830/2003) Irradiation (1999/2, 1883/2003), allergens (2007/68, 2000/13), ...) ...

Stability data with the reference (ICH ?), does it need homogenization, ...

In addition, BECARRE Natural completed the form of a preparation to additional food safety information when available, although Annex III is not needed..

- **Exposure Level** : consumption of the plant, of the extract
- **Risk analysis** : toxicity studies, genotoxicity, mutagenicity, safety, NOAEL
- **Traditional use**
- **Possible evolution** of the process

Annex III

This third part relates to the safety of the plant preparation, and it must be completed when there is a doubt, or when the plant preparation does not have enough history to justify its safety. Regarding the safety for the consumer, it is provided by the manufacturer of the food supplements, with the support - in our view - of each manufacturer involved.
Annex III may correspond to a 'simple' analysis of the literature of available toxicological data and / or made by the producer, as an extensive risk analysis in the case of conflicting studies, or molecules interaction, or whenever the specific analysis needs.

Which products are concerned by Annex III ?

All products are concerned since the risk analysis must be done on all extracts but not all require a Annex III.
It is important to understand that Annex III is applicable when the plant preparation cannot refer to an existing and traditional use enough to guarantee the safety of a plant preparation (or food supplements), as it exists and has existed on the market.
Thus, a plant extract may be traditionally produced in a PER of 15:1 and by using a high solvent (eg, pure ethanol). It is this extract which is known, and can prove its safety - and so would not need an Annex III. Speaking of food safety, **we can refer only to what is clearly known**.

Collect of information

The traditional use can be justified by various ways, including probably monographs, references in pharmacopoeia (with specific description of the extract and not only of the plant), references to EMA, relation to the WEU (Well Established Use), or from pharmaceutical agency, etc ... describing the extract (plant part, solvents and concentration processes, ratio), and with the Annex II to confirm that the plant extract that is offered is conform to traditional extract.

From Risk analysis to Annex III

3 possible cases

The **preparation is described in the literature** to demonstrate the history of use and safety. It is sufficient to indicate.
The **preparation is not described in the literature** but the **argument** shows **that the extract is equivalent to one described preparation**. It should provide the rationale for comparing the described preparation and its extract.
The **preparation is not described in the literature** and **no equivalent that can be demonstrated**: it is necessary to bring the safety analyzes - including toxicology - in relation to the identified hazards to be indicated in Annex III.


Ministero della Salute

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Italy : « Regulations on the use substances and plant preparations in food supplements »

FOCUS HINTS