BEE PRODUCTS – FOOD - FOOD CONSTITUENTS, HOW DOES THEIR FUTURE LOOK LIKE?

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• Regulation 1924/2006 on nutrition and health claims made on foods specifies in article 13 that health claims describing or referring to:
  • the role of a nutrient or other substance in growth, development and the functions of the body;
  • psychological and behavioral functions;
  • without prejudice to Directive 96/8/EC, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet, which are indicated in the list provided for in paragraph 3, may be made without undergoing the procedures laid down in Articles 15 to 19, if they are:
    - based on generally accepted scientific evidence;
    - and well understood, accepted by the average consumer.
Bee products, can they present nutritional and health claims?
Bee products – what is the category in which they could be included: foods, diets, probiotics, botanicals, vitamins, minerals, others?
Common or at least similar provisions for the health claims associated with bee products are becoming now a reality once that the Regulation 1924/2006 is put into practise and an evaluation from the EFSA (European Food Safety Authority) is still in progress.

Thus all the knowledge accumulated along the young scientific history of apitherapy with: authoritative bodies’ appointments, books, reviews, clinical trials, human studies, animal studies were considered valuable tools in building up the health claims for at least those bee products that cannot be really defined as medicines.
Bee products – legal status
## Nutritional and/or therapeutic value of the bee products

<table>
<thead>
<tr>
<th>Product</th>
<th>Nutritional value</th>
<th>Therapeutic importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bee Pollen</td>
<td>FOOD</td>
<td>Medicine</td>
</tr>
<tr>
<td>Honey</td>
<td>FOOD</td>
<td>Medicine</td>
</tr>
<tr>
<td>Royal Jelly</td>
<td>Food</td>
<td>Medicine</td>
</tr>
<tr>
<td>Propolis</td>
<td>None</td>
<td>MEDICINE</td>
</tr>
<tr>
<td>Bee venom</td>
<td>None</td>
<td>Medicine</td>
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</tbody>
</table>
Unfortunately, EFSA have already published many unfavourable opinions on bee products and supplements based on bee products and these opinions were linked to the “poor quality of the information” provided to EFSA. Information gaps included, for instance: the inability to identify the specific substance on which the claim is based; the lack of evidence that the claimed effect is indeed beneficial to the maintenance or improvement of body functions; or the lack of precision regarding the health claim being made.
So, is bee pollen FDA approved or disapproved? To answer the question shortly, the Food and Drug Administration does recognize the bees pollen substance to be a food that is generally safe for human consumption (but, as mentioned in the paragraph before, people with allergies should be really careful when dealing with bee products like honeybee pollen since they could suffer an allergic reaction by consuming this organic ingredient). However, natural pollen bee cannot be marketed as a medicine or drug that is able to heal diseases such as cancer (since there is no conclusive evidence that bees pollen can be used with the treatment of cancer for example).
Propolis as medicine

Clinical Studies

Scientific References

Validation Procedures

Technological Process

Technical Specification

Pharmaceutical Dossier

Expert Advice
(formulation, technology, technical specifications etc.)
The food(s)/food constituent(s) that are the subject of the health claims are propolis or flavonoids in propolis related to the following claimed effects: “respiratory health”, “antibacterial and antifungal activities”, “throat comfort”, “gut health”, “supports immune defences”, “maintenance of oral health”, “helps to maintain a normal blood circulation” and “hepatoprotective”.

The references provided reported on differences in biological activity between propolis preparations from different sources. Levels of what are assumed to be biologically active constituents in some propolis preparations are low or undetectable in other propolis preparations. Further, the papers provided for the scientific substantiation of the claims reported on a wide range of different propolis preparations, extracts and isolated components, and it is not clear for which type of propolis preparation/constituent the claims are made.
Propolis – oral health

Clinical Studies

- Rêgo D.M., H.C.N. Mota, and E.M. Silva, - Clinical evaluation of the effects of propolis on biofilm and chronic gingivitis - Seq #82 - Therapeutic Intervention - Adjunctive Treatment
ROYAL JELLY HEALTH CLAIMS

Royal jelly related to the following claimed effects:
—natural defence/immune system,
—metabolism,
—vascular function,
—glands function,
—skin health,
—tonus/vitality—an anasthénique, immunostimulant,
—ménopause, effet oestrogénique, hypolipidémiant,
—vitalité physique et intellectuelle and
—helps heart health and to maintain a balanced level of cholesterol and lipids in the body (ID 1225, 1226, 1227, 1228, 1230, 1231, 1326, 1328, 1329, 1982, 4696, 4697).

In the human studies provided which addressed outcomes related to the claimed effects the origin and composition of the royal jelly used was not specified.

The Panel noted that from the references provided it was not possible to characterise royal jelly in general, nor the specific components of royal jelly mediating the functions for which the claims were made.

The Panel considers that royal jelly, which is the subject of the claims, is not sufficiently characterised in relation to the claimed effects considered.

The Panel concluded that a cause and effect relationship cannot be established between the consumption of royal jelly and the claimed effects considered.
**Royal jelly – immune system health**

**Human studies – meta-analysis**

**Animal studies**

**In vitro and in vivo studies**
Conclusions

• According to their properties, supported by scientific evidence, as shown already, bee products can be appointed as both medicines, food and food supplements and also as active ingredients in the composition of cosmetic care products;

• Each type of products however, should comply with the European legislation in force as with EMEA, EFSA etc.

• The legislation related to medicines is highly demanding but still bee products as propolis, and hopefully bee venom, could find their way as natural medicines with really proven clinical efficacy.
Thank you for your attention!