

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

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APIMONDIA 2011 – BUENOS AIRES ARGENTINA



# The Nutrition and Health Claims Regulation (EC) No. 1924/2006

- 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?





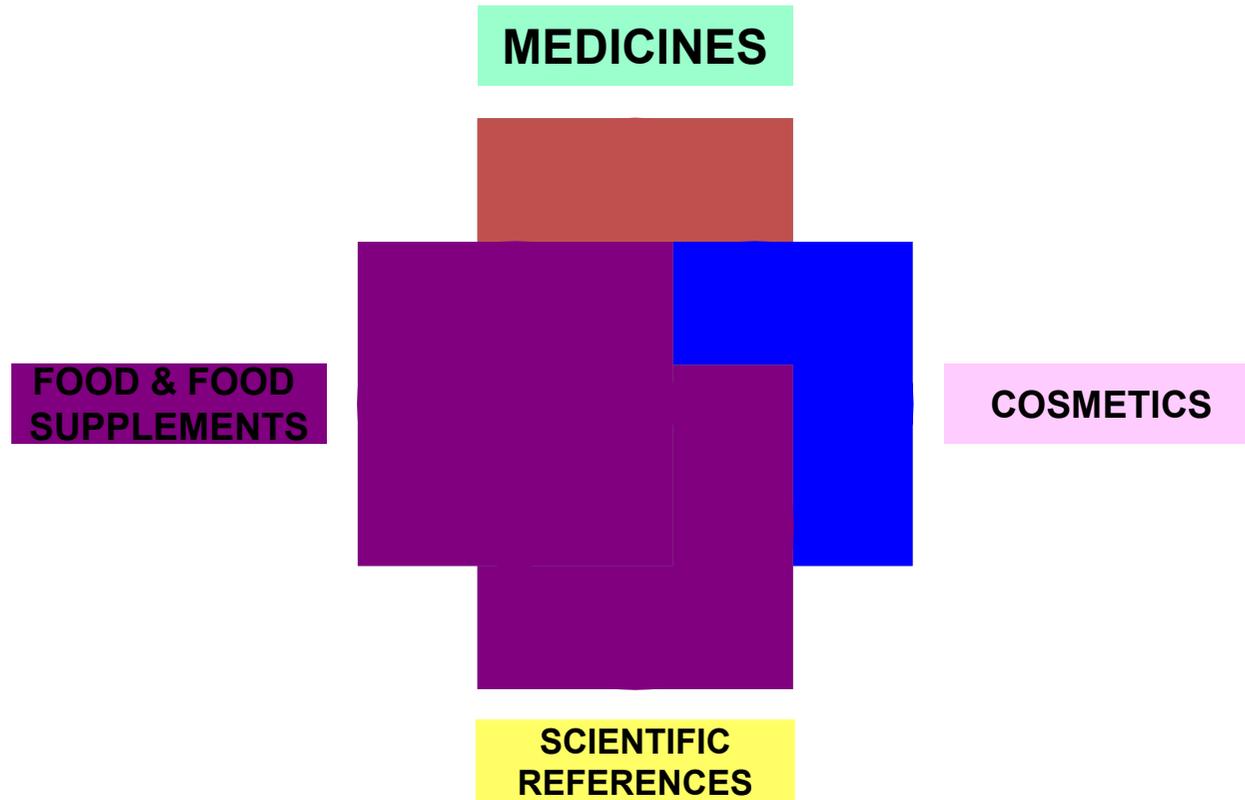
Bee products – what is the category in which they could be included:  
foods, diets, probiotics,  
botanicals,  
vitamins,  
minerals,  
others?



# The Nutrition and Health Claims Regulation (EC) No. 1924/2006

- **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

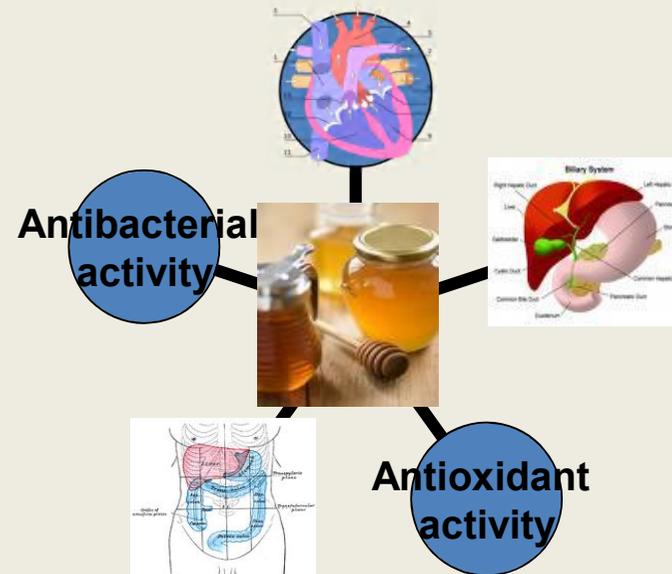
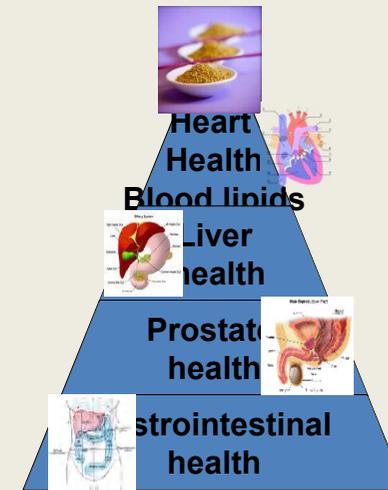


# Nutritional and / or therapeutic value of the bee products

<u>Product</u>	<u>Nutritional value</u>	<u>Therapeutic importance</u>
Bee Pollen	FOOD	Medicine
Honey	FOOD	<i>Medicine</i>
Royal Jelly	<i>Food</i>	Medicine
Propolis	None	MEDICINE
Bee venom	None	Medicine

# Nutrition and Health Claims for Bee Products

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.

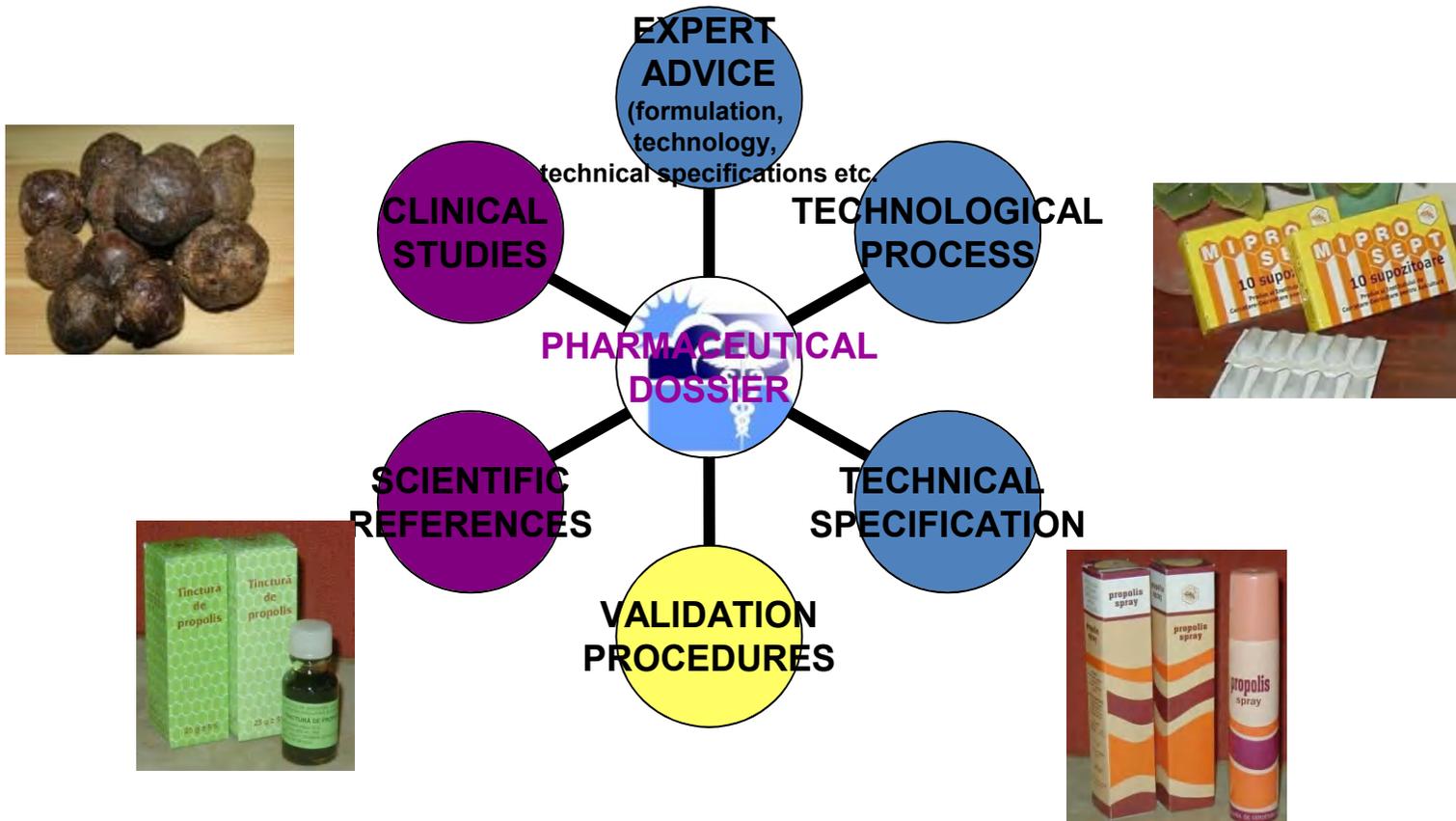


# Bee pollen

- 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



## PROPOLIS HEALTH CLAIMS

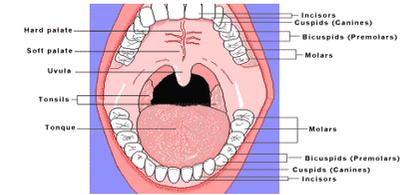
The food(s)/food constituent(s) that are the subject of the health claims are propolis or flavonoids in propolis related to the following claimed effects: “respiratory health”, “antibacterial and antifungal activities”, “throat comfort”, “gut health”, “supports immune defences”, “maintenance of oral 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.

Claim ID	Food or Food constituent	HEALTH RELATIONSHIP	Proposed wording
1242	PROPOLIS	improvement of ventilatory functions /Respiratory health	Promotes upper respiratory tract health Contributes to the resistance of the organism Supports the natural defence mechanism, especially at the level of the upper respiratory tract Pleasant for temporary croakiness For an appropriate and easy respiration Contributes to the respiratory comfort
1244		Antibacterial and Antifungal activities Target Group : For children and adults older than three years old Excluded Group : Avoid use during pregnancy and breast-feeding. Not for children younger than 3 years old, nor for people who are allergic to the propolis. Clarification provided Oral microbial balance	Soothing for throat and chest (airways).  Flavonoids contained within the propolis contribute to the microbial balance in the body organs and tissues.



# Propolis – oral health



## Clinical Studies

- - Botushanov,-P-I; Grigorov,-G-I; Aleksandrov,-G-A - A clinical study of a silicate toothpaste with extract from propolis. -Folia-Med-(Plovdiv). 2001; 43(1-2): 28-30
- - Gafar M, Dumitriu H, Dumitriu S, Guti L. Apiphytotherapeutic original preparations in the treatment of chronic marginal parodontopathies. A clinical and microbiological study -Rev Chir Oncol Radiol O R L Oftalmol Stomatol Ser Stomatol. 1989 Jul-Sep;36(3):161-6. (Romanian).
- - Ikeno K, Ikeno T and Miyazawa C. Effect of Propolis on dental caries in rats. Caries Res 1991 ;25: pp.347-51.
- - Ioniță R, Săcăluș A, Jivănescu M, Constantinescu I, Stanciu V, Bodnar C, Săcăluș C. - Experimentation of apiarian preparations for the direct and the indirect capping of the dental pulp] Stomatologie. 1990 Jan-Feb;37(1):19-30. Romanian.
- - Koo H, Cury JA, Rosalen PL et al. Effect of a mouthrinse containing selected propolis on 3-day dental plaque accumulation and polysaccharide formation. Caries Res 2002; 36(6): pp. 445-448
- - Kosenco SV, Kosovich Tiu. - The treatment of periodontitis with prolonged action Propolis preparations (clinical x-ray research). Stomatologia -MOSk 1990; 69: pp. 27-9.
- - Margo-Filho O and de Carvaho AC. Application of Propolis to dental sockets and skin wounds. J Nihon Univ Sch Dent 1990; 36:4-13.
- - Murray, M. C., et al. A study to investigate the effect of a propolis-containing mouthrinse on the inhibition of de novo plaque formation. J Clin Periodontol. 24(11): pp. 796-798, 1997.
- - Neumann, D., Gotze, G., and Binus, W. Clinical study of the testing of the inhibition of plaque and gingivitis by propolis. [Klinische Studie zur Untersuchung der Plaque- und Gingivitis-Hemmung durch Propolis.]. Stomatologie der DDR (1986) 36 (12) 677-681
- - Park YK, Koo MH, Abreu JA et al. Antimicrobial activity of propolis on oral microorganisms. Curr Microbiol 1998; 36(1): 24-28
- - 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
- - Samet N., , Caroline Laurent<sup>1</sup>, Srinivas M. Susarla<sup>1</sup> and Naama Samet-Rubinsteen<sup>1</sup> - The effect of bee propolis on recurrent aphthous stomatitis: a pilot study - Clinical Oral Investigations Volume 11, Number 2 / June, 2007 pp. 143-147
- - Santos FA, Bastos EM, Maia AB, et al. Brazilian propolis: physicochemical properties, plant origin and antibacterial activity on periodontopathogens. Phytother Res 2003;17:285-289.
- - Steinberg D, Kaine G, Gadalia I. Antibacterial effect of propolis and honey on oral bacteria. Am J Dent 1996; 9(6): 236-239

## ROYAL JELLY HEALTH CLAIMS

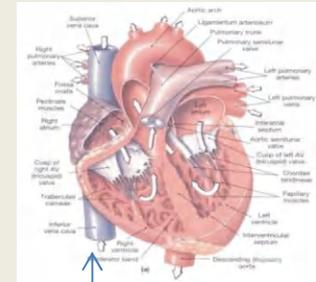
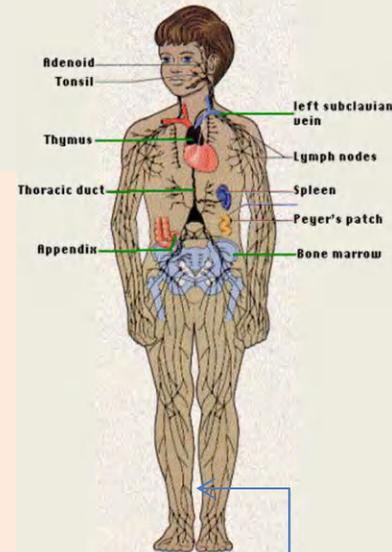
Royal jelly related to the following claimed effects:  
—natural defence/immune system, —metabolism,  
—vascular function, —glands function, —skin health,  
—tonus/vitality—anti-asthenic, immunostimulant,  
—menopause, effect oestrogenic, hypolipidemic,  
—physical and intellectual vitality and —helps 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.

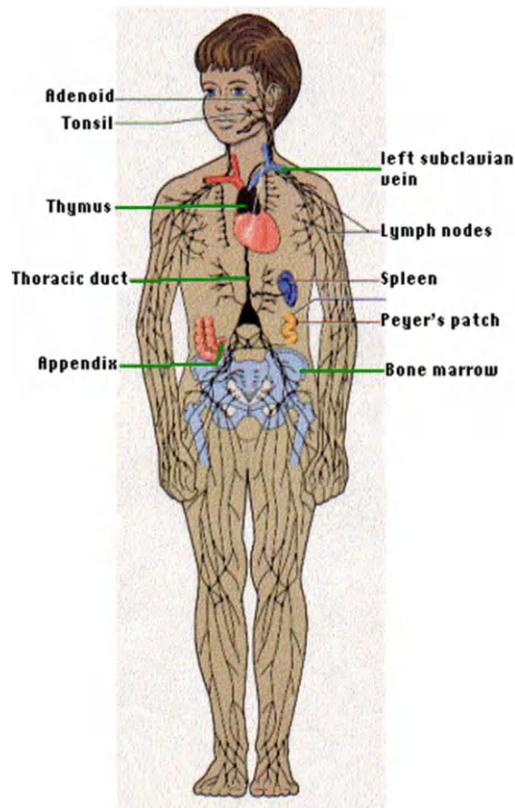
The Panel noted that from the references provided it was not possible to characterise royal jelly in general, nor the specific components of royal jelly mediating the functions for which the claims were made.

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**

- - Erem C, Deger O, Ovali E, Barlak Y. 2006 - The effects of royal jelly on autoimmunity in Graves' disease. *Endocrine*. 2006 Oct;30(2):175-83. PMID: 17322576 [PubMed - indexed for MEDLINE]
- - Kramer, K.J. Tager, H.S., Childs, C.N. and Spiers, R.D. (1977) Insulin-like hypoglycemic and immunological activities in honeybee royal jelly. *Journal of Insect Physiology* (1977), 23 (2): 293-295.

## **Animal studies**

- - Bincoletto C, Eberlin S, Figueiredo CA, Luengo MB, Queiroz ML. - Effects produced by Royal Jelly on haematopoiesis: relation with host resistance against Ehrlich ascites tumour challenge – *Int. Immunopharmacol.* 2005 Apr;5(4):679-88
- - Oka H, Emori Y, Kobayashi N, Hayashi Y, Nomoto K.- Suppression of allergic reactions by royal jelly in association with the restoration of macrophage function and the improvement of Th1/Th2 cell responses.- (2001) - *Int Immunopharmacol.* Mar;1(3):521-32.
- - Sver L, Orsolić N, Tadić Z, Njari B, Valpotić I, Basić I. - A royal jelly as a new potential immunomodulator in rats and mice. - *Comp Immunol Microbiol Infect Dis.* 1996 Jan;19(1):31-8
- - Taniguchi Y, Kohno K, Inoue S, Koya-Miyata S, Okamoto I, Arai N, Iwaki K, Ikeda M, Kurimoto M.-(2003) - Oral administration of royal jelly inhibits the development of atopic dermatitis-like skin lesions in NC/Nga mice. *Int Immunopharmacol.* Sep;3(9):1313-24

## **In vitro and in vivo studies**

- - Kimura M, Kimura Y, Tsumura K, Okihara K, Sugimoto H, Yamada H, Yonekura M. – (2003) - 350-kDa royal jelly glycoprotein (apisin), which stimulates proliferation of human monocytes, bears the beta1-3galactosylated N-glycan: analysis of the N-glycosylation site. *Biosci Biotechnol Biochem.* Sep;67(9):2055-8.
- - Kohno K, Okamoto I, Sano O, Arai N, Iwaki K, Ikeda M, Kurimoto M. – 2004, Royal jelly inhibits the production of proinflammatory cytokines by activated macrophages. *Biosci Biotechnol Biochem.* Jan;68(1):138-45.
- - Majtán J, Kováčová E, Bíliková K, Simúth J. - The immunostimulatory effect of the recombinant apalbumin 1-major honeybee royal jelly protein-on TNFalpha release. *Int Immunopharmacol.* 2006 Feb;6(2):269-78. Epub 2005 Sep 6.
- - Okamoto I, Taniguchi Y, Kunikata T, Kohno K, Iwaki K, Ikeda M, Kurimoto M. - Major royal jelly protein 3 modulates immune responses in vitro and in vivo. - *Life Sci.* 2003 Sep 5;73(16):2029-45
- - Vučević D, Melliou E, Vasilijic S, Gasic S, Ivanovski P, Chinou I, Colic M. - Fatty acids isolated from royal jelly modulate dendritic cell-mediated immune response in vitro. - *Int Immunopharmacol.* 2007 Sep;7(9):1211-20. Epub 2007 Jun 6
- - Wang, Guo-Yan; Lin, Zhi-Bin. Effects of 10-hydroxy-2-decenoic acid on phagocytosis and cytokines production of peritoneal macrophages in vitro. *Zhongguo Yaoli Xuebao* (1997), 18(2), 180-182.

# 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!**