

Legal issues related to the medicinal use of propolis and other bee products in Europe, in contrast with other continents, including North and South America
(paper presented during the international Apitherapy Symposium organized by [Nippon Apitherapy Society](#) in Japan, June 2006)

Situation in Germany:

- **Propolis tincture** is considered as a **medicinal product** and those that sells it needs to have a **legal certification** for their products;
 - **Raw Propolis** can be sold as a food supplement^[1], without any problem, as long as it has no medicine related advertising written on the label;
 - The **raw honey sellers** (original producers = *Urerzeugers*) needs to sell a honey that is at least 60% produced in their own apiaries; 40% of the sold honey by them can be bought from other beekeepers; the original honey producers does not need to be registered, especially if the number of their colonies is small (under 30 beehives);
 - Honey is considered as a FOOD and not as a medicinal drug and that is why it is not allowed to be advertised as a medicine; being considered as a FOOD it does not need complicate approvals to be sold;
 - Honey being a Food, it is forbidden to write on the label that it can help against various diseases, that it can diminish the risk of getting ill or it can protect against illnesses;
 - If somebody wants to certify a certain honey as being useful in the treatment of various diseases it must follow all regulations needed to get the approval for a classical medicinal drug;
 - The practice of Apitherapy (which is basically a healing method, a treatment) is allowed in Germany only to the medical doctors (included veterinarians) and to the licensed naturopaths (◆*Heilpraktikern*◆). The profession as ◆Apitherapist◆ is for the time being not recognized officially. All other non-MD◆s or non ND◆s people practicing Apitherapy can be punished by the law;
 - Since December 2005 the Apitherapy treatment, like any other natural healing treatment, can be paid by the state insurance companies in those cases that can not be solved by the classical, allopathic medicine;
 - If you are not a medical doctor, you are not a naturopathic doctor, you have not a big laboratory, being just a normal person, a small beekeeper or a small producer passionate of Apitherapy, the advise is to:
 - Tell as often as possible to all your customers on your own experience with bee products (how you got cured/improved of a certain disease/condition), or how somebody from your family or your best friends was protected from getting ill; nobody in this world can block you to speak on your experience or on the experience of other people you know; that is why, making step by step your real Data Base with ◆testimonials◆ (see <http://www.apitherapy.com/testimonials.php> as a model) is a very good idea;
 - Tell your customers on the huge variety of Apitherapy related literature (books, booklets, articles, journals, congress proceedings, CD◆s, DVD◆s, Videos, etc., etc.); in this literature the customers can find exactly why and how the bee products can prevent or cure a certain disease or condition, in humans or animals;
 - Create an Apitherapy Information Office that has as goal to spread various information on Apitherapy like where are the nearest approved Apitherapists, what are the best books on Apitherapy, etc.; to create such an office in Germany there is no need for a special approval; anybody can do it, in a simple room having inside an
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Apitherapy related library + a phone, a fax and a computer connected to the Internet; however, one must be cautious to not advertise the bee products and the use of

Apitherapy as a cure all method (panacea), having no risks;

- To create a National or a regional chapter of the larger National Apitherapy Society. A good example in Japan is Nippon Apitherapy Society. The Unity makes the Force!

Situation in Romania

Institute of Beekeeping Research and Development

Propolis tincture, **Miprosept** (propolis suppositories) and **Propolis Spray** (against burns and skin lesions) are considered medicinal remedies, because they have a clear medicinal destination, being used against clearly stated diseases.

Apireven (bee venom) cream + **Propoderm** creams are considered cosmetically products because their destination is skin care.

In Romania there are for the time being over 300 medical doctors licensed as Api-Phytotherapists. Romania is the first country in the world offering post-graduate Courses on Api-Phytotherapy to already working medical doctors.

Situation in Brazil

Pharma Nectar (President Jose Alexandre Abreu) released recently (June 05, 2006) through our E-mail Discussion List (Apitherapy-List) the following announcement:

Propolis (raw and extract), bee pollen, roval jelly and honey was regulated in Brazil as ordinary foods from animal origin, under sanitary inspection of Ministry of Agriculture. The standards for quality control and minimum requirements can be seen at the website of Ministry of Agriculture www.agricultura.gov.br : **Instru^o Normativa N. 3, de 19 de Janeiro de 2001.**

However, after a great pressure from apitherapists, researchers and pharmaceutical industry, since October 2005 it is possible to get a registration of propolis as a medicine, under some specific requirements from Ministry of Health:

- **This technical note covers all the propolis made products with any therapeutic indication.**
- Imported propolis made products must be in accordance with this technical note as well as the specific regulation for imported products.
- Minimum quality standards should be validated toward quality control inspection.
- Sales restrictions may be applied, depending on the pharmaceutical form and therapeutic indications, according to the general medicine regulation # RDC 138/2003.
- Eventual restrictions toward use indications may take in consideration the traditional use.
- Associations of propolis with other synthetic active ingredients may be considered **new medicines** and the registration request will be subjected to the **new medicines** regulation.
- Herbs extracts and/or their isolated substances associated to propolis may be accepted as long as they are used as adjutants.

Minimum Quality Requirements:

- Sensorial Characteristics: aspect, color and odor;
- Physico-chemical requirements: desiccation loss, total dust, insoluble dust in HCl, density, viscosity and pH;
- Figures: alcoholic grade (when applied), antioxidative activity, chemical markers (qualitative and quantitative), total phenolics, flavonoids, volatiles compounds, wax;
- Undesirable Contaminants: Microbiology pathogens including *Paenibacillus larvae*, coliforms, fungi east, additives, heavy metal, pesticides, foreign matters.
- Manufacturing process.
- Technical reports should be issued with all the above mentioned information.
- Description of bee species and botanical origin on the production site.
- Additional tests: antimicrobial activity (*in vitro*).

Safety and Efficacy Proves ♦

Efficacy tests are not demanded for topic use products with anti-inflammatory, anti-septic and healing indications. For other indications different from the traditional indications and associated with herbs extracts or any other active ingredients the manufacturer must show the following proves:

- 1) Phase III clinical trial on the therapeutic effect and toxicological tests.
- 2) Safety and efficacy proves may be demonstrated by means of indexed papers as long as the data base has been originated from the specific propolis to be registered. In this case a minimum 8 papers on clinical trials and safety are demanded.

Mr. Jose Alexandre S. Abreu (Nectar Farmaceutica Ltda)
(E-mail: pharmanectar@pharmanectar.com.br) adds:

♦The "Technical Note" just refers the products sold with some therapeutic indication; it is not enforcement to all grades of propolis but only for products sold as drug. Nowadays we cannot even make simple claims such as its well known antioxidant activity. So, in theory this new regulation will allow for an adequate room so that companies could produce and sell propolis made drugs. If we consider this side of coin, it could be an important and decisive step for *Propotherapy*. We could properly advertise for example the chemotherapeutic effect of propolis at high dosage and concentrations, we could define therapeutic protocols and most important do everything legally and openly. Propotherapy and Apitherapy would gain a lot, all chain, from the beekeepers to the patients.

What are the negative sides of this regulation? Clinical trials, toxicological tests and a pharmaceutical grade production plant is practically impossible to afford for a small beekeeping industry (in Brazil 95% of them are small). So, with the time being, the beekeeping industry will just be forced to abandon the propolis market because the end user will prefer to buy a propolis with some therapeutic indication than an ordinary propolis. We are sure that in terms of propolis, the pharmaceutical industry will gradually swallow the beekeeping industry.

As an intermediary remedy for this situation propolis could be registered optionally and additionally as a functional food, which is a truth and also allows for a set of health claims, but under the scope of food and not medicine. This transitory grade could allow the beekeeping industries to prepare themselves to fulfill the demanding pharmaceutical standards.

On the other hand it seems ironic that while [PubMed](#) (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed>) shows 85 works on the expression "propolis and cancer" (most conclusions of these documents suggest the chemotherapeutic or chemo-preventative use of propolis), we insist on keeping propolis as a mere food or food supplement...

Situation in USA

*U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
March 1999:*

Propolis, bee pollen^{2[2]}, and royal jelly are all co-products of honey production that are used in dietary supplements^{3[3]}

FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), **the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed.** FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. *Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements.* Manufacturers must make sure that product label information is truthful and not misleading.*

FDA's post-marketing responsibilities include monitoring safety, e.g. voluntary dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts, and accompanying literature. The Federal Trade Commission regulates dietary supplement advertising. Source: <http://www.cfsan.fda.gov/~dms/supplmnt.html>

CONCLUSION

Each company can register its products according to the target they have: general population, in pretty good health or ill people.

When the [target](#) is the general population the registration of the bee products is usually asked as **FOOD SUPPLEMENTS**.

When the [target](#) is though the ill population (including the hospitals and pharmacies) and when on the product label is clearly written that the indication of the product is to cure this or that disease, then the registration must be as a **MEDICINAL PRODUCT**.

When the bee product is sold as a **Food Supplement**, on the label are written the following kind of things:

- **Composition**
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- lower concentrations of the active ingredients is usually related with a Food Supplement or cosmetically use registration;
- the concentration of the ingredients is not always mandatory (qualitative composition is usually enough);
- **Properties, actions, effects:**
 - it is a tonic for the health
 - it blocks the free radicals and thus has anti-oxidant properties
 - it helps the immune system;
 - it acts as a preventative against premature ageing;
 - it increases the mental capacities;
 - activates the metabolism;
 - it improves the blood flow, etc.
- **Indications, Contra-Indications, Limits:**
 - in the vast majority of cases nothing on this subject is here written; if a claim is though made (like ♦it cures hepatitis♦ or ♦it cures cancer♦), the producer will be soon in a big trouble because it will be attacked by the Medicinal Drugs related official personnel from his country.

When the bee product is sold as a **Medicinal Product**, on the label are written the following kind of things:

- **Composition:**
 - high concentrations of the active ingredients (flavonoids) (e.g. over 10%) in the case of propolis products is usually related with a registration as a Medicinal Product;
 - all active ingredients are listed, together with their concentrations (qualitative and quantitative composition);
- **Properties, actions, effects:**
 - **Clear list of pharmacological properties is given (e.g. anti-inflammatory, antiviral, antitumor, etc.);**
- **Indications, Contra-Indications, Limits:**
 - Clear list of indications, contra-indications, limits, adverse reactions and possible allergies needs to be stated in the product leaflet.

♦♦ If we analyze the whole medical and Apitherapy related literature published in the last 50 years or so, we reach the following general conclusions:

- **honey and pollen** are mainly considered as **foods**;
- **honey of medical grade** can be used as a modern wound management product; recently in New Zealand, Great Britain, Holland and Germany a special type of **honey dressing preparation** (used in the treatment of wounds) (♦HoneySoft dressings ♦Mediprof♦) is more and more accepted by the medical communities (for details see: Prof. Peter Molan, *Journal of Wound Care*, Vol. 13, No. 9, October 2004 + ♦Honey: A modern wound management product, an excellent book edited by Richard White, Rose Cooper and Peter Molan);

- **royal jelly** is an excellent micro-nutrient, it enters usually in the category of **food supplements** but it has many other properties and uses, including in the **medical** field (eg. antiviral, against anemia, etc.);
- **propolis in its raw form** is considered in almost all countries worldwide as a food supplement;
- **propolis in various extracts (ethanol extract, mono-propylene glycol extract, etc.)** enters usually in the **food supplements area** when the concentration of its ingredients is less than 10%; however, due to its clear medicinal properties there are more and more countries like **Romania and Germany** that are registering it as a **medicinal product**;
- **beeswax** is mainly used in cosmetics, as a slow releasing of active ingredients/nutrients product
- **Apilarnil (drone larvae extract)** is considered in Romania, Taiwan, China as a **food** and/or as a **food supplement**. However, as the studies showed in Romania, Apilarnil is an excellent product to fight many human diseases, including the sexual related ones (impotence, infertility, etc.).
- **Bee bread** (pollen fermented naturally in the honeycombs in the beehive) is considered either as a **food**, either as a **food supplement**; however, as many studies showed especially in Romania and Lithuania, it gives excellent results when used against **liver** and **heart related diseases**.
- **Bee venom** is considered officially, in most of the countries as a **medicinal product**, however, in some countries like Uruguay, Argentina, Brazil, bee venom can be sold in tablet form, for sublingual administration, without any need of a medical prescription; also, there are various companies in New Zealand, United Kingdom, Canada that are selling honey-bee venom blends (also for sublingual administration), usually against various forms of arthritis, through their network of clients, but also through health food stores.

So, with the exception of bee venom and beeswax that can not be considered as foods, or food supplements, all other main bee products (honey, honeydew honey, bee pollen, bee bread, propolis, royal jelly and Apilarnil) are officially registered as:

- foods
- functional foods
- food supplements
- medicinal products (under certain quality and processing related conditions).

Bee venom	<ul style="list-style-type: none"> • Medicinal product • Supplement in honey blends (against blood flow disorders especially in the joints)
Honey	<ul style="list-style-type: none"> • Food • Food supplement (when mixed with other foods, other bee products or herbs) • Medicinal grade product when used against wounds • Cosmetically product (when used in masks but also in Honey detoxification massage)
Honeydew honey	Same as above
Propolis (raw)	<ul style="list-style-type: none"> • food supplement (no medical claims; used like garlic added to the

	food)
Propolis in various extracts (ethanol extract, mono-propilene glycol extract, etc.)	<ul style="list-style-type: none"> • food supplement when the concentration of its ingredients is less than 10% (no medical claims); • as a medicinal product (with medical claims); • as a cosmetically product when added in various skin creams
Beeswax	<ul style="list-style-type: none"> • as a cosmetically product • as a supplement in the Romanian honey-uncappings wax mixture used against hay fever; • as a slow heat natural product releaser, when used with propolis tincture against low back pains (caused by the coldness)
Royal jelly	<ul style="list-style-type: none"> • Micro-nutrient • Food supplement • Medicinal product (when medical claims are listed on the label)
Apilarnil	<ul style="list-style-type: none"> • Same as to Royal jelly (see above)
Bee pollen and bee bread	<ul style="list-style-type: none"> • Food • Food supplement (when mixed with other foods, other bee products or herbs) • Medicinal grade product when used against liver, heart or nervous system diseases (with claims) • Cosmetically product (when used in facial masks)

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