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MEDI-BEEB

MODULE 10

LEGAL STATUS OF BEE PRODUCTS AND APITHERAPY

2021-1-TR01-KA220-VET-000034632

INDEX

10.0 Introduction

- **Beneficial effects of products obtained by beekeeping**
- Beyond producing honey and beehive products as royal jelly, bee pollen and propolis, bees are crucial to maintaining healthy ecosystems and securing food supplies. In traditional medicine, people have long used natural bee products due to their biological actions and enhanced health attributes.
- During recent years, **natural bee products have become highly attractive to the pharma and food supplement sector.** Organizations have had the opportunity to look more closely at their pharmacological potentials and therapeutic applications in preventing and coping with diseases.
- **Anti-inflammatory and antimicrobial properties** of natural bee products such as honey and propolis make them helpful in wound healing. They can rapidly **remove bacteria from infected areas**. Furthermore, their capacity as coating and dressing compounds enhance fibroplasia and angiogenesis in skin damage.
- The non-invasive nature that beehive products share provides high quality medical care for children in a safe environment. From immunization to symptom relief, apitherapy can highly strengthen youngster's wellbeing.

10.0 Introduction

- **Bee products like propolis** exert antioxidant, anti-inflammatory and analgesic effects that can improve diabetic complications. By reducing the expression of glucose, propolis acts as an **agent for the treatment of insulin-insensitive diabetes**, while honey offers a healthier alternative to refined sugars.
- The **strong antioxidant and antibacterial properties of propolis** make it one of the best ingredients for balancing problematic skins. Royal jelly also offers nourishing and non-irritating replacements to more aggressive skin-popular products like retinol.
- The **benefits of bee products** offer both treatment and prevention capacities that enhance gastrointestinal health. Experts agree that manuka honey can act as a prebiotic to balance the bad bacteria in the gut; soothing digestion. On the other hand, propolis and bee pollen can induce the growth of healthy bacteria.
- Propolis is widely used in toothpastes and mouthwashes to **decrease permeability and restore dentin**, counteracting tooth sensitivity. As agents in oral hygiene, manuka honey and propolis effectively fight against oral infections and treat caries or gingivitis amongst others.

10.0 Introduction

- Besides the all-time effective method of bringing relief to sore throats with honey, bee health products have been found to treat **pharyngitis and upper-respiratory tract infections** more effectively than modern medicines.
- Royal jelly's antioxidant properties improve oxidative damage, helping **prevent pancreatitis and other organ inflammations**. Beehive products also offer a protective effect on the liver and pancreas, helping keep the tissues performing at its best.
- Extracts of propolis and pollen are thought to prevent and regulate hypertension by inhibiting the functioning of inflammatory pathways. Cardiovascular disease is one of the most common disorders globally, while bee health products **largely reduce the risk factor** associated with it.
- The **antioxidant nature of bee health products like royal jelly** has proved to prevent chronic diseases and to decelerate the effects of aging. Neuroprotective and nerve-tonic characteristics of honeybee bioactive compounds have the ability to block and treat cognitive behavioral deficits.

10.1 Medicines and Food Supplements

- **How to use bee-based remedies coping correctly with laws**
- Research and innovation have played a key role in materializing the benefits of bee products. **From consumable dietary supplements to medicinal remedies, these sectors are constantly working towards exploiting the infinite qualities of bee-based ingredients.**
- Bee products are **rich in salubrious molecules**; such as **proteins**, **simple sugars**, **essential amino acids** and **monounsaturated fatty acids**. Suppliers in the food sector transform bee products into natural and ready-to-use **supplements that can be easily incorporated into human diet.**
- Depending on consumer preferences and needs, food supplements can range from gummies, snacks and sprays to functional foods and honey blends amongst others. **A smart way to integrate an extra boost to the immune system and overall body health with bee products.**
- **Bee health products have been used in traditional healing practices to treat and prevent many types of disorders forever.** Biochemical compounds found in them have been demonstrated to display antibacterial, antiviral, and antiparasitic properties. To offer the best possible treatment to specific conditions, suppliers in the pharma sector can now offer an array of formats ranging from capsules, syrups, mouthwashes and creams to vials, tablets and emulsions.

EUR-Lex

10.1 Medicines and Food Supplements

- **Food supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect**. People take supplements **to correct nutritional deficiencies**, ensure that they take in enough of certain nutrients, or **to support specific physiological functions**.
- **Food supplements** are designed to be taken in **small quantities** and are sold in different forms, such as:
  - **capsules**
  - **powder sachets**
  - **drop dispensing bottles**
- Whether you manufacture, sell or import food supplements, you need to ensure that the product complies with **national and EU rules**.
- In the **European Union** specific laws have been approved with reference to **compliance with rules for food supplements, EU Directive on food supplements**
- https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02002L0046-20170726

10.1 Medicines and Food Supplements

- **Nutrition claims**
- EU law permits certain nutrition claims, which you may use if:
  - you can prove that your product complies with the official definition
  - the product complies with the conditions for making the nutritional claim (example: 'salt-free' can be used only if the product contains less than 0.005 g of sodium per 100 g).
- **Nutrition claims authorized under EU law are updated and available here:**

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1924-20141213#tocId21

- **Health claims**
- A regularly updated list of authorised and non-authorised health claims is available in the EU Register of Nutrition and Health Claims
- Food businesses active in the EU can use the authorised health claims only if they comply with the specific and general requirements. National authorities monitor the use of claims through inspections and legislation.

10.1 Medicines and Food Supplements

- To make a claim not already in the EU Register of Nutrition and Health Claims the information you will need to provide is listed under **Article 15** of the EU regulation .
- Further information on the **authorisation procedure** appears on the European Commission's food portal.
- More specifically it can be found the procedure to be followed for health claims on Required information for nutrition and health claim applications and with regard to national authorities taking part in the EU National authorities for submitting nutrition and health-claim applications .
- **Health claim** can be used only if it is displayed together with the following **information on the product's label**, presentation, and advertising:
  - a statement indicating the importance of a balanced diet and healthy lifestyle
  - the **quantity of the food and pattern of consumption required** to obtain the claimed beneficial effect (example: '30 g of walnuts consumed per day will improve the elasticity of blood vessels')
  - where appropriate, a statement addressed to persons who should avoid using the food (example: '**Not suitable for pregnant or breast-feeding women**')
  - a warning for products that are likely to present a health risk if consumed to excess.

10.2 Labelling in the European Union

- **Labelling requirements**

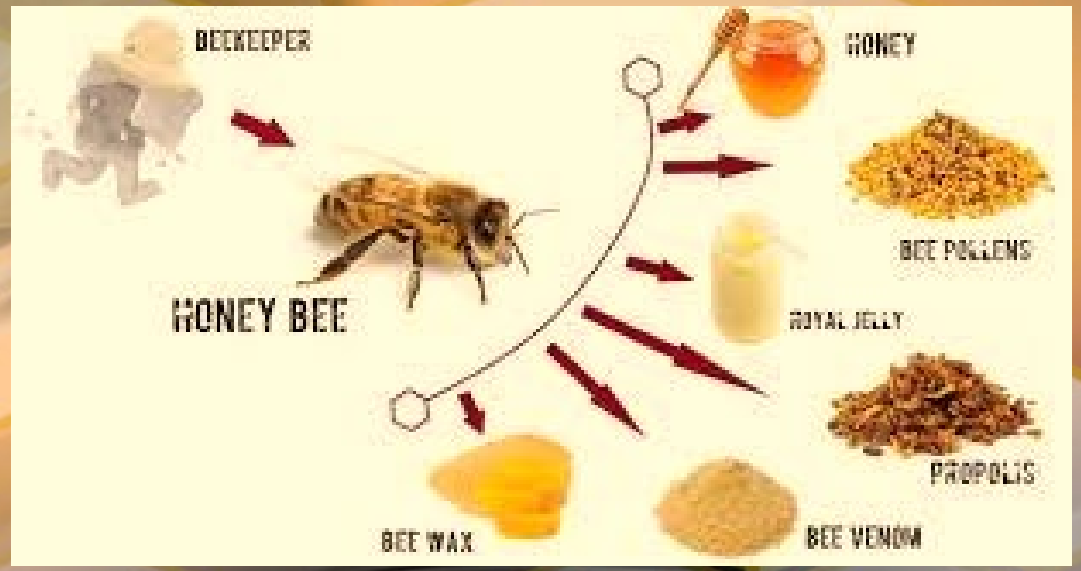
- **Food supplements must comply with general food labelling rules and display**:

  - portion of the product recommended for daily consumption
  - warning not to exceed the recommended daily dose
  - statement that food supplements should not be used as a substitute for a balanced diet
  - statement that the product should be stored out of the reach of young children.

- **Warning**: The labelling, presentation or advertising of food supplements **are forbidden from** featuring claims that the product prevents, treats or cures a disease.

10.3 Bee products and their use as ingredients in pharma and food supplements

- **Apitherapy products.**
- In all four countries participating to the project, **Türkiye, Lithuania, Poland and Italy, there are firms producing medicinal beekeeping products**, mostly from **propolis**, **pollen** and **royal jelly**, recommended as associated to conventional medicines. Few companies are producing **bee venom** for the **pharmaceutical** or **cosmetic industry**.
- The use of those **natural ingredients** is regulated by the **Directive 2004/24/EC** on traditional medicine, based on natural pharmaceutical products officially used since at least 30 years, of which at least 15 years in the European Union and with sufficient data proving that they are not dangerous for health and effective vs demonstrated experience and use.



10.3 Bee products and their use as ingredients in pharma and food supplements

- Also concerned is the European Community Catalogue on **medicines for human use** by **Directive 2001/83/CE**, in which the medicine for humans is **defined as**:

➢ any substance or combination of substances presented as **having curative or prophylactic properties against human disease**;

➢ any substance or combination of substances that can be used by humans administered to humans for the purpose of **restoring, correcting or modifying physiological functions, exercising an immunological or metabolic pharmacological action**, or to **establish a medical diagnosis** (see picture aside).

Regulatory pathway	Main requirements on safety and efficacy	Where to apply
Traditional use registration (Article 16a(1) of Directive 2001/83/EC)	▸ No clinical tests and trials on safety and efficacy are required as long as sufficient safety data and plausible efficacy are demonstrated ▸ Involves assessment of mostly bibliographic safety and efficacy data ▸ Must have been used for at least 30 years, including at least 15 years within the EU ▸ Are intended to be used without the supervision of a medical practitioner and are not administered by injection	▸ National competent authority of a Member State for national, mutual recognition and decentralised procedures
Well-established use marketing authorisation (Article 10a of Directive 2001/83/EC)	▸ Scientific literature establishing that the active substances of the medicinal products have been in well-established medicinal use within the EU for at least ten years, with recognised efficacy and an acceptable level of safety ▸ Involves assessment of mostly bibliographic safety and efficacy data	▸ National competent authority of a Member State for national, mutual recognition and decentralised procedures ▸ EMA if centralised procedure applies
Stand-alone or mixed application (Article 8(3) of Directive 2001/83/EC)	▸ Safety and efficacy data from the company's own development or a combination of own studies and bibliographic data	▸ National competent authority of a Member State for national, mutual recognition and decentralised procedures ▸ EMA if centralised procedure applies

Source: European Commission

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10.3 Bee products and their use as ingredients in pharma and food supplements

- Based on the **Directive 2004/24/EC** has been created a Community list of natural substances with use in the medicinal field for a sufficiently long period to be considered harmless under normal conditions of use
- **Community monographs** have been released relating to traditional medicines that contain the scientific opinion of the Committee based on the evaluation of available scientific data (well estabilished use) or on the historical use of the product in the European Community.
- **130 monographs are currently available on the website of EMA** (**European Medicine Agency**) with publication of summary of recommendations in a clear and simple language for the public.

10.3 Bee products and their use as ingredients in pharma and food supplements

- **Use of medicinal beekeeping products in veterinary medicine.**
- The use of medicinal beekeeping in veterinary medicine is at initial stage as there is a lack of scientific studies, but perspectives are very promising, so scientific research projects in collaboration with universities, laboratories and other public institutions are foreseen be developed.
- The main reason is that beehive products have as potential sources **many flower species**, and therefore they have **extremely variable characteristics**, and it is necessary to determine the overall quality of each product and/or its therapeutic properties to create a quality mark and a certification of this products.
- In the treatment of **skin lesions** with honey it is possible to combine propolis or phytotherapy principles (e.g. essential oils) to deter animal's licking, to repel flies and to enhance the healing effect.
- Veterinarians recommend organizing **practical training courses to form specialized veterinarians** on this issue and creating a working group of veterinarians specialized in apitherapy, to share skills and updates on the theme.
- **Doses and application protocols** should be moreover defined for their topical and oral use in veterinary for the different animal species. **A datasheet model for the description of the clinical cases** and the collection of national experiences should be implemented to create a database.

10.3 Bee products and their use as ingredients in pharma and food supplements

- About the **venom therapy in veterinary medicine**, starting from the animal welfare practices, it should start with the determination of whether the patient is allergic by administering a small amount of venom intradermally. If there are no adverse reactions, then it is possible to increase gradually over several weeks until the maintenance dose is achieved.

- The **bee wax**, deriving from the glandular secretion of bees, is for the most part reused in the same production cycle beekeeping, to produce wax sheets.

- However, **bee wax is also used in numerous fields**, mostly in sectors others than medicine, i.e. as a waterproofing and protective material, in the precision engineering industry, for paints and for some products of the house, for wood and leather processing, in art, in medicine, in some pharmaceutical preparations, cosmetic and candle making industries.

10.3 Bee products and their use as ingredients in pharma and food supplements

- **Use of natural compounds from beekeeping in the food sector.**
- Even larger than in medicine, for humans or for animals, is the **use of natural compounds from beekeeping in the food sector**, that has been established under several European Regulations:

- EC Regulation 178/2002: Foods
- Directive 2002/46/EC: Food supplements
- EU Regulation 2015/2283: New foods
- EC Regulation 1924/2006: nutrition and health claims (claims) proposed on food labels and/or advertising
- EC Regulation 1170/2009: lists of vitamins and minerals and their forms that can be added to foods, including dietary supplements
- EC Regulation 353/2008: implementation rules for applications authorizing the health claims provided for in Article 15
- EC Regulation 1169/2009: amending regulation 353/2008

10.3 Bee products and their use as ingredients in pharma and food supplements

- EC Regulation 116/2010: amending Regulation (EC) No. 1924/2006 as regards the list of nutrition claims
- EU Regulation 1169/2011: food labeling
- EU Regulation 432/2012: list of authorized health claims,
- Regulation 609/2013: infant formula, for special medical purposes, whole food ration
- EU Regulation 907/2013: rules relating to questions concerning the use of generic descriptors, names traditionally used to indicate the peculiarity of a category of food or drink, produced with at least 20 years of use within the European Union.
- EU Regulation 828/2014: information absence or reduced presence of gluten.

10.4 Borderline food/medicine bee products and their classification

- With regard to the authorization process, consumer information and distribution channels, European and national legislation consider food supplements (FS) in the same way as "food". **One of the more complex issues regarding FS is the fact that many substances are used both as ingredients of FS and as active ingredients of medicines**. At the moment, there are no unambiguous scientific and regulatory criteria to distinguish the food use from the pharmaceutical use of a substance and the two fields of application frequently overlap.
- The European Commission has tried to put order for "**borderline**" **products**, identifying the following criteria to define a FS:

➢ a product intended for the general population that is healthy or has a risk factor for the development of disease;

➢ a product whose consumption favors the maintenance of a physiological function of the body or the reduction of a risk factor;

➢ a product that cannot boast preventive and therapeutic effects against a pathological condition;

➢ a product characterized by nutritional and health indications (claim) proposed on the labels and/or with advertising in accordance with the current Community regulation on the matter.

10.4 Borderline food/medicine bee products and their classification

- Another element which, for some molecules, is used to distinguish the use of a certain active ingredient as a supplement or as a medicine is the dose. When the molecule is offered in doses that overlap the **recommended daily intake** (**RDI**), it is classified as FS; **if the proposed consumption unit significantly exceeds the RDI, the preparation should be classified as a medicine**.
- If a product, even if already used as a food supplement, were to be offered in a "therapeutic" context, it would therefore fall into the category of medicines.
- An important aspect refers to those products defined as "**medical devices**" which could probably contain the substances mentioned above. In particular, some substance-based medical devices could represent a sort of "middle ground" between food supplements and medicines.
- For **beekeeping substances** also, such as **propolis**, it could be considered the use as medical device in case of treatment targeted to stop inflammation of the throat or an incipient cold. The difference with respect to the FS lies in the fact that medical devices may contain substances intended to be used in humans for the purpose of diagnosis, prevention, control, therapy or mitigation of a disease through a main action not exerted by pharmacological or immunological, nor by metabolic process, but whose action can be assisted by such means (**EU Regulation 2017/745**) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745 .

Conclusions and lessons learnt

- The **European Parliament resolution** of 1 March 2018 on prospects and challenges for the EU apiculture sector (2017/2115(INI)) had **stressed the strategic importance of beekeeping for pollination and therefore for a sound agriculture within a natural context**.
- **Beekeeping products other than honey are increasingly sought after on the market** for their use in formulations of **healthy food supplements** or in **pharmaceutical preparations** as **medical devices** dedicated to human or animal care.
- In recent years, **traditional medicine of oriental origin**, which has used products such as pollen, propolis and royal jelly for decades, has tended to move closer to **conventional Western medicine** and to **extend the use of products derived from beekeeping to preventive medicine**.
- Some countries including **Poland**, **Lithuania** and **Türkiye** have acted as a bridge for this rapprochement, while **Italy** has only in the last decade shown sensitivity towards the importance of using such products especially as food supplements.
- The **European Commission**, together with the **European Parliament** and the **Council**, and the **EFSA** (European Food Security Agency) have followed this evolution over the years, considering the scientific results achieved in the use of these products in the pharmaceutical sector as positive and also in terms of **economic advantages for beekeepers**, **thus promoting their survival and future development**.
- The foundations have therefore been laid for **legislation** that is **able to incorporate in a clear and updated manner the positioning of the different products and their distinction between food supplements and medical devices and the role of apitherapy**.

2021-1-TR01-KA220-VET-000034632

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This presentation was made as part of the European project MEDI-BEEB Medicinal Beekeeping for Beekeepers

To know more about the project, please visit our website
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2021-1-TR01-KA220-VET-000034682