THE EU LEGISLATION FOR HONEY RESIDUE CONTROL

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Purity and absence of residues characterised honey market for many years and after the recent dioxin scandal, Foot & Mouth Disease and BSE crisis consumers are really worried about food safety. Consumers' and beekeepers' susceptibility on this subject increased rapidly, and sometimes this interest is disproportionate to the real toxicological risk and with respect to the economic value of the honey market. Initially the attention was directed to environmental pollution (heavy metals) and to the problem caused by the use of pesticides in agriculture pest control. Subsequently the severity of the varroosis crisis in Europe and the need for repeated acaricide treatments made it more important to control and keep under control the residues of varroacides products. More recently the interest of beekeepers and consumers has been shifted to the presence of residues of antibiotics and sulphonamides in honey.

Initially, these residues were considered related to the extra community honey production, but the intensification of the official controls and the improvement of the performances of the analytical methods, led to the conclusion that it was related also to the European honey production.

From the legislative point of view a further difficulty derives from the fact that the legislation is complex and is not always clear and homogeneous in the EU.

Sometimes it is necessary to extrapolate indications from rules related to other foods.

Few specific official limits were defined. In fact, while for the authorized veterinary medicinal products it is necessary to define the Maximum Residue Limit, based on toxicological studies, (Regulation 2377/90 EEC) before the product is put on the market.

In this legislation the following definitions are used:

> **Residues of veterinary medicinal products** means all pharmacologically active substances, whether active principles, excipients or degradation products, and their metabolites which remain in foodstuffs obtained from animals to which the veterinary medicinal product in question has been administered;
>
> **Maximum Residue Limit** (MRL) means the maximum concentration of residue resulting from the use of a veterinary medicinal product which may be accepted by the Community to be legally permitted or recognized as acceptable in or on a food. For its calculation many safety factors starting from ADI (Admissible Daily Intake) or NOEL (No Observed Effect Level) are included. In fact MRL should not be considered as safety limits

In table 1 are listed the chemical substances that until now have been evaluated by EMEA committee.

Table 1 chemicals substances evaluated by EMEA for use in bee diseases.

Veterinary drug	MRL ppb	Food stuff	Annex
Tau-fluvalinate (Apistan®)	-	-	II
Flumethrin (Bayvarol®)	-	-	II
formic acid	-	-	II
Lactic acid	-	-	II
Menthol	-	-	II
Thymol	-	-	II
Eucalyptol	-	-	II
Camphor	-	-	II
cymiazole (Apitol®)	1000	honey	III
amitraz (Apivar®)	200	honey	I
coumaphos (Perizin®)	100	honey	I

Other veterinary drugs not listed are not allowed and the Regulation 2377/90 defined as not authorized substances or products: substances or products the administering of which to animals is prohibited under Community legislation, and as illegal treatment the use of unauthorized substances or products or the use of substances or products authorized under Community legislation for purposes or under conditions other than those laid down in Community legislation or, where appropriate, in the various national legislations.

For illegal or not authorized products great arbitrariness is left to the single countries, despite the existing regulation.

The official control activity requires the monitoring of many compounds including not only authorised drugs but also unauthorised substances.

The Directive 96/23/EC contains guidelines for residues control in animals and in their products (honey included), detailed procedures to set up a National monitoring plan and details on sampling procedures.

For any type of animal or food there is a definite set of substance categories that must be monitored.

The substances were divided into two main groups

GROUP A - Substances having anabolic effect and unauthorized substances
(1) Stilbenes, stilbene derivatives, and their salts and esters
(2) Antithyroid agents
(3) Steroids

(4) Resorcylic acid lactones including zeranol
(5) Beta-agonists
(6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90

GROUP B - Veterinary drugs and contaminants

(1) Antibacterial substances, including sulphonomides, quinolones

(2) Other veterinary drugs
(a) Anthelmintics
(b) Anticoccidials, including nitroimidazoles
(c) Carbamates and pyrethroids
(d) Sedatives
(e) Non-steroidal anti-inflammatory drugs (NSAIDs)
(f) Other pharmacologically active substances

(3) Other substances and environmental contaminants
a) Organochlorine compounds including PCBs
b) Organophosphorus compounds
d) Chemical elements
d) Mycotoxins
e) Dyes
f) Others

The categories highlighted in bold have to be monitored in beehives products

In this context there are three different situations in terms of interpretations of results depending on the residues considered:

1. **Authorised drugs**: in this case the evaluation of the observance of the MRL
2. **Not authorised veterinary drug** an Action Limit the principal items to be considered are consumers' safety, the reliability of analytical techniques used and the knowledge of metabolism or distribution kinetics. In many countries a general safety limit exists when no limits are defined.
3. This limit is generally 0,01 mg/kg (10 ppb), close to a generic instrumental detection limits.
4. **Forbidden substances**: in this case a Zero tolerance exists. Generally action limit is fixed at 1 ppb. More recently for this residues category the EC has requested a very low limit of detection (LoD = 0,3 ppb for chloramphenicol),
5. For the forbidden or not authorised substances a limit of action doesn't correspond in any case to authorise its use, the limit in this context is indicative, if a laboratory has better performances in terms of LoD, the sample must be considered irregular.

In the present situation, discordant behaviour around EC Member States generates confusion and paradoxically the exaggerated lowering in the detection limit of the analytical procedures (which, in some cases, is very far from performance of the

standard analytical food control laboratories) instead of increasing the trust in the controls and the food safety, produces more confusion.

These problems are well known and the legislator tried to solve them by a very new Commission Decision 2002/657/EC (12 August 2002) Implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results, starting from these considerations:

- It is necessary to ensure the quality and comparability of the analytical results generated by laboratories approved for official residue control.
  It is necessary to determine common criteria for the interpretation of test results of official control laboratories in order to ensure a harmonised implementation of Directive 96/23/EC.
  It is necessary to provide for the progressive establishment of Minimum Required Performance Limits (MRPL) of the analytical method for substances for which no permitted limit has been established and in particular for those substances whose use is not authorised, or is specifically prohibited in the Community, in order to ensure harmonised implementation of Directive 96/23/EC.

In future a MPRL defined by the Community will produce a better harmonised behaviour within the EU.

Residues in food, especially in honey, is a very sensitive subject and it is very difficult to give correct information considering that the consumer's perception of hazard differs a lot from the real risk. For example, in the list of possible hazard (see table 2), food additives and pesticide residues are considered the most important items but from the scientific point of view the main problem is derived from microbiological contamination and natural toxins

Table 2 - consumer perception list of possible risk in decreasing order of importance.
1.Food Additives
2.Pesticide residues
3.Nutritional component
4.Accidental Contamination
5.Microbiological Contamination
6.Natural Toxins

A correct management of the risk analysis is made up of different important steps such as:

1. **Risk assessment** Hazard identification, Hazard characterisation, Exposure assessment and Risk characterisation)
2. **Risk management** Risk evaluation, Option assessment, Option implementation, Monitoring and review)
3. **Risk Communication**

but in the recent scandal we observe that the simple hazard identification generates a serious impact on public opinion.

A similar scheme of evaluation and management of a direct or indirect risk to human health from food or feed is defined in the Regulation EC/178/2002 referring to the European Rapid Alert System.

This system is organised in a network involving member states, the Commission and the European Food Safety Authority (EFSA).The information from a member of the network shall be immediately notified to the Commission and then through the network.

The EFSA may supplement the notification with scientific or technical information.

Three different levels of information exist:

1. **Alert Notification**

   The conditions are that food is still on the market, that more than one Member State is involved and that an immediate action is required (real risk, withdrawal of the product from the market).

2. **Information Notification**

   When an action is not immediately required, it is necessary to provide useful information to Member State. No actions are required

3. **News**

   Neither Alert nor Information, and no Actions are required

However in this context any subject in food chain and food control (consumer, industry, analyst) has a different opinion in terms of appropriate limit, a summary of the different opinions of scientists and producers is presented.

a) Food must be safe for consumers, residues must be absent and a minimal concentration is considered acceptable.

b) From the toxicological point of view the same consideration on safety for humans, was based on evaluation based on technical data like ADI, NOEL and ARfD (Acute Reference Dose) , and the low honey consumption in the normal diet,

c) In the analytical laboratory the main topic is the reliability of results and a simply robust procedure able to cover a wide range of compounds in the same test.
   In this context it is necessary to consider that the performance of a laboratory in terms of Limit of Quantification (LoQ) and Limit of Determination (LoD) strongly depends on instruments and laboratory experience.

d) Industries and importers are generally concerned with consumers' safety, but they are at the end of the production chain. They hope they will have few problems for packed honey on the market in official control and they need few imported batches rejected

e) The beekeepers are the first subjects in the production chain, the most important point of the chain to avoid honey contamination. They are mainly interested in the quality of beehives product, but they need more disease control tools.

Considering that the authorisation of new veterinary products is subjected to more restrictive rules, the experimental protocol for testing a new product needs an evaluation of the impact on the beehive products.

The recent European alarm related to the presence of residues of chloramphenicol in Chinese honey and royal jelly opened a new scenario, it was demonstrated that also in bees product it is possible to find dangerous substances and that in the future it will be difficult to obtain from the legislative bodies (at a National and European level) any special consideration for honey and other bees products.
In any case to solve the problem it is necessary that the EU will make a decision on official limits such as MPRL, but as has been mentioned above there are many different possible points of view and they are subject to different pressure (public opinion, producers, industries or consumers associations), in this context research institutes have to give their high-qualified technical advice.