Antibiotic residues: New Implementing Regulation 2018/470/EU

Summary:

In our opinion, the applicability of Implementing Regulation 2018/470/EU to honey is only given in absolute exceptional cases and furthermore only for honey produced in the EU. As a laboratory, we generally cannot check the applicability of the regulation in the case of positive antibiotic findings. Therefore, from our point of view nothing changes in the interpretation of the residue analysis of antibiotics in honey and bee products and positive findings will continue to be assessed by us according to the zero tolerance in the EU.

Our recommendation to the honey traders in the EU is, that if in an exceptional case an antibiotic authorised for other animal species or humans has actually been rededicated in strict accordance with Directive 2001/82/EC, which has thus demonstrably caused an antibiotic residue in a honey batch, the corresponding veterinary documentation of the treatment of all bee colonies whose honey has been processed in a batch contaminated with antibiotics should be inspected at the EU honey supplier in order to verify the possible applicability of the provisions of Regulation 2018/470/EU and the correct compliance with the waiting times laid down by the veterinarian.

As such exceptional case will presumably not occur in our opinion, we recommend continuing with the current practices for the quality control of antibiotics residues under the zero tolerance for honey and bee products.

Explanation:

Antibiotic residues in honey and bee products are currently known to have zero tolerance in the EU (Regulation 96/23/EC in conjunction with Regulations 470/2009/EC, 37/2010/EU, Tables 1 and 2). This zero tolerance is interpreted more or less strictly depending on the substance and authority, which is due to the toxicity of the individual substances. This is also visible when viewing the messages in the European Rapid Alert System RASFF. The prohibited substances (e.g. chloramphenicol, nitrofurans, metronidazole) are usually handled more strictly with regard to official measures. However, zero tolerance gives rise to a certain degree of legal uncertainty in trade, since any positive finding of an antibiotic residue in honey can potentially be problematic. However, the value “zero” does not exist from an analytical point of view. It depends on how sensitive the laboratories can reliably detect the substances and from when they report the results (limit of quantification / LOQ). In the global honey trade, specifications are applied analogously which require the absence of antibiotic residues. However, it is often not specified with which limit of quantification a honey must be free of residues. For many years, the industry has therefore wanted a regulation on antibiotics that offers greater reliability and legal certainty.

The Implementing Regulation 2018/470/EU of 21 March 2018, which is to be applied for the control of animal foods such as honey, has just been published. For the species "bees" Article 3 (c) of the Regulation would apply. Thereafter, for the control of the target tissue honey the lowest maximum residue limit set in Table 1 of Regulation 37/2010/EU could be applied. For example, this would be a maximum residue level of 200 µg/kg for streptomycin (for milk) or 100 µg/kg for oxytetracycline (for meat/muscle and milk). The question now arises as to whether this maximum residue level is actually applicable to traded honey and thus represents a reliable limit value?

Prerequisite for the applicability of Article 3 of Regulation 2018/470/EU is that the animal species "bees" must have been treated in accordance with Article 11 of Directive 2001/82/EC, within the EU and not in a third country. Thus the applicability of Regulation 2018/470/EU for third country goods is obviously already ruled out. Since no antibiotics are authorised in the EU for the treatment of the animal species "bees", a veterinarian must personally rededicate a medicinal product authorised for another animal species (e.g. cattle) or humans. To our knowledge, however, this is an absolute exception and rarely happens in practice. The rededication only applies to acute emergencies in order to avoid unacceptable suffering for animals (Article 10 of Directive 2001/82/EC). The veterinarian must give precise reasons for the requirements of the application (which disease was treated, why, with which antibiotic, for how long, etc.) and document the rededication under his personal responsibility. The veterinarian must also establish a waiting period after which the administered medicinal products are sufficiently degraded so that the expected residue levels in the target tissue are below the established maximum levels. According to Article 11, he must keep the documents for rededication at the disposal of the authorities for three years in accordance with the provisions of Article 10.

In our opinion, however, a rededication of antibiotics for bees is hardly possible, since the residue levels in the honey target tissue after application to the bees would exceed the permitted levels. There have been several studies published on this topic, e.g. for tetracyclines [1].

Since antibiotics in honey are not metabolized or broken down - like in the living animals or in the target tissues of treated animals (muscle, liver, kidney, etc.), which may only be processed after the waiting period, respectively - in our opinion no sensible waiting period for the honey harvest can be determined by the responsible veterinarian[2]. Furthermore, there are only the American and the European foulbrood as possible bacterial diseases of bees, which could justify a treatment with antibiotics. Most other bee diseases are parasitic (Varroa, Nosema) and are not treated with antibiotics but with antiparasitic drugs such as Amitraz or Coumaphos, for which there are also maximum residue limits in honey (Regulation 37/2010/EU). American foulbrood is also notifiable and must not be treated with antibiotics, but in Germany, for example, in accordance with the Bee Disease Ordinance.

[1] Thompson H. et al (2005) - Effects of European foulbrood treatment regime on oxytetracycline levels in honey extracted from treated honeybee (Apis melifera) colonies and toxicity to brood. Food Addit. Contam., 22(6): 573-578

[2] Gačić M. et al.: Degradation of Oxytetracycline, Streptomycin, Sulphathiazole and Chloramphenicol Residues in Different Types of Honey, Food Technol Biotechnol. 2015 Jun; 53(2): 154–162.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5068408/