

France's proposal for Guidelines about setting Maximum Residue Limits in honey

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Abstract

Background: Honey is produced in an environment potentially polluted by different sources of contamination, so it is necessary to set Maximum Residue Limits (MRLs). These MRLs should be fixed as low as possible in relation to Good Agricultural Practices (GAPs).

The guidance provided in this Draft Working Document gives advice on:

- when and for what kind of active substance a MRL has to be set in honey
- how to propose a temporary MRL for a given active substance
- how to design, prepare and realise supervised residue trials when necessary

Results: The proposed approach is based on using the available data before an active substance or product is registered, and is divided into several successive steps, represented in a global decision-making scheme. The MRL will be set depending on the results obtained at each different step.

Besides, the applicants will have the choice between different methods to set a provisional MRL in pre-registration.

Conclusion: The initial proposal was a protocol on field residue trials proposed by Germany. The approach used in this guidance document proposes also other possibilities for fixing MRL without conducting systematically field trials. This proposition will be discussed at European level.

Keywords: Regulation 396/2005, MRL, honey, plant protection product

Introduction

Within the framework of Regulation 396/2005, guidelines relating to setting Maximum Residue Limits in honey have to be written. France was designated by the European Commission and other Member State to take in charge the writing of this guidance document. The French Ministry of Agriculture (the risk manager) asked Afssa (French agency in charge of the risk assessment) to make a proposal. In October 2007, the 'Working Group Afssa-MRL in Honey Working Group' was created, with the aim to propose a document for the end of 2008 that will then be submitted to the European Commission and other Member States.

Bees mainly produce honey, but also wax, pollen loads, propolis and royal jelly. Although these latter three are products for human consumption, their consumption is of low importance and honey remains the main beehive product used as food. The average consumption of honey per capita and per day in Europe is quite low (less than 5 g/capita/day) and represents a very small part of the total diet (between 0.04% and 0.17%). This would consequently not imply a significant contribution to the Total Maximum Daily Intake (TMDI), usually calculated in order to assess the chronic risk of dietary exposure.

Considering the acute risk, according to the EFSA Model for risk assessment of pesticides MRLs (PRIMO, Pesticide Residue Intake Model) and the lowest ARfD established today, it appears that, when there is no use in Europe, a default MRL set at 0.01 mg/kg is sufficient to guarantee the consumer safety. Otherwise, consumer risk assessment related to the consumption of honey will have to be evaluated.

To propose a residue definition

Honey is made mainly from nectar that is partially modified by bees and so by enzymes of animal origin. As a consequence, it appears that a specific residue definition should be established for this commodity, but, as

honey consumption should have little impact on TMDIs, if no specific metabolism study has been undertaken, the following definition of residue in honey is suggested as a default approach for monitoring and risk assessment:

Residue is the sum of parent and/or of all metabolites included in the residue definition for monitoring in plants and foods of animal origin.

To focus on potential exposure

Veterinary medicinal use

When an active substance is already used for beehive treatment (mainly to control bee diseases or parasites), this use is considered as a worst case, as the product is generally applied close to bees and honey. In that case the MRL defined under Council Regulation (EEC) No 2377/90 applies.

Intended Use

Crop attractivity, melliferous capacity: A given crop is more or less attractive to bees according to availability, quantity, quality of pollen and/or nectar (as well as that of honeydew). Moreover, the melliferous aspect of the crop has also to be considered. Indeed, even if a crop is attractive to bees, no residue will occur in honey if it is not melliferous.

Application before or during attractive periods (flowering, honeydew): the application period has to be considered to assess the exposure of bees to residues and then the risk of honey contamination.

‘Residue in plant’ properties

Systemic activity: systemic activity of the compounds included in the plant residue definition (active substance and/or its relevant metabolites(s)) has to be considered.

Residue level in aerial part of the crop: Depending on the residue level in aerial parts of the crop (if possible in flowers) or in honeydew, and on the physico-chemical properties of the compounds included in the plant residue definition, no further data may be necessary. It is considered that if the residue level measured in aerial parts of the crop is below 0.05 mg/kg, then the residue level expected in honey is assumed to be below 0.05 mg/kg. Therefore a default MRL of 0.05 mg/kg is fixed, based on a transfer factor of 1, that could be considered as conservative compared to data available in the literature (values from 0.0065 to 0.25¹).

To propose a choice of methods to fix a provisional mrl in pre-inscription

If the residue level is above the trigger value of 0.05 mg/kg it is necessary to propose a MRL, so that honey likely to contain residues may be marketed. Different options are proposed:

- considering data on residue in aerial parts of the crop,
- considering data from studies on transfer from syrup,
- considering data on residue stability in honey,
- considering data from field residue trials,
- considering monitoring data.

Use of data on residue level in aerial parts of the crop

Only data from aerial parts sampled during the attractive period of the crop or its weeds can be used (two to four trials could be considered sufficient). Aerial parts of the crop include leaves, flowers or nectar (grains are not considered). Based on a transfer factor of 1, an MRL proposal could be made with a suitable rationale. However, in order to set the MRL at a level as low as possible, analysis in flowers or nectar could be required if the residue level in leaves or whole plants is higher than 0.5 mg/kg.

Studies on transfer from syrup to honey

Spiking syrup used to feed bees has to be performed with compounds included in the plant residue definition at a level close to the one measured in aerial parts of the treated plants. If the residue amount in honey produced is lower than 0.05 mg/kg, then this value could be considered to propose a MRL.

If residue level is higher than 0.05 mg/kg, a MRL will be defined by extrapolation from data on transfer from syrup to honey (if these data are considered relevant).

Then a provisional MRL could be set from the Highest Residue (HR) [in plants] x average transfer factor (from syrup to honey).

Trials on the residue stability in honey

In order to check the stability of the residue in honey, the following method is proposed:

- Honey is spiked in triplicate with compounds included in the plant residue definition at a level corresponding to the highest residue measured in the aerial parts of the crop.
- Residues (compounds included in the honey residue definition) are quantified using a validated method on honey (according to document SANCO 3029 ²) after a storage period of one month at room temperature (around 20°C).

If the residue level measured after one month under these conditions is below 0.05 mg/kg, a default MRL is fixed at 0.05 mg/kg.

If the residue level is higher than 0.05 mg/kg, a MRL could be proposed by extrapolation from stability data at the level measured in honey.

Use of monitoring data

Data from monitoring studies from non EU countries (if available) can be considered when the residue level is supposed to be higher than 0.05 mg/kg in plants, and to propose an MRL. These monitoring data may be obtained from different study plans, but a certain number of points must be addressed:

- The data concerning residue levels in honey (according to residue definition in honey) should reflect exposure of honeybees to residues,
- The data should be representative of critical exposure situations,
- The data have to be representative of different geographic areas and/or foraging activity of bees during foraging of nectar from treated plants,
- Statistical analysis of the results has to be performed and a statement on the reliability of the proposed MRL should be established.

Field or tunnel residue trials (allowing production of capped honey, and determination of the residue level in honey)

Tunnel or field trials are considered as the best way for studies to define MRL in honey. These trials can be performed using open field design or using tunnels (in the latter case the main condition is to obtain capped honey).

Results

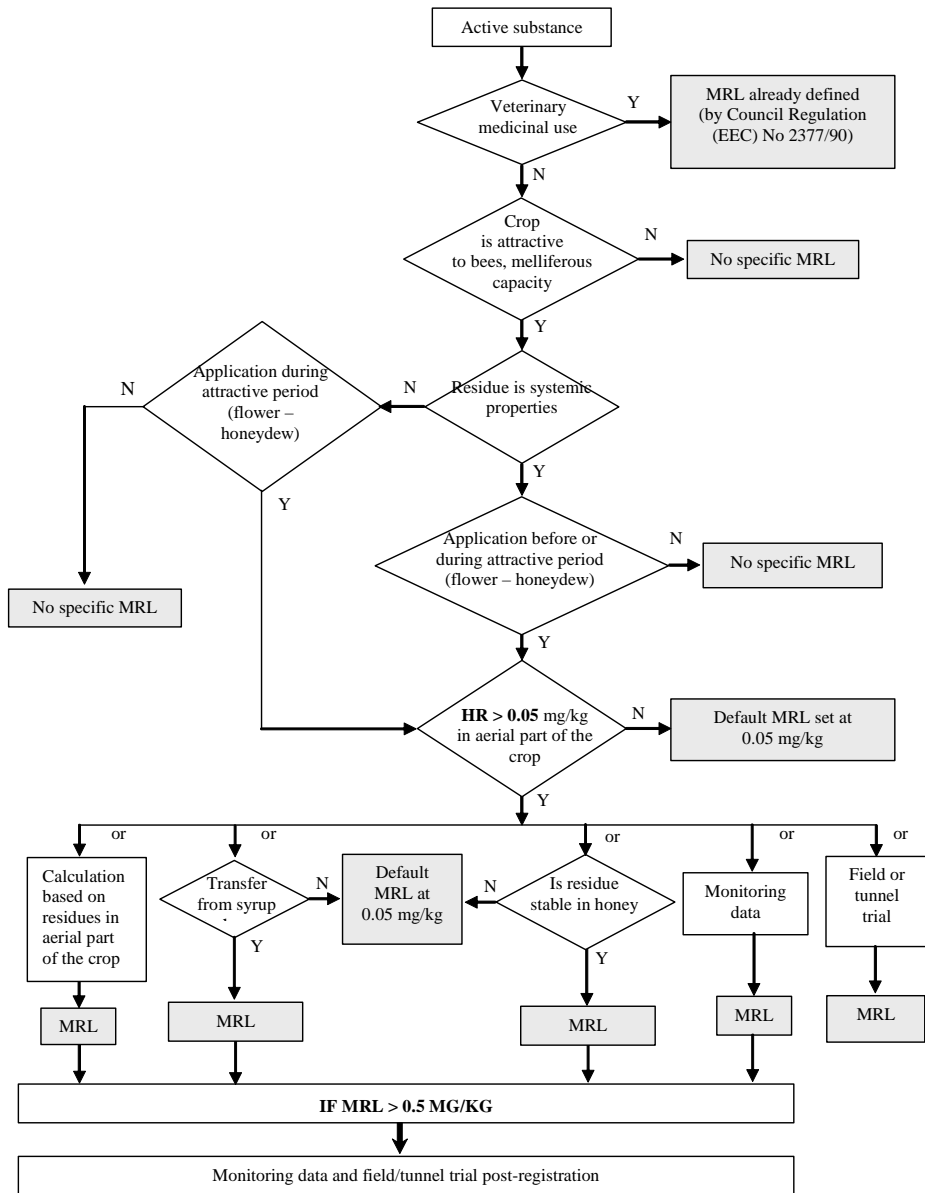
See the decision making scheme for MRL setting in honey (see diagram).

Conclusions

From the entry into force of the EU so called *MRL regulation* (regulation CE 396/2005³), MRLs of pesticides have to be set on new commodities, and honey is one of them. As a consequence, new guidelines have to be proposed to define MRLs on these commodities. So, the EU commission asked France to propose an approach to set MRL in honey. Considering that human exposure to plant protection products residues via honey is of little incidence, the approach proposed by Afssa⁴, aimed to be as pragmatic as possible, is based on all available data and knowledge already acquired on a given active substance and its degradation products. This approach resulted in a draft document that describes a stepwise approach in order to propose a provisional or final MRL in honey. This document remains today a proposal and has no legal value, neither in EU, nor in France. France sent this proposal to the EU commission and then it will be discussed and amended in a near future, and may result in a guidance document in the coming years.

References

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MRL : Maximal Residue Level – HR : Highest Residue

Diagram Decision making scheme for MRL setting in honey, as proposed by Afssa⁴.