Question and Answer on the Residue Monitoring Plan

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Introduction

What is the Residue Monitoring Plan (RMP)?

The Residue Monitoring Plan (RMP) is a risk assessment of honey production and processing methods which must be carried out by any country wishing to export honey to the European Union. A country's approved Residue Monitoring Plan acts as an assurance to the European Union that all honey exported from that country will be free from dangerous levels of **chemical residues**, and that future monitoring will maintain this at a minimal level. This is laid down in **Council Directive 96/23/EEC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23/5/1996)**. Honey is considered as an animal product.

What are Residues in honey?

The sorts of chemical residues which may be present in honey may originate from veterinary medicines used on bee colonies, (e.g. antibiotics); or from environmental pollutants that bees have picked up.

The three main groups of residues targeted for examination are:

- Banned veterinary substances (such as chloramphenicol)
- Authorised veterinary substances (but found in excess of their authorised limits, such as antibiotics and insecticides)
- Environmental pollutants (such as pesticides or heavy metals)

There is a Maximum Residue Limit (MRL) set within each country's RMP. Samples containing levels of residues above the MRL will be an indication that something is wrong and the country's RMP will usually not be approved[1].

Is the RMP necessary?

Yes, if a non E.U. country wants to export honey (and any other animal products) to the European Union, it must possess an approved Residue Monitoring Plan, which will place it on the list of Third Countries eligible for export. This has been a compulsory requirement since 2001 (under **Commission Decision 2001/700/EC**).

[1] There have been exceptions, for example in the case of *streptomycin,* an antibiotic found in Zambia honey later proved to be naturally occurring and harmless to health.

No, if there are no honey traders in the country intending to export to the European Union.

Why was it introduced?
The aim of the legislation is to protect the E.U. public from food contaminated by dangerous levels of residues. For example, when chloramphenicol was found in Chinese honey, in February 2002 (a banned antibiotic), China was taken off the list of Third Countries, and imports into the European Union were banned until the RMP for China could be proven to be working properly.
The legislation is not designed to keep new exporters out but to ensure the safety of new honeys before they arrive on the market.

Who approves a country's RMP?
The RMP is approved by the European Union Standing Veterinary Committee, DG SANCO.

What does an exporter need to do to have a Residue Monitoring Plan?

1) Who should be involved?
A Residue Monitoring Plan is shared by all potential honey exporters in any one country. This means that they must collaborate to put together the RMP even if their end markets are different and they do not wish to cooperate in any other way.
Whether the RMP is led by the government or the private sector depends on the situation in each country, but in any case the Plan must have the approval of a government official who endorses it and acts as mediator between the European Union and the exporters.
If the RMP is led by the private-sector, the various actors involved (both current exporters and potential exporters, if there is any chance of them exporting in the near future) usually unite to form an association responsible for the RMP.

2) What does the RMP consist of?
A summary of all the information that must be submitted in a Residue Monitoring Plan is listed in *annexe 1*. Generally, the first time a Third Country presents its RMP, it is necessary to present the general context in which the plan is situated. This includes:
- The legal framework for the residue monitoring plan;
- The structure of the official services in charge of the controls;
- The laboratories undertaking the official analysis and their qualifications;
- The official sampling procedure
- The measures taken in case of non-respect of the legislation.

When the RMP is simply being renewed it is not necessary to present the context unless it has changed.
In addition, the RMP must present the results of laboratory testing of a range of samples, (and compare these results to the previous year's results, if an application is being renewed). The samples must be tested for residues divided into 5 sub-groups, which are as follows:
B1- Antibacterial substances, including sulphonomides and quinolones;
B2c- Carbamates and pyrethroids;
B3a- Organochlorine compounds including PCBs;
B3b- Organophosphorus compounds;
B3c- Chemical elements.
The precise compounds to be tested are referred to in ***annex 2***.

3) How do you go about it**?**
Type of RMP
The **type of RMP** submitted depends on the potential **size of honey exports** and the **degree of risks** posed by production methods of the exporting country. In countries where several thousand tonnes of honey per annum are being exported, the government will consider it worth the

investment to fund a special department within the Ministry of Agriculture to be responsible for the national RMP.

However, there are also many countries, especially in Africa, who have not yet exported honey. Typically such countries might have only a few companies interested in developing honey exports and it would be unlikely that honey exports would rise above a few hundred tons per annum. In these situations the government would be unlikely to invest funds in the RMP because it would only benefit a few companies. The cost of a full-scale RMP would be too great for these few industries to support between them, and they would not want to invest in the growth of the sector if they could not access the bigger markets, so these countries would be effectively barred from developing their honey exports. However, these countries typically have the potential to produce and export much larger quantities of honey produced under chemical risk-free situations (for example, bee diseases which are treated with antibiotics in the countries where beekeeping operations are larger scale are not yet prevalent in Africa).

The European Union does not want restrict trade in honey to only the larger established exporters. Therefore if exports are not likely to exceed 300 tons per annum and production methods do not use dangerous chemicals etc then a simplified scheme will be accepted. This involves taking fewer samples and is less costly.

This is the case in Zambia, where instead of the government being responsible for the implementation, the industry itself is responsible and bears the financial cost. Zambia is a **low-risk** situation because the bee colonies are essentially wild and occupy vast areas of virgin forest. The only manipulation of the colony is during harvest, veterinary medicines are not used and there is no history of bee diseases.

Sampling
The procedure for collecting the **samples** must be accountable. Samples must be taken at random and must cover the whole range of geographical areas where the honey to be exported may originate from. After the samples have been collected, sealed and tagged, they are sent to the responsible government official who writes a covering letter detailing the samples.

4) How long does it take to set up the RMP?
The time-scale for implementing an RMP depends on the funding available. In the case of Zambia, there was a need to create a Plan as quickly as possible when the new legislation came in. Since Zambia was already exporting, failure to come up with a Plan would mean that the market niche for Zambian honey in the U.K. would have been lost, so the whole process, from elaboration to approval only took a few months. In the case of Uganda, the RMP was set up through collaboration between the government, development partners and the private sector. In comparison, the Uganda RMP was more costly, involving the analysis of hundreds of samples, and took several years to achieve.

5) How much does it cost?
This depends on many factors, e.g. how many samples need to be taken and whether there is a competent laboratory (approved by the E.U.) to analyse them within the country. In low-risk situations, the minimum number of samples required for each sub-group of residues to be analysed is ten. If it can be proved that any of these subgroups of residues pose no risk at all to the honey, they do not necessarily need to be tested[2].

[2] For example, in the Zambian RMP, the second category, group B2c (carbamates and pyrethroids) is not tested. This group contains residues left when hives are treated for bee diseases and mite infestation. Hives in Zambia are predominantly fixed comb, where it is not possible to administer veterinary medicine, and there have been no incidences of mite infestation, so there is no risk of contamination.

In Zambia, four of the five sub-groups must be examined, so this means 40 samples. They are analysed in laboratories in Germany and England. **Each sample costs ….** The cost of the Zambian RMP is around $2-3,000 per year and so can be supported from exports of a few 18 ton containers per year.

6) When is it submitted?
Residue Monitoring Plans are submitted before 31st March of each year. They must be renewed each year (i.e. samples tested; changes documented and explained).

7) What next?
The Commission services will examine the plan and if it meets their approval, an appropriate legislative decision will be sent to the relevant Standing committee for approval. If the plan needs some development, this would be discussed with the country in question. After the RMP has been approved, the legislation is passed so that the new country joins the list of Third Countries eligible for export and the European Port Health Authorities are informed that imports from this country are now allowed into the E.U.

Countries whose residue plans are approved are listed in the amendments of **Commission Decision 2004/432/EC on the approval of residue plans of third countries according to Council Directive 96/23/EEC**.

Additional questions and further information

Is it necessary to set up an RMP for exporting other bee products to the European Union (i.e. beeswax, propolis, pollen, royal jelly?)
No. Honey is the only bee product covered by legislation 96/23/EEC.

Which countries are already on the list of approved Third Countries?
These countries are listed in ***annex 3.***

Once you have an approved RMP, do you have a guarantied market in the European Union?
No. It just means that your honey is legally permitted to enter any of the E.U. countries and be sold on their markets. You must find your own buyer.

When is the best time to set up an RMP?
Since the RMP requires an investment, it is wise to be sure that expansion of export into European Union markets is a viable objective. You will need to bear in mind;
-Quantity
If the RMP is going to be financed by the honey industry, you will need to have a production capacity of export quality honey of at least 100 tonnes per annum in order to cover the cost of a simple RMP.
Perhaps you will consider that it is better to first attain status as approved importer to the European Union, which will then give producers a better incentive to increase their production for a bigger potential market in Europe.
-Market
It is wise to test the water first: if you already have a potential buyer in the E.U. who is interested in buying enough of your honey at a price you are happy with once you have an approved RMP, you are taking less of an investment risk. Make a careful market plan, based on knowledge of accessible markets: Look at the needs on the local and regional market before definitively setting your objectives on export to Europe.

Do you need to have an approved RMP before you send samples to prospective buyers?
No. You can justify sending samples which are not intended for commercial use, in order to get them analysed and explore market prospects. If you are sending them to a potential buyer, make it clear that your country is not yet on the list of approved countries.

Links to relevant legislation

http://europa.eu.int/eur-lex/en/oj/index.html

Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products:

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31996L0023&model=guichett

Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products:

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31997D0747&model=guichett

Commission Decision 2006/208/EC of 7 March 2006 amending Decision 2004/432/EC on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC
http://eur-ex.europa.eu/LexUriServ/site/en/oj/2006/l_075/l_07520060314en00200025.pdf

ANNEX 1
SUMMARY OF INFORMATION TO BE SUBMITTED CONCERNING A RESIDUE MONITORING PLAN FOR HONEY

1. GENERAL INFORMATION

1.1. **Legislation** concerning the use of substances of Annex I (Directive 96/23/EC -Article 7§1).

1.2. **Infrastructure of the official services**; information on co-ordination of the activities of central and regional departments (Directive 96/23/EC - Article 7§2 and article 4).

1.3. **List of Official Laboratories** (Directive 96/23/EC - Article 7§3).

1.4. **Level of competence of the National Reference Laboratorie(s)**, as well as routine Laboratories, particularly as regards the implementation of Quality Assurance, or good laboratory practices.

1.5 **National tolerance limits (MRLs)** for authorised substances and environmental contaminants (Directive 96/23/EC - Article 7§4).

1.6. **Official sampling procedures** in the field, including information on how samples are secured after collection (using flow charts).

1.7. **Description of measures taken by the competent authorities** where residues are detected (Directive 96/23/EC - Article 7§7-8)

2. BACKGROUND INFORMATION ON PRODUCTION

2.1. **Total figures of production**.

2.2. **Type of production** of 2.1. (intensive, extensive, wild or mixed systems)

2.3. **Production planned to be exported to the EU.** (Decision 97/747/EC).

3. SCOPE OF THE RESIDUE PLAN

3.1. **Groups of residues covered** (as listed in Directive 96/23/EC - Annex I);
Breakdown of substances monitored (Directive 96/23/EC - Article 7§5).
- Cf. Table

3.2. **Details of analysis methods** - screening/routine and confirmation, with action levels and detection limits (Directive 96/23/EC - Article 7§5).
- Cf. Table

4. FREQUENCIES AND LEVELS OF THE CONTROLS

4.1. **Number of samples** to be taken for each sub-group of substances (Dec 97/747/EC). For third countries, the figures could only refer to exports to EU; in that case, guaranties for appropriate segregation and control must be given (Directive 96/23/EC - Article 7§6).
- Cf. Table

5. TARGETING CRITERIA

5.1. **Results** from previous years.

5.2. **Changes** based on analysis of the residue plan of the previous years (whereas such plans exists), particularly as regards problem areas identified (Directive 96/23/EC - Article 8§2).

ANNEX 2

Table summarising the annual requirements for residue monitoring plan (points 3. and 4. of the guidelines) for honey

Country:

Total honey production (tonnes) exported to the EU the previous year :

Period covered by the plan:

Group of substances (Directive 96/23/EC)	Compounds analysed	Material analysed/ Method	Detection level	Level of action	Number of samples	Laboratory
B1 - Antibacterial substances, including sulphonomides, quinolones.						
B2c - Carbamates and pyrethroids						
B3a - Organochlorine compounds including PCBs						
B3b - Organophosphorus compounds						
B3c - Chemical elements						

ANNEX 3	**Third Countries Eligible to import honey into E.U.**		
Country	**April 2004**	**11th March 2005**	**7th March 2006**
Argentina	•	•	•
Australia	•	•	•
Bulgaria	•	•	•
Brazil	•	•	
Belize	•	•	•
Canada	•	•	•
Switzerland	•	•	•
Chile	•	•	•
China		•	•
Serbia and Montenegro	•	•	
Serbia			•
Montenegro			•
Cuba	•	•	•
Guatemala	•	•	•
Croatia	•	•	•
Israel	•	•	•
India	•	•	•
Jamaica	•	•	•
Kenya	•	•	•
Kyrgyzstan		•	•
Moldova	•	•	
Mexico	•	•	•
Nicaragua	•	•	•
Norway	•	•	•
New Zealand	•	•	•
Pitcairn			•
Paraguay	•	•	•
Romania	•	•	•
Russia	•	•	•
San Marino	•	•	•
El Salvador	•	•	•
Thailand	•	•	•
Turkey	•	•	•
Taiwan	•	•	•
Tanzania	•		•
Ukraine	•	•	•
Uganda		•	•
United States		•	•
Uruguay	•	•	•
Vietnam	•	•	•
South Africa	•	•	•
Zambia	•	•	•