AGENCE FRANÇAISE DE SÉCURITÉ SANITAIRE DES ALIMENTS

Maisons-Alfort, le 13 janvier 2009

LA DIRECTRICE GENERALE

AVIS

de l'Agence française de sécurité sanitaire des aliments relatif à la rédaction d'un projet de document guide de fixation des LMR de pesticides dans le miel dans le cadre du règlement (CE) n° 396/2005

L'Agence française de sécurité sanitaire des aliments (Afssa) a été saisie le 1 juin 2007 par la Direction générale de l'Alimentation (DGAl) d'une demande pour rédiger un projet de document guide pour la fixation des limites maximales de résidus (LMR) de pesticides dans le miel dans le cadre du règlement (CE) n° 396/2005[1].

CONTEXTE DE LA DEMANDE

Lors de la réunion du Comité Permanent de la Chaîne Alimentaire et de la Santé Animale (CPCASA), section "Résidus de pesticides" des 26 et 27 mars 2007, la Commission européenne a indiqué qu'un document guide sur la fixation de limites maximales de résidus (LMR) de pesticides dans le miel devait être rédigé dans le cadre du règlement (CE) n° 396/2005.

De par son expérience dans ce domaine, la France a été sollicitée par la Commission européenne pour prendre en charge la rédaction de ce projet de document guide qui sera ensuite soumis à l'ensemble des Etats-membres.

Un groupe de travail spécifique a été créé avec mission de préparer un projet de document guide pour la fin de l'année 2008. Constitué de membres du Comité d'experts spécialisé "Produits phytosanitaires :substances et préparations chimiques" et de représentants des différentes unités concernées de la DiVE, le groupe a été élargi à des structures compétentes externes (DERNS[2], ANMV[3], LERPRA[4], installations d'essais apicoles). Des représentants de la filière miel française ainsi que de l'industrie phytopharmaceutique ont également été consultés lors de l'élaboration de ce projet de document guide.

Après consultation du Comité d'experts spécialisé "Produits phytosanitaires : substances et préparations chimiques" réuni le 18 et 19 novembre 2008, l'Agence française de sécurité sanitaire des aliments émet l'avis suivant.

INTRODUCTION

Les abeilles produisent principalement du miel mais aussi de la cire, du pollen, de la propolis et de la gelée royale. Ces différents produits (à l'exception de la cire) peuvent être ingérés par l'homme même si le miel reste le principal produit consommé. La FAO (Food and Agriculture Organisation of the United Nations) a dressé un bilan des productions et des consommations de miel dans le monde, par pays. Ainsi, en France, la production s'élèverait à 15530 tonnes par an (moyenne 2000-2005) avec une consommation de 1,35 g/jour et par habitant.

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1 Règlement (CE) n°396/2005 du Parlement européen et du Conseil du 23 février 2005, concernant les limites maximales applicables aux résidus de pesticides présents dans ou sur les denrées alimentaires et les aliments pour animaux d'origine végétale et animale et modifiant la directive 91/414/CEE du Conseil (JOCE du 16/03/2005) et règlements modifiant ses annexes II, III et IV relatives aux limites maximales applicables aux résidus des produits figurant à son annexe I.

2 Direction de l'évaluation des risques nutritionnels et sanitaires de l'Afssa

3 Agence nationale du médicament vétérinaire

4 Laboratoire d'études et de recherches sur les petits ruminants et les abeilles de l'Afssa

Des enquêtes alimentaires permettent d'avoir une estimation plus réaliste de cette consommation. En France, l'enquête INCA 1999[5] révèle que la consommation moyenne de la population française est de 1,2 g/jour (± 4,9) mais que chez les seuls consommateurs, cette consommation s'élève à 7 g/jour (± 9,7) et chez les forts consommateurs (95ème percentile), elle peut atteindre 40 g/jour. La consommation de miel représenterait 0,04 à 0,17 % de l'ensemble du régime alimentaire selon des groupes d'âge et les Etats-membres. En France, une très faible proportion de la population consomme du miel à l'état brut (0,1 %) mais 17,6 à 23,1 % de la population en consomme, en tant que tel ou sous forme de produit transformé.

De ces quelques chiffres, il apparaît clairement que la consommation de miel est très faible et qu'elle représente également une part très faible dans l'ensemble du régime alimentaire. En terme de risque pour le consommateur, le miel ne contribuera que très faiblement à l'apport journalier maximum théorique, utilisé pour évaluer l'exposition chronique alimentaire.

Concernant l'exposition aiguë, si l'on considère le modèle PRIMo établi par l'AESA[6] et la plus faible dose de référence aiguë (ArfD) définie à ce jour, il apparaît qu'une LMR par défaut de 0,01 mg/kg pour les produits phytopharmaceutiques non autorisés en Europe est suffisante pour garantir la sécurité du consommateur.

Pour les autres substances actives, le risque pour le consommateur lié à l'ingestion de miel devra être évalué, afin de définir une éventuelle LMR par défaut.

OBJECTIF DU PROJET DE DOCUMENT GUIDE

Le miel est produit dans un environnement potentiellement pollué par différentes sources de contamination, notamment par les produits phytopharmaceutiques appliqués sur les plantes. Aussi, afin de permettre la surveillance et le contrôle de ces produits, et par conséquent de protéger le consommateur, il convient de fixer des LMR dans le miel, ainsi qu'il en existe déjà dans certaines denrées d'origine animale, pour certaines substances actives entrant dans les produits phytopharmaceutiques. Ces LMR doivent être les plus basses possibles au regard des Bonnes Pratiques Agricoles (BPA).

Il est possible de détecter des résidus dans le miel :
- lorsque les cultures traitées sont mellifères ;
- lorsqu'un produit phytopharmaceutique est appliqué pendant ou peu de temps avant la floraison ;
- lorsqu'un produit phytopharmaceutique est appliqué avant la floraison mais que la substance active présente un faible taux de dégradation et/ou qu'elle est systémique.

De manière générale, les animaux d'élevage peuvent être exposés à des produits chimiques de trois manières différentes :
1 après application directe du produit sur l'animal,
2 après traitement des bâtiments d'élevage (notamment les ruches),
3 du fait de la présence de résidus dans leur alimentation.

Les abeilles peuvent être exposées à des produits de traitements provenant d'un usage vétérinaire (cas 1 et 2). Dans ces deux cas, les LMR sont fixées dans le cadre du règlement (CEE) n° 2377/90[7].

Dans le 3ème cas, des résidus de produits phytopharmaceutiques peuvent se retrouver dans le miel, via la récolte de nectar et/ou de pollen par les abeilles, dans des cultures traitées.

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5 VOLATIER, J.-L.. Enquête INCA individuelle et nationale sur les consommations alimentaires. *Agence Française de Sécurité Sanitaire des Aliments (AFSSA)*, 2000, Tech & Doc, Paris.

6 Autorité européenne de sécurité alimentaire (EFSA : European authority of food safety)

7 Règlement CEE n° 2377/90 du Conseil du 26 juin 1990 établissant une procédure communautaire pour la fixation des limites maximales de résidus de médicaments vétérinaires dans les aliments d'origine animale (JO L 224 du 18.8.1990).

L'objectif de ce projet de document guide est de proposer une démarche pour savoir :
- quand et pour quelles substances actives des LMR doivent être fixées dans le miel ;
- comment proposer une LMR temporaire pour une substance active donnée ;
- comment concevoir, préparer et réaliser des études permettant de fixer une LMR dans le miel.

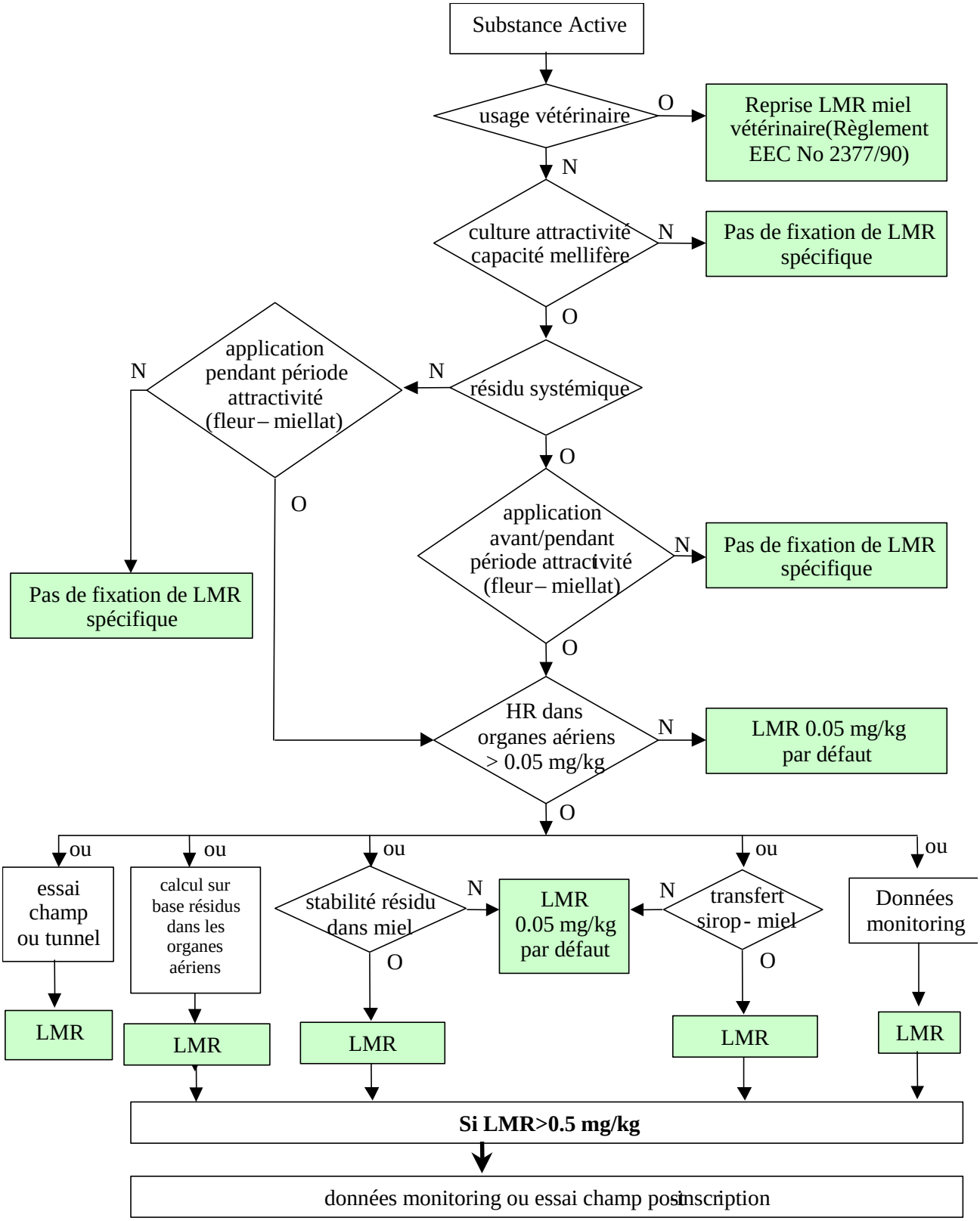
Le schéma décisionnel ainsi que des commentaires sur les différentes étapes figurent à l'annexe 1. L'annexe 2 contient l'ensemble du projet de document guide.

L'Agence française de sécurité sanitaire des aliments, estimant que ce projet de document guide propose une démarche adaptée à la fixation de limites maximales de résidus dans le miel, émet un avis favorable à la transmission de ce document qui servira de base aux discussions européennes sur le sujet.

Pascale BRIAND

Mots-clés : projet document guide, LMR, miel

Annexe 1
Schéma décisionnel pour la fixation des LMR



LMR : limite maximale en résidus – HR : plus haut résidu

Les explications suivantes apportent des précisions sur les différentes étapes du schéma.

Remarque : il est à noter que lorsque des données sur la culture (prélèvements de fleurs) ou des essais au champ sont nécessaires, une situation de "pire-cas" peut être envisagée. Cela signifie qu'il est possible d'obtenir ces données non seulement sur les cultures pour lesquelles des usages sont revendiqués, mais aussi sur une culture représentant le "pire cas" en termes de résidus dans le miel, par exemple sur colza, jachères fleuries (phacélie, mélilot) ou culture fortement mellifère. Dans ce cas, les paramètres d'application utilisés doivent être les plus critiques parmi tous les usages revendiqués.

Usage vétérinaire
Lorsque l'usage d'une substance active est autorisé pour le traitement des ruches, cet usage est considéré comme un pire cas et la Limite Maximale en Résidus (LMR) définie pour le miel dans le cadre de cet usage est reprise comme LMR miel dans le cadre des usages phytopharmaceutiques.

Attractivité, capacité mellifère de la culture revendiquée
La notion d'attractivité et de capacité mellifère englobe :
- l'attractivité de la culture proprement dite (considérée dès l'apparition des premières fleurs) ;
- l'attractivité liée à la présence, dans la culture, de plantes elles-mêmes attractives (adventices ou plantes d'enherbement) ;
- l'attractivité liée à la présence de miellat permettant la production de miel (résineux, céréales et maïs par exemple) ;
- mais également la qualité "mellifère" de cette culture (production de nectar utilisé pour la production de miel).

Pour illustrer cette notion, tous les arbres fruitiers peuvent être considérés comme attractifs, alors qu'ils peuvent l'être au moment de la floraison (pommier) ou non (noyer). Ceux qui le sont n'entrent pas tous dans la catégorie des plantes mellifères (pour les pommiers par exemple, l'attractivité est essentiellement liée à la collecte de pollen). En revanche la présence potentielle dans tous les vergers, d'adventices ou de couvert végétal en inter-rang produisant des fleurs, font que les arbres fruitiers seront tous considérés comme attractifs.

Une liste des cultures considérées comme attractives et mellifères est donnée dans le document guide.

En l'absence d'attractivité pour les abeilles de la culture traitée, le niveau de résidu attendu peut être considéré comme nul et aucune LMR spécifique ne serait fixée.

Résidu systémique
La notion de résidu correspond ici à la définition du résidu telle que fixée au niveau européen dans la monographie de la substance active considérée, définition donnée dans les plantes pour la surveillance et le contrôle. La systémie des différents composés compris dans la définition du résidu doit être prise en compte dans l'évaluation du risque de contamination des fleurs.

La systémie qualifie la capacité d'une substance, après pénétration dans la plante, à migrer à l'intérieur de celle-ci. Le caractère systémique ou non d'un composé devra être justifié, à partir des études de métabolisme chez la plante par exemple.

Par défaut et/ou en l'absence de données, le résidu sera considéré comme systémique et le raisonnement sera à poursuivre.

Application avant/pendant la période d'attractivité
L'application d'un produit non-systémique à une période où la culture n'est pas visitée par les abeilles engendre un risque d'exposition des abeilles, et donc de contamination du miel, limité si ce n'est nul. Dans cette situation, aucune LMR spécifique ne serait fixée. Si l'application a lieu à une période où la présence de fleurs ou de miellat peut intervenir, il convient d'examiner le niveau de résidus dans les parties attractives pour les abeilles.

L'application d'un produit systémique après la période d'attractivité de la culture (après floraison et en l'absence de présence future d'adventices en fleur ou de miellat) engendre un risque d'exposition des abeilles, et donc de contamination du miel, limité si ce n'est nul. Dans cette situation, aucune LMR spécifique ne serait fixée. Lorsqu'un produit systémique est appliqué avant floraison, il convient d'examiner le niveau de résidus dans les parties attractives pour les abeilles.

Résidus (HR) dans les organes aériens

En fonction de la teneur en résidus dans les organes aériens (si possible dans l'organe visité par l'abeille) ou dans les miellats et des propriétés physico-chimiques des molécules entrant dans la définition du résidu (risque consommateur dans les végétaux), il ne serait pas nécessaire d'engager des études sur le transfert et/ou la concentration potentielle de ces molécules dans le miel. En dessous d'un niveau de résidus de 0,05 mg/kg dans les feuilles / organes aériens, le risque de contamination du miel serait considéré comme < 0,05 mg/kg et la LMR fixée, par défaut, à 0,.05 mg/kg.

Pour des concentrations en résidu supérieures au seuil fixé, la proposition d'une LMR est indispensable pour que les miels, dans lesquels des résidus seraient susceptibles d'être retrouvés, puissent être commercialisables. Les différentes approches suivantes seraient alors applicables, au choix du pétitionnaire :

- exploitation de données résidus dans les organes aériens,
- exploitation de données de stabilité dans le miel,
- exploitation de données d'études de transfert sirop – miel,
- exploitation de données en provenance d'essais au champ ou sous tunnel,
- exploitation de données de surveillance.

La LMR provisoire ainsi calculée serait, après autorisation de la substance active, à confirmer par des études de surveillance ou par des essais au champ, dans le cas où elle serait supérieure à 0,5 mg/kg (exceptée si la LMR est fixée à partir des essais en champ ou sous tunnel).

Exploitation des données résidus dans les organes aériens

Les données résidus susceptibles d'être prises en considération doivent provenir d'organes aériens prélevés pendant la période d'attractivité de la culture (un nombre d'essais de l'ordre de 2 à 4 avec données dans les organes aériens serait suffisant). Les organes aériens comprennent les feuilles, les fleurs ou le nectar de la culture. Les graines ne sont pas considérées. Lorsque des plantes adventices sont susceptibles d'être en fleur ou en période de production d'exsudats dans la zone traitée, des données sur les concentrations retrouvées dans ces organes doivent être fournies.

Les teneurs en résidus trouvées dans ces organes aériens servent de base au calcul d'une LMR dans le miel qui serait égale au plus haut résidu mesuré dans les organes aériens (hypothèse facteur de transfert =1).

Afin de respecter le principe de fixation d'une LMR à un niveau aussi bas que possible, des analyses de fleurs ou de nectar sont exigées si la présence de résidus au delà de 0,5 mg/kg est mise en évidence dans les feuilles ou la plante entière.

Définition du résidu dans le miel pour la surveillance et l'évaluation du risque pour le consommateur

La définition suivante est proposée : somme des molécules entrant dans la définition du résidu pour les denrées d'origine végétale et animale et pour les procédés de transformation.

Stabilité du résidu dans le miel

L'expérimentation comprendrait :

- une surcharge du miel avec les molécules comprises dans la définition du résidu dans les plantes, à un niveau correspondant au plus haut résidu mesurés dans les organes aériens ;
- la quantification des résidus (avec une méthode validée pour la matrice miel conformément au document SANCO 3029) sur la base des molécules comprises dans la définition du résidu dans le miel après un séjour d'un mois à température ambiante (environ 20°C).

Si le niveau de résidus dans le miel est inférieur à 0,05 mg/kg après un mois de stockage à 20°C, une LMR par défaut est fixée à 0,05 mg/kg.

Dans le cas contraire, on définit une LMR par extrapolation des données de stabilité sous réserve de la pertinence des données fournies. La LMR est alors fixée au niveau de résidu mesuré dans le miel.

Transfert sirop – miel
Une expérimentation de type alimentation sur sirop de nourrissement est proposée, à conduire conformément au protocole présenté dans le document guide.

Pour les analyses, la méthode devra être validée sur la matrice miel conformément au document SANCO 3029 sur la base des molécules comprises dans la définition du résidu dans le miel.

Si le transfert dans le miel à un niveau supérieur à 0,05 mg/kg n'est pas confirmé, une LMR de 0,05 mg/kg est fixée.

Si le risque de présence de résidus dans le miel à un niveau supérieur à 0.05 mg/kg est encore probable, une LMR provisoire devra être fixée à partir des données obtenues, sous réserve de leur pertinence (HR x facteur de transfert sirop-miel).

Données de surveillance
L'utilisation des données de surveillance, si existantes, est suggéré pour affiner le résultat et aboutir à une LMR. L'utilisation de données provenant de l'étranger est aussi envisageable.

Essai au champ ou sous tunnel
A conduire selon les protocoles proposés dans le document guide.

Annexe 2

November 2008
Rev. 00

FRANCE PROPOSAL FOR A

D R A F T W O R K I N G D O C U M E N T
Guidelines relating to setting Maximum Residue Limits in honey
EC Guidance Document Part C4.

1. INTRODUCTION

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 however be fixed as low as possible in relation to Good Agricultural Practices (GAPs).

In the document Sanco/10440/2005 rev.7 (16 September 2007) *Draft data requirements (do not necessarily represent the views of the Commission services) Revision of Sections 6 and 8 of part A of Annexes II, III to Directive 91/414/EEC - Residues in or on treated products, food and feed* the question of defining MRLs for pesticides in honey arises in chapter 6-10-1: "*Effect on the residue level in honey*".

The circumstances in which such studies are required are limited to a certain number of cases:

- when a plant protection product (pesticide) is used during or shortly before blossoming of the crop or
- when a plant protection product is used before blossoming and the active substance used has a low degradation rate and/or is systemic

and

- when these flowering crops are used to produce pure blossom honey.

Honey has been considered as a food of animal origin. As a general rule, pesticides may be ingested or absorbed by livestock in three ways:

1. following direct application of the product to the animal,
2. as a result of treatment of their accommodation,
3. through residues in feeding stuffs.

Residues of pesticides arising from uses as veterinary medicinal products or after accommodation (beehive) treatment (cases 1 and 2) must be taken into consideration when setting MRLs for plant protection products.

In the first two cases MRLs have been set in the past by Council Regulation (EEC) No 2377/90.

In case 3, pesticide residues may arise in honey from current pesticide GAPs. MRLs established in this case should in principle be set on the basis of appropriate supervised residue trials data.

Residues may be taken up by the honey bees during collection of nectar and/or pollen when plant protection products are used while the treated crops are flowering. In the case of honey, document Sanco/10440/2005 clearly states that other data, such as that from scientific publications, supervised uses, etc., may be used in support of decisions, but cannot normally replace data from supervised residue trials. This document also states that, the setting of a MRL in honey can be achieved after authorisation for use in the target crop has been granted.

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

- when and for what kind of active substance an 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

2 GENERAL INFORMATION

2.1 Beehive products and their importance in human food in Europe

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 human food.

- Food Balance Sheets data

Data on production and availability of food for human consumption, including natural honey, are obtained from the Food Balance Sheet (FBS) compiled by the Food and Agriculture Organisation of the United Nations (FAO). The FBS provides a comprehensive picture of the pattern of a country's food supply during a particular reference period. The total quantity of foodstuffs produced in a country added to the total quantity imported and adjusted for any change in stocks that may have occurred since the beginning of the reference period, gives the supply available during that period. On the utilisation side, a distinction is made between the quantities exported, fed to livestock, or to manufacture for food use and non-food uses, lost during storage and transportation, and available as food for human consumption at the retail level. The *per caput* food supply of each food item available for human consumption is then obtained by dividing its respective quantity by the related data on the population actually partaking it. The following table presents an average of data from 2000 to 2005.

Table 1. Data on production and consumption of natural honey within the European Union

Countries	**Annual production quantity (1000 tonnes) (Average 2000–2005)**	**Food consumption quantity (g/capita/day) (Average 2000–2005)**
Austria	7.50	4.05
Belgium	1.71	1.57
Bulgaria	7.23	0.65
Cyprus	0.77	3.39
Czech Republic	7.01	1.54
Denmark	0.00	0.71
Estonia	0.50	1.57
Finland	1.67	1.44
France	15.53	1.35
Germany	21.91	3.01
Greece	15.93	4.29
Hungary	17.65	1.20
Ireland	0.22	1.02
Italy	8.67	0.91
Latvia	0.65	0.98
Lithuania	1.13	0.90
Luxembourg	0.16	1.41
Malta	0.00	0.04
Netherlands	0.00	0.88
Poland	10.22	0.85
Portugal	6.10	1.82
Romania	15.59	0.96
Slovakia	3.45	0.92
Slovenia	2.33	2.79
Spain	34.20	2.40

Countries	Annual production quantity (1000 tonnes) (Average 2000–2005)	Food consumption quantity (g/capita/day) (Average 2000–2005)
Sweden	3.00	1.60
United Kingdom	4.82	1.36

Source : FAOSTAT | © OAA Statistics division 2007 | http://faostat.fao.org/default.aspx last consultation : 30 November 2007.

Three countries out of 27 (Denmark, Malta and the Netherlands) are not known to have produced natural honey between 2000 and 2005. Among the producers, the amounts average between 160 tonnes per year in Luxembourg and 34 200 tonnes per year in Spain. It is important to underline that non-commercial and subsistence-level production, which may be important for natural honey, are usually not included in these estimates.

The quantity available for human consumption stands between 0.04 g/capita/day in Malta and 4.29 g/capita/day in Greece. Because waste at home is not taken into account, FBS data may slightly overestimate real consumption.

- Individual consumption data

Individual surveys provide more-accurate estimates of food consumption, as their objective is to collect data on the quantities of food items consumed by a representative sample of individuals selected from the population. This kind of data is nevertheless not easily available throughout the Member States, especially for honey which has not been included in the European Food Safety Authority (EFSA) European Food Consumption Concise Database. Nonetheless, some data are available for Germany, the Netherlands, Spain and Sweden in the model developed by EFSA for risk assessment of pesticide MRLs (EFSA,2007). They are presented in Table 2, completed with French individual consumption data.

Table 2. Individual consumption habits of honey in g / capita / day

Country	Population	Based on	Average consumption ± standard deviation (% in the diet)	High percentile of consumption	Source
Netherlands	General population (1 – 97 years) (n = 6250)	Consumers only	-	P97.5: 40.0	EFSA, 2007
Sweden	General population (1 – 74 years) (n = 3258)	Whole population	-	P90: 1.9	EFSA, 2007
France	Adults (> 14 years) (n = 1474)	Whole population	1.2 ± 4.9 (0.05%)	P95: 8.0	Volatier, 2000
		Consumers only (N = 259)	7.0 ± 9.7	P95: 25.0	Volatier, 2000
Spain	Adults (> 17 years) (n = 1060)	Whole population	1.2 (0.09%)	-	EFSA, 2007
France	Children (3 – 14 years) (n = 1018)	Whole population	0.7 ± 3.3 (0.04%)	P95: 3.0	Volatier, 2000
		Consumers only (N = 235)	2.9 ± 6.5	P95: 10.7	Volatier, 2000
Germany	Children (2 – 5 years) (n = 475)	Whole population	1.6 (0.17%)	-	EFSA, 2007
		Consumers only	-	P97.5: 22.1	EFSA, 2007
Spain	Children (7 – 12 years) (n = 903)	Whole population	0.7 (0.05%)	-	EFSA, 2007

n: number of respondents, P90, 95, 97.5: 90th, 95th and 97.5th percentiles of consumption.

Average consumption for the whole population – between 0.7 and 1.2 g/capita/day – is consistent with the FBS estimate for France (1.35 g/capita/day) but can be as little as about one-third or one-half the FBS estimates for Spain and Germany respectively (the two greatest honey producers in the European Union). Honey consumption would represent between 0.04% and 0.17% of the total diet, according to the age-group and Member State. A small proportion of the population would actually consume honey (0.1% of the French population consume honey itself and between 17.6% and 23.1% consume honey itself and honey in the form of an ingredient, Volatier, 2000). The consumption level among consumers stands between 10.7 and 40.0 g/capita/day according to the percentile (95 or 97.5) and the Member State (France, Germany, the Netherlands), representing seven to 45 times the levels estimated in the FBS data.

- Considerations in term of risk to consumers

It is clear that 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% as estimated from the available data). 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 of exposure, according to:

- the EFSA Model for risk assessment of pesticides MRLs (PRIMo, Pesticide Residue Intake Model) :
  - critical Large Portion of 0.63 and 1.37 g/kg bw respectively defined for adults (NL) and children (DE),
  - case 1 equation (International Estimate Short Term Intake (IESTI) = LP x HR / ARfD),
- an Acute Reference Dose (ARfD) of 5.10^{-5} mg/kg bw/day, which corresponds to the lowest ARfD established to date (for chloropicrin)),

a maximum level of honey contamination can be set at 0.036 mg/kg.

This calculation shows that any MRL, even the default value of 0.05 mg/kg proposed below, should be checked for acute risk of dietary exposure, using PRIMo.

So, when there is no use in Europe, a default MRL should be set at 0.01 mg/kg or at the limit of quantification (LOQ) as defined in Annex 5 of Regulation 396/2005.

2.2 Honey composition

Honey is defined as the natural sweet substance produced by *Apis mellifera* bees from the nectar of plants, from secretions of living parts of plants or excretions of plant-sucking insects on the living parts of plants, which bees collect, transform by combining with specific substances on their own, deposit, dehydrate, store and leave in honeycombs to ripen and mature. Therefore, some honey components come from plants, others are added by honeybees, and others are due to biochemical reaction taking place during honey maturation. For more details concerning honey see Council Directive 2001/110/EC and the document available online at http://www.bag-anw.admin.ch/SLMB_Online_PDF/Data%20SLMB_MSDA/Version%20F/23A_Miel.pdf (2008).

Honey is composed primarily of sugars and water. The average honey content is 80% sugars and 18% water (Sporns *et al.*, 1992). The primary sugars are fructose and glucose. These 'simple' 6-carbon sugars are readily absorbed by the consuming organism. Other sugars include maltose, a 12-carbon sugar composed of two glucose molecules, and saccharose, a 12-carbon sugar composed of a glucose and a fructose molecule (Sabatini *et al.*, 1989; Sabatini *et al.*, 1990).

Honey also contains acids, some proteins, a small amount of minerals and a number of other minor components including pigments, flavour and aroma substances, sugar alcohols, colloids, free amino acids and vitamins (Iglesias *et al.*, 2006; Yao *et al.*, 2004). This latter group of materials constitutes about 2% of the total composition.

The detailed composition of honey depends on its origin (honeydew or nectar) and for a given source, from the plant producing the nectar or honeydew. Examples of detailed composition are given in APPENDIX I.

Honey is also known to be acid (Wootton *et al.*, 1976) and this acidity plays an important role in the system which prevents bacterial growth. The pH of honeys may vary from approximately 3.2 to 4.5 (average pH= 3.9) making it, together with other substances, inhospitable for most bacterial development (Baltrusaityte *et al.*, 2007).

2.3 Honey production by bees

The worker bees raise larvae and collect the nectar that will later be transformed into honey in the hive. They collect the sugar-rich flower nectar and return to the hive. The conversion of nectar into honey involves physical and chemical changes. In the hive, the foraging bees give the nectar to the house bee. House bees extend their mouthparts, pushing a drop of the ripening nectar to the tip of their tongue, sucking it back into the mouth and then out again. This process exposes the nectar and helps to reduce its moisture content. At the same time the young house bees add and mix enzymes in the new honey (Root, 1990).

Hydrolysing enzymes break down the principal saccharose of nectar to the simpler monosaccharides glucose and fructose present in honey. Immediately behind the bee's honey stomach is the proventricular valve or honey stopper. It retains the nectar load in the honey stomach, controls passage of food into the midgut or ventriculus, and prevents food substances in the midgut from returning to the honey stomach.

Honey is then stored in the honeycomb unsealed. Bees inside the hive "fan" their wings, creating a strong draft across the honeycomb. This enhances evaporation of much of the water from the nectar, saving storage space. The reduction in water content, which raises the sugar concentration, prevents fermentation by increasing osmotic pressure (Root, 1990). Cells containing mature honey are sealed with beeswax. Ripe honey, as removed from the hive by the beekeeper, has a long shelf life and will not ferment.

During the process of conversion of nectar into honey, bees add enzymes to nectar, among them, glucose oxidase and invertase. The enzyme glucose oxidase reacts with a small amount of glucose to produce hydrogen peroxide and gluconic acid, both of which have antibacterial properties. This system is most active in dilute honey and helps to preserve honey diluted for brood food use.

3 RESIDUE DEFINITION

As mentioned above, honey is made mainly from nectar but is also partially modified by bees and modified 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 residue definition in honey is suggested as a default approach:

- for monitoring and risk assessment : the sum of parent and/or of all metabolites included in the residue definition for monitoring in plants and foods of animal origin.

4 EXTENT OF DATA REQUIRED

As pointed out in the Introduction above (§1), residues in honey are expected whenever plant protection products have been applied according to Good Agricultural Practice (GAP):

- during the blossom stage of the crop, or
- in cases where the active substance of the plant protection product has systemic properties and can be translocated into the pollen and/or nectar and application occurs prior to the flowering stage, or
- via honeydew collected on plant-sucking insects.

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. The MRL will be set depending on the results obtained at each different step.

A global decision-making scheme is presented in APPENDIX II and supplementary information is given below.
In cases where data on crop (samples of flowers) or field trials are necessary, it is possible to consider a "worst case" situation. This means that it is possible to obtain these data not necessarily on the crops requested but on a crop representing the worst case in terms of residue in honey. For example, rapeseed, *Phacelia*, sainfoin or crops with high melliferous capacity.
The application parameters considered (number, rate and stage of application, etc.) must then be the critical ones among those intended.

4.1 Is the active substance included in a veterinary medicinal product?

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 product is generally applied close to bees and honey. In that case the MRL defined under Council Regulation (EEC) No 2377/90 applies.

4.2 Does the crop have 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).
However, it must be kept in mind that attractivity is not only linked to the crop but also to other factors such as:

- presence in the foraging area of alternative sources of nectar/honeydew of higher/lower attractivity,
- presence in a non-attractive crop of spontaneous or sown flora more attractive than the crop itself (the case of white clover grown in orchards or vineyards for instance)

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 (the case of early-flowering trees: peach trees, berries, plum trees, etc.).
Besides plants' attractiveness, the table presented in APPENDIX III summarises the possibility of producing honey via nectar or exudates of plant-sucking insects.
If the intended use of the active substance does not concern any crop considered as very attractive to bees and/or melliferous, there is no need to define a specific MRL in honey.

4.3 Does the "residue" present systemic activity?

The "residue" considered here corresponds to the residue definition in plant (active substance and/or its relevant metabolite(s)).

If metabolism studies in crops (studies conducted according to guideline 7028/VI/95 rev.3) clearly establish that neither the parent nor toxicologically-relevant metabolites are present in a non-treated part of the plant when the active substance is applied according to critical GAPs, then it can be considered that the active substance is not systemic.

If such a substance is applied at a time when bees are not foraging the crops, then the risk of exposure of bees to residues is low and the risk of contamination of honey can be considered negligible. As a consequence, there is no need to define a specific MRL in honey.

In the same way, if an active substance for which "residue" clearly shows systemic activity is applied after flowering, at a time when the crop is no more melliferous, then the risk of exposure of bees to residues is low and the risk of contamination of honey can be considered negligible. Once again, there is no need to define a specific MRL in honey.

If an active substance with no systemic "residue" is applied during flowering, or, if an active substance with systemic "residue" is applied before or during flowering, then the level of "residue" (according to the monitoring residue definition in plants) has to be assessed, mainly in the parts of the plant foraged by bees.

4.4 What is the "residue" level in aerial parts of the crop?

Depending on the residue level in aerial parts of the crop (if possible in flowers at flowering) 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 0.25; Kubik *et al.*, 1999).

Other rationales are acceptable, based on physico-chemical properties of the metabolites for instance, to show that the nectar does not contain metabolites included in the residue definition. Important conclusions concerning the behaviour of the active substance and/or its metabolites in honey can be drawn simply by looking at the distribution coefficients for n-octanol/water and solubility behaviour. For example, when the log Pow is greater

than three, one can assume that the residue will be preferentially concentrated in wax, whereas good water-solubility indicates that residues can be expected in honey.

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 available to applicant:

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

4.5 Are the data on residue level in aerial parts of the crop sufficient to establish an MRL in honey?

Only data from aerial parts sampled during the attractivity period of the crop or its weeds can be used (two to four trials are considered sufficient).
Aerial parts of the crop comprise leaves, flowers or nectar. Grains are not considered.
Based on the hypothesis of a transfer factor of 1, an MRL proposal could be made with a suitable rationale.

However, in order to set a MRL at a level as low as possible, analysis in flowers or nectar will be required if a residue level higher than 0.5 mg/kg is measured in leaves or whole plants.

4.6 Is the “residue” transferred from syrup to honey?

An experiment based on syrup feeding is proposed. This method is described in APPENDIX IV.

Spiking the syrup 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 is lower than 0.05 mg/kg, then this value is considered as a default MRL.
If the residue level is higher than 0.05 mg/kg, an MRL will be defined by extrapolation of data on transfer from syrup to honey (if these data are sufficiently relevant).
Then a provisional MRL could be set from the value : Highest Residue (HR) [in plants] x average transfer factor (from syrup to honey).

4.7 Is the “residue” stable in honey?

As indicated in § 2, honey is an acidic medium, containing enzymes produced by bees and is kept in the beehive for at least one month at a relatively high temperature, meaning water evaporates.

These conditions are clearly hydrolytic and could be considered close to those defined for pasteurisation in hydrolytic studies performed for assessment of the effect of industrial process and household preparations (document SANCO 7035/VI/95 rev.5 : Appendix E). This can significantly affect stability of a chemical compound, as has been clearly established in the past (BALAYANNIS and SANTAS, 1992).

If such hydrolytic studies are available, metabolites of concern should be assessed if they are toxicologically relevant.
If not, the proposed residue definition is wide enough to consider that if new metabolites appear during honey formation from nectar, they will be of low toxicological significance, in relation to the others already considered, and low daily honey consumption.
On this basis it may be concluded that if residues (as defined in § 3) are not stable in honey, they degrade to non-toxicologically relevant metabolites.

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 with a validated method on honey (according to document SANCO 3029) after a storage period of one month at room temperature (around 20°).

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 greater than 0.05 mg/kg, an MRL is defined by extrapolation from the stability data (if these data are sufficiently relevant) at the level measured in honey.

4.8 Are monitoring data available?

Data from monitoring from outside the EU (if available) can be used when the residue level is higher than 0.05 mg/kg in aerial parts, and to propose an MRL.
There is considerable freedom concerning the way in which these monitoring data may be obtained, 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 plants that have been treated
- 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 collection of nectar from treated plants,
- Statistical analysis of the results has to be performed and a rationale given about the reliability of the proposed MRL.

4.9 Are field or tunnel data available?

Tunnel or field trials are considered as the best way to define a 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).

As a general rule it is necessary to clearly establish :

- that colonies used are well defined, as homogeneous as possible, in good health and not affected by foraging in the treated area,
- as the bees are flying freely, that they have chiefly foraged plants treated according to critical GAPs (critical considering honey contamination so that it is a realistic indication of the highest bee exposure),
- that honey produced from treated plants is clearly identified,
- that dosing of residues has been achieved on “mature” and marketable honey and in conditions that allow full confidence in the analytical results.

An example of the protocol proposed by German authorities is presented in APPENDIX V and a protocol for trials in tunnels is described in APPENDIX VI.

Whatever the protocol and/or design used, the results must allow confirmation that:

- residues are at or about the LOQ in control samples,
- no adverse effects on health of the honey bees has been established,
- an MRL in honey can be proposed on the basis of reasoned opinion.

5 POST-REGISTRATION DATA

It seems unnecessary to provide new post-registration[8] data on a systematic basis. It is proposed that data be required if the MRL defined in the previous steps is greater than **0.5 mg/kg** (except in cases where the MRL was defined from field or tunnel trials).
If the calculated MRL is higher than 0.5 mg/kg then post-registration monitoring data or field/tunnel trials are required.

5.1 Monitoring data

In document Sanco/10440/2005 rev.7 (16 September 2007) it is clearly established that MRLs in honey can be set on the basis of monitoring data.

There is considerable freedom concerning the way in which these monitoring data may be obtained, but a certain number of points must be addressed:

[8] That is, either after Annex I inclusion of an active substance **or** national authorisation of a plant protection product.

- The data concerning residue levels in honey (according to residue definition in honey) should reflect exposure of honeybees to plants that have been treated
- 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 collection of nectar from treated plants.
- Statistical analysis of the results has to be performed and a rationale given about the reliability of the proposed MRL.

5.2 Trials

To be performed according to the proposed field protocol (see Appendix V) or the tunnel protocol (see Appendix VI).

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APPENDIX I:
Detailed composition of some honeys (HONEY COMPOSITION AND PROPERTIES - J. W. WHITE, JR. AND LANDIS W. DONER (1) BEEKEEPING IN THE UNITED STATES AGRICULTURE HANDBOOK NUMBER 335 Revised October 1980) - © 1999-2001 BeeSource.Com / info@beesource.com

TABLE 1. - *Average composition of floral and honeydew honey and range of values* (1)

Characteristic or constituent		Floral honey		Honeydew honey	
		Average values	Range of values	Average values	Range of values
Color(2)		Dark half of white.	Light half of water white to dark.	Light half of amber.	Dark half of extra light amber to dark.
Granulating tendency(3)		Few clumps of crystals 1/8- to 1/4-inch layer.	Liquid to complete hard granulation.	1/16- to 1/8-inch layer of crystals.	Liquid to complete soft granulation.
Moisture	percent	17.2	13.4-22.9	16.3	12.2-18.2
Glucose	do	38.19	27.25-44.26	31.80	2.91-38.12
Fructose	do	31.28	22.03-40.75	26.08	19.23-31.86
Saccharose	do	1.31	.25-7.57	.80	.44-1.14
Maltose	do	7.31	2.74-15.98	8.80	5.11-12.48
Higher sugars	do	1.50	.13-8.49	4.70	1.28-11.50
Undetermined	do	3.1	0-13.2	10.1	2.7-22.4
pH		3.91	3.42-6.10	4.45	3.90-4.88
Free acidity(4)		22.03	6.75-47.19	49.07	30.29-66.02
Lactone(4)		7.11	0-18.76	5.80	.36-14.09
Total acidity(4)		29.12	8.68-59.49	54.88	34.62-76.49
Lactone ÷ free acid		.335	0-.950	.127	.007-.385
Ash	percent	.169	.020-1.028	.736	.212-1.185
Nitrogen	do	.041	0-.133	.100	.047-.223
Diastase(5)		20.8	2.1-61.2	31.9	6.7-48.4

(1) Based on 490 samples of floral honey and 14 samples of honeydew honey.

(2) Expressed in terms of U.S. Department of Agriculture color classes.

(3) Extent of granulation for heated sample after 6 months' undisturbed storage.

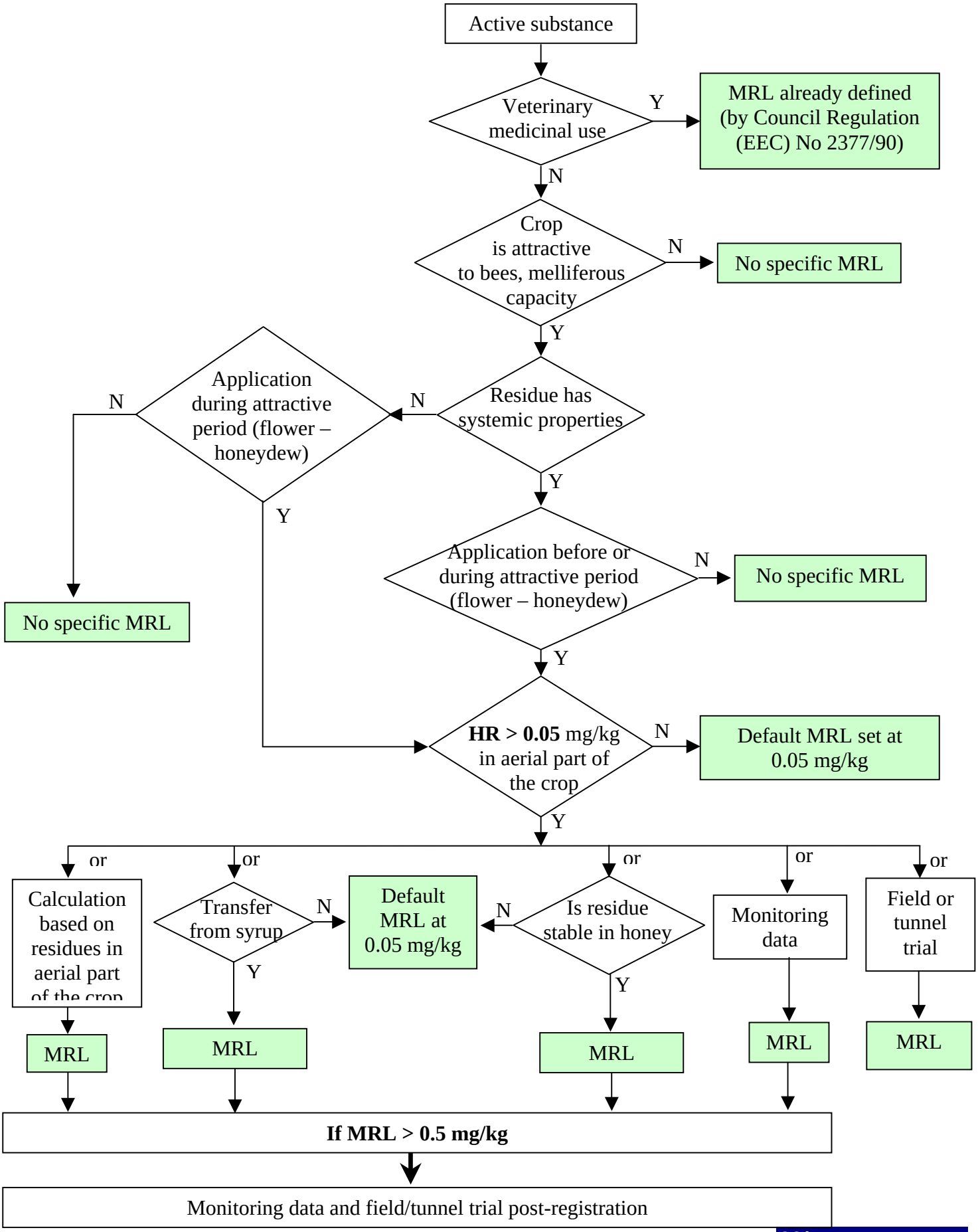
(4) Milliequivalents per kilogram.

(5) 270 samples for floral honey.

TABLE 2. - *Carbohydrate composition of honey types*

Number of samples	Floral type	Glucose	Fructose	Saccharose	Maltose	Higher sugars
		Percent	*Percent*	*Percent*	*Percent*	*Percent*
23	Alfalfa	33.40	39.11	2.64	6.01	.89
25	Alfalfa-sweetclover	33.57	39.29	2.00	6.30	.91
5	Aster	31.33	37.55	.81	8.45	1.04
3	Basswood	31.59	37.88	1.20	6.86	1.44
3	Blackberry	25.94	37.64	1.27	11.33	2.50
5	Buckwheat	29.46	35.30	.78	7.63	2.27
4	Buckwheat, wild	30.50	39.72	.79	7.21	.83
26	"Clover"	32.22	37.84	1.44	6.60	1.39
3	Clover, alsike	30.72	39.18	1.40	7.46	1.55
3	Clover, crimson	30.87	38.21	.91	8.59	1.63
3	Clover, Hubam	33.42	38.69	.86	6.23	.74
10	Cotton	36.74	39.28	1.14	4.87	.50
3	Fireweed	30.72	39.81	1.28	7.12	2.06
6	Gallberry	30.15	39.85	.72	7.71	1.22
3	Goldenrod	33.15	39.57	.51	6.57	.59
2	Heartsease	32.98	37.23	1.95	5.71	.53
2	Holly	25.65	38.98	1.00	10.07	2.16
3	Honeydew, cedar	25.92	25.16	.68	6.20	9.61
5	Honeydew, oak	27.43	34.84	.84	10.45	2.16
2	Horsemint	33.63	37.37	1.01	5.53	.73
3	Locust, black	28.00	40.66	1.01	8.42	1.90
3	Loosestrife, purple	29.90	37.75	.62	8.13	2.35
3	Mesquite	36.90	40.41	.95	5.42	.35
4	Orange, California	32.01	39.08	2.68	6.26	1.23
13	Orange, Florida	31.96	38.91	2.60	7.29	1.40
4	Raspberry	28.54	34.46	.51	8.68	3.58
3	Sage	28.19	40.39	1.13	7.40	2.38
3	Sourwood	24.61	39.79	.92	11.79	2.44
4	Star-thistle	31.14	36.91	2.27	6.92	2.74
8	Sweetclover	30.97	37.95	1.41	7.75	1.40
3	Sweetclover, yellow	32.81	39.22	2.94	6.63	.97
4	Tulip tree	25.85	34.65	.69	11.57	2.96
5	Tupelo	25.95	43.27	1.21	7.97	1.11
7	Vetch	31.67	38.33	1.34	7.23	1.83
9	Vetch, hairy	30.64	38.20	2.03	7.81	2.08
12	White clover	30.71	38.36	1.03	7.32	1.56

APPENDIX II: Decision-making scheme for MRL-setting in honey



MRL : Maximal Residue Level – HR : Highest Residue

APPENDIX III:
Possibility of producing honey from available nectar and/or honeydew in crops

level	Code no. (1)	Groups to which the MRLs apply	Examples of individual products within the groups to which the MRLs apply	Scientific name (2)	Examples of related varieties or other products included in the definition to which the same MRL applies	Possibility of presence of nectar or honeydew
1	100000	1. FRUIT FRESH OR FROZEN; NUTS	FRUIT			
2	110000	(i) Citrus fruit	Citrus fruit			**Yes**
2	120000	(ii) Tree nuts (shelled or unshelled)	Tree nuts (shelled or unshelled)			**Yes**
4	120010		Almonds	*Prunus dulcis*		**Yes**
4	120040		Chestnuts	*Castanea sativa*		**Yes**
4	120060		Hazelnuts	*Corylus avellana*	Filbert	**Yes**
4	120110		Walnuts	*Juglans regia*		**Yes**
2	130000	(iii) Pome fruit	Pome fruit			**Yes**
2	140000	(iv) Stone fruit	Stone fruit			**Yes**
2	150000	(v) Berries & small fruit	Berries & small fruit			**Yes**
3	151000	(a) Table and wine grapes	Table and wine grapes			**Yes**
3	152000	(b) Strawberries	Strawberries	*Fragaria* x *ananassa*		**Yes**
3	153000	(c) Cane fruit	Cane fruit *Framboises, Mûres*			**Yes**
3	154000	(d) Other small fruit & berries	Other small fruit & berries			**Yes**
2	160000	(vi) Miscellaneous fruit	Miscellaneous fruit			
3	161000	(a) Edible peel	Miscellaneous fruit (edible peel)			**No**

APPENDIX III: Possibility of producing honey from available nectar and/or honeydew in crops						
level	**Code no. (1)**	**Groups to which the MRLs apply**	**Examples of individual products within the groups to which the MRLs apply**	**Scientific name (2)**	**Examples of related varieties or other products included in the definition to which the same MRL applies**	**Possibility of presence of nectar or honeydew**
4	161020		Figs	*Ficus carica*		**No**
4	161030		Table olives	*Olea europaea*		**No**
3	162000	(b) Inedible peel, small	Miscellaneous fruit (inedible peel, small)			**No**
4	162010		Kiwi	*Actinidia deliciosa* syn. *A. chinensis*		**No**
3	163000	(c) Inedible peel, large	Miscellaneous fruit (inedible peel, large)			
4	163010		Avocados	*Persea americana*		**Yes**
4	163020		Bananas	*Musa x paradisica*	Dwarf banana, plantain, apple banana	**No**
4	163080		Pineapples	*Ananas comosus*		**No**
1	200000	2. VEGETABLES FRESH OR FROZEN	VEGETABLES FRESH OR FROZEN			
2	210000	(i) Root and tuber vegetables	Root and tuber vegetables (incl. potatoes)			**No**
3	211000	(a) Potatoes	Potatoes	*Tuber form Solanum* spp.		**No**
3	213000	(c) Other root and tuber vegetables except sugar beet	Other root and tuber vegetables except sugar beet			
4	213010		Beetroot	*Beta vulgaris* subsp. *vulgaris*		**No**
4	213020		Carrots	*Daucus carota*		**No (except for seeds production)**
4	213030		Celeriac *Celeri rave*	*Apium graveolens* var. *rapaceum*		**No**

APPENDIX III: Possibility of producing honey from available nectar and/or honeydew in crops						
level	**Code no. (1)**	**Groups to which the MRLs apply**	**Examples of individual products within the groups to which the MRLs apply**	**Scientific name (2)**	**Examples of related varieties or other products included in the definition to which the same MRL applies**	**Possibility of presence of nectar or honeydew**
4	213040		Horseradish *Raifort*	*Armoracia rusticana*		**No**
4	213050		Jerusalem artichokes *Topinambour*	*Helianthus tuberosus*		**Yes**
4	213060		Parsnips *Parnais*	*Pastinaca sativa*		**No (except for seeds production)**
4	213070		Parsley root *Persil tubéreux*	*Petroselinum crispum*		**No (except for seeds production)**
4	213080		Radishes	*Raphanus sativus* var. *saitvus*	Black radish, Japanese radish, small radish and similar varieties	**No (except for seeds production)**
4	213090		Salsify	*Tragopogon porrifolius*	Scorzonera, Spanish salsify (Spanish oysterplant)	**No**
4	213100		Swedes *Rutabaga*	*Brassica napus* var. *napobrassica*		**No**
4	213110		Turnips *Raves*	*Brassica rapa*		**No**
2	220000	(ii) Bulb vegetables	Bulb vegetables			**No**
4	220010		Garlic	*Allium sativum*		**No**
4	220020		Onions	*Allium cepa*	Silverskin onions	**No**
4	220030		Shallots	*Allium ascalonicum* (*Allium cepa* var. *aggregatum*)		**No**
2	230000	(iii) Fruiting vegetables	Fruiting vegetables			

APPENDIX III:
Possibility of producing honey from available nectar and/or honeydew in crops

level	Code no. (1)	Groups to which the MRLs apply	Examples of individual products within the groups to which the MRLs apply	Scientific name (2)	Examples of related varieties or other products included in the definition to which the same MRL applies	Possibility of presence of nectar or honeydew
3	231000	(a) Solanacea	Solanacea			**No**
3	232000	(b) Cucurbits - edible peel	Cucurbits - edible peel			**Yes**
4	232010		Cucumbers	*Cucumis sativus*		**Yes**
4	232020		Gherkins	*Cucumis sativus*		**Yes**
4	232030		Courgettes	*Cucurbita pepo* var. *melopepo*	Summer squash, marrow (patisson)	**Yes**
3	233000	(c) Cucurbits-inedible peel	Cucurbits-inedible peel			**Yes**
4	233010		Melons	*Cucumis melo*	Kiwano	**Yes**
4	233020		Pumpkins	*Cucurbita maxima*	Winter squash	**Yes**
4	233030		Watermelons	*Citrullus lanatus*		**Yes**
3	234000	(d) Sweet corn	Sweet corn	*Zea mays* var. *sacharata*		**No**
2	240000	(iv) Brassica vegetables	Brassica vegetables			**Yes**
2	250000	(v) Leaf vegetables & fresh herbs	Leaf vegetables & fresh herbs			**No**
3	251000	(a) Lettuce and other salad plants including Brassicacea	Lettuce and other salad plants including Brassicacea			**No**
4	251010		Lamb's lettuce	*Valerianella locusta*	Italian cornsalad	**No**
4	251020		Lettuce	*Lactuca sativa*	Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos)	**No**

APPENDIX III:
Possibility of producing honey from available nectar and/or honeydew in crops

level	Code no. (1)	Groups to which the MRLs apply	Examples of individual products within the groups to which the MRLs apply	Scientific name (2)	Examples of related varieties or other products included in the definition to which the same MRL applies	Possibility of presence of nectar or honeydew
					lettuce	
4	251030		Scarole (broad-leaf endive)	*Cichorium endiva*	Wild chicory, red-leaved chicory, radicchio, curled leave endive, sugar loaf	**No**
4	251040		Cress	*Lepidium sativum*		**No**
4	251050		Land cress	*Barbarea verna*		**No**
4	251060		Rocket, Rucola	*Eruca sativa (Diplotaxis* spec.)	Wild rocket	**No**
4	251070		Red mustard	*Brassica juncea* var. *rugosa*		**No**
4	251080		Leaves and sprouts of Brassica spp	*Brassica spp*	Mizuna	**No**
3	252000	(b) Spinach & similar (leaves)	Spinach & similar (leaves)			**No**
3	253000	(c) Vine leaves (grape leaves)	Vine leaves (grape leaves)	*Vitis euvitis*		**Yes**
3	254000	(d) Water cress	Water cress	*Nasturtium officinale*		**No**
3	255000	(e) Witloof	Witloof	*Cichorium intybus*. var. *Foliosum*		**No**
3	256000	(f) Herbs	Herbs			
4	256020		Chives *Ciboulette*	*Allium schoenoprasum*		**No (except for seeds production)**
4	256030		Celery leaves *Ache des marais (feuilles de celery)*	*Apium graveolens* var. *seccalinum*	fennel leaves , Coriander leaves, dill leaves, Caraway leaves,	**No (except for seeds production)**

APPENDIX III: Possibility of producing honey from available nectar and/or honeydew in crops						
level	**Code no. (1)**	**Groups to which the MRLs apply**	**Examples of individual products within the groups to which the MRLs apply**	**Scientific name (2)**	**Examples of related varieties or other products included in the definition to which the same MRL applies**	**Possibility of presence of nectar or honeydew**
					lovage, angelica, sweet cicely, other Apiacea	
4	256040		Parsley *Persil*	*Petroselinum crispum*		**No (except for seeds production)**
4	256050		Sage *Sauge*	*Salvia officinalis*	Winter savory, summer savory,	**No (except for seeds production)**
4	256060		Rosemary *Romarin*	*Rosmarinus officinalis*		**Yes**
4	256070		Thyme *Thym*	*Thymus* spp.	marjoram, oregano	**Yes**
4	256080		Basil *Basilic*	*Ocimum basilicum*	Balm leaves, mint, peppermint	**No (except for seeds production)**
4	256090		Bay leaves (laurel) *Laurier*	*Laurus nobilis*		**No (except for seeds production)**
4	256100		Tarragon *Estragon*	*Artemisia dracunculus*	Hyssop	**No (except for seeds production)**
2	260000	(vi) Legume vegetables (fresh)	Legume vegetables (fresh)			**No**
4	260010		Beans (with pods)	*Phaseolus vulgaris,*	Green bean (French beans, snap beans), scarlet runner bean, slicing bean, yard-long beans	**No**
4	260020		Beans (without pods)	*; Phaseolus vulgaris*	Broad beans, Flageolets, jack bean, lima bean, cowpea	**No**
4	260030		Peas (with pods)	*Pisum sativum*	Mangetout (sugar peas)	**No**
4	260040		Peas (without pods)	*Pisum sativum*	Garden pea, green pea, chickpea	**No**

APPENDIX III: Possibility of producing honey from available nectar and/or honeydew in crops						
level	**Code no. (1)**	**Groups to which the MRLs apply**	**Examples of individual products within the groups to which the MRLs apply**	**Scientific name (2)**	**Examples of related varieties or other products included in the definition to which the same MRL applies**	**Possibility of presence of nectar or honeydew**
					chickpea	
4	260050		Lentils	*Lens culinaris* syn. *L. esculenta*		**No**
2	270000	(vii) Stem vegetables (fresh)	Stem vegetables (fresh)			**No**
4	270010		Asparagus	*Asparagus officinalis*		**No**
4	270020		Cardoons	*Cynara cardunculus*		**No**
4	270030		Celery	*Apium graveolens* var. *dulce*		**No**
4	270040		Fennel	*Foeniculum vulgare*		**No**
4	270050		Globe artichokes	*Cynara scolymus*		**No**
4	270060		Leek	*Allium porrum*		**No**
4	270070		Rhubarb	*Rheum x hybridum*		**No**
2	280000	(viii) Fungi	Fungi	(viii) Fungi	(viii) Fungi	**No**
1	300000	3. PULSES, DRY	PULSES, DRY			**No**
4	300010		Beans	*Phaseolus vulgaris*	Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas	**No**
4	300020		Lentils	*Lens culinaris* syn. *L. esculenta*		**No**
4	300030		Peas	*Pisum sativum*	Chickpeas, field peas, chickling vetch	**No**

APPENDIX III: Possibility of producing honey from available nectar and/or honeydew in crops						
level	**Code no. (1)**	**Groups to which the MRLs apply**	**Examples of individual products within the groups to which the MRLs apply**	**Scientific name (2)**	**Examples of related varieties or other products included in the definition to which the same MRL applies**	**Possibility of presence of nectar or honeydew**
4	300040		Lupins	*Lupinus* spp.		**No**
1	400000	4. OILSEEDS AND OILFRUITS	OILSEEDS AND OILFRUITS			
2	401000	(i) Oilseeds	Oilseeds			**Yes**
4	401010		Linseed	*Linum usitatissimum*		**Yes**
4	401030		Poppy seed	*Papaver somniferum*		**Yes**
4	401040		Sesame seed	*Sesamum indicum* syn. *S. orientale*		**Yes**
4	401050		Sunflower seed	*Helianthus annuus*		**Yes**
4	401060		Rape seed	*Brassica napus*	Bird rapeseed, turnip rape	**Yes**
4	401070		Soya bean	*Glycine max*		**Yes**
4	401080		Mustard seed	*Brassica nigra*		**Yes**
4	401100		Pumpkin seeds	*Cucurbita pepo* var. *oleifera*		**Yes**
2	402000	(ii) Oilfruits	Oilfruits			**No**
4	402010		Olives for oil production	*Olea europaea*		**No**
1	500000	5. CEREALS	CEREALS			**No**
1	900000	9. SUGAR PLANTS	SUGAR PLANTS			**No**
4	900010		Sugar beet (root)	*Beta vulgaris*		**No**
4	900020		Sugar cane	*Saccharum officinarum*		**No**

APPENDIX III: Possibility of producing honey from available nectar and/or honeydew in crops						
level	**Code no. (1)**	**Groups to which the MRLs apply**	**Examples of individual products within the groups to which the MRLs apply**	**Scientific name (2)**	**Examples of related varieties or other products included in the definition to which the same MRL applies**	**Possibility of presence of nectar or honeydew**
4	900030		Chicory roots	*Cichorium intybus*		**No**
1		10, Forage Plants	FORAGE			
2		(i) gramineous	gramineous			**No**
2		(i) legumes	legumes			**Yes**
1		11, Agro-forestry and ornamental	TREES			
2		(i) Flowering trees	Flowering trees			**Yes**
2		(i) Conifers	pine trees			**Yes**
1		12, Fallow	FALLOW			
2		(i) Flowering plants	Flowering plants			**Yes**
2		(i) Non-flowering plants	Non-flowering			**No**
1		13, Perfume and medical plants	Perfume plants			
2		(i) Perfume plants	Perfume plants			
4			Lavender			**Yes**
4			Rose			**No**
2		(i) Medical plants	Medical plants			**Yes**
4			Poppy	*Papaver somniferum*		**Yes**
4			Sage			**Yes**

APPENDIX IV:
Study of residue transfer from syrup to honey

1 Objectives

In cases where an MRL has to be set on honey (when the highest residue level in aerial parts of the crop is greater than 0.05 mg/kg) one possibility is to study the transfer from syrup to honey, in order to refine the residue level.

2 Biological context

Bees collect nectar and honeydew from visited plants. These ingredients are then stored inside beehives. Therefore it is possible that honey contains residues of plant protection products (pesticides).

3 Experimental conditions

3.1 Test principle

Spiked sugar syrup is placed in a colony feeder, honey bees collect it and store it in the cells of beehive frames. After transformation the ripe honey is analysed to determine the “residue” of the tested active substance. Control syrup is spiked with the solvent used to dilute the test compound.

3.2 Test conditions

Beehives are placed in tunnels protected with an insect-proof net so that no residue dilution will occur in honey due to bee foraging on another nectar source. The tunnel surround is empty of melliferous plants. Bee colonies are well-defined, as homogeneous as possible and in good health. All frames are built; empty combs from the brood chamber are removed before the syrup is introduced and replaced by combs full of food. Thus the syrup will not be stored inside the brood chamber; only the honey supers on the top of the hive are intended for this use.

3.3 Experimental system

Each colony placed in a tunnel (or part of a split tunnel) represents a trial element. They must then be kept away from each other.

3.4 Honey bee preparation

Healthy queen-right colonies are used with enough worker honey bees to cover all combs (at least 20 000 honey bees, depending on beehive types and on the season).
Each colony presents brood with all the different stages : eggs, larvae, capped brood as well as the natural bee bread and the honey stocks.
The colony will have at least five brood frames containing all brood stages and also food store frames (to feed the bees).
Honey supers with empty combs are placed on the top of beehives and the syrup collected by bees will be stored there. It is possible to use pre-built plastic frames.

Protein supplements (between 50 and 100 g /day) are provided in the form of pollen or patties in order to avoid a drastic drop in protein sources.

4 Treatments

4.1 Treatments

The study design consists of a control (one colony in a control tunnel) and three treated plots (three colonies in three tunnels containing contaminated syrup).

4.2 Application method

Syrup is spiked with compounds included in the plant residue definition. These compounds (active substance and/or its metabolites) are prepared immediately with demineralised water, if possible.
If the compounds are not soluble at the studied concentration, it is possible to use other solvents (acetone for example). In this case it is recommended that solutions be prepared in a way that the final solvent concentration in the syrup ranges between 1% - 10% (v/v). When several concentrations are tested it is necessary to maintain a constant concentration of solvent in the syrup.

The syrup is constituted of saccharose diluted in demineralised water at a rate greater than or equal to 750 g/L. It is distributed in a sufficient quantity to enable storage in combs. A syrup quantity of 5 L for a colony of 10 combs and 20 000 honey bees is considered sufficient.

4.3 Application rate

Compounds applied are active substance and/or metabolites as defined in the **plant** residue definition. Thus the tested concentrations are chosen on the basis of the residue level measured in aerial parts of the treated crop (leaves, flowers or nectar). It is strongly suggested to check the exact amount of residues in the syrup.

4.4 Timing and frequency

Syrup is distributed in the feeder all at once.

5 Observations and results

5.1 Sampling

A few days after the syrup distribution, honey bees produce honey under the action of the enzyme invertase, which changes saccharose (into glucose, fructose, maltose…) and by evaporation-concentration.
Samples are collected on frames from the supers, from capped cells. If cells are not closed, the syrup is not sufficiently concentrated and is too similar to the initial syrup.
It is suggested that honey be sampled when super frames are capped on at least 80% of their surface so that there is no risk of fermentation (normally about 15 days after application of syrup).
According to the laboratory recommendations, a part of a frame containing capped honey can be sampled with a sharp tool, or it will be necessary to sample liquid honey. In that case, honey will be extracted from combs by gravity or centrifugation (if the quantities are sufficient).

5.2 Residues analysis

The method must be validated on honey matrix according to document SANCO 3029. One analysis can be made per sample.

6 References

BALAYANNIS P.G., SANTAS L.A.. Dissipation of malathion and fluvalinate residues from honey. *Journal of Apicultural Research*, 1992, 31 (2), 70-76.

FAUCON J.P., AURIERES C., DRAJNUDEL P., *et al.*. Experimental study on the toxicity of imidacloprid given in syrup to honey bee (*Apis mellifera*) colonies. *Pest Management Science*, 2005, 61, 111-125.

TREMOLADA P., BERNARDINELLI I., COLOMBO M., *et al.*. Coumaphos distribution in the hive ecosystem: case study for modelling applications. *Ecotoxicology*, 2004, 13, 589-601.

APPENDIX V:
Field residue trials for the assessment of honey contamination
(based on Germany proposal)

1 Objectives

The objective of these studies is to determine the inadvertent residue in honey arising from pesticide use, in order to allow a dietary risk assessment and to establish scientifically-based MRLs.

2 Test procedure

2.1 Test substance(s)

The test substance should be applied in a realistic worst-case scenario with respect to residues in honey, as described for the design, preparation and realisation of residue trials in plants. The residue trials should be based on the highest authorised or proposed rate of application consistent with Good Agricultural Practice in the flowering crop and region concerned.

2.2 Design of trials sites

As the bees are flying freely, the field size must be adapted to conditions of the surroundings to achieve results that are not influenced by these conditions. In the case of an isolated field with no other melliferous crops around the trial site, a field size of 1 ha may be sufficient. As this may not normally be achieved, a field size of 3 ha with no other flowering crops within a 2 to 3 km radius should be sought (minimum 500 m radius in the case of less-attractive flowering crops compared to the treated crop).

The treated crop area in these trials is very large compared to standard supervised crop field trials. This is necessary to ensure that the bees are exposed to the plant protection product according to "realistic worst-case" conditions., It is therefore desirable to generate these types of data after the authorisation in the target crop has been granted and (preferably EU) MRLs have been set. Otherwise, crop destruction is necessary, with the attendant expense.

2.3 Honeybee colony preparation

Healthy queen-right colonies are used with enough worker honey bees to cover all combs (at least 40 000 honey bees, depending on beehive types and on the season).
Each colony presents brood with all the different stages : eggs, larvae, capped brood as well as the natural bee bread and the honey stored by bees.
The colony will have at least seven brood frames containing all brood stages and also food store frames.
Honey supers with empty combs are placed on the top of beehives. It is possible to use pre-built frames in plastic.

2.4 Number of trials

To achieve the objectives a minimum of three trials is necessary. In each trial site, two beehives per hectare should be used in order to collect sufficient number of honeycombs.

Trials from one vegetation period are sufficient. They should be conducted in different regions.

2.5 Duration of trials

The bee hives should be brought onto the field three days prior to the application of the plant protection product. After application of the plant protection product at the critical GAP the bee hives should be left within the field until the honeycombs are closed, i.e., the honey is mature (normally 14-21 days after application or start of flowering stage).

2.6 Sampling, method of analysis

Beneath the general requirements concerning sampling and methods of analysis as described elsewhere, the following points should be taken into consideration:

At each site pollen traps should be used to collect pollen in order to analyse for pollen types and, where desirable, for residues. To analyse honey (and the treated crop, if desired) for the relevant residue, a suitable validated analytical method should be chosen. Honey is one of the more difficult matrices. On the other side honey gains the reputation of a natural healthy product. It is therefore desirable to achieve a limit of quantification as low as possible. A value of 0.01 mg/kg is favoured.

For sampling take at least one honeycomb from each beehive. The honey should be extracted from them by centrifuging de-capped broodless combs. The laboratory sample should contain at least 0.1 kg of honey.

3 Report

A report on residues in honey should include all relevant data in a suitable format. The report for an entire residue study could, for example, be sub-divided into the following sections:

- Summary
- Objectives
- Field part
- Sample preparation
- Extraction, clean-up, determination, evaluation
- Results and discussion.

3.1 Summary

This summarises the key results, the evaluation of these results and any anomalies of the study, with reference to the objective.

3.2 Objectives

The objective section of the report again describes the aims of the study in detail and formulates the questions to be dealt within it.

3.3 Field part

This section of the report summarises the key points documented in the log book. The documentation should include information on

- Site parameters, including crops growing in the surroundings,
- Application parameters,
- Weather data for the application and sample collection period,
- Duration of trial, incl. period prior to application,
- Number of beehives,
- Health effects.

Reference should be made to the critical points of the animal trial component, and special techniques and events should be described.

3.4 Sample preparation

This section should be used to describe sampling techniques including nature, number and size of samples taken and, where appropriate, intermediate storage, as well as the production of the laboratory or analysis samples and the storage and dispatch thereof.

3.5 Extraction, clean-up, determination, evaluation

This essentially describes the method used to prepare and measure the samples. This section of the report contains the residue levels in honey and, where desirable, in pollen and the treated crop.

3.6 Results and discussion

This section of the report discusses and evaluates the reported measurements in the light of the questions outlined in the objectives section. The relevance of results should be discussed in relation to the proposed uses of the plant protection product, including a critical appraisal of the study and the results. In particular the following points must be addressed:

- A residue at or about the LOQ in control samples
- Adverse effects on health of the honey bees
- MRL proposal, with reasoning.

4 References

BORNEMANN V.. Personnel communication, 2003 (from Germany proposal).

Council of the European Communities. Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. OJ N° L 10 of 18.8.1990, p. 1.

Council of the European Communities. Council Directive 2001/110/EC of 20 December 2001 relating to honey. OJ N° L 224 of 12.1.2002, p. 47.

European Commission. Proposal for a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in products of plant and animal origin, COM, 2003, 117 final, Brussels.

APPENDIX VI:
Tunnel residue trials for the assessment of honey contamination

1 Objectives

The objective of these studies is to determine the inadvertent residue in honey arising from pesticide use, in order to allow a dietary risk assessment and to establish scientifically-based MRLs.

2 Trial design

2.1 Test substance(s)

The test substance should be applied in a realistic worst-case scenario with respect to residues in honey. The proposed trial design, by confining bees within tunnels, ensures that they are allowed to forage only on the treated crop, mimicking commercial situations in which large areas of crop may be grown and treated more-or-less simultaneously.
The residue trials should be based on the highest authorised or proposed rate of application consistent with Good Agricultural Practice in the flowering crop and region concerned.
Application(s) is/are made within the tunnels the morning after introducing the hives.

2.2 Design of trials sites

The study should be conducted in tunnels placed in crop fields, to maximise exposure of the bee colonies to treated plants. Each trial should consist of a control plot and three “treated” plots : three tunnels with one bee colony in each, placed in a field treated with the relevant plant protection product .
The trial site must then be large enough to accommodate four tunnels.

The tunnel size should be at least 120 m^2 with one path of approximately 50 cm width in the middle, necessary for the application of the test substance.

Products containing the tested active substance must not be used as maintenance chemicals, either on treated or untreated plots. In the same way, products likely to cause ill effects on honeybees must be avoided.

2.3 Number of trials

To achieve the objectives a minimum of three trials is necessary. Trials sites must be situated at different locations, at a minimum of 10 km apart.

2.4 Honeybee colonies

The colonies will be queen-right and contain enough bees to produce the requisite amounts of honey. The colonies will have at least four to five brood frames containing all brood stages and three to five empty frames. The colony will be kept in one brood chamber. Optionally, a super may be added in case the bees collect a volume of honey greater than that available in the storage area in the lower body.

The colonies should be brought in one brood chamber to the test site on the evening before the application, to avoid the collection of untreated nectar and reduce the duration of confinement and, hence, bee stress. In the evening prior to the application, or in the morning prior to the application, two to three empty combs should be placed in the brood body on places which were blocked with barriers. Although this measure is not in keeping with normal commercial bee-keeping practice, it will reflect the worst case, since all the honey taken afterwards will result from nectar collected from the treated plants.

After application, the bee hives should be left within the tunnels until the honey is ripe, or comb-closure (normally 14-21 days after application or start of flowering), or the end of flowering, whichever is the earliest.

2.5 Duration of field trials

Bee colonies will remain in the tunnels until comb-closure or the end of flowering. If comb-closure occurs first or the water content in honey is below 20%, the residue samples should be collected and the trial ended. If comb-closure has not occurred or the water content in honey is above 20% by the time the crop has finished flowering, it will be necessary to move the colonies to remote locations (away from any crops treated with the active substance) and allow the bees to continue foraging until comb-closure occurs or the honey is mature (<20% water content - measured with refractometer) and the honey samples can be collected.

2.6 Sampling, method of analysis

Honey will be sampled when it has reached commercial maturity (comb closure or the honey water content is below 20%). Sufficient honeycombs must be collected to provide the required sample weight for analysis. For each sample, 100 g of honey will be taken, or as close as possible to this.

Honey should be removed from the sampled honeycomb by extraction of the de-capped broodless comb by each field phase.
The three replicates of the treated samples (from the three treated colonies) should be prepared and analysed separately.

To analyse honey for the relevant residue a suitable validated analytical method should be chosen. Honey is one of the more difficult matrices. However it has the reputation of a natural healthy product. It is therefore desirable to achieve a limit of quantification as low as possible. A value of 0.01 mg/kg is favoured.

2.7 Health effects on honey bees

The health of the colonies will be assessed prior to introduction to the tunnels and at the end of the trial when the honey has been collected.
The following parameters will be assessed :

- Strength of the colony (number of frames covered with bees),
- Presence of a healthy queen (i.e., presence of eggs or presence of queen cells),
- Visual assessment – percentage of frames containing pollen, nectar, and brood (eggs, larvae and capped cells). For these assessments, one frame of comb (both sides) will equal 100% and from this the percentages area of brood, pollen and nectar will be estimated. All frames in each colony will be assessed and the mean values for each colony will be calculated.

3 Report

A report on residues in honey should include all relevant data in a suitable format. The report for an entire residue study could, for example, be sub-divided into the following sections:

- Summary
- Objectives
- Tunnel part
- Sample preparation
- Extraction, clean-up, determination, evaluation
- Results and discussion.

3.1 Summary

This summarises the key results, the evaluation of these results and any anomalies of the study, with reference to the objective.

3.2 Objectives

The objectives section of the report again describes the aims of the study in detail and formulates the questions to be dealt with in the study.

3.3 Tunnel part

This section of the report summarises the key points documented in the log book. The documentation should include information on

- Site parameters,
- Application parameters,
- Weather data for the application and sample collection period,
- Duration of trial, incl. period prior to application,
- Health effects.

Reference should be made to the critical points of the animal trial component, and special techniques and events should be described.

3.4 Sample preparation

This section should be used to describe sampling techniques including nature, number and size of samples taken and, where appropriate, intermediate storage, as well as the production of the laboratory or analysis samples and the storage and dispatch of these.

3.5 Extraction, clean-up, determination, evaluation

This essentially describes the method used to prepare and measure the samples. This section of the report details the residue levels in honey and, where desirable, in pollen and the treated crop.

3.6 Results and discussion

This section of the report discusses and evaluates the reported measurements in the light of the questions outlined in the objectives section. The relevance of results should be discussed in relation to the proposed uses of the plant protection product, including a critical appraisal of the study and the results. In particular the following points must be addressed:

- A residue at or about the LOQ in control samples
- Adverse effects on health of the honey bees
- Proposal for MRL, with reasoning.

4 References

EPPO. Guideline on test methods for evaluating the side-effects of plant protection products on honeybees. *EPPO Bulletin,*1993, 22, 203-215.