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POLICY DEPARTMENT A
ECONOMIC AND SCIENTIFIC POLICY

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Impact of the European Court of Justice Ruling on the Honey Directive and Relevant Existing Legislation

NOTE

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Abstract

This report reviews the honey industry in the European Union (EU), legislation within the EU that is relevant to the honey industry, the European Court of Justice (ECJ) ruling from September 2011 on honey and the potential impact of this ruling on the EU honey industry.

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LIST OF ABBREVIATIONS

ECJ	European Court of Justice
ECoB	European Coexistence Bureau
EU	European Union
FEEDM	European Federation of Honey Packers and Distributers
FIC	Food Information to Consumers
GM	Genetically modified
GMO	Genetically modified organism
km	kilometres
MS	Member States
OSR	Oil Seed Rape
PCR	Polymerase chain reaction
RASFF	Rapid alert system for food and feed
SCFCAH	Standing Committee on Food Chain and Animal Health

1. EXECUTIVE SUMMARY

On 6 September 2011 the European Court of Justice (ECJ) ruled that honey and food supplements containing pollen (derived from varieties of genetically modified (GM) crops) constitute foodstuffs which contain ingredients produced from genetically modified organisms (GMOs) within the meaning of Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed. The Court found that such pollen is 'produced from GMOs' and that it constitutes an ingredient of the honey and pollen-based food supplements.

The Honey Directive, Council Directive 2001/110/EC, provides the legislative criteria for honey produced and marketed in the European Union (EU). It defines honey as:

"Honey is the natural sweet substance produced by *Apis mellifera* bees from the nectar of plants or from secretions of living parts of plants or excretions of plant-sucking insects on the living parts of plants, which the bees collect, transform by combining with specific substances of their own, deposit, dehydrate, store and leave in honeycombs to ripen and mature."

Regulation (EU) No 1169/2011 Food Information to Consumers (FIC) provides the legislative framework for food labelling, effective from December 13 2014. It defines an ingredient as:

"'ingredient' means any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as 'ingredients'."

Regulation (EC) No 1829/2003 on GM food and feed, and Regulation (EC) 1830/2003 on the traceability and labelling of GMOs provide the legislative framework for GM labelling.

The consequences of the ECJ ruling on named existing legislation have been identified and, where possible, practical effects approximated in cost terms.

The effect has been viewed not only on the honey packers, but on the supply chain as a whole. Areas that are unclear against the current legislation, have been identified.

The immediate effect concerns the potential labelling of GM ingredients.

'Secondary' effects are the general labelling of pollen as an ingredient of honey, and the subsequent commercial and technical requirements of the food supply chain in complying with legislation and good manufacturing practice.

2. INTRODUCTION

This short study on the impact of the European Court of Justice (ECJ) ruling on the Honey Directive and relevant legislation, has been prepared for the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) in July 2013.

2.1. Aim

This report provides a summary of the ECJ ruling; an overview of the production of honey; a summary of the labelling requirements for genetically modified (GM) organisms; and outlines the impact of the ECJ ruling on the Honey Directive, GM Regulation, Labelling Directive and Labelling Regulation.

2.2. Method

2.2.1. Sources of information

Information has been taken directly from the named legislation and standards, minutes of the Scientific Committee on the Food Chain and Animal Health (SCFCAH) meetings; relevant scientific literature and websites, as well as drawing on information from the websites of relevant national and European trade associations and other stakeholders.

3. BACKGROUND

KEY FINDINGS

- Honey is a natural product produced by honeybees from a variety of flowering plants.
- There are European compositional and quality standards for the various types of honey for use by packers.
- Beekeepers in the EU vary greatly in their commercial nature – from 'professional beekeeper Member States' to amateur status.
- Honey is packed and traded on a global basis.

This chapter briefly describes honey, its production and the legislation of relevance in relation to the ECJ ruling.

3.1. Honey

Honey is defined (Codex Alimentarius (2001) and the Honey Directive 2001/110/EC), as the sweet natural substance produced by honeybees (specifically *Apis mellifea,* 2001/110/EC*)* from the nectar of plants (Blossom honey or nectar honey) or from the secretions of living parts of plants, or excretions of plant-sucking insects on the living parts of plants (Honeydew honey), which the bees collect and transform by combining with specific substances of their own, deposit, dehydrate, store and leave in honeycombs to ripen and mature.

Honey from bees which collect most nectar from a certain type of flower is called monofloral honey and has a distinctive flower dependent flavour. Polyfloral honey comes from bees that collect nectar from different types of flowers. The most widely available honey is blended honey – a homogenous mixture of two or more honeys differing in floral source, colour, flavour, density or geographic origin.

The type of honey made will depend upon the types of foliage and flowers available to the bees. A crop such as oilseed rape will produce a large quantity of honey that will set very hard. Other sources, such as garden flowers, will produce a clear liquid honey.

3.1.1. Honey production

Bees produce honey as a food store for the colony to use, usually when there are no flowers or when the climate is adverse.

Bees take nectar and mix it in their mouths with enzymes. This mix is stored in hexagonal wax honeycombs until the water has been reduced to approximately 17%. The honeycomb cell is then capped with a thin layer of wax until required by the bees. (The British Beekeepers Association, 2012).

The production of honey for human consumption typically involves its extraction from the honeycombs which is achieved by a number of methods – namely draining, centrifugal force, pressing or filtering (although honeycomb honey is also available).

3.1.2. Honey composition

Honey is not a single commodity (as discussed in section 3.1) and therefore does not have a single standard composition. The Codex Alimentarius standard and the Honey Directive set compositional criteria. Honey consists of different sugars as indicated in Table 1 (essentially fructose and glucose), organic acids, enzymes, solid particles (e.g. beeswax) derived from honey collection and usually contains a diversity of minor constituents which will include minerals, proteins and vitamins.

In addition the compositional criteria state that "no pollen or other individual ingredient of honey is to be removed, unless it is inevitable when organic and inorganic foreign materials are removed". The process of filtering (for the specific intention of removing foreign materials) may be conducted in such a way so as to result in the unintentional but significant removal of pollen. Where this filtering occurs the consumer must be informed to that effect by means of an appropriate indication on the label – i.e. the honey should be labelled as filtered honey in accordance with the Food Information to Consumers Regulation (EU) No 1169/2011 (FIC), Annex VI; Particulars accompanying the name of a food.

Table 1 Composition of honey

Product	Component	Limit
Honeydew honey:	Fructose / Glucose	Not less than 45g / 100g
General:	Fructose / Glucose	Not less than 60g / 100g
	Sucrose	Not more than 5g / 100g
	Moisture content	Not more than 20%
	Water insoluble content*	Not more than 0.1g / 100g

Source: Codex Standard 12- 1981 for Honey

* Pollen is part of the water insoluble content.

3.1.3. Honey – trade routes

The European Union (EU) accounts for approximately 20-25% of the world's honey consumption (310,000 tonnes, 2007). The EU is also the second largest producer of honey accounting for 13% of the global honey production (CBI, 2009). In recent years European beekeeping has been seriously threatened by varroasis (a large parasitic mite of honey bees) and colony collapse disorder (the sudden and steep decline of a seemingly healthy honeybee colony).

Trade is mediated through importers, packers, wholesalers and retailers. Packers will tend to blend most of the polyfloral honey to make table honey. The imports of honey into the EU amounted to €375 million in 2007. The honey market is divided into honey for household consumption and honey for industrial use. 85% of all honey goes to direct consumption and is mainly used as a spread or as a natural sweetener. The food industry also accounts for other parts of the honey market which includes bakery, confectionary and the cereals sector. Honey is also used in other markets such as cosmetics and toiletries and 'over-the-counter' medicinal preparations.

Trade channels and market entry is usually straightforward. Importers usually combine the functions of importing honey into the EU with processing, blending and packing the honey.

Packer-producers are beekeepers in the EU and have facilities for processing and packing of honey. They sell directly to consumers or nearby retailers. Packer-co-operatives comprise groups of beekeepers who purchase, process/pack and market honey often under their own label.

Packers purchase honey directly and indirectly from beekeepers in their country, import and may also purchase from other importers. They will have their own brand label or pack for retailer brands. Importers/packers will sell the end product to wholesalers and retailers in consumer packaging.

The European Commission reported almost 1.4 million hives across Member States in September 2010. There are significant differences between Member States' apicultural features, such as the number and the qualification of beekeepers (amateur versus professional), hive-density or the beekeeping operation method (stationary or mobile apiaries, transhumance). Several Member States have especially favourable environmental and agricultural conditions for apiculture, such as France, Greece, Hungary, Italy, Poland, Portugal, Romania and Spain. Due to higher hive density and number of professional beekeepers these countries are often referred to as the 'professional beekeeper Member States' (Europa Ref: IP/10/1121).

Organic honeys command a price premium of 10-20% over conventional honey. An estimate of the total market for organic honey in Europe is around 6500 tonnes per year (some 2% of the total honey market). Germany accounts for 2500 tonnes of the EU consumption of organic honey. Organic honey is mainly used as table honey. The production of organic honey is covered by the Organic Regulation and includes the apiaries being placed in areas which ensure nectar and pollen sources consist essentially of organically produced crops or, as appropriate, of spontaneous vegetation or non-organically managed forests or crops that are only treated with low environmental impact methods; and apiaries being kept at sufficient distance from sources that may lead to the contamination of beekeeping products or to the poor health of the bees.

3.2. Legislation

Honey is regulated by legislation which includes compositional standards. Legislation of particular significance to this study is listed below.

The main relevant legislation is generally referred to by the use of short titles. Hence, for simplicity and clarity, this legislation is referred to throughout this report by the use of these short titles (as indicated in the parentheses below):

- Council Directive 2001/110/EC of 20 December 2011 relating to honey

  (The Honey Directive)
- Regulation (EU) No 1169/2011 on the provision of food information to consumers

  (FIC)
- Council Directive 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

  (Labelling Directive)
- Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs (Nutrition labelling Directive)

- Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control
  (The Organic Regulation)
- Regulation (EC) No 1829/2003 of 22 September 2003 on genetically modified food and feed

  (The GM Regulation)
- Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.

  (Deliberate Release Directive)
- Regulation (EC) No 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

  (The Traceability Regulation)
- Codex Standard 12 – 1981 for Honey

4. ECJ RULING

KEY FINDINGS

- In September 2011 the ECJ ruled that honey and food supplements containing pollen derived from GM crops, are foodstuffs that contain ingredients produced from GMOs.
- The court found that such pollen is 'produced from GMOs' and that it constitutes an ingredient of honey and pollen-based food supplements.

A dispute arose in Germany, between an amateur beekeeper (Mr Bablok) and the state of Bavaria (Freistaat Bayern) which owned a number of plots of land on which genetically modified MON 810 maize was cultivated for research purposes. In 2005 DNA from the pollen of this MON 810 maize was detected in the maize pollen and in a number of samples of honey produced by Mr Bablok. As a result the beekeeper alleged that, due to the presence of residues of genetically modified maize, his products were unsuitable for marketing and consumption and, along with four other amateur beekeepers, brought legal proceedings against Freistaat Bayern before the German courts.

The Bayerischer Verwaltungsgerichtshof (Bavarian Higher Administrative Court, Germany) asked the European Court of Justice whether the mere presence in the products of genetically modified maize pollen had the consequence that those products may not be placed on the market without authorisation.

On 6 September 2011 the ECJ ruled that honey and food supplements containing pollen (derived from varieties of genetically modified crops) constitute foodstuffs which contain ingredients produced from GMOs within the meaning of Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed. The Court found that such pollen is 'produced from GMOs' and that it constitutes an ingredient of the honey and pollen-based food supplements.

5. IMPLICATIONS AND CONSEQUENCES

KEY FINDINGS

- Requirements for labelling of honey will affect both production in the EU, as well as production from third countries.
- The uncertain nature of bee foraging behaviour and coexistence requirements mean that a large proportion of honey in countries where GM crops are widely grown will have to be labelled to indicate the presence of genetically modified pollen.
- Honey from EU Member States and from third countries, containing genetically modified pollen, can only be marketed in the EU if the GMO from which the pollen is derived is authorised for use as a food via the EU authorising system.

Following the ECJ ruling in 2011, the European Commission was asked to clarify the labelling and legal consequences for the honey industry (European Parliament, Parliamentary Questions). The European Commission responded by organising workshops and seminars and by proposing to amend the relevant legislation. Nevertheless, there is still no single point of reference providing clear instructions on honey labelling and analysis to ensure legal compliance.

This chapter considers the practical consequences of implementing the ECJ Ruling in relation to current legislation, namely the Honey Directive, Labelling Directive and GM Regulation.

5.1. Honey production - Coexistence

According to the European Commission; '*Coexistence refers to the choice of consumers and farmers between conventional, organic and GM crop production, in compliance with the legal obligations for labelling defined in Community Legislation. The possibility of adventitious presence of GM crops in non-GM crops cannot be excluded. Therefore, suitable measures are needed during cultivation, harvest, transport, storage and processing to ensure coexistence.'* (Commission of the European Communities, 2009)

The Commission does not set out coexistence requirements for individual Member States (MS), instead each MS is responsible for developing its own coexistence strategy. A report on coexistence published by the Commission in 2009 (Report to the Commission, 2009) identified fifteen Member States that had adopted specific legislation on coexistence, and a further three Member States who had draft legislation in place. In different Member States there are different requirements for notifying the authorities and public regarding the location of GM crops, ranging from case by case approval (depending on the GM trait) through to no stipulation for notification. In most Member States there is a requirement for growers of GM crops to inform immediate neighbours, operators with whom they share machinery and the owners of the property on which the cultivation is intended. Three of the Member States that reported in 2009 stated that they had an obligation to keep beekeepers informed if they were within a certain perimeter of GM crops.

Separation distances in the coexistence legislation are targeted at preventing pollen transfer to non-GM crops rather than to bees and their honey. These isolation distances range from 25m–600m for conventional maize and 50m-600m for organic maize, insufficient to protect against GMO transmission to honey. In only one set of coexistence measures were GM crop growers required to observe isolation distances in relation to established bee keeping sites.

In order to prevent pollen from GM crops entering into the honey supply, there are two key areas that need to be considered:

- the distance the hive is from the GM crop and therefore the risk of bees foraging in the crop, and
- the likelihood of volunteers[1] appearing in following seasons.

It has been reported that the maximum distance honey bees may forage is up to 13.5km from the hive in order to find suitable nectar and pollen sources (Frisch et al, 1967), although it has been found that it is more normal for bees to forage less than half of this distance (Beekman, M and Ratnieks, FLW 2000). The distance that bees travel on their foraging trips is affected by the quality and quantity of the nectar sources near the hive. They will travel greater distances when nectar sources are patchier in nature (with variable quality and quantity).

The two main potential sources of GM pollen within Europe are oilseed rape and maize. Oilseed rape is predominantly cross pollinated by bees and other insect species rather than self fertilised. Maize is not particularly attractive to bees as it does not produce nectar due to being self fertilised. However, bees will collect pollen from this crop (Erikson et al, 1997; Keller et al, 2005).

Studies on oilseed rape pollen flow indicate that there are a number of factors affecting pollen flow and cross pollination rates between crops. These include proximity of crops to neighbouring crops, size, shape and orientation of the field, type of oilseed rape variety, topography, prevailing wind direction, physical barriers and abundance of insect pollinators.

Studies have shown that although the majority of oilseed rape seed that is shed at harvest will germinate or become unviable within the first year, some seed can persist for as long as 10 years. This would result in a potential GM volunteer population of around 100 plants in every hectare after a GM crop was grown on the field (Andersen et al 2010; Beckie HJ and Warwick, SI 2010; D'Hertefeldt et al 2008; Lutman et al 2005). It is however possible to reduce harvest losses of seed from GM crops by harvesting at slightly higher seed moisture or using combines with advanced cutter bars (Sausse, C et al 2006). Once harvested a sufficient period of time between seed shed and cultivation needs to be left to allow as much spilt seed as possible to germinate prior to herbicide application and cultivation. Use of deep ploughing prior to drilling non-GM oilseed rape crops (following GM crops) could minimise the amount of volunteers.

In 2012 the European Coexistence Bureau (ECoB) secretariat presented a summary of proposals for a Best Practice Document for coexistence between GM maize and honey production based on contributions from 10 Member States (European Coexistence Bureau, 2012). This recommended that all professional and amateur beekeepers supplying to the food chain should be considered if new coexistence measures are established.

[1] Volunteers – GM plants growing in the wild, outside of the original area or when the original crop has been removed.

This document considered honey to be a single food ingredient and as such the maize pollen content is extremely unlikely to exceed the threshold of 0.9% of the total mass of the product and therefore no additional measures for the coexistence of GM maize would be required. However, were pollen to be considered an ingredient of honey the level of GMO pollen that is acceptable falls and further measures would be needed. In order to protect beekeepers from getting GMO pollen in their honey, the working group report from the International Workshop on the consequences of the ECJ ruling (Hofmann, F 2011) suggests it would be necessary to set up isolation zones from flowering GMO crops, with Member States proposing a range in size for such zones varying from 1-10 km (but typically about 5km). (Despite a previous study reporting the foraging range of bees as being up to 13.5km (Frisch et al, 1967)) This temporal aspect would mean that hives would only need to be excluded from an area for part of the year. In addition, attention would need to be paid to the risk of volunteers releasing GM pollen in subsequent years.

5.2. Labelling

Labelling Regulation (EU) No 1169/2011 Food Information to Consumers (FIC) effective from December 13 2014 (replacing and updating Directives 2000/13/EC on the labelling of foodstuffs and 90/496/EEC on nutritional labelling) provides the legislative framework for food labelling.

Prior to the ECJ ruling, pollen was considered to be a component of honey and as such the pollen did not require any specific labelling. Whilst methods exist to remove pollen from honey (ultra-filtration), the compositional criteria state that pollen should not be intentionally removed and where filtration has been used consumers should be informed. Therefore where pollen is present, packers have no alternative but to leave it in place unless it is unintentionally removed during filtering to take out foreign inorganic or organic matter and labelled as 'filtered'.

The ECJ ruling however states that pollen is considered to be an ingredient of honey.

The FIC defines an ingredient as:

"*any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as 'ingredients'.*"

The potential implications for the labelling requirements under the FIC Regulation of honey, if pollen is considered to be an ingredient, are discussed below.

5.2.1. Ingredients list

Honey will be required to carry an ingredients list in which pollen will need to be included.

FIC Article 18 states:

> "The list of ingredients shall be headed or preceded by a suitable heading which consists of or includes the word 'ingredients'. It shall include all the ingredients of the food, in descending order of weight, as recorded at the time of their use in the manufacture of the food"

On pack, this would appear as: 'Ingredients: honey, pollen'.

Although comprising more than one ingredient, honey could be exempted from the requirement to carry an ingredients list by an appropriate amendment to the FIC, perhaps by extending Article 19 (1)(d) which already provides a similar exemption for cheese, butter, fermented milk and cream.

5.2.2. Nutritional labelling

Annex V of the FIC states that unprocessed products that comprise a single ingredient or category of ingredients are exempt from nutritional labelling requirements. Honey is currently an unprocessed single ingredient product and is therefore exempt from mandatory nutritional labelling. If it is no longer considered to be a single ingredient, honey will be required to carry mandatory nutritional labelling.

The approximate cost of nutritional analysis is €94 per test based on FIC nutrition labelling requirements.

5.2.3. Compound ingredient listing

Where the honey is to be used as an ingredient in a food product, it would be considered a compound ingredient and need to be declared as such in the ingredients list of the finished product, unless the honey constitutes less than 2% of the finished product (under Annex VII, Part E of the FIC, compound ingredients are not required to be broken down in ingredients lists to declare their components if the composition of the compound ingredient is defined in current Union provisions (which honey is) and the compound ingredient constitutes less than 2% of the finished product).

5.2.4. Commercial documentation

Although the general labelling legislation does not apply directly to bulk business-to-business transactions in honey, commercial buyers will undoubtedly demand product information via commercial documents, such as a specification. Generally, this would be expected by the buyer to include a list of ingredients and perhaps their proportions in the product. It will not be possible for honey packers to provide this information since pollen is not added to honey in a controlled manner as a stage in its human processing. Extensive product testing may therefore be required to satisfy commercial requirements unless buyer expectations can be managed, for instance by exempting honey from the need to provide an ingredients list (see 5.2.1, above).

5.2.5. Potential costs of label changes and testing

If pollen is considered to be an ingredient of honey a number of label changes may be required as described above, which will involve additional costs to the producer and / or packer. The projected costs in Table 2 below are based on the honey retail industry only (exclusive of products that use honey as an ingredient) and on single label changes and single product testing.

Table 2 Potential costs of label changes and testing based on a single label change and single product testing

Requirement	One-off or Continual	Estimated cost (€)
Ingredients list change	One off	72,000 to 329,000
Nutritional analysis per tonne honey produced	One – off and periodic due diligence analysis	2,474
Identification of the presence of GM pollen	On-going	6,578
Determination of the amount of pollen present	On-going	5,263

5.3. GM Labelling

The ECJ ruling states that pollen is an 'ingredient' of honey, rather than a natural component. This means that the same requirements apply for pollen as they do for any other food ingredient. If pollen from a GM plant is present in honey, then it is classed as an ingredient 'produced from GMOs' and falls under the scope of Regulation (EC) No 1829/2003 (Article 3(1)). In terms of labelling requirements there are two broad groups of products in which impacts from the ECJ ruling may arise:

1. Honey and food supplements containing pollen produced in EU MS
2. Honey and food supplements containing pollen produced in third countries and imported to EU MS

These are discussed in turn in the sections below.

5.3.1. Honey produced in EU Member States

In 2012 five EU MS were commercially cultivating GM crops, largely in the form of MON 810 insect resistant maize; Spain, Portugal, Czech Republic, Romania and Slovakia (James, C. (2012). Many EU MS currently hold, or have in the past held, research trials of GM crops – including those not approved for commercial cultivation in the EU. Unauthorised GM crops and ingredients derived from them, are not permitted on the market, therefore the GM Labelling Regulations do not apply. GM Labelling Regulations will only apply to authorised GM crops and ingredients derived from them.

As such, currently the largest impacts of the ECJ ruling would be felt by honey producers in those MS who are commercially cultivating the authorised GM crops such as MON 810 maize.

Maize plants may provide an important source of pollen for foraging honey bees (Erickson, E. H., B. H., Flottum, P. K., Wyman, J. A., Wedberg, J. L. & Page, R. E. (1997). For honey producers in countries that are commercially growing authorised GM crops such as

MON 810 maize; they should be aware that if pollen from such a plant is present in honey then it is classed as an "ingredient produced from a GMO" (under Regulation (EC) 1829/2003). Pollen must be identified on the honey label as being from genetically modified organisms.

This applies unless the GM pollen was proven to be under 0.9% of the total pollen in honey and only if this presence can be proved to be adventitious or technically unavoidable. In the EU if the honey producer was located in a country where GM crops were grown it is unclear whether they would be able to prove that any presence was adventitious or technically unavoidable considering the known risk that GM crops may have been cultivated. It is unclear whether a producer could use evidence that appropriate coexistence distances had been respected to prove that pollen was 'GM-free'.

If honey was found to contain pollen 'produced from GMOs' the honey would require the wording:

"Ingredients: honey, pollen (genetically modified)" or

"Ingredients: honey, pollen (produced from genetically modified maize)"

to appear clearly on the label (based on requirements under Article 13 of Regulation (EC) No 1829/2003).

For producers who are at risk from their bees foraging on GM plants, if that producer did not want their honey to be labelled as containing GM pollen, testing would be needed to validate the claim.

If beekeepers in MS cannot prove the absence of GM pollen in their products, would they be required to label their products as potentially containing GM pollen as a matter of course?

Or if beekeepers are able to prove that their beehives are located a certain distance from GM plants, would this exempt their products from being labelled as containing GM pollen?

This situation is unclear. Under current legislation on GMOs there are no set limits for the distance beehives should be placed from GM plants, to ensure that the honey produced does not include GM pollen.

Under Article 13 of the Organic Regulation it is stated that for honey to be labelled as 'organic', nectar and pollen sources within a 3km radius of apiaries must be organically produced crops/spontaneous vegetation and/or crops treated with low environmental impact methods.

A 3km radius is thus considered adequate to ensure honey is produced without pollen from non-organic sources (including GM).

For beekeepers who wish their honey to be certified as organic, a map must be provided to the control authority or control body listing the location of hives, and appropriate documentation and evidence that areas accessible to colonies meet the conditions of the Regulation (i.e. accessible areas can be classed as 'organic').

Technical Aspects

In Europe, GM labelling is triggered by GM levels above 0.9% with respect to the plant ingredient from an approved GMO variety, assuming that the GM presence is 'adventitious or technically unavoidable'. If this assumption is not applicable, GM labelling is triggered by the presence of any level of ingredient from the GM source, no matter how low this is.

If this labelling approach is applied to honey, as would be required by the Court Ruling Case C-442/09 Karl Heinz Bablok and Others v Freistaat Bayern, the labelling would relate to the levels of GM pollen with respect to the total pollen, so there would be a need to detect and quantify the amount of GM pollen with respect to total pollen.

Furthermore, in countries that grow more than one authorised GM crop, there is potential for the pollen to come from more than one GM source. For labelling purposes, there would then need to be clarification of the trigger level. For example, the GM pollen in a honey may derive partly from an authorised GM maize, partly from an authorised GM oil seed rape and partly from an authorised GM soy. If this is the case, is the trigger level a total GM pollen proportion of 0.9% relative to the total pollen content, or is it a GM maize pollen proportion of 0.9% relative to the total maize pollen content, with similar triggers for the other two GM sources taken individually?

The ingredients lists may look very different in each scenario:

> "Ingredients list: honey, pollen (genetically modified)"

versus

> "Ingredients list: honey, pollen (produced from
>
> then one or more of:
>
> genetically modified maize, genetically modified oil seed rape, genetically modified soy)".

If the intention of the labelling requirements of the GM Regulation is that GM labelling would reveal the GM plant species involved, then only the latter interpretation of the requirement for pollen achieves this.

Honey Origin and risk of containing GM pollen DNA

GM pollen will normally be derived from commodity crop species such as oilseed rape, maize, cotton and soy. However other GM crops in field trial situations could be a source. Thus, it is important to know where the honey is from.

European honey is unlikely to contain GM pollen unless it is produced by bees whose hives are located near to experimental GM crops or to locations where commercially cultivated GM maize is present (only a few locations in Europe). North American honey is likely to contain GM DNA if pollen is collected from the high levels of GM commodity crops.

Detection of GM pollen DNA

The pollen component of honey may vary but is generally less than 0.1% of the total honey mass, thus enrichment of the pollen fraction is required for analysis purposes. The actual quantity of pollen from a particular species is dependent on various factors, including the season and the crop species present in the location of the beehive.

Genetically modified DNA is detected using real-time PCR (polymerase chain reaction) with PCR primers designed for amplification of DNA from either specific GM crop events, GM traits or general GM target sequences, such as promoters and terminators, common to the majority of GM crops. DNA is extracted from pollen using an appropriate technique. A common approach would involve centrifugation of melted honey to sediment the solids, including the pollen, followed by CTAB-based DNA extraction and finally purification of the total genomic DNA (Waiblinger HU, et al). A phased approach would then be used for GM DNA detection.

Firstly real-time PCR would be used to detect a specific plant (ie. oilseed rape, cotton, soya or maize), followed by GM DNA screening assays (Cauliflower Mosaic Virus (CaMV) 35S promoter, Nopaline synthase (Nos) terminator, Figwort Mosaic Virus (FMV) promoter) and finally specific GM crop event detection (to differentiate between authorised and non-authorised events). Quantification would be performed for the events detected. If no plant DNA from the main crop species is present further testing would not be required. If plant DNA from the main crop species is present, the GMO DNA screen will identify the potential presence of GM DNA, but if negative again no further testing will be required.

Problems with accurate quantification of GM pollen DNA

In order to quantify GM pollen DNA accurately, the use of GM pollen standards would be required. These are not currently available and potentially would be difficult to produce. For honey samples where GM pollen is present from several different GM events and crop species it would be difficult to quantify the level of GM DNA. However, as a rough estimation, the CaMV35S promoter could be used; amplification from the target could be compared to amplification of a generic plant DNA target or general species target (eg. maize) and compared to standards prepared similarly.

Validation study

The European Reference Laboratory for Food and Feed recently published an inter-laboratory validation study (European Commission, 2012) for the extraction and detection of GM MON 810 maize pollen in honey. The results indicated that it was possible to detect the GM maize DNA in the honey spiked with representative low levels of GM maize pollen and that there was some correlation between the DNA ratios determined and the actual levels of GM pollen and non-GM pollen present in the samples although this was not the focus of the work. Further validation of quantification methods of GM pollen from other crop events would need to be carried out.

Potential costs involved

Routine GMO testing is performed by hundreds of laboratories across Europe. Testing honey does offer some challenges but most laboratories will have the capabilities to carry out the work. Potential costs of pollen enrichment, DNA extraction followed by an initial plant and GMO screen (CaMV35S promoter, FMV promoter, Nos terminator) will be in region of 150-250 Euros per sample. Further GM event detection and quantification on a single sample will be up to 100-200 Euros per event. So the overall cost of testing of one honey sample could potentially be several hundred Euros if GM pollen is present and event specific detection and quantification performed.

Whilst throughout the EU there is a generally strong tradition of compliance with EU Food Law, the credibility of the practical application of the ECJ ruling will be dependent on effective official controls being in place. In particular, the new labelling provisions that may arise will need to be backed up by enhanced levels of inspection, sampling and analysis.

5.3.2. Imports

Imported honey products are also affected by the ECJ ruling, as the same labelling rules apply as to products produced in the EU. The EU has the highest per capita honey consumption in the world, and domestic production only meets approximately 60% of this demand. In 2011 the EU imported approximately 146,742 million tonnes of honey, with China being the largest supplier (USAID, 2012). Under Commission Decision 2011/163/EU, 82 third countries are authorised to export products of animal origin to the EU. Of 82 two third countries, 41 currently have EU approved residue monitoring plans in place for honey, enabling them to export honey to the EU. Examples of these 41 countries which are cultivating at least one species that has been genetically modified and is attractive to bees are given in the Table 3.

Table 3 Examples of Third countries authorised to export honey to the EU that cultivate GM crops

Third country authorised to export honey to the EU	Species of crops that have been genetically modified and approved for commercial cultivation by the Third Country
Argentina	Soybean, maize, cotton
Australia	Cotton, oilseed rape (OSR)
Brazil	Soybean, maize, cotton
Canada	OSR, maize, soybean, sugarbeet
Chile	Maize, soybean, cotton
China	Cotton, papaya, poplar, tomato, sweet pepper
Cuba	Maize
India	Cotton
Mexico	Cotton, soybean
United States	Maize, soybean, cotton, OSR, sugarbeet, alfalfa (lucerne), papaya, squash
Uruguay	Soybean, maize

Source: List of third countries authorised to export honey to the EU (Commission Decision 2011/163/EU), GM crops authorised for cultivation in these countries (James, C 2012)

The EU has a zero-tolerance policy on the marketing of food containing GMOs, or ingredients produced from GMOs (under article 3(1) of the GM Regulation 1829/2003) if they are not approved for food use in the EU. This means that if imported honey contains pollen 'produced from GMOs' that are not authorised for food use in the EU it cannot be sold or marketed. As such, if any country authorised to export honey to the EU were growing GM crops not authorised for food use this would mean that honey would need to be tested to ensure it does not contain pollen produced from un-authorised GMOs. Current EU authorisations for GMO use in foodstuffs, cover strains of cotton, maize, OSR, soybean and sugarbeet.

If imports of honey were made into the EU, and traces of unauthorised GM material were found at any level (even less than 0.1%) this could lead to the import being unmarketable and thus, rejected. This presents a technical challenge as ensuring an absolute separation of authorised and non-authorised material in honey may be difficult. Testing methods to verify no presence of unauthorised GMOs vary depending on the type of material imported to the EU, and as such responsibility may lie with different stakeholders.

Typically the impact will fall on those involved in the export supply chain to monitor, and clean shipments, to ultimately satisfy the EU that their products are free from contamination (Kerr, W & Hobbs, J. (2012).

The majority of cotton, maize and oilseed rape lines grown in the countries in Table 3 are authorised for food use in the EU, however this would need to be verified. In particular, herbicide tolerant alfalfa (lucerne) is not approved for food or feed use in the EU, and as such honey containing pollen produced from this crop would not be authorised for food use. For the countries listed in Table 3, it is likely that the majority of honey imported into the EU would need to be labelled to indicate the presence of GM pollen, due to the widespread cultivation of GM crops in these countries.

In September 2011 the European Federation of Honey Packers and Distributers (FEEDM) outlined possible economic consequences of the ECJ ruling. They highlighted that in many developing countries such as those in Latin America, many beekeepers belong to the small farming sector, and as such costs for testing honey are disproportionate to their business operations (FEEDM, 2011). Others have suggested that the ruling may result in an upward surge in honey prices, or that major exporters to the EU such as Argentina and Brazil may ship more to US markets at a lower price (Phipps, R 2011).

6. WHAT HAS HAPPENED SINCE THE ECJ RULING?

A recent study of the labels of honey available on supermarket shelves indicated that none were labelled as containing possible GM material. It was concluded that no obvious label changes have taken place (Scottish Beekeepers Association, 2012).

The European Commission has tabled a proposal for a directive of the European Parliament and of the Council amending Directive 2001/110/EC relating to honey. Following the ECJ judgement, this proposal is intended explicitly to classify pollen as a special component of honey rather than an ingredient. As of July 2013, this proposal had still not been adopted.

Monsanto introduced an application to cover MON 810 pollen in the marketing authorisation, on which EFSA gave a favourable scientific opinion in December 2012.

The Standing Committee on the Food Chain and Animal Health (SCFCAH) meeting held in Brussels on 12 December 2011 advised that Member States wait for the methods of extraction and detection to be harmonised before acting to enforce legislation as interpreted by the ECJ.

As of end May 2013, there was no method available for the quantification of GM pollen in total pollen.

At a SCFCAH meeting held on 12 January 2012, a Member State explained that although MON 810 is cultivated in its territory no samples out of the 11 samples of local honey analysed contained MON 810 pollen.

There have been no notifications in the Rapid Alert System for Food and Feed (RASFF) on GM contaminated honey.

7. CONCLUSIONS

7.1. Labelling

Under legislative requirements for labelling in the EU, both honey produced in Member States, and that imported from third countries would be affected by the ECJ ruling. For producers in EU MS the chief impacts arise due to testing that would be required to determine whether honey contains pollen from GMOs or not. Likewise any honey imported from third countries that grow GM crops would need to be tested to determine whether pollen was produced from GMOs and whether or not those GMOs were authorised in the EU. Whilst the majority of cotton, soybean, maize and OSR varieties are approved in the EU, herbicide tolerant alfalfa (lucerne) grown in the US is not yet approved. For any honey products adhering to specific GM-free product schemes, the threshold stipulated in these agreements for presence of GM ingredients will need to be adhered to.

7.2. Authorisation

The marketing of non-authorised GMOs, and ingredients derived from them, is not permitted in the EU.

Honey producers in areas that conduct GM crop testing, (where the GM crop will not yet be authorised); may need to consider adoption of organic standards in order to establish a case to demonstrate that the pollen in the honey does not originate from GMOs.
Honey imported from third countries will have to comply with EU legislation in order to be placed on the EU market but since there are GM crops grown in third countries that are not EU authorised, there may be a greater chance of unauthorised GM pollen being present in honey from third countries.

7.3. Coexistence

Coexistence measures are decided on at the EU MS level and are principally to ensure adequate separation of GMOs from conventional and organic varieties, and are not specifically developed to ensure adequate separation distances for honey producers wishing to keep their honey 'GM-free'. There is a high level of uncertainty in terms of bee foraging behaviour, and various studies suggest this can be anywhere from 5-13.5km. In addition volunteers from the GM crop may appear up to 10 years after cultivation (for oil seed rape), and thus coexistence requirements may also need to take into account temporal separation. As such, if a honey producer is located in a country widely growing GM crops (such as Spain) then ensuring bees do not forage on GM crops may be difficult and testing would be required to prove the honey is free from *pollen produced from GMOs.*

Under the Organic Regulations (889/2008), for honey to be classed as 'organic', nectar and pollen sources within a 3km radius of apiaries must be organically produced (or natural). As such, this requirement suggests that a distance of 3km is adequate for separation of GM crops and organic honey which may inform the debate on appropriate coexistence distances to assure honey can be classed as 'GM-free', or any GM presence classed as 'adventitious or technically unavoidable' and thus without consequence for labelling.

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Impact of the European Court of Justice Ruling on the Honey Directive and Relevant Existing Legislation