EUROPEAN PARLIAMENT

Clarifying the status of pollen in honey

Substitute Impact Assessment of EC Directive Amending Council Honey Directive 2001/110/EC

PE 514.066

IMPA
Ex-Ante Impact Assessment

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Abstract

Following the ruling by the Court of Justice of the European Union (CJEU) in the Bablok case, the European Commission proposes to clarify the status of pollen in honey and to define it as a natural constituent of honey rather than an ingredient, as decided by the CJEU. This has practical implications on European labelling, supervision and authorisation requirements for honey. In addition, it has potential economic, social and environmental implications. The European Commission proposal to change the status quo was not accompanied by an impact assessment.

This substitute impact assessment provides an overview of the European honey industry and a legal analysis of a change in the status of pollen in honey. From this, the most important economic, social and environmental impacts are identified and presented.

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Contents

List of figures

List of tables

List of abbreviations

BBKA	British Beekeepers Association
CIF	Cost-insurance-freight
CJEU	European Court of Justice
EC	European Commission
EFSA	European Food Safety Authority
ENVI	Environment, Public Health and Food Safety
EP	European Parliament
EPBA	European Professional Beekeepers Association
EU	European Union
EUR	Euro
F.E.E.D.M.	European Federation of Honey Packers and Distributors
FAO	Food and Agriculture Organization
GDP	Gross Domestic Product
GM	Genetically Modified
GMO	Genetically Modified Organism
GNI	Gross National Income
GNP	Gross National Product
ISAAA	International Service for the Acquisition of Agri-biotech Applications
N/A	Non-availability of data
Prod.	Production
Prof.	Professional
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
UK	United Kingdom
Unpf.	Unprofessional
US	United States
USD	US dollar
WHO	World Health Organization
WTO	World Trade Organization

Executive summary

On 6 September 2011, the European Court of Justice (CJEU) ruled in the Bablok case that "pollen in honey is considered to be an ingredient within the meaning of Directive 2000/13/EC on the labelling, presentation, and advertising of foodstuffs". This ruling provided a departure from the past in that it formally established a labelling requirement for pollen. In addition, it set additional supervision and authorisation requirements for various stakeholders in the honey value chain.

One year later, on 21 September 2012, the European Commission proposed a clarification of the Directive, suggesting that the status of pollen in honey be changed (back) to being a natural constituent of honey. This proposal provides more flexibility as to the information that needs to be provided on the label of honey and carries fewer supervision and authorisation requirements. However, no impact assessment accompanied the European Commission proposal.

This substitute impact assessment seeks to fill in the void and analyse the main economic, social and environmental impacts of a change in the status of pollen in honey from an ingredient of honey to being a natural component of honey. In order to understand the baseline for this impact assessment, the honey industry value chain, trade flows and relationships between major stakeholders are analysed. In addition, a legal assessment is made of the labelling, supervision and authorisation requirements under two policy scenarios: maintaining and implementing the CJEU ruling versus the adoption of the Commission proposal.

The practical implications of a change in the status of pollen are measured through the identification of key impact indicators. These indicators are scored based on the expected effect of a change in the status of pollen on those indicators. The subsequent economic, social and environmental effects are identified and summarised.

A change in the status of pollen in honey from an ingredient to a natural constituent could have the following impacts:

1. increased honey imports to countries in the European Union (EU) from non-EU countries;
2. less disruption to the international trade regime;
3. less stringent requirements to mention pollen on the honey's label may facilitate the cultivation (pollination) of GM crops insofar that beekeepers will face less restrictions in locating their hives nearby GM fields;
4. no significant cost change for stakeholders in the honey industry.

1. Introduction

The purpose of this substitute impact assessment is to assess the economic, social and environmental impacts underlying the qualification of pollen as either an ingredient or a natural component of honey.

In order to do this, the impacts of the status quo or baseline scenario to keep pollen qualified as an ingredient of honey as interpreted by the European Court of Justice (CJEU) in the Bablok ruling (2011) will be compared with the expected impacts arising from the Commission proposal (2012) to change the qualification of pollen back to being a natural component of honey. For purposes of this impact assessment, it will be assumed that the two above-mentioned scenarios are the only policy options.

The technical specifications (Terms of Reference) for this assignment state that the Substitute Impact Assessment should determine how the Commission proposal might affect the following three research questions:

What, if any, is the impact of the qualification of pollen as an ingredient of honey:

- On the application of Directive 2000/13/EC on the approximation of the laws of the Member States relating to the **labelling, presentation and advertising of foodstuffs**;

- On the **authorisation and supervision requirements** in Articles 3, 4, 5 and 9 of Regulation No 1829/2003 on procedures for the authorisation and supervision of **genetically modified food and feed**;

- On the **labelling requirements** in Articles 12 and 13 of Regulation No 1829/2003 on procedures for the authorisation and supervision of **genetically modified food and feed**?

In addition to the regulatory and legal framework, the practical implications of the two policy options will be taken into consideration vis-à-vis the stakeholders involved in the honey market, including: farmers, beekeepers, retailers and consumers.

To do this, the research questions were translated into guiding questions for the impact assessment. A sample of secondary questions is presented in the next section.

I - Methodologies

Extensive desk research was done on the basis of materials supplied by the European Parliament and the existing literature available on the internet. Interviews were conducted across the legal, economic, social, and environmental dimensions of this impact assessment.

A selection of methodologies that were used for the impact assessment include:

- A literature and documentary review;
- Interviews with experts from the economic, social and environmental factions in the debate[1];
- Stakeholder mapping;
- Value chain analysis;
- Trade flow assessment;
- Impact score matrix.

The description of the honey industry in Chapter 3 was done through a combination of desk research and interviews. The legal assessment in Chapter 4 was based entirely on a thorough desk review by our legal team. For Chapter 5 we developed an indicator matrix (see below) and for Chapter 6 we designed an impact score matrix that measured the impacts along the two policy options.

Some methodologies were selected to serve as input for other methodologies. For example, the desk research provided an important basis for the formulation of interview questions. Similarly, interview outcomes were critical for the Industry description and Impact Analysis.

Translation of the research questions into practical implications

In order to develop SMART indicators that could measure the economic, social and environmental impacts of the three research questions mentioned above, secondary guiding questions were formulated. A sample of secondary questions used for the identification of indicators is presented below.

Table 1.1 Sample of secondary questions used for the identification of indicators

1- Labelling, presentation and advertising of foodstuffs
• What does the market for honey look like in Europe? • Who are the main honey producers in Europe and what are their relationships? • What are the production costs (labelling, presentation, and advertising)? • What would be the expected impact of the Commission proposal on the size of industry? • What are the major trade flows in honey? What percentage of honey exports contain GM pollen?
2- Authorisation and supervision requirements of GM food and feed
• What are the location and control costs (indoor versus outdoor beekeeping)? • What consumer risks are potentially involved (if any) in case the Commission proposal was implemented? • What will be the expected impact on transparency for consumers? What will happen to the reputation of honey as a healthy / natural product? • What non-EU countries are most affected by the proposed changes to the Directive? • What might be economic impacts on farmers/ agriculture in general and on eco-systems, with regard to bees as pollinating insects in the medium and long term?

[1] For more information about the interviews, please refer to Annex A.

3- Labelling requirements on GM food and feed

- What would be the expected consequences regarding liability for contamination of honey with GM-pollen?
- Who bears the (expected) costs of labelling and testing, and other control systems?
- What is the effect of an EC endorsement of EFSA's positive opinion that MON810 pollen is safe on marketability of honey?

While the above secondary questions are not exhaustive, they serve as an example for how measurement indicators were developed for the economic, social and environmental impacts, described in more detail below.

Definition of the indicators measuring impact

Indicators were developed based on the practical implications of the two policy options for specific groups, types of activities, resources used, and existing infrastructure. The indicators serve as the basis for the impact analysis in the study (Chapter 5) and the impact score matrix (Chapter 6) covering relevant impacts alongside the policy options.

Below, a summary matrix with a number of indicators identified for this study is presented. The final selection of indicators used in the comparison of options was based on broader considerations, including the importance attached to the indicators by interviewees.

Table 1.2 Summary matrix with relevant indicators

Economic Indicators	Social Indicators	Environmental Indicators
• production costs; • retail prices; • honey yield and productivity (per colony); • EU imports; • EU exports; • Intra-EU trade; • International trade; • cost of pollination services.	• reputation of bottled or packaged honey as a healthy/natural product; • effects on hobby and professional beekeeping activities in Europe – jobs/societal value; • change in product transparency for consumers; • effects on quality (colour) and taste of honey; • effects on consumer health; • effects on food safety.	• biodiversity of bee populations; • land use; • pollination; • transportation and logistics for distribution; • potential for GM crop cultivation.

Risks and Limitations

Given the study took place at a short notice in the middle of summer (late July, August 2013), there was a risk of not obtaining enough reliable data as a result of limited interviewee availability. Even though it proved difficult to come into contact with several organisations, including those proposed by the EP, we managed to interview five by phone while two sent us their replies to the interview questions in writing. The omission of some stakeholder groups in the interviews was compensated via extra efforts in our literature review[2].

[2] For more information about the interviews, please refer to Annex A.

II - Outline

This substitute impact assessment will follow the following structure:

Chapter 2: presents the problem definition.

Chapter 3: describes the honey industry: its value chain, international trade flows, stakeholder relationships, and associated social and environmental factors. Focus of this chapter will be to describe the current situation (baseline), observed problems, and underlying causes for a clarification in the status of pollen in honey.

Chapter 4: elaborates on the legal assessment of the tri-part research question presented in the Terms of Reference. This is important to establish a more sophisticated understanding of the legal consequences of a change in the status of pollen in honey.

Chapter 5: examines the major economic, social and environmental impacts of both the CJEU ruling and the Commission proposal. This step will include an impact score matrix to highlight which impacts are most poignant.

Chapter 6: a review is presented of two policy options (baseline and Commission proposal) along the economic, social and environmental impacts described in the previous section. One scenario (baseline) is the no-policy change option. Where possible, legal consequences of an action will be considered.

Chapter 7: presents the summary conclusions of the substitute impact assessment, including a policy recommendation based on the findings in the report.

2. Problem Definition

I - Background

The proposed clarification of the nature of pollen by the European Commission is a consequence of a ruling by the European Court of Justice (CJEU) in the Bablok case on 6 September 2011, where a dispute had arisen between an organic beekeeper and local state authorities which owned several plots of land where the GM crop, MON810 maize, was cultivated for research purposes. Very small particles of the GM crop had been found in the beekeeper's honey, who claimed that this made his honey unsuitable for marketing and consumption. [3]

The CJEU ruled in favour of the beekeeper and concluded that "pollen in honey is considered to be an ingredient within the meaning of Directive 2000/13/EC" (on the labelling, presentation, and advertising of foodstuffs). Since then, honey containing traces

[3] John Durkacz, Report from the International Workshop on the ECJ Ruling on GM Pollen in Honey.

of pollen from GM plants requires prior supervision and authorisation before it may be marked as food in the EU. The labelling rules of the EU would also apply (Chapter 4).

The CJEU ruling creates legal uncertainty for the European and international honey markets, which affects, inter alia, beekeepers, farmers, and food manufacturers who use honey in their products. This has been an important basis for the European Commission to re-consider the basis for the CJEU ruling and propose a proposal to Directive 2001/110/EC related to honey to clarify the status of pollen in honey as a 'natural component' rather than an 'ingredient'. However, no impact assessment was done to measure the economic, social and environmental impacts of the Commission proposal. According to European Union law, the Commission does not have the jurisdiction to overrule the CJEU. It can, however, do so if the proposal is adopted through the ordinary legislative procedure by the Council and the European Parliament.

Prior to the CJEU ruling, relevant EU directives have been considered to be more in line with the Codex Alimentarius Standard in that they stated that honey does not only consist of sugars but also of other substances, including solid particles derived from honey collection. Pollen, then, was considered a natural component of honey and *not* as an impurity, substance, or ingredient. However, the Codex Standard does not explicitly state that pollen is a natural substance. As such, the European Commission's argument that pollen is a constituent of honey and not an ingredient may arguably *not* be supported by the Codex Alimentarius Standard for honey. The current Codex standards and related texts are not a substitute or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply.

The CJEU ruling does not necessarily establish a legal precedent within the framework of Directive 2001/110/EC on honey. Questions for preliminary rulings ensure uniform application of EU law throughout the EU Member States, and inasmuch as rulings delivered by the CJEU have a force of *res judicata*, and are binding not only for the national court that requested the preliminary ruling, but also for all other national courts throughout the EU. Therefore, rulings delivered by the CJEU set a precedent and must be observed. However, it is *de facto* possible for national courts to deviate from the CJEU's judgments, for example, in the event that the case before them provides for a different scenario, where the same provision of EU law interpreted by the CJEU has to be applied in such a diverse context, that a different interpretation thereof is necessarily required. In such case, nothing forces national courts to address the CJEU and request a new preliminary ruling.

In October 2013, the European Parliament's ENVI Committee is set to vote on the European Commission's proposal. This substitute impact assessment seeks to fill the current void in knowledge and to provide a better picture of the economic, social and environmental impacts of the CJEU ruling and the Commission's proposal. In principle, in the event that a new EU legislative act within this framework becomes legally binding, rulings of the CJEU will be rendered out-dated and are no longer valid.

II – Establishing a baseline: current labelling, authorisation and supervision requirements

Over the past two decades, two distinct approval and labelling regimes have emerged which largely distinguish the US and Canada from Europe.

At the European level the responsibility for risk assessment and risk management is divided. Risk assessment based on scientific evidence is generally upheld by the European Food Safety Authority (EFSA), while risk management or an approval decision is more complex and involves the European Commission, the Council of the European Union and the European Parliament.[4]

Practical implications need to be taken into account when deliberating about the best option for the European Union. Economic problems emerge purely from "the social construction of what is considered as GM, conventional or organic, and whether they need to be approved or labelled in order to be marketed legally."[5] In short: the issue is related to the legal definition of goods and the segmentation of markets by labels and approval procedures.

In order to assess the merits of the Commission proposal on the status of pollen in honey, it is necessary to understand *current* European labelling, authorisation and supervision requirements that affect the European and international honey market. Below follows a basic description of these requirements. This section, therefore, will focus on describing the requirements only. A more detailed legal assessment of these requirements can be found in Chapter 4.

In general, this substitute impact assessment refers to the CJEU ruling as its baseline scenario and the Commission proposal as the intervention scenario. The terminology "baseline" has to be interpreted with caution, though. Normally, a baseline describes a status quo and clearly establishes a situation, or state of the economy, upon which a change, e.g. policy measure, is imposed. However, in this particular case the baseline has not been completely established. In other words, the CJEU ruling is not fully implemented in practice. As such, the industry finds itself in a state of either transition or waiting for legal certainty. Consequently, the baseline can be interpreted as a description of effects if the Commission proposal is not adopted.

III - Labelling requirements

General labelling aims to provide consumers with necessary information to enable them to make safe, healthy and sustainable food choices. This might include information about the ingredients and additives of food, and about the presence of allergenic elements or

[4] Justus Wesseler, Volker Beckmann, Claudio Soregaroli, "Coexistence of GM and non-GM supply chains in the EU: policy framework and economic aspects", International workshop on socio-economic impacts of genetically modified crops", p75.
[5] Justus Wesseler, Volker Beckmann, Claudio Soregaroli, Ibid., p75.

information on the product's durability. Additionally, regulation demands that information provided by manufacturers is accurate and not misleading. In making the disclosure of information obligatory, the labelling regulation attempts to overcome market failures, as this information would otherwise not have been provided by all companies in the market.

European labelling regulation is set up to ensure the functioning of the Single European Market, while at the same time maintaining labelling as an effective marketing tool for the food industry. A common framework on labelling regulation reduces the barriers to free circulation of goods and stimulates competition across borders. It also ensures that no company can gain an unfair advantage in the market place by making unjustified claims or withholding potentially harmful information about the characteristics of its products.

The legal basis for the European policy on general food labelling can be found in Directive 2000/13/EC.[6] This Directive deals with labelling, ingredient lists, minimum durability of foodstuff, packaging, etc. For the indication (or not) of pollen in the list of ingredients, it is crucial to know whether pollen is considered a natural constituent of honey or an ingredient of honey. If pollen is considered as a natural constituent, there appears to be no obligation to list it in the ingredients list under Directive 2000/13/EC.

For genetically modified (GM) food, there are additional rules regarding labelling, presentation and advertising of foodstuffs[7]. The presence of material containing, consisting of or produced from authorised GMOs in food must be labelled except where that presence does not exceed 0,9% of each ingredient. When this border is exceeded, it has to be stated in the list of ingredients that "the product contains GM pollen". When there is no list of ingredients, it has to be stated on the label. Honey containing traces of pollen from GM plants is only marketable in the EU if the GMO (in this case GM pollen) has received prior authorisation.

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[6] As from 13 December 2014, Directive 2000/13/EC is repealed by *Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ 2011/L 304, p. 18–63* (Article 53(1) of Regulation No (EU) 1169/2011). According to Article 55 of Regulation No (EU) 1169/2011 this Regulation shall enter into force on the 20th day following its publication in the Official Journal of the European Union. Regulation No (EU) 1169/2011 shall apply from 13 December 2014, with the exception of point (l) of Article 9(1), which shall apply from 13 December 2016, and Part B of Annex VI, which shall apply from 1 January 2014.

[7] These rules can be found in the Regulation No 1829/2003 on genetically modified food and feed, Section 2. Even if under Directive 2000/13/EC there would be no obligation to list pollen in the list of ingredients due to the proposal to treat pollen as a natural constituent, Regulation No 1829/2003 is still applicable.

IV - Authorisation and supervision requirements

To protect the health of people, animals and the environment, the EU sets rules for the use of GM in food. These rules can be found in the Regulation No 1829/2003 on genetically modified food and feed. Section 1 deals with authorisation and supervision. According to Article 3.1, honey pollen belonging to GMOs for food use, lies within the scope of the regulation.

There are several requirements for the honey pollen to become authorised (Article 4.1):

- They may not have adverse effects on human health, animal health or the environment;
- They may not mislead the consumer;
- They may not differ from the food intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

When these requirements are fulfilled, a company may apply for authorisation. The European Food Safety Authority (EFSA) did scientific research regarding the properties and impact of GM honey pollen on health and environment and the EFSA concluded that data on molecular characterization of maize MON810 did not raise any safety concerns with respect to its pollen. For this specific type of GM pollen, the way is open for authorisation. Monsanto's recent announcement that it will withdraw all its GM applications in the European market *except* MON810, corroborates the prevailing view that the MON810 re-authorisation procedure will be successful. Please see Chapter 5 for a legal assessment of the re-authorisation procedure.

After authorisation, there is still control to guard the safety of humans, animals and environment. The authorisation-holder has the obligation to submit reports to the Commission, and the Commission is monitoring. There is also a requirement for the authorisation holder to inform EFSA, who will, in turn, inform the Commission when there is any new scientific or technical information. The Commission is always free to revoke its decision.

3. The honey industry

This section focuses on describing the general structure of the honey industry. It will be built up along the following lines:

- Honey value chain ;
- EU production and consumption;
- Relevant trading partners of the EU;
- Stakeholders;
- Cost breakdown.

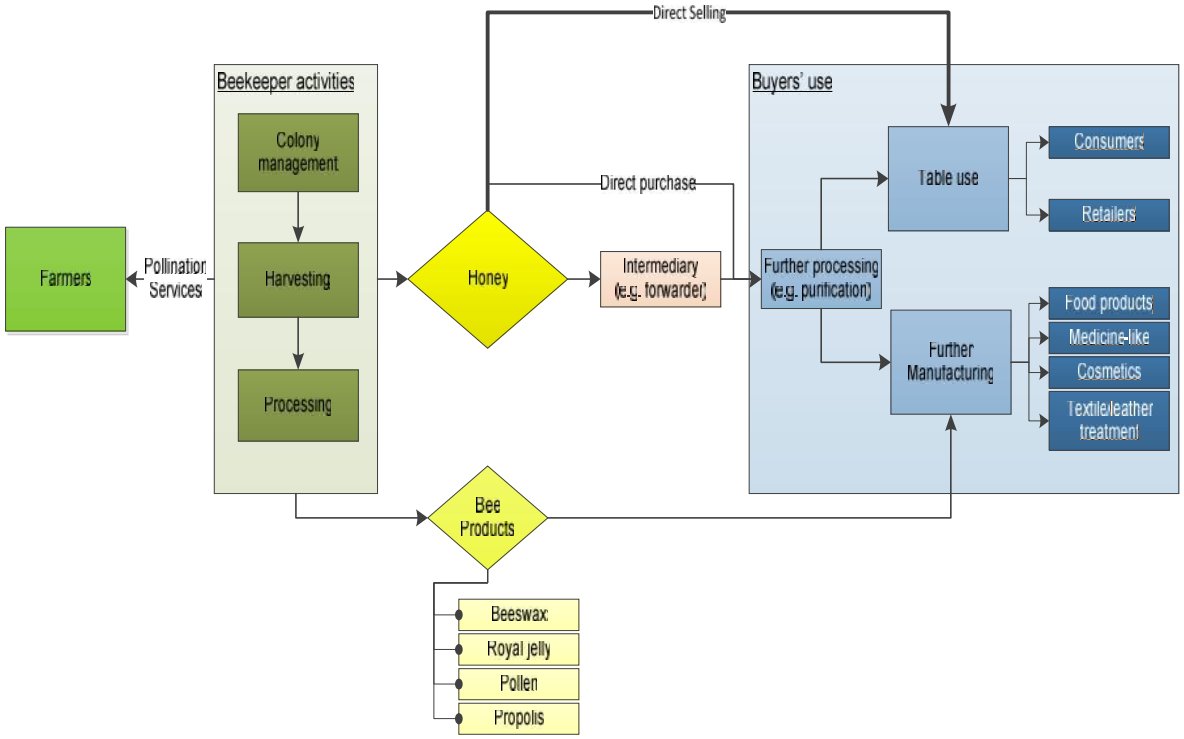
In order to assess the economic impacts of the CJEU ruling it is paramount to provide a description of the baseline. This chapter shortly describes the EU honey industry and puts it in an international context. Insights from this chapter build the foundation to provide a differentiated assessment.

I - The honey value chain

Figure 3.1represents a stylised value chain for honey by summarising the main activities.

The main activities a beekeeper carries out in the production process are colony management, harvesting, and processing. Colony management includes measures that increase the colony yield, e.g. swarm control, feeding during off-season, and pest and disease control. Furthermore, it typically involves moving the hive or honey super to places for pollination. This is a crucial service for farmers. In Europe these pollination services are mostly free of charge and beekeepers and farmers mutually benefit from each other. In other countries, as for example the US, pollination jobs are paid by the farmer. In an interview it was stated that these jobs cost the farmer approximately 200 USD per colony and pollination job. This lets beekeepers have an alternative source of income. However, in contrast to their European counterparts, US farmers face significant costs.

Figure 3.1 Stylised honey value chain



1. GMO considerations

Within the scope of the current GMO debate beekeepers have to include GMO aspects in their colony management. This means they need to know where GMO crops are cultivated. As there is a strong consumer preference for non-GMO honey, beekeepers try to place their hives in regions where non-GMO crops are cultivated. Assuming that a beekeeper is active in a country where GMO crops are cultivated, there are two main aspects that make it difficult to ensure that the produced honey does not have any GMO content.

First, information about the regions with GMO cultivation is not available in all exporting countries. In Europe, a regional registry is mostly available. For example, the GMO Free Europe initiative provides detailed information about GMO crop cultivation in Europe and some other third countries on the regional level. However, such detailed information is not available for all countries. For beekeepers operating in these countries, it means that there is an information asymmetry and uncertainty as to which extent they run the risk of producing honey containing GMO pollen.

Second, coexistence measures that accommodate beekeeping activities need to be in place in each Member State and third countries. This is currently not the case. In principle this concerns the regulated separation distance between GMO cultivations and non-GMO fields. Given the forage range of bees experts conclude that a separation distance of 10 km would suffice to minimize the risk of GMO contamination. Shorter distances may be possible taking into account the attractiveness of a given crop for bees.[8]

2. Processing, packaging, marketing, and selling

Once the honey is harvested a first step of processing typically takes place, in which the raw honey is purified. This activity is usually carried out by the beekeeper. It is done through centrifugation, which also played a role in the Bablok case as further explained in the legal assessment (Chapter 4).

Once the honey is purified, the product is generally ready to be sold. Which economic operator carries out further value-adding activities like labelling, packaging, or marketing, as well as any kind of distribution activities strongly depends on the degree of vertical integration of the beekeeper. In other words, a completely vertically integrated operator conducts all activities ranging from the actual production to eventually selling the product to the end-user, i.e. consumer.

In Europe, many beekeepers have a high degree of vertical integration and as such perform many of the downstream activities themselves. Such operators are also referred to as packer-producers. Often, they follow a business model based on emphasising a strong regional connection between production, the product, and the consumer.

[8] Haefeker, W. (2012). GM crop cultivation and beekeeping – Coexistence measures and monitoring requirements. Presentation at ApiEcoFloara.

Depending on the scale of their production, in some cases retail channels, i.e. supermarkets, are also used to bring the final product to the end-user.
In addition, beekeepers also organise themselves into packer-cooperatives that are not only integrated along the whole value chain but also compensate supply shortages or widening their product range through importing honey from third countries.

Honey produced in most area of Europe falls in the category of high-quality products, which results in a relatively high retail price. However, a large proportion of approximately 40% of honey consumed and used in Europe is imported from third countries. Too a large extent, this honey typically serves the low-shelf-end of the product range and is as such available at comparably low retail prices. Naturally, there are exceptions, meaning imports that are marketed as specialities and sold at a relatively high price.

The majority of honey enters Europe in bulk since pre-packaged honey would compromise efficiency in transportation. The unit of transportation are so called drums, which can carry as much as 300 kg, or 200 litres, of honey. Export cooperatives consolidate the honey in the country of departure. This means that a drum mostly contains honey from different beekeepers operating in different regions of the exporting country. Industrial users require a different packaging method. Since their production is large scale they buy larger batches at a time. As such, honey is often either transported in truckloads of approximately 25.000 kg, or in so-called "cubitainers" of 10.000 kg.

Once the product enters Europe, packers perform the value-adding activities necessary to sell the product to the end-user. Depending on the degree of vertical integration the product is either marketed directly or sold to wholesalers and/or retailers.

Throughout the production process bee-products like beeswax and royal jelly are produced, which enter further manufacturing. These function as ingredients to cosmetics, medicine-like, or leather treatment products. Furthermore, honey itself can be processed further as an ingredient to other food products like muesli or function as a natural sweetener.

II - EU production and consumption

Table 3.1 presents the production structure of the EU honey industry in 2010. In total, EU countries produced approximately 200.000 tonnes. The largest producers are Spain, Romania, and Germany, accounting for ca. 78.000 tonnes. In addition to total production per Member State, Table 3.1 presents detailed information about the number of professional and unprofessional beekeepers and the corresponding number of hives operated on average by each of the groups. As such, the highest number of hives is located in Spain, France, Greece, Poland, Romania, and Italy. In all of these countries more than one million hives are operated by their beekeepers. In Spain, the country with the highest production figures, more than two million hives are located.

Given that Germany is among the top three producing countries in terms of tonnes, it is surprising that the number of hives is comparably small. Consequently, the yield in kg per hive is among the highest of all Member States. This yield is mainly dependent on the size of the colony and hive management techniques to optimise productivity. However, a high hive yield seems not to be necessarily correlated with the level of professionalism. Finland for example, has only 1.48% professional beekeepers but the highest yield per hive. The highest percentage of professional beekeepers can be found in Greece (ca. 40%) and Spain (22%). In both countries they manage 80% of the domestic hives. It can be expected that the degree of professionalism finds relevance in how organisations deal with regulatory changes. Professionals with a larger scale of production and a focus on only beekeeping-related activities might be more capable of implementing new regulatory measures efficiently.

Comparing professional and unprofessional beekeepers, a common characteristic in all Member States is the significantly higher number of hives operated by professional beekeepers. The largest difference can be found in Sweden, where on average professional beekeepers operate 500 hives compared to 7 hives managed by unprofessional beekeepers. The highest number of hives managed per unprofessional beekeeper can be found in Romania. The reason for this is that almost 10% of all EU hives are located in Romania, of which only 17% of them are under the control of professional beekeepers, and that there is only a comparably low number of total beekeepers active. Other countries with a similar amount of hives, e.g. Italy, have many more active beekeepers.

Overall, Table 3.1 below shows that the production side is very fragmented with many small operators, or micro-enterprises, serving the market. Taking into account the very high demand on the EU consumer side, the scale of production of such micro-enterprises needs to be complemented by imports from third countries. In addition, smaller enterprises usually serve a market with limited geographical scope. As already mentioned in the value chain description a reoccurring theme during the interviews was the regional focus of many EU beekeepers business models. Table 3.1 does not per se describe the target market of EU beekeepers. However, figures complement and support the descriptions of our interviewees.

Table 3.1 EU honey industry landscape

EU 2010	Hives			Beekeepers			Stats			
Country	Total	% of Total	Professional	Total	Professional	% prof.	Hives/ prof.	Hives/ unpf	Prod (t)	Kg per hive
Austria	367583	2.63	60280	24451	248	1.01	243	13	4700	12.79
Belgium	112000	0.80	1500	7600	7	0.09	214	15	2600	23.21
Bulgaria	617420	4.41	n/a	29097	320	1.10	n/a	21	10595	17.16
Cyprus	43975	0.31	24524	588	66	11.22	372	37	590	13.42
Czech Republic	497946	3.56	23694	46033	97	0.21	244	10	7455	14.97
Denmark	170000	1.22	80000	4300	250	5.81	320	22	1500	8.82
Estonia	24800	0.18	1077	2416	4	0.17	269	10	681	27.46
Finland	46000	0.33	11000	2500	37	1.48	297	14	1700	36.96

EU 2010	Hives			Beekeepers			Stats			
Country	Total	% of Total	Professional	Total	Professional	% prof.	Hives/ prof.	Hives/ unpf	Prod (t)	Kg per hive
France	1338650	9.57	615779	73500	2205	3.00	279	10	15974	11.93
Germany	711913	5.09	n/a	n/a	n/a	n/a	n/a	n/a	23137	32.50
Greece	1502239	10.74	1200000	19392	7665	39.53	157	26	14300	9.52
Hungary	900000	6.44	220000	16000	1000	6.25	220	45	16500	18.33
Ireland	24000	0.17	n/a	2388	25	1.05	n/a	10	170	7.08
Italy	1127836	8.06	800000	70000	7500	10.71	107	5	9400	8.33
Latvia	64133	0.46	23310	3700	105	2.84	222	11	676	10.54
Lithuania	117977	0.84	20825	13000	118	0.91	176	8	1764	14.95
Luxembourg	8171	0.06	974	348	4	1.15	244	21	204	24.97
Malta	2722	0.02	n/a	182	n/a	n/a	n/a	15	n/a	n/a
Netherlands	80000	0.57	n/a	8000	n/a	n/a	n/a	10	n/a	n/a
Poland	1123356	8.03	59754	44999	237	0.53	252	24	12467	11.10
Portugal	562557	4.02	214897	17291	594	3.44	362	21	7426	13.20
Romania	1280000	9.15	216501	14000	n/a	n/a	n/a	76	22222	17.36
Slovakia	235689	1.69	27938	14699	175	1.19	160	14	4500	19.09
Slovenia	142751	1.02	n/a	8838	n/a	0.00	n/a	16	1910	13.38
Spain	2459373	17.59	1967498	23816	5361	22.51	367	27	34000	13.82
Sweden	150000	1.07	50000	15000	100	0.67	500	7	3100	20.67
United Kingdom	274000	1.96	40000	43900	200	0.46	200	5	6300	22.99
Totals and Averages	13985091	100	5659551	506038	26318	5.20	215	17	203871	16.98

Source: European Commission, DG Agri. Presentation on Apiculture Programmes. 18 April 2013.
n/a = non-availability of data.

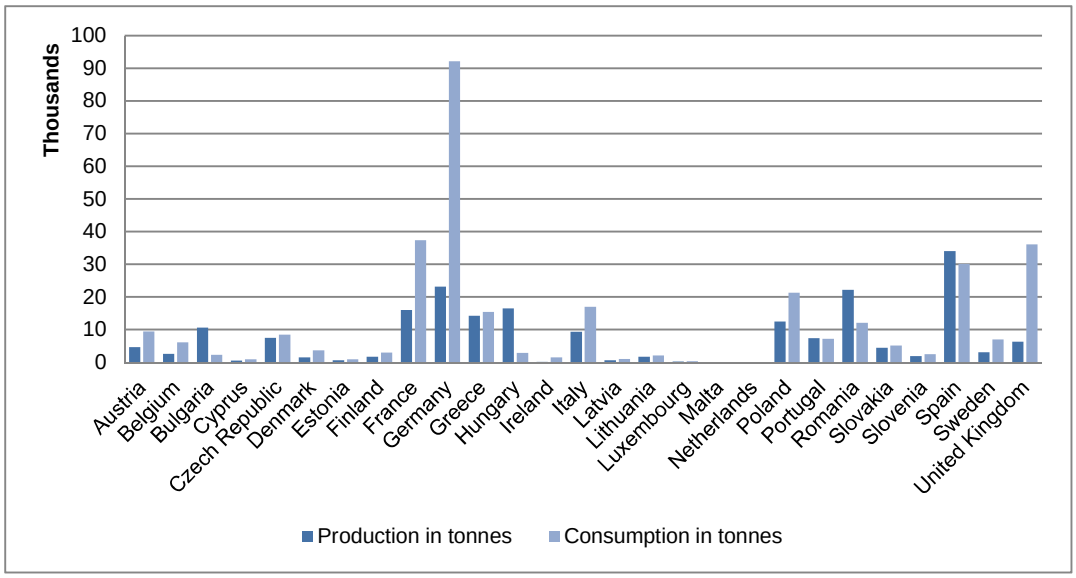
Based on the total production figures and trade statistics (see next section) it is possible to calculate consumption via the following equation, or accounting identity:

$$C = P + I - X$$

Whereas C is consumption, P denotes production, and I and X stands for imports and exports, respectively. Figure 3.2 compares the calculated consumption with production statistics already presented in Table 3.1. With more than 90.000 tonnes Germany is the biggest market for honey. This is not surprising giving the large population and a relatively high per head consumption of 1.13 kg honey per year. Given that ca. 80-85% of the EU honey is for table use, the driving force for consumption is mainly taste and eating habits.

Another aspect, which can be derived from Figure 3.2 is that Germany, France, Italy, Poland, and the UK are mainly responsible for import demand for honey as their production cannot cover large parts of consumption. Note, that the differences in consumption and production in Figure 3.2 can also be covered by intra-EU trade. However, given the scale of deficits and surpluses in production in the EU it becomes clear that the majority of the deficit is imported from third countries.

Figure 3.2 EU production and consumption in 2010[9]

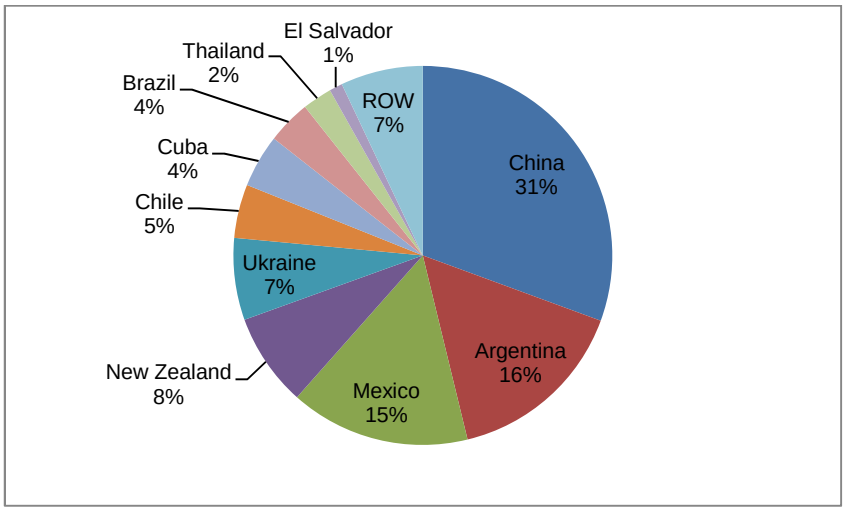


Source: Author's calculation based on FAOstat and COMTRADE data.

III - Relevant trading partners of the EU

Overall, imports from third countries accounted for approximately 330 million Euro in 2012. This is a significant increase from ca. 190 million Euro in 2007. Figure 3.3 shows the share of import sources. China, Argentina, Mexico, New Zealand, and the Ukraine account for more than three quarters of total imports from third countries. Please note that the country selection is on the one hand based on main import sources as well as on the countries identified by the ISAAA Brief on the Global status of Commercialized biotech/GM Crops in 2008.

Figure 3.3 Share of EU imports from 3rd countries in 2012



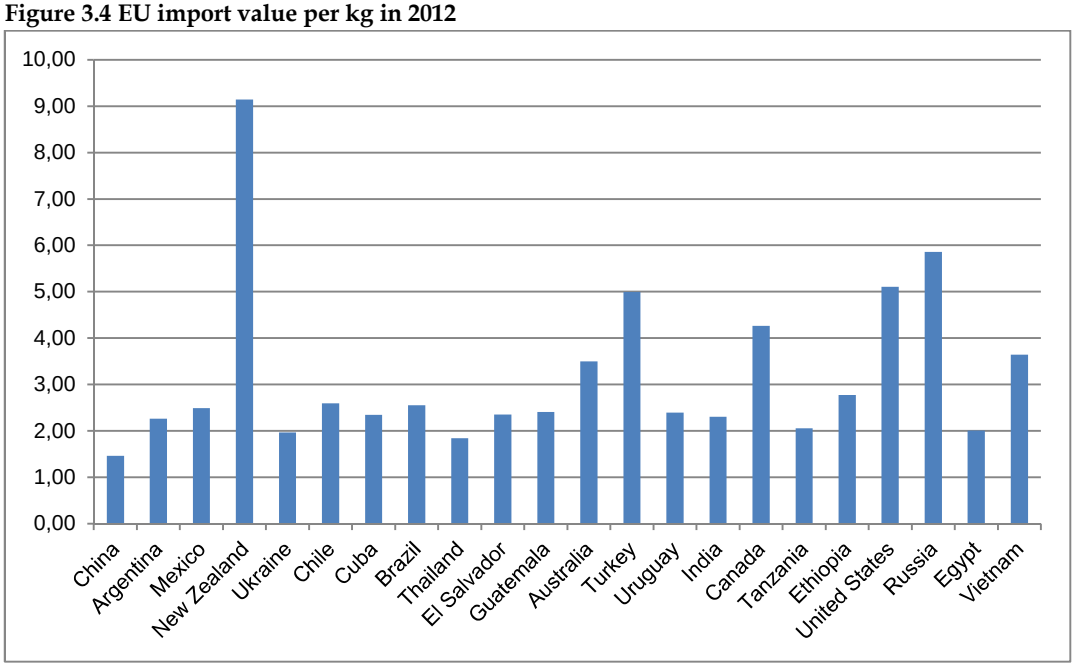
[9] Production data for Malta and The Netherlands not available for 2010 at FAOstat.

With 31%, China is the largest exporter of honey to the EU. The main reason is the relative price competitiveness of Chinese production activities. It was already described in the value-chain description that a large proportion of the imported honey serves the low-shelf market segment. This was highlighted by an interviewee who mentioned as an example the large low-cost retail chains that primarily sell imported honey. The high proportion of imported honey for table-use stand in contrast to the US, where price competitive imported honey is mainly used by the food industry for further processing.

In general there are two regions from where the EU imports honey. On the one hand, Latin American countries (Argentina, Mexico, Chile, Cuba, Brazil, and El Salvador) account for 45% of EU imports, whereas the two big Asian exporters (China and Thailand) make up 33%. Other import sources can be found in Figure 3.3. Larger ones, albeit smaller than the ones presented in Figure 3.3 are Guatemala, Australia, Turkey, and Uruguay.

The value per unit of imported honey from various third countries can be found in Figure 3.4. The range of values is relatively wide reaching from ca. 1 Euro from Myanmar to over 18 Euros for South Korean honey. As mentioned above, some imports are marketed and sold as specialities as for example the Manuka honey of New Zealand.
Combining what is presented in Figure 3.3 and 3.4 it becomes clear that the overwhelming majority of imported honey must serve the low-shelf-end as most of the honey imported from the big exporters has a comparably low unit value, mostly around 2 Euro measured as the cost-insurance-freight (CIF) price, which is still without retail margin.

Figure 3.4 EU import value per kg in 2012

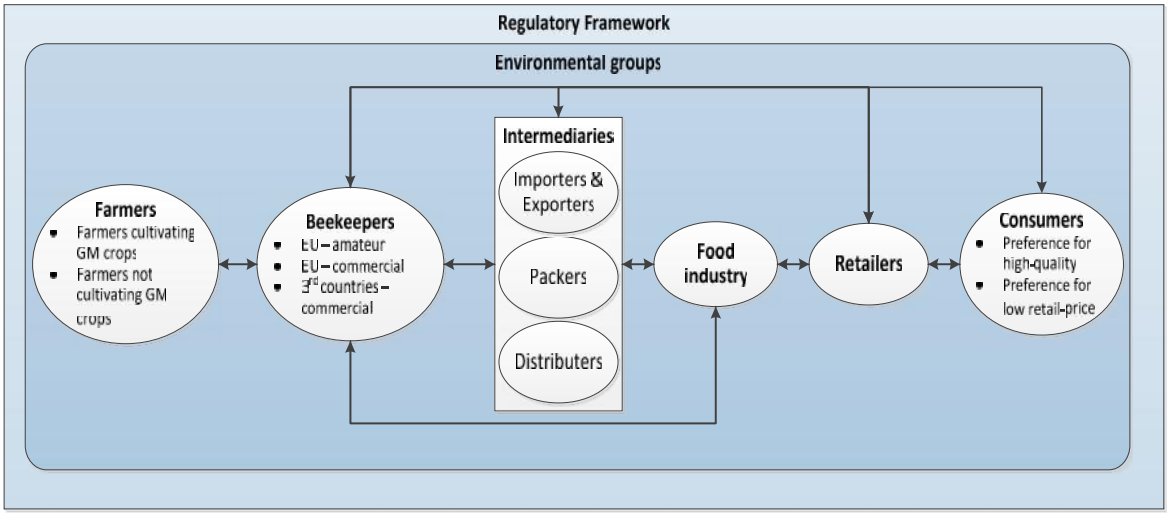


Source: COMTRADE.

IV - Stakeholders

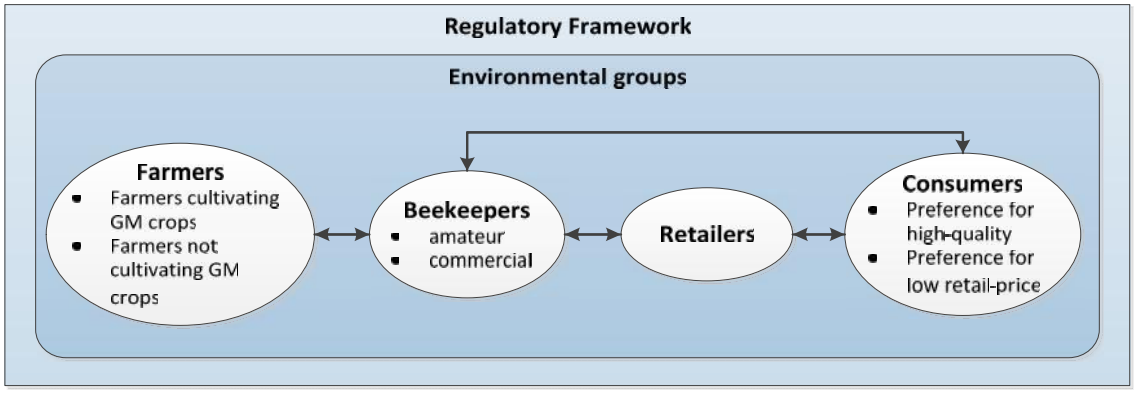
The main stakeholders with regard to the Commission proposal of the Honey Directive are the actors in the honey value chain, environmental groups and regulatory bodies. These stakeholders and their interactions are depicted in Figure 3.5.

Figure 3.5 Main stakeholders in the Honey Industry



As explained in the industry description, in the EU, most of the honey is produced small-scale and the value chain is fairly integrated. Generally, honey produced within the EU is for table use and beekeepers in the EU market there honey through retailers or directly to consumers without making use of intermediaries. Hence, the interactions between different stakeholders are different for different levels of integration of the value chain. Figure 3.6 illustrates the main stakeholders and their interactions in case of this integrated value chain.

Figure 3.6 Main stakeholders in the Honey Industry in case of an integrated value chain



Farmers

Because of their role in the honey value chain, farmers are considered important stakeholders. Within this stakeholder group we can distinguish between two different 'sub-groups' of farmers: those who cultivate GM crops and those who do not. This distinction is made because the impacts of the Commission proposal are likely to differ between these two stakeholder sub-groups.

Beekeepers

Beekeepers are at the core of the honey value chain and therefore considered important stakeholders. Within this stakeholder group we can distinguish between three sub-groups that may experience different impacts in case the Commission proposal is adopted: the amateur beekeepers in the EU, the commercial beekeepers in the EU and the commercial beekeepers from third countries.

Consumers

Consumers are the end users of honey and therefore important stakeholders. They may purchase honey for table-use as well as products in which honey is processed. In purchasing honey for table-use, preferences of consumers may differ; some people prefer high-quality honey whereas other prefer honey with a low retail-price. As the producers of these different types of honey may experience different impacts if the Commission proposal of the Honey Directive is adopted, so will the different sub-groups of consumers.

Retailers

Products in which honey is processed as well as honey for table-use are generally sold through retailers. Although small-scale producers might opt to sell directly to consumers through for example farmers' markets, retailers are the main sales channel and therefore considered important stakeholders.

Food industry

Honey can either be produced for table-use or for further processing in other products such as muesli and chocolate. In case of the latter, the food industry plays an important role in the honey value chain and is therefore considered an important stakeholder in this matter.

Intermediaries

The majority of honey consumed and processed in the EU is imported from third countries. Producers in these third countries generally makes us of one or more intermediaries (such as importers/exporters, packagers and distributers) to either market their honey for table use or to sell it for further processing in the EU. Because of their role in honey value chain, these intermediaries are considered important stakeholders.

Environmental organisations

The pollination by bees is of great importance for biodiversity and the ecosystem in general. Moreover, co-existence policies and risks of GM contamination are important topics in the discussion on GM crop cultivation. Therefore, environmental organisations,

although they are not actors in the honey value chain, are considered important stakeholders in this matter.

Regulatory framework

The way in which the honey value chain operates and which requirements have to be met are partly dependent upon the regulatory framework. Moreover, regulatory bodies establish whether or not specific GM crops are allowed to be cultivated and/or imported into the EU and what the effect of specific GM material is on food safety and consumer health. Therefore, regulatory bodies such as the European Commission, the European Parliament and national governments as well as EFSA and national food-standard and -safety organisations are considered important stakeholders.

Relationships and interactions between stakeholder groups

Farmers ⇔ Beekeepers

There is a mutual dependency between beekeepers and farmers: beekeepers want to locate their hives on a location rich in crops and flowers and farmers need the pollination that is provided by the bees. All interviewees mentioned that this is a very important and in general good relationship within the honey value chain. Whereas in for example the United States it is common for farmers to pay for pollination services, this is in general not the case in the EU.

The location of a beekeeper's hives determines what type of pollen will be collected and what type of honey will be produced. Important to note is that in case of unauthorised events, the liability falls on the beekeepers; in such a case, the beekeeper is not able to market his or her honey, but there are no (direct) consequences for the farmer whose crops are responsible for his event.

Beekeepers ⇔ Intermediaries

Particularly beekeepers that are producing large-scale and/or outside of the EU make use of one or more of these intermediaries. Several of the interviewees indicated that these intermediaries in general request certificates or analysis results of the beekeepers to determine the origin of the honey.

Beekeepers ⇔ Food industry & Intermediaries ⇔ Food industry

In case the honey produced is used for further processing, the beekeepers or, more commonly, the intermediaries, will supply the honey to the food industry. Several interviewees indicated that the food industry maintains high standards, is highly informed about the topic at hand, and sets the standards for analysis of the content and origin of the honey.

Beekeepers ⇔ Retailers & Intermediaries ⇔ Retailers & Food industry ⇔Retailers

Most honey, and products in which honey is used as an ingredient, are marketed through retailers. These products are either directly supplied to the retailer by the beekeepers, or by the intermediaries or the food industry. Several of the interviewees indicated that

retailers are very cautious and critical of what they put on their shelves in order to provide consumers with the most demanded and desired products and to protect the reputation of the shop(s). Hence, also retailers often request certificates or analysis results to prove the origin and composition of the honey.

Beekeepers ⇔ Consumers & Retailers ⇔ Consumers
Honey, and products in which honey is used as an ingredient, are either marketed directly to consumers by the beekeepers (on for example Farmers' markets) or through retailers. Consumers, specifically those who buy high-end honey, perceive honey as a natural, wholesome and nutritious product. The reputation of honey is an important aspect of the relationship with the consumers.

The descriptions of all of these relationships indicate that high standards are used and that practically everywhere in the honey value chain certification, analysis or other proof is requested to confirm the origin and/or composition of the honey.

4. Legal assessment

I - Introduction

This legal assessment examines the labelling of pollen in honey under Directive 2000/13/EC, possible authorisation and supervision requirements of pollen as GMO under Regulation (EC) No 1829/2003 and its corresponding labelling requirements under two different legal scenarios:

1) the Baseline scenario, i.e., pollen is defined as an ingredient of honey (interpretation of the CJEU in the Bablok case under Regulation (EC) 1829/2003);

2) the Commission proposal scenario, i.e., pollen is defined as a natural constituent of honey (according to the Commission proposal).

Key findings

1. General EU labelling requirements under Directive 2000/13/EC

- Under the *Baseline scenario*, the legal assessment concludes that under current EU legislation, pollen, as an ingredient of honey, needs to be declared as an ingredient of honey in the list of ingredients under Directive 2000/13/EC.
- If the Commission proposal is adopted under the *Commission proposal scenario*, pollen, as a natural constituent of honey, must not be regarded as an ingredient of honey and does not have to be indicated in the list of ingredients.

2. Authorisation and supervision requirements under Articles 3, 4, 5 and 9 of Regulation (EC) No 1829/2003

- Under the Baseline scenario, honey with GM pollen is covered by Regulation (EC) No 1829/2003 and is subject to the respective authorisation (before it can be marketed in the EU) and supervision requirements.
- The Commission proposal (Commission proposal scenario) does, in essence, not alter the fact that honey with GM pollen is covered by Regulation (EC) No 1829/2003 and is subject to the respective authorisation and supervision requirements.
- The Commission proposal does not change anything to the fact (as established by the CJEU) that honey containing GM material must receive prior authorisation before it can be marketed in the EU.

3. Labelling requirements under Regulation (EC) No 1829/2003

- Under the Baseline scenario, the labelling requirements of Article 12 of Regulation (EC) No 1829/2003 apply. The 0.9% threshold will most likely be exceeded if it applies to pollen as an ingredient (the 0.9% threshold applies to 0.9% of the total pollen content as an ingredient, and not to 0.9% of the total honey content, as it would be the case if it was considered a food consisting of a single ingredient). Honey with authorised GM pollen must, therefore, be labelled as "produced from genetically modified pollen".
- Under the *Commission proposal scenario*, it must be concluded, in light of the above, that honey with GM pollen (authorised in the EU) is excluded from the labelling requirements of Regulation (EC) No 1829/2003.

4. Consideration of the status of MON810 GM Pollen

- The conclusions for the Baseline scenario and the Commission proposal scenario are only valid for GM pollen which is authorised in the EU. From the outset, honey cannot be marketed in the EU if it contains (either as ingredient or natural constituent) non-authorised GM pollen. In this respect, it is noted that no GM pollen is currently authorised in the EU.
- Under the *Commission proposal scenario*, it must be concluded that honey with MON810 pollen is, in practice, excluded from the labelling requirements of Regulation (EC) No 1829/2003, provided that EFSA's favourable decision on MON810 pollen is endorsed by a regulatory decision on the renewal of the authorisation of MON810 maize (including maize pollen).

II - Background

The Judgment of the Court of Justice of the European Union (CJEU) of 6 September 2011 in a reference for a preliminary ruling from the Bayerischer Verwaltungsgerichtshof (Germany) - Karl Heinz Bablok and Others v. Freistaat Bayern[10] (Case C-442/09, the Bablok case) concerned the interpretation of several provisions of *Regulation (EC) No*

[10] Case C-442/09, Judgment of the Court (Grand Chamber) of 6 September 2011 (reference for a preliminary ruling from the Bayerischer Verwaltungsgerichtshof (Germany) under Article 234 EC (Article 267 TFEU)) — Karl Heinz Bablok and Others v. Freistaat Bayern, OJ C 311, 22.10.2011.

1829/2003 on genetically modified food or feed[11] (hereinafter, Regulation (EC) No 1829/2003), of *Council Directive 2001/110/EC related to honey*[12] (hereinafter Directive 2001/110/EC) and of *Directive 2000/13/EC on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs*[13] (hereinafter, Directive 2000/13/EC).

The reference was made in the context of a dispute between Mr Bablok and three other beekeepers on the one side and the Free State of Bavaria, on the other, with Monsanto as an intervening party, concerning the presence, in apicultural products, of pollen from GM maize.

On concluding the Bablok case, the CJEU issued a ruling whereby it qualifies pollen in honey as an ingredient within the meaning of Article 6(4)(a) of Directive 2000/13/EC. The CJEU considered that the presence of pollen in honey is mainly the result of the action of the beekeeper himself by virtue of centrifugation which he carries out for the purposes of collection.

1. General EU labelling requirements under Directive 2000/13/EC

1.1 Baseline scenario

Under the *Baseline scenario*, pollen is defined as an ingredient of honey, according to the interpretation of the CJEU in the Bablok case under Regulation (EC) No 1829/2003.
As a preliminary remark, Article 2 of Directive 2001/110/EC states that Directive 2000/13/EC is applicable to products covered by it.

Article 3(1)(2) of Directive 2000/13/EC requires that, in accordance with Articles 4 to 17 thereof and subject to the exceptions contained therein, indication of the list of ingredients is compulsory on the labelling of foodstuffs.

Article 6 and Annexes I, II, III and IIIa of Directive 2000/13/EC provide for more detailed rules in relation to the indication of ingredients. In particular, Article 6(4)(a) of Directive 2000/13/EC defines ingredient as "*any substance, including additives and enzymes, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.*"

A list of foodstuffs where ingredients do not need to be indicated is provided in Article 6(2) of Directive 2000/13/EC and includes, *inter alia*, fresh fruit and vegetables, including potatoes; carbonated water; certain fermentation vinegars; cheese, butter, fermented milk and cream (provided that no ingredient has been added other than lactic products, enzymes and micro-organism cultures essential to manufacture, or the salt needed for the manufacture of cheese other than fresh cheese and processed cheese).

Honey is not among the exceptions established in Article 6(2) of Directive 2000/13/EC. Therefore it must bear a list of ingredients.

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[11] *Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed*, OJ L 268, 18.10.2003, p. 1.
[12] OJ L 10, 12.1.2002, p. 47.
[13] OJ L 109, 6.5.2000, p. 29.

Under Article 6(2)(c) of Directive 2000/13/EC, ingredients need not be listed on products comprising a single ingredient, where the trade name is identical with the ingredient name, or the trade name enables the nature of the ingredient to be clearly identified.

In practice, it appears that honey has so far been considered commonly as a product of only one ingredient. According to this understanding, honey fell under the exception of Article 6(2)(c) of Directive 2000/13/EC, with the result that ingredients needed not be listed. A list of ingredients was required only when a mixture from multiple, independently derived different types of honey, *inter alia*, mixture of honey and honeydew honey was placed on the market.[14]

In the Bablok case, the CJEU held that "*[a]s regards pollen contained in honey, it should be observed that, according to the first paragraph of Annex II to Directive 2001/110, honey consists not only of different sugars but also of other substances, including solid particles derived from honey collection*".[15]

In fact, the first sentence of Annex II of Directive 2001/110 provides that "*[h]oney consists essentially of different sugars, predominantly fructose and glucose as well as other substances such as organic acids, enzymes and solid particles derived from honey collection*". Therefore, honey cannot be interpreted as a product containing a single ingredient and the exception of Article 6(2)(c) of Directive 2000/13/EC from the obligation to bear a list of ingredients does not apply.

Under Article 6(4)(c) of Directive 2000/13/EC, the following shall not be regarded as ingredients: "*(i) the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions; (ii) certain additives and enzymes; (iii) substances used in the quantities strictly necessary as solvents or media for additives or enzymes or flavourings; and (iv) substances which are not additives but are used in the same way and with the same purpose as processing aids and are still present in the finished product, even if in altered form*".

Pollen is not listed in Article 6(4)(c) of Directive 2000/13/EC as a substance that must not be regarded as ingredients.

In relation to the classification of pollen as ingredient, the CJEU concluded the following in paragraphs 72 to 78 of the judgment in the Bablok case:

"*72 (...), it is thus necessary to consider principally whether that pollen can be classified as an 'ingredient'.*
73 Under Article 2.13 of Regulation No 1829/2003 and Article 6(4)(a) of Directive 2000/13, an ingredient is 'any substance … used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form'.

[14] Dr. Achim Willand and Dr. Georg Buchholz, *Auswirkungen des Urteils des EuGH vom 06.09.2011 (Rs. 442/09 – „Honig-Urteil") auf die Kennzeichnung der Zutaten von Honig*, Kurzgutachten im Auftrag des Deutschen Imkerbundes – DIB,; Zipfel/Rathke, Lebensmittelrecht, Kommentar, Chapter 350, Honig Verordnung, Stand: März 2009, § 3 Rn. 5.
[15] At para 75.

74 Pollen contained in pollen-based food supplements must be classified as an 'ingredient', since it is introduced into those products in the course of their manufacture or production.
75 As regards pollen contained in honey, it should be observed that, according to the first paragraph of Annex II to Directive 2001/110, honey consists not only of different sugars but also of other substances, including 'solid particles derived from honey collection'.
76 Pollens are solid particles actually derived from honey collection, partly due to bees but mainly due to the centrifugation carried out by the beekeeper. Furthermore, in accordance with the third paragraph of Annex II to Directive 2001/110, 'no pollen … may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter'.
77 Pollen is therefore not a foreign substance or impurity in honey, but rather a normal component of it which, according to the intention of the European Union legislature, cannot in principle be removed from it, even if the frequency with which it is incorporated and the quantities in which it is present in honey are attributable to certain random factors arising during production.
78 In that context, under Article 6(4)(a) of Directive 2000/13, pollen, which comes within the very definition of honey as laid down in Directive 2001/110, must be regarded as a substance which is 'used in the manufacture or preparation of a foodstuff and still present in the finished product'.
79 It must therefore also be classified as an 'ingredient' within the meaning of Article 2.13 of Regulation No 1829/2003 and Article 6(4)(a) of Directive 2000/13".

Conclusion
Under the *Baseline scenario*, the legal assessment concludes that under current EU legislation, pollen, as an ingredient of honey, needs to be declared as an ingredient of honey in the list of ingredients under Directive 2000/13/EC.

1.2 Commission proposal scenario
This section evaluates the *Commission proposal scenario*, *i.e.*, pollen is defined as a natural constituent of honey in the Commission proposal.

Recital 1 of the Commission proposal describes the reasons for the Commission proposal of Directive 2001/110/EC as follows:

"*Following the judgment of the Court of Justice of 6 September 2011 in case C-442/09, pollen in honey is to be considered as an ingredient within the meaning of Directive 2000/13/EC (...). The judgment of the Court was based on the consideration relying on the facts brought before it that pollen in honey is mainly due to the centrifugation carried out by the beekeeper for the purposes of honey collection. However, pollen only enters into the hive as a result of the activity of the bees and it is naturally present in honey regardless of whether or not the beekeeper extracts the honey through centrifugation. It is necessary therefore to clarify, without prejudice to the application of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed to genetically modified pollen in honey, that pollen is a constituent of honey, which is a natural substance that has no ingredients, and not an ingredient within the meaning of Directive 2000/13/EC. Therefore, Council Directive 2001/110/EC of 20 December 2001 relating to honey should be amended accordingly*".

Article 1 of the Commission proposal establishes that in Article 2 of Directive 2001/110/EC the following should be added:

"5. Pollen, being a natural constituent particular to honey, shall not be considered an ingredient, within the meaning of Article 6(4) of Directive 2000/13/EC, of the products defined in Annex 1 to this Directive".

The Commission is thus proposing a derogation for pollen from the definition of "ingredient", as interpreted by the CJEU in the Bablok case. Article 6(4)(a) of Directive 2000/13/EC, defines ingredient as "*any substance, including additives and enzymes, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form*".

Therefore, the Commission proposal considers that pollen is not a substance used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form. Furthermore, the Commission states that pollen only enters into the hive as a result of the activity of the bees and it is naturally present in honey regardless of whether or not the beekeeper extracts the honey through centrifugation. Human intervention is, according to the Commission proposal, not necessary for pollen to get into honey.

Article 6(4)(c) of Directive 2000/13/EC establishes certain substances that must not be regarded as ingredients:

"*(i) the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions; (ii) certain additives and enzymes; (iii) substances used in the quantities strictly necessary as solvents or media for additives or enzymes or flavourings; and (iv) substances which are not additives but are used in the same way and with the same purpose as processing aids and are still present in the finished product, even if in altered form*".

Albeit in another legal act (Directive 2001/110/EC instead of Directive 2000/13/EC), the Commission proposal adds a further derogation from the definition of "*ingredient*".

The Commission remarks in its proposal that its intention is to get back to the *status quo* which prevailed the CJEU judgment: "*As regards the nature of pollen in honey, the general interpretation which prevailed before the judgment was that pollen was a constituent of honey, and not an ingredient within the meaning of Article 6(4)(a) of Directive 2000/13/EC. As a result the labelling rules applicable to ingredients set out in Directive 2000/13/EC (inter alia, the list of ingredients) were not deemed to apply to honey*".

Conclusion

Without evaluating whether the Commission is correct in establishing a derogation from the definition of "*ingredient*" in another act than Directive 2000/13/EC, it must be noted that, if the Commission proposal is adopted under the *Commission proposal scenario*, pollen (as a natural constituent of honey) must not be regarded as an ingredient of honey and does not have to be indicated in the list of ingredients.

2. Authorisation and supervision requirements under Articles 3, 4, 5 and 9 of Regulation (EC) No 1829/2003

2.1 Baseline scenario

Under the *Baseline scenario*, pollen is defined as an ingredient of honey, according to the interpretation of the CJEU in the Bablok case under Regulation (EC) No 1829/2003.

Under Article 4(2) of Regulation (EC) No 1829/2003 "*[n]o person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation (...) and the relevant conditions of the authorisation are satisfied*". Article 3(1) covers (a) GMOs for food use; (b) food containing or consisting of GMOs; and (c) food produced from or containing ingredients produced from GMOs.

Point 14 of Article 2 of Regulation (EC) No 1829/2003 defines "*placing on the market*" as "*the holding of food or feed for the purpose of sale, including offering for sale, or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves*".

According to Article 4(4) of Regulation (EC) No 1829/2003, "*[t]he authorisation referred to in paragraph 2 may cover: (a) a GMO and foods containing or consisting of that GMO as well as foods produced from or containing ingredients produced from that GMO; or (b) food produced from a GMO as well as foods produced from or containing that food; (c) an ingredient produced from a GMO as well as food containing that ingredient*".

In the Bablok case, the CJEU held that honey with GM pollen falls under Article 3(1)(c) of Regulation (EC) No 1829/2003 as "*food produced from GMOs*". In essence the CJEU stated that *"products such as honey and food supplements containing such a substance constitute 'food … containing ingredients produced from GMOs' within the meaning of Article 3(1)(c) of Regulation No 1829/2003*".[16]

This interpretation depends on the concept of "*food*" within the meaning of Article 2 of Regulation (EC) No 178/2002, and also on the concept of "*food produced from GMOs*" within the meaning of point 10 of Article 2 of Regulation (EC) No 1829/2003. Insofar as honey is a product intended to be ingested by humans, it constitutes "*food*" according to Article 2(1) of Regulation (EC) No 178/2002.

According to point 10 of Article 2 of Regulation (EC) No 1829/2003, "*produced from GMOs means derived, in whole or in part, from GMOs (…)*". Honey, according to the first paragraph of Annex II to the Directive 2000/110/EC, contains also "*solid particles derived from honey collection*". Therefore, honey is derived in part from pollen. The CJEU held in the Bablok case that "*when the conditions set out in Article 3(1) of Regulation No 1829/2003/EC are fulfilled, the authorisation and supervision obligation exists irrespective of the proportion of genetically modified material contained in the product in question*".[17]

[16] Para. 93 of the judgment.
[17] Para. 103 of the judgment.

Consequently, under the *Baseline scenario*, honey with GM pollen constitutes food "*produced from GMOs*" within the meaning of point 10 of Article 2 of Regulation (EC) No 1829/2003. Therefore, as food containing an ingredient produced from a GMO, it can only be placed on the market if it is covered by an authorisation according to Article 4(2)(c) of Regulation (EC) No 1829/2003 and the relevant conditions of the authorisation are satisfied.

The authorisation procedure, which is set out in Article 5(1) and (2) of Regulation (EC) No 1829/2003, provides that in order to obtain the authorisation referred to in Article 4(2), an application must be submitted to the national competent authority of an EU Member State which (i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt; (ii) shall inform without delay the European Food Safety Authority (hereinafter, EFSA); and (iii) shall make the application and any supplementary information supplied by the applicant available to EFSA. EFSA must inform without delay the other EU Member States and the European Commission of the application.

Article 9 of Regulation (EC) No 1829/2003 establishes supervision criteria (*inter alia*, for post-market monitoring) and sets out that after an authorisation has been issued, the authorisation-holder and parties concerned must comply with any conditions or restrictions which have been imposed in the authorisation and must, in particular, make sure that products not covered by the authorisation are not placed on the market as food or feed.

Conclusion
Under the *Baseline scenario*, honey with GM pollen is covered by Regulation (EC) No 1829/2003 and is subject to the respective authorisation (before it can be marketed in the EU) and supervision requirements.

2.2 Commission proposal scenario
The question is whether under the *Commission proposal scenario,* honey with GM pollen would be covered by Regulation (EC) No 1829/2003 even if pollen is considered as a natural constituent of honey.

The Commission proposal contains a number of references to Regulation (EC) No 1829/2003. In the "*Explanatory memorandum (Context of the proposal)*", under point 1(b), it states that "*[t]he aim of the proposal to amend Directive 2001/110/EC relating to honey is to in the context of the judgment of the Court of Justice in case C-442/09, and, without prejudice to the application of Regulation (EC) No 1829/2003 on genetically modified food and feed to honey containing genetically modified (GM) pollen, clarify explicitly the status of pollen as a constituent particular to honey rather than an ingredient of honey*" (emphasis added). This aim is repeated in recital 1 of the Commission proposal.

Under point b) of the "*Grounds for and objectives of the Commission proposal*", it reads that "*[t]his clarification would however not prevent the applicability of Regulation (EC) No 1829/2003*

to honey containing GM pollen, and in particular will not affect the conclusion of the Court of Justice that honey containing GM pollen can be placed on the market only if it is covered by an authorisation in accordance with that Regulation".

Finally, under the point "*General context*", the Commission proposal adds that "*[this amendment will not alter the conclusion of the Court of Justice in case C-442/09 that honey containing GM pollen falls under the scope of Regulation (EC) No 1829/2003. Indeed, after the amendment of Directive 2001/110/EC, honey containing GM pollen will continue to fall under Article 3(1)(c) of that Regulation, as "food produced from GMOs*".

In fact, in the Bablok judgment, the CJEU dismissed the European Commission's argument that honey containing pollen does not come within the scope of Article 3(1)(c) of Regulation (EC) No 1829/2003 and emphasised that honey containing GM pollen cannot escape the corresponding safety checks. In that case, the Commission argued that a distinction must be drawn between the concept of "*ingredient*" and that of "*natural component*" and that pollen as a natural component of honey and not an ingredient does not come within the scope of Article 3(1)(c) of Regulation (EC) No 1829/2003. The European Commission had moreover argued in the Bablok case with recital 16 in the preamble to Regulation (EC) No 1829/2003, from which it must be inferred that foods of animal origin may be considered to be produced from a GMO only if the animal itself has been genetically modified.

The CJEU held in the Bablok case that the distinction between the concept of "*ingredient*" and that of "*natural component*" does not take account of the particular conditions under which pollen is incorporated into honey or of the voluntary maintenance of that pollen in the composition of the end product. The CJEU concluded that the interpretation proposed by the European Commission would undermine the objective of protecting human health, since a foodstuff such as honey would escape any safety checks, even though it might contain significant quantities of genetically modified material.[18] The determining criterion for the application of Regulation (EC) No 1829/2003, as set out in recital 16 in the preamble thereto, would be disregarded, namely that as to "*whether or not material derived from the genetically modified source material is present in the food …*".[19]

Even if pollen is considered as a natural constituent of honey, honey would remain food containing GM material (*i.e.* GM pollen). The main criterion for the application of Regulation (EC) No 1829/2003 would be met. Therefore, the judgment of the Court of Justice in the Bablok case has to be interpreted as meaning that honey containing traces of pollen from GM plants, independently of these being considered "*ingredients*" or "*constituents*", must receive prior authorisation before it may be marketed as food in the EU.

[18] Para. 82 of the judgment.
[19] Para. 83 of the judgment.

The CJEU held that the exclusion of any food would undermine the objective of human health protection,[20] since such food would escape the prescribed safety checks. According to this line of reasoning, the objective of protecting human health would continue to be respected in the case that GM pollen was considered a "*natural component*" of honey and not an "*ingredient*" thereof.

Conclusion
The Commission proposal does, in essence, not alter the fact that honey with GM pollen is covered by Regulation (EC) No 1829/2003 and is subject to the respective authorisation and supervision requirements. The Commission proposal does not change anything to the fact (as established by the CJEU) that honey containing GM material must receive prior authorisation before it can be marketed in the EU.

3. Labelling requirements under Regulation (EC) No 1829/2003

3.1 Baseline scenario

Article 12 of Regulation (EC) No 1829/2003 establishes labelling rules for foods which are to be delivered as such to the final consumer or mass caterers in the EU and which (a) contain or consist of GMOs; or (b) are produced from or contain ingredients produced from GMOs.

Paragraph 2 of Article 12 sets out that the labelling rules do *"not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable."*

Therefore, under Article 12(2) of Regulation (EC) No 1829/2003, there are two cumulative conditions to be met for a food which contains or consists of GMOs or is produced from or contains ingredients produced from GMOs to be excluded from the labelling requirements of Regulation (EC) No 1829/2003:

a) the GM material present in food must be below the threshold of 0.9% (of the food ingredients considered individually or food consisting of a single ingredient);

and

b) the presence of the GM material must be adventitious or technically unavoidable.

Under the *Baseline scenario*, pollen is defined as an ingredient of honey, according to the interpretation of the CJEU in the Bablok case under Regulation (EC) No 1829/2003. If the 0.9% threshold applies to pollen as an ingredient, this threshold will most likely be exceeded, inasmuch as it applies to the total pollen content (as an ingredient of the honey), and not to the total honey content (as a food consisting of a single ingredient).

[20] Paras. 82, 106 and 107 of the judgment.

Honey with authorised GM pollen as ingredient falls, therefore, under the labelling requirements of Article 12 of Regulation (EC) No 1829/2003.

According to Article 13(1)a) of Regulation (EC) No 1829/2003 foods to which the labelling requirements of Regulation (EC) No 1829/2003 apply are subject to the following specific labelling requirements:

"*[w]here the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified (name of the ingredient)' shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned*".

Honey with authorised GM pollen must therefore be labelled as "*produced from genetically modified pollen*".

Conclusion
Under the *Baseline scenario*, the labelling requirements of Article 12 of Regulation (EC) No 1829/2003 apply. The 0.9% threshold will most likely be exceeded if it applies to pollen as an ingredient (the 0.9% threshold applies to 0.9% of the total pollen content as an ingredient, and not to 0.9% of the total honey content, as it would be the case if it was considered a food consisting of a single ingredient). Honey with authorised GM pollen must, therefore, be labelled as "*produced from genetically modified pollen*".

3.2 Commission proposal scenario
Under the *Commission proposal scenario*, pollen is defined as a natural constituent of honey in the Commission proposal. According to point 3 of the third paragraph to Annex II to Directive 2000/110/EC, the water-insoluble content of honey (including pollen) must in general be not more than 0.1/100g. In case of pressed honey, it must be not more than 0,5g/100g. The water-insoluble content in honey (including pollen) is, therefore, very low. In the light of these compositional requirements, the 0.9% threshold will never be reached, inasmuch as, in the assumption that pollen is a natural constituent of honey, it applies to the total honey content. Therefore, the first condition of Article 12(2) a) is met.
As stated above, under Article 12(2)b) of Regulation (EC) No 1829/2003 there is a second condition to be met so that a food which contains or consists of GMOs or is produced from or contains ingredients produced from GMOs be excluded from the labelling requirements of Regulation (EC) No 1829/2003, *i.e.*, the presence of the GM material must be adventitious or technically unavoidable.

The third paragraph of Annex II to the Directive 2000/110/EC establishes that "*(…) no pollen or constituent particular to honey may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter*". Arguably, the presence of pollen in honey is technically avoidable, but cannot be removed due to the provisions in Directive 2001/110/EC.

The presence of the GM pollen in honey could also be considered as adventitious. The CJEU argued in the Bablok case that "*[p]ollen is (…) not a foreign substance or impurity in*

honey, but rather a normal component of it which, according to the intention of the EU legislature, cannot in principle be removed from it, even if the frequency with which it is incorporated and the quantities in which it is present in honey are attributable to certain random factors arising during production".[21] The Advocate General in the Bablok case had argued that "*[p]ollen harvested by bees for feeding purposes may find its way into honey either accidentally, through the action of bees during honey production, or as a result of a technical process, when honeycombs are centrifuged in the harvesting of the honey, which may result in the extraction of the content not only of cells filled with honey, but also of neighbouring cells intended for the storage of pollen*".[22]

Therefore, the presence of pollen in honey can, arguably, be considered as adventitious. Both alternative conditions of Article 12(2)b) of Regulation (EC) No 1829/2003 for a food which contains or consists of GMOs or is produced from or contains ingredients produced from GMOs to be excluded from the labelling requirements of Regulation (EC No 1829/2003 (i.e., the presence of the GM material must be adventitious or technically unavoidable) are arguably met under the *Commission proposal scenario.*

Article 12(3) of Regulation (EC) No 1829/2003 requires that "*[i]n order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material*".

Conclusion
Under the *Commission proposal scenario*, it must be concluded, in light of the above, that honey with GM pollen (authorised in the EU) is excluded from the labelling requirements of Regulation (EC) No 1829/2003.

4. Consideration of the status of MON810 GM Pollen

The conclusions for the *Baseline scenario* and the *Commission proposal scenario* above are only valid for GM pollen which is authorised in the EU. From the outset, honey cannot be marketed in the EU if it contains (either as ingredient or natural constituent) non-authorised GM pollen. In this respect, it is noted that no GM pollen is currently authorised in the EU.

Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON 810), pursuant to Council Directive 90/220/EEC[23], authorised MON810 maize. The authorisation is, in principle, valid for a period of ten years. According to the EU Register of authorised GMOs,[24] the authorisation covers the following foods and food ingredients produced from MON810

[21] Para. 77 of the judgment.
[22] Opinion of Advocate General Yves Bot delivered on 9 February 2011 in Case C 442/09 Karl Heinz Bablok, Stefan Egeter, Josef Stegmeier, Karlhans Müller, Barbara Klimesch v Freistaat Bayern (Reference for a preliminary ruling from the Bayerischer Verwaltungsgerichtshof (Germany)), at para 44.
[23] OJ L 131, 5.5.1998, p. 32–33.
[24] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

(including food additives): maize flour, maize gluten, maize semolina, maize starch, maize glucose and maize oil. It should be noted that maize pollen is not among the authorised GM foods.

In 2007, Monsanto applied for its authorisations of MON810 maize to be renewed according to Article 8 and Article 11 of Regulation (EC) No 1829/2003. That application is still under consideration.[25] Under Article 11(4) of Regulation (EC) No 1829/2003, the duration of an authorisation is extended until such time as a decision is taken (*i.e.*, until the European Commission decides on the renewal of the authorisation). In July 2013, Monsanto has reportedly announced the withdrawal of almost all current applications for GM crops from the EU approval process. The announcement appears to concern seven applications (*i.e.*, one for soybean, one for sugarbeets and five for maize), and sources suggest that only the application for renewal of authorisation of maize MON810 would be upheld.[26]

On request from the Competent Authority of the Netherlands for an application submitted by Monsanto,[27] EFSA adopted on 6 December 2012 a Scientific Opinion on an application[28] for the placing on the market of maize MON810 pollen under Regulation (EC) No 1829/2003. In this opinion, the EFSA GMO Panel addresses the safety of maize MON810 pollen to complete the scope of an application (RX-MON 810) for the marketing of GM maize MON810 with the use of MON810 pollen as or in food. The EFSA GMO Panel has previously assessed the safety of the newly expressed Cry1Ab protein in maize MON810 and states that the assessment and conclusions of the GMO Panel on the safety of the newly expressed Cry1Ab protein, including its potential toxicity and allergenicity, also apply to the Cry1Ab protein expressed in MON810 pollen. In its opinion of 6 December 2012, the EFSA GMO Panel, in essence, concludes that while it is not in a position to conclude on the safety of maize pollen in or as food in general, it concludes that the genetic modification in maize MON810 does not constitute an additional health risk if maize MON810 pollen is to replace maize pollen from non-GM maize in or as food.[29]

This is where the renewal of the authorisation procedure of MON810 maize (now including the authorisation of GM maize pollen) and the corresponding EFSA opinions become important for the labelling of honey. If the European Commission endorses, by favourable regulatory decisions on Monsanto's applications, EFSA's favourable scientific opinion on MON810 pollen, honey containing MON810 pollen would be marketable in the EU, different from the present.

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[25] Opinion of Advocate General Yves Bot delivered on 9 February 2011 in Case C 442/09 Karl Heinz Bablok, Stefan Egeter, Josef Stegmeier, Karlhans Müller, Barbara Klimesch v Freistaat Bayern (Reference for a preliminary ruling from the Bayerischer Verwaltungsgerichtshof (Germany)), at paras 38 and 135.

[26] Euro food law of 23 July 2013, Monsanto to withdraw from EU GM approvals process, available on the internet at: http://www.eurofoodlaw.com/food-technology/monsanto-to-withdraw-from-eu-gm-approvals-process--1.htm (last accessed on 24 July 2013).

[27] Question No EFSA-Q-2012-00408.

[28] EFSA-GMO-NL-2012-107.

[29] EFSA Journal 2012;10(12):3022.

Under the *Commission proposal scenario*, this would mean that honey containing GM pollen would have to be labelled only where the 0.9% threshold, as applied to the total honey content, was surpassed, according to Article 12(2) of Regulation (EC) No 1829/2003. Pursuant to this provision, the presence of material containing, consisting of, or produced from authorised GMOs in food shall not be labelled where that presence does not exceed 0.9% of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable. Conversely, under the *Baseline scenario*, following the interpretation of the CJEU, the 0.9% threshold would apply to the total pollen content, since pollen would be considered an ingredient of honey, rather than a natural food constituent of honey. Therefore, under the *Baseline scenario*, honey containing authorised GM pollen would need to be labelled as "*produced from genetically modified pollen.*"

Conclusion
Under the *Commission proposal scenario*, it must be concluded, in light of the above, that honey with MON810 pollen is, in practice, excluded from the labelling requirements of Regulation (EC) No 1829/2003, provided that EFSA's favourable decision on MON810 pollen is endorsed by a regulatory decision on the renewal of the authorisation of MON810 maize (including maize pollen).

5. Analysis of impacts

In addition to current labelling, authorisation and supervision requirements, the specific impacts on the European and international honey market and their relevant stakeholders – ranging from beekeepers, farmers, intermediaries, food manufacturers, retailers and consumers – will need to be identified, as well as the broader effects of a Commission proposal on social and environmental factors.

This section focuses on describing in more detail the most important economic, social and environmental impacts of both the baseline (CJEU ruling) and Commission proposal scenarios. These impacts will be measured according to the importance attached to them in the desk literature and the interviews conducted. Summary results will be presented in an impact score card.

Key findings

1. Economic impacts

- A classification of pollen as an ingredient would add significant testing costs in order to obtain the information necessary for labelling.
- Reactions from the demand side to a label stating that the product may contain GMO content are expected to be highly negative.
- The CJEU ruling caused legal uncertainty that particularly has a potential impact on international trade.

2. Social impacts

- If the Commission proposal of the Honey Directive is adopted, the labelling requirements will be much less stringent and hence consumers will receive less information on the product.
- There is disagreement among different beekeeper associations about the potential reputational impact of labelling GM honey. By calling honey pollen an ingredient consumers may think that pollen is a separate product that is added to the honey. This might be an option (see manipulation of honey below) but is usually not the case.

3. Environmental impacts

- The (potential) presence of GM crops and the practical implications this has on beekeepers may affect the common practice of offering free pollination services to farmers.
- If the Commission proposal on the Honey Directive is adopted, it is less likely that the threshold for labelling pollen as an ingredient is exceeded. Hence, the consequences for small amounts of GM contaminated pollen in honey may be perceived lower and therefore beekeepers might not feel the need to relocate to GM-free areas. The size of this impact depends, amongst other things, on the standards the beekeepers set for themselves and their honey, and those set by the food industry and/or retailers.
- Most of the stakeholders in the honey value chain fear contamination. Contamination is possible at three different levels: crops, bees, and the honey production process.

4. Further reflections

- It appears that a vote on the clarification of pollen of honey would, under either scenario option, stand to improve legal certainty with stakeholders and, more specifically, clear up consumer confusion. This is said to benefit all stakeholders, as some players are currently unsure which rules or regulations apply.
- In case the Commission proposal is not adopted, current practice by national enforcement authorities to 'tolerate' honey to be exempted from broader labelling requirements will likely be lifted, increasing expenditure for food business operators.

I - Economic impacts

The assessment of economic impacts will be based on the honey industry description, and responses of our interviewees. Throughout the interviews three main reoccurring themes were recognized. First, it was stated that a classification of pollen as an ingredient would add significant testing costs in order to obtain the information necessary for labelling. Second, reactions from the demand side to a label stating that the product may contain GMO content are expected to be highly negative. Third, the CJEU ruling caused legal uncertainty that particularly has a potential impact on international trade.

1. Impact on costs and revenues

Throughout the interviews it was mentioned that commissioning a test that is accepted as a measurement method to comply with the criteria laid down in the CJEU ruling would cost approximately 150 Euro per batch. In order to assess the economic impact it is first important to define who will be responsible for organising and eventually paying such a test. Generally, it was mentioned that beekeepers will have to carry this responsibility.

However, given that Article 17 of Regulation (EC) No 178/2002 establishes the following:

"1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.
2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.
For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive (emphasis added)".
As well as, Article 3 of Regulation (EC) No 178/2002 establishes that:

"For the purposes of this Regulation:
1. "food law" means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals;
2. "food business" means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;
3. "food business operator" means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;
8. "placing on the market" means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;
16. "stages of production, processing and distribution" means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed".

It seems not as clear cut from a legal perspective that beekeepers will be the ones having the sole responsibility to provide information about the GM content of honey. However, assuming that the assumption of our interviewees holds and beekeepers will be de facto, not particularly de jure, the ones who would have to implement testing then the impact strongly depends on the on the current production cost structure. This varies among

beekeepers across Member States. A rough estimation and classification provided by some Member States is the following[30]:

- high cost: EUR 112 to 142 per hive (Germany, Sweden, Finland, United Kingdom, Netherlands);
- medium cost: EUR 56 to 91 per hive (Austria, Denmark, Belgium, Luxembourg, Portugal);
- low cost: EUR 20 to 41 per hive (Greece, Spain, France, Italy).

Assuming that there is only one harvest per year constituting the batch of honey that needs to be analysed for GM content the cost impact is significant and exceeds current production costs per hive. This batch-wise analysis was deemed necessary by one of the interviewees stating that, given the zero-tolerance of GM content from the consumer and retailer side as well as movements of the hive to different locations, a case-wise analysis of the product is the safest way to obtain detailed information of the product. This particularly holds for packers that are organising the import from third countries. As described in the value-chain analysis the honey coming from different regions is consolidated into bigger units to be shipped overseas. As such, it is not possible anymore to trace the origin of the consolidated blend. Prior testing certificates by the beekeepers are required to make a differentiated assessment of the GM content.

Since the cost impact is substantial, industry participant are looking for alternatives to provide the required information. An interviewee stated that a potential way of circumventing testing might be detailed information about whether the region the honey was produced in is subject to GMO cultivation. This would require the establishment of monitoring programmes that provide information to beekeepers about GMO cultivation in the region they plan to operate in. Furthermore, suitable coexistence measures would establish a framework that minimizes the risk of GM contamination.

As such, GMO registers and monitoring programs as well as suitable coexistence measures provide valuable information for beekeepers. As a consequence, they would have better control over the production process.

A GMO registry would also be in line with Article 18 of Regulation (EC) No 178/2002, which concerns traceability and provides:

"1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.
2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

[30] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52001DC0070:EN:HTML

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.
4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions".

Traceability is defined in Article 3 of Regulation (EC) No 178/2002:

"15. "traceability" means the ability to trace and follow a food, feed, food- producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;"

Impacts on the revenue side are difficult to assess. Generally, it was coherently stated in the interviews that the industry standard is very high, meaning that retailers implement a zero-tolerance policy towards GM in honey. This is mainly driven by EU consumer expectations and their attitude towards GMOs. As such, downstream participants of the value-chain are favouring procurement of honey with certification already supplied. This provides certainty and promises of non-GM honey can be made to consumers. Assuming that a classification of pollen as an ingredient would lead to GMO labelling it can be expected that many EU consumers would react negatively. As a consequence, beekeepers subject to such labelling would lose a significant share of the market. This is particularly true for third country producers, who do not have the regional customer base as many of the EU beekeepers.

2. Impact on trade

In general, the international standard for honey, Codex Alimentarius, defines honey as *"as the natural sweet substance produced by honey 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 the honey comb to ripen and mature"*. The Codex Standard does not explicitly state that pollen is a natural substance. This is why it could be the case that the European Commission's argument that pollen is a constituent of honey and not an ingredient may arguably not be supported by the Codex Alimentarius Standard for honey. This is explained by the fact that, although the first sentence under point 3.1, on the essential composition and quality factors, provides that *"honey sold as such shall not have added to it any food ingredient, including food additives, nor shall any other additions be made other than honey"*, it also states in the fourth sentence of point 3.1 that *"no pollen or constituent particular to honey may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter"*.

Codex standards and related texts are not a substitute for, or alternative to, national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply. Codex standards and related texts contain requirements

for food aimed at ensuring for the consumer a safe, wholesome food product free from adulteration, correctly labelled and presented. Codex Standards are recognised by the WTO as an international reference standard for the resolution of disputes. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) encourages governments to "harmonise" or base their national measures on the international standards, guidelines and recommendations developed in international organisations. In relation to food safety, the relevant organisation is the joint FAO/WHO Codex Alimentarius Commission. Given all this, it might not be the case that the current Codex standard on honey is overruled by EU legislation.

Also, Article 13 (International standards) of *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety7 provides that "[w]ithout prejudice to their rights and obligations, the Community and the Member States shall: (a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards; (b) promote the coordination of work on food and feed standards undertaken by international governmental and non- governmental organisations; (c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures; (d) give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries; (e) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced.* Regulation (EC) No 178/2002 does not state that international standards must be implemented in EU law.

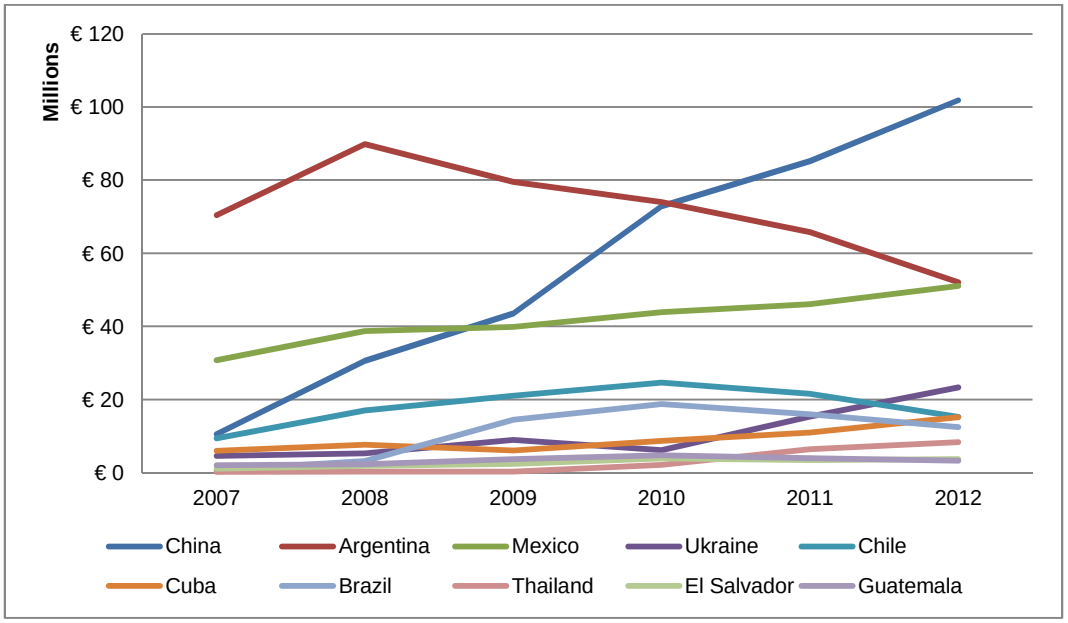
Despite this background, the CJEU ruling has already had an impact in an international context. At the meeting of the Committee on Technical Barriers to Trade (hereinafter, TBT Committee) of November 2011, soon after the delivery of the Court's ruling, several WTO Members expressed their concerns in connection with the outcome of the said ruling. Subsequently, at the meeting of the TBT Committee of 13 June 2012, the issue was raised again. WTO Members (Argentina, supported by Brazil, Mexico, the US and Uruguay) raised a specific trade concern, expressing that the implications of the ruling delivered by the CJEU would hinder international trade in honey. In particular, WTO Members expressed their worries that the new consideration of pollen as an ingredient, and no longer as a natural constituent of honey, would impose burdensome requirements that would translate as obstacles to their exports of honey to the EU. The European Commission referred to the pending authorisation procedure for MON810 pollen and declared that it is also currently "shaping the EU Honey Directive" to avoid causing unnecessary disruptions to the supply of honey to the EU. At a later meeting of the TBT Committee, in March 2013, concerns raised by WTO Members were further aggravated by the alleged situation of uncertainty caused by the adoption, in September 2012, of the Commission proposal.

The EU replied to the above concerns by acknowledging that the ruling of the CJEU stood to have numerous effects, and that the EU was working to ensure the proper implementation of the CJEU's consideration in the least disruptive manner. At the meeting in March 2013, the EU representative explained how the Commission proposal had been drafted to minimise the trade-disruptive effects of the Court's ruling.

In case the Commission proposal to amend Directive 2001/110 on honey is not adopted, WTO Members could request consultations with the EU and follow the abovementioned procedure. The industry itself cannot start such proceedings at the WTO, but it may lobby a Government to do so.

Figure 5.1 below shows EU imports from the top ten third countries over the last 5 years. Most noteworthy are the steep increase of Chinese exports to the EU, and the decline of EU imports from Argentina since 2008. The reason for this substitution can not only be found in the price competitiveness of Chinese honey but also because of the legal uncertainty that was created by the CJEU ruling, which may have contributed to discussions at the WTO TBT Committee as described above, and a decline in Argentinian exports to the EU since 2011. As a response, Argentina started increasing its market share in the US market, which was further catalysed by the appreciation of the US Dollar to the Euro.

Figure 5.1 EU imports from top 10 3rd countries



Next to China, imports from Cuba, the Ukraine, and Thailand increased. Note that these countries were not part of the complaint at the WTO and are also, with the exception of China, not identified by the aforementioned ISAAA report as countries subject to GM cultivation. As such, it can be inferred that the impact on imports very much depends on the source country and it cannot be generalized that the CJEU ruling has a negative effect for all third countries exporting honey or honey products to the EU.

II - Social impacts

The social dimension in the honey debate is less tangible than the economic dimension. Firstly, honey has a reputation to keep as a healthy and natural product. If honey is labelled with GM pollen as an ingredient, this will clearly affect honey's reputation as a natural product. Secondly, it will reduce willingness to buy premium honey, unless it is beyond doubt that the source of the product is transparent.

Other indicators for the social dimension include:

- the effects on hobby and professional beekeeping activities in Europe – in terms of employment and societal value;
- the effects on the quality and taste of honey;
- the effects on food safety and consumer health.

1. Transparency

Given the CJEU ruling, pollen in honey have to be declared in a list of ingredients and, as a result, consumers are informed about the pollen in the honey and whether or not the honey contains GM pollen. If the Commission proposal of the Honey Directive is adopted, the labelling requirements will be less stringent and hence consumers will receive less information on the product.

2. Reputation and perception of honey

Honey has the reputation to be a natural, wholesome, healthy product. As a result, consumers buying honey, especially those buying high-end honey, have expectations about the product. The interviewees expressed different views on how labelling impacts the perception that consumers have of honey.

The European Professional Beekeepers Association does not see labelling of honey as an issue. In their opinion, there is nothing bad about stating that there is pollen in your honey, because (high-end) consumers love the fact that honey contains pollen.

The British Beekeepers Association (BBKA), on the other hand, fears that the reputation of honey is harmed by labelling pollen as an ingredient. The reason for this is that by calling pollen an ingredient, consumers may think that pollen are a separate product that are added to the honey, whereas this is not the case.

The origin of honey can be established by analysing the pollen[31]. The European Federation of Honey Packers and Distributers (F.E.E.D.M.) expressed the concern that when pollen is labelled as an ingredient there is the risk that it opens the door to adding or subtracting pollen to manipulate the results of the analysis of the pollen. This can for example make multi-floral honey appear to be mono-floral honey. See also section 4

[31] http://www.foodsafetynews.com/2011/11/tests-show-most-store-honey-isnt-honey/#.UZo8OMry2So.

under the environmental impacts on the "manipulation of honey". Moreover, honey from one country can appear to be honey from another country due to the addition or subtraction of pollen. This will hurt the reputation of honey being a natural product without additives and consumers will no longer want to pay for differences in honey origin and honey varieties.

3. Impact on beekeeping

When pollen in honey is considered an ingredient, this will burden all beekeepers. The impact on beekeeping will differ for the commercial and professional beekeepers. Most of the amateur beekeepers produce only small batch numbers. The production will become uneconomic because of the high costs associated with testing and labelling. The professional beekeepers produce larger amounts of honey, and due to the scale effects, they can easily bear the burden. This is also the case for the big exporters: the costs of testing are relatively small for them. It is possible that some amateur beekeepers stop with beekeeping. As amateur beekeepers are by far the majority of the beekeepers in Europe (see Table 3.1), this may have a big impact on the European honey industry.

4. Food safety and consumer health

Defining pollen as a natural constituent or an ingredient of honey will have no direct impact on food safety and/or consumer health, as long as the 'product' in question, namely honey, does not change. Most food safety concerns are based on the assumption that MON810 will become an authorized GM-crop. The European Food Safety Authority's (EFSA) Panel on Genetically Modified Organisms (GMO) delivered a positive scientific opinion on Monsanto's application to place GM pollen on the market for use 'in or as foods'. The EFSA GMO panel concluded that scientific research did not raise any safety concerns with respect to its pollen.

Friends of the Earth Europe stated two main shortcomings with the EFSA opinion. The first is EFSA's short-term perspective. According EFSA, MON810 pollen has no negative impacts on the environment, but this cannot be concluded from short term trials conducted in a lab. To test for impacts on the broader ecosystem, which are all medium to longer term effects, actual field trials would need to be conducted. A second shortcoming is the fact that only the impact of MON810, and not GM in general, was studied. The ecosystem is highly interdependent; therefore a total effect would need to be measured as well.

As long as the wider implications and long term effects of GM products are unknown, retailers will be reluctant to sell GM honey for reputational reasons. In the end, retailers have the highest bargaining power in the honey value chain. When they say they will not sell a product, it will not be sold, even when GM honey is allowed by law. This "zero tolerance" mentality of retailers is a very important control mechanism in the market for honey. As retailers protect their reputations they de facto provide a means for the continued production of non-GM honey.

III - Environmental impacts

The potential environmental impacts of the Commission proposal are a big concern for a number of stakeholders. For beekeepers, farmers, and shopkeepers, the issues surrounding GM pollen affect their ability to run a business. For farmers and consumers, the potential (legal) precedence for the production of other GM food and feed play an important role. While this wider implications of GMO on the environment falls outside the scope of this substitute impact assessment, it is worth noting that most of the stakeholders interviewed noted their conviction that a Commission proposal on the nature of pollen in honey will directly impact the broader GM debate. To this end, this section will include some of the (narrow) GM implications that adoption (or not) of the Commission proposal might have.

The expected impacts for the environment will fall on the biodiversity of bee populations, pollination and land use, remuneration of pollination services, changed farmer-beekeeper relationship, contamination and co-existence.

1. Pollination and land use

Bees are of critical importance in the environment: they provide pollination for a wide range of crops and in that way, they sustain biodiversity. According to estimates of the Food and Agriculture Organization (FAO), of the 100 crop species that provide 90 per cent of the food worldwide, 71 are pollinated by bees[32]. When crops are not pollinated in the period they have flowers, both the quantity and quality of the harvest will be reduced. This loss can be quite substantial; for some crops the FAO estimates the loss to be 75 per cent[33].

The presence of GM crops and the potential consequences for the beekeepers resulting from this may lead to relocating by beekeepers to "GM-crop-free" areas. This relocation takes place to avoid unauthorised events and/or to ensure that their bees will not pick up GM pollen that will become part of the honey that is produced. When this relocating occurs, only few pollinators, such as bees not belonging to beekeepers' colonies and other insects, will remain in an area with GM fields. This reduction in pollination potential will hurt the ecosystem in that area and moreover it will impact the farmers. Not only the farmers cultivating GM crops experience this impact; also farmer without GM crops but with fields in the area.

If the Commission proposal is adopted, it is less likely that the threshold for labelling pollen as an ingredient will be exceeded. Hence, the consequences of having small amounts of GM pollen in honey may be perceived lower and therefore beekeepers might not necessarily opt for relocation to GM-crop-free areas. The incentive and perceived need for relocation is dependent on, amongst other things, the standards the beekeepers set for themselves and their honey, and those set by the food industry and/or retailers. The (additional) requirements that are set on the presence of GM pollen in honey may nullify the impact.

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[32] http://www.fao.org/ag/magazine/0512sp1.htm.
[33] ftp://ftp.fao.org/docrep/fao/012/i0842e/i0842e09.pdf.

2. Remuneration for pollination services

In Europe, in general, pollination services are currently provided free of charge to farmers by beekeepers. According to the British Beekeepers Association, there are some beekeepers that get money for their pollination services, but most of them have no income from the farmers. There is a tradition for dividing the incomes: the farmer gets pollination and the beekeeper the honey. When there is no GMO in the neighbourhood, than this will not change with the adoption of the Commission proposal.

The (potential) presence of GM crops and the potential consequences for the beekeepers resulting from this may change this common practice of offering free pollination services. When honey contains GM pollen, the willingness for consumers to pay a premium for high-end honey will likely decrease as the presence of GM pollen hurts the reputation of honey as a natural and healthy product. Since beekeepers generally will not be able to sell their honey at a lower price, it is expected that farmers will have to start paying for pollination services to cover this loss.

3. The farmer-beekeeper relationship

The relationship between farmers and beekeepers is characterised by an interdependency: farmers need pollination for their crops and beekeepers want to locate their hives in crops and flower rich areas. The interviewees indicated that in the European Union, generally, the relationship between farmers and beekeepers is good, but that, in some Member States, tension between them has increased because of (increasing) uncertainty of the presence of GM crops. According to EU Directive 2001/18/EC, all GM fields in a country should be registered. However, it appears that this Directive has not yet been implemented fully in all Member States, which creates uncertainty for beekeepers about the possible presence of GM crops near their hives.

One country where this uncertainty exists is Spain. GM maize currently accounts for 14 per cent of the total cultivation. The location of these GM maize fields is not registered; only the sales are. For the beekeeper it is therefore impossible to determine if his hives are close to GM fields. Moreover, there is no definite answer to how far GM pollen spread and thus what is a safe distance to avoid this pollen ending up in your honey. The estimates for this vary from a couple of meters to 100 km[34].

This uncertainty about the presence of GM fields and the resulting impacts appears to be at the core of the discussion on environmental impacts in general and the impact on pollination in particular. It should be noted, however, that this impact is not directly related to the Commission proposal of the Honey Directive, but rather to the result of several countries not yet properly implementing the Directive on the registration of GM fields. To this end, it is a secondary order impact that nonetheless has a big influence on stakeholder perception on the issue and therefore should be mentioned here.

[34] http://orgprints.org/20589/2/2-Biofach_2012_-_Uli_Broeker_-_Apicon.pdf.

4. Manipulation of honey

The CJEU ruling makes it possible to add or subtract ingredients to honey. Pollen in honey contains information about the geographical origin and the flower origin of honey. E.g. to label your honey as clover honey, you need at least 50% of the pollen to be clover. If that amount is not reached "naturally", additional clover pollen can be added to it. This form of pollen manipulation is now forbidden under Codex Alimentarius rules.

5. Contamination and co-existence

Most of the stakeholders in the value chain fear contamination. Contamination is possible at three different levels. The first level is contamination of crops. In GM crop fields, so-called pollen drift, or release of pollen in the atmosphere, creates obvious problems for nearby non-GM or organic crops. Sugar beet, maize and oil seed rape pollen is light enough to travel long distances.[35] Even when farmers are not growing GM crops themselves, they risk crop infection through contamination of a neighbour's GM crop. This means an additional risk for the beekeepers, because the GM component in the honey pollen could be accidental. Unfortunately, identifying cross-contaminated plants is only possible through laboratory testing. This means that the beekeepers will always have to test the honey, no matter how small the risk of contamination.

The second level is contamination by bees. Bees pollinate up to 5000 flowers in one day. Usually, bees pollinate in a circle of almost 5 kilometers around the hive. When bees land on flowers, some of the pollen gets stuck in the hairy dress of the bee, which then get passed on to other flowers as they land on them next. Bees collect pollen both from GM and non-GM crops. They fly from one to another and contaminate the non-GM crops with the GM pollen.

The third level is contamination of honey in its production process along the value chain. It is a long way from flower to beehive to supermarket and this asks for additional, often costly, measures by various stakeholders. The first chain is the beekeeper. When the beehives from the beekeeper are in different regions, extra care needs to be taken with the collection of honey. When there are no GM crops near the beehives, there is no problem. But when there are GM crops, the beekeeper has to separate everything to avoid contamination of non-GM with GM honey. Moreover, the materials that are needed for collecting the honey and the barrels holding them have to be cleaned regularly. The barrels also need to be labelled before shipping, so that the collecting point does not mix GM honey with non-GM honey in the same barrel. The honey collector, in turn, will do his or her own additional tests for GM before taking the honey. All barrels have to be separated until the results are available. Only after the collector approves the honey after testing, can different honeys be blended. Even then, the barrels and testing materials need to be surgically clean. Finally, the volume of packaging might change, according to the type of honey being packed. Transport and logistics will be adapted to the honey being transported as well.

[35] http://www.gmeducation.org/environment/p149075-contamination%20of%20crops%20.html.

IV - Further reflections

1. Legal certainty

The CJEU ruling describing pollen as an ingredient rather than a natural constituent of honey has provided some legal uncertainty for the honey industry. For example, many stakeholders interviewed during the course of this impact assessment believe that the CJEU ruling contradicts the (current) Codex Alimentarius standard definition of honey, which contains requirements for food aimed at ensuring for the consumer a safe, wholesome food product free from adulteration, correctly labelled and presented. Codex standards are recognised by the WTO as an international reference standard for the resolution of disputes. They are not mandatory. However, a number of small to medium sized players in the honey value chain still appear unsure how to proceed in the market. A simple desk review shows that the EU legislation on honey does not contradict the Codex standard on honey. Codex standards and related texts are not a substitute for, or alternative to, national or EU legislation.

2. National enforcement of labelling requirements

Related to the above, every country's laws and administrative procedures contain provisions with which it is essential to comply. The WTO Agreement on Sanitary and Phytosanitary Measures (SPS) encourages governments to "harmonise" or base their national measures on international standards, guidelines and recommendations developed in international organisations. Whatever the outcome of the Commission proposal, an updated decision on the status of pollen in honey will provide more clarification on this matter, also on international level.

6. Comparison of options

In this step the different options will be compared (i.e. which scenario is the preferred policy option?). The results will be presented in an Impact Score Matrix (scenario against impacts) to compare the merits of the status quo (no intervention) versus introducing the Commission proposal (proposed intervention). The baseline scenario is the reference scenario. For purposes of simplicity, we assume the baseline scenario to be one in which the CJEU ruling is fully implemented (which is not the case in practice at the moment). Where possible, broader (legal) consequences, risks and uncertainties will be addressed.

I - Key Findings: the Impact Score Matrix

The Impact Score Matrix provides an immediate overview of the effects of placing the main impact indicators against the two policy options. These effects can be either negative (-), positive (+), or present no significant change (0).

Table 6.1 Impact Score Matrix

Impact Indicator	Policy Option	
	No intervention (CJEU ruling)	Proposed intervention (EC proposal)
Economic impact indicators:		
• (1) Production costs	-	0
• (2) Retail prices	-	0
• (3) Profit	-	0
• (4) EU imports	-/+	+
• (5) EU exports	-	0
• (6) Intra-EU trade	-	0
• (7) Pollination services	-	0
Social impact indicators:		
• (1) reputation of bottled or packaged honey as a healthy/natural product	0/-	0
• (2) effects on hobby and professional beekeeping activities in Europe – jobs/societal value	-	0
• (3) change in product transparency for consumers	+	0
• (4) effects on quality and taste of honey	0	0
• (5) effects on food safety and consumer health	0	0
Environmental impact indicators:		
• (1) biodiversity of bee populations	0	0
• (2) land use	-	0
• (3) pollination	0	0
• (4) transport and logistics for distribution	0	0
• (5) potential for GM crop cultivation	0	+

Symbols used for impact:	
0	No impact compared with the base situation
+	Positive impact compared with the base situation
-	Negative impact compared with the base situation
0/-	The impact will be negative or negligible
-/+	The impact will be either negative or positive

Economic impacts of the qualification of pollen as an ingredient of honey:

(1): The lower threshold measurement taking pollen as a basis increases the probability of GMO labelling. Considering that there is a strong demand for non-GMO honey, industry standards will require testing, which has a significant impact on production costs.

(2): increased production costs because of enhanced testing requirements will result in higher retail prices. Testing costs as per cent age of total production costs are too high to be absorbed by the retail margin or efficiency gains.

(3): not all of the increased cost burden will be absorbed by the customer. As such, it is expected that a certain part of the profit margin of value-chain actors is decreased. This has a negative impact on revenues.

(4): trade statistics show that on some countries the CJEU ruling already may have contributed to a negative impact. However, substitution effects seem to be present, opening up possibility for other third countries to increase their market share in the EU.

(5): if the substitution effect does not cover the loss in imports form certain third countries, then it might be the case that internal production starts serving the internal market. This would lower exports to third countries.

(6): in the EU, GMO presence in certain countries will trigger the same effects as for trade with third countries. As such, countries with a high awareness of the GMO debate, e.g. Germany, might be reluctant to import from other EU countries with a high degree of GMO cultivation. However, in the EU GMO monitoring systems are present that decrease the likelihood of GMO contaminated honey, as beekeepers will want to move their hives to non-GMO regions.
(7): as an indirect effect the CJEU ruling might make beekeepers reluctant to provide pollination services to farmers. However, these are crucial for farming activities.

Social impacts of the qualification of pollen as an ingredient of honey:

(1): mentioning pollen as a separate ingredient may create the perception that pollen is added to the product, which might hurt the reputation of honey being a natural product. However, some interviewees indicated that labelling pollen as an ingredient will not be an issue, as high-end consumers appreciate that there is pollen in honey.

(2): if pollen is qualified as an ingredient of honey, beekeepers will have to incur (additional) costs for testing and labelling. This burden will be felt more by the beekeepers that produce on a relatively small-scale.

(3): if pollen is qualified as an ingredient of honey, labelling requirements will be more stringent and as a result consumers will receive more information on the product.

(4): from the interviews and the literature there appears to be no reason to assume changes in quality and/or taste of honey as a result of the two policy options.

(5): the legal analysis shows that authorisation requirements are the same under the baseline scenario and the Commission proposal. As a result, there will always be a check for unauthorised events and food safety and as a consequence, consumer health will not be affected by either of the policy options.

Environmental impacts of the qualification of pollen as an ingredient of honey:

(1): the interviewees, nor the literature, suggest that the biodiversity of bee populations will be affected by either of the policy options.

(2): both the desk research and the interviews suggest that consumers prefer not to buy products of which the label mentions "contains GMO". When pollen is qualified as an ingredient of honey the threshold of the labelling requirements is lower and hence beekeepers will want to avoid any possible trace of GM pollen in their honey. As a result, beekeepers will relocate their hives to ensure sufficient distance from GM fields. Note, however, that the impact is dependent on the thresholds/requirements set by the food industry and the retailers: their (additional) requirements may nullify the impact.

(3): it was suggested by some interviewees that tension might arise between farmers and beekeepers as farmers need pollination and beekeepers are not sure where GM fields are located in some countries. However, this uncertainty is not directly related to either of the policy options, but rather to the fact that some countries have not yet properly implemented the Directive on the registration of GM fields.

(4): neither the interviewees, nor the literature suggest that transport and logistics responsible for the distribution of honey will be affected by any of the examined scenarios.

(5): less stringent requirements to mention pollen on the honey's label may facilitate the cultivation (pollination) of GM crops insofar that beekeepers will face less restrictions in locating their hives nearby GM fields.

II – Comparing Policy Options

On the basis of this substitute impact assessment we can conclude that the change in status of pollen in honey does not have direct significant economic, social or environmental impacts. Adopting the Commission proposal will lead to two main developments:

1. more honey being imported into the EU from third countries. Trade statistics show that the CJEU ruling already may have contributed to a negative impact on some countries. However, substitution effects seem to be present, opening up possibility for other third countries to increase their market share in the EU.

2. labelling requirements would not necessitate mentioning pollen on the honey's label. This may facilitate the cultivation (pollination) of GM crops insofar that beekeepers will face less restrictions in locating their hives nearby GM fields.

III - Issues that need further consideration

The limited scope of this substitute impact assessment did not allow for an extensive analysis of additional factors that would have an impact on stakeholders in the honey market. Below we present a number of issues that are beyond the scope of this study which need to be taken into account when considering the Commission proposal to clarify the status of pollen in honey.

Legal precedence

During the course of this substitute impact assessment, the question arose whether the CJEU ruling carried the risk of legal precedence. The answer is no. The Bablok judgment does not establish a legal precedent within the framework of Directive 2001/110/EC on honey. The Commission proposal explicitly states that "*[it is necessary therefore to clarify, without prejudice to the application of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed to genetically modified pollen in honey, that pollen is a constituent of honey, which is a natural substance that has no ingredients, and not an ingredient within the meaning of Directive 2000/13/EC. Therefore, Council Directive 2001/110/EC of 20 December 2001 relating to honey should be amended accordingly*".

Legal uncertainty

It appears that, in addition to legal precedence, stakeholders are confused about the broader legal facts surrounding the status of pollen in honey. For example, stakeholders, intentionally or not, expressed their concerns that the CJEU ruling was incompatible with the Codex Standard for Honey. This is not the case, since Codex does not define the nature of pollen explicitly. Moreover, the Codex standards are not legal instruments that can be enforced, but an international, voluntary, mechanism.

Mandatory versus voluntary labelling requirements

The Commission proposal would reduce the burden for *mandatory* labelling since a classification of pollen as a natural constituent of honey will not require further clarification of its ingredients. However, the cost burden will remain for beekeepers, farmers and other suppliers in the honey value chain, because of the additional *voluntary* requirements demanded by retailers. Retailers and consumers alike are demanding more transparency about the origin of the products sold/consumed. Retailers enforce these labelling requirements because they want to protect their reputation with consumers. Consumers will have a reduced willingness to pay a good price for a product that traditionally holds a reputation for being "natural and healthy" once the nature of that product is put into question.

National enforcement

Related to point (3), the current practice by national enforcement authorities to 'tolerate' honey to be exempted from broader labelling requirements will likely be lifted if the Commission proposal is not adopted, increasing expenditure for food business operators.

Wider implications of GM legislation

Bigger economic, social and environmental impacts are expected once the wider implications of adopting GM legislation are taken on board, including the role of national enforcement in this regard. The wider implications of a European GMO legislation are, however, beyond the scope of this study. A parallel study being conducted at this time by the European Parliament should reveal more results in this regard.

7. Conclusions

This substitute impact assessment compares the clarification of pollen in honey as an ingredient or natural constituent on the basis of the economic, social and environmental impacts arising out of labelling, supervision and authorisation requirements.

More specifically, this report addressed the following questions set out in the Terms of Reference from the European Parliament:

What, if any, is the impact of the qualification of pollen as an ingredient of honey:

- On the application of Directive 2000/13/EC on the approximation of the laws of the Member States relating to the **labelling, presentation and advertising of foodstuffs**;

- On the **authorisation and supervision requirements** in Articles 3, 4, 5 and 9 of Regulation No 1829/2003 on procedures for the authorisation and supervision of **GM food and feed**;

- On the **labelling requirements** in Articles 12 and 13 of Regulation No 1829/2003 on procedures for the authorisation and supervision of **GM food and feed**?

Since the main objective of this substitute impact assessment was to determine the different labelling, supervision and authorisation requirements under the CJEU ruling (baseline) and the Commission proposal (intervention), particular emphasis was placed on the legal dimension of such a change. The **key findings** from the legal assessment (Chapter 4) include:

1. General EU labelling requirements under Directive 2000/13/EC

- Under the *Baseline scenario*, the legal assessment concludes that under current EU legislation, pollen, as an ingredient of honey, needs to be declared as an ingredient of honey in the list of ingredients under Directive 2000/13/EC.
- If the Commission proposal is adopted under the *Commission proposal scenario*, pollen, as a natural constituent of honey, must not be regarded as an ingredient of honey and does not have to be indicated in the list of ingredients.

2. Authorisation and supervision requirements under Articles 3, 4, 5 and 9 of Regulation (EC) No 1829/2003

- Under the *Baseline scenario*, honey with GM pollen is subject to the respective authorisation (before it can be marketed in the EU) and supervision requirements.
- The *Commission proposal scenario* does not alter the fact that honey with GM pollen is subject to the respective authorisation and supervision requirements.
- The *Commission proposal* does not change anything to the fact that honey containing GM material must receive prior authorisation before it can be marketed in the EU.

3. Labelling requirements under Regulation (EC) No 1829/2003

- Under the *Baseline scenario*, the labelling requirements of Article 12 of Regulation (EC) No 1829/2003 apply. Honey with authorised GM pollen must, therefore, be labelled as "*produced from genetically modified pollen*".
- Under the *Commission proposal scenario*, it must be concluded, in light of the above, that honey with GM pollen (authorised in the EU) is excluded from the labelling requirements of Regulation (EC) No 1829/2003.

4. Consideration of the status of MON810 GM Pollen

- The conclusions for the *Baseline scenario* and the *Commission proposal scenario* are only valid for GM pollen which is authorised in the EU. From the outset, honey cannot be marketed in the EU if it contains non-authorised GM pollen. In this respect, it is noted that no GM pollen is currently authorised in the EU.

Under the *Commission proposal scenario*, it must be concluded that honey with MON810 pollen is, in practice, excluded from the labelling requirements of Regulation (EC) No 1829/2003, provided that EFSA's favourable decision on MON810 pollen is endorsed by a regulatory decision on the renewal of the authorisation of MON810 maize (including maize pollen).

Comparing Policy Options

On the basis of this substitute impact assessment, we can conclude that a change in status of pollen in honey does not have major economic, social or environmental impacts. However, some impacts were observed that will affect the honey industry in general and specific dimensions of the value chain in particular. As the impact score matrix showed (see Chapter 6), adopting the Commission proposal will lead to the following **impacts**:

- **More honey could be imported into the EU from third countries.** Trade statistics show that the CJEU ruling may already have had a negative impact on some countries. However, substitution effects seem to be present, opening up possibility for other third countries to increase their market share in the EU.
- **Less disruption to the international trade regime.** Less disruption to the global trading regime is preferable over restrictive measures that can be interpreted as protectionism. Trade flows show that negative impacts of non-adoption of the EC proposal will be felt by non-EU countries exporting honey to the EU.
- **Less stringent labelling requirements** to mention pollen on the honey's label may facilitate the cultivation (pollination) of GM crops insofar that beekeepers will face less restrictions in locating their hives nearby GM fields.
- **No significant cost change for EU stakeholders.** Current labelling, supervision and authorisation requirements will remain regardless of

whether the CJEU ruling or Commission proposal is upheld. In absence of legislation or mandatory requirements, the market will resolve any concerns that consumers may have about the nature of pollen in honey through voluntary labelling requirements.

The above key findings from the legal analysis as well as the economic, social and environmental impacts, need to be taken into consideration in order to make a reasoned judgment of a change in status of pollen in honey.

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Annex A – Interviews

We conducted five interviews by phone and two organisations responded to our questions in writing. Table 0.1 provides an overview of the organisations that we contacted and their response to our invitation.

Table 0.1 Response to interview invitations

Organisation	Response to interview invitation
European Professional Beekeepers Association	Positive - interview conducted by phone.
British Beekeepers Association	Positive – interview conducted by phone.
FoodDrinkEurope	Positive – interview conducted by phone.
Friends of the Earth Europe	Positive – interview conducted by phone.
F.E.E.D.M.	Positive – interview conducted by phone.
COAG	Replied to interview questions in writing.
FRUCOM	Replied to (most of) the questions by sending us a joint FRUCOM-F.E.E.D.M. statement.
EuroCommerce	Due to holidays no one available on short notice – forwarded invitation to FRUCOM.
BEUC	Negative - given limited resources, BEUC has to prioritize its work and will therefore not be able to participate through an interview.
EFSA	Negative – did not consider themselves most appropriate interview candidates.
OCU - Spanish consumer organisation	Negative – there is no information on the topic available within the organisation.

Although we made an effort to talk to at least one representative for each stakeholder group identified in section 3 IV, we did not receive answers to the interview questions from retailers, consumers and regulatory organisations. Because of the limited timeframe we were not able to contact any other organisation within these stakeholder groups. We compensated for this omission by additional desk research.

All interviewees received an interview protocol with the main interview questions, information on the substitute impact assessment in general and on the interview in particular. The interview questions were based on the information gathered through desk research and the identified gaps in information.

Interview questionnaire

For all interviews the following set of main questions was used:

- What are the main elements of, and the main actors in, the honey value chain?
- Could you please briefly summarise your position regarding the EC's proposal on clarifying the status of pollen in honey as a natural constituent rather than an ingredient?
- What are the practical implications and main impacts of the Commission proposal from your perspective?
- If pollen are qualified as an ingredient of honey, how would this be put in practice and who will bear the costs?
- What are the implications for third countries (non EU) if pollen are qualified as an ingredient of honey? What is non-EU honey generally used for (% manufactured vs. table honey)?
- Who do you consider the other main stakeholders in this issue?
- Are there any other issues you would like to address with regard to the Commission proposal of the Honey Directive?

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