

Establishment approval in international trade of animal products



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Contents

	Summary	6
	Acknowledgement	7
1	Introduction	8
2	Framework for analysing establishment approval	9
	2.1 Definition and scope	9
	2.2 Framework for analysing requirements and conformity assessment of establishment approval	9
3	Trade data analysis for country and product selection	12
	3.1 Aggregation of product categories	12
	3.2 Indicators used in the selection of product and country combinations	12
	3.3 Results of country and product coverage	13
4	Comparative analysis of establishment approval	14
	4.1 General aspects of the requirement of establishment approval	14
	4.2 Country level requirements and verification	16
	4.3 Firm-level requirements and verification	18
	4.4 Management of listing	21
5	Summary and conclusions	22
	Literature and websites	24
	Appendices	
	A1 Product aggregation and classification used (HS codes)	25
	A2 Product-country combinations identified in the trade data analysis	28
	A3 List of relevant authorities and websites per country under review	33
	A4 Questionnaire guiding the interviews about establishment approval	37

Summary

For many products of animal origin, establishments must first qualify as eligible by the importing country before export can take place. Eligible firms are listed, and this process is called establishment approval. Establishment approval is often used by importing countries as a means to achieve a desired level of food safety and quality. Importing countries set up their establishment approval requirement in different ways, which makes establishment approval a complex matter and causes costs for firms that intend to export.

This report provides an overview of different approaches of establishment approval as well as its implementation and organisation in international agrifood trade. The focus is on animal products as establishment approval is particularly used for exporting these products. Based on trade data, we select eight countries, which are important markets for EU exporters in general and Dutch exporters in particular, for a comparative analysis on their approaches to establishment approval: China, Hong Kong, Japan, Mexico, Russia, Saudi Arabia, South Korea and the United States (US). In the analysis, we differentiate requirements and conformity assessments for establishment approval at the country level and at the firm level. For both levels, we collect and compare the respective information, which includes information about transparency and the organisation of establishment approval. The main source of information are the official websites of the respective importing countries, the EU as well as the Netherlands.

Our findings suggest that country level requirements could generally be considered to be the first bottleneck since firms located in a country that is not recognised as an eligible exporting country would not be approved by the importing country. Country-level requirements usually stipulate that the exporting country has an appropriate sanitary and phytosanitary (SPS) system, in addition to the requirements of being free of diseases (disease-free status).

The requirements for firms to be approved for exporting are related to import requirements and in some cases also refer to the requirements for domestic firms selling on the domestic market of the importing country. A key issue of conformity assessment is whether the authorities of the importing country conduct own inspections to check the compliance of the firms in the exporting country. Amongst the countries under review, China, Japan, Russia and the US inspect firms in the exporting country; South Korea also inspects establishments for their first approval. Although the US officially claims that they do not apply establishment approval, foreign firms are regularly inspected during an equivalence check of the SPS system of exporting countries. Furthermore, the actual inspection criteria and procedures of verification are not always defined. This particularly seems to be the case for Russia and China, which gives the impression that the establishment approval in these countries is not as transparent as desired and gives options for differential treatment of certain firms and/or countries. For all countries under review, only little information about the procedure of governing the de-listing as well as the possibility of returning to the list (re-listing) is publically available.

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1 Introduction

In the context of agrifood trade, requirements that aim to ensure a desired level of food safety and quality but also to protect animal and plant health, play an increasingly important role. In addition to standard import requirements for products that are checked at the border, importing countries may require that foreign food producing and processing firms meet certain requirements to sell on their respective domestic market. The process involved in the approval of complying firms for exporting is commonly called establishment approval. Usually, the firms approved are noted on a list of firms eligible for exporting.

Establishment approval as a means to achieve food safety and quality can generally be considered to be controversial for several reasons. First, establishment approval determines market access since only those firms approved are allowed to supply the market of the respective importing country. Second, establishment approval as a prerequisite for exporting can affect competitive positions and market power in international trade, depending on the impact on firms and on whether they can meet the requirements for being approved. Tight requirements can lead to high additional costs for individual companies, effectively preventing some companies from exporting. Importing countries set up their requirements for establishment approval in different ways. The different approaches and corresponding requirements are not always transparent and easy to understand. This makes establishment approval a complex matter for firms and governments. For firms, dealing with complex establishment approval adds costs for exporting, as already mentioned. For governments, diverse and non-transparent requirements for example complicate negotiations of bilateral and multilateral trade agreements with such countries. Insights into establishment approval contribute to a better understanding of the different requirements and systems, which could help to find solutions to overcome possible barriers and improve trade between countries.

In the report, we provide an overview of the mechanism of establishment approval as well as its implementation and organisation in international agrifood trade. A detailed one-to-one comparison of establishment approval systems of different countries is beyond the scope of the study.

We apply a comparative approach by looking at the establishment approval approach in different countries. In the comparison, we focus on specific aspects of establishment approval as a requirement for exporting relevant products of animal origin to main importing countries, thereby taking the Dutch perspective. We focus on products of animal origin because establishment approval seems to be more relevant for firms dealing with animal products, in comparison with firms trading plant products. This may be the case since animal products are considered to be particularly prone to sanitary and hygiene issues. The respective product-country combinations are identified in a trade data analysis.

The report is structured as follows: We first present a framework for analysing establishment approval (chapter 2). This is followed by the trade data analysis used to identify relevant product-country combinations for the subsequent analysis (chapter 3). Chapter 4 contains the comparative analysis of establishment approval. The members of the project team collected the information for the respective countries under review as follows: Marie-Luise Rau (South Korea and the US), Lan Ge (China, Hong Kong and Mexico) and Natalia Valeeva (Japan, Russia and Saudi Arabia). The report ends with a summary and conclusions.

2 Framework for analysing establishment approval

2.1 Definition and scope

Importing countries use establishment approval to identify foreign firms that comply with requirements and that are thus considered eligible to sell products on the market of the importing country. In this case, establishment approval becomes a pre-requisite for exporting to the respective importing countries. We focus on establishment approval as a requirement in international agrifood trade and do not consider other requirements or mechanisms that help to ensure trade of products complying with import requirements, for example health or export certificates. We also do not look at the details of actual requirements at the firm level, which could be elaborated further in specific case studies.

Approved establishments are usually registered on a list of eligible exporters, and only these firms are actually allowed to export to the respective market. One way of handling establishment approval is pre-listing, in which importing countries accept the listing of eligible establishments determined by the competent authority of the exporting country and based on the guarantees of the competent authorities of the exporting countries. As such, importing countries do not carry out lengthy and costly inspections of each establishment (before they are listed), but instead periodically carry out a performance-based audit of the competent authority of the exporting country.¹

We take the EU requirement of establishment approval as the starting point for our analysis; for details see for example European Commission (2011). In order to obtain first-hand information about the practical application of establishment approval, we conducted interviews with Dutch exporters and sector experts. The questions guiding the interviews are provided in Appendix 4.

The framework developed looks at the following questions:

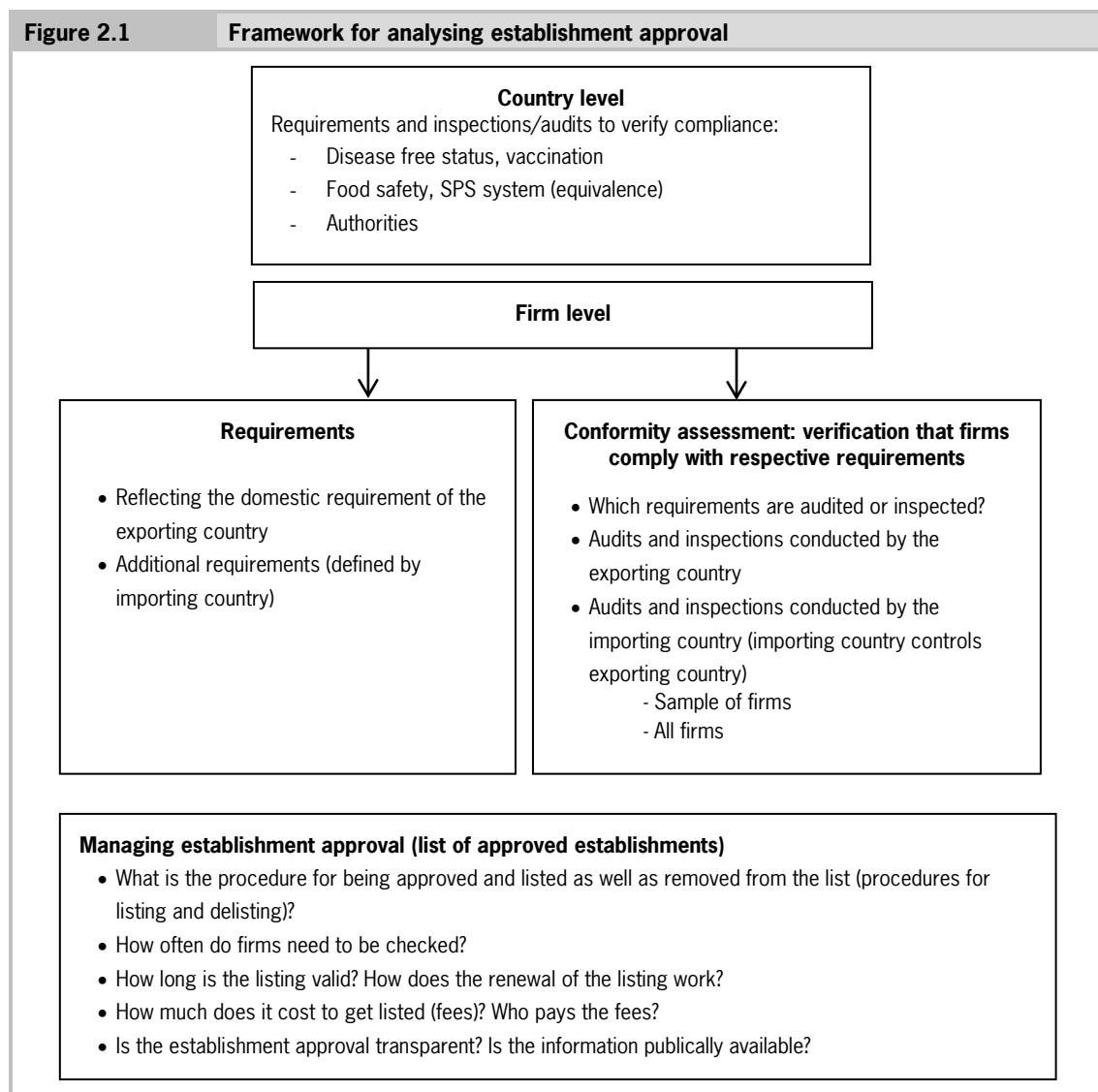
- How to get on the list of approved establishments?
- How to stay on the list: check of consignments, check of establishments?
- How to get back on the list in case of removal?

2.2 Framework for analysing requirements and conformity assessment of establishment approval

Before applying the framework, it should first be clarified if the respective importing country requires establishment approval, and if so, which firms have to be approved for selling which products on the market of the importing country. The question about the product is important since firms only need to be approved for exporting specific products. Such requirements may vary between countries. While the approval of firms in animal production is often asked for, plant firms may not need to be approved. Furthermore, establishment approval may not target firms in primary production; for example farmers may not need to be approved. Processing firms or those firms that directly engage in selling products on the market of the importing country usually have to be approved and put on a list of eligible firms.

¹ The EU uses the pre-listing approach and considers it as a key tool to facilitate market access and trade.

Figure 2.1 presents a framework for analysing establishment approval in the trade context. As shown, we first differentiate between the actual requirements and conformity assessment on the one hand and the management of the lists of approved establishments on the other hand. When looking at requirements and conformity assessment, we differentiate between the country level and the firm level.



The country level can be considered to be the first bottleneck in the system of establishment approval. For example, if a country is not free of an epidemic disease, firms located in that country would not be approved by an importing country, even if they comply with the requirements of the importing country. In addition to the disease-free status, equivalence of the food safety and quality system prevailing in the exporting country is usually necessary at the country level. Countries, often reciprocally, negotiate equivalence of their SPS systems. As a consequence, the importing country may accept the inspections and audits undertaken in the exporting country as providing the necessary evidence of compliance.

Often, countries reciprocally negotiate equivalence and the respective systems are then mutually approved as resulting in a similar and thus acceptable level of food safety and quality.¹ The approval at the country

¹ Note that in case of the EU, the individual member states usually negotiate and agree with the respective importing country about the export conditions for their products. Thus, equivalence in the context of establishment approval is also individually negotiated, while

level can be manifested in some kind of arrangement between the importing and exporting country, which eventually makes two countries trading partners. At the firm level, there are on the one hand requirements for firms to be put on the list, and on the other hand, there is conformity assessment that verifies the compliance with the requirements. The requirements are demanded by the respective importing country and could be different from the requirements the firms face when supplying the domestic market. There are different types of requirements, and without giving details of specific requirements, we consider them in broad terms in the analysis. With regard to conformity assessment, the main question is which requirements are checked for compliance and who is involved in the audits and inspections. More specifically, auditing and inspections can be conducted by the official authorities in the exporting country, and in this case, the importing country trusts the exporting country's inspection or auditing results.

The authority of the exporting country may give some kind of guarantee that the products of the firm comply, noting down the compliant firm on the list of eligible firms. The authority of the exporting country in essence compiles the list of firms eligible to export to the respective exporting country. Alternatively, the importing country checks compliance of exporters itself by checking either all firms applying to export to the respective importing country or a sample of the firms that the exporting country already put on the list.

With regard to organisational matters, an important aspect is the transparency of the establishment approval system. The question is whether the procedures are transparent and whether the listing procedure but also the removal from the list is explained: How does the procedure of establishment approval work? Are roles and responsibilities defined? Against which criteria are establishments verified? Are the procedures formulated such that the text can be referred to in case of doubt, for example?

Moreover, the information should be made available to firms and others. This could mean publishing the results of inspections and/or giving explanations of deficiencies but also includes making the lists of approved firms publically available. Another question relates to the fees for establishment approval and, for example, who has to pay them.

3 Trade data analysis for country and product selection

We conducted a trade data analysis in order to determine which product and country combinations are relevant and interesting to look at from the Dutch exporters' perspective. The data have been extracted from the Comtrade database of international trade and refers to the years 2007-2009. The year 2009 is the most recent data available. The average value of trade flows between countries is calculated in USD to identify main exporters and importers in terms of trade value. The products are given in the harmonised system of trade data classification (HS codes). For the detailed product classification and the resulting product categories, see Appendix A1.

3.1 Aggregation of product categories

In the trade data analysis, we look at live animals (including bovine semen¹), meat including offal and meat preparations, dairy products and eggs. Hatching eggs are however not specifically classified in the trade data and can thus not be identified. Furthermore, it is not always possible to determine the purpose of live animals in the product classification of the trade data. The sub-categories of the HS codes sometimes give clues: for example breeding bovine livestock and pigs. Although trade in breeding animals is increasingly important, the product classification does not allow for this distinction of live animals. We therefore only use the species of animals in the trade data analysis.

With regard to meat, we differentiate between bovine, pork and poultry meat products. Edible offal is listed within these main meat categories. The category of other meat products contains fats, other offal preparations and meat waste. Meat preparations are found in a separate category of processed products, whereby the distinction between bovine, pork and poultry is not explicitly made.

3.2 Indicators used in the selection of product and country combinations

In the trade data analysis, we used import and export indicators to identify the product and country combinations.

The import indicators are a negative trade balance, main non-EU importers (in terms of trade value), growth of imports, and since we take the Dutch export perspective, we will also look at the indicator of the Dutch share in main import markets. The latter is particularly interesting since the market share of Dutch products in the main importing countries gives information about whether Dutch exporters actually have market access and can realise their trade potential in comparison with other competitors.

The export indicators are main exporters to non EU-markets, relevance for Dutch exports and competitors, both EU and non-EU competitors. Note that we do not consider intra-EU trade since we aim at identifying countries and product combinations in order to analyse establishment approval as an import requirement, and the import requirements on the EU common market can be considered to be harmonised in the international comparison. Intra-EU trade is thus not relevant for the country and product selection.

¹ The trade data only contains information for bovine semen; other semen is not specified.

3.3 Results of country and product coverage

In the trade data analysis, the most relevant trading countries are identified with regard to the respective products of animal origin. The most important product-country combinations refer to the trade value in USD. The tables in Appendix A2 give an overview of the results of the trade data analysis. The detailed lists of product-country combinations according to indicators are available upon request. Using the results of the trade data analysis, Table 3.1 presents the product-country combinations that we analysed in the comparative analysis of the requirements for establishment approval.

Note that table 3.1 lists product-country combinations based on all trade indicators used. This means that for some product-country combinations, Dutch firms export the respective products to the respective countries, but for others, the countries and products are generally important in world trade. In the latter case, Dutch exporters may not supply the country listed. The country is listed because it is the main importing country worldwide and thus a potential and interesting trade partner for the Netherlands.

Table 3.1		Product-country combinations reflecting the importance of trade according to trade data indicators (import and export indicators)
	Product	Country
Live animals	Poultry/chicken (specifically day-old chicks for breeding)	China, Hong Kong, Japan, Saudi Arabia, Russia
	Pigs (specifically breeding pigs)	China, Russia, US
	Semen (bovine)	China, Japan
Meat	Poultry	China, Hong Kong, Japan, Russia
	Pork	China, Hong Kong, Japan, South Korea, Russia
	Beef	China, Japan, Mexico, Russia, US
Dairy	Cheese	China, Japan, Mexico, Russia, US
	Milk	China, Hong Kong, Mexico, Saudi Arabia

Source: Results of the trade data analysis using Comtrade data, trade values in US\$.

4 Comparative analysis of establishment approval

Applying the framework developed, we collected information regarding establishment approval for the following eight importing countries and/or administrative region: People's Republic of China (China), Hong Kong Special Administrative Region (Hong Kong), Japan, Mexico, the Russian Federation (Russia), Saudi Arabia, South Korea, and the United States (US). For each importing country, special attention was paid to include information concerning the products that are considered of high importance for Dutch exporters of animal products. The relevant country-product combinations are identified in the trade-data analysis (see table 3.1 in section 3.3).

We mainly collected information from official websites of the importing countries, the EU as well as the Netherlands. Where possible or necessary, we contacted the relevant authorities. The websites and authorities per country are listed in Appendix A3. The lists of detailed information per country are available upon request.

In this chapter we present a comparative analysis of the main elements of establishment approval in the aforementioned countries according to the framework developed in section 2.2. A detailed one-to-one comparison is beyond the scope of the study. The analysis refers to establishment approval systems as of the time of research (October - December 2011). If future changes were known, they were also considered. In the analysis, we specifically compare and discuss the following main aspects:

- General aspects of the requirement of establishment approval
- Country level requirements and verification
- Firm-level requirements and verification
- Management of establishment approval

It should be noted that the comparative analysis in this section does not give any information about the impact of establishment approval, and the strictness of the requirements is also not considered. That is because we have collected information provided in legal texts and official documents, which are published by the respective countries under review. This kind of information may give clues about the effect of the respective establishment approval system, but a separate in-depth analysis would be necessary for an appropriate impact assessment.

4.1 General aspects of the requirement of establishment approval

Establishment approval is commonly used as a means to ensure a desired level of food safety and quality of import commodities in the context of agro-food trade. For products of animal origin, the general approaches to establishment approval are greatly conditioned by the importing countries' policies on trade, food safety and animal health. As a result, we observe significant differences between the establishment approval systems in the different countries under review as well as between their implementation.

Not all countries require establishment approval. However, those countries that do use establishment approval systems are important trade partners for the Netherlands. In most cases, establishment approval is required for exporting products that are considered to pose high risks to human and animal health in the importing country, for example meat and live animals. As such, countries tend to take a risk-based approach that emphasises the strong role of science and risk assessment.

In China for example, meat products (including all meats of animal origin and edible by-products and offal) are the first category of food products for which establishment approval is required. All foreign establishments that produce meat products must be registered and approved by the Chinese authority. It should be noted that for China, the list of products that require establishment approval is currently being

extended to fish and dairy product and possibly to more food products in the future. The new regulation with regard to establishment approval is expected in the course of 2012. Besides meat products, Russia also requires establishment approval for fish and fishery products, milk and dairy products, feed and feed additives.

The legal basis for establishment approval can take the form of specific regulations or acts or is embedded in domestic regulations with respect to food safety and public health. For example, the current legal basis for establishment approval by China is laid out in the Regulation on Registration for Foreign Establishments Intended to Export Foods to China (Order No.16, 2002, issued by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, AQSIQ). For South Korea, establishment approval is based on the Animal Disease Control Act of the South Korean Ministry for Food, Agriculture, Forestry and Fisheries (MIFAFF) as well as bilateral agreements between exporting countries and South Korea on veterinary requirements for import of specific animal products. According to the Korean provision, not all animal products are subject to establishment approval: Meat products generally need establishment approval while all dairy products can be traded without establishment approval.

Establishment approval is not explicitly required by Hong Kong. The Food and Environmental Hygiene Department (FEHD) of Hong Kong is responsible for implementing policy instruments for food safety and enforcing relevant food legislation. The legal framework of food safety control is laid down in Part V of the Public Health and Municipal Services Ordinance (Laws of Hong Kong, Chapter 132) and its subsidiary legislation. The basic requirement, as stipulated in section 54 of the Ordinance, is that food intended for sale should not be unfit for human consumption. Under the Regulations on imported game, meat and poultry (Chapter 132, Subsidiary Legislation AK), there are specific legal requirements on imports of fresh or chilled or frozen game, meat or poultry to Hong Kong; for details, see the respective websites listed in Appendix A3.

In the US, all products of animal origin are subject to the requirements of the Animal and Plant Health Inspection Service (APHIS). The Food Safety Inspection Service (FSIS) is the public health agency. More specifically for meat, it is the meat inspection service that regulates meat, poultry, and egg products for consumption, including animal food production. The FSIS works on a government-to-government basis with the exporting country, which must undergo an equivalence evaluation whether their inspection system provides an equivalent level of protection to that provided by FSIS in US establishments. Once FSIS approves that the respective exporting country has an equivalent inspection system, the exporting country determines the individual establishments that meet the standards of their equivalent system. In the context of establishment approval, the US does not conduct inspections and audits of foreign firms. However, there are lists of firms eligible to export to the US, and we accordingly consider the US in our analysis of the requirements for establishment approval. Note that the EU and the US signed a veterinary equivalence agreement, which provides information relevant for establishment approval for trade of animal products. For EU meat exports to the US, the current approval system is based on the EU-US Veterinary Equivalence Agreement.

Establishment approval involves either authorities of the importing countries (IAs) or the authorities of the exporting country (EAs) or both (see Figure 1 in section 2.1). In general, the authorities in all importing countries require guarantees from the authorities in an exporting country that the export commodity meets the appropriate level of SPS protection set by the importing country. Importing countries often verify these guarantees by carrying out on the spot audits and/or inspections of establishments in exporting countries.

Table 4.1 provides an overview of the key aspects of the listing procedure in the countries under review. As shown, the establishment approval systems set by the respective importing countries differ considerably from the EU pre-listing system. For example, countries such as China, South Korea and Russia allow the authorities of exporting countries to designate the eligible establishments, they conduct own inspections of the exporting establishments. Such inspections can cover all establishments proposed by authorities of exporting countries (for example China and South Korea) or a selected sample of establishments to verify their eligibility (for example Japan).

Table 4.1 Overview of establishment approval systems in different countries				
Importing country or region	List of products for which the authorities of importing countries require establishment approval	Acceptance of listing by authorities of exporting countries	Inspection of exporting establishments	
			By authorities of exporting countries	By authorities of importing countries
China	Yes (meat, dairy*)	No	Yes	Yes
Hong Kong	No	Yes	No	No
Saudi Arabia	No	Yes	No	No
South Korea	Yes	Yes	Yes	Yes (for the first approval and with exceptions for 'good businesses')
Japan	Yes	Yes	Yes	Yes
Mexico	Yes (beef)	Yes	Yes	No (in some cases inspections for first approval)
Russia	Yes	No	Yes	Yes
US**	Yes	Yes	Yes	Not formulated as a requirement for establishment approval

Note: * Dairy for feed only. New rules on establishment approval for dairy for human consumption and fish are expected in the course of 2012.
 ** The US claims that they are not using establishment approval, as explained above, but there is a listing of foreign firms eligible to export to the US.

The approach applied for establishment approval crucially depends on trade agreements between trade partner countries. Trade agreements can thus influence establishment approval. Establishment approval by Russia, for example, is currently much influenced by the establishment of the custom union (CU) between Russia, Kazakhstan and Belarus, henceforth referred to as CU. A current concern is that, in practice, the listing of new establishments is no longer accepted on the basis of written guarantees of the exporting country with the entry into force of the CU (van Berkum and Dovortsin, 2011).

4.2 Country level requirements and verification

Meeting country level requirements is the first step for establishment approval since firms located in the respective country can obviously not achieve approval without the acceptance of country level requirements. For example, China only considers applications of establishment approval from countries that meet the prerequisites at the country level. In the US, country level requirements seem to play a major role with the US FSIS working on a government-to-government basis. As already mentioned, the US requires an equivalence evaluation of the SPS control and inspection system of the exporting country before exporters can supply the US market. Currently, the SPS system of the Netherlands (and the EU) is recognised by all countries under review in this study. Table 4.2 presents an overview of key features of the country level aspects for establishment approval.

Importing country or region	Is compliance with country level requirements sufficient for establishment approval?	Regular auditing and inspection of the SPS system of the exporting country
China	No	Yes
Hong Kong	Yes	No
South Korea	No	No
Japan	No	No
Mexico	Yes	Yes
Russia	No	Yes
Saudi Arabia	Yes	No
US*	Yes	Yes

Note: * The US claims that they are not using establishment approval, as explained above, but there is a listing of foreign firms eligible to export to the US. We thus consider the US in our analysis.

In addition to the requirements for the SPS control and inspection system of the exporting country, the OIE disease-free status is a crucial aspect with regard to country level requirements. Countries generally accept the guidelines about the disease-free status, including the imposition and lifting of bans due to disease outbreak or other incidences, as suggested by the World Organisation for Animal Health (OIE). This is, however, not always the case. The countries under review, for example, still do not allow imports of beef and bovine products of animals of younger than 30 months from EU member states due to BSE, although the disease status of the EU member states can be considered to be recovered (compare SPS Export Database, part of the EU Market Access Database). These BSE import bans do not conform to the OIE guidelines. Import bans and other protective measures could hamper trade despite trade agreements and/or tariff liberalisation.

Hong Kong, Mexico, and Saudi Arabia stand out insofar as export certificates play a prominent role for foreign firms selling meat products in these countries. Export certificates seem to be more important than establishment approval systems. Once a country is recognised as an eligible exporting country (for example, the Netherlands), export certificates are sufficient for firms to be approved as being eligible for exporting. The export certificates are issued by the authorities of the exporting country. In this case, export certificates seem to replace establishment approval, but a listing of firms is nevertheless used.

The verification of country level requirements can take different forms. The US FSIS, for example, verifies on-going equivalence through re-inspection of imported products upon entry to the US and through periodic audits of the foreign inspection system. US audits include on-site audits in the foreign country on a periodic basis. Another form of verification is established by agreements on import-export protocols, including animal health and export certificates. For products that are exported for the first time, the negotiation can potentially take a long process.

In general, it can be argued that bilateral trade agreements can simplify the process of establishment approval since approval by the exporting authority (in the form of listing or certificates) may be sufficient and relieves the burden on exporters. It should be noted that although simplifying the process of establishment approval, the trade agreement does not influence the list of products for which establishment approval is required. The importing country of course continues to perform border controls to check compliance with requirements. For trade taking place without specific trade agreements, Russia explicitly defines the criteria for accepting compliance guarantees from the competent authorities of the exporting countries. One criterion at the country level refers to the level of development of the competent authority of the trade partner country.

4.3 Firm-level requirements and verification

Establishment approval at the firm level comes after the exporting country is recognised as eligible. The application process for establishment approval is usually initiated by the competent authorities in the exporting country, because export firms cannot apply for approval directly to the importing country. There is also the possibility that the importer firm starts the procedure by applying to the competent authority of the importing country, thereby arranging the trading possibility with the firm in the exporting country that eventually needs to be approved. In this case, the competent authority in the exporting country may not be involved in the establishment approval system because the exporting firms could register via the importer - a potential customer - on the exporting country's list of eligible exporters.

In this section, we look at the firm-level requirements, followed by the verification of compliance in terms of conformity assessment in audits and inspections. It should be noted that establishment approval is only a prerequisite for accepting import commodities. Shipments from eligible establishments are still subject to strict border checks, which can lead to the denial and destruction of the shipment and the removal of the list. For exporting meat products to Mexico, foreign establishments, for example, must obtain prior approval by the Mexican Ministry of Agriculture (Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food, SAGARPA) and make sure that their export products meet the respective import requirements. Note that Mexico has increasingly applied country approval such that countries are approved for exporting to Mexico and after the successful country approval the respective authorities in the exporting country issues export certificates. In Mexico, this system seems to replace the approval of individual firms. In general, information prior to shipment is also required by other countries, for example the US, but for the US there is no prior approval requirement for the export of meat products. Prior notice only applies to products that fall under the jurisdiction of the US Food and Drug Authority (FDA).

Details about the firm-level requirements for establishment approval demanded by China, Japan, Russia and South Korea can be found on the official governmental websites in firms' application forms for approval (see Appendix A3). Sometimes a brief translation in English is available. Details are usually given in the official language of the importing country, but there is the option to contact the respective authorities for specific information according to commodity and in case of questions. Requirements at the firm level may also be made available from the authority in the exporting country. For example, the Dutch Food and Consumer Product Safety Authority (nVWA) publishes export requirements for importing countries. At the EU level, the Market Access Database (MADB) gives a first overview about requirements, referring to the regulations and legal texts of the importing country. The EU Directorate General Health and Consumers and Directorate General Trade provide information, in particular information about agreements between the EU and the third country. Note that there is a special webpage about EU-Russia SPS issues, which includes information on establishment approval, see http://ec.europa.eu/food/international/trade/eu-russia_spsissues_en.htm.

Looking at the countries under review, main features of firm-level requirements for establishment approval are summarised in Table 4.3. Note that the summary contains some kind of evaluation based on the interviews, which we conducted about the practical implementation of the establishment approval systems, and also reflects our experiences with the data collection. In the following paragraphs, we further elaborate on the firm-level requirements and verification.

Importing country or region	Requirements additional to EU standards	Definition of evaluation criteria and process	Is detailed information about inspections publically available?	Limited validity of the establishment approval
China	No	No	No	Yes
Hong Kong	No	n/a	n/a	n/a
South Korea	No	No	Yes	No
Japan	Yes	Yes	unknown	No
Mexico	Yes	No	n/a	Yes
Russia	Yes	No	No	No
Saudi Arabia	Unknown	No	n/a	n/a
US*	No	Yes	Yes (incl. info about results of inspections)	No

Note: The information provided contains some kind of evaluation based on interviews about the practical implementation and implications of establishment approval. Transparency is evaluated according to the information publically available and our experiences with the data collection. N/a means that 'not applicable' because establishment approval is not really required on the firm level for foreign establishments. 'Unknown' means no information was found with regard to establishment approval on the firm level for foreign establishments.

* The US claims that they are not using establishment approval, as explained above, but there is a listing of foreign firms eligible to export to the US. We thus consider the US in our analysis.

Requirements for approval

Identifying the requirements relevant for establishment approval is not as straightforward as expected. The requirements for firms eligible to export are related to import requirements and in some cases also refer to the requirements for domestic firms selling on the domestic market of the importing country. It is often not possible to disentangle the requirements relevant in trade so as to obtain specific information about the firm-level requirements necessary to be put on the list of eligible firms. When specifically asking about establishment approval, it is likely that the potentially large number of different requirements is mentioned. This includes other instruments relevant in trade, such as health or other export certificates for example.

Where available, we looked at the application forms and/or inspection reports to obtain information about the firm-level requirements relevant for establishment approval. For example, Russia provides checklists for foreign firms, and the information contains details on specific products and includes the general import requirements. China provides a specific application form for establishment approval. For the application for establishment approval for exporting meat products, China (like other countries) requires that the authorities in the exporting country fill in a questionnaire by the Chinese authority, Certification and Accreditation Administration of the People's Republic of China (CNCA). Additionally, firms have to fill in an application form with information on the respective facility, inputs, labour conditions, products, processes, while supporting the information by documents such as certificates and business records.

South Korea requires application forms of the government of exporting countries with attachment of checklists for exporting establishments made by authorities of exporting countries. The checklists contain general and sanitary information of the establishments. The model checklists are usually discussed by South Korea and its trade partners in advance.

For the US, we obtained information about the main firm-level requirements by looking at the reports about the US inspections of foreign firms (foreign audit reports), which are part of the equivalence evaluation of the SPS control and quality system of the exporting country. In comparison with other countries, the US seems to emphasise process requirements such the HACCP system. Note that the US can be considered to be rather transparent since the information about requirements but also about inspection results is made publically available. The official documents about inspection results can be accessed on-line.

Verification of compliance with requirements

To verify compliance with requirements, all importing countries require detailed information about the establishment with supporting documents. However, the decision-making (whether firms are approved or not) is not always clear. For example, the Chinese Certification and Accreditation Administration (CNCA) organises an expert group to evaluate the eligibility of the establishments based on the provided information and decides whether on-site inspection is necessary. Although the questionnaire and application form are publicly available, it is unclear how the evaluation is carried out and no evaluation report is found.

Firms that wish to export products of animal origin to Russia and its custom union with Kazakhstan and Belarus (CU) for the first time are inspected for compliance by the CU members. Once approved in these specific inspections, firms are registered and listed as eligible. For Russia, the dates for the inspections and audit will be determined after analysing the information and laboratory data, which are initially submitted by the authority of the respective exporting country. Furthermore, the establishments that are delisted are usually provided with results of the laboratory data. Russia regularly inspects firms in order to verify the correct listing.

For pork and poultry, Japan accepts the listing of approved establishments by the authorities of the exporting country, as agreed in bi-lateral agreements between Japan and the trade partner country. Pre-heated poultry products constitutes an exception since the Japanese animal health authority conducts its own on-site inspections of proposed facilities at the expense of the exporting country to confirm whether requirements are met. Currently, the Japanese Food Safety Commission carries out a risk assessment of products, and given the results, there will be a decision about the inspections necessary or whether Japan or the exporting country verifies the compliance of establishments.

South Korea also conducts own inspections in the exporting country. South Korea first evaluates the checklists made by the authorities of exporting countries which were provided together with the completed application forms. If the checklists satisfy the requirements, the Animal, Plant and Fisheries Quarantine and Inspection Agency (OIA) conducts on-site inspection of firms in the exporting country. Based on the result of on-site inspection, the QIA decides upon the approval of the establishments. Note that with regard to processed food, firms may be exempted from inspection if the product is manufactured by an excellent import business or when it is demonstrated that the sanitation level is maintained in accordance with international standards of which the level is equal to, or higher than the standards set by the Korea Food and Drug Administration (KFDA).

Frequency of inspection

For South Korea, inspections are mostly conducted for the first approval of establishments. If there are food safety incidences, the South Korean authorities decide if urgent on-site inspections in exporting countries are necessary. Processed food for special uses such as infant formulas, growth formulas, cereals, and all other food products designated for the infant and child market are reviewed once per year. Other food products are reviewed more than once every two years.

In the case of China, although the application form is publicly available, it is unclear how applications and more specifically the compliance with the requirements are evaluated.

Other countries do not provide information on how often firms should be inspected in the context of establishment approval. The next section provides some information about the validity of the lists of approved firms, which is directly related to the frequency of inspections.

4.4 Management of listing

For all countries, lists of approved establishments are publicly available. The lists of Dutch establishments approved by trade partner countries can be found at the website of the Dutch Food and Consumer Product Safety Authority (nVWA). The listing can of course change over time as new establishments are added to the list or/and some firms approved may be delisted. The lists thus need to be regularly updated by the relevant authorities.

As indicated in the official documents of all importing countries under review, establishment approval can be interrupted by high-risk events such as disease outbreaks in the exporting country. In the case of major non-compliance of the establishment with the import requirements discovered during border inspection of the shipments or during on-site inspections, the respective firm is delisted and thus not any more eligible to export to the importing country in question. For controlling imports, it should be noted that the importance of border check prevails in addition to establishment approval.

The Russian authorities provide some information about the management of the lists of approved firms in the custom union between Russia, Kazakhstan and Belarus. However, it seems that the criteria give rise to different interpretations. It is not always clear what would constitute a valid reason for refusing firms to become listed, and no information about the time periods for such decisions is given. To be re-listed, after being removed from the list, firms have to show written guarantees that corrective actions have been put in place, and the respective guarantees need to be positively assessed by the Russian authorities. There is no indication of the period. In general, the lack of information and clear definitions of criteria and/or procedures gives the impression that the system of establishment approval in Russia and the CU with Kazakhstan and Belarus is rather arbitrary.

The duration of the validity of the listing of approved firms varies across countries. For example, the establishment approval for meat establishment to export to China is valid for four years. One year before the expiration of the approval, establishments need to apply for prolongation of the approval, which will be evaluated by the authorities. The Chinese authorities decide whether an inspection is needed for the extension. For other countries, no duration of validity is indicated. It seems that those countries that apply a more flexible establishment approval system leave the decision on the validity of the lists of eligible firms to the exporting country, as long as the results of the importing country's border controls do not show non-compliance. It should be noted that the importing country may inspect the country level requirements on a regular basis, and such inspections can also involve checks of firms. For example, the US conducts country level audits, including inspections of firms, every year or every other year.

While Russia, South Korea and the US provide details about system audits, inspection and planning of on-site visits, China and Japan provide limited information. Saudi Arabia does not conduct own tests, and thus no information is necessary. In general, it can be said that only little information about the procedure of governing the de-listing as well as the possibility of returning to the list (re-listing) was found.

5 Summary and conclusions

Importing countries use establishment approval to identify foreign firms that comply with requirements and that are thus considered eligible to sell products on the market of the importing country. As such, establishment approval becomes a pre-requisite for exporting. In our framework for analysing different approaches of establishment approval, we differentiate between the country level and the firm level. For each level, we look at main aspects of requirements on the one hand and conformity assessment in terms of inspection and audits on the other hand. Our analysis focuses on products of animal origin since establishment approval seems to be particularly relevant for trade in animal products. The information about requirements for establishment approval refers to the time period October-December 2011. New developments may change the establishment approval situation. This would require an update of the analysis, leading to different results.

In the system of establishment approval, country level requirements can generally be considered the first bottleneck. Firms located in a country that does not qualify as an eligible exporting country would not be approved by the importing country, whether or not individual firms comply with the requirements of the importing country. In addition to the disease-free status, equivalence of the food safety and quality system prevailing in the exporting country is usually necessary at the country level. Countries, often reciprocally, negotiate equivalence of their SPS systems, and as a consequence the importing country may accept the inspections and audits undertaken in the exporting country as providing the necessary evidence of compliance.

At the firm level, the requirements for firms being approved for exporting are related to import requirements and in some cases also refer to the requirements for domestic firms selling on the domestic market of the importing country. Identifying the concrete requirements relevant for establishment approval is not straightforward, and this poses a limitation to the comparative analysis conducted. It is likely that the potentially large number of requirements and other instruments relevant in trade, such as health or other export certificates for example, are somewhat covered when searching for information and/or specifically asking about establishment approval.

Inspections and audits to assess and prove compliance with requirements are one main aspect of establishment approval. In fact, major differences appear depending on whether the importing country acknowledges the exporting country's food safety and quality system or not. In the latter case, the authorities of the importing country conduct its own inspection to check the compliance of the firms in the exporting country. Amongst the countries under review, China and Russia respectively inspect firms in the trade partner country, and only after their inspections, the complying firms are approved and listed as firms eligible to export. Inspections of a selective sample of firms or inspections of those firms applying to export for the first time (first approval) may be sufficient for the importing country, and in this case, the exporting countries compile the list of eligible firms. South Korea also conducts its own inspections in the exporting countries, but inspections are generally only necessary if a firm exports for the first time to the Korean market. This is similar for Japan's establishment approval.

The US seems to be a special case as it claims not to apply establishment approval. However, there are listings of firms eligible to export to the US and we therefore consider the US in our analysis. In the context of establishment approval, the US does not conduct inspections and audits of foreign firms, but foreign firms are regularly inspected during equivalence checks of the SPS system of the exporting country. The US authorities approve that the exporting country has a SPS system, which provides an equivalent level of protection to that provided by the US authorities in domestic establishments, and the exporting country can then determine the individual establishments that meet the standards of the equivalent system. As such, the US establishment approval can be considered relatively flexible.

Although general information can be found on importing requirements and establishment approval, the actual inspection criteria and procedures of verification are not always defined. This particularly seems to be the case for Russia and China, which gives the impression that the establishment approval in these countries is not as transparent as desired and gives options for differential treatment of certain firms and/or countries. For all countries under review, only little information about the procedure of governing the de-listing as well as the possibility of returning to the list (re-listing) was available. However, the contact details of the respective authorities for specific information according to commodity were found and in some cases could be used as information source. The availability of information was particularly limited for Saudi Arabia.

Concerning transparency, the US seems to lead by example. In comparison to the other countries, the US makes available all information about their equivalence evaluation and corresponding requirements, including rationale and explanation. Inspection results are also publically available on-line.

In this study, we do not specifically look at the importance of establishment approval in terms of impact or costs for exporters. An in-depth detailed analysis, possibly focusing on specific case studies, would be necessary for a proper impact assessment. We also do not look into the question whether establishment approval is efficient to achieve the level of food safety and quality desired and to solve the sanitary and phytosanitary (SPS) issues between trade partners. A cost-benefit analysis of establishment approval and alternative measures is beyond the scope of the study.

Our analysis provides an overview of different systems of establishment approval by evaluating information provided in official documents of the importing countries under review. In addition to differences and similarities of systems of establishment approval, as described above, our comparative analysis shows that establishment approval does not replace other trade policy instruments, which control trade or create trust between trade partner countries, such as export certificates. Furthermore, border checks remain important, also with regard to removing firms from the list of complying firms (delisting). This means that shipments from eligible establishments are always subject to strict border controls, and non-compliance at the border will lead to the denial and/or destruction of the shipment and can result in the respective firms being removed from the list.

Literature and websites

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Appendix A1

Product aggregation and classification used (HS codes)

Chapter 1: Live animal: bovine, pigs and poultry

0102 - H0H1H2H3 - Live bovine animals
010210 - H0H1H2H3 - Live bovine animals: pure-bred breeding animals
010290 - H0H1H2H3 - Live bovine animals other than pure-bred breeding animals
0103 - H0H1H2H3 - Live swine
010310 - H0H1H2H3 - Live swine: pure-bred breeding animals
010391 - H0H1H2H3 - Live swine other than pure-bred breeding animals, weighing < 50kg
010392 - H0H1H2H3 - Live swine other than pure-bred breeding animals, weighing 50kg/more
0105 - H0H1H2H3 - Live poultry, that is to say, fowls of the species Gallus domesticus, ducks, geese, turkeys and guinea fowls
010511 - H0H1H2H3 - Live fowls of species Gallus domesticus, weighing not >185g
010512 - H1H2H3 - Live turkeys, weighing not >185g
010519 - H0H1H2H3 - Live ducks/geese/guinea fowls, weighing not >185g
010591 - H0 - Fowls, live domestic > 185 grams
010592 - H1H2 - Fowls, domestic, live we
010593 - H1H2 - Fowls, domestic, live we
010594 - H3 - Live fowls of species Gallus domesticus, weighing > 185g
010599 - H0H1H2H3 - Live ducks/geese/turkeys/guinea fowls, weighing >185g

Chapter 5

051110 - H0H1H2H3 - Bovine semen

Chapter 2 - meat & Chapter 16 -meat preparations

Bovine meat
0201 - H0H1H2H3 - Meat of bovine animals, fresh or chilled
020110 - H0H1H2H3 - Carcasses/half-carcasses of bovine animals, fresh/chilled
020120 - H0H1H2H3 - Meat of bovine animals, fresh/chilled (excl. of 0201.10), bone-in
020130 - H0H1H2H3 - Meat of bovine animals, fresh/chilled, boneless
0202 - H0H1H2H3 - Meat of bovine animals, frozen
020210 - H0H1H2H3 - Carcasses/half-carcasses of bovine animals, frozen
020220 - H0H1H2H3 - Meat of bovine animals, frozen (excl. of 0202.10), bone-in
020230 - H0H1H2H3 - Meat of bovine animals, frozen, boneless
020610 - H0H1H2H3 - Edible offal of bovine animals, fresh/chilled
020621 - H0H1H2H3 - Tongues of bovine animals, frozen
020622 - H0H1H2H3 - Livers of bovine animals, frozen
020629 - H0H1H2H3 - Edible offal of bovine animals (excl. tongues & livers), frozen
021020 - H0H1H2H3 - Meat of bovine animals, salted/in brine/dried/smoked
1602 - Meat preparations
160250 - H0H1H2H3 - Prepared/preserved preparations of bovine animals

Pork
0203 - H0H1H2H3 - Meat of swine, fresh, chilled or frozen
020311 - H0H1H2H3 - Carcasses/half-carcasses of swine, fresh/chilled
020312 - H0H1H2H3 - Hams, shoulders & cuts thereof, fresh/chilled, bone-in
020319 - H0H1H2H3 - Meat of swine (excl. carcasses..) fresh/chilled
020321 - H0H1H2H3 - Carcasses/half-carcasses of swine, frozen
020322 - H0H1H2H3 - Hams, shoulders & cuts thereof, frozen, bone-in
020329 - H0H1H2H3 - Meat of swine (excl. carcasses...), frozen
020630 - H0H1H2H3 - Edible offal of swine, fresh/chilled
020641 - H0H1H2H3 - Livers of swine, frozen
020649 - H0H1H2H3 - Edible offal of swine (excl. liver), frozen
021011 - H0H1H2H3 - Hams, shoulders & cuts thereof, of swine, salted/in brine/dried/smoked, bone-in
021012 - H0H1H2H3 - Bellies (streaky) & cuts thereof, of swine, salted/in brine/dried/smoked
021019 - H0H1H2H3 - Meat of swine (excl. hams/shoulders & bellies), salted/in brine/dried/smoked
1602 - Meat preparations
160241 - H0H1H2H3 - Hams & cuts thereof
160242 - H0H1H2H3 - Shoulders of swine & cuts thereof
160249 - H0H1H2H3 - Prepared/preserved preparations of swine (excl. of 1602.41, 1602.42 & homogenised preparations), incl. mixtures
Poultry meat
0207 - H0H1H2H3 - Meat and edible offal, of the poultry of heading 01.05, fresh, chilled or frozen
020710 - H0 - Poultry, domestic, whole, fresh or chilled
020711 - H1H2H3 - Meat of fowls of species Gallus domesticus, not cut in pieces, fresh/chilled
020712 - H1H2H3 - Meat of fowls of species Gallus domesticus, not cut in pieces, frozen
020713 - H1H2H3 - Cuts & edible offal of species Gallus domesticus, fresh/chilled
020714 - H1H2H3 - Cuts & edible offal of species Gallus domesticus, frozen
020721 - H0 - Fowls, domestic, whole, frozen
020722 - H0 - Turkeys, domestic, whole, frozen
020723 - H0 - Ducks, geese and guinea fowls, domestic, whole, frozen
020724 - H1H2H3 - Meat of turkeys, not cut in pieces, fresh/chilled
020725 - H1H2H3 - Meat of turkeys, not cut in pieces, frozen
020726 - H1H2H3 - Cuts & edible offal of turkey, fresh/chilled
020727 - H1H2H3 - Cuts & edible offal of turkey, frozen
020731 - H0 - Fatty livers (geese,ducks) domestic fresh or chilled
020732 - H1H2H3 - Meat of ducks/geese/guinea fowls, not cut in pieces, fresh/chilled
020733 - H1H2H3 - Meat of ducks/geese/guinea fowls, not cut in pieces, frozen

Chapter 4: Dairy: cheese, butter and milk

0402 - H0H1H2H3 - Milk and cream, concentrated or containing added sugar or other sweetening
040210 - H0H1H2H3 - Milk in powder/granules/other solid form, fat content by weight not >1.5%
040221 - H0H1H2H3 - Milk in powder/granules/other solid form, unsweetened, fat content >1.5%
040229 - H0H1H2H3 - Milk in powder/granules/other solid form, sweetened, fat content >1.5%
040291 - H0H1H2H3 - Milk & cream, concentrated (excl. in powder), unsweetened
040299 - H0H1H2H3 - Milk & cream, concentrated (excl. in powder), sweetened
0405 - H0H1H2H3 - Butter and other fats and oils derived from milk; dairy spreads
040500 - H0 - Butter and other fats and oils derived from milk
040510 - H1H2H3 - Butter
040520 - H1H2H3 - Dairy spreads
040590 - H1H2H3 - Fats & oils derived from milk, other than butter & dairy spreads
0406 - H0H1H2H3 - Cheese and curd
040610 - H0H1H2H3 - Fresh (unripened/uncured) cheese, incl. whey cheese, & curd
040620 - H0H1H2H3 - Grated/powdered cheese, of all kinds
040630 - H0H1H2H3 - Processed cheese, not grated/powdered
040640 - H0H1H2H3 - Blue-veined cheese
040690 - H0H1H2H3 - Cheese (excl. of 0406.10-0406.40)

Appendix A2

Product-country combinations identified in the trade data analysis

Note that we use trade value in USD in the trade data analysis, and the order of the countries is according to their importance in terms of trade value.

Table A2.1		Chapter 1: Live animal: bovine animals, pigs and poultry, main importer		
Product	Main importing country (non-EU27)	Increasing imports	NL share in main import markets	Changes in NL share between 2007-2009
Bovine animals	US Indonesia Venezuela Russia Lebanon Croatia Mexico	China Indonesia	US (no share) Indonesia (no share) Venezuela(no share) Russia (24.7%) Lebanon (0.6%) Croatia (2.6%) Mexico (no share)	Russia (decreasing)
Pigs	US China, Hong Kong Russia Singapore Croatia China, Macao SAR	China Hong Kong Russia US (decreasing)	US (no share) China, Hong Kong (no share) Russia (only small) Singapore (no share) Croatia China, Macao(no share) Ukraine (no share) Mexico (no share) China (no share) Belarus (no share)	n/a
Poultry	Singapore Russia Ukraine US Canada China, Mexico Morocco	Saudi Arabia Turkey Palestine China Ukraine Russia	Russia Turkey Belarus China	Ukraine (decreasing) China (decreasing) Thailand (decreasing) Turkey (increasing)

Source: Result of the trade data analysis.

Table A2.2		Chapter 1: Live animal: bovine animals, pigs and poultry, main exporter (The data used refers to exports to the non-EU market only)		
Product	Main export destination for NL exports : non-EU27	Main exporting country	Main exporting country: EU27 competitors	Main exporting country: non-EU competitors
Bovine animals	Russia (most important, decreasing) Jordan Algeria	France Canada	Germany Romania (decreasing) Hungary (increasing) Netherlands (decreasing)	Canada Australia Mexico(decreasing) Brazil (increasing)
Pigs	Croatia (most important) Russia (increasing) Moldavia	Netherlands Denmark Canada China	Lithuania Poland Germany Netherlands	Canada China (increasing)
Poultry	Sudan (decreasing) Belarus (decreasing) Philippines Kazakhstan Malaysia	Netherlands Germany France US Malaysia UK	France Netherlands UK (decreasing) Germany	US Malaysia
<p>Note: For Dutch exports to non-EU third countries, poultry animals are most important, followed by bovine animals. Swine animal exports only make up for 25% of the Dutch exports of animal products Source: Result of the trade data analysis.</p>				

Table A2.3		Chapter - Bovine semen- HS-code: 051110. main importer		
Product	Main importing country (non EU27)	Increasing imports	NL share in main import markets	Changes in NL share
Bovine Semen: (051110)	Venezuela Mexico Brazil Japan US*	China Brazil Canada	Venezuela (no market share) Brazil (16.5%, decreasing) Japan (8%)	Brazil (- 2%) Turkey (-1.5%), China (+3 %)
<p>Note: *The US has a positive trade balance and is thus a net exporter while being a main importer. Source: Result of the trade data analysis.</p>				

Table A2.4 Chapter - Bovine semen- HS-code: 051110, main exporter (The data used refers to exports to the non-EU market only)				
Product	Main export destination for NL exports (non EU market)	Main exporting country (worldwide)	Main exporting country: EU27 competitors	Main exporting country: non-EU competitors
Bovine Semen: (051110)	China (increasing) Brazil Japan	US Canada Colombia Netherlands UK Germany	Netherlands France Germany UK	US Colombia (decreasing) Canada

Source: Result of the trade data analysis.

Table A2.5 Chapter 2 (Meat) and Chapter 16 (Meat preparations), main importer				
Product	Main importing country (non EU27)	Increasing imports	NL share in main import markets	Changes in NL share, 2007-2009
Bovine meat	US* Japan Russia Mexico	Russia China	US (0.001%) Japan (no share) Russia (0.1%) Mexico (no share)	No noticeable changes
Pork	Japan Russia China, Hong Kong US	China Hong Kong China	Japan (0.9%) Russia (2.4%) China, Hong Kong (7.8%) US (1%) Mexico (no share)	No noticeable changes
Poultry	Japan Russia China, Hong Kong China	China Hong Kong China	Japan (no share) Russia (0.6%) China, Hong Kong (1%) China (0.003%)	No noticeable changes
Other meat	Russia Japan Switzerland Mexico	Russia Japan China, Hong Kong Ukraine	Russia (5.4%) Japan(no market share) Switzerland (1.5%) Mexico (no market share)	No noticeable changes

Note: *The US has a positive trade balance and is thus a net exporter while being a main importer.
Source: Result of the trade data analysis.

Table A2.6		Chapter 2 (Meat) and Chapter 16 (Meat preparations), main exporter (The data used refers to exports to the non-EU market only)		
Product	Main export destination for NL exports (non EU market)	Main exporting country	Main exporting country: EU27 competitors	Main exporting country: non-EU competitors
Bovine meat (34% of NL exports)	Croatia Switzerland	Brazil Australia Netherlands US (increasing most)	Germany Italy Netherlands	Australia (decreasing) Brazil US (increasing) New Zealand Canada Argentina
Pork (33% of NL exports)	China (increasing) Hong-Kong Russia (decreasing) Japan South Korea	Germany Denmark US Netherlands Spain Canada Belgium	Denmark Germany (increasing) Netherlands Spain	US (increasing) Canada
Poultry (28% of NL exports)	Russia Benin (increasing) Ghana China Hong-Kong (increasing)	Brazil US Netherlands	France Netherlands Germany	Brazil (increasing) US (increasing)
Other meat (5% of NL exports)	Russia (decreasing)	Germany Brazil (increasing)	Germany France Italy Denmark Spain	US China Brazil (increasing)

Note: Pork exports to China are most important in terms of value in comparison with exports of the other Dutch meat exports to the various export destinations outside the EU.
Source: Result of the trade data analysis.

Table A2.7		Chapter 4: Dairy: cheese, butter and milk, main importer		
Product	Main importing country (non EU27)	Increasing imports	NL share in main import markets	Noticeable changes in NL share between 2007-2009
Milk	Algeria Mexico Saudi Arabia Indonesia	China (increasing most) China, Hong-Kong Algeria	Algeria (2.9%) Mexico (no share) Saudi Arabia (24.4%) Indonesia (3.2%) Emirates (29.6%) China, Hong-Kong (33.8%)	Emirates (-3.5%) Vietnam (-7.4%)
Butter	Russia Mexico Egypt Morocco Singapore US Saudi Arabia	Egypt (increasing most) Mexico China (increasing)	Russia (1.9%) Mexico (0.3%) Egypt (7.8%) Morocco (11%) Singapore (18.9%) Japan (20.5%)	Morocco (-3.7%) Japan (-12.2%) Saudi Arabia (-6.7%)
Cheese	US Russia Japan	Russia Switzerland	US (5.9%) Russia (6.6%) Japan (3.8%) Mexico (7.6%) Venezuela (11.9%)	Venezuela (-4.5%)

Source: Result of the trade data analysis.

Table A2.8		Chapter 4: Dairy: cheese, butter and milk, main exporter (The data used refers to exports to the non-EU market only)		
Product	Main export destination for NL exports (non EU market)	Main exporting country	Main exporting country: EU27 competitors	Main exporting country: non-EU competitors
Milk (72% of NL dairy exports)	Saudi Arabia (decreasing) Nigeria Arab Emirates	New Zealand Netherlands Germany US	Netherlands Belgium Denmark France Germany	New Zealand US Australia
Butter (19% of NL dairy exports)*	Iran (decreasing) Japan (decreasing) Singapore Syria	New Zealand Netherlands Belgium Ireland Germany France	Netherlands France Finland Belgium	New Zealand Belarus Australia US
Cheese (9% of NL dairy exports)*	Russia US Japan Mexico Algeria	Germany France Netherlands Italy Denmark New Zealand	France Italy Germany Netherlands Denmark	New Zealand Australia US Belarus Ukraine

Source: Result of the trade data analysis.

Appendix A3

List of relevant authorities and websites per country under review

China

Authorities related to import control of food and agricultural products:

- Ministry of Agriculture of the PRC (MOA): www.moa.gov.cn
- Certification and Accreditation Administration of the People's Republic of China (CNCA): www.cnca.gov.cn
- General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ)
- Entry-Exit Inspection and Quarantine Authorities of China (CIQ), consisting of different entry ports, e.g., Jiangsu Entry-Exit Inspection and Quarantine: www.jsciq.gov.cn/default.shtml (Chinese only)
- China Ministry of Commerce (MOFCOM): www.mofcom.gov.cn.

Useful websites

Agricultural laws and regulations: http://english.agri.gov.cn/ga/plar/index_1.htm

CNCA Regulation: www.cnca.gov.cn/rjwzcjgb/bmgz/images/20061016/470.pdf

Application form: www.cnca.gov.cn/cnca/extra/xzzq/00032.pdf

Enquiry registered establishments: www.cnca.gov.cn/rjwzcjgb/qwfbcx/jkspqy/default.shtml

Customs lawyer: www.customslawyer.cn/swzs/ckspjy/jckspzcdj/200610/13198.html

China Inspection and Quarantine Service: www.ciqcid.com/

Animal and its products: <http://en.ciqcid.com/Commodity/animal/>

Regulations on Inspection of Exit-Entry Dairy Products:

[http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Regulation%20on%20Inspection%20of%20Exit-Entry%20Dairy%20Products%20\(Draft\)_Beijing_China%20-%20Peoples%20Republic%20of_3-24-2011.pdf](http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Regulation%20on%20Inspection%20of%20Exit-Entry%20Dairy%20Products%20(Draft)_Beijing_China%20-%20Peoples%20Republic%20of_3-24-2011.pdf)

Hong Kong

Authorities related to import control of food and agricultural products:

- Agriculture, Fisheries and Conservation Department (AFCD), responsible for the import of live animals and animal products (www.afcd.gov.hk/eindex.html)
- Food and Environmental Hygiene Department (FEHD), responsible for the import of foods of animal origin (www.fehd.gov.hk/english/index.html tel: 2868 0000)
- Centre for Food Safety, The Government of the Hong Kong Special Administrative Region (www.cfs.gov.hk/eindex.html)

Internet sources

Guide to import of Game, Meat and Poultry into Hong Kong:

www.cfs.gov.hk/english/import/import_icfsg_04.html

Import and Export of Animals and Animal products into Hong Kong:

www.afcd.gov.hk/english/quarantine/qua_ie/qua_ie.html

Export requirements for Hong Kong for US producers:

www.fsis.usda.gov/regulations/hong_kong_requirements/index.asp

Export requirements for Hong Kong for Canadian producers:

www.inspection.gc.ca/english/fssa/meavia/man/ch11/coupay/hongkonge.shtml

Details of the Hong Kong Special Administrative Region food legislation:

www.cfs.gov.hk/english/food_leg/food_leg.html

www.legislation.gov.hk/blis_export.nsf/home.htm

Details of the Guide to Import of Game, Meat and Poultry into Hong Kong and Guide to Application for

Import License: www.cfs.gov.hk/english/import/import_icfsg_04.html

Japan

Authorities related to import control of food and agricultural products:

- Ministry of Agriculture, Forestry and Fisheries of Japan and Japanese animal health authorities (www.maff.go.jp/aqs/english/product/import.html)

Internet sources:

News letters of Veterinary Information Point, Dutch Product Boards for Livestock, Meat and Eggs:

www.pve.nl/wdocs/dbedrijfsnet/up1/ZwcdvknIQ_bijlage_08.PDF

Examples of inspection certificates attached to an animal product: Examples of Inspection of certificates attached to an animal product (PDF : 281KB)

Existing certificate procedures (NL-Japan)

Pig meat and meat products: www3.vwa.nl/werkwijzer/Roodvlees/RL-194%20Japan.pdf

Bovine semen: www3.vwa.nl/werkwijzer/Levend/RNDSU-32%20Japan.pdf

Runderembryo's: www3.vwa.nl/werkwijzer/Levend/RNDEU-11%20Japan.pdf

Live pigs: www3.vwa.nl/werkwijzer/Levend/VRKUV-04%20Japan.pdf

In case of the inspection by the Dutch authority, see check lists per category:

www.vwa.nl/onderwerpen/werkwijze-food/dossier/erkenningen-vergunningen-registraties/erkenningen

The list of approved firms is to be found in the system BERREG.

Coldstore (29 establishments): www3.vwa.nl/EULijst%20Exportregistratie-Japan-koel-%20en%20vrieshuis.pdf

Cutting plant red meat (34 establishments): www3.vwa.nl/EULijst%20Exportregistratie-Japan-uitsnijderij%20roodvlees.pdf

Meat products: www3.vwa.nl/EULijst%20Exportregistratie-Japan-vleesproducten.pdf

Saudi Arabia

Authorities related to import control of food and agricultural products:

- Importation of Meat: (www.the-saudi.net/business-center/regulation-import.htm)

Internet sources:

Existing requirements for export certificates:

Beef: www3.vwa.nl/werkwijzer/Roodvlees/RL-137%20Saoedi-Arabi%C3%AB.pdf

In case of the inspection by the Dutch authority, see check lists per category:

www.vwa.nl/onderwerpen/werkwijze-food/dossier/erkenningen-vergunningen-registraties/erkenningen

Coldstore beef (3 establishment): www3.vwa.nl/EULijst%20Exportregistratie-Saoedi%20Arabie-koel-%20en%20vrieshuis%20rundvlees.pdf

Cutting plant bovine (6 establishments): www3.vwa.nl/EULijst%20Exportregistratie-Saoedi%20Arabie-uitsnijderij%20rundvlees.pdf

Slaughterhouse bovine (5 establishments): www3.vwa.nl/EULijst%20Exportregistratie-Saoedi%20Arabie-slachthuis%20runderen.pdf

No establishments for poultry (note that a certificate of "Halal" meat is needed)

Russia

Authorities related to import control of food and agricultural products:

- The CU laws and regulations are available on the official website of the Customs Union (in Russian) (www.tsouz.ru)
- Official site Federal Service for Veterinary and Phytosanitary Surveillance, also in English (www.tsouz.ru/db/techregulation/vetmeri/Pages/Reestrorg.aspx, <http://fsvps.ru/fsvps/importExport>)

Internet sources:

History of approval, suspension, restriction: <http://fsvps.ru/fsvps/importExport/golland/statusHistory.html?id=13188& language=en>

Inspection checklist - meat products (as provided in July 2009):

- Checklist for meat-processing factories ahead of the Russian inspection (For the period of preparation and organisation of the inspection):

http://ec.europa.eu/food/international/trade/docs/ru_meat_plants_072009_en.pdf

- Instructions regarding the procedure for the implementation of veterinary expertise of project documentation for building and renovating animal-breeding farms and dairy processing, meat-processing and eggs establishments, destined for industrial purposes; and veterinary and sanitary requirements for building and renovation: http://ec.europa.eu/food/international/trade/docs/RF_list_vet_facilities_en.pdf

Inspection checklist Russian authorities - dairy products (documents provided in July 2009)

Questions to milk processing enterprise during preparatory organisational period:

http://ec.europa.eu/food/international/trade/docs/ru_questions_for_milk_processing_companies_tables_en.pdf

Questions to dairy farm: http://ec.europa.eu/food/international/trade/docs/ru_questions_to_the_dairy_farm_en.pdf

In case of the inspection by the Dutch authority:

(a) see check lists per category of meat-related product: <http://www.vwa.nl/onderwerpen/werkwijze-food/dossier/erkenningen-vergunningen-registraties/erkenningen>

(b) see check lists per category of milk products: www.cokz.nl/Diensten/Supervision_EU-hygiene_Regulations.aspx

Food Safety - Main Russian standards applicable to food are to be found at:

http://ec.europa.eu/food/international/trade/ru_allfoodprod_en.htm

Product groups as specified on the website:

(<http://fsvps.ru/fsvps/importExport/golland/enterprises.html?product=47&productType=3&language=en>)

History of establishment approval: (when it was approved, when temporary restrictions were imposed):

<http://fsvps.ru/fsvps/importExport/golland/statusHistory.html?id=13188&language=en>

Establishment approval by Russia for firms from Canada

www.inspection.gc.ca/english/fssa/meavia/man/ch11/coupay/russie.shtml

www.inspection.gc.ca/english/fssa/fispoi/commun/20090211e.shtml

South Korea

Authorities related to import control of food and agricultural products:

- Korea Food and Drug Administration (KFDA)(import control of processed food products, except for processed animal products)
- A Foreign Inspection Division was created in 2009 in order to conduct the inspections of foreign firms that wish to export food products to Korea (This division can be contacted at Tel: +82 2 3801565).
- Animal, Plant and Fisheries Quarantine and Inspection Agency (QIA) (import control of primary plant, fisheries and animal products, and processed animal products).

Internet sources:

Import requirements of processed food (except for processed animal products), in particular overview of system of onsite inspection of foreign establishments, registration of foreign firms and certificates

<http://eng.kfda.go.kr/index.php>

Import requirements of primary plant, fisheries and animal products, and processed animal products, in particular bilateral veterinary requirements between South Korea and exporting countries and list of approved establishments by country: www.qia.go.kr

Food and Agricultural Import Regulations and Standards -Country Report, provided by the US government, Global Agricultural Information Network (GAIN):

http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative_Seoul_Korea%20-%20Republic%20of_1-11-2011.pdf

EU market access database for import requirements for EU exports: importing country South Korea:
<http://madb.europa.eu/mkaccdb2/datasetPreviewFormIFpubli.htm>

US

Authorities related to import control of food and agricultural products:

- The United States Department of Agriculture (USDA)
- USDA Food Safety and Inspection Services (FSIS), meat inspection service
- Animal and Plant Health Inspection Service (APHIS), veterinary service
- US Food Safety Authority (FDA): responsible for food products in general, but not responsible for meat and egg products that falls under the responsibility of the FSIS

Internet sources:

List of foreign establishments eligible to export to the US:

[www.fsis.usda.gov/Regulations & Policies/Eligible Foreign Establishments/index.asp](http://www.fsis.usda.gov/Regulations%20&%20Policies/Eligible%20Foreign%20Establishments/index.asp)

US import requirements: [www.fsis.usda.gov/Regulations & Policies/Import Information/index.asp](http://www.fsis.usda.gov/Regulations%20&%20Policies/Import%20Information/index.asp)

Foreign Audit Reports: [www.fsis.usda.gov/Regulations & Policies/Foreign Audit Reports/index.asp](http://www.fsis.usda.gov/Regulations%20&%20Policies/Foreign%20Audit%20Reports/index.asp)

EU market access database for import requirements for EU exports: importing country: US:

<http://madb.europa.eu/mkaccdb2/datasetPreviewIFpubli.htm>

Mexico

Authorities related to import control of food and agricultural products:

- SENASICA: Servicio Nacional de Sanidad, Inocuidad, y Calidad Agroalimentaria (The National Service of Agro Alimentary Health, Safety and Quality) : www.senasica.gob.mx, responsibility with the Directorate General of Animal Health
 - Consultation database of Animal Health requirements: www.senasica.gob.mx/?id=2587
 - Animal and plant health inspection, including regulated products: www.senasica.gob.mx/?id=599
 - Agreement for import of regulated products: www.senasica.gob.mx/?id=621
- SAGARPA: Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (The Ministry of Agriculture, Livestock, Rural development, Fisheries and Food), grants establishment approval www.sagarpa.gob.mx, responsibility with the Directorate General of Animal Health
 - OSAAP: El Oficial de Seguridad Agropecuaria, Acuicola y Pesquera (OSAAP), inspects the import goods and documents
 - OISA: La Oficina de Inspección de Sanidad Agropecuaria

Internet sources:

Online information centre on zoo-sanitary requirements for importing animals and animal products (in Spanish): <http://sistemas2.senasica.gob.mx/mcrz/>

Export requirements for Mexico (CFIA for Canadian exporters)

www.inspection.gc.ca/english/fssa/meavia/man/ch11/coupay/mexie.shtml

Export requirements for Mexico (USDA for US exporters):

[www.fsis.usda.gov/regulations/Mexico Requirements/index.asp](http://www.fsis.usda.gov/regulations/Mexico%20Requirements/index.asp)

Database on non-tariff measures (SPS measures):

http://madb.europa.eu/madb_barriers/sps_barriers_details.htm?barrier_id=040051&version=7 and

http://madb.europa.eu/madb_barriers/sps_barriers_details.htm?barrier_id=040092&version=6

Import requirements on specific products: <http://sistemas2.senasica.gob.mx/mcrz/moduloConsulta.jsf>

Appendix A4

Questionnaire guiding the interviews about establishment approval

Country level issues

- With which countries does the Netherlands have export protocol/agreements?
- What are the country level approval requirements in general? Which topics are looked at when deciding on country approval (e.g. disease free, no vaccination, good or rather equivalent food safety control system)?
- Are the Netherlands generally accepted as eligible or not? Which topics are critical?
- Have necessary adjustments been made at the country (Dutch) level in order to meet the requirements of a specific third country?
- Who is responsible to make an approval decision for a particular establishment (within NL or the importing country)? Who makes the list - the Netherlands (who? PVE?) or the importing country?

Firm-level issues

- What are the requirements to get on the list of the approved establishments? Are they additional or different from the domestic or the EU requirements to sell on the EU market?
- How did you find relevant information for the establishment approval? Could you find all information that was needed?
- What is your experience with establishment approval of the countries from the above list your company exports to?
- Does it take long to get approved? How long?
- What is the order of magnitude of labour of company personnel and costs (preparing application and audits, during audits, after audits)? For example man power: 1 full time person working on the pre-listing, fees to get on the list, additional costs due to paper work...
- What were the necessary adjustments made to the firm in order to meet the requirements and what was the order of the related labour and costs?
- Was the firm inspected/audited? By which authority (NL, importing country/trade partner)? How often audits/inspections are made (NL vs. importing country authority)?
- Were there problems in the approval process/de-listing/re-listing?
 - Lack of information (which information? Language barrier? Vague information?)
 - Lengthy process with much iteration? (in weeks, months, years?)
 - Uncertainty about the approval criteria (language barrier, multiple interpretations, changing standards and requirements, inconsistent standards)?

General

- Do competitors in other countries (EU and non-EU) experience the same establishment approval constraints as your company? Or are their requirements tighter or less tight?
- What are the disadvantages and advantages of establishment approval in your opinion?
- What are the possibilities to solve the problems and improve the situation?
- Which role could or should the government play in solving the issues?

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