

Defra International Animal Health Division

Importation to the EU of Composite Food Products Containing
Products of Animal Origin (POAOs)
Summary of Animal Health Risk Analysis

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Does not consider public health risks.

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1. Introduction

1.1 Composite food products:

- Contain mixtures of one or more POAO and other edible material.
- The 100% POAO would be subject to the vet checks regime, including BIP checks certification, approved country, approved establishment as applicable.
- May or may not be cooked or otherwise processed.
- May be imported ready for retail sale or intended for further processing in the community.
- Are intended for human consumption.

1.2 Examples:

Raw cookie dough (egg)	Ravioli (meat)	Sports drinks (milk)
Cake (egg/milk)	Pizza (meat/cheese)	Egg mayonnaise
Bread (milk)	Cheese sandwich	Milk chocolate
Pot noodles (egg, meat)	Chicken curry	Battered fish (egg/milk)
Ice cream (non-milk fat)	Coconut milk	Canned meat stew

2. Objectives

This document suggests options for risk management which could:

- Achieve a negligible risk of serious animal pathogens being present in a composite food product at the point of importation into the EU.

- Identify categories of product which could reasonably be imported outside the veterinary checks regime, with no official certification and with no systematic inspection at a BIP.
- Apply a proportionate regulatory burden to importers and minimise expenditure of official resources controlling low risk imports.
- Be enforced by physical examination of the product and its accompanying commercial documentation. Checks to be carried out on the basis of risk in accordance with Official Food and Feed Controls under the new EU hygiene regulations from 1 January 2006.

3. General characteristics of composite food products intended for human consumption within the EU

- Should be produced hygienically resulting in minimal contamination, in particular faecal contamination.
- Should be produced from healthy animals.
- Should be traceable within the EU.
- If described as cooked and cooking is incomplete, the quality of the product is unlikely to be acceptable to the consumer. Economics would therefore drive businesses not to import unfit products.
- Preservation measures are taken to ensure that safety and quality are maintained, either at ambient temperatures, chilled or frozen.
 - In many (but not all) cases, stability at ambient temperatures implies an absence of significant numbers of micro-organisms likely to cause spoilage or disease.
 - Chilling or freezing is likely to preserve rather than destroy viral pathogens.
 - However, viruses require a living host so cannot multiply in food products (unlike bacterial contaminants).
- Food products should be packaged to prevent contamination after manufacture.
- Food products should be identifiable from examination of the packaging and accompanying commercial documentation as intended for human consumption.
- The ingredients and their relative proportions should be stated on the label in accordance with Codex Alimentarius standards.
- Manufactured foods are very likely to be cooked or eaten by people (or their pets). Either outcome results in negligible animal health risk.
- It is possible that a large quantity of out of date or spoiled food could be disposed of within the EU as waste. Even if this happens then full compliance with waste disposal rules should ensure negligible risk to animal health.

4. Options for risk management

4.1 In each case, the product should be:

- securely packaged in clean containers and;

- identified on packaging or accompanying documents as food intended for human consumption and;
- accompanied by a commercial document stating the nature of the product, country of despatch, its ingredients and any processing to which it has been subjected, as applicable.

4.2 Composite products containing egg:

- Permit any imports from countries eligible to export fresh poultry meat. Must be on the poultry meat list and not subject to safeguard measures.
- Permit imports from any country of foods which are stable at ambient temperatures or which appear to be fully cooked throughout their substance. These may also be refrigerated or frozen to preserve their quality.
- Foods required to come from approved establishments in respect of their principal ingredient (e.g. battered fish) may be imported without any conditions applied to the egg content provided that the part containing the egg (e.g. the flash fried batter coating) appears to be fully cooked.
- We could consider importing foods containing less than 1% egg without restriction.
- Any foods not meeting the above criteria could be imported as egg products (with added ingredients) under the vet checks regime with the necessary certification. They would then have to come from approved establishments in approved countries.

4.3 Composite products containing milk:

- Permit any imports from countries eligible to export single pasteurised milk. Must therefore be on the 'A' or 'B' list and not subject to safeguard measures.
- Permit imports from any country of foods which are stable at ambient temperatures or which appear to be fully cooked throughout their substance. These may also be refrigerated or frozen to preserve their quality.
- Foods required to come from approved establishments in respect of their principal ingredient (e.g. battered fish) may be imported without any conditions applied to the milk content provided that the part containing the milk (e.g. the flash fried batter coating) appears to be fully cooked.
- We could consider importing foods containing less than 1% milk without restriction.
- Any foods not meeting the above criteria may be imported as milk products (with added ingredients) under the vet checks regime with the necessary certification. They would then have to come from approved establishments in approved countries.

4.4 Preliminary assessment for composite products containing ruminant meat:

- Meat from ruminants raises concerns about Transmissible Spongiform Encephalopathies which are not reliably inactivated by temperatures used in food processing.
- Meat could appear to be cooked without necessarily reaching the 70C or more generally required to inactivate viruses although this is unlikely to be the case in commercial practice, particularly if canned.

4.5 Preliminary assessment for composite products containing pig meat:

- Pig meat products (dried ham, fermented salami) can be ambient stable and still contain many infectious doses of African Swine Fever (ASF), Classical Swine Fever (CSF) and Foot and Mouth Disease (FMD) virus. ASF can be resistant to temperatures below 80C.
- Pigs are the species of greatest concern because, if there is non-compliance with the by-products rules, they are most likely to be offered and to eat waste food. It is also possible that waste food could be scavenged by wild boar or feral domestic pigs.
- Meat could appear to be cooked without necessarily reaching the 70C or 80C required to inactivate viruses although this is unlikely to be the case in commercial practice, particularly if canned.

4.6 Preliminary assessment for composite products containing poultry meat:

- Poultry meat could appear to be cooked without necessarily reaching the 70C required to inactivate viruses although this is unlikely to be the case in commercial practice. ND and AI are relatively fragile viruses.

Annex 1. Summary of Risk Assessment for Eggs

A1.1 Hazard identification

Many diseases may affect domestic poultry but only Newcastle disease (ND) and avian influenza (AI) have been made notifiable in the EU. They are subject to specific controls when disease occurs in the EU and for imports from third countries. Therefore, only the risk of introduction of these two diseases has been considered.

A1.2 Risk estimation

A1.2.1 Composite food products containing egg from countries approved to export eggs in shell to the EU present negligible risk.

A1.2.1.1 There is an acceptable standard for disease freedom – approval for import of poultry meat or eggs into the EU. This standard is comparable to that applicable in EU countries. It does not mean that disease could never be present in the country because there is a constant threat, mainly from migrating birds. However, if disease is present then it should be detected quickly, reported and controlled to minimise the risk of infected eggs entering the food chain. EU rules permit imports of raw eggs for human consumption from these countries without certification and there is no logical reason to exclude composite food products containing egg.

A1.2.2. Composite food products containing egg present negligible risk when it is evident that they have been subjected to extensive heat treatment. This requirement could be met by the composite food product being stable at ambient temperature and being cooked to the point where its colour and texture have changed throughout its substance.

A1.2.2.1 Countries which are not listed for export of eggs to the EU may or may not be free from ND or HPAI. We have no assurances that disease will be detected, reported or controlled. This also applies to countries approved only for the export of egg products to the EU.

A1.2.2.2 We therefore require the risk to be managed in some other way. In the case of composite food products, the manufacturing plant is potentially the most reliable place to reduce, exclude or inactivate virus.

A1.2.2.3 Egg protein changes colour and texture at temperatures above 70C. It hardens and becomes opaque. Heat treatments sufficient to produce a physical change in the egg or food product are likely to inactivate any virus. Baked goods typically need to attain an internal temperature of 88C in order to appear fully cooked. This should be evident to an inspector at a port or at an establishment within the EU.

A1.2.2.4 In order to be stable at ambient temperatures, the product should have been processed in a way which inactivates micro-organisms liable to cause spoilage. It may be chilled or frozen to maintain quality but can be examined after thawing if necessary.

A1.2.2.5 Products such as bread or cake would fall into this category. There is no EU approval process for plants producing baked goods but we can be reasonably assured that contamination after processing would be minimised by packaging. Any gross surface contamination with raw product should be evident on inspection.

A1.2.3 Composite food products containing egg (or egg products containing other food ingredients) present negligible risk when there is some assurance that they have been produced hygienically and subjected to heat treatment.

A1.2.3.1 The hygienic production requirement could be met by:

- Product coming from an egg products plant approved by the competent authority to export to the EU or;
- Product coming from any food plant approved by the competent authority to export to the EU.

A1.2.3.2 The heat treatment requirement could be met by:

- Being certified as egg product and therefore having been pasteurised or;
- The composite food product being stable at ambient temperature or;
- The composite food product (or at least the part containing egg) being cooked to the point where its colour or texture has changed throughout its substance.

A1.2.3.3 Countries which are not listed for export of raw eggs to the EU may or may not be free from ND or HPAI. We have not been assured that disease will be detected, reported or controlled. This also applies to countries approved only for the export of egg products to the EU.

A1.2.3.4 We therefore need to mitigate the risk in some other way and in the case of food products, the manufacturing plant is potentially the most reliable place to exclude or inactivate virus. However, manufacturing processes can fail and in the case of heat treatments which are only marginally effective, official supervision may be insufficient to detect this. At least two risk mitigation measures should give reasonable certainty of achieving negligible risk of virus being present at the time of importation.

A1.2.3.5 Hygienic production to EU standards for public health provides some animal health assurance because it suggests that raw materials come from healthy birds and that manufacturing processes are designed and operated to minimise contamination during and after processing. These conditions must be met in a plant approved for export of egg product to the EU and they are

likely to be met in a plant approved for export of other foods of animal origin, for example fish coated with batter.

A1.2.3.6 Heat treatment should inactivate virus and can be assured through official certification of pasteurisation, a process which may leave the egg in a liquid state and physically unchanged. This is only meaningful if it comes from an approved egg products establishment in an approved country and if the consignment is checked at a BIP.

A1.2.3.7 Other heat treatments (equivalent to pasteurisation) likely to inactivate virus will produce a physical change in the egg or food product which should be evident to an inspector at a port or at an establishment within the EU.

A1.2.3.8 In certain cases, for example raw fish which has been coated with batter and then flash fried in an EU approved plant, only the part containing egg may be cooked and this is acceptable. The product may also be frozen to preserve its quality, in which case it could be examined after thawing to see to what extent it had been cooked.

A1.2.4 Composite food products containing egg and which are to be imported outside the veterinary checks regime should meet the following requirements:

- a) Securely packaged in clean containers;**
- b) Identified as intended for human consumption;**
- c) Accompanied by a commercial document stating the nature of the product, country of despatch, its ingredients and any processing to which it has been subjected.**

A1.2.4.1 Products containing egg which present negligible risk at the point of production need to remain in that state during storage and transport. Packaging in secure, clean containers (which may be plastic wrappers) should ensure this and would be normal for a food product.

A1.2.4.2 This risk assessment concerns food for human consumption and certain risk factors depend on the products being intended for that purpose. It should therefore be possible to ascertain that the product being imported is intended for human consumption. A label on the packaging could state this explicitly but any indication printed on the packaging or accompanying documentation that this was the case (and an absence of information that it was intended for another use) should suffice.

A1.2.4.3 In the absence of official certification, an official wishing to determine whether a composite food product met the criteria outlined in these conclusions should be able to make an initial decision on the basis of a documentary check. Commercial documents accompanying the consignment must therefore at least state the country of origin, should indicate that the product is intended for human consumption and should indicate any processing which may have been applied. In the latter case 'cooked' or 'dried' would suffice – specific times and temperatures are not essential.

A1.2.5 There is no realistic limited percentage inclusion rate of egg within a composite food product from a non-EU approved country which would itself result in negligible risk.

A1.2.5.1 ND and AI viruses can be found in eggs from infected birds at such a high concentration that a chicken infectious dose may be contained in less than 1g of egg. Mixing with other food ingredients such as flour or sugar could not be expected to inactivate virus. Dilution with other ingredients to a level of 10% for example would still potentially leave an infectious dose in less than 10g of product – an amount easily consumed by a scavenging wild bird or farmyard bird. Many composite food products contain more than 10% egg.

A1.2.5.2 However, even in an ND or AI infected country, it is not the case that every hen in the national flock is maximally viraemic at all times. Infected birds are more likely to die than to lay eggs. Any infected egg is likely to be diluted with egg from other birds and other flocks. In addition, egg used by food processors is likely to be pasteurised. It may therefore be possible to set a minimal percentage (e.g. 1%) below which it would be reasonable to import without specific animal health controls.

A1.2.6 Eggs, egg products and food products containing egg which
a. do not come from EU approved countries and
b. have not been hygienically produced and heat treated and
c. have not been extensively heat treated
present a non-negligible risk unless additional guarantees can be provided.

A1.2.6.1 If none of the above criteria can be met, there is uncertainty of the ND and AI situation in the exporting country, there is uncertainty about whether any heat treatment has been carried out reliably and there is uncertainty whether the product has been contaminated during or after manufacturing. In such cases products may present a risk which is higher than negligible.

A1.2.6.2 These uncertainties may be reduced by providing official assurances from the competent authority of the exporting country that the egg ingredient is EU compliant for example. Such assurances should be systematically checked at the point of import in the UK, preferably from approved countries and within the veterinary checks regime.

Annex 2. Summary of Risk Assessment for Milk

A2.1 Hazard identification

A2.1.1 Milk is likely to be produced by ruminants. There is limited local consumption of mare's milk. Sows are not milked for human consumption.

A2.1.1 Many diseases may affect domestic ruminants but only a limited number of these are notifiable in the EU. They are subject to specific controls when disease occurs in the EU and for imports from third countries. Of these, the most significant disease likely to be transmitted in milk is foot and mouth disease (FMD). This is recognised in Commission Decision 2004/438.

A2.1.2 Raw milk products intended for human consumption may only be imported from third countries included in Column A of Annex I. They are (April 2005) Andorra, Canada, Switzerland, Chile, Iceland, New Zealand and the USA.

A2.1.3 Heat-treated milk, heat-treated milk-based products or milk-based products made from heat-treated milk (single pasteurisation) intended for human consumption may be imported from third countries included in column B of Annex I. Column B identifies countries 'where there is no threat of FMD'. They are (April 2005) the list A countries, Australia, Bulgaria, Greenland, Croatia, the Former Yugoslav Republic of Macedonia and Romania.

A2.1.4 Should FMD occur in any of these countries then safeguard measures would be taken.

A2.1.5 Heat-treated milk, heat-treated milk based products or milk-based products made from heat-treated milk (treatment more than single pasteurisation, which may include sterilisation or acidification) intended for human consumption must come from third countries included in column C. Column C includes countries with a potential threat from FMD. They may not be free from infectious diseases of livestock transmissible in milk and in this respect are no different from an unlisted country. These include (April 2005) 40 countries from Albania to Zimbabwe.

A2.1.6 Bovine tuberculosis and bovine, ovine or caprine brucellosis are also of concern. These diseases are the subject of certification of herd freedom or pasteurisation.

A2.1.7 Import of pig's milk is unlikely to occur but pigs are the species most likely to be fed waste food (this would contravene by-products rules). They are unlikely to become infected with bovine TB, bovine, ovine or caprine brucellosis. Pigs could be infected with FMD.

A2.1.8 This animal health risk assessment therefore focuses on FMD, although the conclusions would be applicable to a range of bacterial and viral diseases.

A2.2 Risk estimation

A2.2.1 Composite food products containing milk from countries approved to export raw (list A) or pasteurised (list B) milk to the EU present negligible risk.

A2.2.1.1 There is an established standard for disease freedom – approval for import of raw or single pasteurised milk into the EU. This standard is comparable to that applicable in EU countries. It does not mean that disease could never be present in the country because there is a constant threat of introduction, for example through illegal imports and spread from infected countries in the region. However, import controls are comparable to those of the EU and if disease occurs then it should be detected quickly, reported and controlled to minimise the risk of infected milk entering the food chain.

A2.2.1.2 TB and brucella are not necessarily absent from every herd or flock in these countries but their status is equivalent to that of EU member states in that disease is well controlled and pasteurisation is routinely applied to protect public health.

A2.2.1.3 Composite food products from these countries are unlikely to be made from infected milk and will probably be made from pasteurised milk so it would be reasonable to import them on the same basis as food products traded within the EU with no certification and no systematic official controls.

A2.2.2. Composite food products containing milk present negligible risk when it is evident that they have been subjected to processing equivalent to OIE standards. This requirement could be met by the composite food product being stable at ambient temperature and being cooked to the point where its colour and texture have changed throughout its substance (as applicable to the nature of the product).

A2.2.2.1 Countries which are not on lists A or B for export of milk to the EU may or may not be free from FMD. We have no assurances that disease will be detected, reported or controlled. This also applies to countries on list C.

A2.2.2.2 In these cases, we need the risk to be managed in some other way. In the case of composite food products, the manufacturing plant is potentially the most reliable place to reduce, exclude or inactivate pathogens.

A2.2.2.3 It is likely that single pasteurisation would inactivate any FMD or other pathogens present to a level where an animal could not consume an infectious dose. However the OIE recognises further treatments which should be applied to milk from an FMD infected country:

1. a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or;

2. if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]), or;
3. if the milk has a pH of 7.0 or over, the HTST process applied twice.

A2.2.2.4 Food manufacturing processes are likely to be equivalent to these standards, in particular if they result in a product which is fully cooked and stable at ambient temperatures:

- Milk powder is roller dried (typically used in chocolate) using steam heated (100C) rollers or spray dried using hot air at 220C. Freeze dried milk powder could in theory be produced but a commercial source could not be found anywhere in the world other than as a component of 'astronaut diets'.
- Bread or cake is typically baked to an internal temperature of 88C for a sustained period in order to appear fully cooked.
- Cheese is often made with pasteurised milk. Even when made with raw milk, it requires a pH below 5 to produce an edible product. The minimum pH is typically achieved at the end of the draining process and reflects the fact that rennet is a stomach enzyme, adapted to working in an acid environment.
- Shelf stable drinks containing milk (e.g. 'sports drinks') must be UHT to remove spoilage organisms and remain fit for sale at ambient temperatures.

A2.2.2.5 The product should therefore be suitable for storage at ambient temperatures or obviously cooked throughout its substance. It may be chilled or frozen to maintain quality but can be examined after thawing.

A2.2.2.6 Products such as bread or cake would fall into this category. There is no EU approval process for plants producing baked goods but we can be reasonably assured that contamination after processing would be minimised by packaging. Any gross surface contamination with raw product should be evident on inspection.

A2.2.3 Composite food products containing milk (or milk products containing other food ingredients) present negligible risk when there is some assurance that they have been produced hygienically and subjected to heat treatment.

A2.2.3.1 The hygienic production requirement could be met by:

- Product coming from a milk products plant approved by the competent authority to export to the EU or;
- Product coming from any food plant approved by the competent authority to export to the EU.

A2.2.3.2 The heat treatment requirement could be met by:

- Certified as pasteurised milk product or;
- The composite food product being stable at ambient temperature or;

- The composite food product (or at least the part containing milk) being cooked to the point where its colour or texture has changed throughout its substance.

A2.2.3.3 Countries which are not on list A or B for export of milk to the EU may or may not be free from FMD. We have not been assured that disease will be detected, reported or controlled. This also applies to countries approved only for the export of double heat treated milk to the EU (list C).

A2.2.3.4 We therefore need to mitigate the risk in some other way and in the case of food products, the manufacturing plant is potentially the most reliable place to exclude or inactivate virus. However, manufacturing processes can fail and in the case of heat treatments which are only marginally effective, official supervision may be insufficient to detect this. At least two risk mitigation measures should give reasonable certainty of achieving negligible risk of virus being present at the time of importation.

A2.2.3.5 Hygienic production to EU standards for public health provides some animal health assurance because it suggests that raw materials come from healthy animals and that manufacturing processes are designed and operated to minimise contamination during and after processing. These conditions must be met in a plant approved for export of milk products to the EU and they are likely to be met in a plant approved for export of other foods of animal origin, for example fish coated with batter.

A2.2.3.6 Heat treatment should inactivate virus and can be assured through official certification, although the process may leave the milk in a liquid state and not ambient stable. This is only meaningful if it comes from an approved establishment in an approved country and if the consignment is checked at a BIP.

A2.2.3.7 Other treatments (equivalent to pasteurisation) likely to inactivate virus should produce a physical change in the milk or food product which should be evident to an inspector at a port or at an establishment within the EU.

A2.2.3.8 In certain cases, for example raw fish which has been coated with batter and then flash fried in an EU approved plant, only the part containing milk may be cooked and this is acceptable. The product may also be frozen to preserve its quality, in which case it could be examined after thawing.

A2.2.4 Composite food products containing milk and which are to be imported outside the veterinary checks regime should meet the following requirements:

- a) Securely packaged in clean containers;**
- b) Identified as intended for human consumption;**
- c) Accompanied by a commercial document stating the nature of the product, country of despatch, its ingredients and any processing to which it has been subjected.**

A2.2.4.1 Products containing milk which present negligible risk at the point of production need to remain in that state during storage and transport. Packaging in secure, clean containers (which may be plastic wrappers) should ensure this and would be normal for a food product.

A2.2.4.2 This risk assessment concerns food for human consumption and certain risk factors depend on the products being intended for that purpose. It should therefore be possible to ascertain that the product being imported is intended for human consumption. A label on the packaging could state this explicitly but any indication printed on the packaging or accompanying documentation that this was the case (and an absence of information that it was intended for another use) should suffice.

A2.2.4.3 In the absence of official certification, an official wishing to determine whether a composite food product met the criteria outlined in these conclusions should be able to make an initial decision on the basis of a documentary check. Commercial documents accompanying the consignment must therefore at least state the country of origin, should indicate that the product is intended for human consumption and should indicate any processing which may have been applied. In the latter case 'cooked' or 'dried' would suffice – specific times and temperatures are not essential.

A2.2.5 There is no realistic limited percentage inclusion rate of milk within a composite food product from a non-EU approved country which would itself result in negligible risk.

A2.2.5.1 FMD virus can be found in milk from infected animals at such a high concentration that a pig infectious dose may be contained in less than 1ml of milk from an individual infected cow. Mixing with other food ingredients such as flour or sugar could not be expected to inactivate virus. Dilution with other ingredients to a level of 10% for example would still potentially leave an infectious dose in less than 10g of product – an amount easily consumed by a pig. Many composite food products contain more than 10% milk.

A2.2.5.2 However, even in an FMD infected country, it is not the case that every cow in the national herd is maximally viraemic at all times. Any infected milk is likely to be diluted with milk from other cows and other herds. In addition, milk used by food processors is likely to be pasteurised. It may therefore be possible to set a minimal percentage (e.g. 1%) below which it would be reasonable to import without specific animal health controls.

A2.2.6 Milk, milk products and food products containing milk which
a. do not come from A or B list countries and
b. have not been hygienically produced and heat treated and
c. have not been extensively heat treated
present a non-negligible risk unless additional guarantees can be provided.

A2.2.6.1 If none of the above criteria can be met, there is uncertainty of the FMD situation in the exporting country, there is uncertainty about whether any

heat treatment has been carried out reliably and there is uncertainty whether the product has been contaminated during or after manufacturing. In such cases products may present a risk which is higher than negligible.

A2.2.6.2 These uncertainties may be reduced by providing official assurances from the competent authority of an approved exporting country that the milk ingredient is EU compliant. Such assurances should be systematically checked at the point of import, preferably within the veterinary checks regime.