

To
Australia Notification Authority
Market Access and Biosecurity.
Agriculture, Fisheries and Forestry Australia.
GPO Box 858.
Canberra ACT 2601.
Telephone: +(612)6272 4146.
Telefax: +(612)6272 3678.
E-mail/Internet: sps.contact@affa.gov.au.

Dear Madam or Sir,

The European Community thanks Australia for having notified the "Generic Import Risk Analysis (IRA) for Pig Meat, August 2003" in notice G/SPS/AUS/150 and appreciates very the opportunity to provide comments on the mentioned text.

The annexed comments, have been drafted in collaboration between the Commission Services and experts from the Member States. The text has been drafted by Mr. Alberto Laddomada (Mailto:alberto.laddomada.cec.eu.int) for further clarification of technical nature concerning the EC comments please contact directly Mr. Laddomada with copy to this Enquiry Point.

The EC is of the opinion of that the notified IRA for Pig Meat ,

1. Has not taken into account the risk assessment techniques developed by the relevant international organizations, and are therefore inconsistent with Article 5.1, as well as paragraph 4 of Annex A, of the SPS Agreement.
2. Has not taken into account the sanitary characteristics of the European Union, *inter alia*, the level of prevalence of specific diseases, the existence of useful eradication and control programmes. Furthermore, from the examination of the IRA, it appears evident that Australia does not recognize the concepts of pests- or disease- free areas and areas of low pest or disease prevalence, what is inconsistent with Articles 6.1 and 6.2 of the SPS Agreement.

In conclusion, the proposed measures are not based on international standards, guidelines or recommendations and are therefore inconsistent with Article 3.1 of the SPS Agreement and if maintained, the measures will be more trade-restrictive than required to achieve the Australia's appropriate level of protection and therefore are breach of Article 5.6 of the SPS Agreement.

BEGINNING OF THE EC TECHNICAL COMMENTS

1. Preliminary Remarks.

The document of the Australian Department of Agriculture, Fisheries and Forestry “Generic Import Risk Analysis (IRA) for pig meat” is presented as a generic import risk analysis. However, as drafted, it still presents major barriers to imports of pig meat, especially fresh meat.

The Commission notes that most of the measures proposed by Australia differ remarkably from the standards established by the relevant international bodies (OIE, Codex) and/or are not based on solid scientific grounds but rather propagate a zero-risk approach which cannot be accepted, as is against the principles of the SPS Agreement.

The risks posed by disease agents that could be potentially introduced into Australia via import of pig meat or pig meat products have very often been overestimated. Examples of overestimation of risks and absence of scientific grounds of the proposed measures are given below.

2. OIE List A diseases

Basically, a zero-risk approach has been kept for OIE list A diseases. In many circumstances the available scientific evidence indicating that the viruses in question would be inactivated by certain treatments of pig meat have been considered as insufficient or misinterpreted, despite that - at least for certain diseases - the same scientific evidence forms the basis of OIE standards, which have been accepted by the scientific community and Member Countries, whilst being disregarded by the IRA.

For Foot and Mouth Disease (FMD) either the pig meat must derive from a country or zone recognised by Australia as FMD free or it must be heat treated to at least 100°C, which is the only treatment considered by Australia sufficient to inactivate FMD virus in pig meat. This is excessive when compared with OIE standards on treatments of meat which are able to ensure FMD virus inactivation.

Curing and maturation of certain typical European products such as Parma Ham and Serrano Ham have not been considered by the IRA as sufficient for virus inactivation. This conclusion is not based on science. Indeed, the results of the experiments cited in the IRA concerning FMD, African and classical swine fever and swine vesicular disease, have showed that curing and maturation of these products fully inactivate all these viruses and that - amongst the viruses above - FMD virus was the one more rapidly inactivated.

For Parma ham - for example - these experiments showed FMD virus persistence on samples taken up to day 96 of maturation, while full virus inactivation was shown on samples taken at 108, 136, 170 and 227 days of maturation. Despite these findings and the fact that Parma ham has a minimum maturation period of 10-14 months, the IRA concludes that there would be a “very low” likelihood that FMD virus would survive in this type of ham when cured for a minimum of 170 days. As a consequence, the IRA arrives at the conclusion that the import of Parma ham would pose unacceptable risks for Australia. This conclusion is unreasonable given the clear experimental results, which themselves are based on worst-case scenarios.

This is a very clear example of misinterpretation of scientific data and overestimation of risk. Indeed, in the light of the experiments above mentioned the likelihood of persistence

of FMD virus at the end of the curing period of all products in question should be considered as “negligible” by Australian Authorities.

For Classical Swine fever (CSF), African Swine Fever (ASF) and Swine Vesicular Disease (SVD) under the IRA, either:

- i) the pig meat must derive from a country or zone recognised by Australia as free or
- ii) it must be heat treated to at least 100°C or
- iii) it must come from farms free from evidence (clinical serological and virological) of these diseases and undergo the treatment established for certain typical European products (Parma Ham and Serrano Ham).

As for FMD, the experimental evidence that the viruses in question are fully inactivated during the curing and maturation process of these products has not been taken into account. Again the available OIE standards - for example the ones on inactivation of CSF virus in pig meat products - have not been taken into account.

The additional requirements proposed by the IRA before importing certain typical European pig meat products (clinical, serological and virological testing of pigs in their farms of origin during three-six months before slaughter) are very trade restrictive, in particular those on serological and virological testing and they are not justified, given that as indicated by the OIE, the incubation period for the disease in question is much shorter and clinical signs of disease would allow clinical recognition within a few weeks from virus entry into the farm.

A requirement for absence of any detection of clinical signs of the disease in question in the farm of origin a few weeks before and after the slaughter of the pigs from which the hams have been produced would be much less trade restrictive whilst providing the same level of protection, but still not appropriate and excessive.

2. PRRS

Another example of the very restrictive approach of the IRA is in relation to PRRS.

The Australian measures are based on experimental data, which do not in fact reflect the field situation. Australia should take into account the very low probability that:

- slaughter pigs will be viraemic,
- after slaughter of these pigs, the PRRS virus will be present in significant amount in the meat,
- the virus will survive in the meat despite maturation, other treatments like freezing or curing or any other exposure to environmental conditions causing virus inactivation (this virus is very labile),
- this meat or meat products - still containing significant amount of PRRS virus - will eventually be ingested by Australian domestic or feral pigs.

Therefore, the heat treatment requirement proposed by the IRA is excessively trade restrictive, as a more objective assessment of the risks above would lead to the conclusion that the overall risk due to the importation of pig meat from areas where PRRS occurs is “negligible”.

Moreover there are countries where PRRS has never been recorded, which also should

be taken into account by the Australian authorities.

4. Trichinella

Excessive testing requirements are recommended by the IRA as regards Trichinella. The Commission wishes to point out that appropriate testing methods are applied in the EU, to ensure a very high level of protection against this disease agent. This legislation fully corresponds to OIE and Codex standards.

5. PWMS

In the case of PWMS, Australia would like to take very restrictive measures such as deboning of fresh pig meat, followed by cooking or curing, in relation with the potential introduction of Porcine circovirus 2 (PCV2).

PCV2 does occur in Australia and no measures are in place to prevent pig-to-pig or farm-to farm spread of this virus.

The measures recommended by the IRA are based on the assumption that the unrestricted import of pigmeat containing “exotic” PCV2 would lead to the occurrence of PWMS in Australia, whilst the “local” PCV2 does not cause this disease. No scientific finding supports this assumption, except the claim that “PWMS has been described in most countries but not in Australia”.

Furthermore:

a) PWMS is a multifactorial disease whose occurrence depends on several biological, environmental and management factors and not only the occurrence of PCV2. The claimed absence of PWMS in Australia is not substantiated by any scientific study. If this absence can be substantiated, then it should also be demonstrated that this relates to the absence of PCV2 of exotic origin and not with the absence of the other disease co-factors.

b) it is legitimate to assume that PCV2 is widespread in Australian pigs at the same or at a similar extent as in the rest of the world. A significant part of the pig population in Australia is likely to have developed antibodies and to be immune against any PCV2. This has not been taken into account in the scenarios following introduction of “exotic” PCV2, leading to an overestimation of the consequences of this introduction

c) there is no evidence that ingestion of pigmeat containing PCV2 is a risk factor of any importance in the occurrence and spread of PWMS and no country in the world imposes trade restrictions on pig meat to protect itself against PWMS.

Within this technical context, the current insufficient knowledge on the pathogenesis of this disease cannot be used as a legitimate reason to propose the suggested measures that would have a very negative impact on pig meat imports, without guaranteeing Australia any protection against the disease.

Conclusions

As regards the OIE list A diseases mentioned above, the Commission wishes to point out that the whole European Union is free from FMD, and most Member States are free from CSF, ASF and SVD. In those Member States which are not disease-free, disease control, zoning and regionalization measures are in place.

The Commission therefore requests Australia that:

- as regards those Member States wishing to export pig meat and pig meat products to Australia and which have presented an application in this regard, their free status (of the whole country or of the free regions within the country) should be rapidly recognised by Australia,
- pending the recognition above and in the case of those Member States which have not produced an application for the recognition of their status, Australia authorises the import of pig meat and pig meat products in accordance with the available OIE standards or, where they are not available, with the comments above.

As regards PRRS, the Community requests Australia to take fully into account the comments above. Moreover there are countries where PRRS has never been recorded, which also should be taken into account by the Australian authorities.

As regards Trichinella, the Commission requests that Australia consider the measures in place in the EU as equivalent to the ones recommended by the IRA.

As regards PWMS, Australia is requested not to apply any restrictions to import of pig meat, as the proposed measures are not based on sound scientific evidence.

Finally, as a general comment, under the IRA, only meat from pigs born and bred in the exporting country would be allowed to be exported to Australia. The EU is composed of many Member States and pigs are often traded from one Member State to another in accordance with the health requirements of Community legislation on intra-Community trade. Procedures are in place to ensure that movements between Member States cause no risks as regards transmission of animal disease agents. Therefore, the Commission requests that imports be allowed for any pig meat which is derived from pigs of EU origin or imported into the EU under its import rules.

The Commission is available to provide further information to Australia on the issues above, as appropriate.

[END OF EC TECHNICAL COMMENTS]

We plan to submit these comments also by fax, as soon as possible.

Again, the EEC appreciates the opportunity to comment on the Australian proposal and we are looking forward to your responses.

For simplicity we also append hereby the technical comments in pdf format



d10559R4.pdf

Again, the EEC appreciates the opportunity to comment on the proposal and we are looking forward to your responses.

European Communities Notification Authority & Enquiry Point

[Annex B of the WTO Agreement on Sanitary and Phytosanitary Measures]

See http://europa.eu.int/comm/food/fs/ifsi/ifsi_index_en.html

Attn.: Dr. J. Pérez-Lanzac

Phone +32 (2) 29 55092; Direct Fax: +32 (2) 29 98090 E-mail: sps@cec.eu.int

European Commission Directorate General for Health and Consumer Protection

Directorate E Unit E/3 International Food, Veterinary and Phytosanitary Questions

European Communities Notification Authority

Dr. Henri Belveze

Rue Froissart 101,

Room 4/74

1049 Brussels (Belgium)

Telephone: +32 (2) 29 62812 / 55092

Telefax: +32 (2) 29 98090

E-mail/Internet: sps@cec.eu.int

**Comments to the document of the
Australian Department of Agriculture, Fisheries and Forestry:
“Generic Import Risk Analysis (IRA) for pig meat”**

1. Introduction – general comments

The document of the Australian Department of Agriculture, Fisheries and Forestry “Generic Import Risk Analysis (IRA) for pig meat” is presented as a generic import risk analysis. However, as drafted, it still presents major barriers to imports of pig meat, especially fresh meat.

The Commission notes that most of the measures proposed by Australia differ remarkably from the standards established by the relevant international bodies (OIE, Codex) and/or are not based on solid scientific grounds but rather propagate a zero-risk approach which cannot be accepted, as is against the principles of the SPS Agreement.

The risks posed by disease agents that could be potentially introduced into Australia via import of pig meat or pig meat products have very often been overestimated. Examples of overestimation of risks and absence of scientific grounds of the proposed measures are given below.

2. OIE List A diseases

Basically, a zero-risk approach has been kept for OIE list A diseases. In many circumstances the available scientific evidence indicating that the viruses in question would be inactivated by certain treatments of pig meat have been considered as insufficient or misinterpreted, despite that - at least for certain diseases - the same scientific evidence forms the basis of OIE standards, which have been accepted by the scientific community and Member Countries, whilst being disregarded by the IRA.

For **Foot and Mouth Disease** (FMD) either the pig meat must derive from a country or zone recognised by Australia as FMD free or it must be heat treated to at least 100°C, which is the only treatment considered by Australia sufficient to inactivate FMD virus in pig meat. This is excessive when compared with OIE standards on treatments of meat which are able to ensure FMD virus inactivation.

Curing and maturation of certain typical European products such as Parma Ham and Serrano Ham have not been considered by the IRA as sufficient for virus inactivation. This conclusion is not based on science. Indeed, the results of the experiments cited in the IRA concerning FMD, African and classical swine fever and swine vesicular disease, have showed that curing and maturation of these products fully inactivate all these viruses and that - amongst the viruses above - FMD virus was the one more rapidly inactivated¹.

For Parma ham – for example – these experiments² showed FMD virus persistence on samples taken up to day 96 of maturation, while full virus inactivation was shown on samples taken at 108, 136, 170 and 227 days of maturation. Despite these findings and the fact that Parma ham has a minimum maturation period of 10-14 months, the IRA concludes that there would be a “very low” likelihood that FMD virus would survive in this type of ham when cured for a minimum of 170 days. As a consequence, the IRA arrives at the conclusion that the import of Parma ham would pose unacceptable risks for Australia. This conclusion is unreasonable given the clear experimental results, which themselves are based on worst-case scenarios.

This is a very clear example of misinterpretation of scientific data and overestimation of risk. Indeed, in the light of the experiments above mentioned the likelihood of persistence of FMD virus at the end of the curing period of all products in question should be considered as “negligible” by Australian Authorities.

¹ It is to be underlined that these experiments were carried out under “extreme” conditions that are highly unlikely to occur in the field. They were carried out in parallel in two distinct laboratories, one in Europe and the other in the USA. The hams were produced from seriously sick or even moribund pigs which had very high virus titres in meat at the moment of slaughter. During the curing period virus inactivation was verified by means of pig inoculation, that is a method much more sensitive than ingestion by oral route, which would be, however, the only possible “natural” route of virus transmission via these products. The viruses in question were considered fully inactivated only after that at least two series of samples taken during the curing period at a distance of at least 30 days were found virus negative.

For **Classical Swine fever (CSF)**, **African Swine Fever (ASF)** and **Swine Vesicular Disease (SVD) under the IRA**, either: i) the pig meat must derive from a country or zone recognised by Australia as free or ii) it must be heat treated to at least 100°C or iii) it must come from farms free from evidence (clinical serological and virological) of these diseases and undergo the treatment established for certain typical European products (Parma Ham and Serrano Ham).

As for FMD, the experimental evidence that the viruses in question are fully inactivated during the curing and maturation process of these products has not been taken into account. Again the available OIE standards – for example the ones on inactivation of CSF virus in pig meat products - have not been taken into account.

The additional requirements proposed by the IRA before importing certain typical European pig meat products (clinical, serological and virological testing of pigs in their farms of origin during three-six months before slaughter) are very trade restrictive, in particular those on serological and virological testing and they are not justified, given that as indicated by the OIE, the incubation period for the disease in question is much shorter and clinical signs of disease would allow clinical recognition within a few weeks from virus entry into the farm.

A requirement for absence of any detection of clinical signs of the disease in question in the farm of origin a few weeks before and after the slaughter of the pigs from which the hams have been produced would be much less trade restrictive whilst providing the same level of protection, but still not appropriate and excessive³.

2. PRRS

Another example of the very restrictive approach of the IRA is in relation to **PRRS**.

The Australian measures are based on experimental data, which do not in fact reflect the field situation. Australia should take into account the very low probability that:

² McKercher et al., Can. Inst. Food Sci. Technol. J., vol 20 N.4, pp 267-272, 1987

- slaughter pigs will be viraemic,
- after slaughter of these pigs, the PRRS virus will be present in significant amount in the meat,
- the virus will survive in the meat despite maturation, other treatments like freezing or curing⁴ or any other exposure to environmental conditions⁵ causing virus inactivation (this virus is very labile),
- this meat or meat products – still containing significant amount of PRRS virus - will eventually be ingested by Australian domestic or feral pigs⁶.

Therefore, the heat treatment requirement proposed by the IRA is excessively trade restrictive, as a more objective assessment of the risks above would lead to the conclusion that the overall risk due to the importation of pig meat from areas where PRRS occurs is “negligible”. Moreover there are countries where PRRS has never been recorded, which also should be taken into account by the Australian authorities.

4. Trichinella

Excessive testing requirements are recommended by the IRA as regards Trichinella. The Commission wishes to point out that appropriate testing methods are applied in the EU, to ensure a very high level of protection against this disease agent. This legislation fully corresponds to OIE and Codex standards⁷.

³ Only in case of SVD clinical signs of disease might not be evident and therefore serological tests appropriate, see the SVD Diagnostic Manual adopted by Commission Decision 2000/428/EC.

⁴ The PRRS virus occurs in low amount in fresh pig meat and it is very labile. As indicated in paragraph 2, viruses such as FMD, CSF, ASF and SVD, which occur in meat in much higher titres and are much more resistant than PRRS virus, are fully inactivated during the curing and maturation of certain typical European products. Therefore, the risk posed by the import of these products in relation to PRRS virus should also be considered as “negligible”.

⁵ For example, virus inactivation has been shown on 14 out of 15 tissue samples kept for 3 days at a temperature (25°C) resembling very common environmental conditions

⁶ The issue is very well dealt in the document of the Danish Bacon and Meat Council “Assessment of the risk that the Porcine Reproductive and Respiratory Syndrome Virus may enter Australia due to the import of fresh Danish bone-in hams”, which has already been brought to the attention of the Australian authorities

⁷ The testing methods which are accepted in the European Union are: i) trichiniscopy using 0,5 g of muscle, ii) artificial digestion using 1 g per animal. These samples are pooled until a total amount of 100 g of meat is examined (pooled sample digestion method). Several pieces of equipment to support this pooled sample digestion method are described in detail and accepted after community-wide experiments (Stomacher

5. PWMS

In the case of PWMS, Australia would like to take very restrictive measures such as deboning of fresh pig meat, followed by cooking or curing, in relation with the potential introduction of Porcine circovirus 2 (PCV2).

PCV2 does occur in Australia and no measures are in place to prevent pig-to-pig or farm-to farm spread of this virus.

The measures recommended by the IRA are based on the assumption that the unrestricted import of pigmeat containing “exotic” PCV2 would lead to the occurrence of PWMS in Australia, whilst the “local” PCV2 does not cause this disease. No scientific finding supports this assumption, except the claim that “PWMS has been described in most countries but not in Australia”. Furthermore:

- a) PWMS is a multifactorial disease whose occurrence depends on several biological, environmental and management factors and not only the occurrence of PCV2. The claimed absence of PWMS in Australia is not substantiated by any scientific study. If this absence can be substantiated, then it should also be demonstrated that this relates to the absence of PCV2 of exotic origin and not with the absence of the other disease co-factors.
- b) it is legitimate to assume that PCV2 is widespread in Australian pigs at the same or at a similar extent as in the rest of the world. A significant part of the pig population in Australia is likely to have developed antibodies and to be immune against any PCV2. This has not been taken into account in the scenarios following introduction of “exotic” PCV2, leading to an overestimation of the consequences of this introduction
- c) there is no evidence that ingestion of pigmeat containing PCV2 is a risk factor of any importance in the occurrence and spread of PWMS and no country in the world imposes trade restrictions on pig meat to protect itself against PWMS.

Within this technical context, the current insufficient knowledge on the pathogenesis of this disease cannot be used as a legitimate reason to propose the suggested measures that

method, Trichomatic). They are all described in detailed protocols in the annexes to Council Directive 77/96/EEC).

would have a very negative impact on pig meat imports, without guaranteeing Australia any protection against the disease.

Conclusions

As regards the OIE list A diseases mentioned above, the Commission wishes to point out that the whole European Union is free from FMD, and most Member States are free from CSF, ASF and SVD. In those Member States which are not disease-free, disease control, zoning and regionalization measures are in place. The Commission therefore requests that:

- as regards those Member States wishing to export pig meat and pig meat products to Australia and which have presented an application in this regard, their free status (of the whole country or of the free regions within the country) should be rapidly recognised by Australia,
- pending the recognition above and in the case of those Member States which have not produced an application for the recognition of their status, Australia authorises the import of pig meat and pig meat products in accordance with the available OIE standards or, where they are not available, with the comments above.

As regards PRRS, the Community requests Australia to take fully into account the comments above. Moreover there are countries where PRRS has never been recorded, which also should be taken into account by the Australian authorities.

As regards Trichinella, the Commission requests that Australia consider the measures in place in the EU as equivalent to the ones recommended by the IRA.

As regards PWMS, Australia is requested not to apply any restrictions to import of pig meat, as the proposed measures are not based on sound scientific evidence.

Finally, as a general comment, under the IRA, only meat from pigs born and bred in the exporting country would be allowed to be exported to Australia. The EU is composed of many Member States and pigs are often traded from one Member State to another in accordance with the health requirements of Community legislation on intra-Community trade. Procedures are in place to ensure that movements between Member States cause no

risks as regards transmission of animal disease agents. Therefore, the Commission requests that imports be allowed for any pig meat which is derived from pigs of EU origin or imported into the EU under its import rules.

The Commission is available to provide further information to Australia on the issues above, as appropriate.