

Committee on Sanitary and Phytosanitary Measures

**PROCEDURE TO MONITOR THE PROCESS
OF INTERNATIONAL HARMONIZATION**

Draft Third Annual Report

Revision

As agreed by the Committee at its meeting of 10-11 July 2001, this draft Third Annual Report has been updated to include comments received at that meeting. It is being circulated for approval on an ad referendum basis, as the Committee requested. If no further comments are received by 14 September 2001, the report will be considered as adopted.

A. INTRODUCTION

1. At its meeting of 15-16 October 1997, the SPS Committee adopted a provisional procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations, as provided for in Articles 3.5 and 12.4 of the SPS Agreement.¹ At its 7-8 July 1999 meeting, the Committee decided to extend the provisional monitoring procedure for at least another two years, to review the operation of the provisional procedure by July 2001, and to determine at that time whether to continue with the provisional procedure, amend it, or develop another one.²

B. ISSUES

2. At its meeting of 7-8 July 1999, the Committee adopted the First Annual Report.³ The Second Annual Report⁴ was approved ad referendum after the 21-22 June 2000 meeting. These reports summarized several standards-related issues that the Committee had considered and the responses received from the relevant standard-setting organizations.

3. Since the First Annual Report was adopted, no new issues have been raised by Members.

C. RESPONSES RECEIVED FROM THE RELEVANT STANDARD-SETTING ORGANIZATIONS

4. At the November 2000 and March 2001 Committee meetings and in submissions all three standard-setting organizations provided updated information to the SPS Committee regarding their

¹ G/SPS/11.

² G/SPS/14.

³ G/SPS/13.

⁴ G/SPS/16.

work on the identified standard-related issues. The information provided on the relevant issues since the circulation of the Second Annual Report is summarized below.⁵

Requirement for control of Infectious Bursal Virus (IBDV) in cooked chicken meat – Response from the OIE

5. The Bureau of the Code Commission noted that Chapter 3.6.1. of the *International Animal Health Code* (the *Code*) provided recommendations on international trade in domestic birds, day-old chicks and hatching eggs from domestic birds, but remained silent on the subject of products derived from birds, and in particular on chicken meat. To decide whether it would be appropriate to include provisions on chicken meat in the aforementioned Chapter, the Bureau asked an ad hoc group of experts for information *inter alia* on the probability of finding the causal virus in fresh meat obtained from chickens that were healthy at the time of slaughter, as well as the effect of refrigeration and freezing on the survival of the virus in chicken meat. It also asked the group to identify key areas where further research is required.

6. When it met at the end of January 2001, the Code Commission took note of the report of the ad hoc group, and requested the Director-General of the OIE to inform the WTO SPS Committee of the replies given by the experts to its questions and the areas in which they considered that additional research was required (attached as Annex 1 and 2).

7. As the experts also prepared a new draft chapter on infectious bursal disease during their meeting, the Code Commission decided to submit it for comment to the delegates of OIE member countries. The new draft chapter includes an article on the requirements for international trade in fresh poultry meat. This draft will be reviewed further during the coming year, before being presented to the International Committee for adoption, taking into account the observations and requests for amendments received in the meantime from member countries. Furthermore, as it is not the role of the OIE to conduct research itself, it is hoped that countries will provide the necessary support for the research to be carried out.

Definition of "quarantine pest" – Response from the IPPC

8. The definition of "quarantine pest" contains the term "officially controlled", which was a source of concern for some Members. Work on a definition for the term "official control", undertaken as a result of the recommendation of the SPS Committee, resulted in a draft definition and guidelines for the interpretation and application of the concept. These were approved by the IPPC's Interim Standards Committee in May 2000 and were subsequently distributed to governments for consultation. The document was then reviewed by the Interim Standards Committee in light of the comments received from governments and was submitted to the Interim Commission on Phytosanitary Measures (ICPM). The ICPM adopted the definition and guidelines at its third Session in April 2001.

Chlortetracycline (CTC) residues in pork and pork products – Response from Codex

9. The only final level established to date for the Chlorotetracycline/Oxytetracycline/Tetracycline group is the Maximum Residue Limit (MRL) of 100 micrograms/kg for Oxytetracycline in giant prawns, which was adopted by the Commission in 1997. All other MRLs for

⁵ Codex responses are reported in G/SPS/R/17, para. 42, G/SPS/R/18, para. 58 and G/SPS/R/20, para. 70; IPPC responses are reported in G/SPS/R/17, para. 43, G/SPS/GEN/146 and G/SPS/GEN/183; and OIE responses are reported in G/SPS/R/17, para. 44, G/SPS/R/18, para. 51, G/SPS/R/20 para. 71, G/SPS/R/21 paras. 72-74, G/SPS/GEN/145 and Add.1, 2 and 3.

this group are currently at Step 7 and will be considered at the forthcoming 13th Session of the Committee on Veterinary Drug Residues in Foods in South Carolina, USA, from 4-7 December 2001.

Frequency of controls to be carried out on bulls in collection centres (brucellosis, tuberculosis, leukosis, IBR) – Response from the OIE

10. The health controls to be carried out on bulls at artificial insemination centres are described both in the *International Animal Health Code* chapters dealing with diseases transmissible by semen and in the appendices relating to artificial insemination in bovines. The Bureau of the Code Commission took note of the conclusions of two meetings of international specialists on reproduction, which enabled the development of revised draft appendices relating to bulls and artificial insemination centres and the hygienic collection and processing of bovine semen. These draft appendices were submitted to the OIE member countries for comment. The meeting of the International Animal Health Code Commission in January 2001 examined the draft appendices, and decided to combine them into a single annex. The Commission clarified the sanitary conditions to be met by bulls before entry into artificial insemination centres and the general organization of these centres into different sectors. The new draft Annex was submitted to and adopted by the OIE International Committee in May 2001. The Code Commission stressed that further harmonization work will be needed to ensure consistency between the provisions of the Annex and those of articles relating to bovine semen in the chapters of the *International Animal Health Code* that deal with animal diseases.

Benzoic acid as a preservative in sauces – Response from Codex

11. Safe levels for benzoic acid are under consideration in the Codex Committee on Food Additives and Contaminants (CCFAC). The March 2000 Beijing meeting of the CCFAC produced a draft standard of 1,000 mg/kg for benzoic acid approved for use in sauces and like products. The revised draft of the general standard for food additives was circulated in November 1999 and governments were asked to comment before the March 2000 meeting. The March 2001 Session of the CCFAC forwarded several proposed draft maximum levels for the Benzoate group to the July 2001 Commission for preliminary adoption at Step 5. Other draft maximum levels for the benzoate group, including a draft level of 1000 mg/kg for benzoates in sauces and like products, are at Step 6 for comments.

Certification requirements for origin of animals – Response from the OIE

12. The International Animal Health Code Commission intends to make use of the scientific articles on traceability of animals and products of animal origin that are due to be published in issue No. 2 of Volume 20 of the OIE *Scientific and Technical Review* in August 2001 to consider the subject in greater depth.

ANNEX 1

REPLIES FROM THE EXPERTS TO THE QUESTIONS ON INFECTIOUS BURSAL DISEASE VIRUS PUT BY THE OIE CODE COMMISSION

1. **What is the probability of finding infectious bursal disease virus in fresh meat obtained from chickens that were healthy at the time of slaughter?**

The experts provided information on the virus titres found in various tissues, based primarily on data quoted or included in Import Risk Analysis reports from an OIE Member Country. According to this data, the very virulent virus could only be detected in muscle of experimentally infected SPF chickens at seven days after infection, but could not be detected at day 14. In another study the classic serotype 1 virus was found in muscle tissues up to four days but not at seven days post-infection. However, the study quoted in the risk assessment reported that the virus was detected in the bursa of Fabricius up to 28 days. In another study a variant serotype 1 virus was detected in the bursa only up to 21 days.

The experts consider that the use of SPF birds in the virus persistence studies referred to in the Import Risk Analysis reports does not represent the situation in the poultry industry, as almost all commercial birds are exposed to either the field or vaccine virus and therefore immune. Consequently the virus is probably only present in the carcasses of immune birds for short periods if at all: one of the experts reported that an intermediate vaccine virus was not detected in the bursa of commercial birds at seven and fourteen days after vaccination (data submitted for publication).

The experts recommended that the work quoted in the Import Risk Analysis should be published in a peer-reviewed publication.

The bursa of Fabricius is the target organ where the highest virus titre is found. The Import Risk Analysis reported that 30 per cent of the carcasses sampled after slaughter still contained some bursal tissue. The experts stated that chicken products such as legs, thighs, breasts and wings would not pose a significant risk, unless they contain some bursal tissues. In whole carcasses, there is a potential for viral presence if bursal tissues are present. Studies on the feasibility of complete removal of bursal tissues during slaughter should be encouraged. If technically and economically feasible, the resulting processes should be adopted.

The experts are of the opinion that certification of absence of clinical signs is not sufficient to ascertain absence of virus, as some birds may be at the viremic phase before appearance of clinical signs when slaughtered or some virus strains will not induce clinical signs.

Vaccination has been used successfully worldwide to control disease. Effective vaccination practices should lower the risk of virus being found in poultry products from immune birds.

A combination of maintaining adequate immunity in meat producing flocks plus slaughter processes or selection of parts to prevent the inclusion of bursal tissues in exported products would decrease significantly the risk of IBDV transmission. Consequently, the presence of antibody in flocks of origin should not be viewed as a negative factor for international trade.

It is important that the vaccination strategies ensure avoidance of residual vaccine virus infectivity in poultry products.

The experts discussed the potential for transmission from imported IBDV infected meat to chickens. So far, there is no documented evidence of such transmission.

- 2. What is the effect, if any, of refrigeration and freezing on the survival time of the virus in chicken meat?**

There is no significant decrease of virus titre by refrigeration or freezing.

- 3. Are there strains with differing degrees of virulence and, if so, do the answers to the previous two questions depend on the degree of virulence?**

There are significant differences in virulence of field as well as vaccine strains. The unpublished data in the Import Risk Analysis would indicate that both a classical virus and a very virulent virus persisted in muscle tissue up to seven days after experimental exposure. Again the experts recommended that the relevant studies be published in peer-reviewed publications.

- 4. What are the determining factors for a country to decide whether or not to vaccinate against infectious bursal disease?**

Vaccination combined with effective sanitary measures is practised worldwide because of widespread occurrence of pathogenic viruses in commercial poultry. The decision to vaccinate commercial poultry is the consequence of the demonstration of clinical or immuno-suppressive disease. The vaccination strategies used are dependent on the virulence of the strains circulating in the country considered.

- 5. If there are strains that differ in virulence, do they require different vaccination strategies?**

See previous point.

ANNEX 2

TOPICS RELATING TO THE INFECTIOUS BURSAL DISEASE ON WHICH ADDITIONAL SCIENTIFIC RESEARCH IS NEEDED

1. Study of the tissue distribution and persistence of the different pathotypes of the virus in the presence of different levels of antibodies simulating commercial conditions.
 2. Development of processing techniques to ensure complete removal of bursal tissue after slaughter.
 3. Study of effective vaccination schedules to avoid the presence of both field and vaccine viruses in carcasses at slaughter.
 4. Development of sensitive procedures for detection of infectious IBDV in meat products.
 5. Development of virulence markers and standardized protocols to differentiate IBDV pathotypes.
 6. Development of practical field monitoring procedures for IBDV infection.
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