

**APPLICATION OF ARTICLE 6 OF THE AGREEMENT ON SANITARY AND  
PHYTOSANITARY MEASURES AS REGARDS ANIMAL DISEASES**

Submission by the European Union

The following communication, received on 26 June 2012, is being circulated at the request of the Delegation of the European Union.

1. The European Union is pleased to describe how its zoning, or regionalization, policy for animal diseases can be successfully implemented. It does this by demonstrating in practice that a correct application of the zoning principle reduces trade disruption to the minimum, both in terms of the geographical area(s) affected and the duration of trade restrictions. Using the example of avian influenza, it shows how this can be done without posing unacceptable risks to the importing country.

**I. THE SPS AGREEMENT AND THE WORLD ORGANIZATION FOR ANIMAL HEALTH**

2. Zoning is a concept whereby an area of a country is recognized as being pest- or disease-free or with low pest or disease prevalence. It allows trade from such areas even if the health status in the rest of the country is not favourable. It is a risk management option which can be applied in a flexible manner, albeit in accordance with a fully harmonized set of principles and rules established through legislation. The European Union recognises the application of this concept by third countries wishing to export to the European Union provided that equivalent guarantees are given by the trading partners.

**A. THE SPS AGREEMENT**

3. Article 6 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) defines regionalization and states the general conditions that facilitate international trade. In addition, since May 2008 the WTO SPS Committee has adopted non-binding "Guidelines to further the Practical Implementation of Article 6 of the SPS Agreement", in order to facilitate the recognition of pest- and disease-free areas or areas of low pest or disease prevalence.<sup>1</sup> These guidelines are intended to provide assistance to WTO Members in the practical implementation of Article 6 by improving transparency, the exchange of information, predictability, confidence and credibility between importing and exporting Members. These guidelines describe in particular the information needed for the recognition of regionalization and the administrative steps an exporting/importing country must take.

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<sup>1</sup> G/SPS/48

**B. THE WORLD ORGANIZATION FOR ANIMAL HEALTH**

4. According to the World Organization for Animal Health (OIE), the terms "zone" and "region" are synonyms which refer to "a clearly defined part of a territory containing an animal subpopulation with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade". Chapter 4.3. of the OIE Terrestrial Animal Health Code gives specific guidelines for performing zoning and compartmentalization. Zoning is implemented with a view to defining subpopulations of distinct health status within a territory for the purpose of disease control and/or international trade. The importing country should recognise the existence of the zone in the exporting country. The following principles should apply when defining a zone:

- (a) The extent of a zone and its geographical limits should be established by the Veterinary Authority on the basis of natural, artificial and/or legal boundaries, and made public through official channels;
- (b) A protection zone may be established to preserve the health status of animals in a free country or zone, from adjacent countries or zones of different animal health status;
- (c) In the event of limited outbreaks of a specified disease within an otherwise free country or zone, a single containment zone, which includes all cases, can be established for the purpose of minimizing the impact on the entire country or zone;
- (d) Animals and herds belonging to separate subpopulations need to be recognisable as such through a clear epidemiological separation and the Veterinary Authority should document in detail the measures taken to ensure the identification of the subpopulation and the establishment and maintenance of its health status through a biosecurity plan;
- (e) Relevant animals within the zone or compartment should be identified in such a way that their movements are traceable.

**II. ZONING FOR ANIMAL DISEASES IN THE EUROPEAN UNION**

5. Within the European Union, the main goal of zoning is twofold: (i) to ensure the effective control of diseases within the affected area and (ii) to limit the impact of diseases on both the EU internal market and on exports.

**A. THE IMPORTANCE OF ZONING FOR THE EUROPEAN UNION**

6. The European Union is a single market comprising the free movement of goods (including animal and animal products), persons, services and capital amongst all EU member States. The Single Market dates back to 1993. To this end, the European Union has developed a comprehensive animal, plant health and food safety policy that ensures a high status of animal and plant health throughout the European Union. This is not only essential to ensure the sustainable development of agriculture and profitability for farmers, the protection of human health and the welfare of animals, it is also fundamental to the functioning of the internal market and to trade. The European Union bases its policy on international standards not only, for the purpose of trading internationally, but also, to ensure the proper functioning of the single market.

**B. HOW IS ZONING APPLIED WITHIN THE EUROPEAN UNION?**

7. Given that animal diseases do not respect national boundaries, the concept of zoning has been present in EU sanitary and phytosanitary legislation long before the establishment of the internal market. With the abolition of border controls and the creation of a single market between member States around twenty years ago, the European Union reinforced and extended this concept to cover all

the pests and diseases of major concern. This has led to a comprehensive body of EU legislation on disease control, on intra-EU trade and on imports of animals and their products. Zoning is an excellent tool to control disease and it is widely applied in the European Union in line with SPS and OIE guidelines and standards.

C. EU HARMONIZED LEGISLATION, NATIONAL CONTINGENCY PLANS AND PREDICTABILITY OF MEASURES

8. In the European Union, a comprehensive body of harmonized legislation is in place, establishing the basic measures and actions to be implemented by the competent authorities in the member States to contain, and eventually eradicate, major animal diseases.

9. In line with EU requirements, **in all EU member States, disease-specific contingency plans are also in place for all major animal diseases**, so that the actions established in the legislation on disease control and trade can be effectively implemented, while taking into account the local circumstances and specific characteristics of each disease outbreak. This emergency preparedness is key to enhance the ability of the European Union to rapidly contain disease. By means of contingency plans, rapid implementation of all appropriate disease control measures and restrictions on trade in animals and their products that could pose a risk, are put in place. This is fundamental for a proper implementation of the concept of zoning when outbreaks of diseases occur.

10. The size of the area in which disease control measures and trade restrictions apply may vary depending on several factors, including the disease in question and local risk factors that are considered in each contingency plan.

11. The disease control measures will also vary depending on the same factors. However, they usually include the stamping-out (humane killing and destruction) of animals in the infected farms (and if necessary, on other at-risk farms identified by means of epidemiological investigations) and/or vaccination. Trade restrictions may include a ban on animal movements within and from the infected areas.

12. Control measures and trade restrictions can only be lifted after appropriate disease surveillance measures have been applied in the affected area, and are modulated on the basis of the outcome of epidemiological investigations. EU legislation and national contingency plans foresee precise timetables for these actions. However, once the appropriate surveillance is carried out and persistence of disease agent in the affected area is excluded, measures are lifted without undue delay. In this way, the impact of trade restrictions is kept to a minimum.

13. In the event of disease outbreaks, the European Commission follows the evolution of the disease situation very closely; working in close cooperation with the affected member State - and other member States - in the framework of the Standing Committee of the Food Chain and Animal Health (SCOFCAH) meetings. In this way, it ensures maximum transparency with respect to the disease situation. Regular reports are published on the SCOFCAH website, usually within 24 hours from the end of the meeting. Transparency is further ensured through audits by the inspection service of the Commission of the control measures implemented. Such audits may be undertaken during a prolonged outbreak to also inform the decision-making process or after the lifting of restrictions to verify the actions taken.

D. MODULATION OF DISEASE CONTROL MEASURES AND OF THE AREAS IN WHICH TRADE RESTRICTIONS APPLY

14. EU legislation and member States contingency plans include the necessary flexibility to ensure that disease control measures and the size of the area under restriction are proportionate to the

risk of further disease spread. Where appropriate, the Commission intervenes with the rapid adoption of further legal texts supplementing the existing legislation and modulating disease control measures, including zoning, as appropriate. In this way, it supports the action undertaken by the affected member State and it provides the necessary guarantees to third country partners as regards the zoning measures adopted. If there is a risk that an outbreak will get out of control, the Commission intervenes by restricting trade from an area bigger than that foreseen in the basic legislation. In extreme circumstances, the area under restrictions may include the whole territory of the affected member State.

#### **E. BENEFITS FOR THE EU MARKET AND FOR EU TRADE PARTNERS**

15. The concept of zoning is primarily applied in the European Union to prevent disease spread from the affected area, for the benefit of the non-affected EU member States, and to prevent disruption to the EU internal market. The restrictions to trade that apply in the European Union affected area apply *both* to intra-EU trade and to exports. The acceptance by non-affected EU member States of the way zoning is applied, is one of the best guarantees that the European Union can provide to its trading partners.

16. The system requires mutual trust and confidence. This has been achieved amongst the EU member States, with the European Commission acting as arbiter. The very high level of transparency that is necessary to ensure the functioning of this system within the EU, also serves as a significant guarantee from the European Union to its trade partners.

17. This system is amongst the best proof that application of zoning for SPS measures, in line with the provisions of Article 5.6 of the SPS Agreement, serves trade well. By choosing the least trade-restrictive measures possible, zoning allows to proceed on a safe basis with appropriate guarantees provided along the way. Application of the principle can also be very beneficial to many developing countries whose health status is not necessarily favourable throughout their whole territory, but who may, nevertheless, be able to export products from a particular area.

### **III. CASE STUDY**

18. The European Union is pleased to provide a case study in annex, which refers to avian influenza.

### **IV. CONCLUSION**

19. The success achieved by the European Union in the last decade in containing, controlling and eradicating outbreaks of diseases such as foot and mouth disease, classical swine fever and avian influenza, and the experience gained by the European Union in applying zoning, or regionalization, to ensure the proper functioning of the EU single market, have demonstrated, time and again, the EU's ability to meet the dual objectives of maintaining a high health status whilst simultaneously minimizing barriers to trade.

Equally, the European Union fully accepts zoning in third countries exporting to the European Union on the basis of the principles of transparency, equivalency and mutual trust between the competent authorities. The European Union continues to encourage all third countries' to accept these principles and to recognize their benefits, both in terms of disease control and in terms of minimizing trade restrictions.

## ANNEX

CASE STUDY ON ZONING (OR REGIONALISATION) APPLIED FOR  
AVIAN INFLUENZA IN THE EUROPEAN UNION

## I. EU LEGISLATION ON AVIAN INFLUENZA CONTROL

1. In 1999-2000 and then in 2003, the European Union experienced major outbreaks of highly pathogenic avian influenza virus (HPAI) originating from the uncontrolled circulation of low pathogenic avian influenza (LPAI) virus in poultry flocks and the subsequent mutation of LPAI into HPAI viruses. These experiences, and advances in scientific knowledge, in particular on the risks that avian influenza viruses may pose to human health and on the role played by wild birds, led to a major revision of EU legislation on avian influenza. In 2005 Council Directive 2005/94/EC<sup>1</sup> was adopted. This legal act lays down surveillance, control and eradication measures for HPAI, and LPAI of the H5 and H7 subtype, when confirmed in poultry and captive birds.

2. The main objectives of EU legislation on avian influenza control are to:

- (i) reduce the risk of LPAI mutation to HPAI by control and eradication of LPAI infections in poultry;
- (ii) reduce the occurrence of large scale HPAI/LPAI outbreaks;
- (iii) limit the spread of both LPAI and HPAI from the originally infected poultry farm and from areas put under restrictions;
- (iv) minimize the risks for human health by means of a rapid detection, control and eradication of both LPAI and HPAI;
- (v) minimize the negative impact of avian influenza outbreaks on trade.

3. In accordance with Directive 2005/94/EC, the classical "stamping-out" policy is applied as a general rule to control and eradicate avian influenza, by culling infected poultry flocks and those that might have had direct or indirect contact with the infected flock. However, the legislation also foresees the possible use of vaccination, and facilitates, in principle, the application of a DIVA (Differentiating Infected from Vaccinated Animals) vaccination strategy in order to prevent the mass killing of birds. However, vaccine use against avian influenza in the European Union has been extremely limited.

4. Directive 2005/94/EC has also been supplemented with further legal acts so that **a very comprehensive legal framework ensures a proportionate response to the different risks posed by the occurrence of LPAI and HPAI under different situations** (LPAI or HPAI; special measures for HPAI H5N1, given the major risk that it poses to human health; occurrence in wild birds, poultry or other captive birds; occurrence of disease in areas with high density of poultry; etc.).

5. In order to ensure the proper implementation of EU legal requirements, all member States have put in place **contingency plans**. These plans detail the provisions necessary for the practical application under the local circumstances of avian influenza control measures such as legal powers, administrative organization for an efficient chain of command, establishment of local and central disease control centres, instructions for laboratories and veterinarians and information to stakeholders and the public. Veterinary authorities must also ensure that sufficient financial and human resources

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<sup>1</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:010:0016:0065:EN:PDF>

and equipment are available for the rapid control of a major outbreak. The plans must be regularly updated and simulation exercises carried out.

6. The European Commission also has the legal powers to adopt further disease control and zoning measures very rapidly if an outbreak in the European Union gets out of control.

7. **This infrastructure ensures that following the detection of both LPAI and HPAI in their territory, EU member States can swiftly establish proper disease control and zoning measures around the affected holdings.** In fact, zoning is firstly applied in the European Union to prevent unnecessary disruption of the EU Single Market, and secondly to provide the necessary guarantees to trade partners so that trade can safely continue from the non-affected areas of their territory.

8. Restrictions within the established zones in relation to avian influenza outbreaks can only be lifted after additional surveillance and testing has been carried out in the poultry holdings (including backyards) within the zones in accordance with the detailed protocols established in the "Avian Influenza Diagnostic Manual<sup>2</sup>", that takes into account the short incubation period of avian influenza. Once all actions foreseen in the EU legislation including the depopulation of the infected holding(s) and the above additional surveillance have been successfully completed and further virus circulation has been excluded, restrictions may be lifted in a relatively short period of time, i.e. after a minimum of 21 days (LPAI) or 30 days (HPAI) from the completion of cleaning and disinfection on the previously infected holding(s).

9. In the paragraphs below, some more details are provided on how disease control and zoning measures are applied in a synergistic way, under different disease scenarios.

## II. SURVEILLANCE, CONTROL AND ZONING MEASURES FOR LPAI IN POULTRY

10. Member States must carry out active sero-surveillance in domestic poultry in order to identify circulation of LPAI viruses which may easily go undetected due to lack of clinical signs. Surveillance enables the CA to adopt measures to possibly prevent mutation of LPAI to HPAI. Surveillance shall be conducted in a targeted manner taking into account specific risk factors such as the location of holdings close to waterways where migratory wild birds gather or/and a high density of poultry holdings in certain areas.

11. If LPAI is confirmed in poultry, control measures proportionate to the risk posed by these viruses must be implemented. All poultry present on the holding must be removed i.e. either by killing and safe disposal or by slaughtering under stringent precautions and biosecurity measures. However, at present member States do not make use of the latter option. A "restricted zone" of at least one km radius around the infected holding must be established, where movement restrictions for live poultry and eggs apply and epidemiological investigations, enhanced biosecurity and cleaning and disinfection must be carried out.

## III. SURVEILLANCE, CONTROL AND ZONING MEASURES FOR HPAI IN POULTRY

12. In accordance with Directive 2005/94/EC, the classical "stamping-out" policy for HPAI is applied by culling infected poultry flocks and those that might have had direct or indirect contact with the infected flock. Certain outbreak situations also require the pre-emptive culling of poultry on holdings at risk of infection in the surroundings of the affected holding. Thorough cleaning and disinfection of the premises must be carried out. Feeding stuffs, contaminated equipment and manure are destroyed or treated to render the virus inactive to further prevent virus spread. Council Directive

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<sup>2</sup> Commission Decision 2006/437/EC:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:237:0001:0027:EN:PDF>

2005/94/EC also foresees the possible use of vaccination, and facilitates in principle the application of a DIVA (Differentiating Infected from Vaccinated Animals) vaccination strategy in order to prevent the mass killing of birds. However, vaccine use against avian influenza in the European Union has been extremely limited.

13. Immediately after the confirmation of the outbreak member States' competent veterinary authorities (CA) must put in place movement restrictions on affected holdings and on all poultry farms located in a radius of at least 3 km (protection zone) and of at least 10 km (surveillance zone). In these zones graduated measures apply for movement restrictions on poultry, captive birds, day-old chicks, hatching eggs, table eggs, carcasses as well as for other possible means for virus spread such as vehicles, manure, litter, equipment and the movement of people. The establishment of these zones takes into account the geographical situation including natural boundaries, the location and proximity and the estimated number of poultry in the holdings located in the zone, as well as facilities to best control the movements. If required by the disease situation, the CA can establish a "further restricted zone" of a more than 10 km radius around the infected holding where some or certain control and restriction measures laid down for the protection and surveillance zones apply. Where necessary a "standstill" can be applied to the whole territory of a member State for movements of poultry, poultry products and vehicles used by the poultry sector.

#### **IV. ADDITIONAL MEASURES IN CASE OF HPAI H5N1 IN POULTRY**

14. Member States are required to define, for their territory, "higher risk areas" for HPAI H5N1 virus introduction based on identified risk factors in relation to the poultry species and production cycle, husbandry systems (e.g. free range), proximity to staging and mixing points for wild migratory waterfowl, in particular those coming from areas and countries with disease presence in poultry or wild birds. At farm level, poultry keepers are obliged to promptly report even slight changes in production such as reduced water and feed intake, egg drop and increased morbidity/mortality above defined thresholds.

15. When HPAI H5N1 infection is suspected or detected in poultry the control measures of Directive 2005/94/EC apply. Taking into account the specificities of the HPAI H5N1 spread by wild birds, additional measures laid down in Commission Decision 2006/415/EC<sup>3</sup> must be implemented. The 3 km protection and 10 km surveillance zones based on the Directive, constitute the high risk "Area A". A larger surrounding low risk "Area B" serves as a buffer zone between the high risk area and the unaffected territory. Further restrictions on movements of live poultry and its products, such as certain by-products and meat of wild feathered game must be applied. Stringent biosecurity must be observed on poultry farms.

#### **V. CONTROL MEASURES FOR HPAI H5N1 FINDINGS IN WILD BIRDS**

16. Decision 2006/563/EC<sup>4</sup> details protection measures in the event that HPAI H5N1 is detected in wild birds. A control area of at least one km radius around the positive wild bird finding must be established where movement restrictions on live poultry and poultry products must be applied until investigations have ruled out a possible virus introduction into poultry holdings. Around the control area a monitoring area of at least ten km radius must be established. Intensified surveillance in wild birds and enhanced biosecurity measures on poultry farms must be implemented. Gatherings of birds, game bird release and hunting are prohibited in those areas. The size and the shape of the areas under restriction can be adapted e.g. to follow rivers, sea and lake shores thereby considering geographical, ecological, wild bird species and habitat specific aspects.

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<sup>3</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:164:0051:0060:EN:PDF>.

<sup>4</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:222:0011:0019:EN:PDF>.

## **VI. CONCLUSIONS WITH RESPECT TO ZONING FOR INTRA-EU AND INTERNATIONAL TRADE**

17. By means of the new legal framework, the European Union has successfully prevented major outbreaks of LPAI and HPAI (including HPAI H5N1) in the European Union. The outbreaks of avian influenza which have occurred in poultry in the European Union in the last six years originated from wild birds and they have been successfully controlled and eradicated in the identified affected areas, with only very limited exceptions that have not led to any serious disturbance to the EU Single Market.

18. While wild birds will continue to pose a risk as regards the spread of avian influenza in poultry in Europe as well as in any other area of the world, the European Union considers that the introduction of new legislation has been very successful in reducing the risks posed by LPAI, HPAI and HPAI H5N1 and it has led to the achievement of the four objectives indicated in paragraph 1.

19. EU disease control and zoning measures are largely predictable, as legislation considers very detailed disease scenarios that are further developed in the member States' contingency plans. Immediate implementation of trade restrictions in the event of an outbreak is followed by a repealing of the measures once there is evidence that the outbreak has been successfully eradicated. Both aspects are essential to minimize the impact of the outbreak on trade.

20. The synergistic way in which disease surveillance, control and zoning measures are applied and the fact that those measures are firstly aimed at preventing unnecessary disruption of the EU Single Market are the best guarantees that the European Union can provide to third countries as regards the safety of the poultry commodities originating from the non-affected areas of the European Union.

21. The Commission is available to provide further information on this issue to third countries' trade partners, if requested.

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