

**CLARIFICATION OF ARTICLE 6 OF THE SPS AGREEMENT**

Communication from the European Communities

The following communication, submitted on 28 June 2005, is circulated at the request of the Delegation of the European Communities.

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A. BACKGROUND

1. Several Members have submitted substantial proposals on the regionalization principle<sup>1</sup> (Article 6 in the SPS Agreement) in an attempt to further the discussion on how to best implement it. The European Communities has submitted two documents over the years to the SPS Committee (G/SPS/GEN/101 and G/SPS/GEN/461). These documents provided practical examples of how the principle had been successfully applied in both the animal and plant health areas.

2. However, most other documents submitted so far to the WTO Secretariat deal with the more general question of exactly what type of information Members need in order to successfully implement Article 6, and to what extent the International Standard setting Bodies (ISB) play a role. On this basis, pre-determined guidelines should then be set by the Committee. No Members have replied to the Chairman's request in October 2004 to submit practical examples as the best means to understand how regionalization is applied, and hence the foreseen workshop on the topic has been postponed.

3. At the last SPS Committee meetings (October 2004 and March 2005), the possibility of putting together a list of questions to be submitted to OIE and IPPC was discussed. The Chairman of the SPS Committee had circulated questions to Members in advance of the October 2004 meeting to facilitate discussion. Although the intention had been to reach a decision quickly so the questions could be discussed at the April and May general meetings of IPPC and OIE respectively, no consensus was reached at the March 2005 meeting of the Committee on the type of questions to be submitted to the ISB.

4. Several Members shared the view that it is preferable to await further developments in the ISB before continuing to discuss development of guidelines in the Committee. This would allow determining gaps and overlaps in the work of the ISB and the SPS Committee and thus identifying needs and avoiding duplication. The European Communities fully subscribes to such arguments, but is convinced that guidance by the SPS Committee should remain as general as possible.

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<sup>1</sup> The term "regionalization" in the context of this discussion covers all other terms discussed in this framework (i.e. zoning, compartmentalisation etc.)

5. At the March 2005 Committee meeting, a proposal for a work programme was discussed but not adopted. The major concerns reflected in the document were the need for guidance on how to implement the regionalization principle as well as the need for clear-cut timeframes. The European Communities felt that if the intention was to ensure rapid implementation of the regionalization principle, this proposal would substantially slow down the whole process.

**B. THE EC POSITION ON REGIONALIZATION ...**

6. Notwithstanding the ongoing efforts and discussions at SPS Committee meetings to make progress on the effective operation and implementation of Article 6 of the SPS Agreement, the result so far has been a delay thereof. The Article has already been applied for several years, although only by a few Members, e.g. the European Communities. Sufficient experience exists upon which can be built; of course this should not hinder inclusion of any new developments.

**A flexible and adaptable practice,**

7. The European Communities has systematically applied the principles of regionalization for many years now, both in the animal health and in the plant health areas, and both in the internal market and with third country partners. Substantial experience has been gained from this practice and overall the balance is very positive. It has been demonstrated that by implementing regionalization, a high standard of animal and plant health can be maintained, whilst not interrupting trade more than necessary. In this way the European Communities deems that it has properly implemented Article 6 of the SPS Agreement and recognizes that, in the first instance, it is an excellent tool to contain and manage animal and/or plant diseases.

8. Over the years this experience has led to the application of the principles of regionalization in as flexible a manner as appropriate and as frequently as possible. This entails that guidelines are well-known and the European Communities is happy to share its experience in the matter. In addition, some examples and further guidance can possibly be provided during a workshop at the WTO, later on this year.

**... based on mutual trust and confidence,**

9. The European Communities considers that mutual trust and confidence building are important elements of this process. The competent authority with the responsibility for implementing the zoning policy (the exporting party) is in the best position to define and maintain the zone. Provided the zone is defined and maintained according to the requirements of the importing party in agreement with criteria such as those laid down in the annex, the decision of the exporting party's competent authority shall be the basis for trade.

10. In order to maintain confidence in the competent authority of the exporting party, the exporting party shall inform the importing party on an ongoing basis and without delay of any evolution in the disease situation and any measure taken.

11. In determining whether trade in animals and animal products can occur, the importing party may decide to carry out an inspection in the territory of the exporting party concerning the implementation and enforcement of the zoning provisions. Such an inspection shall be carried out without delay and shall be carried out on the basis of an audit, including an assessment of the performance of the competent authority. The past history of the results of previous checks and controls on importation should also be taken into account.

12. The final decision whether trade in animals and animal products on the basis of zoning can occur lays with the importing party. In consultation with the exporting party, the importing party may

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decide on additional guarantees or risk mitigating factors, such as deboning/maturation, treatment, quarantine, time delays and tests. Decisions on zoning and risk mitigation/management requirements will be made in a manner that ensures the rights and obligations of both importing and exporting parties under the WTO SPS Agreement.

13. Moreover, the basis for successful regionalization is the animal and/or plant health status and its maintenance through adequate surveillance. These conditions must be managed reliably in order not to jeopardise the animal and/or plant health status in the importing country/zone. There is more to it than a mere trade facilitating measure that can simply be negotiated. Another essential prerequisite to achieve a successful regionalization exercise is the genuine commitment of both parties to obtain such a goal. When the importing country/zone has no intentions to apply it properly and solely uses it as a disguise to disrupt trade, and when the exporting country/zone does not take the requests for information seriously, then of course the whole process cannot succeed. Much of this commitment also plays an important role in determining the timeframes in which success can be obtained.

### **... to be applied without undue delay**

14. In this context the European Communities sees no absolute need to set timeframes. If both parties work together effectively, the regionalization process will automatically follow the “without undue delay” route. In view of the very different circumstances that can occur, this process will, however, not always have the same timeframes. In some instances it might be envisaged to set a maximum deadline, which could be decided between both parties (although this may not be very constructive for the reasons mentioned above) in order to finalize the process within a “reasonable” delay.

15. An additional argument for the redundancy of setting timeframes is that it is in the exporting country’s own interest to regionalise in its own territory as quickly as feasible in the first place to contain a disease (outbreak) but also from a trade perspective, in order to have all documentation at hand upon an importer’s request.

16. In an attempt to further the practical implementation of the Article 6 principle, the European Communities of course relies on the latest developments in the ISB, and in particular the OIE and IPPC. In view of this, the SPS Committee should encourage the ISB to start/continue working thoroughly on the issue in order to make possible and facilitate an efficient implementation of Article 6. An important aspect thereof is to ask the ISB to take into account the geographical basis for recognition of regionalization, beyond all newer concepts. On the basis of the ISB's work and their work programmes, the SPS Committee can then define its own work programme.

17. It is clear to the European Communities that SPS guidelines should be limited to administrative rather than technical guidance. Such an SPS guidance document should limit itself to general issues on the process and procedures to follow rather than on the technicalities, as these will differ from one case to another. In this logic, the European Communities sees no absolute need to await the responses from IPPC and OIE to the SPS Committee’s questions, nor the answers to the Chairman’s questions to Members, before proceeding to develop this general guidance. In addition, there is no absolute need to await the new developments by the ISB, as the SPS guidelines should be drafted in such a way that they automatically cover these or that reference is made to the ISB.

## **C. WORK OF THE INTERNATIONAL STANDARD- SETTING BODIES**

### **1. OIE**

18. Article 1.3.5.1 of the Office International des Epizooties (OIE) Terrestrial Animal Health Code (2004) describes zoning or regionalization (for the purposes of the Code these have the same

meaning) as a procedure implemented by a country to define geographical areas of subpopulations of different animal health status within its territory for the purpose of international trade in accordance with the relevant chapters of the Code.

19. Therefore the implementation of Art. 6 of the SPS Agreement should take into account all new developments in OIE.

## **2. IPPC**

20. The term “regionalization” has not been explicitly referred to in the International Plant Protection Convention (IPPC) text, but some articles thereof are nevertheless of direct relevance (see document G/SPS/GEN/529). In this respect the terms “pest free area” and “area of low pest prevalence” are used. Also many International Standards for Phytosanitary Measures (ISPMs) have relevance to regionalization (see also document G/SPS/GEN/529) although the concept is not explicitly mentioned. The most important ones are ISPM 4 (Requirements for the establishment of pest free areas) and the recently (April 2005) adopted ISPM on “Requirements for the establishment of areas of low pest prevalence”. In ISPM 1, which is currently under revision, a new principle concerning “administrative delays” is proposed.

21. During the seventh meeting of the Interim Commission on Phytosanitary Measures (ICPM), an open-ended working group on regionalization was convened. The ICPM decided *inter alia* that a feasibility study be undertaken on the international recognition of pest free areas, which would take into account legal, technical and economic factors and assess feasibility and sustainability of such a system. It was further decided that a concept ISPM “Guidelines for the recognition of pest free areas and areas of low pest prevalence” would be developed urgently. The ISPM would provide general guidance for the recognition process but would not include specified timelines. Notwithstanding this, the European Communities has already applied the principle both in the own internal market as for some third countries (see G/SPS/GEN/101 and G/SPS/GEN/461).

22. In addition, the implementation of Article 6 of the SPS Agreement should take into account all new developments in IPPC.

## **D. CONCLUSION**

23. The European Communities hopes that guidelines such as those provided in the annex to this document can assist WTO Members to successfully implement the principles of Article 6 of the SPS Agreement.

## ANNEX

### RELEVANT PRINCIPLES AND GUIDELINES TO EFFECTIVELY IMPLEMENT THE PROVISIONS OF ARTICLE 6 OF THE SPS AGREEMENT

#### Regionalization on animal health issues

1. In an attempt to further the ongoing discussion on regionalization in the SPS Committee, the European Communities makes use of the following guidance to implement the principle of Article 6. The overall intention hereof is to convince Members that in principle, bilateral arrangements on regionalization can easily be transposed to a multilateral one when using these general guidelines and hence facilitate trade considerably.
2. The following clarifies in the simplest way what steps need to be taken to apply the principles of Article 6 of the SPS Agreement in the animal health area.
3. Certain principles should be used as criteria for applying and assessing zoning and regionalization (for simplicity the term zone is used henceforth). A very important element to keep in mind is that in terms of their level of relevance, these principles are interdependent and variable, and depend on the epidemiology of the disease in the area in which zoning is applied.
4. Their application and assessment depend on factors such as:
  - OIE notifiable diseases;
  - basic scientific knowledge of the epidemiology of the disease, in particular as regards animals and commodities causing spread of disease;
  - the specificity of the zones:
    - Geographical factors,
    - (Micro) climatological factors,
    - Infrastructural factors,
    - Environmental factors.

#### **A. ZONES OF DIFFERENT HEALTH STATUS**

- (a) Zones may be established in the course of eradication measures to control an outbreak of a disease including zoonoses or,  
  
Zones refer to the presence or absence of the disease / pathogen in a zone, different prevalence of the disease in zones or the control measures (including vaccination) in place in the zones.
- (b) Zones of different health status are separate and distinct. The following zones can be distinguished: infected zone, free zone, buffer zone, control programme/surveillance zone, zones with a certain prevalence and vaccinated zones.

#### **B. BORDERS OF THE ZONE**

- The function of the borders is to protect and/or define the free/buffer/control zone;
- The borders of the zones may be legal, natural or artificial (geographical/physical) barriers;
- Legal borders are legally determined for the competence of an administration such as countries, states, provinces, communes, other administrative entities such as shires, divisions, etc;

- Natural borders include mountains, rivers, seas, lakes, etc;
- Artificial borders include physical features such as roads, canals, railways, and intangible lines such as geographic information system coordinates;
- Regardless of the type of border used, the zone status of each animal and each farm or management unit should be clear. The choice of the type of borders should always take into account the best available option or combination of options.

**C. LEGISLATION**

- Effective legislation must be in force and available to enable the establishment, maintenance and control of the zones and their borders;
- Effective legislation must be available for movement controls and temporary movement restrictions under conditions to be determined by the competent authority for all susceptible animals and animal products and risk material (where relevant);
- Effective legislation must be available for imposing actions to control the disease in the zone and to manage the zones (surveillance, sampling etc);
- The criteria for this legislation are that:
  - it must allow establishment or lifting of zones without delay,
  - it must not be hindered by procedural/competence/budget problems,
  - it must be risk based and flexible, reflecting the different levels of risk.

**D. POWERS AND PERFORMANCE OF THE COMPETENT AUTHORITY**

- In most cases the competent authority is the official veterinary service but may be any service that has been given this responsibility. The competent authority must be able to count on an effective co-operation with the police, army and any other services necessary for the enforcement of the measures;
- The competent authority should be a central service with central power and, in case of decentralised power, (such as federal states and territories or autonomous regions) structured provisions and legislation should be available to ensure an appropriate interregional co-operation.

**E. DISEASE REPORTING**

5. The disease for which zoning is carried out must be notifiable or reportable. Quality of disease reporting/notification depends on:

- disease surveillance, early investigation and reporting;
  - legal provisions for the disease being notifiable/reportable to the competent authority;
  - public awareness;
  - history of disease occurrence;
  - compensation provisions in case of obligatory eradication measures;
  - legal penalties in case of non-compliance.
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**F. EPIDEMIOLOGICAL INVESTIGATIONS**

6. Investigations should take into account the epidemiology of the disease under consideration. For diseases that can be transmitted by contagious means, investigations should focus on tracing forwards and backwards from positive disease findings. For non-contagious diseases the investigation should take into account *inter alia* relevant information related to possible vectors.

7. The effectiveness of these investigations depends on:

- Epidemiological knowledge of a given disease in the zone under consideration;
- Experience, performance and power of the competent authority;
- Performance of the laboratories;
- Knowledge of trade structures and patterns;
- Knowledge of degree of risk posed by feral animal reservoirs;
- Quality of record keeping systems;
- Stability of pathogen or vector systems;
- Traceability of animals and animal products (where appropriate) depends on good identification and/or registration systems.

**G. RELIABILITY OF LABORATORY PROCEDURES**

- Reliability of laboratory procedures is crucial for confirmation of diagnosis, epidemiological investigations, surveillance, and movement controls.
- Reliability must be judged in qualitative and quantitative terms. Laboratory capacity and speed of reporting may be crucial in certain circumstances.

**H. MOVEMENT CONTROL AND TRADE RESTRICTIONS**

- Movement control concerns movements within and between zones.
- For diseases that can be spread by contagious means, the stability of a certain disease status in a zone depends on an effective movement control, which in turn depends on:
  - Performance and power of the competent authority and its co-operation with other services;
  - Traceability of animals and animal products via identification and/or registration systems;
  - Quality of record keeping systems.
- For diseases that cannot be transmitted by contagious means, the value of movement controls on animals or animal products depends on the epidemiology of the disease under consideration.

**I. LEVEL OF SURVEILLANCE**

- To effectively manage the zones, surveillance must be carried out inside and outside the different zones.
- Surveillance programs should consider the epidemiology of the disease, and may include active and passive surveillance, as appropriate according to scientific standards.
- Confirmed and suspected cases should be followed by epidemiological investigations and surveillance.

- Surveillance programs should be designed according to
  - the disease agent as regards:
    - surveys for evidence of the agent,
    - routine sampling on farms, markets and abattoirs,
    - sentinel animal and vector trapping programs,
    - banking of samples for retrospective surveys,
    - analysis of laboratory records;
  - the host population as regards:
    - demographics,
    - movement and trade patterns,
    - interaction between domesticated and wild animals,
    - animal identification and registration systems,
    - management factors;
  - environmental factors as regards:
    - air and quality,
    - vector distribution and competence,
    - topography,
    - meteorology,
    - degree of uniformity of the above;
  - infrastructure as regards:
    - feed distribution,
    - marketing, distribution and slaughter of animals,
    - pharmaceutical and other relevant industries,
    - veterinary and practice;
  - measures taken in the zone – see below.

#### **J. MEASURES IN THE ZONES**

8. If disease is detected in a free/buffer/control zone, the status of that zone must be reassessed. Scientifically supportable measures may be taken to protect or re-establish the status of the zone, including:

- stamping out,
- movement control,
- stand still,
- vaccination (including safety of vaccines used).

#### **K. CONTROL OF ENTRY**

9. Zones of higher health status should be protected from disease incursions by measures that consider the epidemiology of the disease and are consistent with international guidelines. These measures may include controls on the importation of animals, genetic material, animal products, fomites, animal feeds including swill, biologics and border audit (as appropriate). These controls are intended to apply (where appropriate) to the boundary of a free zone, which may or may not be a national border.

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**L. NOTIFICATION TO THE OIE**

10. Where applicable, the party involved notifies the occurrence of the disease to the OIE in accordance with OIE rules.

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