

IMPLEMENTATION OF ARTICLES 70.8 AND 70.9

Responses from Uruguay

The Secretariat has received from the delegation of Uruguay the following communication, dated 5 July 1999, concerning the questions posed by the United States and circulated in document IP/C/W/113 and the questions posed by the European Communities and their member States and circulated in document IP/C/W/137. The communication also points out that these replies supplement Uruguay's earlier replies to the questions posed by the United States which were circulated in document IP/C/W/121.

1. Applications for exclusive marketing rights must be submitted to the General Directorate of Trade (Ministry of the Economy and Finance):

General Directorate of Trade
Colonia 1206 – 2do piso
Tel.: (00-5982) 902.03.19, 902.03.39, 902.10.13
Fax: (00-5982) 902.17.26
E-mail: coexdir@tips.org.uy

2. Under the legislation in force, fees are not charged for granting exclusive marketing rights for a product or family of products.
3. Taking into account the provisions of Decree 500/91,¹ in particular, its Articles 15, 20, 23, 24, 56, 63, 75, 78, 106 and 119, the administrative procedure to be followed in the event of an application for exclusive marketing rights may be described, by way of example, as set out below:

The administrative procedure is initiated at the request of the interested party who must make a specific application for exclusive marketing rights indicating the name and address of the applicant for notification purposes. If the application is signed by more than one interested party, it must designate the person responsible for dealing with the administration. If he is acting on behalf of another party, a power of attorney or authorization must be enclosed.

The legal and factual basis of the application must be set out clearly and precisely. The applicant may attach the documents in his possession, a certified copy or a simple photocopy which the administration will certify immediately after comparing it with the original, which the interested party must produce and which is returned to him after certification. If there are difficulties associated with the number or nature of the documents to be certified, the document administration unit may retain the originals, after issuing the appropriate receipts to

¹ See the notification from Uruguay circulated in document IP/N/1/URY/2/Add.1.

the interested party, for a maximum period of five working days, for the purpose of certifying the corresponding copies. Once these have been certified, the originals are returned to the party concerned. Without prejudice to the above, the administrative body may, at any time, require the production of the original or a notarized copy thereof.

If the documents were issued by the competent public authority of a foreign country, they will be deemed to be authentic in the Republic provided that they have been duly notarized. Moreover, documents that are not in Spanish must be translated by a national public translator.

The agencies concerned advance the proceedings *ex officio*, the corresponding authority taking the appropriate steps and requesting the necessary reports and opinions, without prejudice to any similar action taken by the interested parties.

When a report is requested, the questions which need to be addressed must be indicated clearly and precisely. In the case of exclusive marketing rights, once the technical reports of the Ministry of Health or the Ministry of Livestock, Agriculture and Fisheries have been prepared they must be submitted to the Ministry of Industry, Energy and Mining - National Directorate of Industrial Property – for the purpose of verifying compliance with the requirements of Article 70.9 of the TRIPS Agreement.

Once the substantiation process is complete and the findings show that a decision could be taken against the application, before a resolution is issued, the record of proceedings must be made available to the applicant for a period of ten days.

The right to view the proceedings accorded to the interested parties or their representatives includes not only the right to examine and read the proceedings but also the right to copy or reproduce them by any means, in whole or in part.

The resolution on an exclusive marketing rights application may be appealed through administrative channels and subsequently before the administrative court, so that compliance with the principle of due process is ensured.

The Ministry of the Economy and Finance – General Directorate of Trade must rule on the application within 120 days of the performance of the final act required by the law or regulations applicable. If the authority does not issue a resolution within the time-limit indicated, the application is deemed to be null and void.

Once exclusive marketing rights have been granted, the fact must be made known to the competent agencies and registries through a corresponding government resolution published in the Official Journal.

Under Article 14 of Decree No. 500/91, there are facilities for notification and coordination between the ministries involved (horizontal communication).

4. With reference to how, under Article 70.9 of the TRIPS Agreement, the holder of exclusive marketing rights may enjoy the benefits of such rights, it is pointed out that:

- Once exclusive marketing rights in a product have been granted, under Law No. 16.671,² when third parties submit a request for sanitary approval of the same product directly to the Ministry of Health (MSP) or the Ministry of Livestock,

² See the notification from Uruguay circulated in document IP/N/1/URY/1.

Agriculture and Fisheries (MGAP), as appropriate, the said agencies must follow the procedure laid down. Moreover, the competent services of the MSPM or MGAP, as appropriate, must inform the interested parties of the eventual existence of exclusive marketing rights granted for the product in question.

If the product does not present undue or unacceptable risks for human, plant or animal health or for the environment, sanitary approval will be granted, but the authorization will not take legal effect until the exclusive marketing rights previously granted have lapsed.

- An enterprise that has obtained exclusive marketing rights may take precautionary measures and institute the appropriate civil proceedings against anyone attempting to market the product forming the subject of the exclusive marketing rights.

5. No applications for the granting of exclusive marketing rights have yet been submitted.
