

GENERAL AGREEMENT ON TARIFFS AND TRADE

RESTRICTED

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Special Distribution

Committee on Technical Barriers to Trade

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INFORMATION ON IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

Addendum

The following communication has been received from the delegation of Brazil.

In the health area, two sectors are responsible for the elaboration of technical regulations and standards:

(a) The National Council of Health (Conselho Nacional de Saúde), through Technical Chambers, is charged with the elaboration of technical regulations and standardization, the establishment of concepts and definitions regarding matters of sanitary interest, such as: (1) medicaments, drugs and correlated substances; (2) hemotherapeutic and immunotherapeutic products; (2) narcotic and toxic products; (4) foodstuffs and dietetic products; (5) additives and preservatives (both intentional and accidental); (6) substances related to the technology of production; (7) material for packing, labelling, presenting and preserving products; (8) sampling and analysis; (9) the use of products for assuring the hygiene of food and containers; (10) assuring the hygiene of production sites; (11) stocking, transportation and commercialization of food, medicaments and immunobiologic products; (12) household sanitary items (insecticides and raticides, detergents and antiseptics); (13) cosmetic products; (14) perfumes; (15) personal and environmental hygiene products.

(b) The National Secretariat for Sanitary Vigilance (Secretaria Nacional de Vigilância Sanitária - SNVS) of the Ministry of Health (Ministério da Saúde - MS) - for the areas mentioned above - is charged with the elaboration and supervision of the compliance of the technical regulations and standards in the sanitary field, and also is responsible for the health vigilance in ports, airports and frontier areas.

In the present administration, the Technical Chambers are deactivated. The responsibility for the elaboration of technical regulations and standards has been centralized only in the SNVS, through its Technical Divisions.

This system is supported specially by the national reference laboratory - National Institute for Health Quality Control (Instituto Nacional de Controle de Qualidade em Saúde - INCQS) set up in the framework of Oswaldo Cruz Foundation (Fundação Oswaldo Cruz - FIOCRUZ), part of the Health Ministry.

The INCQS, as reference laboratory, supports SNVS backing its technical and laboratorial activities, in addition to its responsibility for the elaboration of technical criteria for carrying out tests and laboratory analysis in quality control of products object of the sanitary legislation.

All legislation from the Technical Chambers, ratified by the Minister of Health, and all acts pertaining to sanitary legislation from other competent sectors, are published in the Official Federal Journey (Diário Oficial da União - D.O.U.) and can be found in the major Brazilian libraries, compiled in the following publications:

- (a) "Legislação Federal do Setor Saúde"
Consultoria Jurídica do Ministério da Saúde - 1978.
Four volumes containing all legislation from 1935 to 1978;
- (b) "Vigilância Sanitária" - compilation of all legislation pieces in force related to Sanitary Legislation.
Five volumes containing all legislation from 1956 to 1981.

The Ministry of Health (Ministério da Saúde) and the Informatic and Data Processing Center of the Federal Senate (Centro de Informática e Processamento de Dados do Senado Federal - PRODASEN), are compiling for computer use all legislation pieces in force in the period 1982-83, concerning sanitary vigilance. The objective of this work is to keep such an information system up to date and also to include progressively legislation from past years so as to have in the PRODASEN system a complete collection of legislation in this field.

Interested parties may address questions to any computer terminal linked to the PRODASEN system or to:

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The Center of Documentation of the Health Ministry, upon request, may furnish information (both of a general or specific nature), in one or two days. Such information is available in Portuguese only.