AGENDA ITEM: PLACING BIOCIDAL PRODUCTS ON THE MARKET
Directive 98/8/EC

Country Session: The Republic of TURKEY
29 May - 02 June 2006

CONTENT

- Legislative Framework
- Competent Authorities
- Authorisation Procedures
- Inspection System
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LEGISLATIVE FRAMEWORK

- Public Hygiene Law No: 1593
- Regulation on Special Qualifications of Food, Goods and Supplies Concerning General Health
- Circular on Authorisation Requirements for Pesticides and Disinfectants

LEGISLATIVE FRAMEWORK (CONT'D)

- By-law on Medical and Pharmaceutical Products Authorisation
- By-law on The Main Aspects of Applying Pesticides in the Public Health Field
- Law No. 3285 on Animal Health Control
- By-law on Veterinary Equipment and Medical Preparations

COMPETENT AUTHORITIES

Main Group 1: Disinfectants and general biocidal products

Ministry of Health: Human hygiene biocidal products, disinfectants, food and feed area disinfectants, drinking water disinfectants

Ministry of Agriculture and Rural Affairs: Veterinary hygiene biocidal products

Main Group 2: Preservatives (no application up to now)

Main Group 3: Pest Control

Ministry of Health: Rodenticides, Insecticides and acaricides, Repellents and attractants, Molluscicides,

Piscicides and Avicides (no application up to now)

Main Group 4: Other Biocidal Products (no application up to now)

AUTHORISATION PROCEDURES

- Circular No.5677 based on Public Hygiene Law and Regulation on Special Qualifications of Food, Goods and Supplies Concerning General Health

  Authorisation for manufacturing and importing of some types of biocidal products including insecticides, rodenticides, molluscicides, repellents, attractants, disinfectants and their active substances by the Ministry of Health

- By-law on Veterinary Equipment and Medical Preparations

  Authorisation for veterinary disinfectants and their active substances by the Ministry of Agriculture and Rural Affairs

AUTHORISATION PROCEDURES (CONT'D)

According to the Communiqué for Standardization of Foreign Trade relevant competent authorities ask for additional documents in case of authorisation for import products:

- Proforma invoice
- Control Document
- Health and Free Sale Certificate
- Analysis Certificate (prepared by manufacturer)

AUTHORISATION PROCEDURES (CONT'D)

Application Form for Authorising Biocides

- Applicant (name and address)
- Manufacturer of the biocidal product (name, address)
- Trade name of the biocidal product
- Composition of the biocidal product
- Function of the biocidal product
- User (industrial, professional, general public)
- Method of use
- Physical state of the biocidal products
- Results of chemical and physical analysis and analysis methods
- Biological efficiacy tests of biocidal products

AUTHORISATION PROCEDURES (CONT'D)

Application Form for Authorising Biocides

- Stability tests of biocidal products
- Data on toxicity and ecotoxicity for the active substance
- Label in Turkish
- Subcontracting conditions (if intended to be manufactured under subcontract)
- Copy of the Diploma of the Responsible Manager
- Contract of the Responsible Manager
- Capacity report
- Flowchart of production/formulation of the product

AUTHORISATION PROCEDURES (CONT'D)

Labelling

- Name and address of the importing/manufacturing company
- Trade name of biocidal product
- 100 % Formulation and type of preparation (Dust, Granule, liquid etc.)
- Net weight
- Date of issue and number of permit
- Date of production and expiration date
- Charge number
- Controlled harmful organisms (*mosquito*, *musca domestica* etc.)
- Method and dosage of usage
- Poisoning symptoms in humans and domestic animals
- First aid directions
- Antidote
- Poison symbol, if appropriate

AUTHORISATION PROCEDURES (CONT'D)

Principles for the Evaluation of Dossiers

- The competent authority examines the dossier according to the requirements listed in the application form
- In case of data gaps, the competent authority asks for completion
- The complete dossier is send to the commission in competent authority for evaluation
- In certain cases additional data may be required by the commission
- Laboratory tests for the biocidals products are conducted by the designated laboratories
- Taking into consideration of the commission's evaluation the competent authority decides on;
  - whether or not the biocidal products are authorised for manufacturing or importing
  - additional data requirement.

INSPECTION SYSTEM

- Provincial Directorates of the Ministry of Health and Ministry of Agriculture and Rural Affairs conduct inspections in cases of complaints, non-compliance and accidents
- The ministries have the authority to ban manufacturing and import of products, to cancel authorisations and to withdraw products from the market.

STUDIES AND PROGRESS

Twinning Project on Harmonisation and Implementation of the Biocidal Products Directive

Objectives

- Establishment of the inventory of the biocidal products
- Establishment of the competent authority(ies)
- Preparation of EU harmonised national legislation
- Preparation of a detailed action plan
- Training programmes
- Preparation of business plan for RSHC
- Support for accreditation procedures at RSHC laboratory
- Support the RSHC laboratory on technical specifications of equipments

STUDIES AND PROGRESS (CONT'D)

- Assessments of the existing legal, institutional and administrative structures have been initiated.
- A working group has been established within the Ministry of Health with the aim of transposition of the Directive.
- An inventory study for biocidal products has been initiated.

Thank you for your attention