

## Food and Drug Administration, HHS

## § 26.78

new or additional procedures within the scope of that agreement and the relevant sectoral annex.

### § 26.74 Preservation of regulatory authority.

(a) Nothing in this part shall be construed to limit the authority of a party to determine, through its legislative, regulatory, and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment; for consumers; and otherwise with regard to risks within the scope of the applicable subpart A or B of this part.

(b) Nothing in this part shall be construed to limit the authority of a regulatory authority to take all appropriate and immediate measures whenever it ascertains that a product may:

(1) Compromise the health or safety of persons in its territory;

(2) Not meet the legislative, regulatory, or administrative provisions within the scope of the applicable subpart A or B of this part; or

(3) Otherwise fail to satisfy a requirement within the scope of the applicable subpart A or B of this part. Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the regulatory authority takes such action, it shall inform its counterpart authority and the other party within 15 days of taking such action, providing its reasons.

### § 26.75 Suspension of recognition obligations.

Either party may suspend its obligations under subpart A or B of this part, in whole or in part, if:

(a) A party suffers a loss of market access for the party's products within the scope of subpart A or B of this part as a result of the failure of the other party to fulfill its obligations under this part;

(b) The adoption of new or additional conformity assessment requirements as referenced in § 26.73(e) results in a loss of market access for the party's prod-

ucts within the scope of subpart B of this part because conformity assessment bodies (CAB's) designated by the party in order to meet such requirements have not been recognized by the party implementing the requirements; or

(c) The other party fails to maintain legal and regulatory authorities capable of implementing the provisions of this part.

### § 26.76 Confidentiality.

(a) Each party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this part.

(b) In particular, neither party shall disclose to the public, nor permit a conformity assessment body (CAB) to disclose to the public, information exchanged under this part that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.

(c) A party or a CAB may, upon exchanging information with the other party or with a CAB of the other party, designate the portions of the information that it considers to be exempt from disclosure.

(d) Each party shall take all precautions reasonably necessary to protect information exchanged under this part from unauthorized disclosure.

### § 26.77 Fees.

Each party shall endeavor to ensure that fees imposed for services under this part shall be commensurate with the services provided. Each party shall ensure that, for the sectors and conformity assessment procedures covered under this part, it shall charge no fees with respect to conformity assessment services provided by the other party.

### § 26.78 Agreements with other countries.

Except where there is written agreement between the parties, obligations contained in mutual recognition agreements concluded by either party with a party not a party to the agreement from which this part is derived (a third party) shall have no force and effect with regard to the other party in terms