



HARMONIZED SYSTEM  
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O. Eng.

Brussels, 19 February 2008.

CLASSIFICATION OF THE BIOLOGICAL DUAL-USE ITEMS OF THE CONVENTION ON  
THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF  
BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND  
ON THEIR DESTRUCTION  
(Item VI.4 on Agenda)

Reference documents :

NR0713E1a (RSC/36)

NR0722E1b, Annex E/1 (RSC/36 – Draft Report)

I. BACKGROUND

1. At its 36<sup>th</sup> Session, the HS Review Sub-Committee examined the possible amendment of the Nomenclature to provide separately for certain "biological dual-use items", on the basis of a proposal by the Research Group for Biological Arms Control - Carl Friedrich von Weizsäcker Centre for Science and Peace Research, of the University of Hamburg (Germany) (hereinafter "the Research Group"), as set out in Doc. NR0713E1a.
2. The proposal consisted essentially of a list of items which, according to the Research group, should be identified in the HS Nomenclature by individual subheadings. The proposed list contained biotechnology equipment, i.e., equipment for the production of microbial pathogens and toxins, downstream processing equipment such as filters, centrifuges, separators, dryers, milling equipment, biosafety and sterilization equipment, equipment for research and genetic engineering and dissemination equipment, as well as plant inoculation chambers and detection assays. Many of these items concern so-called dual-use items, i.e., goods and technology developed for civilian uses, but which can be used, according to that list, for purposes such as the production of biological weapons or their means of delivery.
3. In order to examine the amendment to the Nomenclature to provide for these "biological dual-use items", the Sub-Committee first considered the current classification of products listed in the proposal of the Research Group.

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4. The Sub-Committee instructed the Secretariat to prepare a list of proposed items to be provided for separately in the HS; this list would be presented to the HS Committee for classification in March 2008. The Secretariat, as far as possible, would indicate its view on the classification of these items in order to support the work of the HS Committee. On that basis a further working document would be prepared for the next session of the Review Sub-Committee in May 2008 which would enable the Sub-Committee to consider the consequences of the proposal.

## II. SECRETARIAT COMMENTS

5. In the following table, the Secretariat has reproduced the relevant information from the list of items which, according to the Research Group, should be identified in the HS Nomenclature by individual subheadings.
- a. The first column contains information on the items to be more specifically identified and its typical use;
  - b. The second column lists the items which, according to the Research Group, should be identified in the HS Nomenclature by individual subheadings (see Doc. NR0713E1a (RSC/36));
  - c. The third column contains the HS subheadings suggested by the Secretariat for the classification of the items mentioned in the second column;
  - d. The fourth column contains the Secretariat's comments regarding the classification of the items.

Description of item and its typical use	Item to be identified individually under an amended HS nomenclature	HS codes	Secretariat's comments
<b>Production</b>			
<b>Fermenters</b> Equipment in which fermentation (growth) of micro-organisms takes place. The equipment needs to provide a standardized environment of pH value, oxygen content, nutrient level, etc. The term "fermenter" includes bioreactors, chemostats, and continuous flow fermentation systems. It includes stainless steel vessels equipped with a jacket, a	Fermenters with a vessel capacity : <ul style="list-style-type: none"> <li>• Up to 5 liters;</li> <li>• Greater than 5 up to 20 liters;</li> <li>• Greater than 20 up to 100 liters;</li> <li>• Greater than 100 up to 1,000 liters;</li> <li>• Greater than 1000 liters.</li> </ul> Continuous flow fermentation systems with a volume: <ul style="list-style-type: none"> <li>• Up to 2 liters per hour;</li> <li>• Greater than 2 liters per hour.</li> </ul>	8419.89	Heading 84.19 includes laboratory equipment, whether or not electrically heated, for the treatment of materials by a process involving a change of temperature such as heating, cooking, roasting, distilling, rectifying, sterilising, pasteurising, steaming, drying, evaporating, vaporising, condensing or cooling, other than machinery or plant of a kind used for domestic purposes.  See also the HS Explanatory Note to heading 84.19, Part (VII), on page XVI-8419-9, on specially designed laboratory apparatus and equipment.

Description of item and its typical use	Item to be identified individually under an amended HS nomenclature	HS codes	Secretariat's comments
<p>stirring system and ports for process parameter probes and capable of in-situ sterilization. This also includes single-use fermentation systems. Widely used in brewing and biotechnology, medical and pharmaceutical industries.</p>			
<p><b>Orbital or reciprocal shakers</b> To cultivate small quantities of micro-organisms, for R &amp; D or seed cultures for larger scale fermentation. The cabinet holds a number of glass conical flasks that are shaken. The flasks contain growth media and micro-organisms. The cabinet is contained in a temperature controlled enclosure.</p>	<p>Orbital or reciprocal shakers and shaking incubators, designed for use with biological material, regardless of size.</p>	<p>8479.89 or 8419.89</p>	<p>If temperature control is subsidiary, classification of the equipment under heading 84.79 could be considered (application of Note 2 (e) to Chapter 84).</p> <p>If temperature control is <u>not</u> subsidiary, the equipment would fall under heading 84.19.</p>
<p><b>Shaking incubators</b> To cultivate small quantities of micro-organisms, for R &amp; D or seed cultures for larger scale fermentation. The temperature controlled cabinet holds a number of glass conical flasks that are shaken. The flasks contain growth media and micro-organisms.</p>		<p>8479.89 or 8419.89</p>	<p>See above. Note 2 (e) to Chapter 84 : Heading 84.19 does not cover machinery or plant, designed for a mechanical operation, in which a change of temperature, even if necessary, is subsidiary.</p>
<p><b>Complex media</b> Food containing all necessary nutrients for the growth of micro-organisms.</p>	<p>Prepared culture media for development of micro-organisms designed for production purposes.</p>	<p>3821.00</p>	<p>Prepared culture media for the development or maintenance of micro-organisms (including viruses and the like) are classified in heading 38.21.</p>

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<p><i>Note: Countries may increasingly produce growth media indigenously; hence this indicator shows also the level of indigenous biotechnological capabilities.</i></p>	<p>Prepared culture media for development of micro-organisms designed for diagnostic purposes.</p>		
<b>Downstream Processing</b>			
<p><b>Continuous and batch centrifuges and separators, including rotors</b> For the separation of solids from liquid. Used to harvest micro-organisms from liquor or concentrate soluble materials in fermentation liquor. An example is the removal of pulp from liquids such as clarifying orange juice.</p>	<p>Centrifuges and specially designed rotors therefore, regardless of size, having all of the following characteristics:</p> <ul style="list-style-type: none"> <li>• Designed for use with biological material;</li> <li>• Capable of in-situ steam sterilization in a closed state.</li> </ul> <p>Batch centrifuges and separators, including rotors, with a rotor capacity of:</p> <ul style="list-style-type: none"> <li>• Less than 25 liters;</li> <li>• 25 liters or greater.</li> </ul> <p>Continuous centrifugal separators or decanters regardless of size.</p>	<p>8421.19</p>	<p>See the HS Explanatory Note to heading 84.21, Part (I), on page XVI-8421-2 :</p> <p>The heading includes :</p> <p>[...]</p> <p>(8) Separators for yeast cultures.</p> <p>(9) Centrifuges for the chemical industry (e.g., high-speed extractors for antibiotics).</p> <p>(10) Centrifuges, mainly used in laboratories, in which liquids are separated in superimposed layers ready for decantation.</p> <p>(11) Centrifuges for separating the plasma from blood.</p>
<p><b>Cross-flow and tangential filtration equipment</b> For the large scale separation of solids from liquid, used to harvest micro-organisms from liquids or concentrate soluble materials in fermentation liquor. Used extensively in the food processing industry, e.g. to remove pulp from liquor such as clarifying orange</p>	<p>Cross-flow and tangential filtration equipment designed for use with biological material with a filter area</p> <ul style="list-style-type: none"> <li>• Under 0,2 m<sup>2</sup></li> <li>• Equal to or greater than 0.2 m<sup>2</sup></li> </ul> <p>and component filter cartridges therefore.</p>	<p>8421.29</p> <p>[with the exception of component filter cartridges – filtering elements (ceramics, textiles, felts, etc.) are classified according to their constituent material]</p>	<p>See the HS Explanatory Note to heading 84.21, Part (II) on page XVI-8421-3. Heading 84.21 covers filters and purifiers of all types (physical or mechanical, chemical, magnetic, electro-magnetic, electrostatic, etc.). The liquid filters separate solid, fatty, colloidal, etc., particles from a liquid, for example, by passing it through a sheet, membrane or mass of porous material (e.g., cloth, felt, wire-cloth, skin, stoneware, porcelain, kieselguhr, sintered metallic</p>

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juice.			powders, asbestos, paper pulp, cellulose, charcoal, animal black, sand). In the treatment of drinking water, some of these materials (e.g., porcelain and charcoal) remove bacteria, etc., in the process of filtration; filters using these materials are therefore sometimes called 'water purifiers'. Filters are also used to eliminate liquids from materials in the form of a slurry (e.g., from ceramic materials or ore concentrates). The heading covers liquid filters whether of the gravity, suction (or vacuum) or pressure types. The heading <b>does not</b> , however, <b>include</b> filter funnels, milk strainers, vessels, tanks, etc., simply equipped with metallic gauze or other straining material, nor general purpose vessels, tanks, etc., even if intended for use as filters after insertion of a layer of gravel, sand, charcoal, etc.
<p><b>Spray drying equipment</b> To dry material in order to prevent breakdown or degradation of product. Used extensively for large scale processing of bio-material, e.g. foodstuffs and micro-organisms. Spray and freeze-drying are the two major ways in bioweapons programmes to dry agents for weapons purposes.</p>	<p>Spray drying equipment</p> <ul style="list-style-type: none"> <li>• Designed for use with biological material;</li> <li>• Not designed for use with biological material.</li> </ul>	8419.39	Heading 84.19 includes spray dryers (see the HS Explanatory Note to heading 84.19, Part (III), Item (F) on page XVI-8419-7).
<p><b>Freeze-drying (lyophilisation) equipment</b> To dry material in order to prevent</p>	<p>Freeze-drying equipment with a condenser capacity:</p> <ul style="list-style-type: none"> <li>• Less than 5 kg of ice in 24 hours;</li> </ul>	8419.39	Heading 84.19 includes laboratory lyophilisation apparatus and freeze drying units. These are used for the stabilising and preservation by

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breakdown or degradation of product. Used extensively for large scale processing of bio-material, e.g. vaccines.	<ul style="list-style-type: none"> <li>5 kg of ice in 24 hours or greater; and specially designed vacuum chambers therefore.</li> </ul>		dehydration of biological specimens such as antitoxins, bacteria, viruses, plasma and serums. The specimens are frozen, and then allowed to reheat gently under very low pressure when the ice sublimates leaving the dehydrated product (see the HS Explanatory Note to heading 84.19, Part (III), Item (B) on page XVI-8419-7).
<b>Drum drying equipment</b> Solid-liquid separation device. Used to harvest micro-organisms. However, not best suited to do this. Is, in combination with appropriate milling equipment, an alternative for spray and freeze-drying of bioweapon agents.	Drum dryers: <ul style="list-style-type: none"> <li>Aseptic (i.e. fully contained and sterilisable);</li> <li>Not designed for use with biological material.</li> </ul>	8419.39 or 8421.19	If it uses centrifugal force to separate components, the equipment is classified in heading 84.21; otherwise the equipment is classified in heading 84.19. See the HS Explanatory Note to heading 84.19, Part (III), Item (D) on page XVI-8419-7, as well as the HS Explanatory Note to heading 84.21, Part (I), on page XVI-8421-2.
<b>Milling equipment</b> Primarily used in the pharmaceutical industry for the production of fine powder that is tableted.	Size reduction equipment (including milling and grinding equipment) capable of producing powders with a mean particle size of 15 microns or less.	8437.80	See the HS Explanatory Note to heading 84.37, Part (II), on page XVI-8437-2.
<b>Biosafety and Sterilization</b>			
<b>HEPA Filters</b> These are consumable items for biological or medical laboratories that have biological safety cabinets. Also used in large numbers by clean room air handling facilities. Now used in household air conditioning systems and vacuum cleaners.	Filters: <ul style="list-style-type: none"> <li>HEPA (High Efficiency-Particulate Air);</li> <li>ULPA (Ultra Low Penetration Air);</li> <li>SULPA (Super-ULPA)</li> </ul> with a DOP rating of 99.997% (at 0.3 micron) or higher.	7019.32	Filtering elements are classified according to their constituent material. Generally, the filter media in High Efficiency Particulate Air (HEPA) Filters is composed of a mat of randomly arranged glass fibres. HEPA Filter media manufactured of microfiber-glass is classified in heading 70.19. Filtering elements manufactured of other materials are classified as follows :

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			<ul style="list-style-type: none"> <li>- of felt : heading 56.02;</li> <li>- of nonwoven : 56.03;</li> <li>- of other textiles : heading 59.11; and</li> <li>- of ceramics : heading 6909.</li> </ul>
<p><b>Biological safety cabinets</b> Or isolators with similar performance standards, e.g. flexible isolators, dry boxes, anaerobic chambers, glove boxes, or laminar flow hoods, and other equipment that can be modified by the addition of HEPA filter units to provide the equivalent level of containment.</p>	<p>Class II and Class III biological safety cabinets or isolators.</p> <p>Rubber gloves specially designed for use with Class III or Class IV biological safety cabinets.</p>	<p>8414.60 or 8414.80 (according to maximum horizontal side)</p> <p>8479.89</p> <p>4015.19</p>	<p>Laboratory hoods, glove boxes. See also Classification Opinion 8414.60 or 8414.80/1, laminar airflow cabinets.</p> <p>Separately presented rubber gloves</p>
<p><b>Autoclaves</b> All microbiological laboratories and hospital departments dealing with clinical waste will have at least one autoclave with an internal volume of 1 cubic meter or more. Also for sterilizing instruments, media, etc.</p>	<p>Double ended autoclaves.</p>	<p>8419.20</p>	<p>Heading 84.19 includes specially designed laboratory apparatus and equipment, generally small in size (autoclaves, distilling, sterilizing or steaming apparatus, dryers, etc.), See the HS Explanatory Note to heading 84.19, last paragraph before Parts, on page XVI-8419-9.</p>
<p><b>Pass through sterilization systems</b> For sterilization of waste water.</p>	<p>Pass through sterilization systems.</p>	<p>8419.89</p>	<p>Sterilizing apparatus is described in the HS Explanatory Note to heading 84.19, Part (VI), on page XVI-8419-8.</p>
<p><b>Positive pressure air-fed suits</b> Widely used for the protection of personnel exposed to hazards, i.e. smoke, fire, chemical spill, etc.</p>	<p>Positive pressure air-fed suits, incorporating respirators which would provide protection from exposure to pathogens.</p> <p>Half suits, helmets and respirators which would provide</p>	<p>61.13</p> <p>6210.40 6210.50</p>	<p>Protective suits, not combined with breathing apparatus :</p> <ul style="list-style-type: none"> <li>- Made up of knitted or crocheted fabrics of heading 59.03, 59.06 or 59.07;</li> <li>- Made up of fabrics of heading 56.02, 56.03, 59.03, 59.06 or 59.07.</li> </ul> <p>Heading 90.20 includes anti-</p>

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	protection from exposure to pathogens capable to be incorporated into positive pressure air-fed suits.	9020.00	contamination protective suits, incorporating breathing apparatus.
<b>Research and Genetic Engineering</b>			
<b>Automatic peptide synthesizers</b> Are useful in toxin production and indicator for technical capability	Automatic peptide synthesizers.	8479.89	Machines having an individual function, not specified or included elsewhere in Chapter 84.
<b>Dissemination</b>			
<b>Nose-only aerosolization equipment</b> Used in R & D to study the effect of inhalation of pharmacologically active molecules.	Nose-only aerosolization equipment, but excluding devices for personal prophylaxis or therapy for medical conditions.	9031.80 [or 84.24 or 90.18]	Complete apparatus, including measuring and testing ability. Otherwise heading 84.24 or 90.18. It is to be noted that aerosol therapy apparatus of heading 90.19 is used for the application of a therapy agent in the treatment of certain diseases.
<b>Aircraft sprayers</b> An aircraft crop sprayer takes a pressurized liquid feed and forces it out through fine nozzles. This has the consequence of producing a fine mist capable of covering all parts of the foliage. Aircraft sprayers can cover a large area quickly. Major use in crop spraying of pesticides. Militarily the most effective way for dispersal of bioweapons agents.	Aerosol disseminators but capable of dispersing aerosols with an initial mean droplet size of 50 microns or less at a flow rate exceeding 1 liter of liquid suspension per minute or 10 g of dry material per minute, and specially designed components (nozzles, tanks, pumps), for fitting to aircraft or Unmanned Aerial Vehicles (UAVs).  Products with the same specification, but specially designed for fitting to aircraft lighter than air vehicles or UAVs.	8424.89	It is to be noted that heading 84.24 does not include, for example, hose pipe nozzles (Section XV, or heading 84.81 if fitted with taps, cocks, valves or other appliances for regulating the liquid flow).
<b>Foggers</b>	Foggers/nebulisers	8424.89	It is to be noted that heading



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<p>Large scale equipment that is capable of producing a fine mist (aerosol) of powder or liquid in to the environment. Used extensively in agriculture for dispersal of insecticides into large enclosed areas, e.g. greenhouses, or more open areas e.g. orchards. Militarily useful for the dissemination of BW agents over a relatively large area, approximately several hundred square meters.</p>	<p>including pulse jet disseminators capable of dispersing aerosols with an ultimate mean particle size of 15 microns or less at a flow rate exceeding 1 liter of liquid suspension per minute or 10 g of dry material per minute, and the following specially designed components:</p> <ul style="list-style-type: none"> <li>• Head unit; and</li> <li>• Nozzle assembly.</li> </ul>		<p>84.24 does not include, for example, hose pipe nozzles (Section XV, or heading 84.81 if fitted with taps, cocks, valves or other appliances for regulating the liquid flow).</p>
<p><b>Aerosol disseminators other than aircraft sprayers or foggers</b></p>	<p>Aerosol disseminators other than aircraft sprayers or foggers.</p>	<p>8424.89</p>	<p>It is to be noted that heading 84.24 does not include, for example, hose pipe nozzles (Section XV, or heading 84.81 if fitted with taps, cocks, valves or other appliances for regulating the liquid flow).</p>
<p><b>Aerodynamic particle-sizing equipment</b> Used to study and characterize aerosols, e.g. size distribution. Essential tool in R &amp; D use in pharmaceutical industry and aerobiology research.</p>	<p>Aerodynamic particle-sizing equipment.</p>	<p>9031.80</p>	<p>Under the assumption that the equipment includes measuring and testing apparatus.</p>
<b>OTHER</b>			
<p><b>Plant inoculation cabinets/chambers</b></p>	<p>Plant inoculation cabinets/chambers providing quarantine.</p>	<p>8419.89 [8436.80]</p>	<p>Equipment can be of the type of "germinators" as described in the HS Explanatory Note to heading 84.36, Part (I), Item (I), on page XVI-8436-2.</p>
<p><b>Detection assays for micro-organisms and</b></p>	<p>Detection assays for micro-organism and toxins, including</p>	<p>9027.10 9027.80</p>	<p>More information is necessary for the classification of this kind of equipment.</p>

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toxins (including immunological and gene probe assays).	immunological and gene probe assays.		

III. CONCLUSION

6. The Committee is invited to examine the classification of the items mentioned in the second column of the Table set out in paragraph 5 above.

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