



**Building Transparency in the World Wide Trade in
Biological Dual Use Equipment**

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Abstract

BWC states parties have been confronted with a lack of transparency right from the birth of the bioweapons control regime in 1972. The lack of reliable information about relevant activities has resulted in violations of the BWC not being discovered and in accusations of non-compliance that were later shown to be wholly unfounded. Increasing transparency, therefore, has been one of the aims of biological weapons controllers for decades.

Information relevant to making judgements about compliance with the anti-bioweapons norm is increasingly available from open sources and therefore, theoretically, transparency should become less dependent on states being forthcoming with information. But so far, open sources have been used only in a haphazard and selective manner. In order to contribute to changing this situation, the Hamburg Research Group for Biological Arms Control has looked at one of the unused open sources of relevant information: international trade data collected on a routine basis for customs purposes. **In this paper we describe a trade monitoring concept for biological dual use equipment which would provide a global overview of countries' capabilities in the biological field and would help to uncover suspicious activities in need of clarification.**

Taking the UNSCOM/UNMOVIC export/import control list as a basis, we developed a list of equipment, the trade with which would need to be monitored. We also identified the Harmonized System (HS) of the World Customs Organisation (WCO) – a system that links a code number to each and every kind of tradable item – as source of global trade data. In order, however, to focus the trade monitoring system properly, amendments to the HS codes would be essential, so that critical items of equipment would be identified clearly and individually. Accordingly, we developed a HS amendment proposal, which was further refined in cooperation with experts from WCO. The amendment proposal – which has received a lot of support from governments, industry and non-governmental experts – needs further discussion in the WCO bodies before it can be put into practice. One way to move the amendment process forward would be for the BWC Review Conference in December 2011 to request the WCO to deal with the amendment proposal further.

The amendment of the HS nomenclature would have economic as well as non-proliferation benefits. It would help to:

- Identify biotechnology items more clearly in customs declarations; and thereby
- Make national export controls more effective and promote the implementation of UN Security Council Resolution 1540 (2004);
- Allow a coordinated view on global trade flows of biological dual use items;
- Provide indications of countries' capabilities in the biological field;
- Allow improved market analysis in the biological area;
- Make trade with biological dual use items more transparent; and
- Allow monitoring trade for signs of suspicious activities related to the development of bioweapons.

Developing our trade monitoring concept further and putting it into practice will, we are certain, contribute to a world that moves away from the threat of misuse of the life sciences for weapons purposes.

1. Introduction

Increasing transparency has been one of the aims of biological weapons controllers for decades. Almost since the international ban on biological weapons came into being in 1972 with the signing of the Biological Weapons Convention (BWC), calls for sufficient information to judge treaty compliance were voiced. Because of the dual use character of most of the activities in biotechnology and the life sciences, information about and the willingness to explain biological activities are essential for building confidence that activities are of a peaceful nature. States have done very little to increase transparency of bioweapons relevant activities, even after the end of the Cold War. This is at least partly due to an increased bioterrorism threat perception. In order to prevent non-state actors with hostile intentions to acquire bioweapons enabling technologies and information, limitations on transfers of agents and equipment, on publications and on scientists' work, and downright classical secrecy seem to be called for. Such secrecy, however, is not reliably attainable, it harms peaceful activities in the life sciences and the biotech industry, and it has given rise to compliance concerns in the past.

Increasingly, information relevant to making judgements about compliance with the anti-bioweapons norm is available from open sources and therefore, theoretically, transparency should be depending less on states being forthcoming with information. But so far, use of open sources has been made only in a haphazard and selective manner. In order to contribute to changing this situation, the Hamburg Research Group for Biological Arms Control has looked at one of the unused open sources of relevant information, international trade data collected on a routine basis for customs purposes. In this paper we describe a trade monitoring concept for biological dual use equipment which, if implemented, would provide a global overview of countries' capabilities in the biological field and would help to uncover suspicious activities in need of clarification.

1.1. Transparency, monitoring, verification and compliance: getting the terms right

The debate on verification, especially in international security policy, is still heavily influenced by the mid-1980s Cold War literature with its focus on the bilateral treaties between the two superpowers. It is commonplace that transparency is quintessential for the effective functioning of international treaty regimes. In order to regulate the behaviour of states and to assess whether a treaty regime is working effectively, actors must have information about the activities they want

to regulate. Insight into treaty relevant activities of members is one of the main sources of confidence in treaty compliance and significantly increases the likelihood that all treaty parties comply with the provisions. (Kraus 1985: 170)

Although transparency plays a crucial role in the effective functioning of international relations, it is seldom addressed as a subject of research. More than a decade ago, Ronald Mitchell provided a detailed analysis and demanded further research. (Mitchell 1998) But lately, not many thoughts seem to have been given to the why and how of transparency. Transparency, so much is clear, refers to the availability of information relevant for making judgements about compliance with agreed norms. Such information can be provided by the actor(s) that are being observed. An example would be annual declarations of states under a treaty verification regime. This kind of transparency could be called active transparency. Information can also be acquired by the observing actor – independent of the observed actor’s cooperation – from independent sources such as the internet, commercial satellite imagery, the measurement of certain parameters in the air, or regular and ad hoc on-site inspections. This kind of transparency could be called passive transparency.

If relevant data are collected continuously, one speaks of “monitoring”. Monitoring can be part of “verification”, which is the process of collecting relevant data – both through monitoring and ad hoc activities such as challenge inspections – and using them to arrive at a judgement about the compliance of actors with an established norm.¹

1.2. The lack of transparency in the international bioweapons control regime

BWC states parties have been confronted with a lack of transparency right from the birth of the bioweapons control regime in 1972. The lack of reliable information about relevant activities has resulted in violations of the BWC not being discovered and in accusations of non-compliance that were later shown to be wholly unfounded. In 2001 the USA, with some clandestine applause from other member states, abruptly terminated negotiations towards a verification protocol. (Hunger 2005, Tucker 2010) At the meeting of BWC states parties in December 2009 they announced the continuation of their policy to obviate any formal mechanism for the mutual

¹ The terms “monitoring” and “verification” have been defined in various ways. Examples include the following: “Verification is the process of gathering and analyzing information to make a judgement about parties’ compliance or non-compliance with an agreement.” (UNIDIR et al. 2003: 1) “Verification is the process that one country uses to assess whether another country is complying with an arms control agreement. ... Monitoring systems collect data on the forces and activities of another country.” (CRS 2010: 3)

monitoring of relevant activities. (Tauscher 2009) The failure of the many years long negotiations towards a verification protocol that would have increased transparency around bioweapons relevant activities is still the greatest challenge of the bioweapons control regime.

With the confidence building measures (CBMs) the BWC has an embryonic active transparency system. The CBMs were created in 1986 and updated in 1992. Under the CBM regime, BWC states parties are requested to annually report relevant information such as biodefence activities or vaccine production facilities. Several recent assessments have found the CBM system to be insufficient.² The CBMs suffer not only from poor participation and a low quality of declared data, but also from out-dated declaration formats. There is little indication that active transparency will considerably increase any time soon. Passive transparency mechanisms are therefore very desirable, both to fill the currently existing transparency gap and as a back-up and check alongside any future improved active transparency system.

1.3. What do we need transparency about?

Checking compliance with the BWC is a complex exercise. A verification mechanism ideally needs to produce unambiguous, comprehensive and detailed information on all the relevant activities of treaty members. However, defining what relevant activities are and where the appropriate level of detail lies was one of the central problems in the development of the failed verification protocol to the BWC, and it remains a problem to this day. During the protocol negotiations, biotechnology and pharma industries claimed that they would have been forced to disclose too much detailed information about their activities, fearing the loss of commercial secrets. Governments claimed that providing detailed information about biodefence activities would undermine national security.

The difficulty is caused by the “totality” of the dual use problem in the biological field. To find out whether there is the intent to misuse a particular technology for hostile purposes, it would be necessary to literally “look into people’s heads”. This is, for sure, not the easiest thing to do, especially when it comes to producing evidence. In other technology fields often a particular piece of equipment or special types of materials are clear indicators of weapons development or at least of questionable technology use. Highly enriched uranium or nerve agents, for instance,

² See Isla 2006, Isla 2007, Lentzos 2008, Lentzos and Hamilton 2009, Lentzos and Woodward 2007, Zmorzynska 2007.

have extremely limited peaceful applications. In biotechnology, on the other hand, any number of types of equipment and materials can be used for a weapons programme. But even in biotechnology, there are certain capabilities and capacities in research and production that would be particularly helpful for a large-scale bioweapons programme and therefore justify further questions and investigation. With few changes in the production chain, for example, a vaccine production site could be transformed into a bioweapons agent production plant.

There have been a number of attempts to define which capabilities and capacities are especially troubling in terms of possible misuse for bioweapons development. In the framework of national export control mechanisms, lists of relevant equipment and materials have been developed. A well known export control list is the one used by the Australia Group, which includes specific items of equipment and related technology and software as well as human, animal and plant pathogens.³ A more comprehensive list of relevant capabilities and capacities was developed by the BWC Ad Hoc Group during the negotiations on a verification protocol in the 1990s. The draft protocol required from states to provide information on specific capabilities such as genetic modification and aerosol work and on certain capacities such as large scale production. The Ad Hoc Group also developed lists of equipment and of biological agents to guide declarations and inspections.⁴ Scientific organisations have looked at which research would be most useful for terrorists trying to acquire biological weapons. The best-known example of such studies is the Fink Report, which lists seven classes of experiments that would justify special scrutiny, including increasing transmissibility and altering the host range of a pathogen. (NRC 2004)

In whatever way one focusses the control efforts, in the biological field it is particularly relevant to put activities in context. Information about a certain piece of equipment, a certain facility or certain research activities is almost useless without knowing how a piece of equipment is employed, who has control over a facility, why activities are undertaken, and how all this information fits with the overall biotech scene of a country. It is exactly at this point, where the trade monitoring concept, which is introduced in this paper, comes in. A detailed understanding of international trade flows in biological equipment that such a monitoring system would provide, would allow insights into bioweapons relevant capabilities and provide a feeling for the overall biotech landscape in individual countries.

³ See www.australiagroup.net/en/controllists.html.

⁴ See document BWC/AD HOC GROUP/56 (parts I and II), available at <http://www.unog.ch/unog/website/disarmament.nsf/%28httpPages%29/F5C615E0217AE11FC12577280032DB46?OpenDocument&uid=FCA0866229E27290C12572BC00327DC2>.

2. The trade monitoring concept

2.1. Origin of the concept

When looking at what lessons could be learned for biological arms control from the inspections in Iraq in the 1990s, we came across the trade monitoring system that was implemented for Iraq. Through the monitoring of trade one of the most important indications for the hidden biological weapons programme was uncovered, the massive import of growth media, the amount of which could not be explained with civilian needs. The question quickly arose whether such a trade monitoring system could be implemented on a global scale.

UNSCOM and its successor organisation UNMOVIC provide a historic example for a trade monitoring mechanism.⁵ An essential part of the extensive mission under UN Security Council mandate 687 (1991) was the monitoring of all nuclear, biological and chemical weapons relevant imports and exports. The resulting export and import control mechanism that came into force in 1996 obliged states to declare all relevant shipments to Iraq.

Already from 1991 on, a monitoring list existed for use during UNSCOM activities inside Iraq. In compliance with the mandate of the early years, the biological part of the monitoring list was so general – it comprised less than a dozen items, but most of these were broad technology areas such as “biohazard containment equipment” – that it stipulated the monitoring of almost everything. (S/22871/Rev.1) It became obvious very soon that trying to take a more focussed look on bioweapons relevant activities required a more specific monitoring. The UN inspectors found that it was of utmost importance to concentrate on what they called “choke-points” in weapons development. Hence, when the export/import mechanism was developed, the items list became much more specific, containing a long and detailed list of specific items of equipment – for example “cross-flow and tangential filtration equipment with a filter area equal to or greater than 0.5 m²” – and lists of bacteria, viruses, toxins and other biological agents several pages long. (S/1995/208)

The export/import mechanism, in combination with interviews and on-site inspections, generated information on general capacities and capabilities of the Iraqi biotech industry, for example on vaccine production. It became clear that Iraq possessed the crucial capabilities for

⁵ UNSCOM, the UN Special Commission for Iraq, was active from 1991 to 1999. It was replaced in December 1999 by UNMOVIC, the UN Monitoring, Verification and Inspection Commission, which was active until 2007.

biological weapons development, but it remained unknown for a long time whether these capabilities were in fact used for weapons purposes, e.g. if the vaccine production plants were misused for the fabrication of bioweapons agents. But the export/import mechanism provided more. It revealed the import of growth media for microorganisms in quantities, that did not fit civilian activities. This discovery eventually led to the uncovering of the Iraqi bioweapons programme. The fact that the monitoring of trade data helped to uncover the Iraqi bioweapons programme led directly to the question: “Could a global trade monitoring system help to verify compliance with the BWC?”

2.2. The trade monitoring concept itself

The general idea of trade monitoring is to track the movements of goods across international borders. This can be done for a number of reasons. National governments want to collect taxes and control what is entering or leaving their territories. International organisations and civil society organisations want to check whether states are complying with agreed norms. A trade monitoring system for bioweapons relevant items would track the movement of biological dual use equipment⁶ with the aim of identifying suspicious trade activities – for example the accumulation of equipment not consistent with the peaceful needs of a specific country – which could be indicators for violations of the international bioweapons prohibition.

In the beginning, we formulated three conditions for a trade monitoring mechanism for biological dual use equipment: 1) Such a mechanism would need to be global in reach. There are mainly two reasons, why only a global system would be effective and politically acceptable at the same time. On the one hand, biotechnology equipment is traded widely; importers as well as exporters are located in all regions of the world. On the other hand, there are no universally accepted “states of bioweapons concern”; instead, because of the strong dual use nature of the life sciences, states worry about the bioweapons relevant capabilities of other states in all regions of the world. 2) A trade monitoring mechanism would have to function with publicly available data. In contrast to the UNSCOM/UNMOVIC export/import mechanism, a global mechanism cannot resort to a UN mandate that obliges traders to inform an international authority about their deals. There is no international organisation mandated to collect data from BWC member states, and it is highly unlikely that there will be one any time soon. 3) The analysis of the data

⁶ Biological agents as well as intangible technology items could also be subject to monitoring. We focus on equipment as a first and the easiest step of a monitoring system for bioweapons relevant items.

should be done preferably by a non-governmental organisation with a strong tradition of transparency. The task is to create a mechanism that facilitates global transparency, not to provide another tool to help a few privileged states to gain additional confidential knowledge.

A global trade monitoring mechanism will be watching the same area as national export controls, but without suffering from the same disadvantages (see box below for more detail). It will be a global, passive, *ex post*, not license-based imaging tool. (Jeremias and van Aken 2006)

The limits of export controls

Export controls as measures to prevent the proliferation of weapons and dual use goods have a long history. They were adapted after the Cold War when the political and strategic environment changed and globalisation tendencies increased. The bloc-orientated threat perception became obsolete; the new threat assumptions forced a reorientation towards the current licensing system that effects a different range of countries and items. Especially, adding dual use items to the traditionally pure military lists characterised the change in export controls.

It is problematic that there is no truly internationally harmonized approach to export controls. Export controls remain being applied on a national (or European) level and many states remain outside the exclusive clubs of existing export control regimes such as the Australia Group. The increasing globalization of markets, the correspondingly increasing volume of international trade and the ever greater number of international companies are leading to a global diffusion of knowledge and equipment that might render the existing export control regimes obsolete in the mid-term future.

Especially in the bio-related field, the decision what a dual use item is and what should be controlled is hard to take. The result of increasing diversity and complexity of biotechnology and a growing number of products and market participants is insufficient market transparency. This insufficiency became clear in connection with the Iraqi bioweapons programme in the late 1980s/early 1990s. This programme was build up with items that were under control, but because export controls are not properly coordinated internationally and individual items do not allow drawing a conclusion about the end-use, none of the individual transfers from different supplier states was considered suspicious. Although a lot has been done to tighten export controls, this weakness remains basically unchanged.

Another weakness of export controls is the licensing process itself. New technologies are developing so rapidly that the systems are often not up to date. In addition, there are no common rules for licensing. Not even members of the existing multilateral export control regimes have implemented common standards. Finally, a lot of detailed information on possible technology applications, the importer and the end-user are needed to issue a reliable end-use and end-user license. This detailed knowledge is often not available to companies and customs officers.

The three basic questions in the concept development were: 1) What do we need to know, i.e. which items of equipment do we need to monitor? 2) What can we know, i.e. where are trade data for these items of equipment publicly available? 3) What do we do with the data collected to arrive at a conclusion about compliance with the BWC? So far, our efforts in developing the trade monitoring concept have been focussed on the first two questions.

2.3. What do we need to know?

A bioweapons related trade monitoring mechanism has to concentrate on a list of items that are – individually or in combination – indispensable parts of an illicit weapons programme. These items have to be carefully chosen so that the monitoring allows an appropriate richness of detail, not too narrow but also not too broad. Three lists of equipment were used to develop our own trade monitoring list: the equipment part of the Australia Group control list, the list of equipment developed by the BWC Ad Hoc Group in the 1990s, and the list of the UNMOVIC export/import mechanism. The UNMOVIC list had been regularly updated until the UNMOVIC mandate was terminated in 2007. Because of its comprehensiveness and level of detail and also because of the similarity in purpose, we used the UNMOVIC list as blue print for the equipment list of our trade monitoring concept. The latest official UNMOVIC list as well as the Australia Group and Ad Hoc Group lists are available in Annexes II to IV. Our list of equipment to be covered by a trade monitoring mechanism aimed at improving transparency of bioweapons relevant activities looks as follows.

List of biological dual use equipment to be covered by a trade monitoring mechanism⁷

Production

Fermenters with a vessel capacity:

- Up to 5 liters;
- Greater than 5 up to 20 liters;
- Greater than 20 up to 100 liters;
- Greater than 100 up to 1,000 liters;
- Greater than 1,000 liters.

Continuous flow fermentation systems with a volume:

- Up to 2 liters per hour;
- Greater than 2 liters per hour.

Orbital or reciprocal shakers and shaking incubators, designed for use with biological material, regardless of size.

Prepared culture media for development of microorganisms designed for production purposes.

Prepared culture media for development of microorganisms designed for diagnostic purposes.

Downstream processing

Centrifuges and specially designed rotors therefore, regardless of size, having all of the following characteristics:

- Designed for use with biological material;
- Capable of in-situ steam sterilization in a closed state.

Batch centrifuges and separators, including rotors, with a rotor capacity of:

- Less than 25 liters;
- 25 liters or greater.

Continuous centrifugal separators or decanters regardless of size.

Cross-flow and tangential filtration equipment designed for use with biological material with a filter area

- Under 0.2 m²;
- Equal to or greater than 0.2 m²; and component filter cartridges therefore.

⁷ This list was originally developed in 2007. It might need updating in light of market trends and technological developments. Given recent concerns about the misuse potential of synthetic biology and the growing market for DNA synthesizing equipment and services, for instance, DNA synthesizers should be considered for inclusion in any future updated list.

We decided against including pathogens and toxins in the list at this point for three reasons. 1) Biological agents are traded in very small volumes. 2) There is a low dependence on trade because many agents can be found in nature. And most importantly, 3) clear definitions are difficult. (One could argue that changing one base pair creates already a new agent which would then require a code number of its own.)

List of biological dual use equipment to be covered by a trade monitoring mechanism ctd.

Downstream processing ctd.

Spray-drying equipment

- Designed for use with biological material;
- Not designed for use with biological material.

Freeze-drying equipment with a condenser capacity:

- Less than 5 kg of ice in 24 hours;
- 5 kg of ice in 24 hours or greater;

and specially designed vacuum chambers therefore.

Drum dryers:

- Aseptic (i.e. fully contained and sterilisable);
- Not designed for use with biological material.

Size reduction equipment (including milling and grinding equipment) capable of producing powders with a mean particle size of 15 microns or less.

Biosafety and sterilization

Filters:

- HEPA (High Efficiency Particulate Air);
- ULPA (Ultra Low Penetration Air);
- SULPA (Super-ULPA);

with a DOP rating of 99.997% (at 0.3 micron) or higher.

Class II and Class III biological safety cabinets or isolators.

Rubber gloves specially designed for use with Class III or Class IV biological safety cabinets.

Double ended autoclaves.

Pass through sterilization systems.

Positive pressure air-fed suits, incorporating respirators which would provide protection from exposure to pathogens.

Half suits, helmets and respirators which would provide protection from exposure to pathogens capable to be incorporated into positive pressure air-fed suits.

Research and genetic engineering

Automatic peptide synthesizers.

Dissemination

Nose-only aerosolization equipment, but excluding devices for personal prophylaxis or therapy for medical conditions.

Aerosol disseminators 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 unmanned aerial vehicles (UAVs).

Foggers/nebulisers 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:

- Head unit; and
- Nozzle assembly.

Aerosol disseminators other than aircraft sprayers or foggers.

Aerodynamic particle-sizing equipment.

Other

Plant inoculation cabinets/chambers providing quarantine.

Detection assays for microorganisms and toxins, including immunological and gene probe assays.

2.4. What can we know?

2.4.1. The Harmonized System as source of information

After deciding what items of equipment the trade monitoring mechanism should focus on, the question of where to get the information had to be solved. To this effect, we contacted a number

of international organisations mandated to monitor trade with certain items or substances. These included the UN Environmental Programme's Ozone Secretariat with a trade monitoring system for ozone depleting substances and the Organisation for the Prohibition of Chemical Weapons with a trade monitoring system for certain chemicals. We found that in many cases monitoring systems use the Harmonized System of the World Customs Organisation to identify traded goods. We also asked how commercial market analysts collate their information. An important source of publicly available information at no cost turned out to be the UN Statistics Division (UNSTAT) which operates the COMTRADE database⁸ and the EU Commission's EUROSTAT site⁹. Everybody can download aggregated data on value and volume of international trade in defined products. Basis for the product definitions is again the Harmonized System of the World Customs Organisation.

The *Harmonized Commodity Description and Coding System* (Harmonized System, HS) is based on an international treaty, the HS Convention of 1983, which entered into force in 1988, and whose 136 member states are a subset of states parties to the World Customs Organisation (WCO). The HS was created

“to facilitate international trade ... to facilitate the collection, comparison and analysis of statistics, in particular those on international trade ... to reduce the expense incurred by re-describing, reclassifying and recoding goods as they move from one classification system to another in the course of international trade and to facilitate the standardization of trade documentation and the transmission of data.”¹⁰

The HS is the common language of international trade. It classifies, describes and identifies items in a hierarchic structure of internationally uniform six digit codes. 21 sections give a broad overview and are divided into 96 chapters containing 1,200 headings. The numbers of the chapters (01-96) and those of the headings result in a four digit code. In some cases these four digits do sufficiently encode a group of commodities. Often, the code is completed by two additional digits (sub-headings) encoding further divisions. For example, code 85 is for the chapter “electrical machinery and parts thereof”; within this chapter code 85.28 is for “reception apparatus for television”; and code 8528.12 is the sub-heading for “colour television sets”.

⁸ See <http://comtrade.un.org>.

⁹ See <http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/>.

¹⁰ See preamble of the HS Convention, available at http://www.wcoomd.org/home_hsoverviewboxes_tools_and_instruments_hsconvention.htm#preamble.

Although in the HS a 6-digit code is allocated to every tradable item, by far not every code identifies a single item as in the case of colour TV sets. Most 6-digit codes identify a larger group of items. These codes are often referred to as “basket numbers”. This is the reason why many, if not all, states have implemented national classification systems that identify items more exactly than the HS does, with up to twelve digits, but all of them use the six-digit code of the HS as a basis.

When importers and exporters fill in their customs declarations, they have to provide the appropriate HS code. These codes are read out by border services. They are processed to avoid the exposure of commercial secrets; data on items that are traded only by a very small number of companies or in very small volumes will, for example, be converted into special accumulative codes. The data are then forwarded to databases, where they are aggregated and published.

According to WCO, 98 per cent of international trade are covered by the HS. This almost complete coverage is due to the fact, that even states that are not members of the HS Convention use the HS codes. Given this broad coverage, it is possible to visualise global trade flows of many items, such as the above mentioned colour TV sets. According to staff at the International Merchandise Trade Statistics Section of the UN Statistics Division, of all globally collected data, trade data are the ones that are displayed with the highest accuracy. When comparing import and export data in a “mirror exercise”, mismatches often occur. But still, the broadness as well as accuracy of trade data is unrivalled.¹¹ Mismatches might not only point to insufficiently effective reporting practices, but may also indicate intentional cheating. With a view to the intended use of trade data for a proliferation related monitoring, staff at the International Merchandise Trade Statistics Section of the UN Statistics Division stated that it will not be possible to produce clear-cut evidence, but that data quality is very likely “good enough to pinpoint problems”.¹² Hence, in principle, the trade data generated under the HS fulfil the requirements of a trade monitoring mechanism.

And in fact, numerous international organisations which are mandated to monitor the implementation of multilateral agreements already use HS data to check treaty compliance, mostly in combination with active transparency systems. For example, the International Narcotics Control Board which monitors three international conventions on narcotic drugs and psychotropic substances uses the HS codes for e.g. amphetamines (HS 2941.46) and

¹¹ Personal communication, October 2009.

¹² Personal communication, October 2009.

benzodiazepines (HS 2933.91). The Organisation for the Prohibition of Chemical Weapons which monitors the Chemical Weapons Convention uses the HS codes for e.g. cyanogen chloride (HS 2851.00) and pinacolyl alcohol (HS 2905.19). The UNEP Ozone Secretariat's use of HS codes for the monitoring of trade in ozone depleting substances is described in more detail in the box below.

But not just international organisations, also civil society organisations use HS-based trade data for monitoring purposes. The Environmental Investigation Agency (EIA), for instance, uses statistics on trade in endangered tropical timber – which is protected under the Convention on International Trade in Endangered Species (CITES) – to detect illicit harvesting and shipments. This passive transparency mechanism does not produce final evidence of non-compliance with CITES. For that to happen, suspicious trade data need to be cross-checked with information from on-site investigations, e.g. at the points of entry. But the analysis of HS-based trade data has in the past uncovered suspicious activities to be further investigated.

The example of the international trade monitoring for ozone depleting substances

In the 1980s, halogenated hydrocarbons used as cooling mediums and propellants were identified as depleting the ozone layer. In 1987, the *Montreal Protocol on Substances that Deplete the Ozone Layer* was adopted. It entered into force in 1989. To limit the consumption of ozone depleting substances (ODS) to an acceptable level, states parties agreed to control the international trade of nearly 100 chemicals and products containing them (e.g. refrigerators). 196 countries have ratified the Montreal Protocol.

Two separate mandatory mechanisms to control and monitor the transfer of ODS are in force today. One is a licensing system for imports, exports and transits, the other a reporting requirement for the trade in ODS. The UNEP Ozone Secretariat that oversees the implementation of the Montreal Protocol decided to use the HS codes for the trade reporting, but also realized that the existing HS codes did not identify the substances under control specifically enough to be able to prove non-compliance on the basis of these data. Consequently, the WCO was asked to revise some sub-headings in the HS nomenclature to identify the relevant substances more accurately. In collaboration with UNEP, the WCO recommended revised HS sub-headings to all member states.

UNEP requested adaptations of the nomenclature on three separate occasions between the early 1990s and 2004. Each revision took two to three years to be completed. Considering the urgent need to monitor the international trade in ODS, the WCO adopted recommendations requesting states to insert the relevant sub-divisions in their national nomenclatures ahead of the amendment of the HS nomenclature at the international level. The current version of the relevant HS codes was adopted by all HS member states during the last regular review cycle of the HS for implementation starting on 1 January 2007. The reporting system has not yet been formally evaluated. However, anecdotal evidence suggests that the system has contributed towards achievement of the overarching goal of facilitating the phase out and elimination of ODS production and consumption.¹³

The Ozone Secretariat, the Protocol's Implementation Committee, and the annual Meeting of the States Parties all have roles in assessing the data collected. The data that are included in the resulting reports are publicly available, and NGOs have been using these data.

¹³ Personal communication with an official of the UNEP Ozone Secretariat, February 2006.

2.4.2. Biotechnology items in the Harmonized System

Moving ahead with the trade monitoring mechanism was not as straight forward, however, as we thought in the beginning. We had to learn that, at the moment, virtually every item on our list of items to be monitored falls under a HS basket number. With one exception – HS 3821.00: prepared culture media for development of microorganisms – no item on our list is identified with an individual HS code. Instead, they are grouped together with a number of non-relevant items. The main reason for this unspecific identification of biotechnology items is the following: when the HS nomenclature was developed in the 1980s, biotechnology was a developing field of research, not the globalising industry branch with trade volumes in the billions of USD it is today.

The identification of biotechnology items in the HS is not only unspecific, it is also ambiguous. Companies use various codes for the same items of equipment. It seems to be extremely complicated to find the right HS code for a particular item. The CEO of a small German company producing bioreactors told us in a telephone interview: “I guess that the HS has four different numbers for turkeys dead or alive, above and below 185 grams of weight, but I have no clue what code I have to use when I am exporting fermenters.”¹⁴ In a telephone survey among a dozen German, Austrian and Swiss small and midsize biotech companies in June 2006, the problem of assigning correct HS codes to specific items of equipment turned out to be widespread. When asked, for instance, which HS code they use for reporting exports of fermenters, companies named four different numbers. This is not because of insufficient knowledge of the HS, but is the result of the unclear classification of biotechnology items in the current HS nomenclature.¹⁵

Accordingly, we had to conclude that, at the moment, the trade data generated by the HS are unsuitable for use in a trade monitoring mechanism for bioweapons relevant items of equipment; use of the existing databases would only produce very blurry results. The mechanism would conceal the relevant information in a multitude of data on items of little or no interest. A challenge emerged: to amend the HS nomenclature in a way that would generate trade data specific enough for our monitoring purposes.

¹⁴ Personal communication, June 2006.

¹⁵ This was confirmed when the HS Secretariat, in February 2008, tried to identify the correct HS codes for the items on our list of equipment to be monitored. For details see WCO document NC1264E1a and section 3.2. below.

3. Moving from theory to practice: amending the HS nomenclature

3.1. The why and how of HS amendment processes

The current HS codes look very different from the ones originally agreed in 1988. They have gone through several amendment cycles. The HS Convention underlines the importance of keeping the HS “up-to-date in the light of changes in technology or in patterns of international trade”.¹⁶ One important reason for amendment is a substantial increase in trade volume. If a certain item is traded in excess of USD 100 million per year, an individual four-digit code is to be created. The threshold for a separate six-digit code is USD 50 million. An amendment process has officially to be initiated by the WCO Council. In practice, however, the fate of an amendment proposal is determined in the HS bodies, in particular the HS Committee. Agreed amendments are implemented *en bloc* at the end of five-year amendment cycles. A transition period of three years allows companies and authorities to put the agreed amendments into force. The last amendment cycle ended in 2009, with the amendments coming into force in 2012. The current amendment cycle will end in 2014.

Amendment processes are usually initiated by states. But also international organisations have in the past asked for HS amendments. In fact, amendment proposals by the relevant international organisations laid the foundations for all the monitoring mechanisms described in chapter 2.4.1.. In all those cases, the amendment proposals aimed at preventing the trade in and proliferation of specific prohibited or regulated goods. Allowing the monitoring of trade in order to strengthen international treaty regimes is another valid reason for amendment of the HS nomenclature, and in line with the conception of the HS as a “multipurpose international product nomenclature”.¹⁷

3.2. Discussions on our amendment proposal at the World Trade Organisation until May 2008

In mid-2007, the Research Group for Biological Arms Control approached the WCO with a proposal to amend the HS nomenclature so that biological dual use equipment would be better represented. The HS Secretariat distributed our proposal as an official paper (NR0713E1a and

¹⁶ See preamble of the HS Convention, available at http://www.wcoomd.org/home_hsoverviewboxes_tools_and_instruments_hsconvention.htm#preamble.

¹⁷ See http://www.wcoomd.org/home_hsoverviewboxes_hsharmonizedsystem.htm.

Annex)¹⁸ and invited us to present the proposal at the 36th session of the HS Review Sub-Committee in November 2007. Although the proposal was put on the agenda by the HS Secretariat, it was not a proposal by the Secretariat; it remained a proposal of our Research Group. This detail would become important later in the process.

During the first presentation of our amendment proposal at the WCO in Brussels, we stressed the non-proliferation advantages, in particular the benefits for the implementation of UNSC Resolution 1540 (2004) and for verifying BWC compliance. During the short plenary discussion following the presentation, Brazil, Canada and the USA commented on our proposal, all positively. One state representative made the point that “previous submissions from non-governmental organizations had been put forward by an authorized administrative body for some form of international accord” and questioned whether such a state sponsor might not be advisable for our proposal. States instructed the HS Secretariat to do further work on the proposal.¹⁹ In the following months, continuous communication and cooperation between the Research Group and the HS Secretariat were established. For example, the Research Group supported, on request, the work of the HS Secretariat with technical expertise.

It quickly became clear that a serious limiting factor in the process were deadlines. The five-year HS amendment cycle drew to a close and would end in early 2009. All necessary technical and political details would have to be decided within only four sessions of the two HS bodies. A tough call, as everyone familiar with the process told us. As a first step, the HS Secretariat had been instructed in November 2007 to clarify under which HS codes the items on our list are currently identified. A respective list was prepared for the 41st session of the HS Committee in February 2008.²⁰ For almost none of our items did this list identify an unambiguous HS code. Often several codes were suggested as applicable. In other cases only one code was assigned, but never without a pointer to technical complexities that eventually may require a different classification.

During the February 2008 HS Committee session, first signs of reluctance to continue the discussion process appeared in the conference room. Several delegates, most notably Japan, “expressed their concern with the procedure, that an initiative of a private organisation, which was neither sanctioned nor affiliated with the [BWC], was apparently being accepted as a proper

¹⁸ A list of all relevant WCO documents is available as Annex V; all documents are accessible at http://www.biological-arms-control.org/projects_trademonitoring.html.

¹⁹ NR0722E1a, p. E/1/2-E/1/3.

²⁰ NC1264E1a.

source for proposed changes of the HS. ... The request by the Research Group could set precedence to a wide variety of sources and private groups outside governmental or intergovernmental organizations for proposals to amend the HS Nomenclature.”²¹ At the same time, the US delegate provided comments on technical details without questioning the legitimacy of the process.²²

As a result of the discussions between November 2007 and February 2008, we widened the arguments for our HS amendment proposal to include non-security related ones. It had become obvious that customs officers and businesses would profit a lot, if our amendment proposal were implemented, independent from any non-proliferation benefits. Besides, stressing the economic arguments for our amendment proposal widened the circle of potential supporters; this was important because the “easy” way through an international organisation implementing the BWC was impossible in our case – no such organisation exists. Besides allowing the monitoring of trade for signs of suspicious activities related to the development of biological weapons, implementation of our HS amendment proposal would:

- Identify bioweapons relevant biotechnology goods more clearly in customs declarations, thereby facilitating certain customs procedures and making national and plurilateral export controls more effective through a clear identification of items under control by an unambiguous HS code on the shipping document;
- Make trade with biotechnology goods more transparent in general, provide more detailed information on biotech-related trade, thereby allowing better market analyses in the biotechnology area which would be of benefit for commercial actors;
- Allow a coordinated view on global trade flows of biological dual use items, make trade with such items more transparent and provide indications of countries’ capabilities in the biological field, thereby providing background knowledge against which to judge specific non-compliance concerns.

For the 37th session of the HS Review Sub-Committee in May 2008, our amendment proposal was presented by the HS Secretariat as “Article 16 procedure. Amendments to the nomenclature”.²³ At the same session, the discussion process was adjourned for procedural reasons. The representative of Canada, noting that a number of delegations had expressed

²¹ NC1310E1b, Annex F/3, p. F/3/1.

²² NC1310E1b, Annex F/3, p. F/3/2-F/3/3.

²³ NR0741B1a, Annex. This latest version of our amendment proposal is contained in Annex I of this publication.

reservations as to the appropriateness of the proposal being submitted by an academic institution, expressed his view that “consideration of the proposal would establish a precedent, which would allow any organization with an interest in an environmental or social issue, to submit a proposal to amend the HS to address their specific needs or concerns. It could even allow commercial interests to submit proposals directly to the Review Sub-Committee, or the HS Committee. That would not be a precedent that Canada could support.”²⁴ Japan supported the Canadian view. In November 2007, Canada had expressed support for the proposal; hence, for sure, no substantial issues were the reason for the refusal, but – like in the case of Japan three months earlier – the fear of creating a precedent.

The Chair reminded the Sub-Committee that during the last session no objection had been raised to continue discussions on the proposal. In the end, because no state actively supported continued consideration of our proposal, the Sub-Committee agreed to not pursue the issue further.²⁵ States suggested finding a state or international organization willing to “adopt” the proposal; in that case the amendment process could be re-activated. The support of major powers such as the EU or the USA would be particularly important.

Biotech industry and the HS nomenclature

Companies which produce and trade in biotech equipment internationally inevitably have experience with the HS nomenclature, since the use of HS codes is obligatory in export declarations. Export commissioners of small and mid-size companies told us in interviews about their problems in identifying the correct HS codes for items of biotech equipment. All companies that we have been in contact with reacted positively to our HS amendment proposal. They see at least two advantages of a better identification of biotechnology equipment in the HS. Firstly, the export control notifications and customs procedures would become simpler, reducing administrative costs. This is especially true for small and mid-size enterprises, where no automated export procedures are established. Secondly, the amendment would lead to better market transparency and greater potential for market analysis.

Although biotech industry has no legal power in the WCO – as any other non-state actor – the success of our HS amendment proposal is more likely if industry supports it. Despite the support expressed in personal contacts with numerous industry representatives, biotech industry has not yet emerged as an active supporter of our amendment in the WCO context. More awareness raising and lobbying activities are necessary in order to change this. Important stakeholders will be European and US biotech industry lobby groups such as Europa Bio and PhRMA.

3.3. Specific amendment requirements

While the amendment process for biological dual use items is not being further pursued at the moment, a number of very specific amendment requirements became obvious during the

²⁴ NR0751E1b, Annex C/15, p. C/15/1.

²⁵ NR0751E1b, Annex C/15.

discussion process at WCO, which are examined in this section. They will become important as soon as the amendment process is re-activated in the future.

Our original items list – just like the UNSCOM/UNMOVIC export/import mechanism control list, the Australia Group export control list or the BWC Ad Hoc Group list of equipment on which it is based – did not meet basic HS requirements. Very soon it became clear that the list indicated the general type of relevant equipment but included thresholds – such as the size of fermenters or the capacity of filtration equipment – which are not easily integrated into the existing HS structure. In contrast to instruments that look at certain aspects of trade only, such as export controls, the HS is an instrument that needs to cover the entirety of global trade. Even if today basket numbers prevent a look at trade in very specific items, these items are still represented somewhere in the trade statistics because of the comprehensiveness of the HS nomenclature.

3.3.1. The capaciousness of new HS codes

Accordingly, the first challenge in proposing individual codes for the items on our list is finding a compromise between the minimal requirement (e.g. one new code for fermenters of all sizes) and the maximum demand (e.g. one new code each for fermenters of very small, small, medium, large and very large size). On the one hand, the compromise needs to respect the integrity and sustainability of the HS nomenclature which, as a six-digit system, is naturally limited in size. In addition, the total number of different codes has to be kept at a manageable level (which is nowhere defined). On the other hand, there exist unofficial upper and lower thresholds in regard to trade volume and value. As mentioned above, the trade value threshold for a separate six-digit code is USD 50 million per year; if a certain item is traded in excess of USD 100 million per year, an individual four-digit code is to be created. These thresholds are not carved in stone. But when codes become too specific, trade volumes and values become too small to guarantee trade secrets and national authorities would not submit trade data for such HS codes separately. A few examples will illustrate these points.

The Preparatory Commission for the Organisation for the Prohibition of Chemical Weapons (OPCW) aimed to identify chemical weapons relevant items, in particular chemical substances, individually in the HS. To allow a detailed analysis, individual codes for hundreds of very similar chemical substances were proposed. This would have blown the structure of the HS nomenclature and was therefore unacceptable. In addition, it was problematic that trade in these

chemical substances individually would have been at too low a scale. The only available alternative was to find less comprehensive basket numbers. According to OPCW experts, the OPCW was not completely satisfied with the outcome since the picture of trade did not become as clear as they had wished for.²⁶

The OPCW example illustrates that individual HS identification for large numbers of very similar items, such as chemical substances, is not achievable in full detail. It is possible, however, for a limited number of clearly distinguishable items of equipment, as foreseen for our trade monitoring mechanism. The following two examples show how this first challenge was dealt with in the development of our amendment proposal.

For fermenters we originally suggested to create individual HS codes as follows: one four-digit code for fermenters, and separate six-digit codes for fermenters up to 5 litres; greater than 5 up to 20 liters; greater than 20 up to 100 liters; greater than 100 up to 1,000 litres; and greater than 1,000 litres; and (possibly under a second four-digit code) additional six-digit codes for continuous flow fermentation systems with a volume up to 2 litres per hour; and greater than 2 litres per hour. Already in 2002, trade in bioprocessing hardware was up to USD 500 million per year.²⁷ And the biotechnology branch keeps growing at high rates. China and India, for example, report approximately 20 per cent annual growth in biotech industries.²⁸ Hence, considering the relevance of fermenters of certain sizes for large bioweapons programmes and the already high and growing trade volume for civilian purposes, it seemed appropriate to propose the introduction of several codes for the different sizes of fermenters. However, the HS Secretariat is keen to keep the total number of codes as low as possible. It eventually proposed to insert just one new code for fermenters, also adding plant inoculation cabinets: “8419.82 -- Other fermenters and continuous flow fermentation systems, orbital or reciprocal shakers and shaking incubators [, designed for use with biological material] and plant inoculation cabinets and chambers providing quarantine.”²⁹ Whether this is an acceptable grouping will likely be an issue at any future negotiations on technical details of our HS amendment proposal.

Trade data on culture media for microorganisms were key to the uncovering of the Iraqi bioweapons programme in the 1990s. Culture media are the only item on our list that is already

²⁶ Personal communication, April 2008.

²⁷ See <http://www.in-pharmatechnologist.com/Industry-Drivers/Dissecting-the-bioprocessing-market-with-D-MD>.

²⁸ See http://ableindia.in/admin/attachments/reports/reports18_Biotech%20in%20India%20Nature%20Biotech%20supplement.pdf and <http://www.fiercebiotech.com/story/china-plots-blistering-pace-biotech-growth/2010-12-08>.

²⁹ NR0741B1a, Annex, p. 4.

identified in the HS with an individual code. They are traded in volumes of several hundred million USD per year. There is good reason for further differentiation, since there are two different kinds of growth media. Culture media for production purposes is produced, shipped and used in bulk quantities, and – as a rather low-tech product – it costs relatively little money. It is, however, particularly important under bioweapons control aspects. Culture media for diagnostic purposes is a high-tech product that allows the growth of microorganisms with very specific nutritional demands. This kind of culture media is only traded in small volumes. It is often very expensive; one kilogram can easily cost several thousand USD. Hence, we proposed to split the HS code into two separate sub-headings, one for culture media for production purposes and one for culture media for diagnostic purposes. In this case, the HS Secretariat followed our proposal.³⁰

3.3.2. Do you speak HS? Comments on the phrasing of items definitions

After it is decided which items need to be individually identified, the next challenge emerges: the descriptions of the new items need to fit the HS “language”. Definitions have to be lean and clearly understandable to everybody who is working with the HS, which includes customs officers worldwide. A typical items description is “machinery for treatment of materials by change of temperature”, which is the HS basket number description under which fermenters currently fall.

Definitions describe items by their material features, not their intended use. In our amendment proposal we repeatedly use the phrase “designed for use with biological material” – for instance in relation to dryers, centrifuges and shakers – in order to distinguish items of equipment that are sterilisable (if not being disposable) and do not release material such as pathogens to the environment. WCO experts were not happy with this phrase because there is no agreed understanding what “designed for use with biological material” means.

In some cases, our items descriptions refer to classification systems of third parties. Biological safety cabinets, for example, are commonly distinguished by safety classes as defined by the World Health Organisation into class I, II or III. WCO experts advised us that any final item description would have to explicitly quote such third party classification standards to avoid intended or unintended misinterpretations.

³⁰ NR0741B1a, Annex, p. 1.

3.3.3. Where to put new codes? Comments on HS topography

Once the items are identified and clearly defined, they need to be integrated into the HS nomenclature at their logical places, respecting the overall HS topography. An early draft of our amendment proposal contained not only new items descriptions, but also new HS codes. Not having any experience with the inner logic of the nomenclature, we simply looked for unused code numbers and filled these gaps with new codes for the equipment we wanted to identify separately. Experts told us to better leave the difficult task of incorporating new code numbers into the nomenclature to the HS Secretariat. Which we did.

4. Addressing criticism of the trade monitoring concept

Two major points of criticism were raised during our many discussions with state and non-state experts from the trade as well as the non-proliferation side: the concept does nothing to prevent bioterrorism, and it is unjust towards developing countries. Both points are addressed in the following.

Since the anthrax letter attacks in 2001, the question how to prevent bioterrorist acts has ruled the debate on biological weapons, in both governmental and non-governmental circles. It is widely assumed that the use of biological weapons as weapons of mass *disruption* will create more challenges in the future than the production of biological weapons of mass *destruction*. The focus in the development of the trade monitoring concept, however, was from the beginning put on helping to prevent large scale bioweapons programmes, because in our opinion the use of bioweapons with catastrophic consequences has such large scale programmes as precondition. Large scale bioweapons programmes remain the greater threat. They must not fall out of focus; active prevention efforts remain an ongoing need.

The most important criticism on the trade monitoring concept, however, was that the system would be unjust because only states not having indigenous capacities to produce biological dual use equipment would be monitored. While the trade monitoring concept was developed as a non-discriminatory tool with global coverage, biotechnology-holding countries would not have to fear that the increased market transparency led to insights about the intentions behind their biotechnology activities. When all bioweapons relevant dual use equipment is produced within a

state, relevant equipment would not cross international borders, and international trade data indicating suspicious activities could never be generated.

Monitoring the location of critical equipment, whether in states capable of producing such equipment indigenously or in states not capable to do this, would be one way to address this weak point of the trade monitoring concept. It would also help to alleviate one of the shortcomings of export controls, namely that in-country transfers to unauthorized places for unauthorized purposes cannot be prevented. RFID technology might make such monitoring possible in the future.

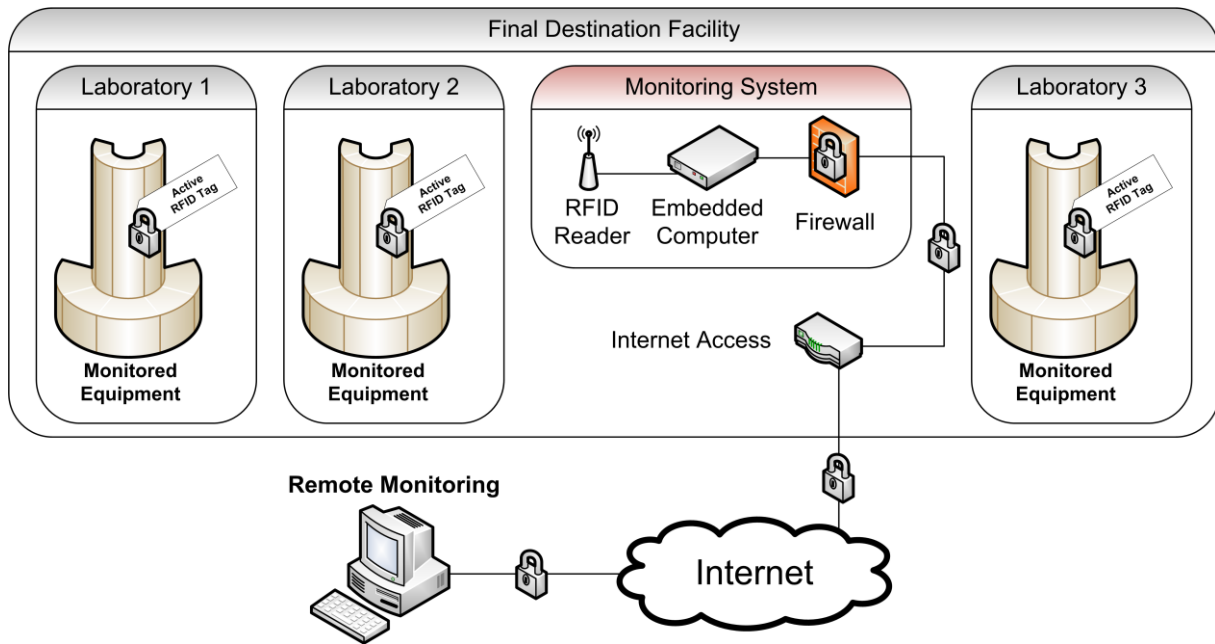
Excursus: use of RFID technology for monitoring the location of individual items of equipment³¹

RFID stands for radio-frequency identification. Widely used in commercial business and logistics for asset tracking and warehouse management, RFID allows objects to be identified remotely, without the need for physical contact or even a free line of sight between the object and the reader. Its basic operating principle is similar to that of well-known bar code technology in that a small and unobtrusive tag is attached to an object, which can quickly be identified by querying the tag with a reading device.

RFID technology uses electromagnetic fields in the radio frequency band for communication between tags and reading devices. It is therefore not limited in range by the need for visual contact. Its limitation lies in the intensity of the electromagnetic fields, which quickly decreases with the distance between tag and reading device. Practical applications show that maximum ranges from a few centimetres to several tens of meters can be achieved.

A basic system for monitoring the location of critical equipment could look like follows: RFID tags are attached to relevant items of equipment. A monitoring system installed at the facility checks the tags through a built-in reading device, verifying that the equipment is present. The monitoring system in turn communicates this information via an internet connection to the monitoring organisation, where irregularities can be registered and acted upon. The following figure illustrates this set-up.

³¹ We would like to thank Michael Büker, Centre for Science and Peace Research, University of Hamburg, Germany, for the detailed research he conducted for this part of the paper.



Lock symbols indicate security components and encrypted data connections.

Technical detail

There are two basic types of RFID tags: passive and active. Passive tags hold no power source of their own, but rather draw their power from the electromagnetic field generated by the reading device. Passive tags are cheap to produce, but they have small operating ranges, usually within a few tens of centimetres. Active tags have batteries implemented from which they draw power, which greatly increases the operating range. The life span of active tags is limited by the life span of their batteries, but is said to possibly be as long as several tens of years. Active tags are more expensive to produce.

For our purposes, active tags are preferable to passive tags. Their greater operating ranges allow less intrusive monitoring set-ups. For example, the reading device may be placed outside a high containment laboratory, when otherwise it would need to be very close to the monitored items of equipment. Additionally, one strategically placed reading device may be able to monitor several items of equipment. Active tags can also perform additional tasks such as monitoring environmental conditions (e.g. vibrations due to moving the equipment around) and actively broadcasting an alarm signal, if necessary.

Additional important technical considerations are the following. Since tag performance on and around metal surfaces varies dramatically across different types of tags, tags may have to be

adapted to particular items of equipment.³² Especially in laboratory environments, susceptibility to metal should be low. Environmental factors such as humidity, corrosive substances or accidental shocks to the tag may call for exceptionally durable tag design. Battery life span needs to be adapted to the frequency of on-site maintenance inspections.

Security considerations

Security measures are essential in any monitoring system. They serve two purposes: to assure that there can be no manipulation by the monitored party, but also to assure the monitored party that the information reaches the monitoring organisation completely and correctly.

Again, active tags are preferable for our purposes. Due to their battery power they can autonomously send an alarm signal to the monitoring system when tampering is detected. Tampering detection is possible using force sensors connected to the tags, as has been demonstrated by studies considering the use of active RFID tags for nuclear verification.³³ Active tags also allow for encrypted communication between the tag and the reading device, providing secure communication for that part of the monitoring system.

Every device connected to the internet can, in principle, communicate with any other device connected to the internet and is, thus, susceptible to attacks. There are, however, tried and tested security instruments such as firewalls, encrypted communication and authentication which can provide very good protection. It is also crucial to allow for the possibility of software updates, because previously unknown security vulnerabilities are constantly being uncovered and the affected software needs to be fixed as quickly as possible. But the internet connection does not only need to be secure, it also needs to be stable so that data can be transferred continuously in real-time. With the internet connection shut off or disrupted, there is no possibility to detect tampering or the removal of the monitored items of equipment from the site.

Costs³⁴

There is little information available on the costs of specific RFID systems, because pricing of the components is highly dependent on the intended use, the resulting technical requirements and

³² Remote monitoring and tracking of UF₆ cylinders using long-range passive ultra-wideband (UWB) RFID tags. Institute of Nuclear Materials Management (INMM), 2007 Annual Meeting, Proceedings.

³³ Development of the RFID system for nuclear materials management. Institute of Nuclear Materials Management (INMM), 2008 Annual Meeting, Proceedings.

³⁴ See <http://www.rfidjournal.com/article/view/1336/1>.

the quantities in which the systems will be needed. While passive tags are as cheap as 0.2 USD per unit, the price of active RFID tags is around several tens of USD a piece. There is no information available on how expensive it would be to integrate force sensors for tampering detection. Costs for a reading device range from 500 to 3.000 USD.

Special software is needed for handling the data exchange between the reading device and the monitoring organisation. Pricing information is hard to find, but may be up to several hundred thousand USD. It is, however, to be expected that with the industry advancing, these costs will decrease. Also, with an appropriate development strategy, these are one-time set-up costs.

Embedded computer systems are needed for the special software to run on. These small, energy-efficient and durable computer systems have been widely used in the IT industry for years and are well developed today. An embedded system with the computing capabilities necessary for the monitoring system as shown in the figure above can be smaller than a shoebox and consume no more than 10–20 Watts.³⁵ The per-unit costs for such systems range from 500 to 1.000 USD.³⁶

If the internet connection at the site is too unreliable, mobile internet connections using GPRS, UMTS or similar technology may be available as the main connection, or as a backup. The costs for such connections approximately match those of an ordinary, land-line based internet connection. In poorly connected areas, however, satellite based internet connections may be the only reliable solution, which is a very costly one.

5. Conclusions and outlook

Convinced that more transparency around bioweapons relevant activities globally would help non-proliferation efforts and prevent biological weapons programmes, our Research Group successfully developed a trade monitoring concept for biological dual use equipment. Taking the UNSCOM/UNMOVIC export/import control mechanism as basis, we worked out a list of equipment the trade with which would need to be monitored. We also identified the HS as source of global trade data. In order, however, to focus the trade monitoring system properly, amendments to the HS nomenclature would be essential, so that critical items of equipment would be identified in a more individual manner. Accordingly, we developed a HS amendment

³⁵ See <http://rtcmagazine.com/articles/view/101076>, <http://www.supermicro.com/newsroom/pressreleases/2009/press050409.cfm> and <http://www.pspsecurity.com/technology2.php>.

³⁶ See http://www.bsicomputer.com/new/embedded/embedded_index.htm.

proposal, which was refined in cooperation with experts from WCO. For procedural reasons, the amendment process was adjourned in May 2008 and has not yet been successfully finished.

Independent of any processing of the specific trade data that would become available if our amendment proposal were implemented, the HS amendment would generate a number of advantages. It would help to:

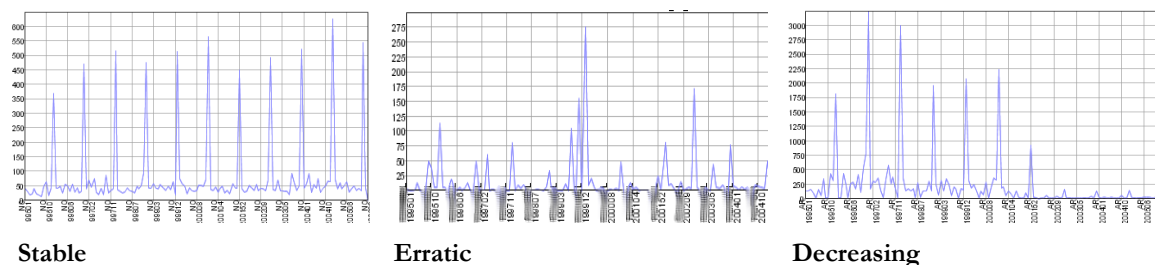
- Identify biotechnology items more clearly in customs declarations; and thereby
- Make national export controls more effective and promote the implementation of UN Security Council Resolution 1540 (2004);
- Allow a coordinated view on global trade flows of biological dual use items;
- Provide indications of countries' capabilities in the biological field;
- Allow improved market analysis in the biological area;
- Make trade with biological dual use items more transparent; and
- Allow monitoring trade for signs of suspicious activities related to the development of bioweapons.

The most important task for the future is, therefore, to re-start the HS amendment process. The last HS review cycle ended in May 2009. There is now a limited time frame until 2014 to re-introduce, discuss and agree on the proposed amendments to the HS nomenclature aimed at improving the identification of biotechnology equipment in the HS. One way to get the amendment process – which has received much support from governments, industry and non-governmental experts – back on track would be for the BWC Review Conference in December 2011 to request the WCO to restart discussions.

Another important task for the future is to start thinking seriously about what we need to do with the new data sets that will become available once the amendment process is successfully finished. This firstly concerns search patterns and the associated software. Simply downloading trade data is not yet trade monitoring. What can we read out of trade data? How can we generate useful information from data sets that will look similar to the ones in the box below?

Secondly, thought needs to be given to follow-up mechanisms. How should search results be interpreted? Which procedures need to be established to deal with unclear or suspicious search results? And who will take care of the follow-up activities?

Three types of trade patterns, using prepared culture media (HS 3821.00) as an example³⁷



A stable trade pattern indicates an established biotech capability with a constant need of culture media. A decreasing trade pattern could mean that the country in question is developing its indigenous capability to produce culture media and does not need imported culture media any longer. Equally, there could be an increasing trade pattern, indicating that a state is developing a certain biotech capability with a growing need for culture media. The pattern requiring explanation is the erratic one, where only targeted inquiries can uncover the reasons for certain peaks in demand.

Further developing our trade monitoring concept and putting it into practice will, we are certain, contribute to a world that moves away from the threat of misuse of the life sciences for weapons purposes.

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ANNEXES

ANNEX I

HS amendment proposal in its latest form

As contained in document NR0741B1a (Annex).

ARTICLE 16 PROCEDURE AMENDMENTS TO THE NOMENCLATURE

CHAPTER 38.

Heading 38.21.

Delete and substitute:

“38.21 Prepared culture media for the development or maintenance of microorganisms (including viruses and the like) or of plant, human or animal cells.

3821.10 - Prepared culture media for the development or maintenance of microorganisms (including viruses and the like), for production purposes

3821.20 - Prepared culture media for the development or maintenance of microorganisms (including viruses and the like), for diagnostic purposes

3821.90 - Other”.

Heading 38.22.

Delete and substitute:

“38.22 Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading 30.02 or 30.06; certified reference materials.

3822.10 - Detection assays for microorganisms and toxins, including immunological and gene probe assays

3822.90 - Other”.

CHAPTER 39.

Subheading 3926.20.

Delete and substitute:

“ - Articles of apparel and clothing accessories (including gloves, mittens and mitts):

3926.21 -- Positive pressure air-fed suits; half-suits for protection from exposure to hazards such as pathogens; accessories thereof (including gloves)

3926.29 -- Other”.

CHAPTER 40.

New subheading 4015.12.

Insert the following new subheading:

“4015.12 - For use with Class III or Class IV biological safety cabinets”.

CHAPTER 61.

Heading 61.13.

Delete and substitute:

“61.13 Garments, made up of knitted or crocheted fabrics of heading 59.03, 59.06 or 59.07.

6113.10 - Positive pressure air-fed suits; half-suits for protection from exposure to hazards such as pathogens

6113.90 - Other”.

CHAPTER 62.

Subheading 6210.10.

Delete and substitute:

“ - Of fabrics of heading 56.02 or 56.03:

6210.11 -- Positive pressure air-fed suits; half-suits for protection from exposure to hazards such as pathogens

6210.19 -- Other”.

Subheadings 6210.40 and 6210.50.

Delete and substitute:

“ - Other mens’ or boys’ garments:

6210.41 -- Positive pressure air-fed suits; half-suits for protection from exposure to hazards such as pathogens

6210.49 -- Other

- Other women’s or girls’ garments:

6210.51 -- Positive pressure air-fed suits; half-suits for protection from exposure to hazards such as pathogens

6210.59 -- Other”.

CHAPTER 70.

Subheading 7019.32.

Delete and substitute:

“7019.33 -- Ultra-low penetration air (ULPA) filters, with a dioctylphthalate (DOP) test rating of 99.999 % at 0.12 micron

7019.34 -- Super ultra-low penetration air (SULPA) filters, with a dioctylphthalate (DOP) test rating of 99.9999 % at 0.12 microns or higher

7019.36 -- Other thin sheets (voiles)”.

CHAPTER 84.

Subheadings 8414.60 and 8414.80:

Delete and substitute:

“ - Hoods having a maximum horizontal side not exceeding 120 cm:

8414.61 -- Class II and Class III biological safety cabinets or isolators

8414.69 -- Other

- Other:

8414.81 -- Class II and Class III biological safety cabinets or isolators

8414.89 -- Other”.

Subheading 8419.20.

Delete and substitute:

- “ - Medical, surgical or laboratory sterilizers:
8419.21 -- Double ended autoclaves and pass through sterilizing apparatus
8419.29 -- Other”.

New subheadings 8419.33 to 8419.38.

Insert the following new subheadings:

- “8419.33 -- For biological material, spray-drying
8419.34 -- For other materials, spray-drying
8419.35 -- Other, freeze-drying, with a condenser capacity less than 5 kg of ice in 24 hours
8419.36 -- Other, freeze-drying, with a condenser capacity 5 kg of ice or more in 24 hours
8419.37 -- Other, drum-drying, aseptic (i.e., fully contained and sterilisable)
8419.38 -- Other, drum-drying, not for use with biological material”.

New subheading 8419.82.

Insert the following new subheading:

- “8419.82 -- Other fermenters and continuous flow fermentation systems, orbital or reciprocal shakers and shaking incubators [, designed for use with biological material] and plant inoculation cabinets and chambers providing quarantine”.

Heading 84.21.

New subheadings 8421.13 to 8421.15:

Insert the following new subheadings:

- “8421.13 -- Batch centrifuges, [designed for use with biological material and] capable of insitu steam sterilization in a closed state, with a rotor capacity of less than 25 l
8421.14 -- Batch centrifuges, [designed for use with biological material and] capable of insitu steam sterilization in a closed state, with a rotor capacity of 25 l or more
8421.15 -- Continuous centrifuges, [designed for use with biological material and] capable of in-situ steam sterilization in a closed state”.

New subheadings 8421.24 and 8421.25.

Insert the following new subheadings:

- “8421.24 -- Cross-flow and tangential filtration equipment [for biological material], having a filter area less than 0,2 m²
8421.25 -- Cross-flow and tangential filtration equipment [for biological material], having a filter area 0,2 m² or more”.

Subheading 8421.91.

Delete and substitute:

- “8421.92 -- Rotors for the apparatus of subheadings 8421.13, 8421.14 or 8421.15
8421.93 -- Other parts of centrifuges, including centrifugal dryers”.

Subheading 8424.81.

Delete and substitute:

- “8424.82 -- Aerosol disseminators, foggers and nebulisers including pulse jet disseminators, capable of dispersing aerosols with an initial mean droplet size of 50 microns or less

at a flow rate exceeding 1 l of liquid suspension per minute or 10 g of dry material per minute

8424.83 -- Other agricultural or horticultural appliances”.

Subheading 8424.90.

Delete and substitute:

“ - Parts:

8424.91 -- Of the apparatus of subheading 8424.82

8424.99 -- Other”.

Subheading 8479.82.

Delete and substitute:

“8479.83 -- Orbital or reciprocal shakers and shaking incubators [, designed for use with biological material]; drum dryers; Class II and Class III biological safety cabinets or isolators; automatic peptide synthesizers; machinery for milling or grinding, capable of producing powders with a mean particle size of 15 microns or less

8479.84 -- Other mixing, kneading, crushing grinding, screening, sifting, homogenizing, emulsifying or stirring machines”.

CHAPTER 90.

Heading 90.20.

Delete and substitute:

“90.20 Other breathing appliances and gas masks, excluding protective masks having neither mechanical parts nor replaceable filters.

9020.10 - Positive pressure air-fed suits, incorporating breathing apparatus

9020.20 - Gas masks, for protection against biological agents

9020.90 - Other”.

New subheading 9027.60.

Insert the following new subheading:

“9027.60 - Nose-only aerosolization equipment, excluding aerosol therapy apparatus”.

Subheading 9031.41.

Delete and substitute:

“9031.41 -- Instruments and appliances for inspecting semiconductor wafers or devices or for inspecting photomasks or reticles used in manufacturing semiconductor devices

9031.42 -- Aerodynamic particle-sizing equipment”.

Subheading 9031.80.

Delete and substitute:

“ - Other instruments, appliances and machines:

9031.81 -- Aerodynamic particle-sizing equipment

9031.89 -- Other”.

ANNEX II

UNMOVIC control list for biological dual use equipment

As contained in document S/2001/560 (15 October 2001), Letter dated 1 June 2001 from the Executive Chairman of UNMOVIC addressed to the President of the Security Council, p. 21-25.

2.1 (Commodity Designator Code: BA002100)

Facilities, rooms or other enclosures that meet the physical containment criteria for P3 or P4 (BL3, BL4, L3, L4) biological containment as specified in the WHO Laboratory Biosafety Manual (Geneva, 1993).

2.2 (Commodity Designator Code: BA002200)

Biological safety cabinets, which allow manual operations to be performed within, whilst providing an equivalent to Class I, II or III biological protection, as specified in the WHO Laboratory Biosafety Manual (Geneva, 1993) as follows:

Class I cabinet: an open-fronted, ventilated cabinet for personal protection with an unrecirculated inward air flow away from the operator. It is fitted with a HEPA filter to protect the environment from a discharge of microorganisms;

Class II cabinet: an open-fronted, ventilated cabinet for personal, product and environmental protection, which provides an inward air flow and HEPA-filtered supply and exhaust air. There are two main variations: the Class IIA type recirculates 70 percent of the air, the Class IIB type recirculates 30 percent of the air; and

Class III cabinet: a totally enclosed ventilated cabinet, which is gas-tight and is maintained under negative air pressure. The supply air is HEPA-filtered and the exhaust air is passed through two HEPA filters in series. Work is performed with attached long-sleeved gloves.

Kits to upgrade Class I biosafety cabinets to Class II or III.

Specially designed long-sleeved gloves for Class III biosafety cabinet.

2.3 (Commodity Designator Code: BA002300)

Flexible film isolators, glove boxes, anaerobic chambers, dry boxes and secondary containment systems using HEPA air filtration, and having access ports for control, manipulation and decontamination.

2.4 (Commodity Designator Code: BA002400)

HEPA filters of a frame area of 0.0625 m² or greater and which have a DOP rating of 99.997 % (at 0.3 micron) or higher.

2.5 (Commodity Designator Code: BA002500)

Autoclaves designed to sterilize infectious material, with an internal volume equal to 1.0 m³ or greater.

2.6 (Commodity Designator Code: BA002600)

Positive pressure air-fed suits, half suits, helmets and respirators designed for biological use.

3.1 (Commodity Designator Code: BA003100)

Fermenters, bioreactors, chemostats, and continuous flow fermentation systems with a vessel capacity of 50 litres or more and the following specially designed components:

- Top plates;
- Vessels;
- pH probes; and
- pO₂ probes.

3.2 (Commodity Designator Code: BA003200)

Specially designed tissue culture cultivation vessels in which each vessel has an effective growth surface area of 450 cm² or greater.

3.3 (Commodity Designator Code: BA003300)

Orbital or reciprocal shakers with a total flask capacity greater than 250 litres, designed for use with biological material.

Shaking incubators with a total flask capacity greater than 250 litres, designed for use with biological material.

4.1 (Commodity Designator Code: BA004100)

Centrifugal separators (or decanters) designed for use with biological material capable of continuous operation at a flow rate of 50 litres per hour or greater and specially designed rotors therefor.

4.2 (Commodity Designator Code: BA 004200)

Batch centrifuges with a rotor capacity of 25 litres or greater, designed for use with biological material.

4.3 (Commodity Designator Code: BA004300)

Cross-flow and tangential filtration equipment designed for use with biological material with a filter area equal or greater than 2 m² and component filter cartridges therefor.

4.4 (Commodity Designator Code: BA004400)

Spray drying equipment designed for use with biological material and the following specially designed components:

- Spray/atomiser units;
- Cyclones;
- Classifiers; and
- Electronic control units.

4.5 (Commodity Designator Code: BA004500)

Freeze-drying (lyophilisation) equipment with a condenser capacity greater than 5 kg of ice in 24 hours, and specially designed vacuum chambers therefor.

4.6 (Commodity Designator Code: BA004600)

Size reduction equipment including milling and grinding equipment) capable of producing powders with a mean particle size of 15 microns or less, and the following specially designed components:

- Grinding heeds;
- Milling heads;
- Milling bodies,
- Grinders; and
- Classifiers.

5. (Commodity Designator Code: BA005000)

Formulated powdered complex growth media prepackaged in a container size of 5 Kg or greater.

Formulated concentrated liquid complex growth media prepackaged in a container size of 5 litres or greater.

Microbiological grade yeast extract when prepackaged in a container size of 5 Kg or greater.

6.1 (Commodity Designator Code: BA006100)

Immunological assay systems for microorganisms, toxins, or genetic material in List 1, with specially designed reagents.

6.2 (Commodity Designator Code: BA006200)

Gene probe assay systems for microorganisms, toxins, or genetic material in List 1, with specially designed reagents.

6.3 (Commodity Designator Code: BA006300)

Biological agent detection systems for microorganisms, toxins, or genetic material in List 1, designed for biological defense or civil defense applications.

6.4 (Commodity Designator Code: BA006400)

Nucleic acid sequencing equipment.

6.5 (Commodity Designator Code: BA006500)

Nucleic acid synthesizers.

6.6 (Commodity Designator Code: BA006600)

Electroporation or biolistics equipment.

6.7 (Commodity Designator Code: BA006700)

Thermal cyclers designed for use in molecular biology.

7.1 (Commodity Designator Code: BA007100)

Aircraft sprayers capable of dispersing aerosols with an ultimate mean size of 15 microns or less at a flow rate exceeding 1 litre of liquid suspension per minute or 10 g of dry material per minute, and the following specially designed components:

Spray tanks;
Certified pumps; and
Spray nozzles.

7.2 (Commodity Designator Code: BA007200)

Aerosol disseminators (other than aircraft sprayers and foggers), capable of dispersing aerosols with an ultimate mean size of 15 microns or less at a flow rate exceeding 1 litre of liquid suspension per minute or 10 g of dry material per minute.

Note: This entry excludes dry powder fire extinguishers.

7.3 (Commodity Designator Code: BA007300)

Foggers including pulse jet disseminators capable of dispersing aerosols with an ultimate mean size of 15 microns or less at a flow rate exceeding 1 litre of liquid suspension per minute or 10 g of dry material per minute, and the following specially designed components:

Head unit; and
Nozzle assembly.

8.1 (Commodity Designator Code: BA008100)

Aerosolization drums, cabinets, chambers, rooms or other enclosures usable in the studies of aerosols.

8.2 (Commodity Designator Code: BA008200)

Nose-only aerosolisation equipment but excluding devices for personal prophylaxis or therapy for medical conditions.

8.3 (Commodity Designator Code: BA008300)

Aerodynamic particle-sizing equipment.

ANNEX III

Australia Group control list for biological dual use equipment (as of September 2009)

Available at http://www.australiagroup.net/en/dual_biological.html.

1. Complete containment facilities at P3 or P4 containment level

Complete containment facilities that meet the criteria for P3 or P4 (BL3, BL4, L3, L4) containment as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004) should be subject to export control.

2. Fermenters

Fermenters capable of cultivation of pathogenic microorganisms, viruses or for toxin production, without the propagation of aerosols, having a capacity of 20 litres or greater. Fermenters include bioreactors, chemostats and continuous-flow systems.

3. Centrifugal separators

Centrifugal separators capable of the continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all the following characteristics:

1. one or more sealing joints within the steam containment area;
2. a flow rate greater than 100 litres per hour;
3. components of polished stainless steel or titanium;
4. capable of in-situ steam sterilisation in a closed state.

Technical note: Centrifugal separators include decanters.

4. Cross (tangential) flow filtration equipment

Cross (tangential) flow filtration equipment capable of separation of pathogenic microorganisms, viruses, toxins or cell cultures, without the propagation of aerosols, having all the following characteristics:

1. a total filtration area equal to or greater than 1 square metre; and
2. having any of the following characteristics:
 - i. capable of being sterilized or disinfected in-situ; or
 - ii. using disposable or single-use filtration components.

(N.B. This control excludes reverse osmosis equipment, as specified by the manufacturer.)

Cross (tangential) flow filtration components (e.g. modules, elements, cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 square metres for each component and designed for use in cross (tangential) flow filtration equipment as specified above.

Technical note: In this control, 'sterilized' denotes the elimination of all viable microbes from the equipment through the use of either physical (eg steam) or chemical agents. 'Disinfected' denotes the destruction of potential microbial infectivity in the equipment through the use of chemical agents with a germicidal effect. 'Disinfection' and 'sterilization' are distinct from 'sanitization', the latter referring to cleaning procedures designed to lower the microbial content of equipment without necessarily achieving elimination of all microbial infectivity or viability.

5. Freeze-drying equipment

Steam sterilisable freeze-drying equipment with a condenser capacity of 10 kgs of ice or greater in 24 hours and less than 1,000 kgs of ice in 24 hours.

6. Protective and containment equipment as follows:

1. protective full or half suits, or hoods dependent upon a tethered external air supply and operating under positive pressure;
Technical note: This does not control suits designed to be worn with self-contained breathing apparatus.
2. class III biological safety cabinets or isolators with similar performance standards (e.g. flexible isolators, dry boxes, anaerobic chambers, glove boxes, or laminar flow hoods (closed with vertical flow)).

7. Aerosol inhalation chambers

Chambers designed for aerosol challenge testing with microorganisms, viruses or toxins and having a capacity of 1 cubic metre or greater.

8. Spraying or fogging systems and components therefore, as follows:

1. Complete spraying or fogging systems, specially designed or modified for fitting to aircraft, lighter than air vehicles or UAVs, capable of delivering, from a liquid suspension, an initial droplet "VMD" of less than 50 microns at a flow rate of greater than two litres per minute.
2. Spray booms or arrays of aerosol generating units, specially designed or modified for fitting to aircraft, lighter than air vehicles or UAVs, capable of delivering, from a liquid suspension, an initial droplet "VMD" of less than 50 microns at a flow rate of greater than 2 litres per minute.
3. Aerosol generating units specially designed for fitting to systems that fulfil all the criteria specified in paragraphs 8.1. and 8.2..

Technical Notes

Aerosol generating units are devices specially designed or modified for fitting to aircraft such as nozzles, rotary drum atomisers and similar devices.

This entry does not control spraying or fogging systems and components as specified in paragraph 8 above that are demonstrated not to be capable of delivering biological agents in the form of infectious aerosols.

Pending definition of international standards, the following guidelines should be followed:

Droplet size for spray equipment or nozzles specially designed for use on aircraft or UAVs should be measured using either of the following methods:

1. Doppler laser method;
2. Forward laser diffraction method.

Items for inclusion in Awareness Raising Guidelines

Experts propose that the following items be included in awareness raising guidelines to industry:

1. equipment for the micro-encapsulation of live microorganisms and toxins in the range of 1-10 um particle size, specifically:
 1. interfacial polycondensators;
 2. phase separators.
2. fermenters of less than 20 litre capacity with special emphasis on aggregate orders or designs for use in combined systems.
3. conventional or turbulent air-flow clean-air rooms and self-contained fan-HEPA filter units that may be used for P3 or P4 (BL3, BL4, L3, L4) containment facilities.

ANNEX IV

BWC Ad Hoc Group control list for biological dual use equipment

As contained in document BWC/AD HOC GROUP/56-1, Annex A, p. 200-206, available at <http://www.unog.ch/unog/website/disarmament.nsf/%28httpPages%29/F5C615E0217AE11FC12577280032DB46?OpenDocument&unid=FCA0866229E27290C12572BC00327DC2>.

1. Aerosol chambers (either static, dynamic, or explosive):
 - (a)
 - Not present
 - Present
 - Utilized
 - Utilized in high biological containment
 - Utilized in maximum biological containment
 - (b) What tests were conducted in those chambers present:
 - (i) Static YES / NO
 - (ii) Dynamic YES / NO
 - (iii) Explosive YES / NO
 - (c) What is the volume of the chamber(s) present and utilized for those tests?
 - (i) For static tests:
 - Less than 1 cubic metre
 - Equal to or greater than 1 but less than 5 cubic metres
 - Equal to or greater than 5 but less than 30 cubic metres
 - Equal to or greater than 30 but less than 100 cubic metres
 - Equal to or greater than 100 cubic metres
 - (ii) For explosive tests:
 - Less than 1 cubic metre
 - Equal to or greater than 1 but less than 5 cubic metres
 - Equal to or greater than 5 but less than 30 cubic metres
 - Equal to or greater than 30 but less than 100 cubic metres
 - Equal to or greater than 100 cubic metres
 - (iii) For dynamic tests:
 - Less than 1 cubic metre
 - Equal to or greater than 1 but less than 5 cubic metres
 - Equal to or greater than 5 but less than 30 cubic metres
 - Equal to or greater than 30 but less than 100 cubic metres
 - Equal to or greater than 100 cubic metres
 - (d) Indicate the type(s) of activities conducted by or in these aerosol systems or chambers:
 - Study of aerosol properties

- Study using aerosol flows
- Explosive/shock wave dissemination of aerosols
- Study of the properties of agents and toxins
- Studies with the use of experimental animals
- Other (specify):

2. Equipment designed or utilized to generate aerosols of microorganisms or toxins [and simulants]:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

(a) Form of source material used to generate aerosol(s) (check all that apply):

- Liquid
- Powder

(b) Mass median diameter of aerosol particles generated (check all that apply):

- Less than 10 micrometres
- Equal to or greater than 10 but less than 50 micrometres

(c) For which purpose was the equipment utilized (check all that apply):

- Aerosol chambers
- Open-air release
- With experimental animals

3. Aerosol analytical equipment to determine the size of particles [of a biological nature]:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

4. Indicate the presence, utilization, and containment usage of the following equipment at the declared facility (check where applicable):

(a) Fermenter(s)/bioreactor(s) with total/internal volume exceeding ... litres:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

- [(b) Chemical reactor(s) with a total/internal volume exceeding ... litres:
- Not present
 - Present
 - Utilized
 - Utilized in high biological containment
 - Utilized in maximum biological containment]
- [5. Indicate the capacity ranges of fermenters/bioreactors at the declared facility (specify which ranges apply):
- (a)
- Less than 100 litres
 - Equal to or greater than 100 but less than 1,000 litres
 - Equal to or greater than 1,000 but less than 10,000 litres
 - Equal to or greater than 10,000 but less than 100,000 litres
 - Equal to or greater than 100,000 litres
- (b) Specify the volume of the largest fermenter/bioreactor.]
6. Equipment for continuous or perfusion growth of microorganisms with a volume over ... litres per hour:
- Not present
 - Present
 - Utilized
 - Utilized with primary production containment
 - Utilized in high biological containment
 - Utilized in maximum biological containment
7. Continuous or semi-continuous centrifuge(s) that are self-sterilizable, with throughput capacity greater than 100 litres per hour:
- Not present
 - Present
 - Utilized
 - Utilized with primary production containment
 - Utilized in high biological containment
 - Utilized in maximum biological containment
8. Cross-flow/tangential filtration equipment with filter area of over 5 square metres:
- Not present
 - Present
 - Utilized
 - Utilized with primary production containment
 - Utilized in high biological containment
 - Utilized in maximum biological containment
9. Freeze dryer(s) with condenser capacity of over 5 kg of ice in 24 hours:
- Not present
 - Present

- Utilized
- Utilized with primary production containment
- Utilized in high biological containment
- Utilized in maximum biological containment

10. Cell disruption equipment capable of continuous operation without the release of aerosols with a flow rate greater than 10 litres per hour:

- Not present
- Present
- Utilized
- Utilized with primary production containment
- Utilized in high biological containment
- Utilized in maximum biological containment

11. Spray dryer(s):

- Not present
- Present
- Utilized
- Utilized with primary production containment
- Utilized in high biological containment
- Utilized in maximum biological containment

12. Drum dryer(s):

- Not present
- Present
- Utilized
- Utilized with primary production containment
- Utilized in high biological containment
- Utilized in maximum biological containment

13. Biological safety cabinets Class III or Class I with accessories for conversion to Class III:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

14. Flexible film isolators or other cabinets with air handling characteristics equivalent to Class III and anaerobic boxes:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

[15. Biological safety cabinets Class II:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment]

16. Micro-encapsulation equipment:

- Not present
- Present
- Utilized
- Utilized with primary production containment
- Utilized in high biological containment
- Utilized in maximum biological containment

17. Automatic DNA synthesizer:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

18. Automatic peptide synthesizer:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

19. Milling equipment designed or utilized to produce a grain mass median diameter of less than 10 micrometres:

- Not present
- Present
- Utilized
- Utilized with primary production containment
- Utilized in high biological containment
- Utilized in maximum biological containment

OR

Equipment designed or utilized to produce dry powders:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

Indicate the grain mass median diameter that applies (check all that apply):

- Less than 10 micrometres
- Equal to or greater than 10 but less than 50 micrometres

20. Plant inoculation cabinets/chambers providing quarantine:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

Indicate the total cabinet/chamber working volume range which applies to equipment present:

- Less than 1 cubic metre
- Equal to or greater than 1 but less than 3 cubic metres
- Equal to or greater than 3 cubic metres

21. Cabinets/chambers designed or used for rearing insects:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment
- Used in quarantine

Indicate the total cabinet/chamber volume range which applies to equipment present:

- Less than 3 cubic metres
- Equal to or greater than 3 cubic metres

22. Self-contained breathing apparatus for other than fire-fighting purposes:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

ANNEX V

List of relevant WCO documents

All documents in the following list are available at http://www.biological-arms-control.org/projects_trademonitoring.html.

| Number | Title | Date | Brief content description |
|---------------------------|--|-------------|--|
| NR0713E1a (+Annex) | Possible amendments of the nomenclature (proposal by the Research Group for Biological Arms Control) (Item III.C.1 on Agenda) | 5 Nov 2007 | Original amendment proposal |
| NR0722E1a | Draft report of the 36 th session of the Harmonized System Review Sub-Committee | 27 Nov 2007 | Sub-Committee requesting HS Secretariat and HS Committee to classify the items in question |
| NC1264E1a | Classification of the biological dual use items of the BWC (Item VI.4 on Agenda) | 19 Feb 2008 | HS sub-headings suggested by the Secretariat for the classification of the items in question |
| Annex F/3 to NC1310E1b | Classification of the biological dual use items of the BWC - Decisions of the HS Committee | Mar 2008 | HS Committee considering procedural and technical questions |
| NR0741E1a (+Annex) | Possible amendments of the nomenclature (proposal by the Research Group for Biological Arms Control) (Item III.A.15 on Agenda) | 28 Apr 2008 | Comments on proposed HS amendments by the Research Group and the Secretariat |
| Annex to NR0741B1a | Possible amendments of the nomenclature (Item III.A.15 on Agenda) | May 2008 | List of proposed new HS codes |
| NR0751E1b | Report of the 37 th session of the HS Review Sub-Committee | 21 May 2008 | Sub-Committee adjourning the amendment process for procedural reasons |