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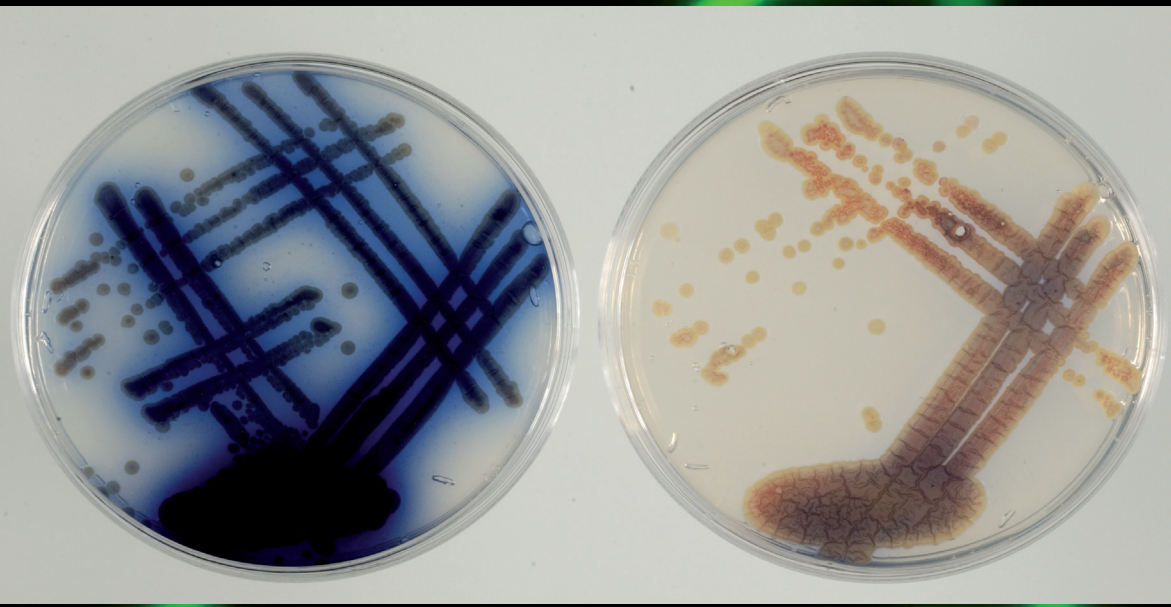

GOVERNMENT OF SPAIN
MINISTRY OF FOREIGN AFFAIRS AND COOPERATION
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No proliferación de agentes biológicos

Fondo de portada y contraportada: La bacteria *Bacillus subtilis* manipulada genéticamente para sobreproducir una proteína fluorescente verde visualizada bajo el microscopio de fluorescencia.

Portada sobrepuesta: Cultivo en medio sólido de la bacteria *Streptomyces coelicolor* manipulada genéticamente para sobreproducir un antibiótico pigmentado en azul, comparada con la bacteria no productora del antibiótico.

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INDEX

Página

1. INTRODUCTION

The international community adopted the "Convention on the prohibition of the development, production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their destruction" (BTWC), done at London, Moscow and Washington on 10 April 1972. Spain ratified the Convention on June 1, 1979. The objective of the Convention is to totally exclude the possibility of bacteriological agents and toxins being used as weapons.

The United Nations Security Council (UNSC), concerned by the threat of terrorism and the risk of non-state actors acquiring, developing or using nuclear, chemical and biological weapons or trafficking with them, adopted the "Resolution 1540" on 28 April 2004, which requested all States to take effective measures for the prevention of terrorism with weapons of mass destruction (WMD), and therefore, of biological terrorism.

Every sovereign State has the liability associated with the maintenance of its national biological security, what is known as "Biosecurity"[1]. The main objective of the biosecurity is to strengthen security in everything related to materials and biological agents and facilities and associated activities, ensuring keeping of such materials and agents as well as their storage and transport. Thus, combating their illicit trade more effectively, and facilitating an appropriate preparation for a possible response to a biological incident, whether natural, intentional or accidental.

[1] For the purpose of this document, biosecurity means the physical protection both outdoor and indoor of the facilities containing biological agents and these agents, equipment and materials and in their transport.

Viruses' outbreaks of zoonotic avian influenza, Severe Acute Respiratory Syndrome (SARS) and the coronavirus Respiratory Syndrome of Middle East (MERS), along with the recent epidemic outbreak of Ebola virus in West Africa, have significantly increased the concern about the potential use of biological agents as WMD.

Within the WMD, the biological weapons are the only ones that have not managed to have a verification regime agreed upon by all States Parties (SP) of the BTWC. The absence of an international authority and of a verification protocol to the BTWC leaves the biological weapons as the easiest ones to acquire by non-State actors or States that support to terrorist organizations.

These deficiencies at the international level increase responsibility of Sovereign States to design and establish measures at the national level to comply with Resolution 1540 of the UNSC. The main issue that each State should face is how to better comply with the obligations arising from the BTWC and the Resolution 1540.

The Spanish National Security Strategy, approved by Decision of the Council of Ministers of 31 May 2013, includes the design and implementation of a National Plan for Biosecurity among its objectives, whose approval and implementation will seek a better fulfilment of Resolution 1540 of the UNSC. Biosecurity is considered a matter of National Security.

A recent publication[2] offers recommendations for improving biosecurity measures. These recommendations frame the objectives of a regime of biosecurity at the national level. The publication also includes recommendations to elaborate a national strategy to counter potential biological attacks, as well as recommendations for maintaining the biosecurity of materials and biological agents, not only in the handling of these agents, but also in the facilities working with them and in the activities relating to them. Finally, this publication indicates the desirability of having some kind of National Authority or Responsible Entity (RE) to supervise the biosecurity regime at the national level.

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[2] Perez Mellado, Rafael. "*Recommendations to improve biosecurity measures"*. Madrid. Spanish Ministry of Foreign Affairs and Cooperation, 2015.

However, the feeling of complexity and the perception of the potential cost and maintenance of the established recommendations and measures included in them, invite to think that setting a national regime of biosecurity is little less than impossible.

The purpose of this document is precisely to review these measures, analysing the logic of their recommendations and simplifying the apparent difficulty of their implementation. The application of common sense to this analysis, as in other areas of the ADM, is a tool of proven effectiveness. This document is based on the premise that a RE to supervise the biosecurity regime at the national level does exist.

2. PATHOGENS: WHERE ARE AND WHICH ARE THEY?

In an exclusively operational way, it is possible to define biosecurity as a set of measures to prevent those personnel members, who are not duly authorized, accessing the pathogens. In other words, they are measures ensuring the physical protection of the pathogens.

The first thing that common sense tells us is that we must know which pathogens, in addition to the existing natural ones, are present in the country and which are the facilities working with them.; in other words, the potential magnitude of the problem must be assessed.

In general, one should seek this information within three types of facilities:

a) Laboratories of Universities and Research Centres at the State and Regional levels, working with human, animal or plant pathogens.

b) Biotech companies and/or agrarian and/or pharmaceutical companies working with human, animal or plant pathogens.

c) Laboratories for clinical analysis in hospitals and veterinary clinics.

This is the first information that should be sought. It might seem an insurmountable task, but it is not so; it does not matter how complex

the State's administrative structure is. All the information already exists in the country; the only thing to do is to collect it from the administrative units which possess it at both, State and Regional levels. The only downside is that if the structure of the country is terribly complex, it may require a legal instrument to facilitate the acquisition of the desired information. Probably, a Rule of Mandatory Compliance, a Ministerial Order or at the most a Presidential Decree, should simplify the problem. In fact, the RE should, since its constitution, have been appropriately empowered, making any additional policy unnecessary.

3. HOW TO DISTINGUISH RELEVANT PATHOGENS FROM THOSE WHICH ARE NOT OR NOT SO MUCH RELEVANT

Undeniably, there is a need for a questionnaire which the different facilities must properly fulfil, so that the RE could get the necessary information. This questionnaire could be of a universal kind, ideally including some type of decision tree (for example: if the answer to question X is no, go directly to question Y) or it could be tailored to each type of facility instead. Some States Parties to the BTWC have jointly submitted a working document to the BTWC Expert Meeting3, which contained annexed a questionnaire of the universal kind, applicable to all type of facilities working with biological agents, natural and/or genetically modified organisms (GMO), including greenhouses and animal facilities, which could eventually be used for pilot plants and facilities undertaking scaling-up processes.

Once the inventory of pathogens at the national level has been established, each country must decide which pathogens must be subjected to preferential physical protection. A way of dealing with that kind of decision could be considering the biological containment level required for handling these pathogens. For instance, pathogens requiring con-

3 BWC/MSP/2014/MX/WP.6. Chile, Colombia, Mexico and Spain.. National implementation of the Convention on Biological Weapons: A tool for the assessment of the facilities working with biological agents. Meeting of Experts of the States Parties to the BTWC. Geneva. Switzerland. August 2014.

tainment levels 3 and/or 4 might be included in the preferential protection list, and, hence, the facilities working with them should be included in a parallel list for preferential physical protection.

Should the number of facilities be high and therefore the physical protection difficult to implement, it would be necessary to apply criteria or additional measures to reduce that number and at the same time, the potential biological risk in general. A typical case could be the laboratories for clinical analysis in hospitals. In this case, it would be sufficient to have a regulation that requires hospitals to send a set of samples containing the high risk detected pathogens to a national reference laboratory and to destroy the remainder samples containing those pathogens "in situ", so that the time of permanence of the high risk pathogens in the hospital would be reduced to a minimum.

4. HOW TO ESTABLISH AN EFFECTIVE BIOSECURITY SYSTEM AT THE FACILITIES SELECTED FOR THEIR PHYSICAL PROTECTION

Logically, these facilities should have deterrent elements to preclude access from outside people and unauthorized vehicles, i.e. physical barriers, controls of redundant access, etc., as well as specialised personnel and/or technical means ensuring the alertness in case of intrusion into the facilities. For example, closed-circuit television, motion sensors, restricted access to particular areas within the facility and monitoring of that restricted access via magnetic cards, eyes, voice or fingerprints scanning etc.

These measures, in order to be effective, might require hiring a specialised surveillance service, whose staff must have a clearance certificate or, alternatively, the surveillance should be exerted by the State's Security Forces. In the first case, the surveillance company must have direct communication with the State's Security Forces, to tackle any possible incident. In this regard, the facility must have contingency and

emergency plans in case of losses of pathogens or sabotage, in addition to the standard emergency plans.

Obviously, the facility i.e. the owner or holder thereof should seek everything described above to work properly, beginning with training of the staff, specifically the staff responsible for the biological security of the facility. The biological facilities, whose physical protection is required, must have a clearance certificate issued by the RE.

5. HOW TO ENSURE THE BIOSECURITY OF BIOLOGICAL AGENTS AND MATERIALS WHEN TRANSPORTED

There are two possible options, either the transport is done by the State's Security Forces, or, alternatively, it is done by a specialised company holding a clearance certificate issued by the RE. The company's personnel should have the appropriate clearance certificate as well. In addition, the company must be in direct communication with the State's Security Forces, to cover all possible accidents or incidents. In order to supervise the transport, the route has to be known and agreed in advance with the RE. In short, the establishment of contingency and emergency plans approved by the RE, must be part of the transport protocol.

6. IMPORT AND EXPORT OF MATERIALS AND BIOLOGICAL AGENTS

It would not make much sense to protect and safeguard the materials and biological agents within the national territory if their import and export are not controlled.

Regarding the import, the RE should dictate standards of mandatory compliance to ensure the entry into the country of these materials and biological agents in a controlled manner and, once their entry is authorised, ensure their custody as indicated above.

Regarding the export of materials and biological agents, the already described security measures relevant to their transport should be applied through the national territory. Additionally, the RE should issue the appropriate clearance certificates for the different operators, importers, consignees, customs agents, etc., so that they could be duly authorized for the handling of those materials and biological agents and, at the same time, ensuring that they are in contact with the State's Security Forces. Moreover, they should be accessible to the supervision of the RE during all processes requiring transportation and/or storage of these materials and biological agents.

7. WHICH COMPOSITION SHOULD THE RE HAVE?

It is clear that biosecurity measures are complex, and of a transversal nature, involving units of different Ministries or Institutions and that, therefore, all the Institutions/Units involved should have the appropriate level of participation in the RE. If biosecurity is considered a matter of national security, it seems obvious that the RE should be chaired by the Ministry responsible for the National Security. Should this responsibility rest in more than one Ministry (e.g. Home Office and Defence), one of them could hold the Presidency and the other the Vice-presidency. Given the particular characteristics of biosecurity and its relevance at the international level, it would be logical to grant a special role to the Ministry for Foreign Affairs.

The remaining Ministries concerned should also be part of the RE. Thus, the Ministries responsible for human, animal and plant health should be represented, as well as the Ministries of transport and foreign trade and those Ministries that host the units responsible for customs. The Ministry hosting the unit responsible for the promotion of research and technological development, should also form part of the RE, as well as the Ministry in charge of national finances, since it facilitates, among many other things, the financing required for the development of biosecurity related activities. The Ministry responsible for industries

related to those sectors from which biosecurity is an important part, should also be represented in the RE.

Obviously, this distribution of responsibilities between the different Ministries involved may vary according to how the National Administration of each State is organized. For example, some countries would have to create an RE "de novo", but in others perhaps it may suffice to increase the capacity of an already existing Entity, as the National Authority for Biological Weapons, for example.

8. DOES THE RE NEED ANY TYPE OF TECHNICAL SUPPORT?

It makes all sense for the RE to be an inter-ministerial body, which would be responsible for taking the appropriate decisions. By definition the RE is a body of administrative and political nature. It will have the decision making responsibility, but it will also require some type of entity to consider and resolve the cases that may arise in the implementation of the biosecurity measures at national level. Namely, the RE needs a Technical Committee (TE).

The TC should be formed by delegates from the relevant technical units of the different Ministries, by technical representatives of the Regional (or Local) Governments, if they exist as such in the State, or, if the Administrative Organization at the national level so advise it. The presence of independent experts as consultants within the TC would be very useful to give support and advice on the technical analysis of the different situations that the TC may face exerting its functions.

The operational efficiency of the TC will no doubt be enhanced if it is provided with a Technical Secretariat (TS) to coordinate the different TC activities. Thus, the TS would be responsible for a smooth functioning of the TC. The possibility that the TS would also work for the RE, would considerably improve the agility in the technical analysis in the TC and, at the same time, in the official decisions making in the RE. The TC and its TS should be formally created if they did not exist previously, as it was mentioned above for the RE.