

**OPINII ALE EXPERTILOR – МНЕНИЯ ЭКСПЕРТОВ – EXPERTS' OPINIONS –
AVIS DES EXPERTS****STRENGTHENING GLOBAL BIOSAFETY & BIOSECURITY****Maureen ELLIS, Executive Director, International Federation of Biosafety Associations***Corresponding author: Maureen Ellis, e-mail: m.ellis@internationalbiosafety.org*

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INTRODUCTION

The International Federation of Biosafety Associations (IFBA) is a global community of 46 biosafety associations, 774 certified biosafety professionals, and other partners with the mission of “safe, secure and responsible work with biological materials”. The IFBA works globally to enhance multi-sectoral collaboration and foster partnerships between its members, government ministries, and other stakeholders in the development and implementation of comprehensive national biosafety/biosecurity strategies. This includes the implementation of the Global Health Security Agenda’s Action Package 3, International Health Regulations, UN Security Council Resolution 1540, Biological Weapons Convention, and other health security initiatives.

The effectiveness of public health functions including surveillance, diagnosis and research are influenced by reliable laboratory services, of which biosafety and biosecurity are central elements. Yet, many laboratories still lack sufficient biosafety and biosecurity practices, equipment and infrastructure to conduct their work in a safe and secure manner. Safe disposal of potentially contaminated laboratory waste also remains a challenge. Attention must be drawn to the serious dangers that can arise from the failure to implement effective biosafety and biosecurity and, importantly, must highlight the significant benefits offered by the implementation of sound biosafety and biosecurity practices including:

- minimising the socio-economic impact of human and animal disease outbreaks and better protection of laboratory staff, the wider community and the environment; and,
- contributing to better biosecurity through control of access to dangerous pathogens, tracking their use, and improving reporting of incidents.

The IFBA and its members are assisting national authorities in integrating biosafety into policies and programs, to improve sustainable laboratory infrastructure and equipment, and to increase biosafety skills and competencies among those working with infectious diseases. Our objective is to build and operate safe, yet, cost-effective laboratories and prevent laboratory exposures to infectious diseases. IFBA’s members understand local challenges in operating safe laboratories and are facilitating simple, yet, effective approaches that can be cost-effectively sustained over the long term. Rather than simply taking a high technology approach of focusing on engineering and equipment, approaches to laboratory containment facilities must balance engineering controls with operational, scientific and management controls. There is no “one size fits all” approach to BSL-2 and BSL-3 facilities. Every biocontainment laboratory should be based primarily on a solid risk assessment and the specific laboratory program requirements.

Bridging the Policy Implementation Gap

While some progress is being made in the development of national biorisk management and biosecurity strategies, there is an increasing awareness on whether these policies do not succeed or fail on their own merits; rather their progress is dependent upon the process of implementation (i.e. turning policy into practice). The space between government’s motivation behind the passage of new legislation and how that intent is translated into reality in many countries becomes an implementation gap when that policy remains on paper only or is implemented poorly. More needs to be done to try to ensure intentions for the safe and secure handling of biological materials are turned into results – in short, that policy failure is avoided.

The IFBA has been advancing ways in which the implementation phase can be strengthened and supported. We recognize that in addition to government accountability and funding investments, implementation is highly dependent on local context and that high-level decision makers cannot succeed without having some understanding of what happens on, or close to, the front line. In many cases, biosafety professionals and those who work directly with biological materials in laboratories on the front line of global health security know a great deal about the challenges and solutions of implementing national biosecurity strategies. A key success factor for bridging the policy implementation gap, therefore, is to tap into the experiences and competencies of these individuals who can positively shape the implementation process.

Moving beyond the dichotomy, between the top-down and bottom-up approaches, the IFBA's approach to implementing biosecurity policy is a synthesis of both perspectives. We encourage a strong collaboration between decision makers and front line biosafety professionals to develop strategies and innovations that will be successful and sustainable over the long term. Additionally, participation in local, national, and international networks allow for a multilateral type of exchange and collaboration between individuals and a vehicle for innovation in best practices. A range of virtual exchange and on-line collaboration formats allows for an information flow across institutions, nations and regions.

Using the internet and social media, the IFBA is connecting individuals that might not otherwise be able to share best practices and sustainable solutions. These settings also give individuals opportunities to acquire new skills that may not be offered by traditional capacity building approaches. What's more, participation in these initiatives fuels their intention to stay in the bio-security and biorisk management field.

Risk-based Sustainable Laboratories

Laboratories are an integral component of global health security and play a major role in the safe and secure handling of biological materials. Building laboratory infrastructure that is highly dependent on engineering controls and technology presents a challenge in many countries where construction and maintenance costs are prohibitive. Rather than taking a high technology approach,

the IFBA adopts a risk-based approach to designing "built-to-purpose" laboratory equipment and infrastructure that is:

- relevant to local circumstances;
- tailored to the actual risks of an individual laboratory;
- economically feasible and cost-effective to maintain.

In 2010, the IFBA's Biocontainment Engineering Working Group (BEWG) was created to serve as a "think-tank" to identify practical and sustainable solutions for biocontainment laboratories around the world. This network of biocontainment engineers and private industry partners are working together on sustainable laboratory design approaches to reduce initial capital and on-going operational costs. Laboratories in lower resource countries often struggle to implement containment solutions, which have been designed for use in other parts of the world where different working conditions prevail. Compounding the problem is a lack of well-trained biocontainment engineers that can adequately maintain and operate laboratories and critical containment equipment (e.g. biological safety cabinets) over the longer term. Effective supplier networks, maintenance provision and other basic measures are often unavailable to those most in need.

To meet these challenges, the IFBA promotes risk-based approaches to laboratory and equipment design that are cost-effective, locally driven, and can be practically implemented over the long term. The vision for risk-based approaches is not to lay out the requirements for a BSL2 or BSL3 laboratory, but rather to describe "how" these facilities should be planned and designed, based on a local biocontainment risk assessment. The resulting facilities would be built-to-purpose, utilizing a more nuanced set of requirements, and would allow for investment in infrastructure, equipment and precautions suited to the type of procedures performed. It is important to note that building sustainable laboratories also requires a strong focus on procedural and human factors, including trained and competent engineering and maintenance staff.

Professional Competency

Ensuring that individuals, who handle biological materials, demonstrate competencies on the safe and secure handling of biological materials is an

essential component of the overall effort of reducing biosafety and biosecurity risks. The IFBA's certification program is the only internationally recognized program to certify the competency of individuals in biorisk management and a variety of related technical disciplines. The program is structured in compliance with the policies and procedures of ISO/IEC 17024: 2012 *Conformity assessment – General Requirements for Bodies Operating Certification of Persons*. Examinations are delivered to candidates worldwide in the following disciplines:

- Biorisk Management (*Pre-requisite certification for all others*);
- Biological Waste Management;
- Biocontainment Facility Design, Operations & Maintenance;
- Biosafety Cabinet Selection, Installation and Safe Use;
- Biosecurity.

To date, the IFBA has issued 959 Professional Certifications to individuals in 65 countries worldwide, a milestone for our growing program. The organization recently collected feedback from their network of certified professionals in Southeast Asia to assess the program's impact in the region. Many respondents said the IFBA's certification program is recognized internationally as a high standard of competency in managing biological risks and was a pathway to enhanced responsibilities at their workplace. The survey also showed a number of ways in which certification has a positive impact on enhancing biosafety and biosecurity practices in the region. The IFBA credential sets biosafety and biosecurity competency standards and recognizes professionals who have demonstrated the knowledge and skills to safely and securely handling of biological materials. With the continued dedication and commitment from IFBA's global community of biosafety associations, and other key partners, the momentum is expected to grow through 2020.

CONCLUSIONS

Over the past years, the IFBA's network of biosafety associations, certified professionals and mentees/mentors have exercised considerable initiative, ingenuity, and drive to implement and sustain biosafety, biosecurity and biorisk management programs and activities in their respective countries. Our activities have formed crucial links between front line biosafety professionals and governments and are participating in the policy-making process and providing input to their governments about biosecurity best practices. They also serve to monitor government actions, helping to hold officials accountable and keep them responsive to actual needs. In this way, biosafety associations can assist government to ensure that practical and locally relevant solutions are reflected in biosecurity laws and their implementation.

Global Mentorship Program

The newly launched IFBA Global Mentorship Program recruits biosafety and biosecurity champions across all regions of the world to provide regionally relevant peer mentorship to developing professionals in their geographic region. Mentors and their mentees discuss foundations of biosafety and biosecurity as it pertains to global and regional standards of practice, as well as emerging trends and threats in health security across diverse professional disciplines in the human, animal and security sectors. Working collaboratively with governments, strong partnerships are being forged between decision makers and frontline workers in turning policy into practice. Feedback from mentorship teams is collected as an informal horizon scan of current norms in biosafety and biosecurity practices across regions.

The pool of mentor/mentee pairs, from an array of professional disciplines and sectors, have been sharing knowledge, skills and experiences towards translating policy objectives into action on the frontlines. Mentorship pairs use One Health approach to harmonize health security approaches across the human and animal health sectors. Mentees are learning how to best translate principles in global health security into strategies and innovations that will be successful and sustainable on the front lines over the long term. In addition to meaningful mentee-mentor collaboration, pairs are participating in regional and international networks to gain additional skills and knowledge for strengthening health security implementation at the local level. The IFBA's south-to-south mentoring program has demonstrated its success as a vehicle for forming crucial links between frontline biosafety professionals, laboratory workers and government decision makers. By supporting regionally relevant peer mentorship programs, the gap between health security policy development and implementation can be narrowed.

Finally, we must remember that the most important aspects of biosafety and biosecurity are the practices and procedures used by trained laboratory staff. The World Health Organization's Laboratory Biosafety Manual states "no biosafety cabinet or other facility or procedure alone guarantees safety unless the users operate safe techniques based on informed understanding." It is the responsibility of everyone, including managers and laboratory workers, to ensure their work is performed in a safe manner. Whether you are new to the field or an experienced biosafety professional, a policy maker or a bench scientist, we need to work together to increase biosafety awareness, leadership, and support for the implementation of national biosafety strategies and laboratory capacity building.

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