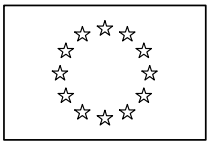

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COMMISSION STAFF WORKING DOCUMENT

SYNTHESIS OF THE REPLIES TO THE GREEN PAPER ON BIO-PREPAREDNESS

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TABLE OF CONTENTS

COMMISSION STAFF WORKING DOCUMENT

SYNTHESIS OF THE REPLIES TO THE GREEN PAPER ON BIO-PREPAREDNESS

GLOSSARY

BSL – Bio Safety Level

BSO - Biological Safety Officers

BTWC - Biological and Toxins Weapons Convention

CEN - the European Committee for Standardization

EAPC - Euro-Atlantic Partnership Council

EBN - European Bio-Network

ECDC - European Centre for Disease Prevention and Control

EFSA - European Food Safety Agency

EMEA - European Medicines Agency

EPA – Environmental Protection Agency

EWRS - Early Warning and Response System

IHR – International Health Regulations

WHO – World Health Organisation

The European Commission published the Green Paper on Bio-preparedness on 18 July 2007[1] with the aim of stimulating a debate and launching a process of consultation at European level on how to reduce biological risks and enhance preparedness and response. The consultation process ended in October 2007.

A total of 82 replies were received. 23 were from EU Member States, 4 from third countries, 4 from representatives of regional authorities, 3 from regional organisations and 1 from the Office of the High Representative's personal representative for non-proliferation. The private sector sent 28 replies, divided between associations, consortia and private companies. Researchers and academics submitted 14 answers, to which 5 replies from individual experts must be added.

The conclusions of the Justice and Home Affairs Council of 6 and 7 December 2007 on addressing Chemical, Biological, Radiological and Nuclear Risks and on Bio-preparedness invited the Commission to provide the Council with an analysis of the responses received to the Green Paper by mid-April 2008.[2]

1. GENERAL COMMENTS

The results of the public consultation on bio-preparedness certainly point to the conclusion that there is a consensus between the EU Member States to raise and tackle the issue of bio-preparedness at EU level. All relevant stakeholders seem to welcome a debate on bio-preparedness and consider it important to deliver concrete actions in this area. The need for more effective cross-sector cooperation, both nationally and at EU level, has also been confirmed.

Replies to the Green Paper also clearly show that most Member States wish to avoid unnecessary duplication with existing rules, guidelines, principles and standards. Therefore, there seems to be a need for an overview of the various existing systems, including the role of the individual players and the links with other networks. This would then provide a basis for an analysis of any existing gaps. Such an analysis is necessary as a starting-point for additional initiatives. Further development of bio-preparedness should be founded on risk assessments of biological threats, both nationally and in the EU. International cooperation at different levels is necessary to improve these efforts.

There seems to be general agreement in the private sector that more needs to be done in the field of bio-preparedness and a wish for the private sector and stakeholders to be fully involved and consulted on future activities. The stakeholders suggested a number of specific activities which could be delivered in this area. The issues of economic proportionality and the need not to hinder research resonated strongly.

1.1. Key principles of bio-preparedness

1.1.1. Is a comprehensive approach to European biological risk reduction and preparedness required?

Public sector

Member States

All the Member State (MS) and public-sector contributors agreed that a comprehensive approach to biological risk reduction and preparedness was required.

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1 COM (2007) 399 final.

2 15127/07.

One MS mentioned that the current legal framework should be used; another stated that better coordination between the existing tools should be put in place (without setting up an additional body).

Third countries

Two countries welcomed a comprehensive and all-hazards global approach, while one believed that the Green Paper could lay the foundation for a bio-defence strategy.

Regional authorities

Three authorities agreed that a comprehensive approach was necessary, with the emphasis on, for example, definitions, criteria, minimum standards, a strong role for security services, individual security assessments and best practice; different European, national and international regulations should be harmonised.

Private sector

The private sector also agreed that this was necessary, but many respondents qualified this with a warning that any approach should not hinder research or exchange of information and pointed out that this area was already heavily regulated.

Associations

All nine associations which replied agreed, in principle, that a comprehensive approach to biological risk reduction and preparedness was required.

A coordinated programme to tackle risk reduction was needed at European level and collaboration with the international community and harmonisation of existing national regulations were required to minimise biological risks, including concepts for bio-preparedness without creating additional new regulations. A comprehensive approach was required to prevent future incidents or misuse of technology. There was a need for simplification of regulations. The comprehensive approach should include a review of capabilities across Europe.

Consortia

One consortium replied. It agreed that a comprehensive approach to biological risk reduction and preparedness was required.

Individual companies

Four individual companies answered the question positively. A holistic approach was necessary, including development of a comprehensive and practicable plan to mitigate threats. Issues for consideration included passive and active surveillance, detection and diagnostics, bio-security, prevention and treatment, and supply chain management. The approach should seek to improve communication, integration and alignment of existing MS controls. Creation of a new layer of regulation or obligations should be avoided since this area was already heavily regulated. Clear responsibilities and coordination needed to be established.

Research/Academia

The academic circles also agreed that this was necessary.

Academia

Three academic bodies replied. Two of them said yes and one stated that any epidemic of an infectious disease would require sustained attention and investment by the trans-Atlantic and global communities. The Green Paper was an important signal that the EU was actively working on bio-preparedness across all MS and the broader international community.

Research

Four research institutes replied positively, in principle. The response to biological risks needed to be coordinated without creating additional new regulations. Clear, straightforward cross-border cooperation was definitely required, whether to prevent or to respond to outbreaks of diseases.

Individual experts

Six individual experts replied. Four of them agreed fully, but stated that many of the resources required to address this issue already existed in the MS, although there was a need to bring them together, which should be done by the EU encouraging trans-border coordination between the MS. One individual expert emphasised that bio-preparedness was an extremely complex and difficult issue and another that it would be preferable to start with multilateral collaboration as a first step.

1.1.2. How could the EU bridge the perceived gap between non-proliferation and international cooperation in a dual-use field such as biology?

Public sector

Member States

The MS gave mixed responses to this question, but one common theme was a call for better coordination between the MS and the Australia Group.

One MS thought that it would not be possible to bridge the gap, while six others clearly called for better coordination and communication and for further development of existing structures. Best practice should be spread, communication should be increased, databases should be set up and cooperation should be enhanced and regulated.

One MS emphasised that efforts should not focus on the potential dual use of research results. Another stated that awareness on the part of scientists should be raised and possible transfers of technology identified. This would be made possible by a European and global approach to bio-preparedness.

Relations with third countries were also mentioned. One MS said that they should comply with the principles of transparency and adopt certain standard procedures. Another mentioned that contacts with third countries could be used to emphasise that non-proliferation was in the interest of every State.

Third countries

One State mentioned that gaps in dual use should be identified and defined; however, new regulatory systems should not impair international cooperation.

Regional authorities

Research should be free, but regulation might be necessary in some cases.

Private sector

The private sector supported closer cooperation and, in addition, suggested that first any specific gaps should be identified and awareness of the existing rules should be raised.

Associations

Seven associations answered, giving a mixed reply.

Relevant comments:

- The EU could bridge the gap, but the mechanisms required need to be explored.
- should be done in close cooperation with international organisations and agencies (e.g. the WHO (World Health Organisation) or ECDC (European Centre for Disease Prevention and Control)) and with the agreement of other major nations.
- Develop opportunities for networking at expert level and for sharing at classified level, with authorisation required for sales of dual-use products.
- Raise awareness, at all levels, of the existing rules and of the EU dual-use legislation and provide clarification on terms and definitions. Keep and update the useful EU-wide system of risk classification (RG 1-4).
- All biological organisms need to be handled in accordance with their risk and keeping in mind the possibility of dual use.
- Legislation often tends to be over-cautious; centralised coordination to form an interface between the public sector/bio-security/industry/academia would allow capacity-building.
- Suitable steps are required that do not disproportionately hinder bio-research, such as certification and accreditation of partner laboratories based on international and European safety standards.

Individual companies

Three individual companies replied, stating, among other things, that there was a need not to duplicate the existing legal framework and that improvements could be achieved by sharing information on a regular basis and cross-border cooperation. It was important not to overstate this *perceived* gap; all technology had the potential for misuse and biology is certainly not unique in this. Policymakers must take care that the benefits of conducting research and development in the EU were not lost because of a very small risk of malicious use.

Research/Academia

Academia

One academia representative responded saying that significant focus for bio-preparedness should focus strongly on medical and public response and recovery activities and also on microbial forensics for attribution of any attack. The EU could make a key contribution to developing clear and globally applied bio-safety standards.

Research

Two research institutes replied positively, stating that raising awareness, at all levels, of the existing rules and of the EU dual-use legislation and providing clarification on terms and definitions were important. Classification and censorship would be detrimental to the transparency of research activities and scientific progress. The EC should consider communication recommendations, including critical risk/benefit evaluation of each experiment prior to conducting and communicating it, and codes of ethics for responsible conduct on the part of life scientists.

Individual experts

Five individual experts replied, stating, among other things, that there was a need for a common definition of dual use. Mutual respect, solidarity and trust were necessary everywhere.

The EU should reinforce the Biological Weapons Convention with a more pragmatic and less diplomatic approach. The gap could be minimised by initiating a programme of cooperative threat reduction activities in biological fields.

1.1.3. Can the current defence mechanisms for facing natural and non-intentional crisis situations become more sufficient to cope with deliberately provoked mass-scale and simultaneous crisis situations?

Public sector

Member States

Most MS agreed that there was room for improvement in the current defence mechanisms and many called for greater international cooperation. Existing mechanisms and tools could and should be revised and upgraded if necessary. Two MS asked for more exercises and exchanges of knowledge and best practice.

Two MS clearly opposed this: one of them said that a coordinated and integrated response was needed, while the other felt that greater international cooperation was needed and that confidentiality should be ensured.

One MS stated that this was an ongoing process and that systems did evolve. Another said that these mechanisms should be set out in the common European strategy, but would entail higher financial and human resources costs.

Third countries

One country agreed that the present systems and approaches could be developed further. Another expressed the idea that bio-security could include, for example, improving systems for risk assessment, connecting laboratory resources, identifying persons and organisations interested in committing bio-terrorism, collecting information and developing and stockpiling medical countermeasures and evaluating their effectiveness.

Regional authorities

Emphasis should be placed on preparedness, emergency planning cooperation and exercises.

Private sector

The private sector agreed that there was room for improvement in the current mechanisms and many respondents called for greater international cooperation.

Associations

Six associations replied to this question. Three said yes, but added comments such as:

- This could be done by raising awareness of security and providing resources for civil defence.
- Mechanisms could be improved, in particular for the transport sector.
- Establishment of different, incompatible concepts on management of intentionally caused crises should be avoided.

The other three made comments such as:

- Current mechanisms could be more efficient if collaboration between stakeholders were improved.
- *In vitro* diagnostics should also be included in any debate.

- The ability to cope with mass-scale, simultaneous situations would depend on the scale and location and on communication and collaboration between areas within a country and between Member States.
- There is a need to agree common aims and a means by which MS, industry, medical, security, intelligence and other stakeholders could communicate and share best practice.

Individual companies

One individual company replied. It believed that MS had already developed good control and response plans for natural and accidental releases and that these could be extended to include deliberate attacks. A coordinated attack would require resources and response and would be different from a natural outbreak managed by civilian agencies.

Research/Academia

Research

One research institute replied that, to be able to cope with or prevent deliberate attacks, bio-security approaches/guidelines should be further developed and, if possible, built on the existing crisis organisation structures in other fields (e.g. food safety or nuclear safety).

Individual experts

Five individual experts replied, expressing mixed views. One said yes, adding that there should be an inventory of responses to various scenarios and that workshops should be organised to enhance the response, especially on agro-terrorism. One said no, because the current mechanisms were limited to responding to low-level biological threats. Another comment was that there was a need to bridge the gap between public health preparedness against natural outbreaks and defence preparedness in the case of bio-weapons. Joint research and exercises with the defence sector were required.

1.1.4. How could the European Centre for Disease Prevention and Control, as well as the European Food Safety Agency, contribute to this endeavour?

Public sector

Member States

Almost all the responses suggested that the Centre and the Agency (which work on a different legal base and don't have the same mandates and competences) should work together on risk assessment, surveillance and coordination of communication.

According to them, the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Agency (EFSA) could play a surveillance role, gather data, maintain a comprehensive database and provide assistance, control and training.

One MS, however, considered that the ECDC and EFSA were not responsible for crisis management, but should integrate bio-preparedness into their responses. Another MS had reservations and raised the question of the added value. Responsibility for risk and crisis management should remain with the MS.

One MS said that the ECDC, together with the EFSA, should become an entity with an integrating role. Another called for the ECDC to train not only experts but also law enforcement officials. One MS mentioned that they could help with balanced development of the asymmetrical capabilities of MS.

Third countries

One country agreed that any new measures should be built on existing measures and structures. The ECDC could be enhanced, e.g. on surveillance and development.

Regional authorities

One authority would achieve this by means of better methodologies, training for laboratory staff, surveillance systems and data analysis. Another mentioned fast detection of pathogens/toxins.

Private sector

Almost all the responses from the private sector also suggested that the Centre and the Agency should work together on risk assessment, surveillance and coordination of communication.

Associations

Four associations answered this question as follows:

- The ECDC and EFSA should ensure coordination and exchanges of information between MS, stakeholders and the international community.
- The ECDC and EFSA could provide research capabilities and knowledge on bio-agents.
- The ECDC and EFSA have a role to play in the rapid alert and testing network for outbreaks and food products that is already in place, but uniform surveillance standards are needed.
- Security experts from these two institutions should work together in a working group to further develop the existing mechanisms for crisis management.

Consortia

One consortium answered that the ECDC and EFSA had key roles to play in coordination and that their emergency planning should be tested.

Individual companies

One company answered that the ECDC could organise the coordination efforts.

Research/Academia

Academia

One academic body replied that an expanded EBN (European Bio-Network) would greatly benefit from the input of the ECDC (on preparedness and response activities).

Researchers

Three research institutes replied that multi-agency cooperation via dialogue was crucial for development of an effective strategy. Active involvement or representation of the Centre and the Agency in the European Bio-Network could be one way of enhancing cooperation. The ECDC should compile all the strains already collected at national level. The EC should devise the method for assessing public risk and incorporate expert advice from the scientific and security communities. Seeking advice from outside experts would enhance the credibility of the risk in the eyes of stakeholders and the public.

Individual experts

The five individual experts who replied made the following comments:

- Develop fully integrated, real-time monitoring and reporting systems. Develop Europe-wide standards and assess the effectiveness of bio-preparedness tools and medical countermeasures.
- Contributions would be necessary in the area of coordination of analysis of distribution of critical ingredients and of relevant production lines and secure administration of data provided by industry.
- Together with the WHO, they could coordinate the health survey and contribute to programmes on education, training, legal issues and sample and analysis management.
- They could develop guidelines, training, education, exercises, advice, R&D and cooperation with third countries. The Centre and the Agency could support international assistance.
- A network of specialists (in agronomy and biology) should be created within agencies responsible for agriculture, consumer protection and security.

1.1.5. Would peer evaluation methods be useful in addressing existing shortcomings across Europe?

Public sector

Member States

Almost all the MS (except three) agreed that peer evaluation methods would be useful.

One MS mentioned that peers should be carefully selected, one believed that the results of peer evaluation could be a useful tool for improving operation of emergency response plans and another stated that MS should be assessed by an independent body.

One MS clearly opposed peer evaluation methods, while another believed that they could be counter-productive, but that investigations within civil society and exchanges of experience could be useful. One MS was in favour of joint exercises and close cooperation.

Third countries

One State agreed with peer evaluation.

Regional authorities

One authority agreed with peer evaluation.

Private sector

Almost all the responses from the private sector agreed that peer evaluation methods would be useful.

Associations

Four associations replied affirmatively. In particular, cross-country peer evaluations could be useful to identify the best existing methods. Evaluation should be supplemented, as special interests could influence the results.

Consortia

One consortium stated that existing shortcomings should be urgently identified in the light of past national experience.

Research/Academia

Research

Two research institutes answered that it would be beneficial if such a system could be established without adding to the regulatory burden for States where existing processes were sufficiently robust and that this should be done by a core group of qualified experts.

Individual experts

Three of the six individual experts said yes, if a survey were conducted of the issues and capabilities across the EU and if the receivers had a comprehensive understanding of issues related to bio-attacks, and that an independent authority would be needed.

One answered no, adding that a specific European approach should be developed.

1.1.6. What role should be played by the private sector in a public-private partnership?

Public sector

Member States

Both the public and private sectors generally agreed that the latter could play a role in consultations, contributing expertise and in R&D. A few responses from the public sector noted that protocols for discussing sensitive information with the private sector should be explored.

The majority opinion was that the public and private sectors should cooperate and should both benefit from this cooperation.

In some MS, this cooperation already existed and was working well.

Many agreed on this partnership, but stressed that the role of the private sector must be clearly defined, together with its duties and responsibilities. A specific legal framework should be envisaged and some MS mentioned that there seemed to be room for improvement of risk awareness in some organisations.

One MS stated that assessment and information provided by the private sector were essential, as it had far more resources than government bodies. Steps should be taken to ensure that no unauthorised person was granted access to restricted areas.

Third countries

One State wanted the role of the private sector to be defined. Another believed that the private sector must be actively involved and new mechanisms developed.

Regional authorities

One authority was in favour of such cooperation, which would be useful in areas such as research and development of diagnostic and therapeutic tools. Another authority believed that this was a difficult issue, raising the question of management of any crisis (responsibility, organisation, costs, etc.).

Private sector

Associations

Six associations replied, making the following relevant comments:

- The private sector should be responsible for putting in place and investing in the system to ensure security.

- The private sector could contribute expertise in the form of involving its R&D departments and personnel and could spread information about safety mechanisms and procedures.
- Involvement in public-private partnerships is fully supported in non-directorial roles, such as contribution of best practice and exchanges of knowledge.
- The private sector often has a broader overview and brings practical experience of what works, what does not and what is missing. The private sector should be involved in the dialogue and the plans.
- The private sector should be involved in the working groups with its security experts.
- Biotechnology firms (even small and medium-sized) and the pharmaceutical industry should engage in initial discussions with governments about available bio-defence technology and should explore alternative, innovative ways to streamline and transform traditional research and development models.

Consortia

Two consortia replied:

- The private sector is important as it has a prominent position in national and cross-border infrastructure; efficient mechanisms for public-private cooperation should therefore be developed.
- Public-private partnership is supported as long as conditions are created to allow all parties to contribute expertise.

Individual companies

One company replied. It said that it would support development of public-private partnerships as long as the conditions for a true public-private partnership were met.

Research/Academia

Academia

One academic body replied, saying that effective bio-preparedness would require new organisational arrangements between the public and private sectors.

Researchers

The three research institutes which replied stated that:

- Involvement of the private sector would promote dialogue and information-sharing between public and private research organisations.
- Private- and public-sector expertise should equally be part of the strategy-building process.
- Key projects should be implemented in the form of joint ventures between public and private stakeholders which must last for a minimum of two years.

Individual experts

Five individual experts replied, commenting that the private sector:

- Is the key to developing the technologies, be they detector platforms or medical countermeasures; functional relationships need to be established between government research facilities, universities and the private sector for ensuring product transition.

- Needs to be integrated into the activities in a coordinated way and also into public mechanisms for crisis management, and the public sector should make better use of the experience built up by the private sector.
- Needs long-term programmes to build knowledge, which is not usually in its portfolio; EU coordination of contracting, technological development and outcome management beyond national capabilities will be required.
- Could play a role in research and development and product development, including in an advisory capacity; incentives will be needed to encourage private-sector involvement.
- Farmers' unions, the food industry and small companies from the biological sector should be involved.

1.1.7. Should an EBN (European Bio-Network) be created in order to support the implementation of the results of this consultation?

Public sector

Member States

The majority of the responses from the MS were positive, but there were five firm negative responses and even the positive replies demanded careful analysis of existing mechanisms, in order to avoid duplication.

Two MS specifically called for a clear understanding of the role and functions of the EBN, and one said that the EBN's tasks were not clearly defined.

One MS saw no need to set up another group. One believed that the range of action was too broad for a single structure, while another stated that coordination of the existing structures was necessary in order to identify the needs for new expert networks.

One MS wanted this issue to be examined in the light of the existing structures.

Third countries

One country asked for a clear mandate and said that overlaps should be avoided. Another felt that an EBN should be built on the existing networks of the ECDC and EFSA.

Regional authorities

One authority replied that this could be considered; tasks could include a platform for cooperation between laboratories, exchanges of information and advice. Another authority felt that the EBN could also be a pool of experts.

Private sector

In general, the private sector supported establishment of an EBN, but pointed out that efforts should not be duplicated with existing networks.

Associations

Eight associations replied. Six of them said yes, but that the role should be clarified before setting up another body, all interested parties should be represented and an EBN would be an appropriate umbrella organisation for working on EU-wide approaches to bio-risk reduction, establishing safety standards and monitoring implementation in the MS.

The other two were less enthusiastic. Establishment of an EBN would be justified only if there were no existing structure to tackle the tasks and if the EBN was the one and only contact point. There might be a danger of hindering bio-scientific research. Expertise from existing associations (NGOs) and government/military authorities should be used as needed;

the grouping might be called EBN but should not add another body and layer to the current system.

Consortia

One consortium replied that an EBN should be established but efforts must be made to avoid duplication and to draw on expertise already available both within and outside the EU.

Individual companies

One individual company could see potential benefits in this proposal but added that, before giving a definitive response, greater clarity was needed on how the network would operate, who would be in it and what its precise role would be.

Research/Academia

In general, the academics supported establishment of an EBN.

Academia

The three academic bodies which replied said yes and that any such EBN should include both public and private components and could play an important role in developing EU bio-safety and sample transport standards.

Researchers

Four of the five research institutes which replied said yes, but that the EBN should draw on the experience of bodies such as the US National Science Advisory Board and the WHO Scientific Working Group on Life Science Research and Global Health Security. A strategic plan should be drawn up by the Commission to rationalise the way forward. Four sub-networks were suggested.

The fifth institute was positive on establishment of the EBN, but only if there were no existing structure to tackle the tasks and if the EBN was the one and only contact point. It saw a danger of hindering bio-scientific research.

Individual experts

All five individual experts responding said this would be useful, provided the network were managed efficiently and in a targeted manner and two conditions were met: (i) willingness of experts to participate and (ii) full-time management of the network by experts. A clear mandate was needed with a view to raising awareness and initiating seminars and debate. To function, the network would need a budget and secretariat (perhaps within the ECDC).

1.1.8. How could cooperation among relevant authorities and agencies at EU level be improved?

Public sector

Member States

The responses to this question were varied, but one recurring theme was closer cooperation on training and designation of a single contact point.

One MS clearly did not want to share highly confidential information.

One MS asked for an inventory of agencies and existing tools to be compiled, so they could be formally contacted by the competent authorities.

Coordinators should be nominated at EU and national levels and visibility should be ensured. One MS added that they should be assigned greater responsibility and decision-making powers.

Cooperation could be improved by means of common training programmes, joint seminars, regular meetings of working committees and exchanges of best practice and opinions (all MS).

Third countries

Exchanges of information.

Regional authorities

Networking, personal contacts, conferences/seminars, emergency cases, etc.

Private sector

Associations

Six associations replied. A European agency should be responsible for coordination and collaboration. Cooperation should be ensured by identifying and involving all relevant stakeholders and could be enhanced by roundtables, workshops and working groups. Nomination and publication of the competent body (contact point) at EU level were needed. Consultation of relevant facilities, institutions and societies must be enhanced. No new structures should be developed. Cooperation should be improved by promoting awareness and understanding of existing regulations, by cutting the number of authorities to reduce complexity, by increasing funding of agencies and by having a coordinating structure at EU level to clarify the roles of the individual departments.

Research/Academia

Academia

One academic body replied: An expanded EBN with a more comprehensive mission that included assessments of national public health preparedness activities, status of medicines and vaccines to counter threats of infectious disease and EU and global activities to improve bio-preparedness capacity and coordination would greatly benefit from the input of the ECDC (on preparedness and response activities) and of the European Medicines Agency (EMEA) (on the status of medicines and vaccines).

Research

Three research institutes replied that this could be achieved by a strategic plan drawn up by the Commission to rationalise the way forward. Nomination and publication of the competent body (contact point) at EU level was needed. Consultation of relevant facilities, institutions and societies must be enhanced. A coordination unit should be established at the level of the Commission President.

Individual experts

Five individual experts replied. Independent scientists should be in charge to improve collaboration with the help of representatives of ministries with specific funding of common activities. A single organisation solely responsible for coordinating and directing EU-wide efforts on bio-preparedness issues should be identified. There was a need to name all relevant authorities and agencies, followed by a binding commitment.

2. PREVENTION AND PREPAREDNESS

2.1. Awareness

2.1.1. Should awareness among stakeholders be increased about possible risks related to biological research and commercial activities and about the rules they have to comply with? If so, how?

Public sector

Member States

All the MS that replied to this question unanimously agreed that awareness among stakeholders must be increased. Possible ways to do so include:

- The Commission should identify the existing campaigns and make them available to the other MS.
- Governments could promote awareness among stakeholders in the area of biological research, by including minimum bio-preparedness requirements in tenders for research.
- Providing appropriate training, supplying necessary information, organising seminars, publishing information brochures, etc.
- Introducing compulsory education modules on existing regulations aimed at, for example, biology, chemistry or pharmacy students and laboratory employees with high responsibility.

Third countries

Both states which replied agreed that awareness must be raised. This could be done via the *accreditation system*, where military security clearances for bio-scientists might be taken as an example or as a source of inspiration, or via annual coordination meetings on new biological risks and regulations.

Regional authorities

Two out of the three regional authorities which replied agreed that awareness-raising was needed; one believed that the current level of awareness was sufficient.

International organisations

Out of the two replies, one believed that there was a need to assess whether current legislation provided sufficient flexibility and legal tools to deal with any crisis in the fields of food safety, animal health and plant health. The other contributor believed that awareness on the part of the whole range of stakeholders (including farmers) about various guidelines, notification schemes, surveillance schemes, laws and rules should be raised.

Others

One contributor emphasised that the Biological and Toxins Weapons Convention (BTWC) already focused on awareness-raising.

Private sector

Associations

All nine associations which answered this question supported the idea of further awareness-raising and education.

Relevant comments:

- Messages should be balanced in order to prevent scare stories and panic.
- The professional associations have an important role to play in this area by bringing this subject to their memberships.
- This is an area for future funding.
- Public workshops should be organised.
- Awareness-raising should also target undergraduate students and staff should also be updated regularly.

Consortia

A consortium considered that governments needed to emphasise the importance of training and preparedness for all companies. Checklists were a good way to start.

Individual companies

All three companies which replied agreed on the need to raise awareness.

Relevant comments:

- Need to target only the relevant audience.
- Need to target correct implementation.
- A "one-stop shop" with clear guidance on each of the relevant areas would help to ensure that requirements were understood and met.

Research/academics

Academics

One university suggested that the bio-network should distribute all relevant information or norms in this field via the media and give practical demonstrations.

Researchers

Three out of the four research bodies which replied supported awareness-raising. One institute considered that awareness-raising might aggravate risks and give ideas to persons with malicious intent.

Relevant comments:

- Raising awareness is crucial for underpinning effective self-regulation by scientists.
- The awareness-raising aspect could be one of the tasks of the EBN with the European Bio-safety Association (EBSA) as an active partner.
- Raising awareness should also include the public.

Individual experts

All five experts who answered this question supported the idea.

Relevant comments:

- An independent study should be carried out to evaluate if all the rules and regulations cover the area sufficiently and to identify any need for improvement, changes and additions.
- An appropriate risk assessment should be communicated to the community of stakeholders.

- The majority of the work on biotechnology research is performed outside Europe; therefore the impact of the EU approach is questionable.

2.1.2. Do you experience difficulties in following new adjustments of rules and restrictions? If so, which ones?

Public sector

Member States

Nine MS experienced difficulties with following and implementing rules and restrictions. The difficulties varied:

- There is overregulation in EU legislation and the regulatory environment changes too quickly.
- Treatment of personal data and restrictions on free movement.
- The rules on the transportation of bio-risk materials have been causing difficulties for smooth management of the control tasks (e.g. delivering BSE samples).
- Information is fragmented between several documents.
- Access to EU regulations and lack of efficient dissemination of information on the EU and national regulations in force.
- The scientific community's general reluctance about its work being subject to restrictions.
- Difficulties with coordination between the institutions of the MS and companies, especially small and medium-sized firms, which often lack legal advice on security matters.

One MS said that it had no problems with following the rules, but believed that not enough time was allowed for adjustment.

Three MS reported no difficulties with following new rules and adjustments, whereas two believed that the question should be addressed to businesses or organisations in the life sciences or to experts.

Third countries

One contributor stressed that research institutes, researchers and small bio-companies with limited resources had difficulties with following new adjustments to the rules and restrictions on certain activities in the field of life sciences. A second State claimed that laboratories faced difficulties with complying with new standards and rules.

Regional authorities

Two contributors reported difficulties, especially when they deemed regulations not to be (e.g. the new hygiene package – Regulations 852/2004 and 854/2004). One representative had no difficulties.

Private sector

Associations

Five associations replied. Three said yes and one that there were problems occasionally. One made other relevant comments.

Relevant comments:

- It is a challenge for companies to identify the relevant agencies in various European countries. The Commission could do a great service by helping to sponsor initial gatherings for information exchange.
- Particular problem are universities and deciding which rules are security-relevant.
- Particularly in relation to new technologies (e.g. genetic technology) which may be of dual use. The problem is the diverse legislation applicable to GMOs and other bio-substances. A single authority should issue permits to handle both these kinds of organism.
- It is better to have EC regulations that apply across all MS. Issues arise with national authorities adding to the burden and reinterpreting.
- This is a particular challenge for those who do not work full-time on bio-safety but need to deliver other activities, such as research or management of a small company.

Consortia

One consortium considered that its members complied with the applicable European and national safety and security legislation and regulatory requirements.

Individual companies

One company considered that the challenge was to keep up to date with changes. Greater stability would be needed and rules should be changed less often.

Research/Academia

Academia

One university said that it had no difficulties.

Research

Relevant comment:

- The EU could consider establishing a common understanding of the role of Biological Safety Officers (BSO) in research institutes and support MS with training them.

Individual experts

Three out of the four experts who replied considered this a challenge. One, however, suggested that this was more relevant to quick analysis of samples in the field and not to normal day-to-day work. One expert considered that this was not a problem.

Relevant comments:

- The following could help: summaries of EU legislation or other easily readable tools (such summaries should contain information on changes, what legislation is changed and what other legislation has been affected by the change).
- New regulations are further restricting the ability of researchers to undertake research on these agents.

2.2. Minimum standards and procedures

2.2.1. Should common minimum bio-standards and the exchange of best practices be developed at the EU level?

Public sector

Member States

A considerable majority of MS (17) that replied to the question believed that common minimum standards were necessary. This should be done either at EU level or by the Commission in cooperation with MS. Two MS believed that the draft ISO Bio-risk Management Standards were a step in the right direction, while another said that the standards should be based on the minimum standards for crisis response laid down by the IHR. One MS also supported preparation of protocols on post-incident notification at EU level.

One MS believed that the term "minimum standards" still needed to be defined and stressed the need for a wider perspective than just the EU view. International minimum standards were needed.

Two MS believed that the need for such minimum standards had to be studied further and existing standards and guidelines needed to be reviewed and gaps identified before more standards were initiated.

Third countries

One of the two States that replied to this question believed that common minimum standards should be developed at EU level and that the ongoing work of NATO/EAPC (Euro-Atlantic Partnership Council) might be taken as a basis. The other stressed that first the term needed to be defined. Nevertheless, harmonisation and exchanges of bio-safety and bio-security practices would be useful.

Regional authorities

One contributor believed that the current work safety standards (L1-4) were sufficient as minimum standards. A second believed that standards should be based on requirements and a third that more than just minimum standards should be established at EU level.

International organisations

The organisation that replied had already put in place a number of guidelines and norms on the safety of veterinary laboratories (whether for research or diagnosis).

Private sector

Associations

Three out of the five associations which replied answered yes and two stressed that some standards already existed in the legislation.

Relevant comments:

- Standards could considerably facilitate implementation of a bio-preparedness initiative; best practice and closer cooperation are the keys to success.
- Bio-safety standards are in place. Security of P3 and P4 laboratories could be enhanced, but security measures should not deal with P1 and P2 laboratories.
- From a counter-terrorism perspective, the minimum standards do not appear to be very useful, as they could easily be overcome by clandestine activities.
- Exchanges of best practice at EU level should be stimulated; professional associations such as the EBSA have a key role to play here.

Consortia

One consortium replied that its companies had internal guidelines that went beyond the legislative requirements (e.g. good manufacturing practices (GMP), bio-safety laboratory

requirements, all-hazard plans and guidelines, environment, health and safety guidelines and SOPs).

Individual companies

Relevant comments:

- Any future approach should strike a balance between security and freedom to conduct research and develop science.
- One company considered the CEN Workshop Agreement on Laboratory Bio-risk Management an excellent example.
- The European Commission should carry out a survey of all the existing standards and make an assessment of any gaps.

Research/Academia

Academia

Three academic institutions replied. One university supported the idea of exchanging best practice. Another saw potential for the EU to contribute to globally applied bio-safety standards. The third believed that safety was covered and that comparable requirements and mechanisms for bio-security measures would seem appropriate.

Research

Four research bodies replied. One said yes. Others made the following relevant comments:

- The EU could play a key role in promoting exchanges of regulatory good practice on bio-safety and bio-security between Member States, but within the existing frameworks.
- All Member States should adhere to best practice rather than simply to minimum standards.

Individual experts

All five experts who replied supported this idea.

Relevant comment:

- Establishing common standards will make it easier for laboratories to exchange samples and staff.

2.2.2. Would you be interested in developing rules for national certification and registering of facilities and researchers which could facilitate European and international exchange of samples and expertise?

Public sector

Member States

Twelve out of the twenty MS that replied to this question seemed to be interested in developing rules for national certification and registering of facilities and researchers.

One MS linked the question to development of common minimum standards. If the latter were to be developed, so would rules for national certification and registration of facilities and researchers.

Five MS saw no need to develop such rules. Three of them believed that developing rules for national certification was a national competence. Only recommendations could be made at EU level.

Two MS stressed the need to avoid unnecessary duplication with the ongoing activities at international level. Such agreements already existed at international level and it was not desirable to change these unilaterally within Europe. One MS also stressed that a laboratory *Bio-risk Management Standard* was being developed and that experience from this process might be drawn on in the future. At the same time, an initiative on a standard for Bio-safety Professional Competency was being driven by EBSA.

Third countries

One of the countries that replied would be interested in developing rules for national certification, whereas the other believed that it would be wise to await the outcome of the Laboratory Bio-risk Management Standard being drafted with financial support from the EU.

Regional authorities

One contributor opposed developing rules for national certification, whereas another would be interested, particularly in the case of cross-border transport of infectious animal samples. The third regional authority believed that the topic fell under national competence.

Private sector

Associations

Three out of the six associations which replied supported certification. One was against and two made specific comments on the subject.

Relevant comments:

- Facilities are registered with authorities. There seems to be potential for international unification of the processes, but there is no need for external certification.
- Permits to work with biological agents should be viewed as "certification" and "registration" of facilities.
- The International Laboratory Bio-risk Management Standard will provide the basis for certification. The EU should, however, look closely at the methods and resources before introducing a certification requirement.

Individual companies

One company was already involved in certification, whereas a second saw no need for new rules to facilitate exchanges of samples or expertise.

Research/Academia

Academia

Two academic institutions considered this activity beneficial and one opposed it on the grounds of costs, demands on personnel and practical implementation, although it would be reasonable to apply such a scheme to pathogen risk group 4.

Research

Four research bodies answered this question. One clearly supported this suggestion. They all supported the idea of easier exchanges of samples without new burdensome rules and procedures. On the other hand, laboratories should already be registered.

Relevant comments:

- No need for central registration of researchers.

- Certification of persons would be acceptable – it would have to be an internationally recognised certificate for researchers of BSL3 and BSL4 laboratories. This would require a standardised course on law, best practice, etc. It could take several days. This could help to increase mobility and exchanges of scientists.

Individual experts

All four experts who replied supported this suggestion.

Relevant comment:

- A Europe-wide network of laboratories similar to the US model should be established. These would provide detection and diagnostic capabilities together with specialist facilities to undertake research related to bio-preparedness.

2.2.3. What should be included in national registers – agents, facilities, activities – ensuring that there are no loopholes and that the security and oversight requirements avoid damaging health, safety, research or industrial activities?

Public sector

Member States

Two MS firmly said that national registers were a purely national competence.

The replies on what should be included in national registers varied from one MS to another. One stressed that the registers should contain no highly detailed information. The following data were listed for inclusion:

- General data on the facility and field of activity;
- Type of biological agents used, catalogued using international organisations' standards;
- Certification and recertification for the facility and classification of the facility;
- The purpose of biological agents stored;
- Place of origin and of delivery of biological agents;
- Data on the organisation supervising the facility;
- An overview of security measures to prevent the spread of dangerous materials;
- All food manufacturing, processing and trading facilities;
- All materials, agents and devices with the potential for dual use;
- Legislative rules;
- List of organisations dealing with bio-terrorism and supervisory bodies;
- Agents, facilities and their purpose; this requirement should apply to all public and private-sector laboratories.

One MS stressed that it was crucial for the registers to be available 24 hours a day for selected State authorities. Another believed that no attempt to register and monitor installations and researchers could be made without the involvement of all stakeholders (academic institutions, firms and public bodies). For that reason, the information to be collected should be defined at a later stage and in a spirit of consensus between all involved.

Third countries

Third countries felt that national registers should include all facilities possessing and handling biological agents (pathogenic agents, GMOs, etc.), plus the specific activities carried out (but not systematically the agents), and should be accessible to the public.

Regional authorities

Two regional authorities believed that the information should include all activities with living disease bugs and products extracted from them, information on existing P3 and P4 laboratories (on the micro-organisms used and management of the laboratory) and establishment of a genetic fingerprint of the substances. A third regional authority believed that the reports on activities and facilities based on the existing safety levels (L1-4) offered sufficient information.

Private sector

Associations

Four associations replied. They raised the following issues:

- This should be discussed by the EBN.
- A list of relevant pathogens should be developed (e.g. focus on group 3 and 4 organisms).
- Dual-use legislation requires registration of facilities.

Individual companies

Both companies that replied suggested that this should be based on risk assessment.

Research/Academia

Academia

One university suggested the following:

- Each research institute should communicate data on the institute, type of product and its period every three years or in the event of changes.

Another university considered that this proposal was of minimal benefit and very high cost. If such an approach were to be adopted, it should apply only to the highest risk materials (group 4).

Research

One research body stated that such registers were already in place.

Individual experts

The following issues were mentioned:

- Dangerous agents and facilities holding, working with or transferring dangerous pathogens and toxins.
- Producers, transporters, processors and other service-providers with access to the processes (such as transport, cleaning, etc.) or information (logistics management, etc.) should be subject to controls.

Relevant comment:

- Private industries will resist providing information on their facilities and research activities due to concerns over intellectual property issues and industrial espionage.

2.2.4. Should a limited number of bio-researchers possess security clearance? If so, on what basis would you identify them?

Public sector

Member States

Among the ten MS in favour of introducing security clearance for a limited number of bio-researchers, one stressed that the security arrangements should include:

- compulsory security screening by the competent authority;
- compulsory central registration of individuals who have access to hazardous substances;
- organisational and physical security measures;
- criteria for access to hazardous pathogenic substances.

One MS would also like to see more thought given to the conditions under which foreign students and researchers were granted access to potentially dangerous sections of laboratories. Intelligence services should develop appropriate measures and criteria for applying them. One MS believed that not only researchers but also companies/laboratories should possess security clearance. Such clearance should be given only to bio-researchers with the necessary knowledge or corresponding training, experience and practical knowledge.

Some of the MS in favour of introducing security clearance believed that the clearance should be subject to certain conditions:

- Security clearances should be introduced if bio-material that is dangerous to plants, animals or humans is handled in the establishment.
- Vetting should be limited to researchers working with particularly dangerous biological agents (e.g. micro-organisms or toxins). Such researchers should be identified by each Member State and should receive clearance by the person responsible in the laboratory first (together with the director of the laboratory) and only subsequently by the Member State's authorities. It is also important to develop a safety and security culture between researchers that goes beyond the biological context, by using security officers ready to discuss and cooperate with researchers.
- Security clearance should be required for everyone (not only researchers) who might have access to substances of terrorist potential (RG 3 and 4).
- Security clearance should be introduced for those with access to classified information (for instance, working with identified hazardous biological agents on an EU list). Criteria and access procedures should be harmonised between the institutions involved and laid down in national legislation.
- Clearance should be required for those with access to facilities or departments where pathogens are handled or stored, or those leading and/or working on research projects where such clearance is considered necessary, or those overseeing confidential research projects.

Three MS emphasised that security clearance procedures were a purely national responsibility and should not be regulated at EU level.

Two MS were explicitly against introducing security clearance. One claimed that such a solution would hinder free exchanges of scientific information and restrict the right to information, while the other believed that this would be discriminatory. An additional MS believed that the question left "security clearance" undefined and might be unanswerable. It

would be impracticable to extend this to commercial or academic circles. Ensuring that everyone working in commercial or academic circles had basic security and legal awareness would be a better solution.

Third countries

One country stressed that a number of bio-researchers already possessed security clearance and that, in areas where such schemes existed and were operating well, work should not be duplicated. Another country believed that it would be difficult to find a common basis for security clearance. It might be necessary to evaluate the overall feasibility of such clearance first.

Regional authorities

One regional authority opposed any such measure, whereas three were in favour. One reply stressed that the clearance requirement should go hand in hand with obligatory reporting in a functional reporting system.

Others

Issues related to security checks on individuals (scientists) and to screening visa applications for admission to study certain sensitive areas of science or conduct sensitive research were discussed by the Member States in different non-proliferation fora.

Private sector

Associations

Seven associations answered this question. Five supported the suggestion.

Relevant comments:

- Any security clearance requirement should be risk-based.
- Security clearance for all researchers would not be helpful.

Two associations opposed such a measure. They considered good education, laboratory management, social control and careful laboratory management much more effective. The OECD best practices guide contained such an approach and could be adjusted for individual purposes.

Individual companies

Three companies replied. They considered that this should apply to only a limited number of bio-researchers and in cases where such an approach was justified (e.g. category 4 pathogens).

Research/Academia

Academia

One university saw that this would have minimal benefit and would result in high costs and have an impact on human resources. If such an approach were to be adopted, it should apply to BSL 4 laboratories only.

Research

Three research institutes supported the proposal. However, the criteria on who should possess such clearance should be defined carefully.

Individual experts

Three experts supported the proposal, but only if it were limited to specific groups performing specific tasks. One expert pointed out that researchers working on bio-defence programmes had such clearance.

Relevant comment:

- Any such measure should be carefully considered in order not to hamper research and not to scare scientists away from working with these agents, as in the USA.

2.2.5. Should a specific and limited number of laboratories, health institutions, production establishments, pharmaceutical and food-processing plants be accredited on the basis of compliance with minimum security standards?

Public sector

Member States

Thirteen MS agreed that a limited number of laboratories, health institutions, production establishments, pharmaceutical and food-processing plants should be accredited on the basis of compliance with minimum security standards. One of them suggested that auditing could be the task of the authority which granted the licence or of an independent assessment/auditing body. Another added that all institutions that handled micro-organisms and dangerous toxins should be accredited or certified. Furthermore, on bio-security issues, an authorisation issued by the competent authorities should be envisaged as well. Such accreditations should be limited to laboratories focusing on bio-security issues. One MS added that with a common standard for certification/accreditation of facilities there would be no need to regulate the number of facilities in each MS.

Four MS opposed introduction of an accreditation system. Three of them stressed that there were already a number of authorisations and national standards to run the establishments in question and that existing systems which were fit for purpose should not be replaced. Nevertheless, one of them felt that it would be desirable to limit the number of authorised researchers who had access to projects or facilities managed and financed by public authorities (because the private sector was already taking other legal measures to protect access to its discoveries). One MS also stressed that accreditation involved significant additional costs and administration. Although accreditation would offer the added value of closer European cooperation, it should not be obligatory.

Two of the MS opposing the accreditation system felt that an overall analysis of the existing legislation, rules, standards, accreditation mechanisms, etc. was needed.

One MS believed that the accreditation should depend on the legal framework.

Third countries

One country considered accreditation necessary, provided the procedures were neither too expensive nor too counterproductive. The other country which replied stressed that first the term “accreditation” should be defined in this context (e.g. licence under national law).

Regional authorities

Two replies stressed that the existing structures were already sufficient. One regional authority believed that such measures made sense and could be implemented as an addition to the current accreditation system.

Private sector

Associations

Six of the seven associations supported the suggestion. One was opposed to it (certainly for BSL 1 and 2 laboratories).

Relevant comments:

- Current accreditation systems should take into account security.
- BSL 3 and 4 laboratories should have good security.

Individual companies

Relevant comments:

- It would perhaps be more appropriate to accredit/certify projects as opposed to facilities or organisations.
- This proposal needs further clarification of its scope and effects on small start-ups.

Research/Academia

Academia

One university considered this crucial. Another saw minimal benefit in it and too high costs, although it could possibly be applied to risk group 4 pathogens.

Research

One response supported the suggestion. Another opposed certification and stressed that compliance with existing legislation was sufficient. The third supported national safety and security standards and exchanges of regulatory best practice across the Union.

Individual experts

One expert supported the idea. Two stated that this system existed at national level.

Relevant comments:

- The problem may be with the quality of certification and accreditation bodies and they should also be checked better.
- Security standards could apply to a very limited number of institutions.
- What would be the real benefit of this approach other than reassuring the public that something was being done?

3. ENHANCING ANALYSIS AND SECURITY ISSUES RELATED TO BIOLOGICAL RESEARCH

3.1. Developing a European analytical capacity for reducing biological risks

3.1.1. Do you agree that an enhanced EU-level capacity for analysis of biological risks is necessary or is the present situation satisfactory?

Public sector

Member States

A significant majority of MS (16) that replied to the question believed that development of analytical capacity within Europe in one way or another was needed. One of these MS emphasised the need to distinguish between the capacity for analytical modelling and for

laboratory analysis. A high-level bio-safety laboratory was not necessarily required in every MS.

A number of areas where more efforts were required were identified by the MS.

The way forward to improve the analytical capacity in Europe might be:

- Speeding up and intensifying the risk assessment process, in line with the stipulated higher frequency of data acquisition and assessment.
- Based on existing structures in Europe, such as the European Medicines Agency, the European Food Security Agency or the European Centre for Disease Prevention and Control, EU funding should also be provided.
- Avoiding duplication (both nationally and internationally). In general, the evaluation of the bio-risks should be supplemented by a sociological and criminological analysis.
- Strengthening analysis and exchanges of information and intensifying monitoring of possible biological threats at national and EU levels.
- Enhancing the analysis at the technical level.

Two MS were explicitly against any EU action on this topic.

Third countries

One country supported an enhanced EU-level capacity for analysis of biological risks.

Regional authorities

All three regional authorities that replied believed that the EU capacity in this field should be improved.

Private sector

Associations

All six associations which replied agreed that analytical capacity should be enhanced within the EU.

Consortia

One consortium pointed out that analyses concerning the safety of food and feed should be better coordinated at EU level. However, mechanisms developed in EU Member States and elsewhere should be used to avoid unnecessary duplication.

Research/Academia

Academia

All four academic respondents supported the suggestion.

Research

Two research bodies supported the suggestion.

Relevant comment:

- Closer coordination should be ensured.

Individual experts

All three experts who replied considered that there was an urgent need to enhance the analytical capacity and modelling.

3.1.2. Should there be EU funding for joint training and awareness raising?

Public sector

Member States

Almost all the MS that replied to the question agreed that there should be EU funding for joint training and awareness-raising. Nevertheless, two stressed that many activities were already being financed under FP6 and FP7 and that the benefits of EU funding would not be clear unless there were precise objectives, a proper risk assessment, a capability gap analysis, a coordinated response, a target audience and, thus, added value.

Some of the activities that could be financed by the EU included:

- Research;
- Joint training;
- Strengthening existing networks and using IT tools for a better exchange of good practices;
- Common activities in the field of education, especially with a view to multisectoral cooperation.

One MS was not in favour of EU funding, as the MS bore primary responsibility for such activities. The EU could perhaps act as coordinator, using existing EU institutions. Should the EU nevertheless decide to provide funding, co-financing should be the rule.

Third countries

There was agreement that EU funding should be available for this field.

Regional authorities

All three replies agreed that EU funding was necessary. One regional authority stressed that awareness work should be done at regional level.

Private sector

Associations

All seven associations saw a need to make funding available for training and awareness-raising.

Relevant comment:

- Training needs to be focused and effective, to enable the trainees to put it into practice in their role and function.

Consortia

One consortium supported the idea and made the following comment:

- Training and awareness-raising should be targeted at the areas identified as the weakest and at improving inter-governmental cooperation and interaction with the private sector.

Individual companies

One company supported the suggestion.

Research/Academia

Academia

All three academic bodies which replied supported the idea.

Relevant comment:

- Training in the areas of agro-terrorism is much needed for those with responsibilities and interest in all sectors of crop agriculture, including extension specialists, students, crop consultants, regulators and farm advisors at various levels.

Research

Both the research bodies which replied supported the idea.

Individual experts

All five experts responding supported the suggestion.

Relevant comments:

- This is the key to harnessing best practice developed by individual Member States.
- There should be joint, scenario-based exercises which model an attack on EU infrastructure involving more than one Member State and all stakeholders. These should become regular events.

3.1.3. Should EU-level lists of biological agents of special security concern be developed jointly by the Member States and the Commission?

Public sector

Member States

Thirteen MS agreed that an EU-level list of biological agents should be established. Nevertheless, some of them warned that the following specific issues should be considered first:

- The need for risk assessment and the related cost-benefit ratio.
- The definition of "special security concern".
- Should the list focus on human pathogens or on plant and animal pathogens as well?
- Compilation of a list of biological agents of special security concern could prove quite difficult in practice.

One MS in particular believed that EU-level lists of biological agents of special security concern should form the basis of a bio-preparedness system and expected that drawing up a single list of dangerous agents would reduce the administrative burden on businesses and institutions working with these agents. When establishing its own list, the EU should draw on existing sources, such as the BTWC and the Australia Group list.

Three MS agreed that a single or core list of organisms, properly coordinated at international level, would be helpful, but stressed the importance of defining the purposes of such lists.

Four MS explicitly opposed such a separate list, because it would entail duplication. One of them would prefer each MS to develop its own pathogen list and to focus instead on exchanges of information between Member States.

Third countries

One country stressed the need for a preliminary assessment of the utility value of existing measures. If the assessment showed that there was a need for such lists, the ECDC should play a leading role in drawing them up.

Regional authorities

Three contributors agreed that EU-level lists of biological agents should be developed. One opposed such a solution as it would increase the risk of misuse of such information.

International organisations

The one organisation that replied believed that first it was necessary to determine which agents were of particularly high concern. Their assessment should be based on risk assessment (including the potential to use them as a weapon and the consequences).

Other

The non-proliferation discussions have moved away from identifying "lists of organisms". The theme is how to cope with new challenges related to progress in science and technology (synthetic biology, genetic modifications, etc.).

Private sector

Associations

All seven associations which replied supported the proposal.

Relevant comments:

- Some of the respondents cannot participate in compiling such a list, as it is against their national law.
- This should be done in cooperation with other international bodies (e.g. the OECD or WHO).
- Scientific expertise needs to give input for this.
- Such lists need to be made available to the relevant stakeholders and should be kept up to date.
- Such lists could also contain advice on ways to detect and identify the substances.
- Lists already exist but need standardisation (a list developed jointly by the EU and MS would lead to harmonisation).

Consortia

One consortium supported the suggestion, while adding that existing lists should be taken into consideration.

Individual companies

Two companies supported the suggestion.

Some stressed that there should be no country-specific lists.

Research/Academia

Academia

Three academic institutions considered that such lists already existed and should be kept up to date.

One academic institution warned the EU against lists because, based on US experience, stricter security rules might actually work to the disadvantage of bio-defence research and development in the USA for a number of reasons:

- The static nature of the Select Agent List does not adequately reflect the evolving nature of the bio-threat.
- The Select Agent Program is not without significant tangible and intangible costs to research.

Research

Two research bodies supported the suggestion.

Individual experts

Four experts supported the suggestion. One of them considered that such lists already existed, e.g. the US Select Agent List. They saw the challenge as the evolving bio-threat underpinned by technological development.

3.1.4. If you believe that each Member State should have its own pathogen lists, do you agree that interaction with other Member States on this topic could be beneficial for your organisation?

Public sector

Member States

First, it must be stressed that MS do not necessarily believe that national pathogen lists would preclude establishing a European list or vice versa.

Eight of the nineteen MS that replied to this question believed that there was no need for separate national lists. They mentioned the need for a "dynamic pathogen list" at European level. One MS also stressed that should MS decide to draw up their own lists, they should inform the other MS of the agents listed for their assessment.

Eleven MS stressed the benefits of and need for exchanges of information on national lists. Some of them considered that national lists should actually be added to the EU-level list.

Third countries

None of the countries that replied believed that national lists were actually needed. Nevertheless, if such lists were compiled, a harmonised, European list of agents of special concern should be made available.

Regional authorities

Two regional authorities believed that there should be a single EU list. One did not believe that exchanges of information on national lists were necessary.

Private sector

Associations

Seven associations replied. Four believed that there should be a single list and no national lists. Two suggested that if there were to be national lists, there should be exchanges between the Member States.

Relevant comment:

- From the bio-security perspective, harmonisation of lists is possible and makes sense. From the bio-safety perspective, harmonisation is problematic because different climate zones, prevention programmes, natural sources of diseases, etc. would have to be taken into consideration.

Individual companies

One company suggested that this idea would be beneficial and would help with transfers of agents between States.

Research/Academia

Academia

One academic institution supported a single list.

Research

Two research organisations replied.

One supported a single international/global list based on security concerns. On the other hand, the same organisation suggested that Member States should be free to add further agents to any such list as they saw fit at national level.

Both organisations agreed that mechanisms to facilitate dialogue between Member States on this issue should be encouraged.

Individual experts

Four experts replied. Two supported an EU list. If that was not possible, then at least exchanges between Member States should take place. One stated that the organisms were well known and the only value added would be if the list were underpinned by an intelligence-based assessment.

3.1.5. Is the current level of research activities on bio-preparedness sufficient in the EU? Which research activities should be prioritised?

Public sector

Member States

Almost all the MS that answered this question agreed that it was important to intensify and better coordinate research activities in Europe.

A number of priority areas were identified.

Furthermore, one MS stressed that publication of a "glossary on biological threats to the European citizen" would be very useful.

Regional authorities

The three regional authorities that replied believed that more should be done in a number of areas.

Private sector

Associations

All six associations responding supported more research.

Relevant comments:

- The private sector has no clear guidance on the direction of such research. In some cases there is duplication between the military and private sectors due to lack of communication.
- Research is not coordinated. A few cross-EU projects are under way, but they are not addressing new/emerging threats. Each country is developing its own research.
- Priority should be given to health and animal diseases.

Research/Academia

Academia

One university replied. It believed that there were some good research results.

Research

One research institute supported the need for more research and better coordination between Member States.

Individual experts

Three experts replied. Two suggested more research. One argued that there was a need to convert the research better as one step forward in bio-preparedness.

Relevant comments:

- Need for further development of bio-sensors, basic knowledge on priority agents, analysis of new potential threats, development of medical countermeasures, risk assessment methods, studies to evaluate potential users of biological agents and toxins, studies to evaluate how plans really work in a critical situation with intentional release of biological agents and support for cooperation with R&D groups outside the EU.
- The EU should focus its research funding on:
    (a) Planning, risk analysis and coordination: identify the risks, come up with solutions and manage the problem:
        – establish EU capacity to analyse the risk posed by different threats, which should be regularly updated to keep pace with changes in technology and natural pandemics such as SARS and influenza;
        – develop scenarios to model the effect of an attack with different agents;
        – use the scenarios as the basis for a training exercise to test national and pan-European coordination;
        – develop communication networks to link key decision-makers.
    (b) Detection and diagnosis: How do we know something has happened, how do we disseminate the warning and to whom?
        – establish EU-wide monitoring programmes similar in concept to the US EPA Biowatch which stands guard over major US cities;
        – determine the background level of bio-threat agents in different environments across Europe to make it possible to distinguish an attack from a natural outbreak;
        – develop hand-held assays capable of detecting the presence of threat agents in environmental and clinical samples;
        – establish a network of validated laboratories able to handle these types of samples as part of an EU-wide response network;
        – when positive results are generated, establish a system to communicate them to experts trained to interpret the results and advise decision-makers;

– develop forensic typing technologies that will enable authorities to determine the source of an agent and could be used to support attribution activities.

(c) Response: How do we respond to an event in terms of treating exposed individuals and containing further spread?

– develop medical countermeasures approved by the European Medicines Agency (EMEA) with which to treat and protect exposed individuals. This is extremely costly as it currently takes many years to develop a product such as a vaccine;

– support research to develop generic medical countermeasures capable of providing broad-spectrum protection against viral and biological agents. A promising approach could be to stimulate the innate immune response;

– develop stockpiles of medical countermeasures that could be shipped to an affected area following an attack. Ideally such medical countermeasures should be suitable for oral administration to allow self-medication;

– develop strategies to contain the spread of highly infectious human agents across Europe; can human quarantine areas be established and enforced?;

– another major component of any bio-terror attack will be the response of the general population. Research should be funded to determine how individuals feel about the risk of a bio-terror attack, how they think they would respond and what measures should be taken to ensure that the population receives the information it needs to minimise fear.

(d) Restoration:

– need to develop technologies to map the extent of the contaminated area;

– need to develop decontamination and remediation approaches capable of returning affected areas to human use;

– need to develop contingency plans for coping with attacks against major public transport hubs such as airports and train terminals.

3.2. Security issues related to biological research

3.2.1. Should public and private funding for research on bio-substances be made conditional on the compliance of bio-standards?

Public sector

Member States

Seventeen MS agreed that research funding should be made conditional on compliance with bio-standards. Nevertheless, some of them warned that, in the spirit of transparency, the norms should be very clear and not be an obstacle to scientific research. Two MS pointed out that bio-standards had to be developed first. The link between research funding and compliance with bio-standards should also apply to activities by third countries, which was one important reason to assist developing countries with meeting safety and security standards

and, thus, to respond to their wish for closer cooperation. According to one MS, funding should be subject to a favourable report by the Biological Security Committee.

Two MS disagreed with such conditional funding. One felt that it was not possible to make private funding for research conditional on compliance with bio-standards and the other believed that research funding was not the appropriate instrument to achieve/maintain high biological standards. They should be achieved by regulating the facilities and/or the activities (not research funding).

Third countries

One reply emphasised that compliance with bio-safety and bio-security standards should not depend on funding but on the legal requirements regarding activities with pathogens.

Regional authorities

One contributor believed that such conditionality was reasonable, while the second opposed any such principle.

Private sector

Associations

All seven associations agreed with the suggestion.

Relevant comments:

- Impractical rules and standards which do not really increase security but prevent financing should be strictly avoided. Furthermore, the standards should be applicable in the same way across the EU to maintain equal opportunities.
- Bio-standards should be based on a risk-based management system and certification of facilities associated with a work permit, while not hindering research.

Individual companies

One company agreed with the suggestion.

Research/Academia

Academia

One university agreed.

Research

Three research bodies answered. Two of them supported the suggestion, the other considered it difficult to implement.

Relevant comments:

- In some countries this is already implemented.
- It is not the role of funding agencies to monitor compliance with bio-standards once a research grant has been awarded and national authorities accrediting facilities have an important role to play.

Individual experts

All four experts who replied agreed with this suggestion.

3.2.2. Do you agree that a publication procedure should be applied where sensitive biological dual-use research should be published in two versions: - a public version with no publishing restrictions (without sensitive content) and

- a restricted version containing the sensitive parts of the research with access only for relevant bio-stakeholders?

Public sector

Member States

MS' opinions on the publication procedure for sensitive biological dual-use research results and the possibility of restricting part of the research to relevant bio-stakeholders were quite divided. Eight MS believed that such a procedure would be impossible in practice due to the fundamental right of speech and access to information. Furthermore, one MS stressed that censoring scientific publications on biological dual-use research was undesirable and raised many questions, e.g. who decided what was dangerous/sensitive? A preferable solution would be an awareness programme for the sector about the potential for misuse of its research and an appeal to collaborate on this with the security services.

On the other hand, ten MS agreed with publication of two versions, one open, the other restricted, as this classification should maintain the balance between disclosure of scientific information and the confidentiality required in handling sensitive aspects of research.

One MS believed that it was difficult to determine at this stage whether restricted publication of sensitive parts of research was feasible and that this was a matter for scientists and publishers of scientific journals.

Third countries

One State believed that such a publication procedure would be a good practical measure to address several concerns, while another considered restriction to publication of scientific results difficult to enforce without impeding scientific progress.

Regional authorities

Two regional authorities disagreed with the suggested publication procedure, while two believed it would make sense to restrict publication of security-sensitive research. However, the principle should not be applied generally.

Private sector

Associations

Eight associations replied to this question. Four supported the suggested approach and some believed that it was working well in the USA. The other four were against the idea on grounds of scientific freedom.

Relevant comment:

- Professional associations should develop guidelines on who can have access, who decides on access rights and which research should not be permitted, for example publication of the sequences of hazardous agents.

Individual companies

Two companies replied. One supported the suggestion and the other required further clarification of what was or was not a sensitive issue or who should police this system.

Research/Academia

Academia

Two academic institutions replied. One university supported the idea. Another suggested that decisions about dual-use issues might best be addressed by a panel that should include scientists, security and law enforcement personnel and policy-makers.

Research

Two out of the three research bodies which replied opposed the suggestion. The third supported the idea on condition that the system did not disrupt research or exchanges of ideas. Scientific peer reviews should be used instead.

Individual experts

Five experts replied. One supported the idea, two were against it and one saw a need only in rare cases. The fifth stated that US journals had already been suggesting changes to texts for security reasons.

3.2.3. Could the EBN assist in the development of bio-security and bio-safety guidelines for publicly funded research?

Public sector

Member States

Eleven out of the eighteen MS which replied believed that the EBN could assist in the development of bio-security and bio-safety guidelines for publicly funded research.

Seven MS opposed such a role for the EBN.

Third countries

Both States that replied agreed that the EBN should assist in the development of bio-security and bio-safety guidelines for publicly funded research. Furthermore, this role should be extended to research in general, not only publicly funded activities.

Regional authorities

One regional authority agreed with such a role for the EBN, another disagreed.

Private sector

Associations

Seven associations replied. Six supported the idea and one opposed it on the grounds of duplication with existing bio-safety networks and organisations with mandates to draft guidelines and consensus documents. Coordination and cooperation between the existing bodies were required.

Individual companies

One company considered no extra guidelines necessary.

Research/Academia

Academia

All three academic institutions which replied supported the idea.

Research

Three research bodies replied. Two supported the idea and one was concerned about duplication of existing structures (e.g. the EBSA).

Individual experts

All four experts who replied supported the suggestion.

3.3. Professional code of conduct

3.3.1. Should mandatory academic courses on bio-standards and best practices become part of the university curriculum in the field relevant to life sciences?

Public sector

Member States

Sixteen out of the nineteen MS that replied to the question agreed that academic courses on bio-standards and best practices should become part of the university curriculum. Nevertheless, three of the MS that supported the idea stressed that the MS were responsible for setting the university curriculum and that this should not be regulated at EU level. One MS believed it would be more appropriate to introduce similar studies by secondary school level at the latest, while others preferred undergraduate and postgraduate studies and more specialised occupational education on health and engineering. Two MS believed that any new training about bio-safety should be built into existing courses.

Two MS opposed the introduction of mandatory courses on bio-standards in the university curriculum. One of them saw no need to make such courses mandatory, as these issues were already tackled in a number of ongoing courses. The other was of the opinion that training in this field must be organised by the employers concerned on a regular basis (at least once a year).

Two MS stressed that responsibility for university curricula lay at national level and emphasised the autonomy of universities to decide their programme.

Third countries

Both countries that replied believed that academic courses on bio-standards and best practices should become part of the university curriculum in the field relevant to life sciences.

Regional authorities

All three regional authorities that replied agreed to mandatory academic courses. One contributor considered them a prerequisite for work in a laboratory.

Private sector

Associations

All eight associations which replied supported the suggestion. Two had reservations about whether the courses should be mandatory, but agreed that they should be available.

Individual companies

One company replied. It supported the idea.

Research/Academia

Academia

All three academic institutions which replied supported the idea.

Research

All three research bodies which replied supported the suggestion.

Relevant comments:

- Scientists, technicians and students working in high-risk areas should receive relevant tailored training from their research institutes on formal regulatory requirements and best practice before initiating such work.
- Appropriate refresher courses (including updates on any new regulatory requirements) should also be provided to such staff at regular intervals.
- Dedicated institutional Biological Safety Officers would have a key role to play in providing this training.
- It is important to introduce training requirements in a flexible way that does not put at a disadvantage visiting scientists from overseas or researchers who move into biosciences later in their careers. For example, any new training could be built into standard health and safety induction programmes in institutions.

Individual experts

All three experts who replied supported the idea. One had reservations about whether it should be mandatory or not.

3.3.2. Should researchers in life sciences be obliged to adopt a professional code of conduct?

Public sector

Member States

Thirteen MS believed that researchers in life sciences should be obliged to adopt a professional code of conduct. Two added that introduction of penalties against researchers who failed to adhere to this code of conduct should also be considered. Although agreeing on the need to establish a professional code, one MS stressed that it would be difficult to implement, as it would be at the margins of the interests of the academic institutes or corporate sector concerned.

One MS warned that enforcement of codes and sanctions should be carefully considered if adoption were to be made mandatory. Without an agreed code of practice and some agreement on curriculum content it might in fact be difficult to secure voluntary acceptance by universities and professional bodies.

Two MS opposed a mandatory code of conduct and believed that one should be developed on a voluntary basis and among scientists themselves. An obligatory code whose legitimacy was disputed by professionals and which was not enforced would be unlikely to have the desired effect.

Three MS emphasised that professional codes of conduct already existed and that duplication at European level should be avoided.

Third countries

One contributor believed that the actual need for a professional code of conduct should be established first. The other considered awareness-raising much more important.

Regional authorities

Two regional authorities opposed such a measure; one believed that researchers should observe the rules even without such a code of conduct. If they wanted to break the rules, the code could not stop them.

Private sector

Associations

Five of the eight respondents supported the suggestion. The other three had doubts about the practicality and usefulness of such a code.

Consortia

One consortium supported this suggestion in the area of research, development, manufacture and distribution of its products.

Individual companies

One company questioned the added value of such a code.

Research/Academia

Academia

Two out of the three academic bodies which replied supported the suggestion. One pointed out that such codes existed and that implementation was monitored by relevant bioethics committees.

Research

One of the two research institutes which replied supported the idea.

Individual experts

Two experts supported the idea and two opposed it.

3.3.3. Should the above-mentioned professional code of conduct be developed at EU level? If so, by whom?

Public sector

Member States

Nine MS believed that the professional code of conduct should be developed at EU level. Two of them said that this should be done in cooperation with other international organisations and taking into consideration existing codes of conduct. Other possibilities included:

- The code of conduct could be developed by a group of experts nominated by MS together with the European Group on Ethics in Science and New Technologies (EGE).
- The code should be developed by the European Commission, with the support of EBN experts and MS.
- The code should be developed by, for example, a joint commission made up of Member States' representatives or by the EBN.
- The code should be drafted by researchers and finalised at EU level by experts.
- The code of conduct should be initiated from within the academic world on a voluntary basis. Universities in MS could collaborate at European level, supported by the EU, to develop a code of conduct. There are also a number of professional associations that could contribute substantially to the consensus-building process.

Two MS believed that the EU should use and enhance the existing ECDC systems and could play a role in encouraging development of codes within MS.

Seven MS opposed development of the code of conduct at EU level. Two of them considered that the code of conduct should be developed within existing structures (for example, a

universal code of conduct had been proposed under the BTWC) and two focused on the fact that development of a professional code of conduct was a national competence. One MS believed that the European Commission should take on the task of disseminating the existing codes of conduct.

Regional authorities

One contributor believed that the code of conduct should not be developed at EU level. The other stressed that, if such a code were to be developed, a wide range of relevant stakeholders should be included in the process.

Private sector

Associations

Six associations answered the question. Two supported the idea and four were against it.

Relevant comments:

- If the EBN were to be established, it should be involved.
- Activities leading to codes of conduct have been started and their effectiveness should be tested.

Research/Academia

Academia

All three academic bodies which replied supported the suggestion.

Relevant comment:

- A European network of bioethics committees should certainly be involved in developing the code of conduct.

Research

Two out of the three research bodies which replied opposed the suggestion.

Individual experts

All four experts responding supported the suggestion.

Relevant comments:

- The code of conduct should be developed by professional organisations and academies for life scientists.
- This should be done by the EBN.

4. IMPROVING SURVEILLANCE CAPACITY

4.1.1. Each Member State depends on the bio-preparedness of others. In view of this, should the current early warning mechanisms within the European Union and Member States be further adapted? If so, in what respect?

Public sector

Member States

Many MS considered the current mechanisms sufficient, but a few said that there was room for improvement, calling for harmonisation of the systems and no duplication of functions.

Two MS asked for an overview of the existing systems, again in order to avoid duplication. Four MS asked for a list of contact points to be compiled and regularly updated. Two MS stressed that warning systems should be harmonised.

One MS mentioned that further investment would be useful for specific agents.

Third countries

One country replied that the mechanism should be based on the existing Early Warning and Response System (EWRS).

Regional authorities

One authority said that key issues included verification, definitions, etc.

Private sector

In general, the private sector called for improvements and investigation into whether the current systems were used effectively.

Associations

Six associations replied. Two answered yes, adding the following comments:

- Alerts need to be shared as quickly as possible so that the parties concerned can be kept informed, but should not be on a public website.
- Early warning mechanisms should be developed, with specific regard to pandemics.

The other four commented as follows:

- A reinforced early warning mechanism is essential for enhancing preparedness.
- One point which should be investigated is whether the existing mechanisms are being used effectively and whether there are problems with communication and collaboration.
- It might be more practical to address common requirements and best practice and to review capabilities across Europe.
- Harmonising the prevention and early warning systems at EU level could be a central task of the EBN.

Individual companies

One individual company replied, indicating that the tools and system already in place should be used. Further details should be given of the controls on and improvements to these systems.

Research/Academia

In general, academic circles were also positive.

Academia

One academic suggested integrating public health and national security committees with a focus on cooperation across borders. The international community must plan coordinated responses to bio-terrorist attacks and epidemics. Such plans should include strategic and operational details commensurate with those prepared by large international security organisations for more traditional threats.

Research

One research institute replied positively: this was exactly the reason why an EU approach was appropriate, because of the interdependence, building on existing EU and national measures. The early warning mechanism should also be taken into consideration in this process. Known and proved practices applied in the nuclear field could be extrapolated to bio-safety/bio-security.

Individual experts

Two individual experts replied, suggesting that the systems in place should be identified and best practices shared and that an indication of cases of infectious diseases occurring in society was needed before the surveillance networks could react, such as from sick leave reporting; indicators could then point towards infectious diseases or intoxication. Cooperation with the Global Public Health Intelligence Network (GPHIN) would be required.

4.1.2. How could the EU coordinate the different initiatives, at national, NATO, G7 and WHO level, in order to increase the overall consistency and effectiveness of an EU capability?

Public sector

Member States

The MS agreed that this was an important point and suggested appointing coordinators who would be responsible for sharing information between the organisations.

One MS stated that the EU should have an autonomous risk analysis capacity. Meetings of experts could be organised by the Council to give the EU a global view of national and international initiatives. One MS mentioned that the EU must take the lead to coordinate all initiatives and organisations. Two MS said that the ECDC should be involved in the process. Three MS also asked for compilation of an inventory of existing knowledge, skills, capabilities and structures.

One MS asked for help for small MS with limited resources. Another underlined that it had no capability for diagnosing biological infections and contamination, for lack of laboratories. One solution would be to create a system and procedures for rapid dispatch of samples to laboratories in other MS.

Third countries

One country believed that a multilateral approach should enhance cooperation with the WHO, NATO and Interpol.

Private sector

The private sector suggested that greater coordination could be achieved.

Associations

Four associations replied, suggesting that coordination should be achieved by regular consultation, with the ECDC's role reviewed, and should be via expert task forces that would be able to take a decision and be accountable and transparent. The different EU departments needed open communication at technical level with the other international stakeholders to harmonise efforts. Publication of a clear guide to roles and responsibilities would help in the short term, as would a European Bio-Preparedness Directory by mapping the stakeholders involved.

Research/Academia

The academic circles suggested that greater coordination could be achieved by means of working groups/task forces or even the EBN.

Academia

One academic institution replied that:

The EU should work proactively on bio-preparedness with other institutions and mechanisms, including NATO, the G8 and WHO – both for surveillance and for response activities.

Research

Two research institutes replied, stressing that the EBN could collaborate with equivalent bodies/structures outside the EU in order to increase overall consistency and effectiveness.

Individual experts

Three individual experts replied. They suggested establishing a single entity for EU bio-preparedness activities and that coordination would be possible under the auspices of a common working group that would have an overview of the resources and the ongoing research topics and results. The ECDC could be given the role of coordination. The EU should promote cooperation via the G7+ and NATO.

4.1.3. Do you consider that coordination of existing warning and detection capabilities, as well as the exchange of best practices in bio-preparedness, should be enhanced at EU level?

Public sector

Member States

All the replies from MS (except one) agreed that capabilities should be enhanced. One MS felt that the existing systems should be better integrated and that coordination should be improved to avoid duplication. One MS mentioned the need for good planning and implementation and to focus on basic principles. Another stressed that this was the role of the ECDC. One MS agreed, but added that defence and industrial confidentiality should be ensured and that existing tools could be used or new alert systems created. One MS underlined the problem of illegal immigrants, who could be carrying diseases.

Third countries

One country replied that coordination should be enhanced within the framework of the ECDC. Another said that disease surveillance should be central for all action to promote bio-preparedness.

Regional authorities

Common agreement.

Private sector

All the replies from the private sector agreed that capabilities should be enhanced.

Associations

The six associations which replied supported this idea.

Relevant comments:

- Coordination should be enhanced to ensure a response proportionate to the situation.
- Warning and detection coordination need to be enhanced and a coordination group is needed at the highest level of the EC and the Secretariat of the Council.

- Yes, between railway companies in Member States.
- A coordination post, perhaps under the EBN, should be established.

Individual companies

One individual company replied that detection systems were required to respond swiftly and appropriately.

Research/Academia

All the replies from academic circles agreed that capabilities should be enhanced.

Academia

One academic institution said that significant steps had been taken by the EU over the last few years to improve regional bio-preparedness. Rigorous analyses of accidents should be performed, "near-misses" should be explored, lessons learned should be disseminated and policies should engage proactively with the public in nearby communities to achieve mutual understanding.

Research

Two research institutes replied positively and one commented that the Joint Research Centre could play an active role in developing test detection methods because of its experience in various domains (bio-safety, nuclear safety and food and feed safety).

Individual experts

The four individual experts who replied were positive and added that coordination was the key to making best use of resources and could only save resources and make the system for biological risk reduction more efficient. It must be enhanced at EU level by means of targeted funding.

4.1.4. Should the EU look into the possibility of developing a capacity for test detection tools on live and dangerous substances?

Public sector

Member States

All the MS that replied to this question agreed that a capacity for test detection tools should be developed.

Two MS asked for mapping of existing capacity. One MS stated that mobile detection systems, standardisation/harmonisation at EU level and EU-level detection systems and instruments should be developed. The infrastructure should be based on networks and cooperation between MS.

One MS recommended that the EU should support research programmes on detection of dangerous live substances. It should also develop mobile analysis capacity and promote interoperability.

One MS believed that this should be done, but not necessarily at EU level. Operational requirements and criteria should be set at EU level for equipment and training.

In the view of one MS, many countries lacked resources.

Regional authorities

One authority considered this a priority, while another replied that this was better done locally.

Private sector

Many of the replies from the private sector to this question agreed that a capacity for test detection tools should be developed.

Associations

The replies from the seven associations that responded were mixed. Four indicated that this was a priority and that research results could serve as a basis for creating demand for bio-safety.

Three associations were less positive, indicating that there were already projects under FP7 and that such tools currently had limited capability. Any improved European capacity for test detection tools should act as a relay between existing public and private capacity.

Individual companies

Two individual companies replied as follows:

- Diagnostic systems are required to ensure appropriate use of limited stockpile resources.
- New knowledge and skills are needed to investigate new emerging issues. Funding has to be made available**.**

Research/Academia

Many academics who replied to this question agreed that capacity for test detection tools should be developed.

Academia

One academic institution said that compilation of lists of dangerous pathogens requiring special regulations and security measures was one step that the EU should carefully consider before taking action.

Research

The two research institutes which replied were in favour.

Individual experts

Six individual experts replied. Three said yes, adding the following comments:

- It is vital to be able to validate the effectiveness of detection technologies in terms of specificity and sensitivity.
- Although this would be cost-intensive and would take a long time, the relevant bodies should be trained to identify circumstances and indicators of potential biological risks.

The other three made the following comments:

- Each country should develop its own infrastructure, based on EU minimum standards.
- There is a huge gap in international cooperation and valuable exchanges of experience in this area, despite the many expert groups.
- Capability is required, but what type and for what purpose exactly still needs to be discussed.

5. RESPONSE AND RECOVERY

5.1.1. Should cooperation among relevant authorities and agencies at Member State and EU level be improved? If so, how?

Public sector

Member States

The MS replied yes, calling for common exercises and training and for improving the flow of information.

Twelve MS proposed the following means: expert panels, common exercises, joint training, a secure information network, a common methodology and national contact points.

One MS stressed that there could be greater liaison between animal health and food policy departments and related research funds. Another believed that this could be centralised within the Health Security Committee. One MS replied that EU agencies should take greater account of the work of national agencies. Some national agencies had built up specific expertise. A system to identify levels of responsibilities should be put in place. Security clearance should be ensured for those involved in bio-preparedness.

Third countries

One State said that the level of cooperation was already quite good.

Regional authorities

One authority proposed exchanges of information, networking, regular meetings, training and education.

Private sector

The private sector was generally positive about common exercises and training and about improving the flow of information.

Associations

Six associations replied, all positively, adding that cooperation and communication should be improved, including the public/private relationship involving the relevant industry at an early stage. There was also a need for uniform bio-safety and bio-security practices. A regular forum for bio-security communication needed to be established. The EBN could serve as an overarching organisation for this cooperation.

Individual companies

One individual company answered. Sharing knowledge between specialists was needed, and interaction between MS was a must.

Research/Academia

The academic respondents were generally positive about common exercises and training and about improving the flow of information.

Academia

Two academic bodies replied, both positively.

Relevant comments:

- Strengthen the networking between the main stakeholders in order to have research projects funded in a consistent way and to share views, ideas and experience and to

enhance preparedness all over the world, in addition to facilitating international cooperation.

- Effective bio-preparedness will require new organisational arrangements between the health and security arms of governments.
  - It would be extremely beneficial to outbreak response if there were global, standard procedures for exchanging biological and clinical samples of infectious agents quickly across national borders during an outbreak.
  - The EU should consider an "EU comprehensive approach" to "network security" drawing on synergies between traditional home/foreign affairs and defence ministries within nations, as in the EU, NATO, UN and WHO. These mechanisms could be especially beneficial for EU Member States whose national bio-security resources may not be developed. Response capacities vary significantly across the trans-Atlantic community.

Individual experts

Three individual experts replied positively and commented that this should be done at national level first. Communication and coordination were vital. Communication networks between agencies were a must, accompanied by joint research, seminars and exercises to test real capabilities.

5.1.2. Are regular exercises and training courses a good approach to enhance bio-preparedness or should other additional actions be pursued?

Public sector

Member States

All the replies (except one) agreed that exercises and training were vital. One MS said that they should be voluntary, another more intensive and practical, one multisectoral and another organised at national and European level.

Two MS asked that the results should be communicated or even made public via media campaigns (in the case of a third MS). One MS asked that conclusions be drawn from these exercises and that they are implemented in practice.

One MS suggested that a handbook on how to respond to an incident should be drafted.

One MS believed that the priorities were research and improving general standards. Exercises were of very limited value.

Third countries

Two States agreed that exercises and training were beneficial and should be pursued. One of them said that this should be done within the framework of the ECDC.

Regional authorities

Common agreement.

Private sector

All the replies from the private sector agreed that exercises and training were vital.

Associations

Four associations replied affirmatively and commented that awareness campaigns and regular meetings to exchange experience were important. Testing networks and surveillance

measures, based on realistic scenarios, was essential to safeguard and maintain effective operation in the wake of naturally occurring and deliberate incidents.

Consortia

Two consortia replied, both positively:

- Exercises and training should also involve the private sector by inviting retailers' representatives to participate in emergency exercises.
- Workers' training is fundamental and drills are very important.

Individual companies

One individual company said that exercises and training courses were essential.

Research/Academia

Most of the replies from academic circles agreed that exercises and training were important.

Academia

One academic said yes and commented:

- High-containment laboratories should have robust training programmes. The research done in high-containment labs is critical to bio-preparedness efforts, but it must be done safely.

Research

Two research institutes replied. One agreed that regular exercises were essential. The other said that awareness, empowerment and accountability of personnel must be ensured. Knowledge of cross-border emergency services should be enhanced.

Individual experts

All five individual experts who replied said yes and commented that the EU should develop its own scenarios and training tools and that appropriate mechanisms and preparedness instruments should be established in the private sector to complete these efforts. Workshops, training courses and local education would be necessary and a focal point for this activity was required.

5.2. Preserving and developing a European response to biological risks and threats

5.2.1. Are regular exercises and training courses a good approach to enhance bio-preparedness or should other additional actions be pursued?

Public sector

Member States

All the replies from the public sector agreed that this would be a good initiative, although one MS mentioned that there were many problems with implementation and that no solution had been found yet. One MS said that this was a difficult question, as solutions could vary from one MS to another.

Two MS believed that MS should assess their capabilities. One MS said that MS were required to build their own stocks and to contribute to any common strategic stocks. One MS underlined that this should be based on existing national capacities, which was why it was advisable to link and coordinate them. Another felt that MS should assess their capabilities for co-funding the project and specify their priorities.

One MS felt that production capacity should also be pooled. Finally, one said that vaccines and medicines (pre- and post-incident) should be developed on the basis of a public/private purchase model.

Third countries

One State considered that international collaboration concerning vaccines was the highest priority. Another believed that the Commission should consider strategies for developing, acquiring and stockpiling drugs and medical material. One MS opposed the idea.

Regional authorities

One authority agreed in specific cases.

Private sector

Almost all the replies from the private sector agreed that this would be a good initiative.

Associations

Seven associations replied. Four were immediately positive and commented that research capacity for developing medical countermeasures should be stimulated in Europe at the same time as building up diagnostic capacity.

One association answered no, saying that this could be done by the Member States.

The other two commented that the cost of mass vaccination needed to be weighed against the cost of developing early warning systems. There was a need to consider the regulatory capacity to allow appropriate studies in animals in certain cases in order to provide substantial evidence of the effectiveness of a new drug. Such regulations existed in the USA.

Consortia

One consortium said yes, a pro-active and complementary research policy was required to deliver tailored countermeasures in real time.

Individual companies

Six individual companies replied, stating that stockpiling medical countermeasures was one critical component, but needed to include planning and clear signals on precisely which products should be developed and to what extent they should be stockpiled. Medical countermeasures could not be developed effectively without clear regulatory guidelines and funding plans. Priority needed to be given to establishing stockpiles of smallpox vaccines.

Existing bio-safety labs already had all the experts, expertise and high-containment facilities available.

Research/Academia

Academia

One academic body replied:

- Stockpiles of agent-specific countermeasures for more than a handful of top threats (e.g. anthrax and smallpox) are neither practical nor affordable.

Research

One research institute replied. It commented that this should definitely be encouraged to improve centralisation and efficient use of stocks.

Individual experts

The four individual experts who replied were all positive, but commented that there was a need to look into exact cases where mass vaccinations would be required. Possible supplies of vaccines, test devices, P4 and P3 labs and other equipment could be of great value. However, large companies were unlikely to become involved in this area because of the lack of a substantial market in Europe. Small and medium-sized industrial partners linking with universities and military forces would be more willing to invest. The EU should finance clinical trials. It should establish a pan-European university-based centre of excellence for developing medical countermeasures, which would link up with industry to turn technologies into licensed products.

5.2.2. Do you agree that the creation of limited EU solidarity stocks, as already exist for animal health, supported by Community funding, would be a way forward?

Public sector

Member States

All the replies received agreed to the creation of EU solidarity stocks. One MS underlined that this topic had already been discussed in the Council where no agreement had been reached. One stressed the need for solidarity stocks and another stated that there might be a case for limited stocks of vaccines against certain agents. One MS considered that central facilities might enhance effectiveness.

Third countries

One State considered that this should be explored, while another was in favour of limited EU solidarity stocks.

Regional authorities

One authority agreed.

Private sector

Associations

Five associations replied. They were all positive, in principle, with two answering directly yes, adding that as long as specific issues were tackled first and the conditions under which the stocks should be created were clarified. The other three commented as follows:

- As this works in the veterinary field, the potential for transfer to public healthcare should be investigated.
- A number of questions need to be answered first, such as who will benefit, who decides the use to be made of the stocks, are they to help protect front-liners and the cost-effectiveness and shelf-life.
- The creation of additional stocks should not adversely affect the normal flow of medicines from manufacturers via wholesalers to pharmacists or hospitals. The issue of contingency stocks needs to be considered, taking special account of questions concerning expiry dates, stock turnover, costs and space.

Individual companies

Two individual companies were, in principle, positive. One said yes and, in particular, believed that solidarity stocks against an influenza pandemic would be useful. The other said that the policy against key pathogens, such as pandemic influenza or smallpox, had international support and was covered by WHO guidance, which recommended building up national and global stockpiles.

Research/Academia

Academia

One academic institution replied, commenting that if the programme was to be a success, it must have sufficient funding and a strong partnership between government and industry. To make it more economically attractive to the biopharmaceutical industry, a "flexible defensive" approach should be adopted, because broad-spectrum products would have markets beyond government purchases.

Research

Two research institutes replied as follows:

- The stockpile of drugs and devices should be monitored at European level.
- The EC should critically evaluate its capacity for addressing questions concerning:
  - prioritisation of threats;
  - availability and prioritisation of procured medical countermeasures;
  - formulation of medical countermeasures for self-administration or capacity for healthcare workers to administer the products in an emergency;
  - diversity of medical countermeasures;
  - delivery mechanisms that take into consideration national boundaries and regulations;
  - use (i.e. which countries and populations would be given priority for use in an emergency);
  - developing appropriate policies on these questions requires a decision-making body that can evaluate the threat and the needs of the scientific and public-health communities.

Individual experts

Three individual experts replied. Two of them were directly positive and the third pointed out the need to look at how vaccines were stored and distributed in a real crisis at EU level.

Relevant comments:

- Several issues need to be tackled, such as which product to stock, who will give the warning for vaccinating, how should the stock be managed, new threats, where the stockpiles should be located, who would pay for the products stockpiled, the shelf-life of each product and the drug packaging and language.
- Such stockpiles are recommended, but in view of the wide range of possible agents it will always be difficult to have appropriate amounts of the right substances ready.

5.2.3. Are the provisions already in place, such as antigen and vaccine banks, or reagent banks, sufficient?

The replies from the stakeholders were mixed. They identified a number of weaknesses and a number of strengths.

Public sector

Member States

Most contributors considered that there was room for improvement.

Third countries

One State considered that the measures should be harmonised within the framework of the EEA Agreement.

Private sector

Associations

Four associations replied. One said no. The other three commented that provisions should be sufficient to deal with the maximum levels of risk and threat conceivable. Existing activities needed to be coordinated and communicated. A feasibility plan and uniform efficiency standards were needed. “Community pharmacists” was one network with potential to safeguard supplies of medicines to the population, including antiviral medication and vaccines.

Research/Academia

Individual experts

Two individual experts replied. They both said no, the provisions already in place were not sufficient.