The International Council for the Life Sciences

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Improving National Biological Risk Assessment Methodology

And

Encouraging International Coordination of Biological Risk Assessment, Management and Mitigation

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Summary

Bugs know no boundaries – geopolitical or bureaucratic. As a consequence, efforts to manage biological risk have to be whole-of-government and international. But effective international coordination of biological risk management requires a common language and common methodologies for biological risk assessment.

Just as Airline A which screens all baggage for bombs will not be safe if it accepts baggage from Airline B which does not screen, so Country A which has the best pandemic preparedness plans in place will not get the full benefits of that investment if its neighbour, Country B, does not. Country A clearly has an incentive to encourage Country B to adopt better preparedness planning and, in some cases, it may be economic for Country A to pay for Country B to improve its preparedness. Furthermore, Country A clearly benefits the most if Country B's preparedness planning is compatible with and complements its own.

Current biological risk assessment methodology does not meet the ideal requirements of policymakers and the biological risk assessment which is performed is done in a bureaucratically compartmentalized way which leads to an under-evaluation of the benefits of preparedness and response measures and hence a suboptimal allocation of resources. Furthermore, there is insufficient international coordination and cooperation with regards to biological risk assessment, mitigation and management. ICLS has projects underway to address current issues with biological risk assessment methodology and practice, and international coordination of biological risk assessment, mitigation and management.

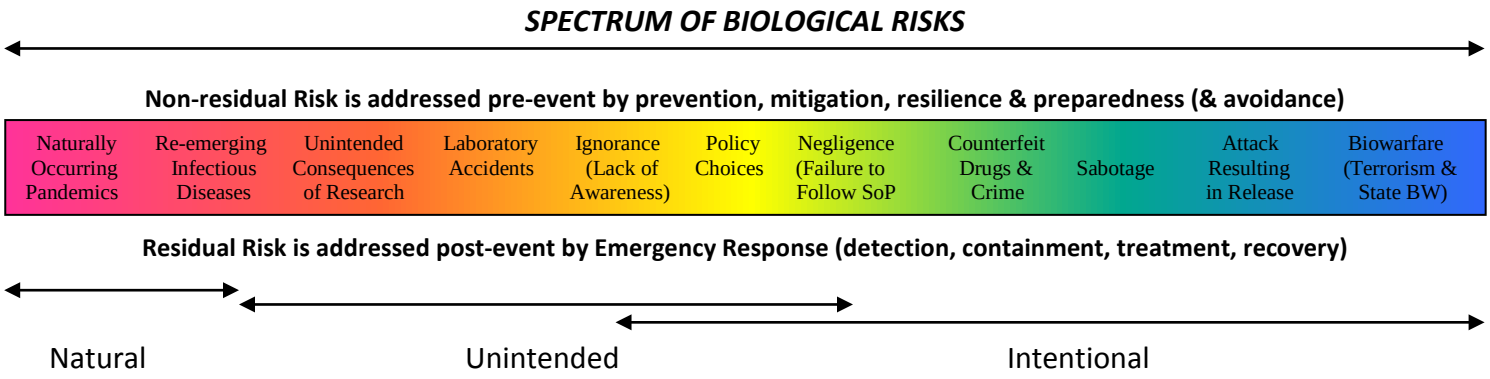
The Issue: Biological Risk

The threat of advances in the life sciences being used for harmful purposes is real. The challenge that the scientific community faces is to identify what measures can be taken to manage or reduce the risk without jeopardizing the enormous potential benefits to society and without unnecessarily impeding the pace of scientific advances.

Over the years, a consensus has emerged among experts in the field that there is a need to develop further upon existing methods for undertaking risk assessments across the full spectrum of biological risks[1], from naturally occurring disease through to the deliberate weaponisation of biological agents (see below).

From a policymaker's perspective, an ideal risk assessment methodology should:

- be consistent, transparent and repeatable;
- employ information technology and quantitative methodologies to the extent possible so as to ensure that the analysis criteria are as objective as possible and that the decision making process and its results are timely, clear, and well documented and hence easily communicated;
- allow for sensitivity analysis and cost-benefit analysis of proposed actions to ensure their viability and effectiveness;
- result in clear priority setting of objectives and means of meeting them to achieve optimal biological security, or at least result in a clear understanding of the issues to assist in subjective decision-making with regards to policy options;
- engender understanding of the risk analysis and decision making process by all who use the results so that may use them appropriately and understand their limits and shortcomings;
- incorporate a feedback mechanism for review and revision to ensure continual updating and refinement;
- perform regular performance checks of the model's output, particularly with regard to outliers; and
- lead to greater and more coordinated international adoption of risk mitigation measures.



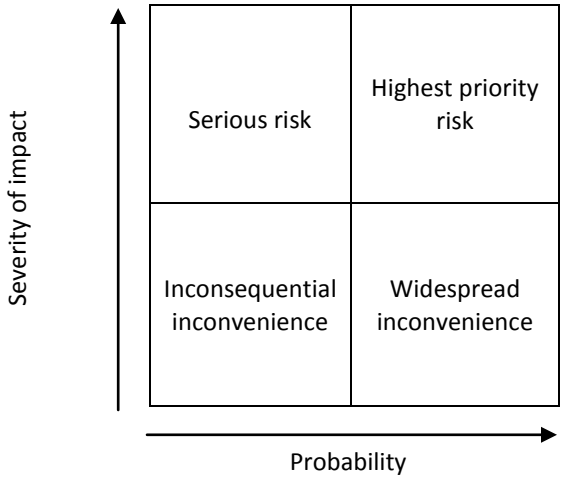
[1] See UN document A/60/825 "Uniting against terrorism: recommendations for a global counter-terrorism policy" and Royal Society Policy Document 17/08

Problems with Existing Biological Risk Assessment Methodologies

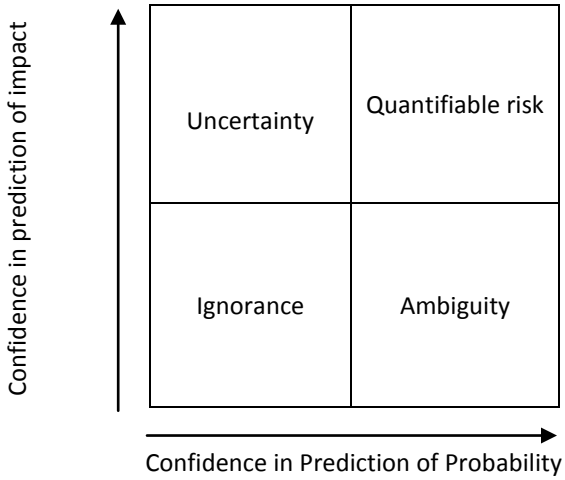
Currently, there are two sets of problems relating to biological risk assessment – those to do with methodology and those to do with implementation or practice.

Problems with Biological Risk Assessment Methodology

With regards to methodology, the standard risk assessment practice is to chart risks on a two or three dimensional grid with probability, severity of impact and pervasiveness of impact as axes:

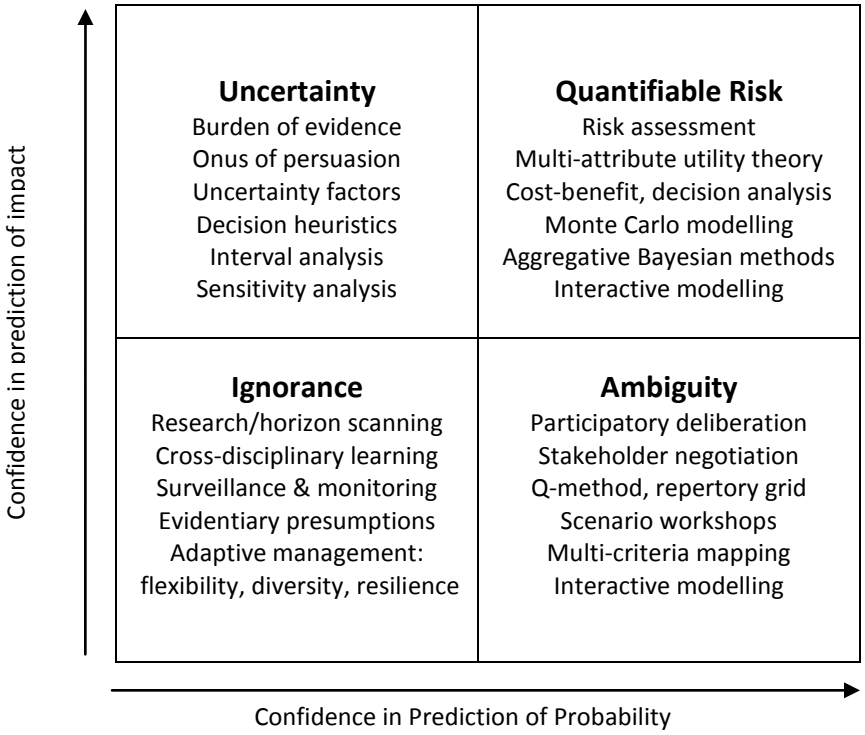


However, data on either the impact or the probability is rarely perfect, which leads to different epistemological outcomes[2]:



[2] Professor A Stirling, Embo reports Vol.8 #4 2007

For each of the four knowledge domains, there are a variety of methodologies available:



The question is, do these methodologies meet the policymakers' criteria set out above? If so, how are they best applied to the case of biological risk assessment and, if not, can we develop new methodologies that do?

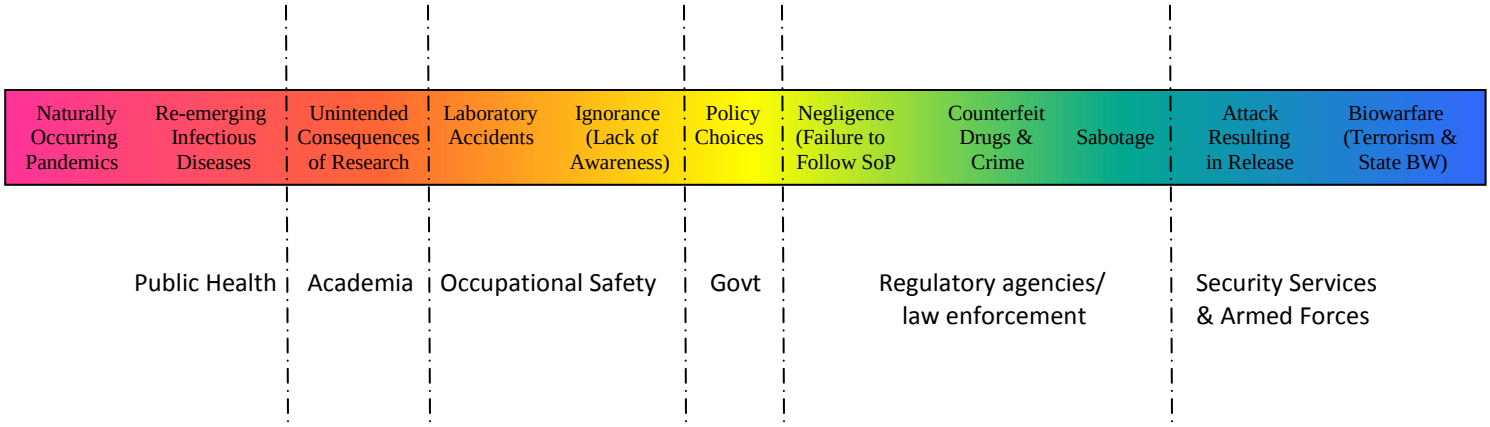
In fact, the prevailing view amongst experts is that available methodologies fall a long way short of the policymaker's ideal as defined in this paper.

Problems with Biological Risk Assessment Practice

Turning to issues of implementation, there are two issues:

1. compartmentalization of responsibility for dealing with, and hence assessing and responding to, biological risk across the spectrum; and
2. insufficient international coordination and cooperation vis-à-vis biological risk assessment, management and mitigation.

With regards to the first, **compartmentalization**, we see the following (mutatis mutandi for different countries):



Namely, different parts of the bureaucracy will analyse the risks associated with only that segment of the overall biological risk spectrum which falls under their purview. If the benefits of risk management efforts for each segment of the spectrum only accrued to that part of the spectrum, then this would not be problematic. But this is not the case. Many of the most effective risk management options provide risk mitigation across the whole spectrum. This is because a bug is a bug is a bug – it does not matter if a disease outbreak is caused by nature, an accidental lab release or the malicious intent of a bioterrorist, we have to identify it, diagnose it, contain it, treat it and recover. Thus efforts to improve early disease surveillance networks, speed up diagnosis and vaccine production, or improve resilience and emergency response will act to mitigate risks across the entire spectrum. But compartmentalized risk analysis by, say, the Department of Public Health, will only address the benefits to public health of taking measures to improve disease surveillance etc… Cost benefit analysis in such a compartmentalized way will automatically lead to an underinvestment in countermeasures as the benefits will always be understated. Conversely, a national, whole-of-government approach to risk analysis will properly capture the full benefits of such investments and so lead to more appropriate resource allocation.

The issue of compartmentalization holds true for the international scene, too, with the WHO, OIE, FAO, UNEP and UNSC all addressing different segments of the spectrum rather than the whole.

Turning to **international coordination of biological risk assessment, mitigation and management**, studies[3] of airline security and risk control related to baggage screening show that the full benefit of countermeasures is not realized unless there is universal adoption of the countermeasures by all airlines who receive luggage from each other for connecting flights. The issue is 'contamination' – even if an airline screens every piece of luggage it receives from passengers it checks in, it cannot be 100% sure that there will be no bombs in the checked luggage (and hence will not receive 100% of the benefit in its baggage screening investment) if it receives connecting flight luggage from an airline which does not screen every piece of luggage. The conclusion is that, in many scenarios,

[3] Heal and Kunreuther "Game Theory and Interdependencies" Appendix H, DHS Bioterrorism Risk Assessment: A Call for Change (National Academy of Sciences, National Research Council)

this contamination is so great that it does not pay for any airline to invest in baggage screening unless most other airlines do. Thus, if there is no coordinated effort to encourage all airlines to invest simultaneously, no airline invests at all.

This is illustrated in Heal and Kunreuther's paper with a classic "Prisoner's Dilemma" pay-off grid (which I have adapted here with arbitrary numerical pay-off values):

		Airline B	
		Screening	No screening
Airline A	Screening	915, 915	715, 800
	No screening	800, 715	720, 720

Heal and Kunreuther's paper suggested that the process of managing biological risk shares this characteristic of 'contamination' and hence risk management and mitigation measures are unlikely to be cost effective for most countries unless there is concerted international action.

The matrix also illustrates another phenomena mentioned in Heal and Kunreuther's paper – "tipping agents". In this grid, if both airlines are in the 'no screening' mode, there is no incentive to either to be the first to invest in screening. They are both on a payoff of 720, and the one that invests in screening alone would drop to 715 while raising the freeloader to 800. However, if an outside party were to invest the implied 85 in screening costs for either A or B, then the dynamics of the situation are changed. The parties are both at a payoff of 800 (as neither has paid the costs of screening) but it is now in the interests of the party with no screening to invest the 85 to bring its payoff up to 915, incidentally bringing the other party's payoff up to 915 too.

Thus, depending on the pay-off rates of the different players in a multi-player game, it is quite possible that it is in the interests of one or more players to subsidise the investments of a/some key 'tipping agent(s)" so that the dynamics of the whole game are changed from not investing to investing.

Currently, to the author's knowledge, there is little formal international coordination and cooperation with regards to biological risk assessment, mitigation and management. Furthermore, there is no common risk assessment methodology or even a common terminology. Terms such as 'biosecurity' have completely different meanings even in countries which share English as a mother tongue. This lack of common approach, communication and coordination is not conducive to most effective international response to the challenges posed by biological risks.

Proposed Actions

A recent meeting hosted by the International Council for the Life Sciences and the Royal Society in London[4] noted that:

- biological risk must be assessed holistically across the whole spectrum of risk;
- creating a single, uniform methodology for assessing biological risk would be challenging but worthwhile in terms of national and international policy-making, resource allocation, cooperation and the spread of best practices. Given the different nature of the risks across the risk spectrum (natural, unintended, intended) and the differing availability of historical data against which to derive or test mathematical models, there was some agreement that a methodology may have to employ a range of models coupled with an overarching model to unify the resultant risk assessments;
- any complete risk assessment would have to incorporate feedback loops to address the public's reaction to government risk management policies, the risks attendant to risk-reducing strategies, potential terrorists' likely reactions to knowledge of the risk management measures, and the synergistic effects of actions taken to reduce the risk of one set of factors also reducing the risk of other sets of factors;
- there should be a diversity of modelling techniques and expertise employed in the uniform methodology to ensure its robustness and resilience. In this regard, it was noted that expertise from insurance, banking, policy-makers, meteorologists, nuclear physics, the oil industry, cyberterrorism and epidemiologists would all be relevant in the formulation of the new methodology and that expertise should be drawn from a broad geographical basis to ensure global relevance; and
- the next logical step would be to commission a paper reviewing risk assessment methodologies currently deployed in a number of geographically representative countries to assist in (a) the analysis of best practices, (b) understanding how and why existing methodologies diverge, and (c) identifying the elements upon which a new, internationally uniform biological risk assessment methodology can be developed. This paper could be printed as a monograph and circulated to policy-makers in all the countries whose cooperation on mitigating and managing biological risk would be necessary for such actions to be optimally effective.

While a monograph on current international best practices (Track 1)would be a major step forward, as noted above, the full benefit of any one nation's risk mitigation and management efforts will not be realized until such measures are adopted by all the key nations.

Consequently, it is suggested that a second work theme (Track 2) should be to develop an high-level, international dialogue between those countries whose coordination of biological risk management and mitigation efforts would have greatest global impact. The aim of this dialogue would be, initially, to obtain a common understanding of the biological risks to which society is exposed and agreement that a common approach to assessment of this risk would be worthwhile. Ultimately, the aim would be to achieve agreement on a common risk assessment methodology and to institute regular meetings of the group to share biological risk assessments and to coordination risk management and mitigation measures.

This points to a third area of work (Track 3), alluded to at the Royal Society/ICLS meeting in London – an effort to move beyond existing risk assessment methodologies and create new approaches. The idea is to bring together government policy-makers in the biological risk area with risk analysis experts from a wide range of disciplines which are faced with the same conceptual problem – how to assess and manage risk in complex systems with multiple variables for which perfect data cannot be available and in which feedback loops affect the environment from one time period to the next. Disciplines mentioned during the London meeting include epidemiology,

[4] See Royal Society Policy Document 08/09

meteorology, finance, insurance, cyberterrorism, nuclear power, the oil industry, and academia (mathematicians and epistemologists). As a first step, this group would compare current sectoral best practices with the aim of encouraging cross-disciplinary learning and adoption and adaptation of techniques from one field to others. Ultimately, the aim of the group would be to assess the whole array of mathematical and epistemological tools currently available to science with a view to developing a new risk assessment methodology with cross-disciplinary applications.

Expected Outcomes/Benefits

The outcome of 'Track 1' should be the publication of a clear, plain English report which fully describes the current state of the art of biological risk assessment and which can be used immediately to move forward to a better, more harmonized approach to this important issue.

The benefits would be clear – a greater comparability of the results of different nations' risk assessments, easier sharing of information and best practices, and better coordination in the allocation of resources to manage and mitigate biological risk internationally.

The outcome of 'Track 2' would be a new mechanism for key countries to coordinate national and international biological risk assessment, management and mitigation. This would have obvious benefits arising from common action - the overcoming of the "prisoner's dilemma" nature of the investment decision for mitigation measures which would otherwise ensure an underinvestment in such measures.

The outcome of 'Track 3' would be an immediately opportunity for cross-sectoral learning vis-à-vis risk assessment methodology and practice, with the hope of a new, better risk assessment methodology with widespread application in many fields of human endeavour.