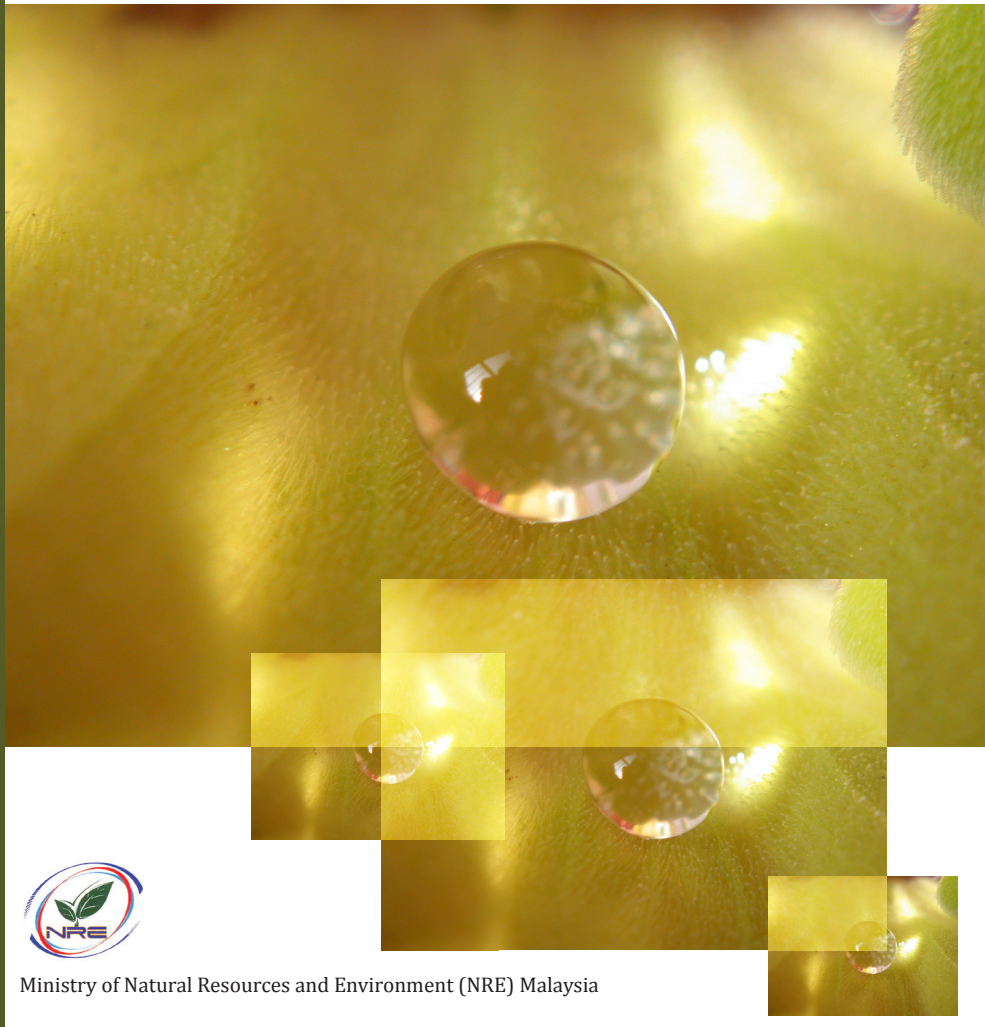
The Biosafety Act of Malaysia:
Dispelling the Myths



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NRE is the lead and focal agency for all matters pertaining to biodiversity including biosafety. The Biosafety Act 2007 (Act 678) was passed by the Malaysian parliament in July 2007. The purpose of the Act is to regulate the release, importation, exportation and contained use of living modified organisms, and the release of products of such organisms, with the objectives of protecting human, plant and animal health, the environment and biological diversity.

This publication is part of NRE's on-going initiatives to raise awareness on biosafety and to promote better understanding on biosafety matters to the public and all stakeholders.

September 2008

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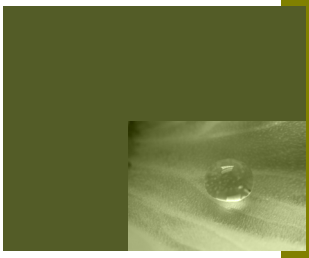


THE BIOSAFETY ACT OF MALAYSIA: DISPELLING THE MYTHS

1. Is the Biosafety Act (BA) anti-biotechnology?

Not at all. The Act follows the broad scheme laid down by the Cartagena Protocol on Biosafety (CPB). Just like the Protocol, Malaysia recognizes the twin aspects of modern biotechnology: the great potential offered by modern biotechnology, and, the need to protect human health and the environment from the possible adverse effects of the products of biotechnology.

This is best reflected by the words[1] of our Prime Minister, '*….while Malaysia is aware that biotechnology holds much promise, we are also concerned that biotechnological products should not pose any threat to the environment, or to human health and safety*'.

'Biotechnological products should not pose any threat to the environment, or to human health and safety'.

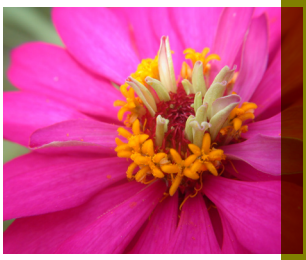
1 Speech by Rt. Hon. Dato' Seri Abdullah bin Haji Ahmad Badawi, Prime Minister of Malaysia at the International Scientific Conference "Biodiversity: Science and Governance", 24-28 January 2005 in Paris, France.

If it (the LMO) is safe, then it is approved.

2. *But it has been suggested that the BA ignores the established experience and knowledge that agri-biotechnology products have been safe and the technology shows a stellar record?*

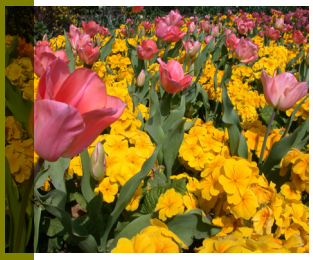
This is a strange suggestion and, with respect, misses the purpose of the BA. Biotechnology is a pillar of the government's wealth creation strategy. The potential benefits of this emergent technology are clearly acknowledged. Yet its safety facets cannot be ignored. As our Prime Minister reminded: *'The international community has recognized the potential hazards and risks of genetic engineering. The principle of precaution underpins the Cartagena Protocol on Biosafety as well as its parent convention, the Convention on Biological Diversity (CBD)'*.

In recognition of this, the BA establishes a process to vet all applications for direct release of living modified organisms (LMOs) into the environment to ensure that the particular LMO is safe. If it is safe, then it is approved. To arrive at this decision, a science based risk assessment report provided by the applicant is reviewed by Genetic Modification Advisory Committee (GMAC) - consisting almost entirely of scientists. The process is as suggested by the CPB. There is no *a priori* (preconceived) assumption against biotechnology or the approval of the LMO.



3. *It has also been said that the BA should not only refer to human and environmental safety and protection of biodiversity. It should also recognise Malaysia's need to accelerate investments in biotechnology, and not place 'unjustified hurdles'.*

The BA does not at all place unjustified hurdles. Applications are vetted by GMAC that will make its recommendation to the National Biosafety Board (the Board) for its decision. This Board consists of representatives of all the relevant Ministries– Ministry of Natural Resources and Envrionment, Ministry of Science, Technology and Innovation, Ministry of Agriculture and Agro-based Industry, Ministry of Health, Ministry of Plantation Industries and Commodities, Ministry of Domestic Trade and Consumer Affairs, Ministry of International Trade and Industry, as well as any person who may have specialized knowledge or experience in biosafety related issues. No more than four such persons may be appointed by the Minister to the Board. The industry must trust the wisdom of the Minister in choosing these members, and the Board in making a decision.



4. *But some say that the BA is not really balanced?*

Considerations of biosafety cannot be overridden by other considerations that would compromise this safety.

Where is the imbalance? You must remember that the BA is a protective Act. It is to ensure that LMOs released into the environment cause no harm to it or to human health. Considerations of biosafety cannot be overridden by other considerations that would compromise this safety. Nor should we seek to outdo other countries in the region in relaxing our laws merely to attract more foreign investment.

The scheme of the BA is to vet applications for direct release of LMOs into the environment. Once approved, the activity can commence. For contained use, there is no need for prior approval. The activity can commence upon mere notification to the relevant authority.

This process clearly allows LMOs that are safe to be released into the environment. This surely is what a responsible government must do - balancing safety concerns against unchecked entry of LMOs. This encourages responsible biotechnology-industry players to participate fully in Malaysia's biotechnology agenda.

5. *But is not the BA broader in scope than the CPB. Is that legitimate?*

Certainly it is legitimate. The CPB sets minimum conditions. This is because the CPB is based on consensus. It is a compromise instrument. So its provisions are the barest minimum that were agreed to, to forge an international treaty. In recognition of this, the CPB has a provision - Article 2(4) of the CPB - that expressly allows countries to *'take action that is more protective … than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's obligations under international law'*.

The point is not whether the law is broader. But really, whether the law thus enacted, adequately protects human health and the environment.

The point is not whether the law is broader. But really, whether the law thus enacted, adequately protects human health and the environment.

6. *But the BA does not mention protection against 'adverse effects' like the CPB. Does that not mean that the BA is in conflict with the CPB? And that Malaysia can exclude LMOs for all kinds of reasons, including if they are beneficial?*

Of course it deals with adverse effects. It is called the Biosafety Act. The long title of the Act states that it is to regulate LMOs *'…with the objectives of protecting human, plant and animal heath, the environment and biological diversity…'*

The introduction to the CPB defines 'biosafety' as the need to protect human health and the environment from the possible *adverse effects* of the products of modern biotechnology'. The regulatory process is to ensure that only LMOs that will harm the health of our people and the environment are excluded.

Section 35 of the BA also explicitly emphasises taking decisions relating to the potential *adverse effects* of LMOs or products on human, plant and animal health, the environment and biological diversity.

So there is absolutely no conflict with the CPB.

7. *But then why regulate 'products' when the CPB does not do so?*

First as stated, national law can be wider, if we feel it is necessary to regulate LMOs and products coming into the country – so that we can ensure that these do not harm human health and the environment. The Prime Minister's quote makes explicit reference to the need to regulate products as well.

Secondly, as the book *'Introduction to the Cartagena Protocol on Biosafety'* by the CBD Secretariat explains: the concept of 'biosafety' refers to the need to protect human health and the environment from the possible adverse effects of the *products* of modern biotechnology'.

Thirdly, the risk assessment principles in the CPB talk of the evaluation of risks associated with LMOs or *products thereof* (Annex III of the CPB).

8. *The decision making process seems to be multi-layered. Is this not unduly burdensome on investors?*

The decision-making process is quite straight forward – especially when compared to that of some developed countries.

Under the BA, the application is made to the designated Director General. He then refers it to GMAC for a scientific assessment, or to a relevant government agency if necessary for the same purpose. They then make a recommendation to the Board for its decision. Any person aggrieved with the decision of the Board can appeal to the Minister.

The decision-making process is quite straight forward – especially when compared to that of some developed countries

9. *Should not GMAC make the final decision?*

A government has to take responsibility for the decision. The Board has to make the decision taking into account all the necessary factors and in the public interest. This requires an evaluation of all stakeholders' interests. No doubt in almost all situations GMAC's scientific assessment will be pivotal in the Board's decision making.

The Board has to make the decision taking into account all the necessary factors and in the public interest.

10. *Why then does not the BA state categorically a decision-making process that is transparent, objective, clear and timely?*

The Act states the flow of decision-making from the time the application is submitted until a decision is made, and beyond – appeal and review. This is very clear. And the process is transparent.

The process is transparent.

As regards the timelines – you must remember that the BA is an enabling law. The details of implementation (how, when, what, etc) is left to be formulated by regulations.

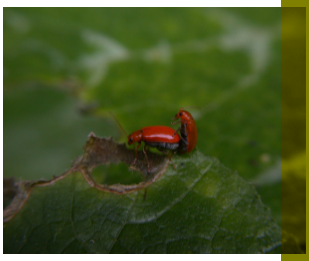
11. *'Enabling law'? Can you clarify this?*

You see, the BA provides for the main features of the Act and delegates the way in which the provisions are to be implemented to delegated legislation, in this case, by regulations.

Thus section 69 of the Act says that for the *better carrying out of the provisions of the Act*, the Minister will, in consultation with the Board, make such regulations as may be expedient or necessary.

Section 69(2) goes on to state that, without prejudice to this general power, regulations may also be made for several matters including (but not limited to) matters relating to: the application for release and import activities, risk assessment and risk management reports, contained use. It is expected that these regulations will set out the details on: the different criteria to apply for different activities; the procedure and content of the applications; the time lines, the fees payable, the details required for the risk assessment and management reports as well as the emergency response plan, the decision-making criteria and the procedure for appeals.

In short the regulations address all matters such as: procedures for submission of applications, the forms to be used, the decision-making process and the criteria to be applied, separate considerations for differentiated processes, the timelines, procedures for appeals, and the fees payable.



12. *Is this a usual mode of implementing laws?*

Yes, indeed. This is how most laws are implemented in Malaysia and many common law jurisdictions. Books have been written about this (example of a standard text book: *Legislative Drafting* by GC Thornton, 4th edn (1996) Butterworths pp. 340 on). It appears that European practice is similar. See for example, Regulation (EC) No 1829/2003 of the EU Parliament and of the Council on GM food and feed - which lays down procedures for the authorisation and supervision of GM food and feed.

13. *Is the Government serious about enacting these implementing laws, or regulations as the BA refers to these?*

Indeed it is. The Government has set up The Biosafety Regulations Advisory Committee (BRAC) which is now in the final stages of drafting these regulations. BRAC consists of representatives of various stakeholders - including industry, various Ministries, consumer groups, non-governmental organizations, research and academic institutions.

14. *It has been said by some industry coordinators that the BA makes it mandatory for socio-economic considerations to be taken into account in the decision-making, and that this is in conflict with the CPB?*

This is absolutely untrue! Both the CPB and the BA say that these considerations *may* be taken into account (Art 26 and section 35, respectively)

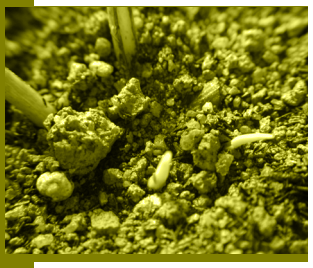
15. But why introduce such considerations in your decision making? Should it not be based entirely on science?

All functioning democracies that are accountable to their people take into account myriad factors in decision-making. In Malaysia, for example, the Government must take into account racial and religious sensitivities. LMOs with certain genes may be anathema or offensive to Muslims,Hindus or Buddhists and other faiths. The Board will need to weigh these factors carefully.

LMOs with certain genes may be anathema or offensive to Muslims or Hindus.

It is noted that risk assessment under the WTO's SPS Agreement also involves a mix of scientific and socio-economic considerations. For example, when assessing risks to animals and plants, Members are to take into account relevant economic factors - including an assessment of the impact that the spread of a pest or disease could have on the production or sales of the affected crops, as well as the costs of controlling or eradicating the pest or disease.

Risk assessment under the WTO's SPS Agreement also involves a mix of scientific and socio-economic considerations.



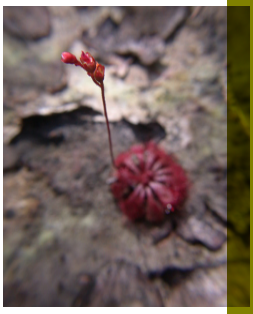
16. I have also heard it said that the BA is a misguided and highly distorted version of the CPB's precautionary approach. Is that true?

Not at all. In fact the precautionary principle (or 'approach' as some prefer to call it) in the BA is faithfully reproduced from the CPB - word for word. How then can it be a distortion of the CPB's formulation? Look at the wording:

BA, section 35: *The Board or Minister shall not be prevented from taking a decision, as appropriate, where there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of LMOs …*

CPB, Article 10(6): *Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of LMOs … shall not prevent that Party from taking a decision, as appropriate, …*

Of course the regulations may provide for the measures that may be taken where action is deemed necessary pursuant to the precautionary principle.



17. But is not the BA's interpretation of precaution misguided in that it is demanding 'zero risk'?

Of course not. The precautionary principle is science-based. It addresses the question: if the scientific assessment cannot point clearly one way or the other as to the consequences, (when there is insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects – as stated in section 35 of the BA) and especially if irreversible damage may result, then should the Government be in a position to act or not? So as a precautionary measure, a decision may be made. There is no question of demanding 'zero risk'. There is no such thing in life!

There is no question of demanding 'zero risk'. There is no such thing in life!

18. Will not the BA's application of the precautionary principle be in conflict with the WTO's SPS (Sanitary and Phytosanitary Measures) Agreement?

Certainly not. The SPS Agreement also provides for a precautionary approach. Its Article 5(6) allows countries to take measures *'in cases where relevant scientific evidence is insufficient'*. Of course the Board will be applying a similar approach … if and when it is necessary to do so.

The SPS Agreement also provides for a precautionary approach.

19. But then there is criticism that the provisions of the BA disregard the benefits of biotech products, are clearly in excess of what is required to justify or manage them and are for these reasons also in violation of the SPS Agreement?

Why should we disregard the benefits? But of course, the LMO must be cleared to be safe first.

This is clearly unfounded. Why should the Board disregard the benefits? But of course, the LMO must be cleared to be safe first. In any event, it is presumptuous to say that the provisions are in excess of what is required to manage the risks. BRAC has yet to draft the necessary measures. These will, naturally, be consistent with the risk assessment and risk management measures of the CPB.

Further, the measures under the CPB have never been considered to be in violation of the SPS Agreement. The CPB's risk assessment requirements are indeed strongly science-based [see Article 11(6), 15(1), 16(1) and (2) and Annex III (3)]. Even the inclusion of the 'precaution language' in the CPB does not alter the SPS Agreement's disciplines as it merely states that countries in the face of uncertainty, may take decisions 'as appropriate' [Articles 10(6) and 11(8)]. It does not say what those decisions may be or sanction a decision that violates other provisions of the Protocol or any other agreement.[2]

2 See Sabrina Safrin, 'The Relationship with other Agreements', in *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?,* Bail, Falkner and Marquand (eds), Earthscan, London, (2002) at p. 450-451.

We fail to see how anybody can conclude that our measures - which will be modeled on the CPB requirements - will be in violation of the SPS. In any event surely it is premature to make any criticism when the regulations have not yet been finalised.

20. Some say that Malaysia can either implement a law that is precautionary or …a law that is science-based. Not both.

This is a false choice. Indeed it is a rather novel and unheard of choice. The precautionary principle is science-based. To reiterate, the decision must be preceded by a scientific assessment. Only when the scientific community cannot agree on the nature and extent of the adverse effects and it is deemed necessary to take preventative measures can the regulatory authority resort to the precautionary principle. As stated earlier, the precautionary principle also appears in the SPS Agreement. It is combined with sound science. The SPS Agreement does not follow the logic of those who say that these two aspects - the precautionary principle and sound science - are mutually exclusive and must be separated.

The precautionary principle is science-based. To reiterate, the decision must be preceded by a scientific assessment.

21. What about the fact that the BA provides for no exemptions while the CPB does?

Section 68 of the BA gives the Minister the power to exempt *'from the application of any or all of the provisions of the Act any person, class of persons, activity, category or activities, LMO or products of such organisms'*. This is a very wide power indeed. And no doubt it will be exercised judiciously in the ripeness of time and the benefit of experience gained in the implementation of the BA. This could take care of the fast tracking of certain applications and possibly, different approaches to different applications.

22. But why cannot be approved applications on the basis that they have been approved elsewhere in the world?

Well this is because - as emphasized by the CPB and for good reasons of biosafety - the objective of risk assessment is to assess potential adverse effects of LMOs in the likely potential *receiving environment*. And be carried out on a case by case basis [CPB Annex III, clauses 1 and 3]. Insofar as the critics are suggesting an automatic approval based on approvals elsewhere in the world, this could be in conflict with the risk assessment agreed to in the CPB.

the objective of risk assessment is to assess potential adverse effects of LMOs in the likely potential receiving environment.

Nonetheless, there could well be a provision in the regulations - in the light of experience gained - such as that in the EU Directive 2001/18/EC which excludes from its purview *'organisms obtained through certain techniques of GM which have conventionally been used in a number of applications and have a long safety record'*. And also simplify procedures for approvals.

23. The BA provides for the application to be disclosed to the public. There are no parameters to the information that may be disclosed. Industry will be disclosing their trade secrets and other confidential information. How can you expect industry to do that?

This again is another myth. An applicant can apply for confidentiality of any commercial and industrial information. The criteria for grant of confidentiality is identical to that in the WTO Trade Related Intellectual Properties Rights (TRIPS) Agreement Article 39(2)(a) – (c) . Any such information cannot then be disclosed to the public. This is made explicit in sections 14(c) and 59 of the BA. Indeed any member of the approving authority who discloses such information is liable to rather severe penalties, including prison term.

In fact the provisions in the BA for public participation and disclosure are less stringent than those in the CPB, Article 23(2).

24. The BA allows the Board to revoke or alter any approval given. Does this not show the anti-GM stance of the Act?

Certainly not. The circumstances when the Board can act are spelt out clearly. These include: where there is a likelihood of danger posed to human, plant or animal health or to the environment or biodiversity; where there is non-compliance with the terms and conditions for the approval, and such like. This provision is necessary from the perspective of biosafety. There is nothing exceptional about such a provision.

25. *It has been said of the BA that 'violations of the provisions of the law, whether substantial or trivial, trigger penalties that can be more severe than found under other regulatory systems found around the world; there is no indication in the law that penalties should be proportional to the offence'.*

Malaysia has a well developed criminal law and procedure jurisprudence. Its sentencing polices are firmly grounded on proportionality.

Well, it is not shown how our laws are more severe. With which countries is the comparison being made? Secondly, penalties are country-specific, depending on policy grounds. Finally, it is absurd to suggest that the meting out of penalties will not be proportional to the offence. Malaysia has a well developed criminal law and procedure jurisprudence. Its sentencing polices are firmly grounded on proportionality. It is assumed, entirely incorrectly, that Malaysia has a penal system that is crude and barbaric! The BA, in any event, makes it clear that penalties are *'not to exceed'* a stipulated amount or period. This implies a scale based, quite naturally, on the principle of proportionality. In particular, judges invariably decide on the punishment according to the severity of the breach.

26. How about the fact that the BA requires labeling. This is not a safety question surely?

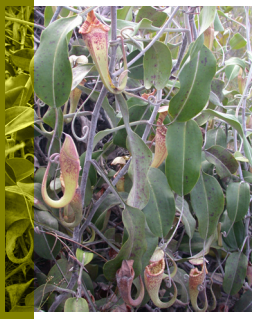
In a sense that is right. The BA deals with all LMOs and products. So it is useful to deal with this issue here. It is the paramount interest of the consumer to know what he or she is buying. Surely no one can quarrel with that!

It is the paramount interest of the consumer to know what he is buying.

27. But then why not have voluntary labeling? It has been suggested that this is a better way to offer consumer choices than mandatory labeling?

This statement – that only voluntary (and not mandatory) labeling will offer consumers choices – is highly contentious and has no universal support. There are indeed several countries – both developed and developing – that have mandatory labeling requirements for LMO products. Voluntary labeling simply does not work. And where it is not done, the consumer's right to know is denied. 'Malaysia requires labeling for so many food products. Here, the CPB has identified LMOs and products as a special category. So we see no objection in principle to labeling in the BA.

Voluntary labeling simply does not work.



28. Why is it alleged that there are some investors who will not invest in Malaysia because of the BA then?

It is difficult to give credence to some of these allegations as they come from the same persons who have been asking for our safety laws to be relaxed well beyond their own domestic laws or those of other countries with whom they do business. In any event, we have yet to finalise the regulations and to implement the law. So applicants and their applications would not have been subjected to the BA.

29. *It has also been suggested that Malaysia's stance in the on-going development of international rules and procedures on Liability and Redress negotiations has put off investors - in particular Malaysia's insistence on strict liability.*

You will note from the most recent bout of negotiations at Bonn in May 2008, that Malaysia led some 82 countries to agree on a proposal that if countries choose to enact laws on civil liability for damage caused by LMOs, then they are free to include either strict, fault-based or a mix of the two liability standards in their laws. Also our positions at these negotiations have received wide support, including from biotechnology countries such as China and India. Detractors, often with links to those with a certain agenda, should not dictate to Malaysia how its negotiators should conduct negotiations. Malaysia's positions are arrived at after the widest consultations with all Ministries and agencies in the country at meetings preceding the international negotiations and are based on what is in the best interest of the country.

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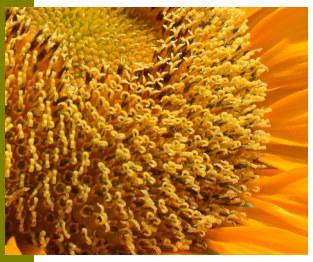
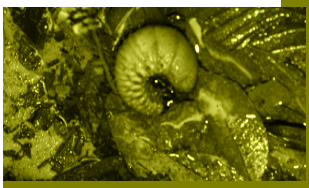


30. How can we improve a better understanding of our BA?

The national interest is best served by a balanced approach to promoting biosafety as we embark on reaping the potential presented by this technology.

Of course we have to explain our BA to interested parties including the policy-makers. It is also important that the misperceptions and myths relating to the BA are corrected – especially by those entrusted with promoting modern biotechnology. We should resist the temptation to be a mere conduit for those who wish to dismantle our biosafety law. And realize that the national interest is best served by a balanced approach to promoting biosafety as we embark on reaping the potential presented by this technology.



MALAYSIA'S BIOSAFETY ACT (BA) – DOES IT EXCEED THE CARTAGENA PROTOCOL ON BIOSAFETY (CPB) SUCH THAT IT COMPROMISES MALAYSIA'S BIOTECHNOLOGY POLICY?

Introduction

1. Critics say that the BA has exceeded the CPB's minimum standards in the approach to biosafety – implying that Malaysia has gone beyond what is required to protect the environment and human health and that this reflects our anti-biotechnology stance.

2. Is this true or even plausible?

3. Malaysia's policy is well reflected in the Prime Minister's statement: that while recognising the promise of biotechnology, '*we are also concerned that biotechnological products should not pose any threat to the environment, or human health and safety*'.

4. For this reason, the BA was enacted in 2007.

5. The issue then really is whether the BA achieves this purpose – ensuring the protection of the environment and human health.

Understanding the CPB

The CPB reflects the political compromises that were made to achieve consensus.

6. The CPB reflects the political compromises that were made to achieve consensus. There were those who did not want a protocol on biosafety at all; while some others wanted a comprehensive protocol. The compromise was to provide for minimum standards but to explicitly allow for each country to enact biosafety laws as they though fit to protect their environment and human health. The following several Articles makes this abundantly clear:

   a. Article 2 (4): the Protocol not to restrict the right of Parties to take action that is more protective ... consistent with the objectives and provisions of the Protocol ...;

   b. Article 5: right of a Party to subject all living modified organisms (LMOs) to risk assessment prior to the making of decisions on import (even though the Protocol does not apply to the transboundary movements of LMO pharmacueticals for humans that are addressed by other relevant international agreements or organisations);

   c. Article 6(1): right of a Party of transit to regulate the transport of LMOs through its territory;

   d. Article 6(2): right of a Party to subject all LMOs to risk assessment prior to the making of decisions of import (even though advance informed agreement procedure in CPB does not apply to LMOs destined for contained use);

   e. Article 11(4): a Party may make a decision on

the import of LMOs intended for direct use for food or feed or for processing (LMOs-FFPs) under its domestic regulatory framework that is consistent with the objectives of the Protocol.

Regulating 'Products'

7. Should we exclude products from regulation as these are not provided for in the CPB?

8. The BA is to protect against the possible adverse effects of LMOs. If the LMOs are incorporated in products and these may pose a risk, should our government exclude oversight of these products? Will not the BA then not adequately provide for all matters relating to biosafety?

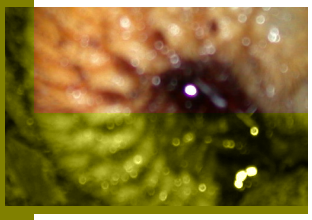
9. The introduction to the CPB[3], produced by the Secretariat of the Convention on Biological Diversity (CBD), states:

   'Biosafety is one of the issues addressed by the Convention. Ths concept refers to the need to protect human health and the environment from the possible adverse effects of the ***products*** *of modern biotechnology'.*

10. The risk assessment in Annex III of the Protocol also lists as one of its general principles (paragraph 5): *'Risks associated with living modified organisms or* ***products*** *thereof ...'*

11. Hence assessing the potential risks of LMO products is not alien to the CPB.

3 www.cbd.int/doc/legal/cartagena-protocol-en.pdf



Adverse Effects

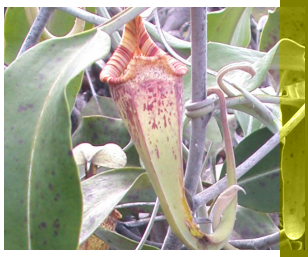
12. It is suggested that the BA, unlike the CPB, does not distinguish between LMOs that may have adverse effects and those that don't – and that this implies that all LMOs are treated as ultrahazardous, thus prejudicing the technology.

13. First, it is not true that the Act makes no such distinction. The Act is replete with several provisions that make it abundantly clear that the Act is to regulate against the adverse effects of LMOs and products:

    a. The Preamble states that the objectives are: '*...protecting human, plant and animal health, the environment and biological diversity ...*' Clearly the term 'protection' implies providing protection against adverse effects.

    b. Section 36(1)(a) states that the risk assessment report (to be submitted by an applicant) '*...shall contain an assessment of the risk and* ***adverse effect*** *that such living modified organisms ...will have or likely have on human, plant and animal health, the environment and biological diversity'*.

    c. Section 36(1)(b) states that the risk assessment and management reports (to be submitted by an applicant) '*...shall contain the proposed measures that shall be undertaken to prevent, reduce or control the risk and* ***adverse effect*** *that such living modified organisms ... will have or likely have on human, plant and animal health, the environment and biological diversity'*.



d. Section 35 states that the Board or the Minister shall not be prevented from taking a decision where there is a lack of scientific uncertainty regarding the *'...extent of the potential* ***adverse effects*** *of living modified organisms or products ...on human, plant and animal health, the environment and biological diversity'*.

Release Activity

14. The BA is said to be wider than the CPB in relation to release activities because in the latter it does not cover products of LMOs, nor does it cover living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFPs) or those intended for contained use. Whereas the BA covers R&D in field experiments, placing on the market, disposal, gift and remediation purposes.

15. First, the BA excludes contained use from the definition of release activity.

16. Secondly, the objective of the BA is to vet all situations where the LMO may pose a potential risk. This is for the sake of ensuring safety. The BA says that the LMO should be cleared for safety if it is to be delivered into the open. How it gets into the open environment should make no difference. The definition in the BA refers to all such situations when the LMO is placed in the open. From the safety perspective, there should be no objection to governmental regulatory oversight.

The BA says that the LMO should be cleared for safety if it is to be delivered into the open. How it gets into the open environment should make no difference.

17. As stated earlier, the CPB countenances that countries may, for reasons of biosafety, enact laws that go beyond its politically compromised provisions.

Mandatory 'socio-economic' considerations?

18. It has also been suggested that the BA, unlike the CPB, makes taking socio-economic considerations mandatory in decision-making.

19. This is, of course, incorrect. Section 35 of the BA states clearly that decisions by the Minister or the Board '... may also take into account socio-economic considerations'.

Recognition of approvals in other countries

20. It has also been suggested that the BA, unlike the CPB, does not provide for the recognition of approvals granted in other jurisdictions.

21. It must be accentuated that - as emphasized by the CPB and for good reasons of biosafety - the objective of risk assessment is to assess potential adverse effects of LMOs in the likely potential *receiving environment* and be carried out on a case by case basis [CPB Annex III, clauses 1 and 3]. Insofar as the critics are suggesting an automatic approval based on approvals elsewhere in the world, this could be in conflict with the risk assessment agreed to in the CPB.

Nonetheless, there could well be a provision in the regulations - in the light of experience gained - such as that in the EU Directive 2001/18/EC which excludes from its purview *'organisms obtained through certain techniques of GM which have conventionally been used in a number of applications and have a long safety record'* and also simplify procedures for approvals.

Simplified Procedures

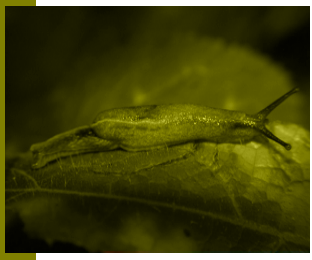
22. It has also been suggested that the BA, unlike the CPB, does not provide for simplified procedures.

23. Article 13 of the CPB gives discretion to the Parties of import to provide mere notification or exemption of certain LMOs from the AIA procedure.

24. This power is preserved in the BA by section 68 - which allows the Minister, on the recommendation of the Board to *'...exempt from the (any) application from any or all of the provisions of this Act any person, class of persons, activity, category of activities, LMOs or products of such organisms'*. This power is wider than that in the CPB, which allows for the simplified procedure only if a minimum level of protection is provided.

25. Further the BA enables the Minister to make, in consultation with the Board *'...such regulations as may be expedient or necessary for the better carrying out of the provisions of this Act'*. This is how Acts are implemented in many countries – the details are left to be provided for in regulations.

This is how Acts are implemented in many countries – the details are left to be provided for in regulations. With experience gained, and in the ripeness of time, Malaysia will no doubt provide for simplified procedures and 'fast-track' approvals, where safety is not compromised.



With experience gained, and in the ripeness of time, Malaysia will no doubt provide for simplified procedures and 'fast-track' approvals, where safety is not compromised. In any event, the BRAC charged with the task of enacting regulations has yet to complete its work.

Bilateral and Multilateral Agreements

26. It has also been suggested that the BA does not provide, like the CPB, for separate agreements to deal with the intentional transboundary movements of LMOs. Article 14 of the CPB allows Parties to do so. The agreements must, in any event, be consistent with the Protocol's objective, and, must not result in a lower level of protection.

27. This means that the agreement will have to provide for equivalent measures as the CPB. These, as a minimum, would be: a mechanism to ensure safe transfer, handling and use of LMOs; and for a method to provide the importing country with an opportunity and a basis for deciding whether or not to consent to the import of the LMOs.

28. While there is nothing to stop Malaysia from entering into such bilateral agreements, it is hardly likely to result in the application of lower standards of safety than those in the BA. Indeed in as much as this also involves an issue of trade in LMOs, any preferential treatment to any party through a lowering of standards could well run against the fundamental provisions of the WTO.

Pharmaceuticals

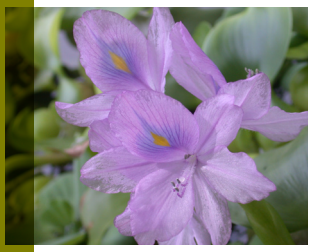
29. It has been suggested that the BA does not exclude pharmaceuticals,unlike the CPB.

30. Article 5 of the CPB excludes pharmaceuticals for humans (such as, the Hepatitis B vaccine, derived from genetically modified micro-organisms). Also, to be exempt, such LMOs must be addressed by other relevant international organisations. The main such organisation appears to be the World Health Organisation (WHO). All other pharmaceuticals are not exempted. This again reflects a compromise formulation. In the CPB negotiations, agreement to include this exemption was secured on the basis that the WHO already had risk assessment incorporated into their 'Certification Scheme on Pharmaceutical Products Moving in International Commerce'.

Article 5 explicitly states that, a Party has the right to subject all LMOs to risk assessment prior to an import decision, despite the exclusion of such LMOs (pharmaceuticals) from the Protocol.

31. As stated earlier, Article 5 recognises the right of countries to subject LMOs that are pharmaceuticals for humans (and that are not within the coverage of relevant international agreements) to risk assessment. This is a right that is inherent in every country to regulate such LMOs so that they accord with national standards on human health.

32. In any event, Article 5 explicitly states that, a Party has the right to subject all LMOs to risk assessment prior to an import decision, despite the exclusion of such LMOs from the Protocol.



33. Nevertheless, Section 68 of the BA gives the Minister the power to exempt 'from the application of any or all of the provisions of the Act any person, class of persons, activity, category or activities, LMO or products of such organisms'. Pursuant to this section, a pharmaceutical LMO may be exempted if it is already regulated by other prevailing laws in the country.

Conclusion

34. All the arguments made by critics of the Biosafety Act suggest that Malaysia's pro-biotech policy is compromised by a restrictive approach to biosafety. This article shows that the so-called restrictions are consonant with the CPB and carefully designed to zealously protect the environment and the health and safety of our citizenry. Thus does the BA best advance the twin aspects of biotechnology – advancing the biotech policy of the country, and, protecting against the possible adverse effects of products of modern biotechnology.

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For more information or clarification, please send your queries to
biosafety@nre.gov.my

The Biosafety Act 2007 (Act 678) can be viewed and downloaded online at
http://www.nre.gov.my
http://bch.cbd.int/