TWN
Third World Network
Email: twn@twnetwork.org
Websites: www.twn.my, www.ftamalaysia.org
Address: 131 Jalan Macalister, 10400 Penang, MALAYSIA
Tel: 60-4-2266728/2266159 **Fax:** 60-4-2264505

Briefing Paper

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The TPPA provides for illegal GMO contamination of our food

Preliminary analysis by Lim Li Lin and Lim Li Ching, Third World Network

Executive summary

Provisions in the Trans Pacific Partnership Agreement (TPPA) provide for the contamination of our food supply with unapproved and illegal genetically modified organisms (GMOs). The intention of Article 2.29 on 'Trade of Products of Modern Biotechnology' is to ensure market access and uninterrupted trade for GMOs. The procedural actions set out within, particularly when 'low level presence' (LLP) occurs, are of lower standard than international norms, including the legally-binding Cartagena Protocol on Biosafety. How Malaysia will implement these at the national level is now an open question, especially in the face of continued pressure by GMO-exporting TPPA countries, including through the Working Group on products of modern biotechnology that will be established by the TPPA. LLP is not quantified, leaving open as to how much contamination could be permissible in each shipment. This, linked with the appropriateness of the action taken by an importing country when faced with contaminated shipments, would be subject to the TPPA's dispute settlement procedures. The net result of these sustained pressures could mean that an importing country like Malaysia may simply choose not to defend their rights to reject GMOs that they have not approved, and to subject those GMOs to a prior risk assessment.

The GMO concern

GMOs are organisms which have been genetically engineered to express certain traits, by modifying their genetic code. There are many concerns over their potential health and environmental impacts, and there is still no scientific consensus on the safety of genetically modfied (GM) foods and crops[1].

At the international level, the UN Cartagena Protocol on Biosafety and the UN's Codex Alimentarius Commission[2] recognise the risks posed by GM foods and crops. Both call for a careful prior assessment of each GMO by national authorities in order to evaluate whether or not the particular GMO satisfies the national safety scrutiny.

At the UN, Malaysia played a pivotal role in establishing the need for a legally-binding international law on biosafety and in launching negotiations that culminated in the Cartagena Protocol on Biosafety. Like other importing countries that prioritised the health, environment and well-being of its people, Malaysia was rightly cautious about the claims of the GM industry and

[1] Hilbeck, A. et al. (2015). No scientific consensus on GMO safety. *Environmental Sciences Europe* 27: 4, doi: 10.1186/s12302-014-0034-1

[2] The Cartagena Protocol on Biosafety is the only international treaty to specifically regulate GMOs. The Codex Alimentarius Commission is a joint body of the World Health Organization and the Food and Agriculture Organization which governs global food safety.

GM exporting countries which downplayed GMO risks and advocated to prioritise the unimpeded trade of GMOs.

The Malaysian response

Malaysia's Biosafety Act 2007 regulates living modified organisms[3] (LMOs) and their products. The Biosafety Act reflects Malaysia's international commitments, as a Party to the Cartagena Protocol on Biosafety, and has the objective of protecting human, plant and animal health, the environment and biological diversity. The Biosafety Act also allows for taking into account socio-economic considerations when making decisions on LMOs.

No release or import of LMOs into Malaysia for release activities can take place without prior approval from the authorities. Release activities are intentional introduction of LMOs or their products into the environment. For example: for research and development purposes in field experiments, supply, sale or placing on the market (e.g. as GM crops or GM foods), and disposal.

Malaysia's case-by-case assessment system requires that the application for approval should be accompanied by a risk assessment and risk management report, and an emergency response plan for when something goes wrong.

The risk assessment and risk management reports must contain an assessment of the risks and adverse effects that the LMO and its products will have or are likely to have on human, plant and animal health, the environment and biodiversity, and the proposed measures to take to prevent, reduce or control the risks and adverse effects. The emergency response plan should detail the safety measures and procedures for protection of human, plant and animal health, environment and biodiversity and all necessary measures to be taken in an emergency.

The global GMO trade situation

Commodity grains (e.g. soya, corn) for food or animal feed are exported and imported around the world in bulk shipments. A number of TPPA member countries (e.g. US, Canada, Australia and Chile) are growers and exporters of GMOs. The rest of the TPPA member countries, including Malaysia, are essentially importers of GMOs.

In most cases, shipments of grains are an inadvertent mixture of non-GM and GM due to the lack of segregation in storage and transportation. In some cases, the GMOs may not be approved in the country of export or in the country of import, or both.

There have been a number of cases where countries have rejected shipments because they contain GMOs that have not been approved by them. For example GM Starlink corn, which contained a potential allergen, was not approved anywhere in the world for food use but found its way into grain shipments and the food chain. Shipments containing Starlink were held up at ports around the world, and it was subsequently subject to numerous recalls in many countries.

GM LL601 rice and Bt10 corn were not approved by any country and were either in field trials or in lab research in the US, but were found in commercial food and feed supply chains all over the world. Shipments of GM MIR162 corn, approved in the US, but not in China, were consistently rejected by the latter for several years. None of these GMOs were subject to prior risk assessment in the importing countries, so they were not able to make determinations about the safety of those GMOs.

Malaysia as an importer

To date, Malaysia has approved 14 GMOs for food, animal feed and food processing[4]. Apart from these 14 events, all other GMOs for these purposes would be unapproved, and would constitute illegal and/or unintentional

[3] GMOs are also known as 'living modified organisms' (LMOs) in the Cartagena Protocol on Biosafety and the National Biosafety Act 2007.

[4] MON 4032 Roundup Ready™ Soybean; MON 603 Roundup Ready™ Maize; MON 810 YieldGard™ Maize against Corn-Borer; MON 863 YieldGard® Rootworm Maize; SYN-Bt11-1 - YieldGard™ Maize; ACS-GM5-3 - Herbicide-tolerant Soybean (A2704-12); MON 89788 Glyphosate Tolerant Soybean (RoundupReady2Yield™); T25 herbicide-tolerant corn (LibertyLink® corn); TC1507 insect-resistant and herbicide-tolerant corn; Imidazolinone-Tolerant CV127 Soybean; Glufosinate tolerant A5547-127 LibertyLink® Soybean; Glyphosate and Isoxaflutole Tolerant FG72 Soybean; Lepidopteran-protected Corn MON89034; and Corn Rootworm-Protected and Glyphosate-Tolerant Corn MON88017. See: http://www.biosafety.nre.gov.my/country_decision/app_ffp.shtml

transboundary movements under Malaysia's Biosafety Act, should they enter the country.

Like most countries in the world, Malaysia thus has 'zero tolerance' for unapproved GMOs, requiring that any GMO imported into Malaysia should pass its safety assessment first.

Article 2.29: Trade in Products of Modern Biotechnology

The TPPA goes beyond previous US free trade agreements by addressing trade in GMOs much more specifically and extensively. Specific provisions on GMOs are contained in Article 2.29 on 'Trade of Products of Modern Biotechnology', in Chapter 2: National Treatment and Market Access for Goods. The intention is clear – to ensure market access and uninterrupted trade for GMOs, referred to here as 'products of modern biotechnology'.

Article 2.29 sets out mainly procedural actions to be taken by Parties:

- For transparency in decision making
- **When 'low level presence' (LLP) occurs**
- On authorisations of plant and plant products derived from modern biotechnology (to reduce the likelihood of trade disruptions from occurrences of LLP)
- For information exchange and cooperation on trade related matters associated with products of modern biotechnology

When low level presence (LLP) occurs

Definition of LLP (Footnote 13)

LLP occurrence is defined as "the inadvertent low level presence in a shipment of plants or plant products, except for a plant or plant product that is a medicine or medical product, of rDNA plant material that is **authorized for use in at least one country, but not in the importing country**, and if authorized for food use, a food safety assessment has been **based on** the Codex Guideline for the Conduct of a Food Safety Assessment of Food Derived from rDNA plants."

The main aim of the Article is to circumscribe what importing TPPA Parties can do when arriving commodity shipments (e.g. soya, corn) and shipments of other plants and plant products (e.g. vegetables, crops for planting) for food or animal feed are contaminated with GMOs that are not approved by them (but approved by at least one other country in the world, which does not even have to be the exporting country). It would seem that even an approval by a non-TPPA Party would also suffice.

The Article does not apply to animals and animal products, nor if the plant or plant product is a medicine or medical product. In these cases, there are no question marks over Malaysia's right to determine its biosafety policy and implement its Biosafety Act.

According to the footnote, if the GMO in question is authorised for food use by a country, the food safety assessment should have been based on the WHO/FAO Codex Alimentarius Plant Guideline. This international guideline has been agreed to by all Codex Alimentarius members and sets standards for GM food safety assessment. However, the food safety assessment in this case merely has to be **based on** the Codex Alimentarius guideline. This is weak and subjective, as it does not concretely hold the GMO "authorized for use in at least one country" to the Codex Alimentarius food safety standard.

However, if the GMO in question is authorised by a country for animal feed only, then no international safety standards need to be adhered to.

Crucially, 'low level presence' is also not quantified, leaving open as to how much contamination could be permissible in each shipment under the TPPA. Importing Parties would likely have to determine a threshold in order to implement this Article. This then, linked with the appropriateness of the action taken by an importing Party (see below) when faced with contaminated shipments, would be subject to dispute settlement.

Lack of concrete obligations on the exporting Party (Article 2.29.6)

The exporting Party is only required to share information with a view to preventing a future

LLP occurrence, "**where available and subject to its laws, regulations and policies"**. These actions

- are only triggered by the importing Party: "**at the request** of an importing Party"

- provide flexibility to the exporting Party to:

    - "provide a summary of the risk or safety assessment or assessments , **if any**"
    - "provide **if known** to the exporting Party, contact information for any entity within its territory that received authorisation for the plant product of modern biotechnology and whom the Party **believes is likely to possess**

        (i) any existing, validated methods for the detection of the plant product of modern biotechnology found at a low level in a shipment;
        (ii) any reference sample necessary for the detection of the LLP occurrence; and
        (iii) relevant information that can be used by the importing Party to conduct a risk or safety assessment or... food safety asseement in accordance with Annex 3 of the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants…"

- do not require the exporting Party to compel the exporter to cooperate with the importing Party: "**encourage** the entity to share information…"

These measures, and the flexibilities afforded to the exporting Party highlighted above, are weaker than provisions in the legally binding Cartagena Protocol on Biosafety and the guidelines of the Codex Alimentarius Commission of the FAO/WHO that relate to these matters.

In contrast, 'Annex 3: Food safety assessment in situations of low-level presence of recombinant-DNA plant material in food' of the Codex Plant Guideline states that its members "**should** make available to a **publicly accessible** central database… information..." including

- "summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline

- where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained"

In addition, "**the product applicant should** provide further information and clarification as necessary to allow the assessment according to this Annex to proceed, as well as a validated protocol for an event-specific or trait-specific detection method suitable for low level situations and appropriate reference materials (non-viable, or in certain circumstances, viable)."

All the TPPA member countries are members of the Codex Alimentarius Commission and should in good faith adhere to this internationally agreed Guideline. However the TPPA provisions are less stringent and legally binding on TPPA Parties. Thus, exporting countries like the US and Canada are likely to simply implement the TPPA provisions. For importing countries like Malaysia, the option of implementing the Codex Alimentarius guidelines at national level with stricter requirements on exporting countries is now in question.

Furthermore, Article 17 of the Cartagena Protocol on Biosafety places obligations on Parties, if there are cases of 'unintentional transboundary movement' (which would include LLP incidents), to notify affected or potentially affected countries and provide available relevant information, and consult affected or potentially affected countries to enable determination of appropriate responses and initiate action, including emergency measures.

None of these obligations - **notification, consultation, appropriate responses and action including emergency measures** - are envisaged in the TPPA.

Half of the TPPA member countries are Parties to the Cartagena Protocol – Malaysia, Vietnam, Japan, Peru, Mexico, New Zealand. But the US,

Canada, Australia, Chile, Singapore and Brunei are not.

Instead of holding non-Cartagena Protocol Parties to the same standard of obligations required by the Protocol, the TPPA now sets much lower standards, to the benefit of major GMO producers and exporters like the US and Canada.

As a Party to the Cartagena Protocol, Malaysia has implemented its obligations through its Biosafety Act. Non-Parties like the US and Canada are not bound by the Cartagena Protocol, but must comply with Malaysia's national law, which does not provide for 'LLP occurences'. The Biosafety Act requires that all GMOs entering the country must have prior approval, without which the GMOs can be subject to seizure, forfeiture and disposal, and offenders subject to fines and/or imprisonment.

Despite this, the lack of explicit policy, legal and regulatory clarity in Malaysia on 'LLP occurences' as defined in the TPPA or in cases of 'unintentional transboundary movement' as specified in the Cartagena Protocol would likely mean that continued pressure by exporting Parties of the TPPA, including through the TPPA's Working Group on products of modern biotechnology, could see Malaysia implementing the lax provisions of the TPPA, instead of the more stringent provisions of the Cartagena Protocol.

Uncertain rights of the importing Party (Article 2.29.7)

When LLP occurs, the importing Party can make a decision on whether or not to dispose of the shipment, but it must "ensure that the measures applied to address the LLP occurrence are **appropriate** to achieve compliance with its laws, regulations and policies".

In addition, a footnote states that "measures" does not include penalties. This is legally ambiguous. One interpretation could mean that importing Parties are not allowed to impose any punishments on the offending Party. Another interpretation could mean that penalties are not subject to the 'appropriateness test', unlike other measures which must be "appropriate to achieve compliance with its domestic laws, regulations and policies". The latter interpretation is more likely.

'Penalties' are not defined, and its normal meaning is 'punishment', which in this case could include a fine or forfeit.

The appropriateness of the measures applied by the importing Party will be subject to the state-to-state dispute settlement mechanism of the TPPA. Should there be a dispute between two states on the measures applied[5], the losing government will have to bring its measure into conformity, in accordance with the dispute panel's ruling. Should the losing government not do so, the winning government can eventually demand monetary compensation, or raise tariffs on specified exports of the losing government, until the latter eliminates the non-conformity or a mutually-satisfactory solution is reached.

Furthermore, nullification and impairment of a benefit that a Party considers it could reasonably have expected to accrue to it under Chapter 2 (and Article 2.29) would also be subject to state-to-state dispute settlement[6]. This could apply even if Malaysia has complied with Article 2.29.

In other words, even if Malaysia implements Article 2.29, but an exporting Party considers that it did not obtain some benefit it could have reasonably expected to gain, e.g. because a shipment with LLP occurrence was rejected or safety measures applied, the exporting Party can still bring a suit against Malaysia.

Furthermore, the appropriateness of the measures taken by the importing Party may be indirectly subject to the investor-state dispute settlement (ISDS) procedures of the TPPA, with a tribunal deciding what is 'appropriate'. Given the lack of clarity on what constitutes an LLP occurence and what measures are 'appropriate' to address it, the possibility of losing and paying potentially huge monetary sums could act as a 'chill factor' for any country, including Malaysia, to not take the necessary and appropriate action to protect health and environment when faced with such a situation.

Under the Investment Chapter, an investor can sue a TPPA government directly when the latter institutes policy changes that affect its investment. Whether or not this will apply if a GM exporting company claims that action taken to address an

[5] Article 28.3
[6] Article 28.3.1c

LLP occurrence is inappropriate, such as a shipment rejection or other safety measures, is uncertain.

The ISDS system propagated by the TPPA is nonetheless structurally biased against host governments. Only the investors can bring claims: states cannot bring an ISDS dispute to the tribunal. Arbitrators are therefore incentivised to interpret and award in favour of investors so as to encourage more claims and more appointments, either as arbitrators or as counsel for foreign investors.[7] Sixty percent of ISDS cases have been decided in favour of the investors[8]. Furthermore, there is no appeals mechanism, unlike other normal courts of law.

Whereas Article 25 of the Cartagena Protocol on Biosafety on 'illegal transboundary movements' (which could include LLP incidents) clearly states that:

"1. Each Party shall adopt appropriate domestic measures aimed at **preventing** and, if appropriate, **penalizing** transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed **illegal** transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to **dispose, at its own expense**, of the living modified organism in question by **repatriation or destruction**, as appropriate."

This affords Parties to the Cartagena Protocol a legal right to take strict and decisive action, including to penalize the offender and to require the disposal of the shipment at the expense of the exporting Party, in order to address what is clearly illegal activity.

Malaysia's Biosafety Act requires that all GMOs entering the country must have prior approval, without which the GMOs can be subject to seizure, forfeiture and disposal, and offenders subject to fines and/or imprisonment. This is clearly provided for by the Cartagena Protocol, but what will now happen in practice if Malaysia becomes a Party to the TPPA?

Conclusion: Whither zero tolerance?

Most countries, including Malaysia, have implicit 'zero tolerance' policies that require all GMOs entering the country to be subject to a prior risk assessment and approvals procedure. As such, most countries do not have laws, regulations or policies on LLP occurrence as this would circumvent their zero tolerance policy and allow shipments contaminated with illegal and unapproved GMOs to enter the country.

The TPPA, by establishing a procedure for Parties to follow when there is an LLP occurrence, may mean that importing Parties may simply choose not to defend their rights to subject all GMOs to a prior risk assessment procedure, before that GMO is released into the environment or is placed on the market, and to reject GMOs that they have not approved, and which are illegal in their countries.

Paragraph 3 of Article 2.29 states: "Nothing in this Article shall require a Party to adopt or modify its laws, regulations and policies for the control of products of modern biotechnology within its territory".

This savings clause may not be sufficient to provide the necessary cover for importing countries like Malaysia to retain their implicit zero tolerance policies. Pressure to implement the Article, including through the Working Group on products of modern biotechnology of the TPPA Parties, could result in effectively circumventing importing Parties' approvals procedure for all GMOs entering the country.

Furthermore, despite setting up a procedure under the Codex Alimentarius Commission to deal with LLP occurrences, paragraph 6 of Annex 3 of the Codex Plant Guideline states that the Annex on

[7] One study looked at 140 international arbitral cases up to May 2010 and found indications of systemic bias in the resolution of issues in investment treaty arbitration. See Van Harten, G. (2012). Pro-Investor or Pro-State Bias in Investment-Treaty Arbitration? Forthcoming Study Gives Cause for Concern. Investment Treaty News, (Issue 3, Volume 2), April 2012; Hachez, N. and Wouters, J. (2012), International Investment Dispute Settlement in the 21st Century: Does the Preservation of the Public Interest Require an Alternative to the Arbitral Model? Leuven Centre for Global Governance Studies Working Paper No. 81. Available at SSRN: http://ssrn.com/abstract=2009327 or http://dx.doi.org/10.2139/ssrn.2009327

[8] Mann, H. (2015). ISDS: Who Wins More, Investors or States? http://www.iisd.org/itn/wp-content/uploads/2015/06/itn-breaking-news-june-2015-isds-who-wins-more-investors-or-state.pdf

LLP does not eliminate the responsibility of industries, exporters and, when applicable, national competent authorities, to continue to meet countries' relevant import requirements, including in relation to unauthorized recombinant-DNA plant material.

In other words, the Codex Guideline, which is relevant to all Codex member countries, explicitly states that exporting countries and entities must respect the importing countries' rules in relation to LLP occurrences, which could include 'zero tolerance'. This is not also the case with the TPPA

In addition, the higher standards of the Codex Alimentarius Commission and the Cartagena Protocol on Biosafety for dealing with unintended and illegal contaminated shipments, which could have afforded better protection and more rights to importing countries, had they explicitly decided to allow for LLP occurrences, may now not be implemented by importing TPPA Parties.

Biotech industry sources have been quoted as saying that taken together, the provisions of Article 2.29, would "encourage countries to synchronize their authorization procedures and could ultimately lead to fewer LLP instances"[9]. Sadly, this might be the case simply because importing Parties of the TPPA might ultimately either be approving the same GMOs that exporting countries have approved, or allowing illegal GM-contaminated shipments to enter the country, once it becomes a Party to the TPPA.

The TPPA's Working Group on products on modern biotechnology, further provides a forum to "exchange, subject to a Party's laws, regulations and policies, information on issues, including on **existing and proposed domestic laws, regulations and policies** related to the trade of products of modern biotechnology"[10]. Apart from providing a forum for major GM commodity exporters (such as the US and Canada) to pressure countries to adopt more lenient approaches to address LLP occurrences, the Working Group may also be used to shape future rules on biotech authorizations that are more trade-friendly, according to industry sources[11].

[9] *Inside US Trade*, November 17, 2015.
[10] Article 2.29.10(a)
[11] *Inside US Trade*, ibid.