

THE *EC BIOTECH* CASE AND ITS IMPLICATIONS FOR MEASURES AFFECTING GENETICALLY MODIFIED ORGANISMS*

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1 Introduction

South Africa has placed itself in the forefront of the development and application of biotechnology products such as genetically modified organisms (GMOs). The country is said to be one of the top six GM crop planting countries in the world.¹ However, not everyone applauds this GMO-friendly policy and a number of non-governmental organisations have asked for a moratorium on the development and import of GMOs and GM products. South Africa did not heed this call, but it did place a moratorium on the clearance of new GM commodity products destined to be used as food or feed. This means that while imports of previously cleared GMOs continue, no new GMO commodities have been imported since 2005, despite the fact that risk assessments were concluded on these commodities. The GMO Council, the primary regulatory body in terms of the GMO Act,² will make a final decision, pending the outcome of a socio-economic study being conducted by the Department of Trade and Industry. This prompts the question what the legal status of such a moratorium under World Trade Organisation (WTO) law is, and to what extent South Africa is violating its legal obligations under the WTO in imposing such a moratorium.

This issue was recently addressed in *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (hereafter *EC-Biotech*)³ in a challenge against a GM moratorium adopted by the European Union (EU). Europe has taken a cautious position on GMOs and the release of GMOs in the European market based on concerns relating to human and animal health, environmental impacts, ethical considerations and socio-economic considerations such as the survival of traditional farming methods and impacts upon indigenous and local communities. Consumer attitude boosted by health scares such as “mad cow disease” and foot-and-mouth disease outbreaks, has contributed to

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¹ *Engineering News* February 2004.

² 73 of 1989.

³ WT/DS291/R, WT/DS292/R and WT/DS293/R 29 September 2006.

this position. Thus in the light of “scientific uncertainty” and “consumer mistrust”, the EU in October 1998 stopped approving new GMOs that would be placed on the market. A group of six member States (France, Denmark, Italy, Greece, Austria and Luxembourg) declared that they would vote against any GMO marketing application until further rules were put into place ensuring first, that GM products can be traced back to their source and secondly, that all GMO-derived products are labelled as such.

The EU based its statutory regulations on the precautionary principle embedded in a number of international conventions and treaties such as Principle 15 of the Rio Declaration and the Cartagena Protocol on Biosafety to the Convention on Biological Biodiversity (CBD) adopted in 2000. The first EU law on GMOs was Directive 90/220 adopted on 23 April 1990, which addressed some of the burning issues of biotechnology, for example mandatory pre-market approval, environmental release and labelling. Unlike countries such as the USA, which considers GM products as being equal to non-GM conventional products, the EC Directive 90/220 treated GM products as “novel” products, hence the need for a specific regulatory framework.

The EU introduced a new regulation in 1997,⁴ which put in place a new mandatory labelling rule. The centrepiece of the regulation was the wide definition of what is referred to as “novel foods”. This is much wider than what is covered by the 1990 Directive. The regulation in pursuit of the EU precautionary principle shifted the burden of scientific proof on the manufacturer of foods derived from GM material to determine whether a product falls outside the regulation. The regulation also allows a manufacturer to introduce certain GM containing products without any pre-market approval but this is possible only on the basis of scientific evidence.

In 2001, the EU adopted a series of new regulations that covered issues such as the environmental release of GMOs (Directive 2001/18), authorisation procedure for new foods and feed containing or produced from GMOs (Regulation 1829/2003), and labelling and traceability standards (Regulation 1830/2003). Directive 2001/18 replaced Directive 90/220, but essentially provided for the same administrative procedures for granting consent for the placing on the market of GMOs. Approval procedures include submission of the application and assessment by the competent authority of the Member State where the GMO will be placed on the market for the first time, as well as community-level mechanisms in case of objections. Where a GMO has been approved for community-wide marketing, member States may not restrict trade in that product. They may, however, adopt provisional safeguard measures to restrict

⁴ Regulation 258/97.

trade in such products if there are reasons to believe, based on new or additional information, that the product constitutes a risk to human health or to the environment.

The trade impact of the EU's new regulatory framework was immediate and adversely affected GM exporters to the EU. The US share of EU maize imports, for instance, fell from around two-thirds in the mid 1990s to almost zero. The GM adopting countries lost market share to GM-free suppliers sparking fears that EU member countries or other food-importing countries would deny market access to products of food exporting countries if any GM products are grown or even imported into those exporting countries.

The EU position was further strengthened when the Cartagena Protocol on Biosafety came into force in September 2003. This Protocol seeks to provide a framework for dealing with trans-boundary movement (including trade) of living modified organisms (LMOs) and the environmental uncertainties posed by LMOs. It explicitly incorporates the precautionary approach but does not provide criteria by which countries can be found to have abused the right to implement a precautionary policy. The EU actively began to draw on the Protocol to justify its moratorium on the approval of GM imports.

The increased disenchantment over the way the EU applied its precautionary measures prompted the US, Canada, and Argentina to seek the establishment of a WTO Dispute Settlement Panel to rule on the WTO compatibility of these measures. This raised the expectation that a WTO decision on this matter would clarify trade obligations regarding GM products and resolve some of the inconsistencies in not only international agreements, but also domestic regulation.

2 The case

On 13 May 2003, the United States and Canada requested consultations with the EC concerning certain measures taken by the EC and its member States affecting imports of agricultural and food imports from the United States and Canada. The US and Canada asserted that the EC applied a moratorium since October 1998 on the approval of biotech products and that this moratorium has restricted imports of agricultural and food products from the US and Canada. They furthermore asserted that a number of EC member States maintained safeguards, namely national marketing and import bans on biotech products, even though those products were already approved by the EC for import and marketing in the EC. On 14 May 2003, Argentina requested consultations with the EC on the same matter.

On 7 August 2003, the US, Canada and Argentina each requested the establishment of a panel. The panel was established under the WTO Dispute Settlement Understanding to consider the consistency of various measures taken by the EC and EC member States with WTO rules. The US, Canada, and Argentina challenged three types of measures:

- The EC moratorium on approvals of biotech products: the claimants argued that a *de facto* suspension of the approval of biotech products amounted to a general moratorium on such products and that pursuant to the moratorium, the EC has suspended consideration of applications for, or granting of, approval of biotech products. The EC denied the existence of a general moratorium on the approval of biotech products and submitted that the alleged practice alone, not based on a formal or informal instrument, would not constitute a measure under WTO agreements.
- Various product-specific EC measures related to the approval of biotech products: in this regard it was argued that the EC failed to consider specific applications for approval of biotech products and that such failure also constituted a violation of WTO agreements. The EC argued that failing to deal with product applications within a specified time frame could not be considered a measure, and thus would only be subject to provisions dealing with the application rather than development of a measure.
- Various EC member State measures related to the import and/or marketing of specific biotech products: the claimants challenged safeguard measures enacted by certain EC member States, including France, Germany, Italy, and Greece. They argued that these measures were not based on scientific evidence, as required by WTO rules. The safeguard measures, permitted by EC regulations, allow EC member States to limit the importation or marketing of certain biotech products already approved by the EC. The EC, however, argued that these measures, given their provisional nature, were in full compliance with relevant WTO disciplines.

Almost three years later, on 7 February 2006, the panel issued an interim report in the matter.⁵ At long last, its final report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, appeared on 29 September 2006.

3 The decision of the panel

A number of WTO agreements regulate trade in GMOs including the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Technical Barriers to Trade Agreement (TBT Agreement), the General Agreement on Trade and Tariffs (GATT) and the Agreement on Agriculture (AoA). The panel found that most of the challenged measures fell under the scope of the SPS Agreement.

3.1 The SPS Agreement

The SPS Agreement aims to elaborate the rules for the “application of

⁵ WT/D5291/INTERIM 7 February 2006.

the provisions of GATT 1994 which relate to the use of sanitary and phytosanitary measures". The Agreement applies to all sanitary and phytosanitary measures that directly or indirectly affect international trade.⁶ Annex A(1) defines SPS measures as:

"Any measure applied:

- a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, disease, disease-carrying organisms or disease-causing organisms;
- b) to protect animal or plant life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- c) to protect animal or plant life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests."

For any measure to comply with the Agreement, the measure must be "necessary to protect human, animal or plant life or health",⁷ it must be based on "scientific principles" and there must be "sufficient scientific evidence" to maintain the measure.⁸

These measures may not be discriminatory or "constitute a disguised restriction on international trade".⁹ The Agreement requires that SPS measures should be based on a risk assessment and when assessing risk, signatories must "take into account available scientific evidence," "avoid arbitrary or unjustifiable distinctions", and avoid measures that are more "trade-restrictive than required".¹⁰ In *EC Measures Concerning Meat and Meat Products*¹¹ (*Beef Hormones* case), the Appellate Body maintained that the risk to be assessed under article 5 of the SPS Agreement should not be a "theoretical uncertainty" but rather an "ascertainable risk".

The SPS also has provisions that require notification when there are changes in measures and requires that these measures be reasonable.¹² The SPS Agreement furthermore lays down certain procedural requirements. Annex C of the SPS Agreement on Control, Inspection and Approval Procedures, provides in paragraph 1 that

"members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: (a) such procedures are undertaken and completed *without undue delay* and in no less favourable manner for imported products than for like domestic products".¹³

Article 8 directs members to observe the requirements in Annex C. Article 7 mandates transparency in procedures and states that

⁶ Art 1.1.

⁷ Art 2.1.

⁸ Art 2.2.

⁹ Art 2.3.

¹⁰ Arts 5.1, 5.2, 5.5 and 5.6.

¹¹ (WT/DS26/AB/R and WT/DS48/AB/R) 16 January 1998.

¹² Arts 7 and 8.

¹³ Emphasis added.

"members shall notify changes in their sanitary or phytosanitary measures and provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B".

The latter provides for publication of regulations, enquiry points and notification procedures.

The complainants in the *EC Biotech* case averred that the EC contravened provisions on risk assessment and scientific principles, discrimination and procedural requirements in that the moratoria were not based on a risk assessment, that they were not based on scientific principles, that they were discriminatory and amounted to a disguised restriction on trade. They also alleged that the procedural provisions were violated as the moratorium amounted to an *undue delay* in the completion of approval procedures.

3 2 Does the SPS Agreement apply?

The EC argued that its measures were applied in part for purposes which are identified in Annex A(1) of the SPS Agreement and in part for other purposes. The EC submitted that to the extent that the relevant EC approval legislation is applied for purposes which are identified in Annex A(1), it is governed by the SPS Agreement, and to the extent that the legislation is applied for other purposes, it falls within the scope of another WTO agreement, possibly the TBT Agreement. The panel to some extent agreed with this view and stated that since approval procedures are conducted for a number of purposes (namely, to avoid various adverse effects), it may conceivably be warranted to view each of the relevant EC approval procedures as incorporating an SPS measure as well as a non-SPS measure.

The panel found, however, that Directives 90/220 and 2001/18 do in fact constitute SPS measures.¹⁴ In assessing the purposes of the EC approval regulation, the panel determined that the purpose of Directives 90/220 and 2001/18 is to protect human health and the environment from adverse effects on human health and the environment which might result from the deliberate release of GMOs into the environment.¹⁵ The panel noted that this was in accordance with Annex A(1)(a) and (b) of the SPS Agreement which covers measures applied to protect animal and plant life or health from certain risks. Thus, to the extent that Directives 90/220 and 2001/18 are applied to protect animals and plants as part of their purpose of protecting the environment, "they are not *a priori* excluded from the scope of application of the SPS Agreement".¹⁶ The panel proceeded to consider the meaning and scope of some of the terms and phrases used in Annex A(1)(a)-(d) and whether certain potential effects of GMOs identified in the Directives meet the definition of these terms and

¹⁴ Pars 7.416 and 7.432.

¹⁵ Par 7.196.

¹⁶ Par 7.207.

phrases. For instance, in applying the concept *pest* to the EC Directives, the panel considered three situations referred to by the parties:¹⁷

- where GM plants grow where they are undesired, for example, as a result of spillage or persistence or invasiveness;
- unintentional gene flow or transfer from a GM plant (“outcrossing”), leading to cross-breeds between GM plants and other plants, whether conventional crops or wild flora, which have undesired introduced traits (such as herbicide or insect resistance) and may establish or spread; and
- where pesticide-producing (for example, insecticide producing) GM plants increase the potential for the development of pesticide-resistance in target organisms, notably insects.

The panel found that the risk of “pest” was inherent in all three these instances. The panel then repeated its analysis with respect to different terms found in Annex A(1)(a), (b) and (c) of the SPS Agreement and established that a number of the potential adverse effects of GMOs identified in Directive 2001/18 indeed fall within the scope of Annex A(1)(a), (b) and (c) of the SPS Agreement.¹⁸

With regard to labelling, the panel determined that the labelling requirement in Directive 2001/18 is rationally related to the purpose of protecting human health and the environment. It accordingly presumed that the labelling requirement is applied to protect human health and the environment from possible unanticipated effects of GMOs. Thus, to the extent that it is applied to protect the environment, it would fall within the scope of Annex A(1)(a), (b) or (d), and to the extent that it is applied to protect human health, it would fall within the scope of Annex A(1)(b) or (c). Accordingly, the panel found that the labelling requirement in question brings Directive 2001/18 within the scope of the SPS Agreement.¹⁹ It concluded that Directives 90/220 and 2001/18 as well as Regulation 258/97, to the extent that it seeks to prevent novel foods from being a danger to the consumer, are SPS measures which may, directly or indirectly, affect international trade within the meaning of Article 1.1 of the SPS Agreement. As such, these provisions are subject to the provisions of the SPS Agreement.

3 3 Was there a moratorium?

The complainants asserted that the EC had maintained a *de facto* moratorium on the approval of biotech products since October 1998. The EC contested the existence of such a moratorium and argued that the complainants could not identify any instrument or other text through

¹⁷ Par 7.235.

¹⁸ Pars 7.21.2-7.379.

¹⁹ Par 7.391.

which the alleged moratorium was imposed, and that their complaint was consequently really one of *delay*.

After examining the approvals procedure of the EC, whether the EC showed intent to suspend approvals and whether there was in fact an absence of approvals, the panel found that a general moratorium on approvals was in effect in the EC between June 1999 and August 2003.²⁰ It considered, amongst others, the fact that not a single biotech application under consideration during this time period had been approved on or before the establishment of the panel. This moratorium applied *de facto*, that is, without having been adopted through a formal EC rule- or decision-making process, and, furthermore, the final approval of applications was prevented by the Group of Five countries and/or the Commission through their actions and/or omissions. The panel decided, however, that the moratorium, ie the alleged failure to consider an application for final approval, does not constitute an “SPS measure” within the meaning of Annex A(1)(a) of the Agreement, since it is a decision concerning the application or operation of a procedure and not an actual procedure or requirement.

With regard to the measures taken by the EC, the panel found that in light of the fact that the moratorium, ie the decision to delay final approval, did not achieve or imply a particular level of protection and is merely procedural in nature, it does not amount to an SPS measure and does not violate article 5.1, which requires WTO members to base their SPS measures on a risk assessment.²¹ For the same reasons, the panel found there was no violation of article 5.6, which provides that SPS measures must not be more trade-restrictive than required to achieve the appropriate level of protection²² or article 5.5, which prohibits members to use “arbitrary or unjustifiable distinctions in the levels of protection it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade”.²³ It also found there was no violation of articles 2.2, 2.3, Annex B(1) and article 7 of the SPS agreement.

3 4 Procedural requirements

The panel established that the EC violated the requirement in Annex C of the SPS Agreement, which requires that procedures are undertaken and completed *without undue delay*, as well as article 8 of the SPS Agreement, which directs members to observe the requirements in Annex C(1)(a). The panel noted that Annex C(1)(a), first clause, requires that there shall not be any “unjustifiable loss of time” and that what matters is whether there is a “legitimate reason, or justification”, for a given delay,

²⁰ Par 7.1272.

²¹ Par 7.1395.

²² Par 7.1404.

²³ Par 7.1419.

not the length of a delay as such.²⁴ A determination of whether a particular approval procedure has been undertaken and/or completed “without undue delay” must, according to the panel, be made on a case-by-case basis, taking into account relevant facts and circumstances. It furthermore suggested that the phrase “without undue delay” relates to both the “undertaking” and the “completion” of the approval procedure.²⁵

The panel thus concluded that the perceived lack of adequate legislation dealing with a particular issue, that is, labelling and traceability, could not be a justification for the delay.²⁶ It noted that alternatives were available to the EC. For instance, the EC could have tried to obtain from applicants either voluntary commitments or a request for suspension of the relevant approval procedure pending the adoption of the new EC legislation or it could have imposed other requirements as conditions attached to approval decisions, provided the imposition of such requirements was WTO-consistent. Procedural delays can also not be used as an instrument to manage or control risks as members could evade the obligations to be observed in respect of substantive SPS measures, such as article 5.1, which requires that SPS measures should be based on a risk assessment.²⁷

It furthermore concluded that the lack of science or the application of a prudent or precautionary approach could also not justify a delay. It stated that if relevant scientific evidence was insufficient to perform a risk assessment, pursuant to article 5.7 of the SPS Agreement, a member may provisionally adopt an SPS measure on the basis of available pertinent information.

The panel thus found that deferring substantive decisions on the grounds of a perceived need for caution and prudence in the assessment of applications may in fact rob Annex C(1)(a) of any effect or meaning.²⁸ A range of options remains available to members, and where it is impossible to provide a straight yes or no to applicants, members may in principle provide time-limited approvals or approvals subject to other appropriate conditions. Alternatively, they may reject applications, subject to review, if and when relevant circumstances change. The panel noted, however, that under certain circumstances delays might in fact be just – for instance if new scientific evidence came to light which conflicted with available scientific evidence and approvals were suspended based on this new evidence.²⁹ Similar findings were made with regard to the product specific measures.³⁰

²⁴ Par 7.1496.

²⁵ Par 7.1501.

²⁶ Par 7.1514.

²⁷ Par 7.1517.

²⁸ Par 7.1527.

²⁹ Par 7.1532.

³⁰ Par 7.2420.

3 5 Individual safeguard measures

With respect to the safeguard measures enacted by individual EC member States, the panel ruled each measure in violation of article 5.1, which requires that a measure be based on a risk assessment. It furthermore determined that the national safeguard measures were inconsistent with the requirements under article 5.7, which apply in cases “where relevant scientific evidence is insufficient”, and which allow members to adopt provisional sanitary or phytosanitary measures on the basis of available pertinent information.³¹ The panel thus also found that there was a violation of article 2.2 of the SPS Agreement, which requires that a measure be based on scientific principles and not be maintained without sufficient scientific evidence.³² It found that safeguard measures were not indicative of a rational relationship between the measures which imposed complete prohibitions and risk assessments which found no evidence that the particular biotech product presented any greater risk to human health or the environment than its conventional (non-biotech) counterpart. The panel noted that for each of the products affected by a national safeguard measure, the EC had given its EC-wide approval based on an evaluation of the potential risks to human health and/or the environment. The panel thus inferred that sufficient scientific evidence was available to permit a risk assessment as required by the Agreement. Consequently, the panel concluded that the EC member States could not justify their SPS measures under article 5.7, which only applied when relevant scientific evidence was insufficient to conduct an adequate assessment.

4 Other WTO agreements

4 1 The TBT Agreement

Labelling is dealt with under the TBT Agreement as it applies to regulations and standards that regulate *inter alia* the production, processes, packaging and labelling of both agricultural and industrial products.³³ A regulation is defined in Annex 1.1 as a “document that lays down product characteristics or their related processes and production methods. . .with which compliance is mandatory”. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. Thus any mandatory labelling requirement would be considered a technical regulation that falls under the ambit of the TBT Agreement.

Canada and Argentina claimed that the EC violated article 2.1 of the TBT Agreement that mandates contracting parties not to discriminate between imported like products in applying its technical regulations, as

³¹ Par 7.3068.

³² Par 7.3399.

³³ Art 1.3.

well as article 2.2, which states that technical regulations may be established for the protection of human and animal plant life and health, as long as they do not amount to “unnecessary obstacles to trade”. The panel did not, however, find it necessary to address the issues raised under the TBT Agreement.

4.2 The GATT

The main legal principles applying to State parties, as embodied in the GATT are:

- Most Favoured Nation (MFN) treatment – that is, no discrimination between States;³⁴
- national treatment – that is, no discrimination between domestic and imported goods;³⁵ and
- a prohibition on quantitative restrictions on imports and exports.³⁶

These legal principles apply *mutatis mutandis* to the trade in GMOs.

Of the three principles, the national treatment principle raises the most complex issues. Article III:4 requires that:

“The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.”

This essentially means that laws, rules and regulations must treat like imported and domestic products similarly. In *Korea – Various Measures on Beef*,³⁷ the Appellate Body explained the three elements of a violation of article III:4:

“For a violation of Article III:4 to be established, three elements must be satisfied: that the imported and domestic products at issue are ‘like products’; that the measure at issue is a ‘law, regulation, or requirement affecting their internal sale, offering for sale, purchase, transportation, distribution, or use’; and that the imported products are accorded ‘less favourable’ treatment than that accorded to like domestic products.”

In the *EC Biotech* case both Canada and Argentina alleged that the EC violated article III:4. The complainants argued that domestically grown non-biotech products are like products to GM products, while the EC disagreed and argued that domestic GM products should be considered the like products, i.e. that conventional products are not “like” biotech products. In determining whether the moratorium amounts to a law in accordance with article III:4, the EC argued that the moratorium was not represented in any official document and as such the moratorium must be considered as a possible delay in the application of a legitimate procedure. Finally, in determining whether the measure amounted to

³⁴ Art I.

³⁵ Art III.

³⁶ Art IX.

³⁷ WT/DS161/AB/R 10 January 2001 par 133.

unequal treatment, the complainants argued that this was indeed the case, as domestically grown GM products do not have to be authorised to be placed on the market, whilst the EC alleged that the same authorisation process is followed for domestic GM products. The panel did not, however, find it necessary to rule on article III:4.

4.3 The relevance of other rules of public international law to the interpretation of WTO agreements

The Cartagena Protocol on Biosafety was adopted on 29 January 2000. In terms of article 1, the aim of the Protocol is

“to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse affect on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movement”.

Member obligations are twofold:

- to implement the Protocol domestically, and
- to ensure that they reduce the risks of living modified organisms (LMOs) to biodiversity and human health in accordance with the Protocol.³⁸

The panel acknowledges that pursuant to article 3.2 of the Dispute Settlement Understanding (DSU), it is required that WTO agreements must be interpreted “in accordance with customary rules of interpretation of public international law” as reflected in the Vienna Convention on the Law of Treaties, but notes that it is only those international rules that are “applicable in the relations between the parties that should be taken into account”.³⁹ In this respect it is only those international agreements that have been signed and ratified by *all* the parties that would be “applicable in the relations between the parties”.

With respect to the CBD, the panel notes that all the parties, with the exception of the USA, have signed and ratified the Convention. The USA signed but did not ratify it. As such the CBD cannot be considered as an international agreement “applicable in the relations between the parties”.⁴⁰ The Cartagena Protocol, according to the panel, can similarly not be viewed as “applicable in the relations between the parties”, as it is only the EC that has signed and ratified it. Canada and Argentina have signed but not ratified it, whilst the USA has not signed the Protocol.⁴¹

The Panel did, however, consider the precautionary principle as a “general principle of international law”. In assessing the status of the precautionary principle in international law, the panel refers to the *Beef-Hormones* case where the Appellate Body observed that uncertainties

³⁸ Arts 2.1 and 2.2.

³⁹ Par 7.71.

⁴⁰ Par 7.74.

⁴¹ Par 7.75.

remain regarding the precise definition and content of the precautionary principle and that some scepticism existed as to whether the precautionary principle has indeed reached the status of a “general principle in international law”. As a result the panel elected not to deal with the issue.

5 Commentary

The regulation of GMOs by individual countries varies dramatically, from relatively unencumbered marketing to outright banning of all GM products. The obvious question arises as to what forms of regulation are permissible under WTO law. The WTO regulatory framework applying to GMOs is extensive and lends itself to conflicting interpretations. The *EC Biotech* case was seen as an opportune moment in WTO law to address and finally resolve some of the conflicts. However, ultimately many of the substantive issues were not addressed. These include (i) “whether biotech products in general are safe or not”; (ii) the challenges under the GATT or TBT Agreement, and specifically the all-important question “whether the biotech products at issue in the dispute are ‘like’ their conventional counterparts”; and (iii) whether the EC product-by-product approval procedures were consistent with the EC obligations under the WTO agreements. This means that while EC regulation relating to biotech remains unaffected, it is not clear whether such legislation fully complies with the WTO agreements.

An area of particular concern relates to the practice of banning imports of GMOs. The *EC-Biotech* panel had to establish whether delaying the approval of GMOs for marketing amounted to an SPS measure as defined in the SPS Agreement. In this regard it distinguished between a ban on the one hand and the EC moratorium on the other. With respect to the latter, it concluded that it falls outside the definition of SPS measure as set out in the second paragraph of Annex A(1) which provides that

“[s]anitary and phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures. . .”.

The moratorium as applied by the EC is a procedural mechanism and not a procedure as referred to in the above definition. It is essentially a decision to delay final positive approval decisions, and not, as the complaining parties argued, an effective marketing ban. One has to question the reasoning of the panel. The EC made the decision to “not make a decision”. In other words it failed to act. This failure to act or to make a decision effectively kept GM products out of the European market. The end result is therefore the same as a ban and the mere fact that this decision (or rather failure to decide) was not contained in a single written document does not detract from the effect thereof. It was in essence a procedure (as defined by Annex A(1) of the SPS Agreement) to regulate GM products in the EC market.

The panel was, however, quite clear on bans or safeguard measures.

The decision lays down the principle that countries may no longer exclude GMOs without a proper assessment of risk and that a precautionary approach will violate trade rules if an evaluation of the potential risks to human health and/or the environment has in fact been conducted. Since the panel concluded that none of the EC member States conducted an assessment of risk in line with the requirements of the SPS Agreement, it is unclear whether it will be possible for EC member States to maintain their current prohibitions and come into conformance with the SPS Agreement (for example, by conducting new risk assessments and basing their measures thereon).

The panel did agree with the complaining parties that EC approval procedures had to be undertaken and completed without *undue delay*. It should be highlighted that the panel specifically considered two arguments for justifying a delay in approval procedures:

- perceived inadequacy of EC approval legislation, and
- evolving science and the application of a precautionary approach.

With regard to the first justification, the panel made it clear that procedural delays in the development of legislation could not be used directly or indirectly as an instrument to evade its obligations under the SPS Agreement. Countries can therefore no longer hide behind time-consuming legislative processes.

As far as the second argument is concerned, the panel recognised the need for a precautionary approach in the assessment of GMO's and GMO-derived products. This acknowledgement was made despite the refusal of the panel to make a finding on the legal status of the precautionary principle. The panel stressed, however, that while a member State may take a precautionary approach to GMOs, it may not delay making a decision. Whilst the case confirms the right of WTO members to regulate GMO and the trade in GMOs, it certainly disappointed those who sought some direction as to the extent to which regulation is permissible.

This brings us to the question of whether, in light of this decision, the current moratorium on new GM commodities violates WTO law. As with the EC moratorium, the South African refusal to clear new GM commodities is not an official policy and the decision by the GM Council has not been officially gazetted. In terms of the panel's view, the South African moratorium amounts to a procedural decision to delay final positive approval decisions, and would not be regarded as a "measure" designed to achieve or imply a particular level of protection. As such it does not violate the substantive requirements of the SPS agreement.

The panel did, however, view a procedural delay of four years as one that violates the requirement in Annex C of the SPS Agreement that procedures are undertaken and completed *without undue delay*. South Africa's moratorium on applications for new GM approvals has been in effect for two years. Is it a time period that runs foul of these procedural

requirements? The panel ruled that it is not the length of the delay that matters, but rather whether the loss of time is “unjustifiable” and whether there is a “legitimate reason, or justification” for such delay. This must be determined based on the specific circumstances of the case. Very little is known about the motivation for the South African moratorium. It is allegedly imposed in the light of uncertainties pertaining to a number of risks, including possible socio-economic risks for farmers. These are certainly valid concerns. However, the panel also made it clear that procedural delays cannot be used as an instrument to manage or control risks as members could evade the obligations to be observed in respect of substantive SPS measures, such as article 5.1, which requires that SPS measures be based on a risk assessment. A speedy decision by the GM Council would therefore be in the interest of South Africa as it currently runs the risk of being found in violation of its WTO obligations.

OPSOMMING

Suid Afrika is in die voorste gelede op die gebied van die ontwikkeling van biotegnologie en spesifiek die ontwikkeling van geneties-gemodifiseerde organismes (GMOs). Daar is egter toenemende weerstand teen die ontwikkeling en invoer van GMOs. Verskeie nie-regeringsorganisasies het oproepe gedoen vir 'n moratorium op GMO-ontwikkeling en -invoere, en Suid Afrika het intussen 'n moratorium geplaas op klarings vir nuwe geneties gemodifiseerde produkte vir gebruik as voedsel of veevoedsel.

Hierdie bydrae bespreek die onlangse beslissing in *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* oor biotegnologiese produkte. In hierdie saak is bevind dat die Europese Unie se moratorium in stryd is met die reëls van die Wêreldhandelsorganisasie (WHO), spesifiek wat betref die prosedurele aspekte daarvan. In die lig van hierdie beslissing word die Suid Afrikaanse moratorium ondersoek en word bepaal of dit moontlik die WHO reëls kan oortree.