BEFORE THE WORLD TRADE ORGANISATION

EUROPEAN COMMUNITIES – MEASURES AFFECTING THE APPROVAL AND MARKETING OF BIOTECH PRODUCTS
(DS291; DS292; DS293)

REQUEST FOR PERMISSION TO SUBMIT INFORMATION TO THE PANEL BY THE FOLLOWING NON-PARTIES (*AMICUS CURIAE* SUBMISSION)

1. GeneWatch UK
The Mill House, Manchester Road, Tideswell, Derbys, SK17 8LN, UK
Tel: + 44 1298 871898 Fax: +44 1298 872531
http://www.genewatch.org
Contact: Dr Sue Mayer, Executive Director
Email: sue.mayer@genewatch.org

2. Foundation for International Environmental Law and Development (FIELD)
52-53 Russell Square, London WC1B 4HP, UK
Tel: + 44 20 7637 7950 Fax: +44 20 7637 7951
http://www.field.org.uk
Contact: Alice Palmer, Programme Director
Email: alice.palmer@field.org.uk

3. Five Year Freeze
94 White Lion Street, London, N1 9PF, UK
Tel: +44 20 7837 0642 Fax: + 44 20 7837 1141
http://www.fiveyearfreeze.org
Contact: Carrie Stebbings, Campaign Co-ordinator
Email: carrie@fiveyearfreeze.org

4. Royal Society for the Protection of Birds (RSPB)
The Lodge, Sandy, Bedfordshire, SG19 2DL, UK
Tel: +44 1767 680551 Fax: + 44 1767 685145
http://www.rspb.org.uk
Contact: Alexandra González-Calatayud, Trade Policy Officer, Environmental Policy Department
Email: alexandra.gonzalez@rspb.org.uk

5. The Center for Food Safety
660 Pennsylvania Ave, SE, #302, Washington DC 20003, USA
Tel: + 1 202 547-9359 Fax: +1 202 547-9429
http://www.centerforfoodsafety.org
Contact: Joe Mendelson, Legal Director
Email: joemend@icta.org

6. Council of Canadians
502-151 Slater, Ottawa, ON K1P 5H3, Canada
Tel: +1 613.233.4487, ext. 245 Fax: + 1 613.233.6776
http://www.canadians.org
Contact: Nadège Adam, Biotech Campaigner
Email: nadam@canadians.org

7. Polaris Institute
312 Cooper Street, Ottawa ON, K2P 0G7, Canada
Tel:+ 1 613.237.1717 Fax: + 1 613.237.3359
http://www.polarisinstitute.org
Contact: Lucy Sharratt, Researcher, Bio Justice Project
Email: lucy_sharratt@on.aibn.com

8. Grupo de Reflexión Rural Argentina
Rondeau 812 Marcos Paz (CP 1727) -PBA- Argentina
Tel: +54 220 477 35 45
http://reflexionrural.galeon.com
Contact: Stella Semino
Helligkorsvej 15 A, DK 4000, Denmark
Tel: +45 46 32 53 28
Email: stella.semino@mail.dk

9. Center for Human Rights and the Environment (CEDHA)
General Paz, 186 - 10mo. Piso, "A", Córdoba 5000, Argentina
Tel: + 54 351 425 6278
http://www.cedha.org.uk
Contact: Victor Ricco, Legal Advisor,
Email: victor@cedha.org.ar

10. Gene Campaign
J-235/A, Sainik Farms, Khanpur, New Delhi - 110 062, India
Tel: +91 11 26517248 Fax: +91 11 26965961
http://www.genecampaign.org
Contact: Dr. Suman Sahai, Campaign Convenor
Email: genecamp@vsnl.com

11. Forum for Biotechnology and Food Security
7 Triveni, A-6 Paschim Vihar, New Delhi-110 063, India
Tel: + 91 11 2525 0494
http://www.dsharma.org
Contact: Devinder Sharma, Chair
Email: dsharma@ndf.vsnl.net.in

12. Fundación Sociedades Sustentables
Seminario 774, Santiago, Chile
Tel: +56 2 2235459
Contact: Maria Isabel Manzur
Email: sustenta@rdc.cl

13. Greenpeace International
Ottho Heldringstraat 5, 1066 AZ Amsterdam, The Netherlands
Contact: Charlie Kronick, Greenpeace UK, Chief Policy Adviser
Email: charlie.kronick@uk.greenpeace.org
Greenpeace, Canonbury Villas, London N1 2PN UK
Tel: + 44 207 865 8228

14. Californians for GE-Free Agriculture
Occidental Arts & Ecology Center
15290 Coleman Valley Rd., Occidental, CA 95465
Tel: + 1 707 874-1557 ext 222
Contact: Renata Brillinger
Email: renata@oaec.org

15. International Forum on Globalisation
1009 General Kennedy Avenue #2, San Francisco, CA 94129, USA
Tel: + 1. 415.561.7650 Fax: + 1 415.561.7651
www.ifg.org
Contact: Debi Barker, Executive Director
Email: dbarker@ifg.org

With reference to Article 13 of the World Trade Organisation's *Understanding on Rules and Procedures Governing the Settlement of Disputes, United States – Import Prohibition of Shrimp and Shrimp Products*, Report of the Appellate Body adopted 6 November 1998, WT/DS58/AB/R, paras 106ff and the *Additional Procedure Adopted Under Rule 16(1) of the* Working Procedures for Appellate Review AB-2000-11, 8 November 2000, WT/DS135/9, the undersigned non-parties hereby request the permission of the Panel to submit information by way of an a*micus curiae* submission in *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (WT/DS 291, 292 and 293).

1. Description of the Applicants:

(a) GeneWatch UK is a not-for-profit, public interest group established in the UK in 1998. GeneWatch UK at monitors developments in genetic technologies from a public interest, environmental protection and animal welfare perspective. GeneWatch believes people should have a voice in whether or how these technologies are used. It campaigns for safeguards for people, animals and the environment by undertaking research, analysis and the production of information materials. The majority of GeneWatch UK's income comes from grants from charitable trusts and foundations.

(b) Foundation for International Environmental Law and Development (FIELD) is a charitable 'not-for-profit' organisation established in the UK in 1989. FIELD's team of public international lawyers is dedicated to promoting environmental protection and sustainable development through law. Our activities include providing legal and policy advice to the international community and promoting the dissemination of law through teaching, training and publications. Where possible, FIELD provides its services for free, deriving income primarily from foundation grants, governmental institutions and individual donations.

(c) The Five Year Freeze is a campaign group established in the UK in 1999 and supported by an alliance of 125 national organizations who share the public's deep concern over the speed at which genetic engineering is being introduced into food and farming. The alliance encompasses a wide range of interests including environmental campaigns, local authorities, trade unions, development charities, religious groups, retailers and consumer bodies. The campaign produces information materials and campaigns for a moratorium on the commercial use of GM crops and foods. It is funded by grants from charitable trusts and contributions from supporting organizations.

(d) The Royal Society for the Protection of Birds (RSPB) is a UK charity working to secure a healthy environment for birds and wildlife. Since its founding in 1889, the RSPB has grown into a wildlife conservation charity with more than a million members, making it Europe's largest wildlife conservation organisation. An elected Council and committees for Northern Ireland, Scotland and Wales oversee the RSPB's work. Its income is derived mainly from membership subscriptions, legacies and grants.

(e) The Center for Food Safety (CFS) is a non-profit public interest and environmental advocacy membership organization established in the USA in 1997 by its sister organization, International Center for Technology Assessment, for the purpose of challenging harmful food production technologies and promoting sustainable alternatives. CFS combines multiple tools and strategies in pursuing its goals, including litigation and legal petitions for rulemaking, legal support for various sustainable agriculture and food safety constituencies, as well as public education, grassroots organizing and media outreach. Its income is largely derived from grants from foundations.

(f) The Council of Canadians was founded in Canada in 1985, and is Canada's pre-eminent citizens' watchdog organization, comprised of over 100,000 members and more than 70 Chapters across the country. Strictly non-partisan, the Council lobbies Members of Parliament, conducts research, and runs national campaigns aimed at putting some of the country's most important issues into the spotlight: safeguarding our social programs, promoting economic justice, renewing our democracy, asserting Canadian sovereignty, advancing alternatives to corporate-style free trade, and preserving our environment. The Council does not accept money from corporations or governments, and is sustained entirely by the volunteer energy and financial assistance of its members.

(g) Polaris Institute is a not-for-profit action-research association established in Canada in 1997 to enable citizen movements to re-skill and re-tool themselves to act for democratic social change in an age of corporate driven globalization. The Institute works with citizen movements in developing strategies and tactics to challenge the corporate power that is the driving force behind public policy making on economic, social and environmental issues. The Institute has done research, education and action on several of the major biotech corporations, both in Canada and internationally. The Polaris program has been primarily funded on a project-by-project or a fee-for-service basis through contracts with constituent organizations and partially from grants by charitable foundations.

(h) Grupo de Reflexión Rural Argentina (GRR) was created as a think-tank organisation in 1998 in Argentina within the non-profit organisation "Reconciliarce con la Tierra". The GRR's main objectives are: to contribute to knowledge of rural issues by developing and encouraging independent research; to enhance awareness of the challenges facing Argentina and to propose alternative solutions, by dissemination of the issues through the media and by organising active forums across the country; and to participate in bringing rural issues to the forefront of the political agenda.
The GRR is financed by its members and donations from trusts.

(i) The Center for Human Rights and Environment (CEDHA) is a non-profit legal organization established in Argentina in 1999, which aims to build a more harmonious relationship between the environment and people. CEDHA's work involves research, capacity-building, legislation strengthening, and litigation, among others, to promote greater access to justice and protect human rights and the environment in all development processes. Its goals are to strengthen and develop the awareness of the linkages between the environment and human rights and the capacity of state, civil society and private sector actors, to work towards more environmentally and socially sustainable development. CEDHA´s income comes mostly from foundation grants.

(j) Gene Campaign, is a non-profit, non-governmental organisation established in India in 1993 by a group of people who were alarmed by the impact of international developments like WTO/TRIPS on the genetic resources of the developing world. It works at grassroots levels in several states in India as well as at the level of international and national policy making. Gene Campaign's mission is to ensure the establishment of national policies and international agreements for food and livelihood security of farming and adivasi communities, on the basis of equity and justice. The organisation depends on individual donations, and grants as well project funding from governmental and individual donors.

(k) The Forum for Biotechnology & Food Security is a collective formed in India in 1996 by some of the well-known policy makers, agriculture scientists, economists, biotechnologists, farmers and environmentalists. It examines and analyses the implications and fall-out of various policy decisions, both national and international. The Forum was successful in stopping the import of recombinant bovine growth hormone (rBGH) into the country, banning terminator technology's entry into India and delaying the introduction of genetically modified Bt cotton. It is funded by public donations and contributions.

(l) Fundación Sociedades Sustentables (Sustainable Societies Foundation) is a Chilean non-governmental organisation created in June1997. Its objectives are to: promote the conservation, protection and preservation of the natural ecosystems of the country; promote the sustainable use of the rural and urban environments; promote environmental education of citizens in order to strengthen their participation in environmental decisions; promote research, elaboration of proposals and scientific, social and cultural activities for a development that is socially and environmentally sustainable.

(m) Greenpeace International was founded in 1971 by a small group of volunteers who set out from Vancouver heading for US nuclear test site off the coast of Alaska. It is now headquartered in The Netherlands. Greenpeace is an independent organisation, working in more than 40 countries, with more than 3 million supporters worldwide. We accept no money from governments or corporations, relying entirely upon the financial support of individuals. Greenpeace stands for positive change through action: the courage, independence and global reach to defend nature and promote peace. Our campaign goals include protecting the climate, defending ocean life and ancient forests, exposing nuclear, chemical and biological threats to the environment and human health, and championing clean production.

(n) Californians for GE-Free Agriculture is a coalition of sustainable farming, environmental and consumer food safety members which represent a combined total of approximately 75,000 individuals. It was established in June 2003 in the USA as a project of the Occidental Arts and Ecology Center, a non-profit public interest organization. The coalition encourages and supports farmers in their rejection of transgenic crops in the state, and is committed to ecologically and economically sustainable farming, which is threatened by genetic engineering technologies. Its income is derived exclusively from foundation, individual and corporate donations.

(o) The International Forum on Globalization (IFG) is an alliance of sixty leading activists, scholars, economists, researchers and writers formed in 1994 in the USA to stimulate new thinking, joint activity, and public education in response to economic globalization. Representing over 60 organizations in 25 countries, the International Forum on Globalization associates come together out of a shared concern that the world's corporate and political leadership is undertaking a restructuring of global politics and economics that may prove as historically significant as any event since the Industrial Revolution. Its income is derived from foundations and membership subscriptions.

2. The Applicants' individual and common interests in this case include: (a) protecting human health, the environment and sustainable livelihoods from the risks of harm associated with genetically modified crops and products; (b) protecting the rights of consumers to make informed choices (c) facilitating the development of laws to protect human health, the environment and the public interest; (d) facilitating an interpretation of international trade law that is consistent with international standards of sustainable development; and (e) ensuring public participation and the representation of public interests in policymaking on international trade and sustainable development.

3. The Applicants intend to address the following specific issues: The nature of the general *de facto* moratorium and the fruitfulness of the disputes and, if the Panel finds that the challenged 'measures' are subject to the relevant WTO Agreements: the relevance of the precautionary principle to the challenged 'measures'; the necessity of the challenged 'measures' within the meaning of SPS Articles 2.2 and 5.6, TBT Articles 2.2 or 5.1.2, and GATT Article XX; the relationship between the challenged 'measures' and science for the purposes SPS Article 2.2, 5.1 and 5.7; the non-discriminatory nature of the challenged 'measures' for the purposes of SPS Articles 2.3 and 5.5, TBT Article 2.1 and GATT Articles III and XX; the publication of the challenged measures for the purposes of SPS Article 7 and Annex B.1, TBT Articles 2.9, 2.10 or 2.11 and GATT Article X.1; and no 'undue delay' in the administration of the measures for the purposes of SPS 8 and Annex C, TBT 5.2, GATT X.3(a).

4. The Applicants' brief will contribute to the Panel's objective assessment of the matter. The Applicants will provide expert factual information and legal analysis informed by individuals and groups whose interests are directly affected by the risks associated with the use, sale and international trade in genetically modified products. The Applicants' brief will raise critical issues of public concern from an individual and non-governmental perspective that is distinct from that of the parties and third parties to the disputes. It will examine the broader implications of the disputes for development, health, human rights, the environment, and other facets of general welfare. As parties likely to be affected by the Panel's recommendations, the Applicants have a direct interest in the resolution of this case. As *amicus curiae*, the Applicants seek to provide creative solutions that reflect unique expertise relating to trade and sustainable development and, in particular, to the interface between the WTO and domestic regulatory issues. The Applicants are confident that they will bring a distinctly valuable perspective to the Panel in its endeavors to reach a fair settlement of the disputes. The Applicants, by virtue of past experience with *amicus curiae* submissions to the WTO dispute settlement process, have a demonstrated capacity to seek solutions that balance the need to reconcile trade, environment, and developmental perspectives, within the overarching objectives of sustainable development.

5. The Applicants' contribution will not be repetitive of party or third party submissions: To our knowledge and to date, only the US has voluntarily made its otherwise confidential First Submission publicly available on the Internet. Nevertheless, we consider that our contribution will not be repetitive of party or third party in the following respects: (i) The Applicants represent the public interests of a coalition of natural and legal persons that transcend national boundaries, and includes the residents of the parties, the third parties, and of the states that are not parties to this dispute; (ii) the Applicants' contribution will reflect perspectives that differ from those that are brought by governments; (iii) the Applicants will address matters not adequately addressed by the parties and third parties; (iv) the Applicants submission will seek to promote the long-term interests of society – in terms of safety, environmental protection and human rights – and to examine the long-term, systemic implications of this decision for the multilateral trading system and its interface with related legal systems.

6. The Applicants are independent of parties and third parties to this dispute. None of the Applicants has any relationship, direct or indirect, with any party or third party to this dispute relevant to the subject matter and outcome of this dispute, or has received any assistance, financial or otherwise, from a party or a third party to this dispute in the preparation of this Application or the proposed written brief.

The Applicants' *amicus curiae* submission is enclosed.

Respectfully submitted by:

Alice Palmer, Programme Director, FIELD, 27 May 2004

On behalf of the following coalition of organisations: GeneWatch UK; Foundation for International Environmental Law and Development (FIELD); Five Year Freeze; Royal Society for the Protection of Birds (RSPB); The Center for Food Safety; Council of Canadians; Polaris Institute; Grupo de Reflexión Rural Argentina; Center for Human Rights and the Environment (CEDHA); Gene Campaign; Forum for Biotechnology and Food Security; Fundación Sociedades Sustentables; Greenpeace International; Californians for GE-Free Agriculture; International Forum on Globalisation.

BEFORE THE WORLD TRADE ORGANISATION

EUROPEAN COMMUNITIES – MEASURES AFFECTING THE APPROVAL AND MARKETING OF BIOTECH PRODUCTS
(DS291; DS292; DS293)

INFORMATION SUBMITTED TO THE PANEL BY NON-PARTIES
(*AMICUS CURIAE SUBMISSION*)

BY

GeneWatch UK; Foundation for International Environmental Law and Development (FIELD); Five Year Freeze; Royal Society for the Protection of Birds (RSPB); The Center for Food Safety; Council of Canadians; Polaris Institute; Grupo de Reflexión Rural Argentina; Center for Human Rights and the Environment (CEDHA); Gene Campaign; Forum for Biotechnology and Food Security; Fundación Sociedades Sustentables; Greenpeace International; Californians for GE-Free Agriculture; International Forum on Globalisation.

TOGETHER REFERRED TO AS THE *AMICUS COALITION*

GENEVA, 27 MAY 2004

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1. EXECUTIVE SUMMARY

Our concerns

1. The issues surrounding genetically modified (GM) crops and food have been intensely controversial across the world. Yet the risks from GM crops and food are serious, likely to be irreversible and have health, environmental, social, cultural and ethical dimensions – all of which may be legitimately protected under WTO rules. No regulatory systems can be foolproof and many of the wider social and ethical dimensions are completely neglected in conventional risk assessments.[1] Therefore, it is crucial that countries have the ability to determine their own approaches on GM crops and food, and that citizens are able to engage fully in these processes, without pressure from large economic interests.

2. As the European Communities, its Member States and other governments struggle to resolve the conflicts between the demands of industry and those of consumers in relation to GM crops and food, the timing of this challenge by the Unites States, Canada and Argentina is difficult to understand – more hostility from the public seems the only outcome.[2] This challenge has been driven by the interests of biotech and large-scale, intensive farming corporations in the countries involved with no regard for the interests of the broader community.[3] In whatever way this dispute is resolved, it will inevitably send a very clear signal to the world beyond the European Communities: to try to protect either the environment or the health of their citizens from the potentially serious impacts of GM crops and food could result in a punishing response from the US and other Members of the World Trade Organisation (WTO) in defence of the interests of their biotech companies.

3. As the First US submission shows in its Statement of Facts,[4] there are complex political and social interests at stake in this challenge. It is not simply a matter of examining bureaucratic or administrative procedures. How the Panel arbitrates these disputes will have far reaching implications for all governments, communities and the environment. We request that, in its recommendations, the Panel upholds the right of governments to protect their citizens' health, the environment and consumer interests, and that it will take account of the broad range of interests, concerns and expertise relevant to these disputes.

Our claims

4. The US, Canada and Argentina (the 'complainants') have challenged the European Communities (the 'EC') over three categories of 'measures': (1) the 'suspension' of GM approvals (EC's general *de facto* moratorium), (2) the failure to consider applications for GM approvals (EC's specific *de facto* moratoria), and (3) EC Member States' 'safeguard' actions on approved GM products under the Deliberate Release Directive and the Novel Foods Regulation.[5]

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[1] *See* e.g. Mayer, S. & Stirling, A. (2002) 'Finding a precautionary approach to technological developments – lessons for the evaluation of GM crops'. Journal of Agricultural and Environmental Ethics. *Journal of Agricultural and Environmental* Ethics 15 (1) 57-71.

[2] *See* Kinderlerer, J. (2003) 'The WTO complaint – why now?' *Nature Biotechnology* 21: 735-736; *see also* Busch, M. and Howse, R., A. (September 2003) (Genetically Modified) Food Fight: Canada's WTO Challenge to Europe's Ban on GM Products CD Howe Institute Commentary 186. Available at http://www.cdhowe.org/pdf/commentary_186.pdf.

[3] *See* e.g. FB Urges 'Immediate Action' on EU Biotech Ban. American Farm Bureau Federation, 18th December 2002 http://www.fb.com/news/nr/nr2002/nr1218a.html; Inside US Trade Bush Set for Decision on WTO Biotech Challenge 31st January 2003; The American Soybean Association is even reported to be 'taking the lead' in drafting a subsequent challenge to Europe on GM food labeling, Inside US Trade: Likely new WTO challenge on EU GMO policy, March 12th 2004.

[4] First Submission of the United States ('First US submission') 21 April 2004, para 64. Available at http://www.ustr.gov/enforcement/2004-04-21-ecbiotech-usfirst.pdf.

[5] *See* the three categories of 'measures' as set out in the Requests for the Establishment of a Panel by the United States (WT/DS291/23), Canada (WT/DS292/17), and Argentina (WT/DS293/17). *See also* Directive 90/220/EEC, of 23 April 1990, on the deliberate release into the environment of genetically modified organisms, OJ L 117 of 8 May 1990 ('Deliberate Release Directive'), replaced by Directive 2001/18/EC, of 12 March 2001, on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106 of 17 April 2001 ('Revised Deliberate Release Directive'); Regulation 258/97/EC, of 27 January 1997, concerning novel foods and novel food ingredients, OJ L 43 of 14 February 1997 ('Novel Foods Regulation').

5. The Amicus Coalition respectfully submits that the 'general' *de facto* moratorium is not a 'measure' subject to the World Trade Organisation's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Agreement on Technical Barriers to Trade (TBT Agreement), or the 1994 General Agreement on Tariffs and Trade (GATT). The 'general' *de facto* moratorium, as recorded in the minutes of a meeting of the Council of the European Union and in statements of Member State officials, is an expression of political intent. It is not legislation of a general nature and it is not mandatory in its effect. The governance structures of the EC are very different from a single national system and a complex procedure must be followed before mandatory laws or guidance can be put into effect. A sovereign entity's expression of political intent is not subject to WTO scrutiny (see section 3.1.1). In our submission, we do not address the question of whether the relevant WTO Agreements apply to the EC's specific *de facto* moratoria or the EC Member States' safeguard actions.

6. If the Panel finds that the three categories of measures' are subject to the SPS Agreement, the TBT Agreement and/or the GATT, the Amicus Coalition respectfully submits that the three categories of measures are consistent with the EC' obligations under those Agreements.In particular, the Amicus Coalition respectfully submits that:

    a) *Precaution*: The 'measures' are an exercise of the WTO right of the EC and its Member States to establish their domestic health and environmental standards in accordance with their respective environmental conditions, needs and priorities (see section 3.2). The measures are based on the precautionary principle and, as such, they are based on international standards. The precautionary principle – recognised in many international agreements and instruments including the Cartagena Protocol on Biosafety – warrants measures aimed at preventing irreversible health and environmental damage even in the absence of full scientific certainty as to the risk of damage (see section 3.2.2).

    b) *Necessity*: The challenged 'measures' restrict trade only to the extent necessary to fulfill their objectives within the meaning of SPS Articles 2.2 and 5.6, TBT Articles 2.2 or 5.1.2, and GATT Article XX. In particular, the challenged measures are necessary to protect human, animal and plant life and health, and to protect the environment, against the risks associated with GM products, and to prevent deceptive practices through appropriate labels on GM products. There were no 'alternative' less trade-restrictive measures reasonably available to the EC which would have provided the EC's desired level of high protection. A global appreciation of the risks associated with GM technology, and the need for appropriate regulation to guard against the risks, is evidenced by the international efforts to agree rules and implement national strategies to avoid harm to people and the environment from genetically modified organisms and GM products (see section 3.2.1).

    c) *Risk Assessment*: The challenged 'measures' are based on scientific principles and have not been maintained without sufficient scientific evidence within the meaning of SPS Article 2.2. In particular, there is a 'rational relationship' between the measures and the assessment of risks to human, animal or plant life or health, for the purposes of SPS Article 5.1 (see section 3.2.2(i)).

    d) *Provisional measures*: Alternatively, the challenged 'measures' are provisional and based on available pertinent information. The EC has continued to seek additional information and has been reviewing the 'measures' within a reasonable time within the meaning of SPS Articles 2.2 and 5.7 (see section 3.2.2(ii)).

    e) *Discrimination*: GM crops and products are not 'like' their conventional counterparts for the purposes of TBT Article 2.1 and GATT Article III. Moreover, the challenged 'measures' do not arbitrarily or unjustifiably discriminate between Members or constitute a disguised restriction on international trade for the purposes of SPS Article 2.3 and GATT Article XX. In particular, a comparison of the challenged measures and the EC's regulation of GM processing aids, or novel

non-GM crops or food derived from novel non-GM crops, does not show an arbitrary or unjustifiable distinction in levels of protection in different situations which amount to discrimination or a disguised restriction on trade (SPS Article 5.5) (see section 3.2.3).

f) *Transparency*: The 'measures' were published in accordance with SPS Article 7 and Annex B.1, TBT Articles 2.9,2.10 or 2.11 and GATT Article X.1. If the Panel applies a broad interpretation to the types of 'measures' that can be the subject of a WTO challenge and assessed for compliance with the WTO Agreements, it must also take a broad interpretation of what constitutes 'publication' for the purposes of WTO rules (see section 3.3.1).

g) *Fairness*: There was no 'undue delay' in the administration of the measures for the purposes of SPS 8 and Annex C; TBT 5.2; GATT X.3(a). The time taken since 1998 to further assess the risks and develop appropriate regulatory controls is a reasonable time frame within which to review the challenged 'measures' in the EC. The EC is a unique WTO Member, representing a union of formerly 15 and now 25 Member States and an assessment of 'undue delay' must take account of the EC's complex decision-making procedures (see section 3.3.2).

7. Finally, we respectfully submit that if the Panel limits its recommendations to the consistency of the challenged 'measures' with the SPS Agreement, those recommendations would apply only to the extent that the 'measures' serve SPS objectives to protect humans, animals, plants and territory from pests or disease, or to protect humans and animals from certain food-borne risks (see section 3.1.2). Our submission does not address the question of whether, if the general and specific *de facto* moratoria are 'measures', they have, as of 18 April 2004 or as of any other time, been discontinued, and whether this would have a bearing on the disputes (see section 3.1.1). However, by way of a general observation, the Amicus Coalition questions whether it is possible for the complainants to have acted in good faith in assessing their challenge to be 'fruitful' within the meaning of Article 3.7 of the WTO's *Understanding on Rules and Procedures Governing the Settlement of Disputes* ('DSU') where the biotech companies affected by the specific *de facto* moratoria might have a right of action in the EC which they have not explored and have instead voluntarily agreed with at least one EC Member State not to not to proceed with the commercialisation of GM crops until the results of large-scale field trials were known (Farm-Scale Evaluations) (see section 3.1.1).

2. STATEMENT OF FACTS

2.1 GM technology

8. Scientific knowledge of genetics is limited.[6] Genes or parts of genes may be involved in different functions, depending on how they are 'read' by the cell and which other genes are involved. Scientific theories and understanding of the ways in which genes work are constantly developing, giving new insights into the complexity of gene function.[7]

9. The application of genetic modification ('recombinant DNA' or 'rDNA' techniques) allows genetic material to be transferred from any species into plants or other organisms. The introduction of a gene into different cells can result in different outcomes and the overall pattern of gene expression can be altered by the introduction of a single gene.[8] The sequence of the gene and its role in the donor organism may have a relatively well-characterised function in the organism from which it is isolated. However, this apparent 'precision' in the understanding of a gene does not mean that the consequences of the transfer are known or can be predicted. Copies of a gene may be integrated, additional fragments inserted, gene sequences rearranged and deleted[9] – which may result in lack of operation of the genes, instability or interference with other gene functions possibly affecting unrelated biochemical pathways.[10]

10. Non-GM methods of plant breeding, including chemical and radiation induced mutagenesis, might also cause random changes with unpredictable outcomes. However, the application of GM raises additional questions. As explained by an independent group of experts established in 2003 by the UK Government to review the science relevant to GM crops and foods (the UK's Science Review Panel): 'the main special feature of GM plant breeding is that it allows a wider choice of genes for modifying crops in novel ways. No other plant breeding technique permits the incorporation of genetic material from such diverse biological sources. Inevitably this raises the possibility that some new consequences of GM plant breeding may be unexpected.[11]

2.2 Uncertain benefits

11. There has been little independent research into the claimed benefits of GM crops or products. Claimed benefits should not be accepted at face value.

2.2.1 Uncertain benefits to developing countries

12. Agricultural biotechnology is unlikely to improve conditions in developing countries and might, in fact, act *against* the needs of the poor and hungry.[12] Factors undermining claims of benefits for developing countries include:

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[6] E.g. findings from studies such as the Human Genome Project have shown that there are far fewer genes in higher organisms than was predicted: 30-40,000 in humans rather than the 120-140,000 originally estimated. *See* International Human Genome Sequencing Consortium. (2001) 'Initial sequencing an analysis of the human genome.' *Nature* 409: 860-921.

[7] E.g. Dennis, C. (2002) 'The brave new world of RNA'. *Nature* 418: 1222-124 and related articles in *Nature Insight* – RNA, 11th July 2002.

[8] Salk, D. (2002) 'A different perspective on GM food'. *Nature Biotechnology* 20: 969.

[9] Labra, M. *et al.* (2001) 'Genomic changes in transgenic rice (*Oryza sativa* L.) plants produced by infecting calli with *Agrobacterium tumefaciens*.' *Plant Cell Reports* 20: 325-330; Shunhong, D. *et al.* (2001) 'Comparative analysis of transgenic rice plants obtained by *Agrobacterium*-mediated transformation and particle bombardment.' *Molecular Breeding* 7: 25–33; Windels, P. *et al.* (2001) 'Characterisation of the Roundup Ready soybean insert'. *European Food Research Technology* 213: 107-112.

[10] Birch, A.N.E. *et al.* (2002) 'The effect of genetic transformation for pest resistance on foliar solanidine-based glycoalkaloids of potato (*Solanum tuberosum*).' *Annals of Applied Biology* 140: 143-149.

[11] GM Science Review Panel. (2003) GM science review. First report (Executive Summary). Available at http://www.gmsciencedebate.org.uk/report/default.htm#first.

[12] Scoones, I. (2003) 'Can agricultural biotechnology be pro-poor' Democratising Biotechnology: Genetically Modified Crops in Developing Countries Briefing Series. Briefing 2. Brighton, UK: Institute of Development Studies.

- The dominance of the private sector in research and development means that the GM crops and traits that have been commercialised to date have been primarily designed to meet the needs of large-scale farmers in industrialised countries.[13] Herbicide tolerance and insect resistance make up nearly 100% of all GM crops grown commercially. However, in developing countries, herbicide tolerant crops and the associated use of chemical weedkillers, may reduce employment on farms and destroy 'weeds' which are collected during manual weeding and used as foods, providing important sources of micronutrients. If it is not consumed as food, the weeds serve as fodder for cattle. [14]
- The protection of intellectual property rights (IPRs) stimulates private research in areas where there is most economic return, excluding those crops of most importance to the poor. IPR protection may also obstruct public plant breeding efforts, acting against the interests of small-scale farmers.[15]
- Very high-cost investment is required for the development and regulation of GM crops and foods, and the current private sector-led GMO research system will need to recoup its costs, which may only come from very large-scale applications. It is unlikely that this same system can serve the local needs of small farmers and poor consumers and promote genetic and nutritional diversity.[16]
- In developing countries, IPRs have led to a concentration of the seed supply system and the acquisition of local seed companies by international corporations.[17] This could adversely affect food security through overpricing of seed and new technologies and the exclusion of small farmers from benefits.[18]
- There is a lack of research into the social, economic, environmental and health impacts of GM crops on developing countries. There are reasons, for example, for considering the biodiversity of developing countries to be more vulnerable to adverse effects arising from the movement of the introduced foreign gene into related wild plants or crops (gene flow). Many crops, including maize and rice, evolved in tropical developing countries and the related wild species, with which GM crops can hybridise, are more prevalent.[19] The vulnerability of developing countries is illustrated by the case of contamination of Mexican maize by GM maize which occurred even though it was illegal to grow GM maize in Mexico.[20]
- The focus on biotechnology may divert efforts from more sustainable and locally appropriate research.[21]
- The systems of cultivating, storing and transporting food grains in developing countries such as India make it impossible to segregate GM from non-GM crops. That means identity preservation and traceability is currently impossible,[22] adversely affecting consumers' right to chose and the adoption of any emergency measures in developing countries.

13. These concerns appear to be arising in Argentina, where the wide-scale adoption of GM herbicide tolerant soybeans is reported to be having adverse impacts on society, the environment and public health.[23] Escalating use of the herbicide, glyphosate (Roundup), is thought to be associated with indirect adverse

[13] Glover, D. (2003) 'Corporate dominance and agricultural biotechnology: implications for development'. Genetically Modified Crops in Developing Countries Briefing Series. Briefing 2. Brighton, UK: Institute of Development Studies.
[14] Sahai, S. (2003) *Genetically Modified Crops in India*. Gene Campaign; New Delhi.
[15] Commission on Intellectual Property Rights. (2002) *Integrating intellectual property rights and development policy.* London: DFID.
[16] Gustafson, D. (2003) 'FAO's Perspective and Programmes on Agriculture Biotechnology.' Paper presented at the National Symposium "Relevance of GM Technology in Indian Agriculture and Food Security", New Delhi, 26-27 November 2003.
[17] Byerlee, D & Fischer, K. (2001) 'Accessing modern science: policy and options for agricultural biotechnology in developing countries.' *IP Strategy Today* 1: 1-27. Available at www.biodevelopments.org/ip/ipst1n.pdf.
[18] Commission on Intellectual Property Rights. (2002) op cit.
[19] *See* e.g. Ellstrand, N. *et al.* (1999) 'Gene flow and introgression from domesticated plants into their wild relatives.' *Annual Review of Ecology and Systematics* 30: 539-563.
[20] Quist, D. & Chapella, I.H. (2001) 'Transgenic DNA introgressed into traditional landraces in Oaxaca, Mexico.' *Nature* 414: 541-543.
[21] Sahai, S. (2003) Social and Ethical Concerns about Agriculture Biotechnology; Gene Campaign: New Delhi..
[22] Tyagi, K.C. and Pattanaik, B.B. (2003) 'Procurement and Storage of Foodgrains in India - Handling GM Crops.' Paper presented at the National Symposium "Relevance of GM Technology in Indian Agriculture and Food Security", New Delhi, 26-27 November 2003.
[23] Joensen, L. (2003) 'Argentina, the GM paradox.' *Third World Resurgence* 159/160 (Nov/Dec, 2003): 36-39; Brandford, S. (2004) 'Argentina's bitter harvest.' *New Scientist* 17 April: 40-43; 'Reporte descriptivo-informativo de los impactos producidos por la aplicación de plaguicidas a los cultivos de soja en La Colonia Loma Senes.' Departamento Pirane – Formosa, National University of Formosa.

effects on the environment as well as encouraging the emergence of resistant weeds.[24] The Roundup Ready soybeans themselves are becoming problem weeds,[25] and other, more harmful, herbicides are being used to control them.[26]

14. Evidence from the use of GM *Bt* cotton in India has shown that it has not provided the expected benefits for farmers.[27] Yields were lower for *Bt* than for conventional cotton, the plants less vigorous, the cotton of a lower quality and one pest, the pink bollworm, was not controlled in the *Bt* crop. As a result, the economic performance of the *Bt* cotton was poor. Earlier reports claiming high yields[28] were collected from experimental fields (trial plots) under optimum conditions and not on data collected from farmers' fields, where optimum conditions are not found.

15. Claims that the EC regulatory process has blocked exports from developing countries[29] are not supported by evidence. 'Roundup Ready' soybeans grown in Argentina can be imported into the EC, but are restricted by lack of market demand, although imports continue for animal feed where the origin is not known by the final consumer. GM cotton is the only other GM crop grown on a significant scale in the South (in South Africa and China),[30] and there is no evidence that trade in this crop has been affected because the use of cotton for fibre is not differentiated according to its GM status.

16. The attitudes of African countries to GM food aid and the claimed 'burdensome' restrictions imposed by the requirement to mill GM maize[31] have to be considered in the context of aid more generally. The United States is unique among industrialised countries in refusing to donate financial aid as food aid and insisting on the provision of US grain generated as agricultural surpluses. Aid is therefore used in an effort to support US corporations and interests as evidenced by the USAID's statement that: 'The principal beneficiary of America's foreign assistance programs has always been the United States. Close to 80% of the USAID contracts and grants go directly to American firms. Foreign assistance programs have helped create major markets for agricultural goods, created new markets for American industrial exports and meant hundreds of thousands of jobs for Americans.'[32]

17. Alternative sources of non-GM food aid are available and best practice in development aid assistance is to source food locally using financial assistance. Good practice in emergency aid is to provide financial support to the World Food Programme (WFP) so that it can buy grain from the quickest and most cost effective sources. Often these sources will be from within the affected region or country. Sourcing food aid locally can strengthen markets and agricultural development. Bringing large volumes of food into a region that already has areas of surplus will have a negative effect. It can lead to a situation where there are food shortages in one part of a country, and locally produced food rotting in other parts – a potential danger known to the WFP.[33] It is for these reasons that Article XII of the 1999 Food Aid Convention, to which the US is a Party, recommends local purchasing.[34]

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[24] *See* www.fcagr.unr.edu.ar/extension/agrom4/malezas%20en%20soja5.htm.
[25] *See* www32.brinkster.com/grrlaplata/Boy.htm.
[26] *See* www.sica.gov.ec/agronegocios/biblioteca/Ing%20Rizzo/oleaginosas/EXPANSIÓN%20DE%20LA%20SOJA%20EN%20ARGENTINA.pdf.
27 Sahai, S. & Rahman, S. (2003) 'Performance of Bt Cotton – Data from First Commercial Crop.' *Economic and Political Weekly* XXXVIII No 30: 3139-3140.
[28] Qualm, M. & Zilberman, D. (2003) 'Yield effects of genetically modified crops in developing countries.' *Science* 299:900-902.
[29] First US Submission, para 64.
[30] James, C. (2002) 'Global review of transgenic crops: 2001.' Feature Bt cotton. ISAAA Briefs No 26. ISAAA: Ithaca, NY.
[31] First US Submission, para 65.
[32] Direct economic benefits of US assistance by State. USAID, 2002. Available at http://www.usaid.gov/procurement_bus_opp/states.
[33] Enabling Development. World Food Programme. (1999) WFP/EB.A/99/4-A.
[34] Article XII, Food Aid Convention, 1999. Available at http://www.igc.org.uk/brochure/fac99e.pdf. *See also* Clay E, Pillai N & Benson C. (1998) 'The future of Food Aid: A Policy Review'. Overseas Development Institute, June 1998, p 35. Available at http://www.odi.org.uk/publications/aid.html#future.

2.2.2 Uncertain nutritional benefits

18. There are no GM crops currently available which are known to offer any nutritional benefits additional to those of their conventional counterparts. Uncertainties exist about whether the addition of micro-nutrients to food may lead to an imbalance in dietary intake and adverse effects as a result.[35] The potential for unintended impacts on other food constituents as a result of the use of GM has led experts to emphasise that any GM foods which have altered nutritional status will have to be subject to more stringent testing than the current generation of GM foods.[36]

19. Claims surrounding the potential benefits of so-called 'golden rice', intended to increase intake of pro-vitamin A for those people on diets which are deficient in this micro-nutrient, remain contentious. Vitamin A deficiency can be solved in a cost-effective manner through supplementation, food fortification and dietary diversification.[37] In contrast, questions remain about whether a GM approach can succeed, including whether the pro-vitamin A is easily absorbed and if a yellow coloured rice will be accepted in some countries.[38]

2.2.3 Uncertain environmental benefits

20. Very often, a correlation between the introduction of a GM crop and changed management practices has been assumed to have beneficial effects with no critical examination of the outcomes.[39] Claimed environmental benefits such as herbicide tolerant crops allowing farmers to use conservation tillage, which involves minimal mechanical tillage of the soil and brings a range of environmental benefits, are questionable. Rates of conservation tillage in the US have been increasing since 1989, with the largest increases between 1991-1993, before GM crops were introduced.[40] In practice, the growth of conservation tillage has slowed since the introduction of GM crops. In addition, conservation tillage can be adopted alongside conventional cropping using approaches such as mulch and ridge tilling.

21. In addition, with some GM herbicide tolerant (GMHT) crops, the use of herbicide has not decreased as anticipated.[41] The use of 'Roundup' and 'Liberty' herbicides on tolerant GM crops has inevitably increased and although they may have replaced more persistent chemicals, there are no data on the effect of this shift in herbicide use on biodiversity.[42] Moreover, any claimed environmental benefits are likely to be context-specific and cannot be assumed to be equal in all countries and in all places.

22. Unintended effects of GM crops are not always detected in laboratory or field trials. For example, GM *Bt* maize varieties commercialised in the US were reported to have tougher stalks, be less palatable to cattle and have slower decomposition. Research then revealed that levels of lignin, a structural component of plants, were higher in the GM varieties leading to these effects and this had not been detected prior to commercialisation.[43]

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[35] ILSI Europe Addition of Nutrients to Food Task Force, Addition of Nutrients to Food: Nutritional and Safety Considerations. Summary of a Workshop held in December 1997, International Life Sciences Institute, Brussels, 1998.
[36] Kuiper, HA *et al.* (1999) 'Commentary: Adequacy of methods for testing the safety of genetically modified foods.' *The Lancet* 354: 9187.
[37] UNICEF. (2001) 'Vitamin A deficiency: world summit for children goal.' Available at www.childinfo.org/eddb/vita_a.
[38] Dawe, D.R *et al.* (2002) 'Golden rice: what role could it play in alleviation of Vitamin A deficiency.' *Food Policy* 27:541-560.
[39] Ecological Society of America. (2004) ESA Position Paper on GEOs; Snow, A.A. *et al. Genetically engineered organisms and the environment: current status and recommendations.* Available at www.esa.org/pao/esaPositions/Papers/geo_position.htm.
[40] *See* Conservation Technology Information Center data. Available at www.ctic.purdue.edu/Core4/CT/CTSurvey/NationalData8902.html; Fawcett R. & Towery, D. (2002) *Conservation Tillage and Plant Biotechnology: how new technologies can improve the environment by reducing the need to plow.* Conservation Technology Information Center;:West Lafayette.
[41] Benbrook, C.M. (2003) 'Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Eight Years.' BioTech InfoNet. Technical Paper No 6. Available at http://www.biotech-info.net/technicalpaper6.html.
[42] Ecological Society of America. (2004) ESA Position Paper on GEOs; Snow, A.A. *et al. Genetically engineered organisms and the environment: current status and recommendations.* Available at www.esa.org/pao/esaPositions/Papers/geo_position.htm.
[43] Saxena, D. & Stotzky, G. (2001) 'Bt corn has a higher lignin content than non-Bt corn.' *American Journal of Botany* 88: 1704-1706.

2.2.4 Other uncertain benefits

23. The US claims that agricultural biotechnology 'is the most cost effective and environmentally sound method of addressing this problem' of crop losses due to pests, diseases and spoilage and extreme weather.[44] The supporting reference (McGloughlin, 2000) provides *no* information on comparative costs and benefits of different approaches to support this claim. Whilst claims are also made for increased yields, these might not be evident in all GM crops in all years, they might be restricted according to geography, or they might not be achieved at all. For example, there is evidence that the introduction of the herbicide tolerance gene into Roundup Ready soybeans results in a 'yield drag'.[45] This might occur because the GM plant has to divert resources from growth or other plant functions to the operation of the introduced GM trait, or because the first GM varieties introduced did not originate from the highest yielding conventional varieties.

2.3 Risks associated with genetically modified products

24. In contrast to the US assertion,[46] GM technology has no proven safety record in the EC or elsewhere. There is a range of potential adverse effects on human health and the environment which may arise from the use of GM crops and foods. The potential adverse effects are recognised by the scientific and regulatory communities, as evidenced by national, regional and international regulations intended to prevent adverse effects occurring.

2.3.1 Risks to human life, health and safety

25. Uncertainty continues to surround the potential for adverse impacts on human health from GM food consumption. Whilst the potential for harm arising is widely recognised, such as through the unintentional introduction of a new allergen or toxin,[47] there is little evidence to call upon to support the claims of safety of GM foods.

26. The UK's Science Review Panel said: 'To date world-wide there have been no verifiable untoward toxic or nutritionally deleterious effects resulting from the cultivation and consumption of products from GM crops. However, absence of readily observable adverse effects does not mean that these can be completely ruled out and there has been no epidemiological monitoring of those consuming GM food.'[48] Emphasizing 'no evidence' as an indicator of no harm is contrary to good scientific practice for risk assessment.[49]

27. We are aware of only one scientific study of the human health effects of consuming GM food.[50] In this study, gene transfer from GM soya to intestinal micro-organisms was detected. The full implications of this are uncertain but, in response, one scientist commented that: 'transfer events seem to have occurred in three of the seven subjects examined, it may be that trans-kingdom gene transfers are not as rare as suggested by the UK GM Science Review Panel. This observation is significant, and it is imperative that the transfer

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[44] First US Submission, para 17.
[45] *See* e.g. Elmore, *et al*. (2001) 'Glyphosate-resistant Soybean Cultivar Yields Compares with Sister Lines.' Agronomy *Journal* 93:408-412. Available at http://screc.unl.edu/Research/Glyphosate/glyphosateyield.html; Benbrook, C. (1999) 'Evidence of the Magnitude and Consequences of the Roundup Ready Soybean Yield Drag from University-Based Varietal Trials in 1998.' Available at http://www.agbiotechinfo.net.
[46] First US Submission, para 27ff.
[47] *See* e.g *Codex Alimentarius* Commission Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, approved at Codex Alimentarius Commission, Twenty-sixth Session, see Report, ALINORM 03/41, paras 51ff and relevant Appendix ftp://ftp.fao.org/codex/alinorm03/al03_41e.pdf..
[48] GM Science Review Panel. (2003) GM science review. First report. Executive Summary. Available on http://www.gmsciencedebate.org.uk/report/default.htm#first.
[49] National Academy of Sciences. (2002) *Environmental impacts of transgenic plants: the scope and adequacy of regulation.* National Academy Press: Washington, p 10.
[50] Netherwood *et al*. (2004) 'Assessing the survival of transgenic plant DNA in the human gastrointestinal tract.' *Nature Biotechnology* 22: 204-209.

events be characterized more fully.'[51] Independent, peer reviewed animal studies are also limited in number and scope,[52] and methodological problems are frequent.[53]

28. The adequacy of risk management systems should also be taken into account in considering the risk of GM food to human health. For example, the StarLink episode in the US in 2000 raised concerns about US risk management systems. GM maize containing a potentially allergenic protein was found in taco shells being sold for human consumption even though it had not been approved for this use and should have been used only for animal feed.[54] StarLink maize is genetically modified to contain a gene coding for an insecticidal *Bt* toxin known as Cry9C and there are concerns that it could be a human allergen.[55] Failures to separate the GM from non-GM maize led to billions of dollars in losses as products were withdrawn from the market. Revising rules in the US, so that approvals are given only if a GM product is considered safe for all uses, has been one consequence of this episode, although there is no foolproof system to predict allergic responses.[56]

2.3.2 Risks to plant and animal life and health, and the environment

29. There remains considerable scientific uncertainty about the impacts of GM crops on the environment. The potential effects include: hybridisation with related organisms and the creation of new pests; direct or indirect harm to non-target species; disruption of ecosystems; loss or changes in species or genetic diversity.[57]

(i) Risk assessment is GM- and site-specific

30. It is not possible to extrapolate directly from the impacts in one country to those in another. Geographical and ecological differences will affect the outcome of a risk assessment including:
    - Whether compatible wild relatives are present with which a GM crop could hybridise. For example, maize has no wild relatives in Europe, but it does in South America. In Europe, wild relatives of oilseed rape and sugar beet are present but are not present as native species in North America;
    - The range and status of biodiversity. For example, North America depends upon its wilderness areas for conservation of biodiversity whereas farmland is much more important in Europe.

31. Therefore, environmental risk assessments have to be specific for a country, area or agricultural system. The Ecological Society of America's recent position statement emphasises that science-based regulation of GMOs should: '(a) subject all transgenic organisms to a similar risk assessment framework, (b) recognise that many environmental risks are [genetically modified organism-] and site-specific, and therefore that risk analysis should be tailored to particular applications, and (c) incorporate a cautious approach to environmental risk analysis.'[58]

(ii) Indirect impacts

32. In Europe, it became clear that there was not sufficient evidence upon which to base an assessment of the indirect impacts of growing GM herbicide tolerant (GMHT) crops on biodiversity – how altered farming

[51] Heritage, J. (2004) 'The fate of transgenes in the human gut.' *Nature Biotechnology* 22: 170-173.
[52] Revista Española de Salud Publica (X) 74 (3) May/June 2000; Domingo, J. L. (2000) 'Health risks of genetically modified foods: many opinions but few data.' *Science* 288: 1748-1749.
[53] Pryme IF. & Lembcke R.. (2003) 'In vivo studies on possible health consequences of genetically modified food and feed--with particular regard to ingredients consisting of genetically modified plant materials.' Nutritional Health 17(1): 1-8.
[54] 'Biotech Critics Cite Unapproved Corn in Taco Shells.' *Washington Post*, September 18th 2000; *see also* www.gefoodalert.org.
[55] National Research Council. (2000) *Genetically Modified Pest-Protected Plants. Science and Regulation*. National Academy Press: Washington DC, p 112.
[56] *See* para 2 of annex on assessment of possible allergenicity, to *Codex Alimentarius* Commission Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, approved at Codex Alimentarius Commission, Twenty-sixth Session, see Report, ALINORM 03/41, paras 51ff and relevant Appendix ftp://ftp.fao.org/codex/alinorm03/al03_41e.pdf.
[57] Ecological Society of America. (2004) op cit.
[58] *Ibid.*

practices associated with the use of a GM crops would affect wildlife. This lack of knowledge was acknowledged by the biotechnology industry, which entered into a voluntary agreement with the UK Government not to proceed with the commercialisation of GM crops until the results of a large-scale study (the Farm-Scale Evaluations, FSEs) of the impacts of growing GM herbicide tolerant crops on farmland wildlife were known.[59] The first results from GM herbicide tolerant spring oilseed rape, beet and maize have now been published.[60] The findings for the crops varied but for spring oilseed rape and beet, dramatic adverse effects on wildlife were recorded. The researchers and the scientific steering committee concluded in relation to oilseed rape and beet that: '1. Growing GMHT beet and spring oilseed rape on a large-scale may disadvantage wildlife, particularly farmland birds, bees and butterflies […] 2. Growing GMHT beet and spring oilseed rape on a large-scale may exacerbate long-term declines of flowering weeds, including those that are important food resources for seed-eating birds. By contrast, however, growing GMHT maize was better for many groups of wildlife than conventional maize.' [61]

33. Until these studies were completed, the question of whether the use of GMHT crops could harm the environment through indirect effects associated with the increased use of broad spectrum herbicides, was a matter of dispute between EC Member States.[62] Evidence emerging through the late 1980s and 1990s showed how intensive agriculture was having an adverse impact on biodiversity in arable farming systems.[63] Serious declines in bird and plant populations have been recorded in the UK and other parts of Europe.[64] Considerable evidence shows that loss of weeds and their associated feed resources through herbicide use in terms of habitats for insects and seed for birds has contributed to these declines.[65] The EU Habitats Directive, the EU Birds Directive and the Convention on Biological Diversity all require EC Member States to safeguard their native biodiversity.[66]

34. The hybrid spring oilseed rape (MS8/RF3) and sugar/fodder beet (Roundup Ready sugar beet – A5/15) studied in the FSEs are being considered by the European Commission for marketing consents, but data to resolve disputes about the likely impacts of these crops was not available before the FSEs were completed. The FSE data are also relevant to the risk assessment of the other herbicide tolerant GM crops marketing applications which have been made in the EC.[67] Without such information it is not possible for a full scientific evaluation of their risks to be made and, in the light of these new data, it is clear that commercial growing of GMHT spring oilseed rape and sugar beet should not be allowed in Europe. Moreover, the Ecological Society of America consider that the FSEs have 'most likely underestimated ecological effects.'[68]

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[59] Announced by Michael Meacher, UK Minister for the Environment, in his evidence to Sub-Committee D of the House of Lords Select Committee on the European Communities on 21 October 1998 (*see* HL Paper 11-II, 2nd Report Session 1998-99, Q 603). And DETR News Release 507, "Voluntary Agreement on GM Crops Extended", 5 November 1999*;* DETR Background Paper, 'The Farm-Scale Evaluations of Genetically Modified Herbicide Tolerant Crops – Rationale and Chronology', January 2001. http://www.defra.gov.uk/environment/gm/fse/background/pdf/docs.pdf.

[60] The Farm Scale Evaluations of spring-sown genetically modified crops. Papers of a Theme Issue. Philosophical Transaction of the Royal Society (B) 358: 1773-1913 (2003).

[61] Burke, M (2003) for Farmscale Evaluations Research Team and Scientific Steering Committee GM crops. Effects on farmland wildlife. http://www.defra.gov.uk/environment/gm/fse/results/fse-summary.pdf

[62] Levidow, L & Carr, S. (2000) UK: precautionary commercialization? Journal of Risk Research 3:261-270.

[63] Robinson, R.A. & Sutherland, W.J. (2002) Post-war changes in arable farming and biodiversity in Great Britain. Journal of Applied Ecology 39: 157-176.

[64] Gibbons, D. *et al* (1994) The New Atlas of Breeding Birds in Britain and Ireland:1998-1991. London: T&A Poyser; Preston C.D. *et al* (2002) The changing flora of the UK. London: DEFRA; Andresen, C. *et al* (1996) Decline of the flora in Danish arable fields. Journal of Applied Ecology 33: 619-626.

[65] E.g Robinson, R.A. & Sutherland, W.J. (2002) op cit.

[66] Convention on Biological Diversity, 5 June 1992, *see* www.biodiv.org; Council Directive 92/43/EEC of 21 May 1992, on the conservation of natural habitats and of wild fauna and flora OJ L 206 of 22 July 1992; Council Directive 79/409/EEC of 2 April 1979, on the conservation of wild birds, OJ L 103 25 April 1979.

[67] E.g Bayer oilseed rape varieties MS1/RF1; MS1/RF2; Falcon GS40/90; Liberator pHoe6/Ac; Liberty Link sugar beet, T120/7; Monsanto's Roundup Ready fodder beet A5/15; Roundup Ready maize, GA21; Roundup Ready oilseed rape, GT73; Syngenta's maize, Bt-11.

[68] Ecological Society of America (2004) op cit.

(iii) Gene flow from GM to non-GM crops

35. Another area of environmental concern in Europe and elsewhere has been the potential for gene flow from GM to non-GM crops. This will affect whether it will be possible to produce non-GM food to meet consumer demand, or whether troublesome weeds may emerge. Research conducted before and after 1998 has provided vital new information. Early studies had shown that the distances over which pollen could move had been underestimated in small-scale trials.[69] More recent studies have revealed the importance of landscape, insect movement and local environmental conditions.[70] In relation to the emergence of weeds, when crop plants emerge in subsequent crops of a different species, they are then unwanted weeds ('volunteers') which have to be removed by the farmer. Studies conducted since 1998, have shown that GM oilseed rape volunteers may act as sources of contamination for up to 16 years if not properly managed.[71]

36. Problems with volunteer oilseed rape weeds are arising in those countries that have commercialised GM oilseed rape already. Volunteers that are tolerant to three herbicides (Liberty, Roundup and Clearfield) were first identified in Canada in 1998, only 3 years after GM herbicide tolerant oilseed rape was first grown.[72] The emergence of such volunteer weeds in Canada is encouraging the use of other more toxic chemical weedkillers, including 2,4D and paraquat (grammoxone), to control them,[73] and could harm wildlife on environmental sensitive areas, including areas set aside for environmental protection.

37. Without information about the way in which pollen moves and how long GM crops may persist as 'volunteers', it is not possible to decide upon scientifically based systems to manage co-existence between GM and non-GM crops and, even so, uncertainties remain that will demand such systems to be monitored.[74] Evidence of pervasive contamination of non-GM seed supplies in the US shows that the existing practice in the US is inadequate, with potentially harmful consequences should drug-producing or other industrial GM crops be introduced.[75]

(iv) Gene flow to wild related plants

38. Gene flow to related wild plants is important to understand in the European context. Wild relatives of oilseed rape and sugar beet exist in Europe with which GM crops could hybridise relatively easily.[76] These are among the first GM crops that could be grown in the EC. Such hybrids could become troublesome weeds for farmers to manage or harm ecosystems if they become invasive or disruptive. Until the advent of GM, there was little research on the movement of genes between crops and their wild relatives. Early research showed that the spread of transgenes from GM oilseed rape to wild turnip, a related plant commonly found in northern Europe, could be more rapid than previously considered.[77] Subsequently, gene flow from oilseed

[69] Scheffler J.A. *et al.*, (1993) Frequency and distance of pollen dispersal from transgenic oilseed rape (*Brassica napus*). Transgenic Research 2 :356-364; Timmons A.M., *et al*, (1995) 'Assessing the risks of wind pollination from fields of genetically modified *Brassica napus* ssp. Oleifera.' Euphytica 85 : 417-423; Lavigne C. *et al.*, (1998). 'A pollen-dispersal experiment with transgenic oilseed rape. Estimation of the average pollen dispersal of an individual plant within a field.' Theoretical and. Applied Genetics. 96 : 886-896.
[70] Ramsay, G. *et al.*, (2003) Quantifying landscape-scale gene flow in oilseed rape. Final report of DEFRA Project RG0216; Reiger, M.A. *et al* (2002) Pollen-mediated movement of herbicide resistance between commercial canola fields. Science 296: 2386-2388.
[71] Squire, G.R. & Askew, A. (2003) Final Report - DEFRA project RG0114: The potential for oilseed rape feral (volunteer) weeds to cause impurities in later oilseed rape crops.http:// www.defra.gov.uk/environment/gm/ research/pdf/epg_rg0114.pdf
[72] Downey, R.K. (1999) Gene flow and rape – the Canadian experience. 1999 BCPC Symposium Proceedings No. 72: Gene flow and agriculture: relevance for transgenic crops. British Crop Protection Council: Farnham; Hall, L. *et al*. (2000) Pollen flow between herbicide-resistant *Brassica napus* is the cause of multiple-resistant *B.napus* volunteers. Weed Science 48: 688-694.
[73] Outcrossing Between Canola Varieties - A Volunteer Canola Control Issue. http://www.agric.gov.ab.ca/crops/canola/outcrossing.html
[74] Agriculture and Environment Biotechnology Commission (2003) *)* GM crops? Coexistence and liability. Available on www.aebc.gov.uk.
[75] Union of Concerned Scientists (2004) Gone to seed. Transgenic contaminants in the traditional seed supply. UCS: Cambridge, MA. www.ucsusa.org/documents/seedreport_full report.pdf
[76] European Environment Agency (2002) Genetically modified organisms (GMOs): the significance of gene flow through pollen transfer. EEA: Copenhagen.
[77] Mikkelsen, T.R., *et al.*, (1996) The risk of transgene spread. Nature 380:31.

rape to wild turnip has been detected following commercial use of GM oilseed rape in Canada.[78] Research from France has shown a potential problem with gene flow to hoary mustard,[79] another weedy relative of oilseed rape found in southern Europe. Following these studies, researchers have shown that the likelihood of gene flow between GM beet and weed beet and from GM oilseed rape to its relative, wild turnip, had been underestimated in the past.[80] Such uncertainties also surround other crop-weed hybridisation that may occur in the US and elsewhere. For example, the original assumption that wheat/jointed goat grass hybrids were sterile and so would not result in the production of problem weeds, has now been overturned.[81]

39. Deciding upon the importance of gene flow remains contentious. Studies highlight the need for caution and there have been relatively few studies on the 'fitness' advantages or disadvantages to a wild plant of acquiring the 'foreign' gene introduced by the genetic modification (known as the transgene). Herbicide tolerance transgenes do not adversely affect survival of hybrids,[82] but may confer a significant advantage only in certain situations – when sprayed with the relevant herbicide. Interestingly, however, wild sunflowers that acquired insect resistance genes from GM sunflowers became hardier and produced up to 50% more seed.[83]

2.3.3 Consumer concerns and informed choice

40. In light of the scientific uncertainty that remains about health, environmental and socio-economic impacts of GM crops and foods, citizens in the EC and many other parts of the world are demanding a cautious approach to GM crops and foods.They want strict regulations to ensure that consumer choice is maintained. Public concern is greatest about long-term impacts, where the difficulties of prediction are compounded because extrapolation from small-scale, short-term field trials may not provide adequate predictive data to deal with the complexities of the natural world.[84]

41. Quantitative research reveals the extent of unease about GM crops and food in Europe. EC-wide polls conducted by the European Commission (Eurobarometer surveys) show that while basic knowledge about GM technology has increased, optimism about its ability to improve the quality of life has decreased.[85] In 2001, Eurobarometer respondents were asked the following question: 'Would you say that you are more inclined to agree or disagree with each of the following propositions on genetically modified foods?'[86] The results are seen in the table below.

[78] Warwick *et al*. (2003) Hybridisation between transgenic *Brassica napus* L. and its wild relatives *: Brassica rapa L., Rahanus raphanistrum L., Sinapsis arvensis* L., and *Erucastrum gallicum* (Willd.) O.E. Schulz. Theoretical and Applied Genetics 107: 528-539.
[79] Lefol, E., *et al* (1995) Gene dispersal from transgenic crops. I. Growth of interspecific hybrids between oilseed rape and the wild hoary mustard. Journal of Applied Ecology 32: 803-808.
[80] Desplanque, B. *et al* (2002) Transgenic weed beets: possible, probable, avoidable? *Journal of Applied Ecology* 39: 561-571; Wilkinson MJ, *et al* (2003) Hybridization between *Brassica napa* and *B. rapa* on a national scale in the United Kingdom. Science.
[81] Zemetra, R. S. *et al*., (1998) Potential for gene transfer between wheat (triticum aestivum) and jointed goatgrass *(Aegilops cylindrica),* Weed Science 46: 3131; Seefeldt, S *et al*., (1998) Production of herbicide resistant jointed goatgrass (*Aegilops cylindrica*) x wheat *(Triticum aestivum*) hybrids in the field by natural hybridization. Weed Science 46: 632-634.
[82] Snow, A.A. *et al* (1999) Costs of transgenic herbicide resistance introgressed from *Brassica napus* into weedy *Brassica rapa*. Molecular Ecology 8: 605-615.
[83] Snow, A.A *et al* (2003) A Bt-transgene reduces herbivory and enhances fecundity in wild sunflowers. Ecological Applications 13: 279-286.
[84] *See* e.g. Kareiva, P. *et al*. (1996) Can we use experiments and models in predicting the invasiveness of genetically engineered organisms? Ecology 77: 1651-1675.
[85] Biotechnology and the European Public Concerted Action Group, 1997. 'Europe ambivalent on biotechnology.' *Nature* 387: 845-847.
[86] EUROBAROMETER 55.2: Europeans, science and technology, December 2001. Directorate-General for Research. - http://europa.eu.int/comm/research/press/2001/pr0612en.html.

	Inclined to agree (%)	Inclined not to agree (%)	Don't know (%)
I want to have the right to choose	94.6	2.5	2.8
I want to know more about this kind of food before eating it	85.9	9.3	4.8
They should only be introduced if it is scientifically proven that they are harmless	85.8	8.0	6.1
I do not want this type of food	70.9	16.9	12.2
They could have negative effects on the environment	59.4	11.9	28.7
The dangers have been exaggerated by the media	33.1	44.3	22.6
This kind of food does not present any particular danger	14.6	54.8	30.6

42. The most recent 2002 Eurobarometer results showed that: 'A majority of Europeans do not support GM foods. These are judged not to be useful and to be risky for society. For GM crops, support is lukewarm, while they are judged to be moderately useful they are seen as almost as risky as GM foods.'[87] A range of other research using qualitative methods underlies these findings and highlights concerns about long-term impacts on health and the environment and also that people do not see any particular benefits from the current generation of GM crops.[88]

43. Europeans are not alone in demanding choice over GM crops and foods. In the US, an ABC News Poll in July 2003 revealed that: 92% of people believe that 'the federal government should [...] require labels on food saying whether it has been genetically modified or bio-engineered'; and 6% do not believe it should be labelled.[89] The same poll showed that 46% of Americans did not think that GM foods were safe to eat.

44. Negative impressions about GM crops are not restricted to the North. For example, in Chile a study of the public perception of GMOs found that out of 300 homes surveyed, 75% would reject GM food. According to the authors of the study, Chile has the second most negative perception of GMOs in the world, after the EC.[90]

45. Declines in approved imports into the EC of maize, oilseed rape and soybeans from the US, Canada and Argentina are attributable to public pressure for the removal of GM ingredients in foods. During 1999, almost all European supermarkets and major food producers reformulated or resourced their supplies. In taking these decisions, food companies took account of consumer concerns which 'go beyond biophysical characteristics – encompassing food safety and quality, environmental sustainability and ethically appropriate methods of production.'[91] A 2004 survey of UK supermarkets shows that they still do not intend to allow GM ingredients in their products.[92]

[87] Europeans and Biotechnology in 2002 Eurobarometer 58.0 A report to the EC Directorate General for Research from the project ' Life Sciences in European Society' QLG7-CT-1999-00286.
[88] E.g Food Standards Agency (2003) Consumer views of GM food. http://www.food.gov.uk/multimedia/pdfs/gm_rep.pdf; The People's Report on GM (2003) http://www.gmjury.org/downloads/report.pdf; Marris, C. *et al* (2001) Public Attitudes to Biotechnology in Europe www.pabe.net.
[89] ABC News Poll: Food Safety - 7/13/03 Foods Give Consumers Pause http://abcnews.go.com/sections/us/Poll Vault/Poll Vault.html
[90] Organismos Genéticamente Modificados. Producción, Comercialización, Bioseguridad, Percepción Pública. L.Gil y C. Irarrázabal (Eds). 2000. Santiago. *See* also 'The Situation of GMOs in Chile: The view of Civil Society' - by Dr Maria Isabel Manzur (FSS); http://www.field.org.uk/biodiversity_current.php.
[91] Levidow, L. & Bijman, J. (2002) Farm inputs under pressure from the European food industry. *Food Policy* 27: 31-45.
[92] Friends of the Earth Press Release: Thursday 15th April 2004 Food firm reject GM ingredients as tougher GM food labels come into force.

46. The US Development Agency has recognised that it is market forces, not regulatory constraints, which have caused a decline in exports of GM crops. The 2003 Exporter Guide for the UK states that: 'Although biotech corn and maize products can be sold in the EU (if labeled as such), the uptake of these products is minimal in the UK. The large supermarket chains have determined that they will not stock products with biotech ingredients in their private label products (these, typically, account for 45-50% of supermarket lines). The labeling of products containing biotech components has resulted in a slow uptake of these by retailer and consumer alike.' [93]

2.4 Regulatory response to risks and consumer demands in the EC

47. The EC – like many other countries around the world[94] – responded to concerns about the potential risks of GM technology to human health and the environment by establishing a regulatory system for the approval of GM products. The EC regulatory system for the approval of GM products has evolved over time, and could be described as having had three phases: (1) 1991-2002; (2) 2002-2004; and (3) present.

48. From 1991 to 2002, GM crops and food were subject to the approval and labelling requirements set out in the Deliberate Release Directive (90/220) and the Novel Foods Regulation (258/97).[95] The revised Deliberate Release Directive (2001/18)[96] has applied since October 2002. In April 2004, new Regulations on Labelling and Traceability (1830/2003), and on GM Food and Feed (1829/2003),[97] entered into force, amending the revised Deliberate Release Directive (2001/18) and the Novel Foods Regulation (258/97).

2.4.1 Review of EC regulation of GM products: Reasons and Process

49. In 1996, the European Commission published a review of the application of the Deliberate Release Directive (90/220).[98] The report identified several deficiencies in the Deliberate Release Directive, including the need to: harmonise risk assessments between Member States; improve the relevance of experimental data collected as experimental trial data on environmental risks was not meeting the requirements of risk evaluation for marketing;[99] and improve labelling of GM products. In an effort to address the identified deficiencies, the Commission initiated a proposal to amend the Deliberate Release Directive.[100]

50. Following the decision to revise the Directive, it also became evident that environmental risk assessment systems were inadequate to address the potential risks of the use of GM organisms or respond to harm if it arose. There was no monitoring system, no assessment of indirect effects arising from the use of a GM product, and no formal requirement to re-evaluate the approval of a GM product after it had been authorised.[101] In addition, scientific studies of environmental impacts such as gene flow,[102] and effects on

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[93] USDA Foreign Agricultural Service United Kingdom Exporter Guide Annual 2003 GAIN Report Number: UK3031 11/4/2003 http://www.fas.usda.gov/gainfiles/200311/145986698.pdf

[94] *See* below.

[95] Directive 90/220/EEC, of 23 April 1990, on the deliberate release into the environment of genetically modified organisms, OJ L 117 of 8 May 1990 ('Deliberate Release Directive'); Regulation 258/97/EC, of 27 January 1997, concerning novel foods and novel food ingredients, OJ L 43 of 14 February 1997 ('Novel Foods Regulation').

[96] Directive 2001/18/EC, of 12 March 2001, on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106 of 17 April 2001 ('Revised Deliberate Release Directive').

[97] Regulation 1830/2003, of 22 September 2003, concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18 ('Labelling and Traceability Regulation'); Regulation 1829/2003, of 22 September 2003, on GM food and feed OJ L 268, of 18 October 2003 ('GM Food and Feed Regulation').

[98] Commission of the European Communities (1996) Report on the Review of Directive 90/220/EEC in the Content of the Commission's Communication on Biotechnology and the White Paper. COM(96) 630 final.

[99] Commission of the European Communities (1996) op cit.

[100] Commission of the European Communities (1999) Amended proposal for a European Parliament and Council Directive amending Directive 90/220/EEC, COM (1999) 139 final.

[101] *See* DEFRA (2001) A consultation paper on the implementation of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. DEFRA, July 2001. www.defra.gov.uk/environment/index.htm.

[102] *See* section 2.3.2.

non-target species,[103] revealed that harm to the environment was possible but not adequately considered in existing risk assessments because of a lack of data.

51. Therefore, further amendments to the 1990 Deliberate Release Directive were discussed between the European Parliament, European Council and the European Commission, resulting in the adoption of the Revised Deliberate Release Directive (2001/18/EC) which entered into force in October 2002. This legislative procedure took longer than average[104] (from the initial proposal in February 1998 to final adoption in March 2001) which was nevertheless not unusual in the EC. The legislative procedure for this dossier was that of 'co-decision' between the Council of Ministers and the European Parliament, where both institutions are co-legislators on an equal footing. The Revised Deliberate Release Directive went through three stages: two readings by the European Parliament and a final round of meetings of the Conciliation Committee to reach final agreement.

52. During those final discussions, the Commission committed to presenting legislative proposals to regulate the traceability and labelling of GMOs, which it did in July 2001. The resulting Regulation took two years to go through the EC's legislative procedure as it was adopted in September 2003, also under co-decision, together with a Regulation on GM food and feed which followed the same timeframe and procedure. The objective of the review of the Deliberate Release Directive was to increase the efficiency and the transparency of the authorisation process for GM products in the EC while ensuring a high level of protection for human health and the environment. The new elements of public information and consultation, strengthened risk assessment and mandatory labelling, all aimed to increase the transparency and efficiency of the new regulatory regime on GM products.

53. During the legislative process to amend the Deliberate Release Directive, additional elements of the regulatory system for GM crops and food were called into question, and other measures were needed to enforce elements of the revised Directive including: the concept of substantial equivalence; the quality of health safety assessments; the lack of monitoring and traceability; the adequacy of the environmental risk assessments; and the impact of GM food and crops on the organic food industry.

54. The concept of 'substantial equivalence' – where the chemical composition of GM food is compared to that of its non-GM counterpart – was the basis upon which GM food was approved for marketing and use in the EC under the Novel Foods Regulation. Whether 'substantial equivalence' was an adequate and sufficiently rigorous basis for safety assessment came under particular scrutiny because of its limited ability to identify unintended changes arising from the introduction of new genes.[105] An international consensus grew that a review of the use of substantial equivalence was needed and that decision-making should be more open and transparent.[106] Furthermore, research suggesting that the consumption of GM potatoes could impair growth and damage the immune system of rats[107] exposed large gaps in research in relation to food safety,[108] compounding concern about the safety assessment of GM food.

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[103] Hilbeck, A. *et al* (1998) Effects of transgenic Bt corn-fed prey on mortality and development time of immature *Crysoperla carnea*. Environmental Entomology 27:480-487; Hilbeck, A *et al* (1998) Toxicity of Bt Cry1 Ab toxin to the predator *Crysoperla carnea* (Neuroptera. Chrysopidae) Biological Control 27:1-9 Hilbeck, A *et al* (1999) Prey-mediated effects of Cry1Ab toxin and protoxin and Cry2A protoxin on the predator *Crysoperla carnea*. Entomologia Experimentalis et Applicata 91: 305-316.

[104] Two years. *See* InfoDoc 'The legislative powers of the European Parliament: Codecision between Parliament and the Council', at http://www.epp-ed.org/Activities/pinfo/info48_en.asp, March 2000.

[105] Millstone, E. *et al* (1999) Beyond 'substantial equivalence' Nature 401: 525-526.

[106] The EU-US Biotechnology Consultative Forum. Final Report, December 2000. http://europa.eu.int/comm/external_relations/us/biotech/report.pdf; The OECD Conference on the Scientific and Health Aspects of Genetically Modified Foods, 28 February – 1 March 2000, Edinburgh. Chairman's Report. http://www.oecd.org/dataoecd/4/25/1897032.pdf.

[107] Ewan, S.W.B. & Pusztai, A. (1999) Effect of diets containing genetically modified potatoes expressing *Galanthus nivalis* lectin on rat small intestine. The Lancet 354: 1353-1354.

[108] *See* section 2.3.1.

55. As a result, the European Commission White Paper on Food Safety[109] undertook to review the Novel Foods Regulation and proposed introducing a risk assessment system at least equivalent to that required under the Revised Deliberate Release Directive.

56. The White Paper also identified the need to improve the transparency of assessment systems and introduce comprehensive labelling systems.[110] This led to the eventual agreement on Regulation 1829/2003 on GM food and feed in September 2003. This regulation was notified to the WTO in November 2003.[111]

57. A requirement for traceability was also part of the Revised Deliberate Release Directive, but it required further regulation for its implementation.[112] The lack of monitoring or traceability systems to identify problems and facilitate product recall for GM foods was inconsistent with European food safety policy, introduced following experiences such as 'mad cow disease' in the UK, and dioxin-contaminated poultry, eggs, beef and pork in Belgium. Traceability has now become a cornerstone of food safety policy in Europe enshrined in the EC 'General Food Law Regulation' where the principle of traceability is defined as: 'the ability to trace and follow a food, feed […] through all stages of production, processing and distribution.'[113]

58. Following discussions on a Commission proposal,[114] Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from GMOs was adopted in September 2003.[115] This regulation was notified to the WTO in November 2003.[116]

59. Furthermore, there was growing demand for protection of non-GM and organic food from contamination by GM crops, but there were few data upon which to design and implement a co-existence scheme. Demand for organic products grew by 8% in Europe in 2002 at a value of US$10.5 billion.[117] In a preliminary effort to facilitate protection of non-GM and organic farming, in July 2003 the Commission adopted a Recommendation (2003/556/EC) on co-existence setting out guidelines for the development of national strategies and best practices to ensure co-existence.[118]

60. In conclusion, the EC's general and specific *de facto* moratoria and Member States' safeguard actions on GM products were introduced at a time when scientists, consumers and EC Member States were expressing increased concerns about the human health and environmental impacts of GM food and crops. EC Member States and their citizens were concerned that the regulatory system for GM approvals was not sufficiently rigorous to prevent harm and they demanded that identified shortcomings be addressed.[119] A majority of EC Member States considered it necessary to review and revise the EC systems intended to protect human, plant and animals health, as well as meeting consumers' demands for more information and choice over the form of labelling and the protection of non-GM food supplies.[120]

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[109] CEC (200) White Paper on Food Safety COM (1999) 719 Final http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub06_en.pdf

[110] CEC (2001) Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed. COM(2001) 425 final.

[111] G/TBT/N/EEC/6/Add.2;G/SPS/N/EEC/149/Add.3 and 5.

[112] Article 21 of the Revised Deliberate Release Directive.

[113] Regulation 178/2002, of 28 January 2002, laying down the general principles and requirements of food law,establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31 of 1 February 2002 ('General Food Law Regulation'), p1.

[114] CEC (2001) Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC COM(2001) 182 final.

[115] *See* above.

[116] G/TBT/N/EEC/7/Add.2;G/SPS/N/EEC/150/Add.3-4.

[117] Willer, H. & Yussefi, M. (Eds) The World of Organic Agriculture - Statistics and Emerging Trends – 2004 Bonn: International Federation of Organic Agriculture Movements, 2004.

[118] Commission Recommendation 2003/556, of 23 July 2003, on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, OJ L 189, of 29 July 2003.

[119] *See* e.g. Torgersen, H. (1996) Ecological impacts of traditional crop plants: a basis for the assessment of transgenic plants. Bundesministerium fur Umwelt: Vienna, Austria.

[120] *See* section 2.3.3 above.

2.4.2 Revised EC Regulatory Framework for GM Products: Main Issues

61. Since it became applicable in October 2002, the Revised Deliberate Release Directive (2001/18) requires:

- an assessment of immediate and delayed, direct and indirect impacts of GMOs. Importantly, this now includes consideration of the effect of new agricultural practices arising from the use of a GMO;
- a post-marketing monitoring plan to detect unanticipated effects and consider whether assumptions made in risk assessments were correct. The importance of a monitoring system as part of a science-based risk management system has been underlined by the Ecological Society of America and the US National Research Council which both highlighted its absence in the US regulatory system;[121]
- time-bound consents – after an authorisation period of 10 years, GMOs must be subject to re-assessment.

62. As of April 2004, the Regulation on GM Food and Feed, and the Regulation on Traceability and Labelling of GMOs and food and feed products produced from GMOs, have introduced the following changes to the EC's regulatory regime:

- substantial equivalence is not a sufficient basis upon which to evaluate the safety of novel foods and notification based on that approach, which was allowed in the Novel Foods Regulation, is now abandoned. This move away from substantial equivalence is supported by learned reports including from the Royal Society of Canada;[122]
- GM crops and products are to be traced throughout the food production system. It facilitates the identification of any adverse effect and the removal of products from the market if required;
- better provision for consumers' choice. Before the new regulations, labelling was restricted to those circumstances where altered DNA or proteins were found in the final product. Current labelling requirements include derivatives of GM crops, such as oil from GM soybean or oilseed rape, which expands consumers' choice.

63. Since 1998, a considerable amount of scientific research has been undertaken,[123] as well as the Farm-Scale Evaluations of the impacts of growing GM herbicide tolerant crops on biodiversity. All this information will allow a better informed risk assessment to be made and better provision to protect non-GM crops.

64. In this respect, the Farm-Scale Evaluations of GMHT crops in the UK have identified the potential for adverse effects of GM crops on biodiversity. If this cautious approach had not been taken, and the assessment of marketing applications for hybrid oilseed rape (MS8/RF3), winter oilseed rape (Liberator), Liberty Link oilseed rape (T45xTopas 19/2), Roundup Ready oilseed rape (GT73), Roundup Ready fodder beet (A15/15) and Roundup Ready sugar beet had not been delayed until these scientific studies were completed, harmful effects on European biodiversity could have occurred.

65. Previous conclusions by scientific committees that these and other crops awaiting marketing consents were 'safe', as referred to in the First US Submission,[124] cannot be relied upon as they have been superseded by an improved risk assessment system and new information. To be scientifically rigorous and command public respect, these risk assessments need to be conducted under the current system with its expanded scope. National bans also have to be considered in this new light, because it cannot be assumed that products approved under the past system would have been judged 'safe' under the revised system.

[121] Ecological Society of America (2004) op cit; NRC (2002) Environmental effects of transgenic plants: the scope and adequacy of regulation. National Academy Press: Washington, DC, p12-14.
[122] Elements of precaution: recommendations for the regulation of food biotechnology in Canada. The Royal Society of Canada, January 2001.
[123] *See* section 2.3.2.
[124] First US Submission, paras 27 & 28.

2.5 EC Regulatory response in a global context

66. Uncertainty surrounding both the potential benefits and risks associated with GM technology has been a subject of international concern since the first genetically modified micro-organisms were created in 1972.[125] Initially, concern centered on whether containment in laboratories was sufficient to protect human health.[126] With the development of the first GM plants in 1984, and the intention to release these into the environment, the scope of the concern increased.[127]

67. Since Agenda 21 stressed the need to identify and control risks arising from GMOs and GM products in 1992,[128] the international community has engaged in an ongoing process of developing rules, standards and institutions to regulate biotechnology and biosafety. These include the 1992 Convention on Biological Diversity, the 2000 Cartagena Protocol on Biosafety, the International Plant Protection Convention, and instruments developed by the *Codex Alimentarius* Commission and other international organisations such as the UN's Food and Agriculture Organisation,[129] and studies by the World Health Organisation.[130]

68. The Cartagena Protocol on Biosafety (CPB) regulates the cross-border movement of GMOs (referred to as 'living modified organisms'), requiring Parties to notify and seek consent prior to the import of GMOs intended to be released into the environment, and to assess the risks associated with that release into the specific environment where the GMO is intended to be introduced.[131] The CPB also requires Parties to inform each other of national decisions concerning GM food and feed products,[132] and to label GMOs and GM products.[133] Negotiations on the CPB commenced in 1996. It was adopted in 2000 and entered into force in September 2003. With nearly 100 Parties,[134] the CPB attests to the global concerns surrounding GM technology.

69. Concerns about the risks associated with GM technology are also reflected in national laws and policies around the world.[135] For example, seventy countries contribute to the UNIDO and OECD databases on regulations and releases of GMOs.[136]

70. However, many countries still do not have policy or regulations in place. For example, when food aid donated by the US was found to be GM, Zambia did not have any biosafety regulations in place. The Zambian Government commissioned a scientific review of the human and environmental safety of GM foods and their impacts on trade, which concluded that GM maize could pose threats to local landraces, and

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[125] *See* Chapter 2 in Wright, S. (1994) Molecular politics. Developing American and British Regulatory Policy for Genetic Engineering, 1972-1982. University of Chicago Press: Chicago.
[126] Wright, S. (1994) op cit.
[127] *See*: Part II Genetic engineering and the environment in 'The BioRevolution. Cornucopia or Pandora's Box?' P Wheele & R McNally (eds) Pluto Press: London pp107-157.
[128] *See* Rio Declaration On Environment And Development, http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm
[129] *See* further Mackenzie R., Globalisation and the International Governance of Modern Biotechnology: The International Regulation of Modern Biotechnology, 2003, www.gapresearch.org.
[130] WHO study on modern food biotechnology, human health and development – ongoing: http://www.who.int/foodsafety/biotech/who_study/en/index.html
[131] *See* Articles 7 and 8 CPB.
[132] *See* Articles 11 and 20 CPB.
[133] Article 18 CPB.
[134] Canada and Argentina are signatories, not Parties. The US is not eligible to become a Party until it ratifies the CPB's parent agreement, the 1992 Convention on Biological Diversity.
[135] Centro de Derecho Ambiental and FIELD, Project on Building Legal and Institutional Capacity on Biosafety in Chile, Comparative Case studies, http://www.field.org.uk/biodiversity_pg8.php; *see* also Baumüller, H. Domestic Import Regulations for Genetically Modified Organisms and their Compatibility with WTO Rules, Some Key Issues, ICTSD/IISD, August 2003.
[136] *See* Binas On-line: http://binas.unido.org/binas/regs.php; *see* also Biotrack http://www.oecd.org/infobycountry/0,2646,en_2649_34385_1_1_1_1_1,00.html They give EU countries separately because of releases data and their own implementing regs.

that uncertainties remained about human health effects as well as possible effects on trade.[137] For these reasons, they recommended that Zambia continue its restrictions on imports of all GM maize and that safety laws be introduced.[138]

71. Citizens in the US, Canada and Argentina and elsewhere have expressed their grave concerns about GMOs and their governments' failure to ensure protection of human health and the environment through appropriate regulation of GMOs and GM products. A small sample of global expressions of concern about GMOs is given below.

72. In the US, the Center for Food Safety and numerous other organizations petitioned the Food and Drug Authority (FDA) in March 2000 to take action regarding the potential human health and environmental impacts associated with the use and commercialization of GM foods.[139] More specifically, the FDA has been requested to initiate a new regulation to establish mandatory pre-market safety, environmental review, and labelling regulations for all GM food and crops. Since the filing of the petition over four years ago, the FDA has failed to take any action concerning the issues addressed in the petition. The National Research Council[140] and the Pew Initiative on Biotechnology[141] are among others who have identified limitations in the US system. Mendocino County in California, USA, has recently voted for a ban on GM crops and animals.[142]

73. In Canada, since 2003, more than 3,500 people have mailed slices of bread to their MPs as part of the Council of Canadians' national campaign against genetically modified wheat.[143] A petition signed by one million Japanese people objecting to the prospect of GM wheat was presented to the Canadian Agriculture and Agrifood Minister in March 2004.[144] A USDA survey also revealed international reservations about GM wheat.[145] Recognising the lack of support for GM wheat, Monsanto has deferred all plans to commercialise it on 10 May 2004.[146]

74. In Argentina, there has been great concern over the impact of introducing GM soya.[147] In Bolivia in July 2002, more than 500 representatives of civil society organisations (mostly indigenous peoples and farmers organisations) rejected the introduction of GM crops into the country and requested that the State declare an indefinite moratorium on the introduction of transgenics.[148]

75. In India, partly in response to concerns expressed about GM crops, a task force was established in 2003 to consider changes needed in the procedures and policies relating to agricultural biotechnology. This task force has recently reported [149] and its recommendations included the need to protect centres of biodiversity, introduce systems of segregation of GM crops, and consider social impacts in prioritising crop development.

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[137] Report of the fact finding mission by Zambian scientists on genetically modified foods, 2002. http://www.genet-info.org/-documents/Zambia_GE_Report.pdf
[138] For broader conclusions on biosafety regulation elsewhere in Africa, *see* Globalisation and the International Governance of Modern Biotechnology, Report of Nairobi Meeting, http://www.field.org.uk/files/nairobi.pdf
[139] FDA Docket No. 00-1211, *see* http://www.centerforfoodsafety.org.
[140] National Research Council (2000) op cit.
[141] Pew Initiative on Biotechnology (2004) Issues in the regulation of biotech plants and animals. Pew Initiative: Washington DC.
[142] Mendocino county voters ban GM crops and animals. March 3rd 2003. http://www.independent-media.tv/item.cfm?fmedia_id=6048&fcategory_desc=Genetically%20Modified%20Foods%20(GM)
[143] http://temagami.carleton.ca/jmc/cnews/30012004/n3.shtml
[144] 1 million Japanese say no to GE wheat! Ottawa, March 18th 2004. News Advisory. http://www.cnw.ca/fr/releases/archive/March2004/18/c1719.html
[145] USDA world survey shows biotech wheat reservations REUTERS, 3 March 2004
[146] Monsanto to Realign Research Portfolio, Development of Roundup Ready Wheat Deferred Decision Follows Portfolio Review, Consultation with Growers Monsanto Press Release, 10th May 2004. http://www.monsanto.com/monsanto/layout/media/04/05-10-04.asp
[147] *See* section 2.2.1.
[148] *See* http://www.redesma.org/transgenicos/doc_up/CruzOMG4-10.PDF
[149] Report of the Task Force on Application of Biotechnology in Agriculture (India), 2004

3.WTO CONSISTENCY OF THE CHALLENGED MEASURES

3.1. Preliminary matters

3.1.1 Treatment of the 'measures' in this submission

76. The US, Canada and Argentina (the 'complainants') have challenged three categories of 'measures': (1) the 'suspension' of GM approvals (EC's general *de facto* moratorium), (2) the failure to consider applications for GM approvals (EC's specific *de facto* moratoria), and (3) EC Member States' 'safeguard' actions on approved GM products under the Deliberate Release Directive and the Novel Foods Regulation.[150] We recognise that the Panel will examine each category of 'measure' independently and on a case-by-case basis. Nevertheless, similar facts are likely to apply to each of the 'measures'. In the interests of brevity, we have considered the consistency of the 'measures' with the relevant WTO Agreements by grouping the 'measures' together where appropriate.

77. In our submission, we do not address the threshold question of whether the relevant WTO Agreements apply to the EC's specific *de facto* moratoria or the EC Member States' safeguard actions. In particular, we do not address the question of whether these 'measures' are: 'sanitary or phytosanitary measures' within the meaning of SPS Annex A.1; 'control, inspection or approval procedures to check and ensure the fulfillment of sanitary and phytosanitary measures' within the meaning of SPS Article 8 and Annex C; 'technical regulations' within the meaning of TBT Annex 1.1; 'conformity assessment procedures to determine that relevant requirements in technical regulations […] are fulfilled' within the meaning of TBT Annex 1.3; or 'measures' or specific types of measures (such as laws, regulations, or requirements) covered by the GATT Articles identified by the complainants.[151]

78. With respect to the first measure – the EC's general *de facto* moratorium – we take note of past panel and Appellate Body reports that have considered the nature of 'measures' subject to the WTO dispute settlement procedures under the WTO's *Understanding on Rules and Procedures Governing the Settlement of Disputes* ('DSU'),[152] the GATT and specific WTO Agreements,[153] and respectfully submit that the Panel should take these reports into account in these disputes.[154] In particular, we note past conclusions that a measure which is legislation of a general nature can be challenged only if it is mandatory and not discretionary.[155] A measure can be challenged even if it is 'not yet applied or in force'.[156] An omission or a failure to act on the part of the Member might amount to a measure where there is a positive obligation on the Member to act under the relevant WTO Agreement.[157] The application of law, in the form of administrative guidance or

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[150] *See* the three categories of 'measures' as set out in the Requests for the Establishment of a Panel by the United States (WT/DS291/23), Canada (WT/DS292/17), and Argentina WT/DS293/17); *see* also Panel TOR WT/DS291/24, WT/DS292/18, WT/DS293/18.
[151] Claims are based on GATT Articles I:1, III:4, X:1, X:3(a) (Argentina only) and XI:1.
[152] *Understanding on Rules and Procedures Governing the Settlement of Disputes* ('DSU'), e.g. Articles 3.3 and 6.2/
[153] Such as the WTO Agreement on Subsidies and Countervailing Measures and Agreement on Trade Related Aspects of Intellectual Property Rights;
[154] Although adopted panel reports are binding only on the parties to the dispute, the Appellate Body has acknowledged that they 'are an important part of the GATT *acquis*. They are often considered by subsequent panels. They create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute.' *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body adopted on 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, pp.6-7 (*Japan – Alcoholic Beverages*), p 14.
[155] *US – Section 301 Trade Act*, WT/DS152/R, (*'US – Section 301')* at para. 7.54. *See* also *US – Anti-Dumping and Countervaling Measures on Steel Plate*, WT/DS206/R, para 7.20 (*US – Steel Plate*); *United States – Countervailing Measures Concerning Certain Products from the European Communities* WT/DS212/R, adopted (with Appellate Body Report WT/DS212/R/AB) on 8 January 2003 (Panel not appealed on this point) (*US – EC Countervailing Measures*) citing Panel Report, *United States - Taxes on Petroleum and Certain Imported Substances* ("*Superfund")*, adopted 17 June 1987, BISD 34S/136, paras 5.26-5.29.
[156] *See e.g. US – Countervailing Measures*, citing *Superfund*.
[157] Appellate Body Report, *United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan*, WT/DS244/AB/R, adopted 9 January 2004 ("Japan Sunset"), (para 81, together with para 85); *Guatemala – Anti-Dumping Investigation Regarding Portland Cement from Mexico*, Report of the Appellate Body, WT/DS60/AB/R, adopted 25 November 1998 fn 47 citing *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint by the United States, WT/DS50/R

practice, can constitute a measure subject to challenge if it requires a violation of WTO rules.[158] A measure allowing the executive authority of a WTO Member the discretion to act in a manner consistent with the relevant WTO rules is not subject to challenge.[159] Finally, it should not be assumed that a broad interpretation of 'measure' in the context of the GATT would be appropriate in the more specific context of measures covered by the SPS and TBT Agreements.[160]

79. The EC's general *de facto* moratorium refers to the expression of political intent by a majority of EC Member States on the issue of GM crops and food. Voicing the concerns of their citizens, declarations made by a majority of Member States in the EC's Environment Council expressed their concerns that existing laws and procedures regulating GM crops and food in the EC failed to provide the necessary protection to human health and the environment. In their declarations, a majority of EC Member States in the Environment Council expressed their intention not to approve GM crops and food under the existing laws and procedures until the review and amendment of the requirements for assessing and monitoring impacts of GM crops and food, and the requirements for consumer information and safety, were complete.[161]

80. The declarations made by a majority of EC Member States in the Environment Council on the subject of GM crops and food were political in nature – they were not 'decisions' of the Council – and as such, they were not legally binding and did not amount to the application of a law requiring EC officials to act inconsistently with WTO rules.[162] The expression of political intent by autonomous sovereign states is not a matter for WTO scrutiny.[163] We respectfully submit that it would be an inappropriate interference with the political process internal to the EC for the Panel to assume jurisdiction over the EC's so-called general *de facto* moratorium. However, in the event that the Panel proceeds with an examination of the EC's general *de facto* moratorium in these disputes, we have included all three categories of 'measures' in our analysis of the substantive and procedural claims.

81. Finally, our submission does not address the question of whether, if the general and specific *de facto* moratoria are 'measures', they have, as of 18 April 2004 or as of any other time,[164] been discontinued, and whether this would have a bearing on the disputes.[165] However, by way of a general observation, the

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and WT/DS50/AB/R, adopted 16 January 1998, and also *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint by the European Communities and its Member States, WT/DS79/R, adopted 22 September 1998.

[158] Namely, there are sufficient incentives or disincentives for the measures to take effect which depend on government action or intervention (*see Japan – Trade in Semi-Conductors*, Report of the Panel, adopted 4 May 1988, BISD 35S/116 (*Japan –Semi-Conductors)*, paras 106 ff); *see* also *US –Steel Plate* and *US – EC Countervailing Measures*, citing *United States – Anti-Dumping Act of 1916* ("US – 1916 Act (EC)"), WT/DS136/R and *United States – Anti-Dumping Act of 1916* ("US – 1916 Act (Japan)"), WT/DS162/R and WT/DS162/Add.1, adopted 26 September 2000, as upheld by the Appellate Body Report, *United States Anti-Dumping Act of 1916* ("US – 1916 Act") WT/DS136/AB/R,WT/DS162/AB/R. *See also United States – Measures Affecting the Importation, Internal Sale, and Use of Tobacco*, adopted 4 October 1994, BISD 41S/131; Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes, Report of the Panel, adopted 7 November 1990, BISD 37S/200; European Economic Community – Regulation on Imports of Parts and Components, adopted 16 May 1990, BISD 37S/132; and *Superfund*.

[159] US-EC Countervailing Measures citing, among others, *US – Section 301*, at paras. 7.53-7.54.

[160] *See India – Measures Affecting the Automotive Sector*, Report of the Panel, WT/DS146/R, (*India – Automobiles*) WT/DS175/R, adopted 5 April 2002.

[161] *See* Declaration by the Danish, Greek, French, Italian and Luxembourg delegations concerning the suspension of new GMO authorizations and Declaration by the Austrian, Belgian, Finnish, German, Netherlands, Spanish and Swedish delegations, MINUTES of the 2194th Council meeting (Environment) held in Luxembourg on 24 and 25 June 1999 http://ue.eu.int/newsroom/NewMain.asp?LANG=1 ('1999 Council Declarations').

[162] Note that under EC law, only measures having legal effects are judicially reviewable. The test is binding force or legal effects: Case 57/95 France v. Commission [1997] ECR 935; Case 22/70 Commission v. Council [1971] ECR 263; Case 60/81 International Business Machines Corporation v. Commission [1981] ECR 2639.

[163] *See* Charter of the United Nations, Article 2, http://www.un.org/aboutun/charter/. *See* also Craig and de Burca EU Law, Text, Cases and Materials, andr Alan Dashwood "Community Decision Making After Amsterdam" 1 (1998) Cambridge Yearbook of European Legal Studies, 25.

[164] 18 April 2004 is the date on which the new Regulations entered into force. An approval of GM maize was granted on 19 May 2004.

[165] Past panels have considered expired measures: *see* e.g.*India-Automobiles* WT/DS146/R para 7.26; *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, Report of the Appellate Body, WT/DS33/AB/R and Corr.1, adopted 23 May 1997., para 6.2; *Indonesia – Certain Measures Affecting the Automobile Industry*, Report of the Panel, WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R, adopted 23 July 1998;.

Amicus Coalition questions whether it is possible for the complainants to have acted in good faith in assessing their challenge to be 'fruitful' within the meaning of Article 3.7 of the DSU[166] where the individuals affected by the specific *de facto* moratoria might have a right of action in the EC which they have not explored.

82. We appreciate that WTO Members themselves are not required to have exhausted local remedies before initiating WTO dispute settlement proceedings.[167] However, when exercising their 'self-regulating' judgement as to the fruitfulness of proceedings in the WTO, it seems fair and appropriate that WTO Members take account of the fact that there are legitimate review procedures that could have been initiated by the concerned individuals: under EC law, any natural or legal person may institute proceedings in the European Court of Justice against a decision (including a failure to act) of the EC institutions addressed to that person or against a decision which is of direct and individual concern to that person.[168] Far from instituting complaint proceedings in the EC, the applicants for GM product approvals voluntarily entered into an arrangement with the UK government not to proceed with the commercialisation of those GM crops until after the completion of the Farm-Scale Evaluations.[169] We question whether the applicants for GM product approvals should have initiated a complaint within the EC's own process for judicial review of administrative procedures before the complainant WTO Members could judge in good faith that the initiation of proceedings in the WTO would be fruitful.

3.1.2 Treatment of the WTO Agreements in this submission

83. The complainants have identified four WTO Agreements as having been violated by the 'measures': the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Agreement on Technical Barriers to Trade (TBT Agreement), the 1994 General Agreement on Tariffs and Trade (GATT), and the Agreement on Agriculture. Our submission is limited to the application of the SPS and TBT Agreements and the GATT.[170]

84. We recognise that, although the SPS and TBT Agreements are the more specialised Agreements when compared with the GATT, each Agreement applies separately and the interpretation of terms in one provision or Agreement should not be assumed to apply where the same term is used in another provision or Agreement.[171] Terms will be interpreted in accordance with their ordinary meaning read in their context and

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[166] On 'fruitful', *see European Communities - Bananas* Appellate Body Report, WT/DS27/AB/R, adopted 25 September 1997, DSR 1997:II, 591, para. 135; *see* also *Mexico - Anti-Dumping Investigation Of High Fructose Corn Syrup (HFCS) from the United States* Report of the Appellate Body, WT/DS132/R/AB, adopted 21 November 2001 paras 72-73. On 'good faith', note that the Appellate Body has said in the context of DSU 3.10: 'The procedural rules of WTO dispute settlement are designed to promote, not the development of litigation techniques, but simply the fair, prompt and effective resolution of trade disputes.' (*United States – Tax Treatment for "Foreign Sales Corporations"*, Report
of the Appellate Body, WT/DS108/AB/R, adopted 20 March 2000, para 166); *see* also *United States – Import Prohibition of Shrimp and Shrimp Products*, Report of the Appellate Body adopted 6 November 1998, WT/DS58/AB/R, para 158 ("*US – Shrimp*") "The chapeau of Article XX is, in fact, but one expression of the principle of good faith. This principle, at once a general principle of law and a general principle of international law, controls the exercise of rights by states. One application of this general principle, the application widely known as the doctrine of *abus de droit*, prohibits the abusive exercise of a state's rights and enjoins that whenever the assertion of a right 'impinges on the field covered by [a] treaty obligation, it must be exercised bona fide, that is to say, reasonably.'.

[167] *See* e.g. *Argentina - Measures Affecting Imports Of Footwear, Textiles, Apparel and Other Items*, Report of the Panel, November 25, 1997 para 3.246.

[168] Treaty Establishing the European Community, as amended by the Treaty of Nice signed on 26 February 2001 and entered into force on 1 February 2003, article 230, http://europa.eu.int/eur-lex/en/treaties/dat/EC_consol.pdf; *see* also Protocol on the Statute of the Court of Justice of the European Communities, 2002 OJ (C 325) 167, Article 40. This cause of action is distinguished from Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others, Case C-236/01, Judgment of the Court of 9 September 2003).

[169] See section 2.3.2(ii) above.

[170] SPS Agreement, Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7, 8, and 10.1 (Argentina only) and Annexes B(1), B(2), B(5), C(1)(a), C(1)(b), C(1)(c) (Canada and Argentina only), C(1)(d) (Argentina only) and C(1)(e); TBT Agreement, Articles 2.1, 2.2, 2.8, 2.9, 2.11, 2.12, (US and Canada only) 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.2.3 (Canada and Argentina only) 5.6, 5.8 and 12 (Argentina only); GATT Articles I:1, III:4, X:1, X:3(a) (Argentina only) and XI:1.

[171] *See European Communities - Measures Affecting the Prohibition of Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, WT/DS135/AB/R, adopted 5 April 2001 (*EC – Asbestos)* para 89, where it said that what constitutes a 'like product' for the purposes of one provision in the GATT is not necessarily the same as for another provision in the GATT or other WTO Agreements.

in light of the object and purpose of the particular Agreement.[172] Nevertheless, similar or the same terms and concepts should be read consistently with each other so as to avoid conflict.[173] In the interests of brevity, we discuss the consistency of the 'measures' with the SPS Agreement, the TBT Agreement and the GATT by grouping similar provisions in those Agreements together. We expect that the Panel will nevertheless consider them separately.

85. We respectfully submit that if the Panel limits its recommendations to the consistency of the challenged 'measures' with the SPS Agreement, those recommendations would apply only to the extent that the 'measures' serve SPS objectives to protect humans, animals, plants and territory from pests or disease, or to protect humans and animals from certain food-borne risks.[174] We submit that any recommendations made by the Panel as to the SPS consistency of the challenged 'measures' would have no impact on the measures in their fulfillment of other objectives – such as the protection of human health or safety, animal or plant life or health, or the environment from harm or risks other than those covered by the SPS Agreement, or the prevention of deceptive practices.[175]

3.2 Substantive claims

86. If the Panel finds that one or all of the categories of challenged 'measures' are subject to the SPS Agreement, the TBT Agreement and/or the GATT, we respectfully submit that the 'measures' are consistent with the relevant substantive provisions identified by the complainants in each of those Agreements. We address specific provisions in turn below.

87. From the outset, we would like to emphasise that the WTO rules recognise and uphold the right of WTO Members to establish their domestic health and environmental standards in accordance with their respective environmental and developmental conditions, needs and priorities.[176] In our view, the 'measures' are an exercise of this WTO right by the EC and its Member States. The measures are based on the precautionary principle and, as such, they are based on international standards (SPS 3.1, TBT 2.4; TBT 5.4). The precautionary principle is an international standard recognised in international agreements and instruments including the Cartagena Protocol on Biosafety and evidenced by Guidelines adopted by the *Codex Alimentarius* Commission.[177]

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[172] 1969 *Vienna Convention on the Law of Treaties*, 11 UNTS 331; 8 ILM 679 (1969) (the "Vienna Convention") is recognised as describing customary rules of interpretation of public international law for the purposes of Article 3.2 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU"). *See United States – Standards for Reformulated and Conventional Gasoline*, Report of the Appellate Body adopted 20 May 1996, WT/DS2/AB/R, pp.10-11 (*Gasoline*); *Japan – Alcoholic Beverages*, pp 6-7.

[173] *See Korea - Definitive Safeguard Measure on Imports of Certain Dairy Products*, WT/DS98/AB/R. Appellate Body Report adopted on 12 January 2000, para 81 and *Gasoline* p. 23 on 'principle of effective treaty interpretation'. *See* also *Indonesia –Automobiles* para 14.28 and *Turkey - Restrictions on Imports of Textile and Clothing Products*, WT/DS34/R, Panel Report (and Appellate Body Report) adopted on 19 November 1999, 9.92 ff, re 'presumption against conflict'.

[174] Within the meaning of SPS Annex A.1(a)-(d).

[175] *See* e.g. legitimate objectives listed in TBT Article 2.2 and categories of measures in GATT Article XX. TBT Article 1.5 states that the TBT Agreement applies exclusively of SPS measures.

[176] Marrakesh Agreement Establishing the World Trade Organisation (1994), Preamble, 1st tiret; Singapore Report of the Committee on Trade and Environment, 12 November 1996, WT/CTE/1, para. 169; Doha Ministerial Declaration, 14 November 2001, WT/MIN(01)/DEC/1, para. 6; WTO Agreement on Sanitary and Phytosanitary Measures , Preamble, and Article 2.3; WTO Agreement on Technical Barriers to Trade, Preamble 6th tiret; *US - Shrimp* paras. 185 – 186; *Gasoline*, p.30; *EC – Asbestos*, para. 168; *EC Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998 ('Hormones') para 172; *Australia – Measures Affecting Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R, adopted 6 November 1998 (*Australia – Salmon*) para. 195.

[177] CPB e.g. Article 1; *see* also Guidelines approved at *Codex Alimentarius* Commission, Twenty-sixth Session, *see* Report, ALINORM 03/41, paras 51ff and relevant Appendices ftp://ftp.fao.org/codex/alinorm03/al03_41e.pdf.

3.2.1 The "measures" are necessary to protect humans, animals and plants against, and to inform people of, any risks associated with GM products

88. As demonstrated in this section, we respectfully submit that the challenged 'measures' restrict trade only to the extent necessary to fulfill their objectives within the meaning of SPS Articles 2.2 and 5.6, TBT Articles 2.2 or 5.1.2, and GATT Article XX. In particular, the challenged measures are necessary to protect human, animal and plant life and health,[178] and to protect the environment,[179] against the risks associated with GM products, and to prevent deceptive practices through appropriate labels on GM products.[180]

(i) The objectives of the 'measures'

89. A majority of the EC Member States considered the general and specific moratoria necessary to give the EC an opportunity to develop 'a tighter, more transparent framework' for GM product approvals, 'in particular for risk assessment, having regard to the specifics of European ecosystems, monitoring and labelling', in order to positively demonstrate that GM products have 'no adverse effect on the environment and human health' and 'to restore public and market confidence'.[181] EC Member States took safeguard action in order to protect human health and the environment.[182]

90. As described in section 2.3 of the Factual Statement, scientific studies and assessments have shown that GM crops and food have the potential to harm human, animal, plant life or health and the environment. GM technology might introduce new allergens or toxins into food, and the systems for managing any health risks might prove to be inadequate.[183] From an environmental perspective, GM seed and crops might hybridise with related conventional crops or wild species thereby creating new pests in the form of herbicide-resistant weeds or causing a loss or adverse change in natural species or genetic diversity. Intensive use of herbicides and pesticides on herbicide- and pesticide- tolerant GM crops might directly harm the environment and human health. It might also cause indirect harm to wildlife, such as birds and insects, which feed on the plants and insects killed through intensive or altered patterns of herbicide and pesticide use.[184] Moreover, surveys show that EC consumers want to be informed of any risks associated with GM products, and want to be able to choose whether or not to buy or consume GM products in light of those risks.[185]

(ii) The EC has chosen a high level of protection against risks of harm

91. The EC is entitled to determine the level of protection it wants to afford its citizens and the environment from the risks associated with GM products.[186] When new scientific studies on the potential harm of GM crops and food emerged and it became apparent that the regulation of GM crops and food in the EC provided inadequate protection and information, the EC chose to ensure no or 'zero' risk of harm to its citizens and their environment by eliminating any chance of exposure to new GM products until new laws and procedures to address the inadequacies of the regulatory system were in place.

92. A majority of the EC Member States considered that the Deliberate Release Directive (90/220) and the Novel Foods Regulation failed to provide the desired 'zero risk' level of protection to EC citizens and their

[178] SPS Article 2.2, TBT Article 2.2 and GATT Article XX(b).
[179] TBT Article 2.2.
[180] TBT Article 2.2 and GATT Article XX(d).
[181] *See* 1999 Council Declarations.
[182] Article 16 of the Deliberate Release Directive (superseded by Article 23 of 2001/18) allowed safeguard measures where a Member State had 'justifiable reasons' to consider that an approved product 'constitutes a risk to human health or the environment'. Article 12 of the Novel Foods Directive allows safeguard measures where a Member State, 'as a result of new information or a reassessment of existing information, has detailed grounds' for considering that the use of an approved food or food ingredient 'endangers human health or the environment'.
[183] *See above* section 2.3.1.
[184] Ecological Society of America (2004) op cit.
[185] *See above* section 2.3.3.
[186] *See above* para 86.

environment.[187] The challenged 'measures' put a halt to any risk of harm to human, animal, plant life or health and the environment, while the EC took steps to develop alternative less trade-restrictive measures necessary to identify and manage the risks associated with GM products.

93. WTO Members are not required to rely on majority scientific opinion when taking account of risks under TBT Article 2.2 or GATT Article XX. The Appellate Body in the *Asbestos* case found that: '[i]n justifying a measure under Article XX(b) of the GATT 1994, a Member may … rely, in good faith, on scientific sources which, at that time, may represent a divergent, but qualified and respected, opinion. A Member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion.'[188]

(iii) There were no alternative less trade-restrictive measures reasonably available

94. There were no 'alternative' less trade-restrictive measures reasonably available to the EC which would have provided the EC's desired level of protection.[189] The approval procedures under the Deliberate Release Directive and the Novel Foods Regulation failed to ensure a high level of protection because their scope and approach were not adequate to address the risks.

95. As described in section 2.4 of the Factual Statement, a review and the process for amending the Deliberate Release Directive and Novel Foods Regulation revealed many deficiencies in the GM approval process, including the need to: harmonise risk assessments between Member States; improve the relevance of experimental data collected as experimental trial data on environmental risks was not meeting the requirements of risk evaluation for marketing; require assessment of direct and indirect effects on the environment; improve the quality of health safety assessments; create a monitoring and traceability system; require reevaluation after approval; improve labelling of GM products; and abandon reliance upon the concept of substantial equivalence. Until these deficiencies were addressed and amendments in force, the EC's regulatory system failed to provide the EC's desired level of high protection of human health and the environment.

(iv) Global appreciation of risks and the need to regulate GM products

96. We submit that a global appreciation of the risks associated with GM products supports a finding that the challenged measures were 'necessary' to fulfill their objectives.[190] The more 'vital and important' the 'common interests or values' represented by a measure's objective, the easier it will be to accept the measure as 'necessary'.[191] A global appreciation of the risks associated with GM technology, and the need for appropriate regulation to guard against the risks, is evidenced by the international efforts to agree rules and implement national strategies to avoid harm to people and the environment from genetically modified organisms (GMOs) and GM products.

97. As described in section 2.5 of the Factual Statement, the international community has been actively engaged in the process of negotiating rules and standards regulating GMOs and GM products since at least 1992.

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[187] See 1999 Council Declarations. To the extent that they reflect the objective of the 'measures', *see* Revised Deliberate Release Directive, Articles 1 (Objective), and 4 (General Obligations) which states that: 'Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs.'; *See* also GM Food and Feed Regulation Article 1 (Objective) which states its objective as being to 'provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed' and Labelling and Traceability Regulation Article 1 (Objective) which states its objective as being to facilitate 'accurate labelling, monitoring the effects on the environment and, where appropriate, on health'.

[188] *EC – Asbestos* para 178.

[189] SPS Article 5.6. *See* further *EC – Asbestos; Korea – Measures Affecting Imports of Fresh, Chilled, and Frozen Beef*, Report of the Appellate Body, WT/DS161/AB/R, WT/DS169/AB/R, adopted 10 January 2001; , *United States – Section 337 of the Tariff Act of 1930*, Report of the Panel, BISD 36S/345, adopted 7 November 1989.

[190] *See e.g. US – Shrimp* reference to CITES and other international agreements, paras 130ff.

[191] *Korea – Beef* para 164; *Asbestos* para 172.

With nearly 100 Parties, the Cartagena Protocol on Biosafety (CPB) regulating the cross-border movement of GMOs (or 'living modified organisms) is significant testament to the international consensus on the need to regulate to protect biological diversity, and health. Efforts to develop appropriate rules and procedures under the International Plant Protection Convention, and by the *Codex Alimentarius* Commission – both recognised as international standard-making bodies under the SPS Agreement – are further evidence that the protection of human health and the environment from risks associated with GM products are common values shared by WTO Members.

3.2.2 Risk assessment, provisional measures and precaution

98. The precautionary principle – recognised in many international agreements and instruments – warrants measures aimed at preventing irreversible environmental damage even in the absence of full scientific certainty as to the risk of damage.[192] As noted above in paragraph 86, the precautionary principle is recognised in the Cartagena Protocol on Biosafety, and is evidenced by instruments and guidelines adopted by international organisations such as the *Codex Alimentarius* Commission – an organisation whose standards are expressly recognised in the SPS Agreement.[193] We respectfully submit that the precautionary principle is an international standard and is relevant to the Panel's analysis of those provisions in the WTO Agreements concerning risk, including SPS Articles 2 and 5, TBT Articles 2.1 and 2.2 and GATT Articles III and XX.

99. In the past, the Appellate Body has acknowledged the overall relevance of the precautionary principle in the SPS Agreement, confirming that an analysis of the SPS requirement concerning sufficient scientific evidence in SPS Article 2.2 should 'bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned.'[194] Moreover, 'responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources.'[195] An assessment of risk, the Appellate Body has said, must evaluate 'not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.'[196]

100. In addition to international agreements and instruments, the EC, its Member States and other WTO Members apply the precautionary principle in their decision-making. Many EC laws and policies concerned with health and environmental protection adhere to the precautionary principle,[197] including, for example, the Revised Deliberate Release Directive.[198] The UK's 2003 Science Review Panel observed that 'precaution appears as an inherently scientific response to challenges of uncertainty, ambiguity and gaps in knowledge: by providing practical guidance to the types of information that might best inform decision making and the most effective ways to gather this information.'[199] Similarly, the Royal Society of Canada recommended in 2001 that Canadian regulators abide by 'the precautionary regulatory assumption that, in general, new

[192] Principle 15, Rio Declaration On Environment And Development, Report of the United Nations Conference on the Human Environment, Stockholm, 5-16 June 1972. *See also* CPB, Articles 10 and 11, Communication from the Commission on the precautionary principle, COM(2000) 1 final, 2 February 200; GM Science Review Panel First report. P 46; National Research Council (1996) Understanding Risk. Informing decisions in a democratic society. National Academy Press: Washington, DC.
[193] SPS Annex A.3.
[194] *Hormones* para 124.
[195] *Hormones* para 194.
[196] *Hormones* para 187; *see* also ESTO (1999) On 'Science' and 'Precaution' in the Management of Technological Risk. European Science and Technology Observatory (A. Stirling, Ed), report to the EU Forward Studies Unit, IPTS, Sevilla, EUR19056 EN. http://esto.jrc.es/detailshort.cfm?ID_report=289; National Research Council (1996) Understanding Risk. Informing decisions in a democratic society. National Academy Press: Washington, DC.
[197] *See* Communication from the Commission on the precautionary principle, COM(2000) 1 final, 2 February 2000.
[198] Article 1 (Objective).
[199] GM Science Review Panel First report (2003) *op cit.* p 46.

technologies should not be presumed safe unless there is a reliable scientific basis for considering them safe.'[200]

(i) The 'measures' are based on a risk assessment

101. As demonstrated in this section, we submit that the challenged 'measures' are based on scientific principles and have not been maintained without sufficient scientific evidence within the meaning of SPS Article 2.2. In particular, there is a 'rational relationship' between the measures and the assessment of risks to human, animal or plant life or health, for the purposes of SPS Article 5.1.[201] In the past, the Appellate Body has concluded that a WTO Member need not carry out its own risk assessment: an SPS measure, the Appellate Body said, 'might well find its objective justification in a risk assessment carried out by another Member, or an international organization.'[202] However, scientific studies forming the basis of a risk assessment must address the particular risk at stake, and not a general risk.[203] The Appellate Body has also found that a risk assessment is not required to establish a certain magnitude or threshold level of risk: the risk assessment is qualitative, not quantitative.[204]

102. Many scientific studies from qualified and respected sources show the potential for harmful effects of GM products on the environment. There are differences in opinion on what constitutes 'irreversible harm' depending on specific physical, cultural and social conditions, and on the likelihood of harm occurring or its effects. Nevertheless, the risk of harm is real, and not merely theoretical.[205] Sections 2.3 and 2.4 of the Factual Statement describe scientific studies identifying potential harm to human health and the environment from GM products, with several studies emerging in the late 1990s to the present.

103. For example, the potential for unintended impacts on other food constituents as a result of the use of GM led experts to emphasise in 1999 that any GM foods which have altered nutritional status will have to be subject to more stringent testing than the current generation of GM foods.[206] Research published in 1999 suggested that the consumption of GM potatoes could impair growth and damage the immune system of rats.[207] Scientific studies from 1998 to 1999 of environmental impacts such as gene flow,[208] and effects on non-target species,[209] revealed that harm to the environment was possible. Moreover, in Europe, scientists considered that the potential for significant adverse indirect effects on biodiversity of GM crops was great because of the importance of agricultural land in maintaining biodiversity – parts of Europe have very limited wilderness areas for conservation of biodiversity.[210]

104. Many international scientific bodies and institutions have reviewed the environmental and health aspects of GMOs. None has said there are no risks and all point to the need for risk assessment and monitoring. Many have also highlighted the need for further research and detailed the range of scientific opinion that exists. None contradict or undermine the approach taken by Europe. For example, the International Council for Science has reviewed the science relating to GMOs and identified areas of scientific convergence,

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[200] Elements of precaution: recommendations for the regulation of food biotechnology in Canada. The Royal Society of Canada, January 2001 Executive Summary.
[201] *Hormones* para 193.
[202] *Hormones* para 190.
[203] *Hormones* para 200.
[204] *Hormones* para 186; *Australia – Salmon,* para 124.
[205] *See ibid*.
[206] Kuiper, HA *et al* (1999). Commentary: Adequacy of methods for testing the safety of genetically modified foods. The Lancet 354: 9187.
[207] Ewan, S.W.B. & Pusztai, A. (1999) Effect of diets containing genetically modified potatoes expressing *Galanthus nivalis* lectin on rat small intestine. The Lancet 354: 1353-1354.
[208] *See* section 2.3.2.
[209] Hilbeck, A. *et al* (1998) Effects of transgenic Bt corn-fed prey on mortality and development time of immature *Crysoperla carnea.* Environmental Entomology 27:480-487; Hilbeck, A *et al* (1998) Toxicity of Bt Cry1 Ab toxin to the predator *Crysoperla carnea* (Neuroptera. Chrysopidae) Biological Control 27:1-9 Hilbeck, A *et al* (1999) Prey-mediated effects of Cry1Ab toxin and protoxin and Cry2A protoxin on the predator *Crysoperla carnea*. Entomologia Experimentalis et Applicata 91: 305-316.
[210] Genetically Modified Organisms. English Nature's view, 1999. http://www.english-nature.org/news/story/asp?ID=85

divergence and where more research is needed.[211] The WHO has described the risk of outcrossing as 'real' in the light of the Starlink episode in the US, and described the EC revision of its regulations as in response to 'legitimate' concerns.[212] The FAO's expert consultation on environmental impacts of GM crops highlighted the lack of knowledge about risks, particularly in relation to the prediction of long-term impacts of gene flow, agricultural inputs and indirect effects.[213]

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105. Although the EC is entitled to rely on divergent scientific opinion,[214] there are no scientific studies that contradict those that have demonstrated the potential for harmful effects of GM products. Any scientific uncertainty surrounding the risks associated with GM products stems from a lack of scientific evidence that positively rules out the likelihood or potential for harm to human health or the environment from GM technology. Faced with evidence of the potential for irreversible harm to the environment, it is appropriate for the EC to have acted with 'prudence and precaution' in halting approvals of GM products.[215] It was equally prudent, in the face of evidence of inadequacy in existing risk assessment systems, for EC Member States to take additional action and ban approved GM products on the basis of their particular national conditions and need to protect human, animal and plant health.

106. For all the reasons discussed in detail in section 2.4 of the Factual Statement, a majority of EC Member States considered risk assessment procedures conducted under the Deliberate Release Directive and the Novel Foods Regulation to be inadequate in their assessment of risks. In those circumstances, they were entitled to disregard the risk assessment undertaken by the EC Scientific Committees under the GM approval process existing at that time and base their measures on other scientific studies.

(ii) Alternatively, the 'measures' are provisional and based on available pertinent information

107. Alternatively, we respectfully submit that the scientific evidence is insufficient and that the challenged 'measures' are provisional and based on available pertinent information. We further submit that the EC has continued to seek additional information and has been reviewing the 'measures' within a reasonable time within the meaning of SPS Articles 2.2 and 5.7.

108. The scientific evidence that currently exists has not allowed adequate assessments of the risks associated with GM products. There is no scientific evidence that positively demonstrates that GM products are safe for human health and the environment.[216] The Cartagena Protocol on Biosafety and the *Codex Alimentarius* Commission Guidelines set out international standards for the assessment of risks associated with certain GMOs and GM products, attesting to the international consensus that appropriate and adequate assessments of risks are necessary on a case-by-case basis.

109. The challenged 'measures' are provisional. A majority of EC Member States indicated that they would halt GM approvals until the EC developed a system of GM product approvals that guaranteed necessary protection of human health and the environment.[217] The measures are based on available pertinent information in the form of scientific studies and information generated through independent research, and in international fora such as under the Convention on Biological Diversity, CPB, IPPC and in the *Codex Alimentarius* Commission, as set out in sections 2.3 and 2.5 of the Factual Statement.

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[211] International Council for Science (2003) New Genetics, Food and Agriculture:
Scientific Discoveries – Societal Dilemmas.
http://www.icsu.org//Gestion/img/ICSU_DOC_DOWNLOAD/91_DD_FILE_GMO_Exec%20Summary.pdf
[212] WHO (World Health Organization).(2002). 20 questions on genetically modified (GM) foods
http://www.who.int/foodsafety/publications/biotech/en/20questions_en.pdf
[213] Report of the FAO Expert Consultation on Environmental Effects of Genetically Modified Crops. Rome, Italy, 16-18 June 2003.
ftp://ftp.fao.org/docrep/fao/field/006/ad690e/ad690e00.pdf
[214] *Hormones* para 194.
[215] *Hormones* para 124.
[216] *See* section 2.3 of the Factual Statement.
[217] *See* 1999 Council Declarations and other statements cited in the US First Submission.

110. The EC has continued to seek additional information about the risks of GM products to human health and the environment. This has included the Farm-Scale Evaluations in the UK, where the biotechnology industry agreed that such studies were needed if an informed decision was to be made. As well as those studies already referred to in section 2.3 above, other research included studies on gene flow and the implications for co-existence,[218] impacts on non-target species, horizontal gene flow, human and animal safety,[219] and the development of improved techniques to determine the safety of GM foods.[220]

111. The time taken since 1998 to further assess the risks and develop appropriate regulatory controls – including the amendment to the Deliberate Release Directive and the Regulations on GM Food and Feed, and Traceability and Labelling – is a reasonable time frame within which to review the challenged 'measures'. To review regulations in a complex area of risk such as GMOs takes considerable time. This is particularly true when rules are intended to apply across a whole region, which now includes 25 countries. As a union of different sovereign states, the EC is a unique WTO Member with a complex decision-making procedures which should be taken into account in assessing the 'reasonableness' of the time taken to review its regulation of GM products. As described in section 2.4.1, the legislative procedure for the regulatory review was that of 'co-decision' between the Council of Ministers and the European Parliament, where both institutions are co-legislators on an equal footing. The Revised Deliberate Release Directive went through three stages: two readings by the European Parliament and a final round of meetings of the Conciliation Committee to reach final agreement.

112. The time taken by the EC to review its regulatory framework for GM approvals is not excessive when compared with international efforts to develop rules and standards governing GM products. For example, the CPB took over 4 years to negotiate and conclude. Gaining agreement on Codex's guidelines on GM food safety took 4 years and the guidelines on labelling are still not agreed after some 5 years discussion. Even individual GMO risk assessments can take years rather than days. For example, the US assessement of an application from Syngenta to deregulate a herbicide tolerant and insect resistant maize, (APHIS petition number 01-331-01p) remains undecided after more than 2 years. Five of the last six crops to be deregulated in the US have taken over 500 days.[221]

3.2.3 Discrimination

113. As demonstrated in this section, we submit that the challenged 'measures' do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, or constitute a disguised restriction on international trade (SPS Article 2.3; GATT Article XX). In particular, a comparison of the challenged measures and the EC's regulation of GM processing aids, or novel non-GM crops or food derived from novel non-GM crops, does not show an arbitrary or unjustifiable distinction in levels of protection in different situations which amount to discrimination or a disguised restriction on trade (SPS Article 5.5).[222] We also submit that GM crops and products are not 'like' their conventional counterparts (TBT Article 2.1 and GATT Article III).

(i) No arbitrary or unjustifiable distinctions in levels of protection

114. To the extent that there are distinctions in levels of protection afforded to GM products and GM processing aids, these are neither arbitrary no unjustifiable. 'Biotech processing aids' are enzymes or other chemicals produced by and extracted from genetically modified micro-organisms (GMMs) grown in a

[218] European Communities Joint Research Centre (2002) Scenarios for genetically modified, conventional and organic crops in European agriculture.
[219] E.g. Duggan PS, et al (2000) Survival of free DNA encoding antibiotic resistance from transgenic maize and the transformation activity of DNA in ovine saliva, ovine rumen fluid and silage effluent. *FEMS Microbiology Letter*s, 191, 71-77. Duggan PS, et al (2003) Fate of genetically modified maize DNA in the oral cavity and rumen of sheep. *British J Nutritio*n, 89, 159-166.
[220] Kuiper H. A., *et al* (2003) Exploitation of molecular profiling techniques for GM food safety assessment. *Current Opinion in Biotechnology*, 14, 238-243.
[221] *See* Information Systems for Biotechnology, Virginia Tech. Database on GMO commercialisation: http://www.nbiap.vt.edu/
[222] *See Australia – Salmon* para. 252 re relationship between Article 2.3 and 5.5.

fermentation vessel in a factory (such as chymosin, for use in cheese making, or enzymes used in bread production). The use of GMOs to produce 'biotech processing aids' is subject to regulation in the EC under the Directive 98/81 on the contained use of GMMs.[223] This Contained Use Directive concerns the environmental and human safety aspects of using GMMs in laboratories and industrial facilities including those manufacturing 'biotech processing aids'. The use of GMMs is subjected to a risk assessment under a Directive which was revised during the period 1996 to 1998 and implemented in 2000. The distinction that has been drawn in the EC between biotech processing aids and GM crops and food relates to the fact that the production of a biotech processing aids does not involve the intentional release of a GMO into the environment.

115. To the extent that there are distinctions in levels of protection afforded to novel non-GM crops or food derived from novel non-GM crops and GM crops and food, these are neither arbitrary nor unjustifiable. As described in paragraph 9, genetic modification may incorporate genetic material from a much wider range of biological sources, raising the possibility of new and unforeseen consequences. The effects of these may vary according to the local environment and farming system. Furthermore, genetic modification allows the same gene constructs to be introduced into a variety of different crop types, which is not achievable by other crop breeding methods. Transferring biochemical pathways or the means to produce a novel protein from one kingdom to another (e.g. animal, human, or viral to plant such as the *Bt* toxin gene from a bacterium to plants) is not possible through non-GM methods and raises complex questions about potential impact, particularly if these techniques become widely used and the organisms multiplied on a large, commercial scale. There is no evolutionary precedence for such organisms. There are no data upon which to base an assumption that GM plants will behave in a similar way to changes induced by other methods – they may or may not. The advent of genetic modification heralds the introduction of completely new mechanisms of disease control, insect resistance and herbicide tolerance, not only into crop species but most likely, over time, into related wild species.[224]

116. Having concluded that there is no arbitrary or unjustifiable distinction in levels of protection, it would be unnecessary for the Panel to consider whether the measures discriminate or amount to a disguised restriction on trade.[225]

(ii) GM crops and products are not 'like' their conventional counterparts

117. GM crops and food are not 'like' their conventional counterparts for the purposes of TBT Article 2.1 and GATT Article III. The four GATT criteria typically used for assessing whether products are 'like' each other ((1) physical characteristics, (2) end-uses, (3) consumers' tastes and habits and (4) customs tariff classifications)[226] must be considered as part of a case-by-case assessment of each measure,[227] taking all of the evidence into account[228] – including evidence relating to the health risks associated with a product.[229]

118. GM and non-GM crops have different physical characteristics. The physical differences between GM and non-GM crops are not minor. Although the difference at a genetic level may be small, the impact on the final crop is large. GM herbicide tolerant crops are no longer killed by the application of a particular

[223] Directive 98/81, of 26 October 1998, amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms, OJ L 330, of 5 December 1998 ('Contained Use Directive').
[224] See GeneWatch UK Briefing No 21. 'Genetic modification: the need for special regulation' January 2003; GeneWatch UK: Tideswell; and references therein. http://www.genewatch.org/Publications/Briefs/brief21.pdf
[225] *See Australia – Salmon* para 194 re all parts of 3-prong test are cumulative and all must be shown by the complainant.
[226] *See* e.g. *EC – Asbestos* para 101; *Japan –Alcoholic Beverages.*
[227] *See Report of the Working Party on Border Tax Adjustments*, adopted on 2 December 1970, BISD 18S/97; *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, para 5.6. Report of the Panel adopted on 10 November 1987, BISD 34S/83; United States – Measures Affecting Alcoholic and Malt Beverages, Report of the Panel, adopted 19 June 1992, BISD 39S/206, para 5.24; *Japan – Alcoholic Beverages*, p.14; and *EC – Asbestos* para 101.
[228] *EC – Asbestos* paras 102, 109, 113. A finding under the first criterion that the characteristics of a product are different places a higher burden of 'likeness' on the remaining three criteria, *see* paras 109 and 118.
[229] *EC – Asbestos* para 113 'We are very much of the view that evidence relating to the health risks associated with a product may be pertinent in an examination of "likeness"'. *See also* para 128.

chemical herbicide because the genetic modification leads to an alteration in the basic biochemical properties of the crop rendering it tolerant to the damaging effects of the herbicide. GM insect resistant crops produce an entirely novel chemical, *Bt* toxin, which is not produced naturally in any plant and is lethal to certain insect pests feeding on the crop. There may be adverse effects on human health or the environment of genetic modifications of crops which vary according to local circumstances. Evidence, such as that from the FSEs, shows that the potential for adverse effects from GM herbicide tolerant crops is not theoretical. Comparable evidence of equal quality is lacking for other GM crop types[230].

119. The food and feed produced from GM crops often has different characteristics from that derived from a conventional crop. It is likely to contain the protein produced by the inserted gene, for example the *Bt* toxin in the case of insect resistant crops or the protein leading to herbicide tolerance. Whether these proteins, or others that may be produced as unintended effects of the GM process are toxic or allergenic is an important question in risk assessment. However, the limitations in detecting unintended changes, allergenicity and toxicity,[231] mean definitive answers about safety are not available.

120. In terms of their end-uses, GM crops and GM food are not treated interchangeably with non-GM crops and non-GM food in the market. As a result of genetic modification, GM crops are managed by the farmer in an entirely different manner from non-GM crops. For GM herbicide tolerant crops, a herbicide can be sprayed over the entire crop which would previously have killed it. GM insect resistant crops no longer need some insecticide sprays. Organic production does not allow for the use of GM methods.[232] Food producers using conventional crops have established identity preservation and other systems to avoid GM ingredients in the final product because they have recognised that their customers to not want to buy it.[233]

121. Consumers distinguish between GM food and non-GM food in their tastes and preferences. As described in section 2.3.3 of the Factual Statement, an overwhelming majority of consumers surveyed in the EC consistently support labelling of GM products. In the 2001 Eurobarometer survey, 94.6% of people wanted to have the right to choice in relation to GM food.[234] Other surveys have given consistently similar results.[235]

3.3 Procedural matters

3.3.1 Transparency

122. We respectfully submit that the 'measures' were published in accordance with SPS Article 7 and Annex B.1, TBT Articles 2.9, 2.10 or 2.11 and GATT Article X.1. The EC's general moratorium was published in declarations made in and recorded by the EC's Environment Council and was the subject of numerous public statements cited by the complainants.[236] The EC's general and specific moratoria were the subject of

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[230] Squire, G.R. *et al* (2003) On the rationale and interpretation of the Farm Scale Evaluations of genetically modified herbicide-tolerant crops. Philosophical Transactions of the Royal Society of London B 358:1779-1799.
[231] *See above* sections 2.1 and 2.3.1.
[232] Council Regulation (EC) No 1804/1999 of 19 July 1999 supplementing Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs to include livestock production (OJ L 222, 24.8.1999, p. 1)
[233] LMC International (2003) Supply chain impacts of further regulation of products consisting of, containing, or derived from, genetically modified organisms. Prepared for DEFRA and FSE. www.defra.gov.uk/environment/gm/resrearch/epg-1-5-212.htm; e.g: The Guardian, 'Shops' unlikely to stock GM', 16 July 2003: "Richard Ali, director of food policy at the British Retail Consortium, said: "Our position remains unchanged. We are neutral on GM technology. But we provide what customers demand and they do not want GM food." […]. The communications director for Safeway, Kevin Hawkins, said: "I think it's very difficult to see what will move public opinion. We have certainly seen no change in what people think about GM." Kate O'Sullivan of Sainsbury's said: "Customers have made it clear they do not want GM ingredients." Tesco and Asda also said they had seen no radical change in public attitude. *See* also: "Where supermarkets stand on GM food," BBC on-line, 21 October 2003. (http://news.bbc.co.uk/1/hi/uk/3211510.stm).
[234] *See* http://europa.eu.int/comm/research/press/2001/pr0612en-results.pdf
[235] *See* e.g Guardian/ICM Poll, 1998: The Guardian June 4th 1998 'Gene genie' – 95% wanted labelling; Consumers' Association, 2002; 94% want labelling. Consumer survey finds 94 percent want GM foods clearly labelled. Daily Telegraph 4th June 2002.
[236] *See* First US Submission.

extensive discussion in meetings of the WTO.[237] If the Panel applies a broad interpretation to the types of 'measures' that can be the subject of a WTO challenge and assessed for compliance with the WTO Agreements, it must also take a broad interpretation of what constitutes 'publication' for the purposes of WTO rules.[238]

3.3.2 Fairness - undue delay

123. We respectfully submit that there was no 'undue delay' in the administration of the measures for the purposes of SPS 8 and Annex C; TBT 5.2; GATT X.3(a).[239] As described in section 3.3.2(ii) in the context of SPS Article 5.7, the time taken since 1998 to further assess the risks and develop appropriate regulatory controls is a reasonable time frame within which to review the challenged 'measures'. The time taken by the EC to review its regulatory framework for GM approvals is not remarkable when compared with international efforts to develop rules and standards governing GM products.

124. The time period must also be evaluated in light of the nature of the EC as entity of a quasi-federal nature, where competences in relation to the regulation of biotechnology are shared between the Member States and the Community, and where the process of harmonization of different Member State regulatory approaches is governed by norms of comity and complex administrative and political procedures and practices. While the internal constitutional structure of the EC does not limit its state responsibility under WTO law as such, it is relevant to the assessment of whether the time periods in question can be considered as "undue delay".

Respectfully submitted by:

Alice Palmer
Programme Director, FIELD

On behalf of the following coalition of organisations: GeneWatch UK; Foundation for International Environmental Law and Development (FIELD); Five Year Freeze; Royal Society for the Protection of Birds (RSPB); The Center for Food Safety; Council of Canadians; Polaris Institute; Grupo de Reflexión Rural Argentina; Center for Human Rights and the Environment (CEDHA); Gene Campaign; Forum for Biotechnology and Food Security; Fundación Sociedades Sustentables; Greenpeace International; Californians for GE-Free Agriculture; International Forum on Globalisation.

[237] *See* e.g. discussions in meetings of the SPS Committee (G/SPS/R/26, para. 35; G/SPS/R//27, para. 56) and the TBT Committee (G/TBT/M/26-28).
[238] Re publication requirements in context of Art 63 TRIPS, *see India - Patent Protection for Pharmaceutical and Agricultural Chemical Products* DS/50/R, adopted (with Appellate Body Report) 16 January 1998, para 6.10, citing *European Economic Community - Restrictions on Imports of Apples, Complaint by the United States*, adopted on 22 June 1989, BISD 36S/135, paras. 5.20 and 5.23.
[239] *See Japan – Semi-Conductors* para. 119 ff. See generally *EC - Bananas*; *European Communities - Measures Affecting the Importation of Certain Poultry Products* WT/DS69/R and WT/DS69/R/AB ; and *Japan – Sunset.*