



EU Food Safety law as a major barrier to developing country exports Regulatory problems and possibilities

Broberg, Morten

Publication date:
2009

Document version
Publisher's PDF, also known as Version of record

Citation for published version (APA):
Broberg, M. (2009). *EU Food Safety law as a major barrier to developing country exports: Regulatory problems and possibilities*. Institut for Internationale Studier / Dansk Center for Internationale Studier og Menneskerettigheder. <http://www.diiis.dk/node/1521>



European Food Safety Regulation and the Developing Countries

Regulatory problems and possibilities

Morten Broberg

DIIS Working Paper 2009:09

WORKING PAPER

MORTEN BROBERG

Consulting Senior Researcher, Danish Institute for International Studies
Associate Professor in International Development Law, University of Copenhagen.
E-mail: mbr@diis.dk

The author is grateful for comments provided by Dr. Laura Nielsen, assistant professor in WTO Law, University of Copenhagen. The usual waiver applies.

DIIS WORKING PAPER 2009:09

© Copenhagen 2009
Danish Institute for International Studies, DIIS
Strandgade 56, DK-1401 Copenhagen, Denmark
Ph: +45 32 69 87 87
Fax: +45 32 69 87 00
E-mail: diis@diis.dk
Web: www.diis.dk

Cover Design: Carsten Schiøler
Layout: Anine Kristensen
Printed in Denmark by Vesterkopi as

ISBN: 978-87-7605-325-3
Price: DKK 25.00 (VAT included)

DIIS publications can be downloaded
free of charge from www.diis.dk

DIIS Working Paper sub-series on Standards and Agro-Food Exports (SAFE)

This working paper sub-series includes papers generated in relation to the research and capacity building programme 'Standards and Agro-Food Exports: Identifying Challenges and Outcomes for Developing Countries' (SAFE). The project, running from 2005 to 2010, is funded by the Danish Development Research Council and is carried out jointly by the Danish Institute for International Studies (DIIS) and the Department of Agricultural Economics and Agri-business at Sokoine University, Tanzania.

The SAFE sub-series is cross-listed with publications from the Trade Law Centre for Southern Africa (TRALAC), based at the University of Stellenbosch, South Africa. The papers are available at: www.diis.dk and www.tralac.org

List of available papers:

1. Ponte, S. (2005) 'Bans, Tests and Alchemy: Food Safety Standards and the Ugandan Fish Export Industry', *DIIS Working Paper 2005:19*. Copenhagen: Danish Institute for International Studies.
2. Grant, C. (2005) 'Geographical Indications: Implications for Africa', *TRALAC Trade Brief 6/2005*. Stellenbosch: Trade Law Centre for Southern Africa
3. Brückner, G.K. (2005) 'Sanitary Standards for sub-Saharan Africa's International Trade in Animal and Animal Products', *TRALAC Working Paper 6/2005*. Stellenbosch: Trade Law Centre for Southern Africa.
4. Ponte, S. (2006) 'Ecolabels and Fish Trade: Marine Stewardship Council Certification and the South African Hake Industry'. *TRALAC Working Paper 9/2006*. Stellenbosch: Trade Law Centre for Southern Africa.
5. Gibbon, P. (with O. Memedovic) (2006) 'Decoding Organic Standard-Setting and Regulation in Europe', *UNIDO Working Paper*, Vienna: UNIDO.
6. Gibbon, P. (2006) 'An Overview of the Certified Organic Export Sector in Uganda', *DIIS Working Paper 2006:13*. Copenhagen: Danish Institute for International Studies.
7. Gibbon, P. & S. Bolwig (2007) 'The Economics of Certified Organic Farming in Tropical Africa: A Preliminary Assessment', *DIIS Working Paper 2007:3*. Copenhagen: Danish Institute for International Studies.
8. Akyoo, A. & E. Lazaro (2007) 'The Spice Industry in Tanzania: General Profile, Supply Chain Structure, and Food Standards Compliance Issues', *DIIS Working Paper 2007:8* Copenhagen: Danish Institute for International Studies.
9. Riisgaard, L. (2007) 'What's in it for labour? Private Social Standards in the Cut Flower Industries of Kenya and Tanzania', *DIIS Working Paper 2007:16* Copenhagen: Danish Institute for International Studies.
10. Gibbon, P. & S. Bolwig (2007) 'The Economic Impact of a Ban on Imports of Air Freight Organic Products to the UK', *DIIS Working Paper 2007:23* Copenhagen: Danish Institute for International Studies.
11. Ponte, S. & J. Ewert (2007) 'South African Wine – An Industry in Ferment', *TRALAC Working Paper 8/2007*. Stellenbosch: Trade Law Centre for Southern Africa.
12. Ponte, S. (2007) 'Governance in the Value Chain for South African Wine', *TRALAC Working Paper 9/2007*. Stellenbosch: Trade Law Centre for Southern Africa.
13. Kadigi, R.M.J. et al. (2007) 'Effects of Food Safety Standards on The Livelihoods of Actors in the Nile Perch Value Chain in Tanzania', *DIIS Working Paper 2007:24* Copenhagen: Danish Institute for International Studies.
14. Lazaro, E.A., J. Makandara & F.T.M. Kilima (2008) 'Sustainability Standards and Coffee Exports from Tanzania', *DIIS Working Paper 2008:1* Copenhagen: Danish Institute for International Studies.
15. Riisgaard, L., & N. Hammer (2008) 'Organised Labour and the Social Regulation of Global Value Chains', *DIIS Working Paper 2008:9* Copenhagen: Danish Institute for International Studies.
16. Akyoo, A., & E. Lazaro (2008) 'Institutional Capacity for Standards Conformity Assessment: A Case Study on Spices in Tanzania', *DIIS Working Paper 2008:10* Copenhagen: Danish Institute for International Studies.

17. Bolwig, S., S. Ponte, A. du Toit, L. Riisgaard & N. Halberg (2008) 'Integrating Poverty, Gender and Environmental Concerns into Value Chain Analysis. A Conceptual Framework and Lessons for Action Research', *DIIS Working Paper 2008:16* Copenhagen: Danish Institute for International Studies.
18. Riisgaard, L., S. Bolwig, F. Matose, S. Ponte, A. du Toit & N. Halberg (2008) 'A Toolbox for Action Research with Small Producers in Value Chains', *DIIS Working Paper 2008:17* Copenhagen: Danish Institute for International Studies.
19. Riisgaard, L. (2008) 'Localizing Private Social Standards: Standard Initiatives in Kenya Cut Flowers' *DIIS Working Paper 2008:20* Copenhagen: Danish Institute for International Studies.
20. Akyoo, A., E. Lazaro (2008) 'An Accounting Method-Based Cost-Benefit Analysis of Conformity to Certified Organic Standards for Species in Tanzania', *DIIS Working Paper 2008:30* Copenhagen: Danish Institute for International Studies.
21. Gibbon, P., Y. Lin & S. Jones (2009). 'Revenue effects of Participation in Smallholder Organic Cocoa Production in Tropical Africa: A Case Study', *DIIS Working Paper 2009:06* Copenhagen: Danish Institute for International Studies.
22. Riisgaard, L. (2009) 'How the Market for Standards Shapes Competition in the Market for Goods: Sustainability Standards in the Cut Flower Industry', *DIIS Working Paper 2009:07* Copenhagen: Danish Institute for International Studies.
23. Broberg, M. (2009) 'European Food Safety Regulation and the Developing Countries Regulatory Problems and Possibilities', *DIIS Working Paper 2009:09* Copenhagen: Danish Institute for International Studies.

CONTENTS

Abstract	2
1. Objective	3
2. The European Community's Food Safety Regime	4
2.1. Development of EU Food Safety Regulation	4
2.2. Implementation	5
2.3. Control and enforcement	5
3. Identifying the Barriers	7
3.1. Overview – treatment of food imports under the EU food safety regime	7
3.2. Composition of Food – Setting the Limit Values	7
3.3. Process Requirements	11
3.4. Authorisation Requirements	17
3.5. Control Requirements	20
3.6. The Role of Private Standards	23
4. Overcoming the Barriers	25
4.1. Outline	25
4.2. Dismissing the barriers	25
4.3. Lowering the barriers	29
4.4. Surmounting the barriers	30
5. Perspectives for the future and Recommendations for improvements	32
5.1. Food safety will continue to be a challenge	32
5.2. A need for increased coordination, communication and cooperation	34
5.3. What specific action may be taken – two immodest suggestions	35
6. Findings	36
References	39

ABSTRACT

This paper examines the European Community's food safety regime in order to identify those legal measures that cause the most problems for developing countries' exporters of food products and to point to possible solutions. It is shown that barriers may arise due to an array of requirements, some of which may appear to be rather minor legal amendments, such as changing a sampling plan. There is no easy solution to this problem, but three specific measures are proposed: Firstly, improved harmonisation of food safety measures in the industrialised countries. Secondly, when proposing new food safety measures the European Commission should identify the proposal's likely consequences on developing countries – and should explain how alternative measures will affect both food safety and the developing countries. And lastly, the European Community should strengthen its provision of development assistance to enable the developing countries to comply with the food safety standards.

I. OBJECTIVE

A large number of developing countries are highly dependent upon exports of agricultural products, and for many of these countries the European Community is the primary export market. However, for decades the European Community's market for agricultural products was protected by high tariff barriers. These barriers were vigorously criticised; not least due to their adverse effects on developing countries' exports to the Community. Today the tariff barriers have been largely dismantled, but in their place a regime of stringent food safety requirements has been formed so that food producers in the developing countries are now faced with a technical barrier when exporting to the European Community and other parts of the industrialised world. Indeed, it has been argued that food safety requirements rank as one of the foremost issues affecting exports of agricultural and food products from developing countries¹ and a survey of low and middle income countries has shown that the market for which SPS requirements are considered to be the most significant impediment to trade is the European Community.² As an illustration of the importance of food safety measures, it has been estimated that by participating in and implementing acceptable international rules, Africa could gain up US\$ 1 billion a year from higher exports of nuts, dried fruits, and other agricultural commodities.³

1 S.J. Henson, R.J. Loader, A. Swinbank, M. Bredahl, and N. Lux, "Impact of sanitary and phytosanitary measures on developing countries", The University of Reading, Department of Agricultural and Food Economics, Centre for Food Economics Research (CeFER), 2000, www.reading.ac.uk/nms/runtime/saveasdialog.asp?IID=17696&slID=72895, at p. 77.

2 Henson et al, *supra* note 1, at p. 33.

For a continent as poor as Africa, a gain of this size may have a significant positive impact on very many Africans' lives.

This working paper provides a legal analysis of some important aspects of the European Community's food safety regime and its consequences for the developing countries. The objective is twofold, namely to identify those legal measures that cause the most problems for developing countries exporters of food products and to point to possible solutions.

Below, in section 2, the working paper first provides an outline of the European Community's food safety regime. Next, in section 3, those barriers to imports of developing countries food stuffs that are created by the food safety regime are identified. In section 4 the working paper goes on to examine different ways of overcoming the barriers. In section 5 the perspectives for the future are considered and recommendations for improvements are put forward. Finally section 6 rounds off the working paper by recapitulating the main findings.

3 John S. Wilson and Victor O. Abiola, "Introduction" in "Standards & Global Trade – A Voice for Africa" (John S. Wilson and Victor O. Abiola, eds), The World Bank, Washington DC, 2003, pp. xxv-liv at p. xxx.

2. THE EUROPEAN COMMUNITY'S FOOD SAFETY REGIME

2.1. Development of EU Food Safety Regulation

When the European Economic Community was established in 1957 food safety did not occupy a prominent position on the political agenda, and in the first many years thereafter the matter only appeared in Community law on an incidental and infrequent basis. This situation gradually changed during the 1970s and 1980s as the European Commission increasingly took the view that Member State food safety measures constituted illegal barriers to the free movement of foodstuffs within the Community and therefore should be eliminated. To this end the Commission challenged the legality of Member State food safety measures before the European Court of Justice and it also took some modest steps towards harmonising certain food safety requirements at Community level. With the entry into force of the Single European Act in 1987 the Community was given increased powers of harmonisation leading to an appreciable increase in Community food safety legislation. Still, food safety continued to be viewed primarily as a barrier to intra-Community trade, i.e. a problem which should be done away with rather than an objective in its own right.⁴

During the 1990s time and again food safety scandals stole the headlines quickly bringing food safety to the top of the European Community's political agenda. An extensive legislative programme was initiated. Thus in 1997 the Commission

published its green paper on the general principles of food law in the European Union,⁵ followed in 2000 by the White Paper on food safety.⁶ In 2002 the foundation of the present legal food safety regime was established through the adoption of Regulation 178/2002 on the General Principles of Food Law.

Today a new legal regime on food safety applies in the European Community.⁷ This regime sports seven important characteristics:

- It is *coherent*, i.e. it covers all types of foodstuffs including also imported products.
- It is *comprehensive*, i.e. it covers the whole food chain from farm to fork.
- Its primary purpose is the *protection of the consumer*.
- An important, albeit secondary, purpose is to further the *free movement of goods* within the Community.
- *Transparency* is given considerable weight, i.e. public consultation and the right to information have been given prominent roles.
- It is *risk-based*, i.e. it is based upon independent, scientific advice.
- *The precautionary principle* is granted an important role, so that protection of public health is given priority even in situations of scientific uncertainty.

⁵ European Commission, The general principles of food law in the European Union – Commission Green Paper, COM1997/176 (final).

⁶ European Commission, White Paper on food safety, COM 1999/719 (final).

⁷ Broberg, *supra* note 4, pp. 9 and 80.

⁴ M.P. Broberg, Transforming the European Community's Regulation of Food Safety, SIEPS 2008, pp. 60-61.

Whilst these characteristics may make good sense in a European context, arguably they do not take into account the consequences of the food safety regime which go beyond the Community's borders.

2.2. Implementation

The Community's food safety regime essentially prohibits food that is unsafe – i.e. injurious to health or otherwise unfit for human consumption – from being placed on the market. However, to the extent that a food product has been produced in compliance with specific Community provisions on food safety the product will be deemed to be safe.⁸ This in itself is a strong incentive for the food businesses to comply with the Community's regulation on food safety since in this way they may avoid liability.

Moreover, it is for the food business operator, i.e. the person controlling a food business, to ensure that the applicable food law requirements are complied with. The obligation of ensuring that the food products are safe is thus firmly placed on the food business operators' shoulders, not on the public authorities'.

As indicated above, the EC food safety requirements have been established in a European context. This has a number of important consequences for food businesses in developing countries, for example *that* limit values of naturally occurring toxins (eg. mycotoxins) are normally set according to what can be required from a European food business operating in a European climate, *that* certification requirements are made on the basis that the

businesses have easy access to accredited laboratories – which is not always the situation in developing countries, and *that* the level of administrative competence of the food businesses as well as of the public authorities is fairly sophisticated.

Below in section 3 it is shown how the European Community's food safety requirements not just place a burden on the food businesses in the developing countries, but rather at times they may constitute a barrier to exports into the Community.

2.3. Control and enforcement

The European Community's food safety control system consists of three layers. The primary control is carried out by the individual food business since it is required to verify and document that it complies with the food safety rules. Where a food business discovers that a requirement has not been met it is moreover required to take corrective action. A central instrument to achieve this objective is the so-called 'hazard analysis and critical control point' (HACCP) system which is considered in section 3.3 below. Not only European Community food businesses selling in the European market must comply with this control requirement. Third country food producers exporting to the Community are also required to comply therewith. In this connection there is an important distinction between products of animal origin and products of non-animal origin. The former is considered to represent the greatest risk and so products of animal origin are subject to stricter controls than are products of non-animal origin. Hence, third country food businesses involved in the production or processing of food products of animal origin must obtain Community approval and registration before exporting to the

⁸ 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, [2002] OJ L31/I, Article 14.

Community. In contrast, if the export concerns non-animal origin food products there is no preapproval requirement. Instead it is incumbent on the Community importer to verify that the third country food business has met the Community's food safety requirements.

Whilst the primary control is carried out by the food businesses themselves, the secondary control is the responsibility of the national authorities. Hence, the 27 Member States must maintain an extensive system of official controls to monitor and verify that the European Community's 7.8 million farms⁹, 300,000 food processing undertakings, and 600,000 retail outlets¹⁰ carry out the required self-control and take corrective action where necessary in accordance with the relevant food law requirements. Moreover, the Member States must lay down rules on measures and penalties to sanction infringements of food law.¹¹ With regard to control of third country food exports to the Community, the distinction between products of animal origin and of non-animal origin again plays an important role. In order to be able to export animal origin food products to the Community, not only the relevant food businesses must obtain prior approval. Also the official control of the export country must be approved by the European Community prior to the initiation of any exports. How extensive the requirements are is apparent from the Commission's 'General guidance on EU import and transit rules for live animals and animals

products from third countries' which in 11 points specifies those issues pertaining to the national food safety authority that are of particular relevance. These include matters such as 'management structure', 'recruitment and training' and 'laboratory services'.¹² The same requirement of prior approval does not apply to products of non-animal origin.

The Member State food safety authorities thus make up the second control layer.

As a third control layer the European Community has set up its own body to control that the Member State food safety authorities duly fulfil their obligations. This is known as the Food and Veterinary Office (FVO) which is a service of the European Commission. The FVO has 163 staff of which 81 are inspectors that carry out on-the-spot inspection missions.¹³ Due to the very limited resources available to it, the FVO is only able to carry out a rather limited control.

Food products imported into the European Community in order to be marketed there must comply with the Community's food safety requirements or with conditions recognised by the Community to be at least equivalent thereto.¹⁴ Whereas the Member State authorities and the Community have the power to carry out control inside the Community they do not have such power with regard to food businesses situated in third countries. The Community therefore has to either rely on the food

⁹ Eurostat Pocketbook – Agriculture, Main Statistics 2005-2006 (EU27), Luxembourg 2007, p. 28.

¹⁰ Eurostat, Structural Business Statistics (EU27), 2005.

¹¹ Regulation 178/2002, supra note 8, Article 7(2).

¹² European Commission, Health & Consumer Protection Directorate-General, 'General guidance on EU import and transit rules for live animals and animals products from third countries', 2007, pp. 11-12, see also p. 9.

¹³ FVO homepage, http://ec.europa.eu/food/fvo/how_en.htm accessed 26 March 2009.

¹⁴ Regulation 178/2002, supra note 8, Article 11.

safety control carried out by the third country authorities¹⁵ or to require that the food products are controlled upon importation.¹⁶ Where a third country has put forward information substantiating that its national food safety control complies with or is equivalent to the Community's food safety requirements, the European Commission may carry out official controls in the third country to verify 'the compliance or equivalence of third-country legislation and systems with Community feed and food law and Community animal health legislation'.¹⁷

When a European Community food business operator imports food products from a third country, the importer may presume these to be safe if the third country in question has been formally recognised as having a food safety control system that either complies with or is equivalent to the system found in the Community. In this situation the fact that the food product originates in a third country is immaterial. In contrast, if the imports are from a third country that has not been so recognised, Article 17 of Regulation 178/2002 requires the European Community importer to ensure that the food products satisfy the relevant requirements of food law and to verify that such requirements are met.¹⁸

¹⁵ Regulation 882/2004, of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, [2004] 2004 L165/1, Article 45.

¹⁶ See eg. Regulation 882/2004, *supra* note 15, Chapter V.

¹⁷ Regulation 882/2004, *supra* note 15, Article 46.

¹⁸ A. Graffham, EU legal requirements for imports of fruits and vegetables (a suppliers guide). Fresh Insights no. 1, DFID/IIED/NRI, 2006, www.agrifoodstandards.net/resources/global/fresh_insights_1_eu_legal_requirements_for_imports_of_fruits_and_vegetables p. 5.

3. IDENTIFYING THE BARRIERS

3.1. Overview – treatment of food imports under the EU food safety regime

Generally speaking it is difficult to question that food safety is both a legitimate and a well-founded objective for the public authorities to pursue. At the same time it is easy to see that food safety requirements that differ from country to country may constitute an important barrier for the international trade in food products. Below we set out to identify the most important barriers to imports from developing countries into the European Community. First the requirements that apply to the composition of the food product as such are considered (section 3.2). Thereupon there is an examination of those requirements which do not concern the composition of the product but rather the process under which it is produced (section 3.3). Next the examination turn to the authorisation requirements that may apply (section 3.4). The following section provides an examination of some of the more technical requirements regarding the control of imports of food products which may pose very substantive hindrances (section 3.5). Finally, the issue of private food safety requirements is briefly considered (section 3.6).

3.2. Composition of Food – Setting the Limit Values

Most food products are made up of a number of different ingredients. Conventional ingredients with a history of safe use in the European Community may be used freely. If a component in a food product does not fall within this category, it may only be used to the extent that it has been considered safe to do so. To this end the

Community has established extensive legislation regulating the matter.

Food products may contain components that are partly or fully unwanted. Broadly speaking, two categories of such components may be distinguished: On the one hand we have additives such as colours, sweeteners and flavourings that are intended to be part of the final food products. On the other hand we have naturally occurring toxins such as mycotoxins, pathogenic bacteria such as salmonellae and residues of for example pesticides or veterinary drugs that all are unwanted in the final product, but which may be difficult to avoid completely. Originally limit values for these types of components were laid down by the individual Member State, but over the years still more limit values have been established by the European Community. Whilst the early Community limit values often appeared to be rather incidental (for example based on a Member State's prior limit value that appeared to have "worked in practice"), the contemporary limit values are scientifically founded.

When setting the limit values, an important objective will always be to secure that the food product is safe for the consumer. Where a food safety matter is covered by an international standard the European Community will take this into consideration, unless it finds the standard to be ineffective or inappropriate.¹⁹

The European Community applies slightly different methods with regard to the different types of unwanted components, but generally speaking the following approach is applied.

First an *acceptable daily intake* (ADI) must be identified, i.e. the highest daily dose of

the component in question which a human may consume without this causing any adverse effects viewed over a lifetime. In theory the identification of an ADI should be done by exposing a number of human subjects to different doses of the relevant component to establish the value at which adverse effects occurs. *Inter alia* for ethical reasons this is not possible, however. Instead experimental animals are used to establish what is termed the *no observed adverse effects level* (NOAEL). The value thus found will then be adjusted by an appropriate safety factor to take account of the difference in sensitivity between the experimental animal and humans and to take account of the difference in sensitivity between different individuals;²⁰ for pesticide residues the NOAEL will usually be divided by 100 to establish the ADI.²¹

When the ADI has been established, it is necessary to clarify how much of the component shall be allowed in different types of food products. This is done on the basis of consumer intake models which take account of the type and quantity of the different food products that are consumed by the Europeans (as well as by the various national populations and sub-populations). In this respect a fair margin of discretion has been left to those setting the levels for the different types of food products. The consequences of changing a limit value – for instance changing the *maximum residue*

20 Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives, OJ [2008] L33/1, Annex II, para. 3.2.3.1.

21 Bernd van der Meulen and Menno van der Velde, "European Food Law Handbook", Wageningen Academic Publishers, Wageningen (the Netherlands) 2008, p. 369.

19 Regulation 178/2002, supra note 8, Article 5(3).

limit (MRL) of a pesticide in certain crops – may be significant.

In 2001 the European Community drastically reduced the MRL for a pesticide commonly used for de-greening pineapples. Ghanaian exporters did not take notice of this change and so their pineapples were rejected at point of entry to the European Community. Had the shipments arrived just a few days earlier, the pineapple would have been allowed to be imported and sold in the Community.²²

The objective of the method outlined above is to fix the limit values at such level that the consumers will not be exposed to unhealthy levels of the various components.

In certain situations the European Community however applies a “double barrier” when laying down its limit values. This means that in addition to calculating the ADI of for example a pesticide the Community will also identify the *as low as reasonably achievable*-level (ALARA); typically this will be the level that may be reached when the farmer applies *good agricultural practices* (GAP) while using the pesticide in question. The lower of the two figures (i.e. ADI and ALARA) found will be adopted as the limit value.²³

Whilst from a consumer perspective the dual requirement is an advantage, it may

constitute a real problem from a developing country point of view. Essentially the problem is that the limits will be based upon what is possible in a European context. For example, it may be that in Europe it is only necessary to use a limited amount of a given pesticide whereas in a tropical climate a higher dose is required leading to a higher residue level. If the European Community’s limit value is difficult to meet when the production takes place in a tropical climate, this may constitute an important barrier for the exports to the European market – even if the developing country product’s actual residue level falls well below the level that gives rise to toxicological concerns (the ADI). This problem applies to the regulation of all types of unwanted substances in foodstuffs.

Aflatoxin is a naturally occurring and often very harmful toxin produced by moulds that may appear inter alia in nuts and dried fruits. A humid and warm climate provides the best growth conditions for the aflatoxin producing moulds. The problem is therefore particularly prevalent in the developing countries. Regulation 1881/2006²⁴ lays down maximum levels for different types of aflatoxins in dried fruits and nuts. Especially aflatoxin B1 is regarded as harmful whereas other aflatoxins are much less toxic. Therefore, the Regulation in its recital 4 lays down that the limit value should ‘be set at a strict level which is reasonably achievable by

²² Graffham, *supra* note 18, p. 18.

²³ Regulation 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs, [2006] OJ L364/5, recital 4.

²⁴ Regulation 1881/2006, *supra* note 23, Annex, section 2.1.3 and 2.1.5.

following good agricultural, fishery and manufacturing practices and taking into account the risk related to the consumption of the food. In the case of contaminants which are considered to be genotoxic carcinogens or in cases where current exposure of the population or of vulnerable groups in the population is close to or exceeds the tolerable intake, maximum levels should be set at a level which is as low as reasonably achievable (ALARA).²⁵ The objective is to ensure that food business operators apply measures to prevent and reduce the contamination as far as possible in order to protect public health. For example, the Regulation lays down that the maximum limit of Aflatoxin B1 is 2.0 µg/kg in dried fruits and nuts intended for direct human consumption. Whilst this limit may be reasonable for European producers of dried fruit and nuts, Otsuki, Wilson and Sewadeh have argued that such very low level could constitute an important hindrance to developing country exporters of nuts and dried fruits.²⁵

Where a food product contains a component for which no limit value has been established and where the component is not a conventional one with a history of safe use in the European Community the maximum residue level is set by default at

25 Tsuehiro Otsuki, John S. Wilson, Mirvat Sewadeh, 'Saving two in a billion: quantifying the trade effect of European food safety standards on African exports', *Food Policy* 26 (2001) 495-514.

the *limit of determination*; LOD.²⁶ Essentially the 'limit of determination' is equivalent to the application of a 'zero tolerance' since the food product may not be marketed in the Community if the substance is detected therein. The problem is, however, that since the developing countries are less attractive markets for pesticide manufacturers than is the European Community, the manufacturers have much less incentive to carry out the required trial work to establish (or to increase) the MRL for pesticides to be used on developing country crops.²⁷ This lack of commercial incentive to bear the costs of trial work for establishing the MRLs is particularly apparent with regard to the older, generic pesticides. But it is precisely these pesticides that are most likely to be used by poor farmers. The consequence is that for a number of pesticides the MRLs have been set, by default, at LOD with respect to a wide range of tropical crops originating in developing countries.²⁸ Frequently, setting the MRL at LOD will preclude the use of the substance on the crop in question.²⁹

26 CTA, "Study of the consequences of the application of sanitary and phytosanitary (SPS) measures on ACP countries – Commissioned by CTA", May 2003, report prepared by Carrex Ltd, UK, p. 34.

27 André Jooste, Erik Kruger, and Flip Kotzé, "Standards and Trade in South Africa – Paving Pathways for Increased Market Access and Competitiveness" in "Standards & Global Trade – A Voice for Africa" (John S. Wilson and Victor O. Abiola, eds), The World Bank, Washington DC, 2003, pp. 235-370 at p. 268.

28 David Hirst, "Recent Developments in EU Pesticides Regulations and their Impact on imports of Tropical Fresh Produce", presentation given to Tropical Agriculture Association, London 27 March 2001, available at www.taa.org.uk/southeast/PaperDavidHirstmay2001.htm, and Wilson and Abiola, *supra* note 3, at p. xxxvii.

29 Hirst, *supra* note 28, and Sabine Willems, Eva Roth, and Jan van Roekel, "Changing European Public and Private Food Safety and Quality Requirements – Challenges for Developing Country Fresh Produce and Fish Exporters – European Union

A further problem arises where different important export markets apply mutually conflicting limit values.

In a study from 1998 it was found that the MRL for the pesticide malathion on apples was 8.0 ppb in the United States, whereas it was only 0.5 ppb in Germany, France, the United Kingdom and the Netherlands. In contrast, the MRL for the pesticide permethryn on apples was 1.0 ppb in Europe but only 0.05 ppb in the United States. An exporter of apples therefore would have to target either the market in the United States or in Europe – or would have to make his production acceptable to both export markets by achieving the strictest standard in each category in order to have flexibility to respond to changing market conditions.³⁰

A similar problem arises where important export markets lay down diverging process requirements, as will be illustrated below in the following section.

3.3. Process Requirements

Prevention is often considered better than cure, both with regard to human diseases

Buyers Survey”, The World Bank, Agricultural and Rural Development Discussion Paper 15, Cost of Compliance with SPS Standards, 2005, p. 16.

30 R. Fischer, “Regulation as a Trade Issue from a Chilean Perspective” in “Regulatory Reform in the Global Economy: Asian and Latin American Perspectives”, Proceedings of the Conference on Trade Policies and Trade Regulations and International Openness, Paris 1998, Organization for Economic Cooperation and Development (OECD), p. 38.

and with regard to food safety. Therefore, with the increased focus upon food safety has come a shift toward process requirements and away from product requirements.³¹ This shift is clearly reflected in the European Community’s food safety regime which to an appreciable extent lays down stringent rules on how to handle the production, processing and distribution of the food products. In this respect the primary instruments are extensive hygiene obligations and the obligation for food businesses to establish a traceability system. The process requirements place a very considerable burden on all food businesses; a burden that is particularly felt by small businesses in the developing countries.³²

European Community standards for milk and milk products require inspection and monitoring at the level of primary production – i.e. in the stable. In India a dairy holding may have just one or two draft animals, so milk from a number of holdings are pooled before it is processed. Arguably, from an economic point of view it will not be feasible to monitor each animal but this is what the European Community standard requires. If the Community

31 Tim Josling, Donna Roberts, and David Orden, “Food Regulation and Trade – Toward a Safe and Open Global System”, Institute for International Economics, Washington DC, 2004, p. 104.

32 Thomas Bernauer and Ladina Caduff, “Food Safety and the Structure of the European Food Industry” in “What’s the Beef? The Contested Governance of European Food Safety” (Christopher Ansell and David Vogel, eds), The MIT Press, Cambridge (MA), 2006, p. 91, Wilson and Abiola, supra note 3, at p. xxxix, and OECD, Working Party on Agricultural Policies and Markets, “Final Report on Private Standards and the Shaping of the Agro-Food System”, AGR/CA/APM(2006)9/Final, 31 July 2006, p. 30.

standards allowed that the quality would not have to be determined before the entry point of the processing unit it would improve Indian producers' access to the European market.³³

For years the European Community has required producers of food products of animal origin to comply with some extensive hygiene requirements; the first one was adopted as early as 1964.³⁴ In 2004 extensive hygiene requirements were also applied to food products of non-animal origin through the adoption of the so-called 'hygiene package'; a common regulatory framework which provides measures and conditions to control hazards in the production of food and to ensure that foodstuffs are fit for human consumption. This 'package' lays down specific requirements, based on good manufacturing practices, which food businesses must satisfy at all stages of production, processing and distribution if food products are to be sold in the European Community.

The requirements are both extensive and detailed whilst at the same time they are often not so very specific. For example one of the rules regarding general requirements for food premises provides the following regarding the availability of washbasins on the premises:

'An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing foods are to be separate from the hand washing facility.'³⁵

Perhaps the most important part of the 'hygiene package' is that it requires all food business operators, with the exception of primary producers, to 'put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles'.³⁶ HACCP – which is the abbreviation of Hazard Analysis and Critical Control Points – is a systematic preventive approach that is set up to identify potential food safety hazards so that certain predefined actions can be taken to reduce or eliminate the risk of the hazard being realised. It is the food business operators who must analyse their own processes in order to themselves put into place a HACCP system. Hence the accuracy of Regulation 852/2004's statement that '[t]he HACCP system should not be regarded as a method of self-regulation ...' appears somewhat open to doubt.

The HACCP system encompasses the following seven steps:

33 John S. Wilson, 'Standards, Regulation and Trade – WTO Rules and Developing Country Concerns' in 'Development, Trade, and the WTO – A Handbook', (Bernard Hoekman, Aaditya Mattoo, and Philip English, eds), The World Bank, 2002, pp. 428-438 at p. 433.

34 Directive 64/433/EEC on health problems related to Intra-Community trade in fresh meat OJ No P 121, 29/07/1994, p. 2012-2032 cf. Holland and Pope, EU Food Law and Policy, p. 155.

35 Regulation 852/2004 of 29 April 2004 on the hygiene of foodstuffs, [2004] OJ L139/1, Annex II, para. 1(4).

36 Regulation 852/2004, supra note 35, Article 5.

- Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels.
- Identifying the critical control points at the steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels.
- Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards.
- Establishing and implementing effective monitoring procedures at critical control points.
- Establishing corrective actions when monitoring indicates that a critical control point is not under control.
- Establishing procedures which shall be carried out regularly to verify that the measures outlined above are working effectively.
- Establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the above measures.

Moreover, food business operators in the European Community must be able to provide evidence of compliance with the HACCP procedures to the competent Member State authorities.³⁷ Obviously, it may be questioned whether all food businesses will maintain accurate records of their actions where damaging information may lead to the authorities penalising the food business.³⁸ So far the primary produc-

³⁷ Regulation 852/2004, *supra* note 35, Article 5(4).

³⁸ Cary Coglianese and David Lazer, "Management-Based Regulation: Prescribing Private Management to Achieve Public Goals", *Law & Society Review*, Vol. 37, No. 4 (2003), pp. 691-730 at p. 722.

ers are not obliged to put into place a HACCP system,³⁹ but instead must comply with some less far-reaching hygiene provisions.⁴⁰ Nevertheless, it is possible that in the future the European Community will also require the primary producers to apply a HACCP system.⁴¹

According to several studies of how the hygiene requirements affect food businesses in the European Community these requirements constitute a heavy burden, not least on small and medium sized enterprises (SMEs) which have only limited resources available. This is particularly so with respect to the HACCP requirements.⁴² Thus, one study found that around 42% of UK SMEs did not understand what 'hazard analysis' meant, what it required them to do, how to implement it into their business or how to evaluate and monitor the steps taken⁴³ whilst another study observed that the SMEs often feel that the difficulties of HACCP are potentially insurmountable.⁴⁴ These problems are even more marked with regard to food businesses in the developing countries where the resources

³⁹ Regulation 852/2004, *supra* note 35, Article 5(3).

⁴⁰ Regulation 852/2004, *supra* note 35, Annex I.

⁴¹ van der Meulen and van der Velde, *supra* note 21, p. 358.

⁴² *Competitiveness of the European Food Industry - An economic and legal assessment - 2007*, J.H.M. Wijnands, B.M.J. van der Meulen and K.J. Poppe (eds), The Hague 2006, p. 79.

⁴³ *Factors affecting food safety compliance within small and medium-sized enterprises: Implications for regulatory and enforcement strategies*, Charlotte Yapp, and Robyn Fairman, *Food Control*, Vol. 17, Issue 1, January 2006, pages 42-51, at p. 45.

⁴⁴ Eunice Taylor and Kevin Kane, "Reducing the burden of HACCP on SMEs", *Food Control* 16 (2005) 833-839, at p. 833.

are appreciably scarcer⁴⁵ and arguably there are reasons to assume that the marginal costs of implementing HACCP are higher in developing countries than in industrialised countries.⁴⁶ Equally, a developing country food producer is likely to find it more burdensome to comply with more different food safety requirements – for example different public standards in the United States and Europe or differences between public and private standards – than will a food producer in an industrialised country.⁴⁷ Thus, it has been pointed out that international harmonisation of food safety standards can produce significant net welfare and trade benefits, in particular for developing countries.⁴⁸

45 Tjaart W. Schillhorn van Veen, "International trade and food safety in developing countries", *Food Control* 16 (2005) 491–496, at pp. 494–495, Steven M. Jaffee and Spencer Henton, *Agro-Food Exports from Developing Countries: The Challenge Posed by Standards*, pp. 91–114 in *Global Agricultural Trade and Developing Countries*, (M. Ataman Aksoy and John C. Beghin, eds), The World Bank, Washington 2005, p. 99, COLEACP-PIP, 'Diagnostic impact study of the new European regulation 882/2004 "official feed & food controls" and recommendations', Phase one / Final report, September 2005, p. 67, John S. Wilson and Victor O. Abiola, "Executive Summary" in "Standards & Global Trade – A Voice for Africa" (John S. Wilson and Victor O. Abiola, eds), The World Bank, Washington DC, 2003, pp. xix–xxiv at pp. xx and xxi and Hezron Omare Nyangito, Tom Olielo, and David Magwaro, "Improving Market Access Through Standards Compliance – A Diagnostic and Road Map for Kenya" in "Standards & Global Trade – A Voice for Africa" (John S. Wilson and Victor O. Abiola, eds), The World Bank, Washington DC, 2003, pp. 1–64 at pp. 51–52.

46 Laurian J. Unnevehr and Helen H. Jensen, The economic implications of using HACCP as a food safety regulatory standard, *Food Policy* 24 (1999) pp. 625–635, at p. 632.

47 Wilson, *supra* note 33, at p. 438. See also Wilson and Abiola, *supra* note 3, at p. xxxv–xxxvi.

48 Wilson, *supra* note 33, at p. 432.

Hence, compliance with food safety procedures may impose prohibitive costs on developing country food producers and governments⁴⁹ as is aptly reflected in reports on the imposition of a HACCP system in Kenya's fish-processing industry which brought with it prohibitive costs leading to the closure of several processing facilities.⁵⁰ Indeed, in countries where it is not possible to certify HACCP systems or where otherwise it is not possible to meet the process requirements, this may discourage production of food products for export.⁵¹

On July 30, 1997, the European Commission banned imports of fishery products from Bangladesh into the European Community.⁵² This ban followed Community inspections that had shown serious deficiencies with regard to infrastructure and hygiene in fishery establishments and insufficient guarantees of the efficiency of the controls carried out by the competent authorities (i.e. Bangladeshi government inspectors). The European Commission concluded that consuming fishery products processed in Bangladesh posed a significant risk to public health. Not only did the Euro-

49 Wilson and Abiola, *supra* note 45, pp. xix–xxiv at p. xxiii and the same authors, *supra* note 3, at pp. xxxviii–xxxix.

50 Jaffee and Henton, *supra* note 45, p. 106.

51 Unnevehr and Jensen, *supra* note 46, at p. 632 and Jaffee and Henton, *supra* note 45, at p. 103.

52 Commission Decision 97/513/EC of 30 July 1997 concerning certain protective measures with regard to certain fishery products originating in Bangladesh, [1997] OJ 214/46.

pean ban have very considerable economic effects on the Bangladesh shrimp producers, the ensuing costs of upgrading the shrimp industry to European Community standards amounted to 9.4% of frozen shrimp export sales for one year and HACCP plan maintenance represented 1.3% of annual export sales.⁵³

For a number of years Tiviski, a small Mauritanian food business, has tried to export camel cheese to the European Community. Camel cheese is a new product developed by Tiviski under considerable costs. The European Community has however rejected the import, invoking that the product is not produced in accordance with Community regulations requiring that dairy products be manufactured from milk produced by animals kept on farms and milked mechanically. This rule particularly precludes imports from developing countries with numerous small producers for whom mechanisation is too costly and in the actual case led to the barring of the camel cheese product from the European market.⁵⁴

As is apparent, the European Community's hygiene requirements constitute a very important barrier to the import of foodstuffs from developing countries. This barrier will become even higher if (or when) the requirements were to be increased. In particular the possible future introduction of HACCP in primary production may create an insurmountable barrier for a large proportion of the farmers in the developing countries.

Where a food business operator discovers a hazard, it is required to take corrective action. For example, this is the case under the HACCP procedure when a critical control point is not under control. If, however, the hazard requiring corrective action is only uncovered after the food product has been passed on in the food chain the potentially unsafe product must be traced in order to be able recall it from the market.⁵⁵ To this end Regulation 178/2002 requires that all food business operators are able 'to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution'.⁵⁶ Hence, each food business operator must have in place a system to identify any person from whom they have been supplied with a food, feed, food-producing animal or substance that will be incorporated into a food or feed as well as to identify the other busi-

53 J.C. Cato, "Seafood safety – Economics of Hazard Analysis and Critical Control Point (HACCP) programmes", *FAO Fisheries Technical Paper 381*, Rome, FAO, 1998, p. 27 and Schillhorn van Veen, *supra* note 45, at p. 494.

54 www.tiviski.com/index6-uk.html accessed 10 May 2009, Michael Byron Nelson and David K. Leonard, "Pro-Poor Livestock Policy Initiative – A Living from Livestock – International Rules, Food Safety and the Poor Developing Country Livestock Producer", *PPLPI Working Paper No. 25*, FAO, 2005, www.fao.org/ag/againfo/programmes/en/pplpi/docarc/wp25.pdf,

pp. 39-40, and Wilson, *supra* note 33, at p. 432.

55 European Commission, *White Paper on Food Safety*, COM(99)719 final.

56 Regulation 178/2002, *supra* note 8, Articles 3(15) and 18(1).

nesses to which the business operator's products have been supplied. In other words, all food businesses in the food chain must know from where they have obtained all supplies and to whom they have sold any products that may be used in a food or feed product, i.e. a 'one-step-back-one-step-forward' traceability system.

Moreover, the food business operators must have in place systems and procedures which allow for this information to be made available to the competent authorities on demand. Provided that this obligation is duly complied with, it will be possible to track, for example, an unsafe food ingredient and thus recall from the market all those food products in which the ingredient has ended up.

On 28 January 2005 an Italian company contacted Premier, a British food business, because it had found traces of Sudan 1 in Premier's Crosse and Blackwell Worcester sauce. Sudan 1 is a red dye that in Europe is used *inter alia* in shoe polish. In Pakistan, India and other parts of Asia it is however also used to dye spices such as chilli powder, but since it has been shown to cause cancer in animals there is fear that it may also be a carcinogen for humans. Therefore, use of Sudan 1 in food products has been prohibited in the European Community. Premier's Worcester sauce not only was used as a tabletop sauce, but also was used as an ingredient by numerous other food businesses. On the basis of the trace-ability system all these products were recalled by food business-

es in at least 20 countries. In the UK alone the Food Standards Agency compiled a list of more than 600 products that had to be recalled.⁵⁷

Maintaining a traceability system fulfilling these requirements places an appreciable burden upon food business operators.⁵⁸ Indeed the burden is exacerbated by the fact that special characteristics such as diverging and converging product streams, inhomogeneity of raw materials and the perishable character of products make traceability in the food industry particularly complex.⁵⁹ Strictly speaking third country food businesses are also required to establish a traceability system regarding products exported to the European Community. However, the Community's Standing Committee on the Food Chain and Animal Health has held that the traceability requirement only applies from entry past the EC border.⁶⁰ This means that the requirement only

57 More recently a somewhat similar recall has been made due to the detection of methyl yellow in spices (curry, curry paste etc.) in Belgium, France, Luxembourg and Germany, cf. Jess Halliday, 'Illegal yellow prompts spate of spice recalls', FoodQuality news.com, 10 April 2009 (www.foodqualitynews.com/content/view/print/242937).

58 Competitiveness of the European Food Industry – An economic and legal assessment – 2007, supra note 42, p. 90.

59 Jacques Trienekens and Jack van der Vorst, Traceability in food supply chains, in Safety in the agri-food chain, P.A. Luning, F. Devlieghere and R. Verhé, eds., Wageningen Academic Publishers, at p. 455-456.

60 Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) no 178/2002 on General Food Law, Conclusions of the Standing Committee on the Food Chain and Animal Health (2004), http://ec.europa.eu/food/foodlaw/guidance/guidance_rev_7_en.pdf, pp. 11 and 27.

weighs on the Community food business operators. Nevertheless, the onus that the European Community's new food safety regime places on food business operators arguably means that Community importers of food products will only buy from third country food businesses that can guarantee the traceability of the products.⁶¹

3.4. Authorisation Requirements

In a number of situations marketing of foodstuffs requires prior authorisation from the authorities. Such authorisation may relate to the ingredients of the food product (i.e. the product as such) or it may concern those producing the product (i.e. the processing of the product).

3.4.1. Product authorisation

As observed in section 3.2 above, conventional ingredients with a history of safe use in the European Community may be used freely. However, for other ingredients authorisation must first be obtained. This means that it is not possible to export food products containing these other ingredients if such authorisation has not been obtained.

The European Community has established so-called positive lists regarding additives (anti-oxidants, preservatives, colours, sweeteners, etc.) and food supplements (vitamins, minerals etc.). These lists set out which additives and supplements may be used in what food products and frequently they also lay down the maximum level of the additive or supplement. The lists are exhaustive meaning that if an additive or supplement is not on the relevant list, it may not be used. In order for

an additive to be added to one of the positive lists, it must first undergo a safety assessment by the European Food Safety Authority (EFSA) whereupon the relevant list must be amended by the Community legislator.⁶² In contrast, for a supplement to be added to the positive list, the addition to the list is made through a so-called comitology procedure; i.e. a much simpler procedure than the one applicable with respect to additives, and a safety assessment by EFSA is not required unless the provision may have an effect upon public health.⁶³ Hence, if a food business wants to use an additive or supplement that is not on the positive list, it must apply for authorisation. Having to first obtain authorisation necessarily constitutes a barrier to sales; albeit presumably not a significant one for developing country food businesses. Firstly, because adding additives and supplements is more widespread among food businesses in industrialised countries and, secondly, because authorisation of an additive or supplement is generic in nature – meaning that when the additive or supplement has been added to the positive list all producers may use the additive or supplement in accordance with the conditions laid down in the positive list in question.

Not only new additives or supplements require prior authorisation before being marketed in the EU. The same is true with regard to so-called novel foods as regulated

⁶² Directive 94/35 of 30 June 1994 on sweeteners for use in foodstuffs, [1994] OJ L237/3, Article 7, Directive 94/36 of 30 June 1994 on colours for use in foodstuffs, [1994] OJ L247/13, Article 5, and Directive No 95/2 of 20 February 1995 on food additives other than colours and sweeteners, [1995] OJ L61/1, Article 6.

⁶³ Directive 2002/46 of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, [2002] OJ L183/51, Articles 5(4), 13 and 14.

⁶¹ Graffham, *supra* note 18, p. 6, and CTA, *supra* note 26, pp. 31-32.

in the Novel Food Regulation.⁶⁴ ‘Novel’ in this context not only means food products that are the result of technical innovation, but also refers to food products that may have been known and consumed for centuries, but which are new in the European Community. This means that food products that may have a long history of safe use in a third-country may not be exported to the European Community without a prior safety assessment followed by an authorisation. Hence, in order to market ‘exotic’ food products such as baobab fruit from Africa⁶⁵ or noni juice from South-East Asia,⁶⁶ authorisation must first be obtained. The noni juice decision took three years, and the scientific assessment included laboratory animal studies for toxicity, genotoxicity and allergenicity; in other words obtaining authorisation was both time consuming and costly.⁶⁷ If the applicant is unable to produce the required data, authorisation will be refused.

64 Regulation 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ [1997] L43/1, See in particular Art. 1(2) og 3(1).

65 Commission decision of 27 June 2008 authorising the placing on the market of Baobab dried fruit pulp as a novel food ingredient under Regulation 258/97, OJ 2008 L183/38.

66 Commission decision of 5 June 2003 authorising the placing on the market of "noni juice" (juice of the fruit of *Morinda citrifolia* L.) as a novel food ingredient under Regulation 258/97, OJ 2003 L144/12.

67 Anne Moorhead, "Missing the market – How exotic foods are being barred from the EU", Novel Food Regulation – joint paper prepared for UNCTAD, the CBI, GTZ, GFU and IPGRI, 2007.

In 1998 Pacific Nuts, an undertaking based in Vanuatu, applied for authorisation to market nangai nuts in the European Community. Nangai nuts are almond sized nuts from the Pacific islands and parts of East Asia where they have been consumed for millennia. However, *inter alia* because of possible allergenicity for some people consuming the nuts the application to allow imports into the Community was turned down.⁶⁸ According to Moorhead, applying this logic, the sales of all types of nuts would be banned in the European Community.⁶⁹

In contrast to the regimes applying to additives and supplements, an authorisation for a novel food product is not generic in nature, but gives only the applicant a right to market the ‘novel food’ in question. The consequence is that where another food business wants to market the same (novel) food product, this other food business must submit a new application; although in this situation a much simplified procedure applies.

The rules on novel food constitute a substantive barrier to a number of food

68 2001/17/EC: Commission Decision of 19 December 2000 on refusing the placing on the market of "Nangai nuts" (as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document number C(2000) 3888), [2001] OJ L4/35 and Ib Knudsen, Inge Søborg, Folmer Eriksen, Kirsten Pilegaard and Jan Pedersen, "Risk assessment and risk management of novel plant foods – Concepts and principles", TemaNord 2005:588, Nordic Council of Ministers, Copenhagen 2005, pp. 44-46.

69 Moorhead, *supra* note 67, p. 6.

products from the developing countries,⁷⁰ and several developing countries have pointed out that it is hard to understand, firstly, why old and well-trying food products are treated just like completely novel and untested products and, secondly, why the Novel Foods Regulation does not apply the same system of generic authorisation as the one applicable to supplements and additives.⁷¹ Apparently, the European Commission has acknowledged the same points of criticism and so it has tabled a proposal for amending the Novel Foods Regulation.⁷² According to this proposal the authorisation of novel foods shall, as a main rule, be generic and a simplified procedure shall apply for ‘exotic’ novel foods so that a notification will be sufficient regarding foods having a history of safe use outside the European Community. By March 2009 the proposal had passed the first reading in the European Parliament, but it would only be able to go through the second reading after the European Parliament election in June 2009.⁷³

In order to complete the picture reference should also be made to the Plant Health Directive.⁷⁴ According to this direc-

70 Neville Craddock Associates (UK), “The EU Novel Food Regulation – Impact on the Potential Export of Exotic Traditional Foods to the EU: Suggestions for Revision”, Discussion Paper prepared for UNCTAD and CBI in cooperation with GTZ, GFU and IPGRI, November 2005, p.

71 Anthony Fletcher, “Global concern over new EU novel food regs”, Nutraingredients.com, Europe, 12 April 2007 (www.nutraingredients.com/news/printNewsBis.asp?id=67019).

72 COM(2007)872 Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX (common procedure) COM(2007) 872 final.

73 Shane Starling, “EU Novel Foods amendment proposal accepted”, FoodQualityNews.com, 30 April 2009, (www.foodqualitynews.com/content/view/print/245327).

74 Directive 2000/29 of 8 May 2000 on protective measures

tive products of plant origin may only be exported to the European Community if prior to the export the competent national plant protection authority of the export State has conducted a phytosanitary inspection and certified that the products are free of those pests and diseases that are listed in the directive. Shipments that do not comply with the Plant Health Directive are liable for rejection and may be destroyed at the exporter’s expense. According to Graffham there have been cases where the exporting country has issued certificates without actually inspecting the shipment.⁷⁵ If the Community authorities uncover such practice it may lead the European Community to require another – reliable – certification of compliance with the directive in order to allow the products to enter the Community market.

3.4.2. Food producer authorisations

Authorisation requirements may also apply to the food businesses as such – i.e. to those processing the food. In this regard the European Community’s food safety regime draws an important distinction between, on the one hand, food products of animal origin and, on the other hand, food products of non-animal origin: Food products of animal origin may only be exported to the European Community *if* the third country appears on a list established by the Community and, in most cases, *if* the third country food businesses appear on a list approved by the Community. It is for the Community importer to ensure that these requirements have been met with regard to

against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community, [2000] OJ L169/I.

75 Graffham, *supra* note 18, p. 21.

the imported food products.⁷⁶ In contrast, when it comes to food products of non-animal origin, there is no general requirement that third countries appear on a list to be eligible for export of such food products and in many cases it will be sufficient that the exporting food businesses in the third country are known to and accepted as suppliers by importers of food into the Community.⁷⁷

That food businesses handling food products of animal origin must appear on a list drawn up by the European Commission is laid down in Regulation 853/2004 – which is part of the Hygiene Package. In order to be placed on this list the competent authority of the third country must provide guarantees that the establishment in question complies with the relevant Community requirements or with requirements that are considered to be equivalent thereto, that official inspections supervise compliance with the requirements and that it is possible to stop the third country establishment from exporting to the Community if it fails to meet the requirements.⁷⁸ Moreover, special provisions are provided for fishery and certain seafood products.⁷⁹

It follows from the above that in order to be able to export food products of animal origin to the European Community a

food business must not only fulfil the Community's hygiene requirements or equivalent, but the third country authorities must also be able to efficiently supervise that the third country food business duly complies with the requirements. For food businesses in developing countries these requirements may constitute important hindrances.

3.5. Control Requirements

Whether or not a food business is located within or outside the European Community it must comply with the Community's rules on hygiene in order to lawfully sell in the European market. Food businesses situated within the Community are subject to official controls by the relevant Member State authorities which in turn are subject to control by the European Commission. In contrast, third country food businesses are outwith the jurisdiction of both the Member States and the European Commission. Exports of food products to the Community may however be conditional upon the third country producer being subject to efficient controls and upon the European Commission (FVO) being permitted to carry out official controls in the third country.⁸⁰ The costs of these controls may be beyond the means of many of the poorest developing countries.⁸¹

⁷⁶ Regulation 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin, [2004] OJ L226/22, Article 6.

⁷⁷ European Commission, Guidance Document – Key questions related to import requirements and the new rules on food hygiene and official food controls, Brussels 2006, p. 10.

⁷⁸ Regulation 854/2004 of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, [2004] OJ L226/83, Article 12.

⁷⁹ Regulation 854/2004, supra note 78, Articles 13 and 15.

In Uganda exports of Nile Perch caught in the Lake Victoria is a very important foreign exchange earner.

⁸⁰ Regulation 882/2004, supra note 15, Article 46, van der Meulen and van der Velde, supra note 21, p. 408, and COLEACP-PIP, supra note 45, pp. 18, 19-20 and 24-25.

⁸¹ Jaffee and Henton, supra note 45, p. 103.

The export industry started to operate in the late 1980s and was primarily aimed at the European Community. However, from 1997 to 2000 the European Community imposed a number of import bans on grounds of food safety. The bans were justified on the poor performance of Uganda's regulatory and monitoring system. The Ugandan industry and authorities therefore had to fix the system of regulations and inspections and to carry out laboratory testing in order to regain access to the European market. The costs of these controls were – and still are – substantial and to an appreciable extent they only exist on paper.⁸²

3.5.1 Control in the third country

When importing food products of non-animal origin – i.e. food products where no prior authorisation is required before importation – it is incumbent upon the Community importer to ensure compliance with the relevant requirements of European food law or with conditions which the Community recognises as equivalent thereto.⁸³ As explained in section 3.3 above, so far the primary producers are not required to put into place a HACCP system, but only have to comply with some less far-reaching hygiene provisions.⁸⁴ There is no

⁸² Stefano Ponte, "Bans, Tests and Alchemy: Food Safety Standards and the Ugandan Fish Export Industry", DIIS Working Paper no. 2005/19, pp. 57-64 and 73.

⁸³ European Commission, *supra* note 77, p. 15.

⁸⁴ Regulation 852/2004, *supra* note 35, Annex I.

obligation to have this compliance certified, but a primary production third country food producer must keep documentary evidence including accurate records and provide these to the Community importer on request.⁸⁵ Where there is an obligation to apply a HACCP system, third country food businesses are required to keep documentary evidence and to make this evidence available to the Community importer on request. In addition, the Community importer will often require the third country food business to submit to a recognised and independent certification scheme.⁸⁶

Part of the control requirements may be that the third country exporter is able to produce laboratory certification that the food product complies with certain specific requirements. For example, where a food business exports chilli or chilli products to the European Community each consignment must be accompanied by an original analytical report demonstrating that there is no Sudan Red in the product; Sudan Red is a colouring that potentially is carcinogenic.⁸⁷ Whilst from a food safety point of view this type of requirement seems well-founded, it will be difficult to comply with where access to accredited laboratories competent to carry out the certification is

⁸⁵ Graffham, *supra* note 18, p. 13.

⁸⁶ Graffham, *supra* note 18, p. 13.

⁸⁷ Commission decision 2005/402 of 23 May 2005 on emergency measures regarding chilli, chilli products, curcuma and palm oil, [2005] OJ L135/34. See also Commission Working Document, Third progress report on the strategy for simplifying the regulatory environment, COM(2009) 17 final, and Draft Commission Regulation of 13 March 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC, SANCO/2697/2009 (POOL/ES/2009/2697/2697-EN.doc), recital 8 and Article 15.

limited – as is the case in some developing countries.⁸⁸ Indeed, lack of test facilities appears to be a general problem regarding implementation of standards in developing countries.⁸⁹ The European Commission is aware of this problem and to some extent has addressed it by adopting Regulation 2076/2005⁹⁰ which grants a transitional period of four years during which laboratories in third countries can adapt to the new situation (this period expires on 31 December 2009).

Also, the laboratory certification costs may be very substantial relative to the total value of the batch, thus reducing small exporters' incentive of exporting to the Community.⁹¹ This is particularly likely to be the case where a food business in a developing country relies on several small suppliers: Testing the supplies from each supplier may be prohibitively expensive whilst testing all the supplies together may be highly problematic where the test uncovers the presence of the unwanted substance without it being possible to exclude only the polluted part; meaning that all supplies will be considered to be polluted. The point to be made here is *not* that this testing is not justifiable; instead

the point is that the testing is particularly burdensome on systems relying on several small suppliers as is often the case in developing countries.

3.5.2. Control upon importation into the European Community

The Community's food safety legislation not only provides for control in the country of export, but also provides for control of food products in connection with the importation. To this end the Member States must designate appropriate border inspection posts where the control of the imported food products can be carried out.⁹² The Member State food safety authorities are responsible for this control which may take many forms.⁹³ Among these different forms sampling and analysis deserve particular attention since what may appear to be only minor changes in the sample plan or in the method of analysis may have important consequences for the access to the European market. The reason for this is that if just a tiny part of a batch of a food product is found to be unsafe then the full batch is regarded as unsafe.⁹⁴ Therefore, if the authorities change their sampling plan to one that is more likely to uncover transgressions of the limit values this will make it more difficult for the exporter to pass the control. The same is true with regard to improvements of the laboratory testing methods. This is particularly the case where the Community applies a zero tolerance approach (in practice: '*limit of determination*' or 'LOD') since such ap-

⁸⁸ Ponte, *supra* note 82, pp. 56-57, COLEACP-PIP, *supra* note 45, pp. 4 and 89, Wilson and Abiola, *supra* note 45, pp. xix-xxiv at p. xxiii, and Nyangito et al, *supra* note 45, pp. 1-64 at p. 57.

⁸⁹ Anwar El-Tawi, "An In-Depth Study of the Problems by the Standardizers and Other Stakeholders from Developing Countries" – ISO/WTO regional workshops – Part 1, International Organization for Standardization, Geneva 2002, p. 4. See also CTA, *supra* note 26, p. 64.

⁹⁰ Regulation 2076/2005, of 5 December 2005 laying down transitional arrangements for the implementation of Regulations 853/2004, 854/2004 and 882/2004 amending Regulations 853/2004 and 854/2004, Article 18.

⁹¹ Jaffee and Henton, *supra* note 45, pp. 96, 99 and 112.

⁹² Regulation 882/2004 *supra* note 15, Articles 15 and 17, and European Commission, *supra* note 12, p. 15.

⁹³ Regulation 882/2004, *supra* note 15, Article 10(1).

⁹⁴ Regulation 178/2002, *supra* note 8, Article 14(6).

proach essentially means that the limit value is set at what is measurable so that any improvement of the possibility of detecting such substance will be equivalent to a *de facto* lowering of the limit value.

Aflatoxin is a naturally occurring toxic substance in nuts and dried fruit for which stringent limit values have been established. In a batch of groundnuts the substance will normally be very heterogeneously distributed. Therefore, if a cargo of groundnuts arrives in a European port, the likelihood of finding a level of aflatoxin exceeding the limit value increases if the sample plan requires a large number of samples to be made from all parts of the cargo as compared to a sample plan that requires for example just two samples to be made and allows these to be made close to one another; thereby failing to take account of the non-uniform distribution of the toxin throughout batch.

There is an abundance of research showing the importance of sampling and analysis methods; thus for example in a comparison of sampling plans used in the United States, United Kingdom and the Netherlands to test raw shelled peanuts for aflatoxin it was found that the Dutch plan rejects the most lots whereas the U.S. plan accepted the most. Whilst the British plan was somewhere in-between the two other, it was also the plan that accepted the greatest number of bad lots. The contemporary European Community sampling plan has been based on the Dutch plan to a large

extent.⁹⁵ In order to limit the variations between the different Member State controls, the European Community has issued specific rules for how to carry out the sampling and the analyses; see for example the 23-page-long ‘Regulation 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs’.⁹⁶

As will be clear from the above, not only tightening the limit values may impede developing countries’ exports. Changes in the control methods – in particular with respect to sampling and analysis – may have precisely the same effect.

3.6. The Role of Private Standards

Where for example a large European supermarket chain imports food products into the European Community, this will be done under a contract specifying matters such as price, quantity, and time and place of delivery. Moreover, the contract will often lay down requirements that are related to the quality of the product; including food safety. In general these food safety requirements go further than what is required by law, for example by laying down stricter MRL requirements, by requiring

⁹⁵ John Gilbert and Eugenia A. Vargas, “Advances in Sampling and Analysis for Aflatoxins in Food and Animal Feed” in “Aflatoxin and Food Safety” (Hamed K. Abbas, ed.), Taylor & Francis, Boca Raton (USA) 2005, p. 239. It may be noted that there continues to be differences between the different Member States with regard to various food safety measures – including differences in sampling methods, cf. Willems et al, supra note 29, pp. ix, 15 and 16.

⁹⁶ Commission Regulation 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs, [2006] OJ L70/12. See also, more generally, European Commission, “Guidance Document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs”, Brussels 13 November 2006.

certification, or by requiring that the food is subject to full traceability (or other additional process requirements). Often the private standards are not established by the individual food importer, but instead by private associations that cover substantial parts of the distributors in the European Community. The most important of these include *GlobalGAP* (formerly *EurepGAP*) established by the EuroRetailer Produce Working Group, *BRC* established by British Retailer Consortium, and *IFS* run by the German Hauptverband des Deutschen Einzelhandels and the French Fédération des entreprises du commerce et de la distribution.

These private food safety requirements impose an additional burden on the food businesses in the developing countries; and sometimes this burden may be much heavier than the one imposed by public food safety legislation.

A case study of the Moroccan exports of tomatoes has shown that the cost of compliance with the *EurepGAP* (now *GlobalGAP*) standard for a highly efficient producer would amount to eight percent of the total farm gate cost. For an average farmer the share would probably be about 16 percent. The authors add that the total cost of compliance may be higher in the case of compliance with multiple standards such as *BRC* + *EurepGAP*.⁹⁷

97 Omar Aloui and Lahcen Kenny, 'The Cost of Compliance with SPS Standards for Moroccan Exports: A Case Study', World Bank, Agriculture and Rural Development Discussion Paper, 2005, p. 27

Moreover, the private food safety requirements may so-to-say render the public food safety legislation partly superfluous. For example, at present the European Community does not require primary producers to put in place a HACCP system. This, however, is only of importance as long as the private standards do not require primary producers to put such system into place. In other words, even if the European Community were persuaded to adapt its food safety legislation to the situation present in the developing countries, this would only have a real effect to the extent that the public requirements are not simply replaced by private ditto. It has however been pointed out that private standards often are closely related to public requirements – for instance by 'plugging' gaps in the regulatory controls.⁹⁸ Private standards therefore curtail the European Community's possibilities of easing developing countries' access to the European market.

Whilst it is true that private standards often constitute an additional burden on food businesses wishing to sell in the European Community, it is important also to recognise that some of these standards are better tailored to the circumstances facing these businesses than are public standards. The reason is that a number of the private standards are developed in close cooperation with those businesses and other stakeholders affected by the standards, and that the standards are regularly reviewed and revised. The primary objective of the standards is not to keep unsafe products out of the market, but rather the objective is to assure that the products ar-

98 Spencer Henson and John Humphrey, "Understanding the Complexities of Private Standards in Global Agri-Food Chains", paper presented at 'International Workshop on Globalization, Global Governance and Private Standards', Leuven, 2008, p. 11.

iving in the market are safe. Perhaps the European Community could draw inspiration from this approach.⁹⁹ For example some private standards have established less burdensome requirements *vis-à-vis* small businesses in order to take account of the more limited resources available to these businesses.¹⁰⁰

4. OVERCOMING THE BARRIERS

4.1. Outline

As should be clear from the preceding examination, European food safety requirements constitute an important barrier to imports of food products from developing countries. The question therefore arises as to how this barrier may be overcome. Essentially there are three different ways in which we may help the developing countries overcome the barriers:

- Dismissing the barriers
- Lowering the barriers
- Surmounting the barriers

Below each of these three routes is considered.

⁹⁹ See in this respect also van der Meulen and van der Velde, *supra* note 21, p. 501.

¹⁰⁰ Marian Garcia Martinez and Nigel Poole, "Ethical consumerism: development of a global trend and its impact on development" in "Standard bearers – Horticultural exports and private standards in Africa", (Adeline Borot de Battisti, James MacGregor and Andrew Graffham, eds), International Institute for Environment and Development (UK), London 2009, pp. 18-22 at p. 22, and van der Meulen and van der Velde, *supra* note 21, p. 499.

4.2. Dismissing the barriers

There seems to be only one realistic way of dismissing the European Community's food safety requirements, namely if it is possible to hold them to be illegal. The Community is founded on law and on several occasions the European Court of Justice has shown itself willing to annul Community legal acts that were in conflict with fundamental Community law principles.

The Community undoubtedly has the power to adopt legislation of food safety so it is not possible to dismiss the European Community's entire food safety regime. However, it may be possible to annul individual legal acts – or parts of these acts – laying down food safety requirements. Such annulment may be founded on several different legal arguments. Below there are brief presentations of those three legal arguments that appear to be particularly relevant. Namely, (i) the duty to take account of the development of the developing countries in all Community policies that may affect these countries, (ii) the duty to observe the proportionality principle, and (iii) the duty to comply with international law (including WTO law).

4.2.1. Duty to take account of the development of developing countries

According to Article 178 of the EC Treaty, in the policies that it implements and which are likely to affect developing countries the Community shall take account of its development cooperation objectives as laid down in Article 177. This means that when adopting food safety legislation, the Community must take account of the sustainable economic and social development of the developing countries, and more particularly of the least developed thereof. Moreover, the Community must foster the campaign against poverty in the developing

countries as well as the smooth and gradual integration of the developing countries into the world economy.

According to a strict reading of Articles 177 and 178, the Community must pay particular attention to the needs of the developing countries when, for example, laying down the food safety requirements for selling food products in Europe. Apparently it is possible to point to one example of this.

The European Community introduction in 1998 of strict limit values for different types of aflatoxins in nuts and dried fruit was met with strong criticism for causing significant problems in the developing countries whilst only producing limited benefits in the Community. Subsequently, the European Food Safety Authority (EFSA) was asked to carry out a new study of the problems related to aflatoxin in nuts. EFSA found that increasing the limit value for total aflatoxins from the Community's 1998-limit-value of 4 µg/kg to 8 or 10 µg/kg would result in an increase in average total dietary exposure to aflatoxins in the region of 1%, i.e. it would have only rather minor effects. However, such increase was likely to allow up to 6% extra batches of nuts onto the European market. EFSA also found that reducing the population's total dietary exposure to aflatoxin could be achieved by reducing the number of highly con-

taminated foods reaching the market and by reducing exposure from food sources other than nuts.¹⁰¹

The above aflatoxin example seems to be the exception that proves the rule. Thus, generally speaking, outside the field of development policy Articles 177 and 178 appear to have been almost completely overlooked by the Community and it seems rather unlikely that the European Court of Justice would be ready to strike down a food safety measure on the basis that it contravenes Articles 177 and 178.

4.2.2. The principle of proportionality

Proportionality has been called the most potent weapon in the arsenal of the public law judge.¹⁰² It essentially allows the Court of Justice to review not only the legality, but also (to some extent) the merits of legislative and administrative measures. The proportionality principle is composed of three cumulative tests. If a measure fails to meet one (or more) of these tests it will be liable to annulment by the Court of Justice. The three tests are:

- The measures must be *suitable* to achieve the legitimate aim (i.e. it is possible to achieve the stated aim through the use of the measure).

¹⁰¹ Opinion of the Scientific Panel on Contaminants in the food chain on a request from the Commission related to the potential increase of consumer health risk by a possible increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products, Question N° EFSA-Q-2006-174, Adopted on 25 January 2007, The EFSA Journal (2007) 446, 1-127, www.efsa.europa.eu/EFSA/efsalocale178620753812_1178620761977.htm

¹⁰² Takis Tridimas, *The General Principles of EC Law*, 2nd ed., Oxford University Press, Oxford 2007, p. 140.

- The measure must be *necessary* to achieve that aim (i.e. no other less restrictive means are available).
- The measure must be *proportionate stricto sensu* (i.e. the measure does not produce any excessive effects on the interests of those affected by it).

Arguably, parts of the European Community's food safety regime will face difficulties if measured against the principle of proportionality.¹⁰³ For example, in its report on the fight against 'mad cow disease' the European Commission observes that the average price of each detected animal suffering from mad cow disease in the period from January 2001 until December 2004 was € 1.56 million.¹⁰⁴ Indeed, in the group covering animals between 30 and 35 months, the price for each detected animal was an exorbitant € 302 million. These costs appear to be out of proportion *vis-à-vis* the benefits they may be expected to produce.

Equally, a number of Community measures appear to impose excessively and prohibitively strict criteria upon food producers in developing countries.¹⁰⁵ This may not only conflict with the Community's proportionality principle, but also with the rather similar necessity principle laid down in Articles 2(2) and 5(6) of the WTO SPS Agreement according to which food safety requirements may be applied only to the extent necessary to protect human, animal

or plant life or health. The question remains, however, whether in the application of the Community's principle of proportionality those consequences occurring outside the European Community weigh the same as those occurring within.

In conclusion, it may be possible to strike down specific Community food safety measures for infringing the proportionality principle, but it remains an open question to what extent the principle will constitute an effective measure where the disproportionate consequences occur outside the Community.

4.2.3. International law obligations

The European Community is bound by international law.¹⁰⁶ Consequently, to the extent that the Community's food safety regime conflicts with the Community's international law obligations, this may mean that the regime must be adapted accordingly.

International law lays down restrictions upon public authorities' interference in matters that take place outside of the territory. Therefore, the European Community may only enforce food safety requirements on parties outside the Community territory to the extent that this does not conflict with international law on jurisdiction. The question therefore arises as to whether the Community's food safety regime infringes this rule? In the view of the present author, this does not amount to an infringement. The third country food businesses are only required to comply with the Community's food safety rules to the extent that they market food products within the Commu-

¹⁰³ Broberg, *supra* note 4, p. 83.

¹⁰⁴ European Commission, The TSE Road Map, (COM (2005) 322 final), Brussels 15 July 2005, table 2 at p. 21.

¹⁰⁵ Neville Craddock Associates, *supra* note 70, p. 38, COLEACP-PIP, *supra* note 45, p. 68, and CTA, *supra* note 26, p. 66.

¹⁰⁶ M.P. Broberg, "The Court of First Instance's Judgment in *Gencor v Commission*". *International and Comparative Law Quarterly* 49, 2000, pp. 172-182, at p. 175.

nity. Formally speaking, the rules only regulate what can be sold on Community territory; they do not regulate the third country food businesses as such. Thus there is no extraterritorial application of the food safety regime.

As a member of the WTO the European Community is bound by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) which regulates the members' access to lay down rules on food safety. The Community's food safety measures must therefore comply with these WTO obligations. In this respect it is of particular importance that the SPS Agreement not only encourages international harmonisation in the field of food safety – it also lays down that when a member decides not to use an existing international standard, the WTO member's alternative measure must be based on a proper risk assessment and is subject to a range of other conditions set out in Article 5 of the SPS Agreement. This limits the Community's possibilities of introducing ever stricter requirements.

Whilst the Community's food safety measures have been challenged under the SPS Agreement on more occasions, developing countries have rarely been among the challengers.¹⁰⁷ This is almost certainly not due to lack of occasions to make such challenges, but rather it is due to lack of expertise and internal capacity, the costs associated with this type of litigation, fears of retaliation by the Community and the uncertain benefits which may be derived from such challenge.¹⁰⁸

¹⁰⁷ Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures – A Commentary*, Oxford University Press, Oxford 2007, p. 306.

¹⁰⁸ Scott, *supra* note 107, p. 307, Spencer Henson and Rupert Loader, "Barriers to Agricultural Exports from De-

The rising importance of private standards and the barriers these may create to developing countries' exports have caused these countries to query the lawfulness of such standards under the SPS Agreement.¹⁰⁹ In principle the WTO Agreement – and the SPS Agreement – only imposes obligations upon the States that are signatories to the Agreement whereas private parties are not obligated by the Agreement. Therefore private standards are only covered by the SPS Agreement to the extent that a State can be held responsible for such standards. In this regard it has been argued that in particular Article 13 of the SPS Agreement may be construed so as to imply an obligation on the States to prevent private parties from introducing private food safety standards.¹¹⁰ The relevant part of the provision provides that '... Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement ...'. The question

veloping Countries: The Role of Sanitary and Phytosanitary Requirements", *World Development*, 2001, Vol. 29, NO. 1, pp. 85-102, at p. 97, and Wilson and Abiola, *supra* note 3, at p. xxxv.

¹⁰⁹ Scott, *supra* note 107, pp. 304-306, and Gretchen H. Stanton and Christiane Wolff, "Private voluntary standards and the World Trade Organization Committee on Sanitary and Phytosanitary Measures" in "Standard bearers – Horticultural exports and private standards in Africa" (Adeline Borot de Battisti, James MacGregor and Andrew Graffham, eds), International Institute for Environment and Development (UK), London 2009, pp. 6-9.

¹¹⁰ WTO: 2007 News, 28 February and 1 March 2007, 'Sanitary and Phytosanitary Measures – Private standards are a mixed blessing, committee hears', www.wto.org/english/news_e/news07_e/sps_28feb_1march07_e.htm, and SPS Committee considers establishing working group on private sector standards, *Bridges Weekly Trade News Digest* – Vol. 12, Number 24, 2 July 2008.

of the application of the SPS Agreement to private standards has become subject of discussion in the WTO's Sanitary and Phytosanitary Measures Committee.¹¹¹ Whilst no conclusion appears to have been drawn until now, in the opinion of the present author it seems very difficult to construe the SPS Agreement so as to generally also cover private standards.¹¹²

As will be apparent, international law places important restrictions on the Community's possibilities of introducing strict food safety measures. But it does not provide a means of fully or partly dismissing the barriers which this regime creates *vis-à-vis* developing countries food exports.

4.3. Lowering the barriers

The second way of strengthening developing countries' access to the European Community market for food products is by lowering the food safety barriers. However, under the WTO Agreement's MFN principle, a member of the WTO may not, as a main rule, offer other WTO members conditions that are less advantageous than those it offers any other country (be it a WTO member or not). This means that if the European Community wants to ease the food safety requirements with respect to imports from developing countries the Community must either ease the requirements *vis-à-vis* all WTO members (developing as well as industrialised countries) or WTO law must allow for preferential treatment of the developing countries. Indeed, the SPS Agreement, in Article 10, allows for such 'special and differential

treatment'. Thus, Article 10(2) provides that: 'Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.' In other words, the SPS Agreement does not allow the European Community to establish lower MRLs or laxer sample plans for products originating in developing countries, but the Community can introduce longer time frames for products of interest to these countries.¹¹³ Moreover, the Community may ease the requirements on (all) third country imports in order to assist developing countries; i.e. the requirements continue to apply to products originating in the Community whereas imports are exempt therefrom.

Only to a limited extent has the European Community eased the developing countries' access to the European market. An example of this is found in Article 50(1)(a) of Regulation 882/2004¹¹⁴, however. This provision empowers the Community's Standing Committee on the Food Chain and Animal Health to establish a phased introduction of import requirements regarding food products from developing countries, provided such phased introduction will have a demonstrable effect in ensuring that developing countries are able to comply with the provisions of Regulation 882/2004.

¹¹¹ WTO, *supra* note 110, and Bridges Weekly Trade News Digest, *supra* note 110.

¹¹² See apparently likewise, Scott, *supra* note 107, p. 306.

¹¹³ See also Melaku Geboye Desta, "EU Sanitary Standards and Sub-Saharan African Agricultural Exports: A Case Study of the Livestock Sector in East Africa", *The Law and Development Review*, Vol. 1, Issue 1, pp. 96-122 at p. 120.

¹¹⁴ Regulation 882/2004, *supra* note 15.

Moreover, as has been observed in section 3.3 above, the Community's Standing Committee on the Food Chain and Animal Health has held that the traceability requirement only applies from entry past the Community border.¹¹⁵ This means that the requirement only weighs on the Community food business operators whilst developing country – as well as other third country – food businesses are exempt from this burden.

It appears that the European Community has not taken other steps towards lowering the barriers for developing country food businesses. For example Regulations 852/2004, 853/2004 and 854/2004 (which together with Regulation 882/2004 make up the so-called 'hygiene package') make no reference to developing countries. On the contrary, Regulation 852/2004 in Article 10 provides that third country food business operators exporting to the European Community shall comply with the Community's substantive hygiene requirements.

Hence, the European Community's preferential treatment of developing countries in the field of food safety is rather insignificant. However, as will be shown in section 4.4 immediately below, the Community instead resorts to the provision of technical assistance as the means whereby the problems should be remedied.

4.4. Surmounting the barriers

If the mountain will not come to Mahomet, Mahomet must go to the mountain. Hence, if the Community's food safety regime cannot be adapted to the special circumstances facing developing country food businesses, these food businesses must adapt to the European Community's food safety regime. The third way in which the European Community may improve developing countries' access to the European Community market for food products therefore is by helping the developing countries meet the Community's food safety requirements.

The European Community is one of the world's largest donors of technical assistance to developing countries. An appreciable part of this assistance is aimed at improving food safety in these countries. This is in line with Article 9 of the SPS Agreement which lays down that WTO members shall '... facilitate the provision of technical assistance to other Members, especially developing country Members ...'.

As of January 1999 the European Community significantly reduced the permissible level of aflatoxin in Brazil nuts (amongst others). Bolivia is the world's largest exporter of these nuts and the European Community is the largest importer. Bolivia claimed that the reduction adversely affected its Brazil nuts exports and brought the matter to the attention of the WTO SPS Committee. Following consultations between Bolivia and the European Community the Community carried out various activities in response, including assistance to strengthen Bolivian institu-

¹¹⁵ Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) no 178/2002 on General Food Law, Conclusions of the Standing Committee on the Food Chain and Animal Health (2004), supra note 60.

tions in ‘order to improve the technical and sanitary control frameworks.’¹¹⁶

Not only the SPS Agreement, but also the European Community’s own food safety regime requires the Community to provide technical assistance in the field of food safety. Thus, recital 44 of Regulation 882/2004¹¹⁷ provides that:

“It is appropriate to take account of the special needs of developing countries, and in particular of the least developed countries, and to introduce measures to that effect. The Commission should be committed to support developing countries with regard to feed and food safety, which is an important element of human health and trade development. Such support should be organised in the context of the Community’s Development Cooperation Policy.”

Moreover, in Articles 32(1)(d) and (2)(e), 50(2), and 51(2) Regulation 882/2004¹¹⁸

¹¹⁶ European Commission, ‘Written question E-2343/99 by Robert Evans (PSE) to the Commission. Aflatoxin fungus’, [2000] OJ 225E 109, European Commission, Bolivia Country Strategy Paper 2007-2013, 12.07.2007 (E/2007/1405), http://ec.europa.eu/external_relations/bolivia/csp/07_13_en.pdf, p. 21, and World Trade Organization – Committee on Sanitary and Phytosanitary Measures, Specific Trade Concerns – Note by the Secretariat – Revision, G/SPS/GEN/204/ Rev.3, 26 March 2003, <http://docsonline.wto.org/DDFDdocuments/t/G/SPS/GEN204R3.doc>, p. 49.

¹¹⁷ Regulation 882/2004, *supra* note 15.

¹¹⁸ Regulation 882/2004, *supra* note 15.

specifically provides for training of experts from developing countries.

It has been argued that the industrialised countries’ food safety requirements *vis-à-vis* developing country products for exports may have a positive ‘spill-over effect’ on those food products that developing country producers sell in the home market.¹¹⁹ This is important, not least since 70% of deaths among children under five in less developed countries are linked to biologically contaminated food according to Unnevehr and Hirschhorn.¹²⁰ Therefore the ‘spill-over-argument’ clearly weighs in favour of strict food safety measures in the industrialised countries combined with extensive development cooperation.

Whilst this spill-over effect may produce benefits in the developing countries,¹²¹ it should not be overlooked that the situation in many developing countries differs significantly from the situation we find in the industrialised countries.¹²² Hence, the bene-

¹¹⁹ Wilson and Abiola, *supra* note 3, at p. xlvi, Apollo Owuor, “The Kenya Horticultural Exporters Ltd experience of private voluntary standards” in “Standard bearers – Horticultural exports and private standards in Africa”, (Adeline Borot de Battisti, James MacGregor and Andrew Graffham, eds), International Institute for Environment and Development (UK), London 2009, pp. 26-29 at p. 29, and Henry Kinyua, “How private standards designed for export produce also influence Kenyan domestic markets in “Standard bearers – Horticultural exports and private standards in Africa”, (Adeline Borot de Battisti, James MacGregor and Andrew Graffham, eds), International Institute for Environment and Development (UK), London 2009, pp. 30-33.

¹²⁰ Laurian Unnevehr and Nancy Hirschhorn, “Designing Effective Food Safety Interventions in Developing Countries”, <http://go.worldbank.org/Y0270X2TE0>, (unpaginated).

¹²¹ Gabriela Rebello da Silva and Lara da Silva Carrilho, “Bridging the Standards Divide – A Case Study and Action Plan for Mozambique” in “Standards & Global Trade – A Voice for Africa” (John S. Wilson and Victor O. Abiola, eds), The World Bank, Washington DC, 2003, pp. 65-164 at p. 104.

¹²² Schillhorn van Veen, *supra* note 45, at pp. 493-494.

fits may be more limited whilst the costs may be more substantial. For example, the very fact that generally the life expectancy is appreciably shorter in developing countries together with the fact that the types of diseases that are most likely to strike in developing countries (AIDS/HIV, malaria, tuberculosis) differ from those that are most common in the industrialised countries (cardiac diseases, cancer) mean that protection against carcinogens is likely to be of much less benefit in a developing country where most of the population will not live long enough to develop cancer. At the same time, the relative costs of complying with the industrialised countries' food safety regimes are likely to be higher in the developing countries than in the industrialised countries.¹²³

Moreover, productions for the home market and for the export markets are often separated – and frequently the types or the quality of products for the domestic and export markets even differ materially.¹²⁴ This makes it much less likely that there will be a spill-over effect. Indeed, where the products basically are the same, it appears likely that the home market (or other low-income-market) will receive those parts of the production that are of inferior quality – including those products that cannot be exported to the industrial-

ised countries because they fail to meet the applicable food safety requirements.¹²⁵

Whilst those benefits which developing countries may derive from the strict food safety regimes of the industrialised countries appear to be rather doubtful, it is submitted that development assistance constitutes an important means for food businesses in developing countries to surmount the barriers created by the European Community's food safety regime.¹²⁶

5. PERSPECTIVES FOR THE FUTURE AND RECOMMENDATIONS FOR IMPROVEMENTS

5.1. Food safety will continue to be a challenge

How will food safety requirements affect the developing countries in the future and what should be done to counter the problems caused by these requirements? The present situation has three important characteristics:

- First, food safety occupies a prominent role on the political agenda in the European Community and other industrialised countries.

¹²³ Spencer Henson and Rupert Loader, "Impact of Sanitary and Phytosanitary Standards on Developing Countries and the Role of the SPS Agreement", *Agribusiness*, 1999, Vol. 15, No. 3, pp. 355-369 at pp. 359-360, and the same authors, supra note 108, at p. 89.

¹²⁴ Wilson and Abiola, supra note 45, pp. xix-xxiv at p. xx, the same authors, supra note 3 at p. xlii, and N. Rudaheranwa, F. Matovu, and W. Musinguzi, "Enhancing Uganda's Access to International Markets – A Focus on Quality" in "Standards & Global Trade – A Voice for Africa" (John S. Wilson and Victor O. Abiola, eds), The World Bank, Washington DC, 2003, pp. 371- 426, at pp. 401-402.

¹²⁵ Jaffee and Henton, supra note 45, pp. 99, 102 and 109, Cathy A. Roheim, "Seafood: Trade Liberalization and Impacts on Sustainability", pp. 275-295, in "Global Agricultural Trade and Developing Countries", (M. Ataman Aksoy and John C. Beghin, eds), The World Bank, Washington 2005, p. 294, and Ramesh V. Bhat and S. Vasanthi, "Mycotoxin Contamination of Foods and Feeds – An Overview", Third Joint FAO/WHO/UNEP International Conference on Mycotoxins, Tunis, Tunisia, 3-6 March 1999, p. 7.

¹²⁶ Likewise Desta, supra note 113, at pp. 121-122, and Henson et al, supra note 1, at pp. 69-71.

- Secondly, private food safety standards play an increasingly important role when it comes to access to the markets in the industrialised countries.
- Thirdly, many developing countries are very dependent upon food exports to industrialised countries – in particular the European Community – and are thus materially affected by the food safety requirements that apply to sales in the industrialised countries.

None of these three characteristics appears likely to change materially within the foreseeable future:

- Food safety is here to stay; and not only does it appear highly unlikely that the European Community or other industrialised countries will be ready to make any fundamental changes to this. On the contrary, it appears much more likely that the pronounced political attention food safety receives in the high income countries will percolate not only to middle income but, ultimately, also to low income countries.
- When it comes to private food safety standards there is nothing indicating that they will cease to exist; although we may expect them to undergo important changes.
- Lastly, many developing countries are likely to continue to be very dependent upon food exports to the European Community and other industrialised countries. For these developing countries food safety requirements in the export markets will continue to be of considerable importance.

It follows that food safety will continue to be a challenge to food product exporters in developing countries.¹²⁷ According to Jaffee Kenya's fresh vegetable industry used the challenge presented by the European Community's rising food safety requirements as an opportunity to redefine the industry's comparative advantage.¹²⁸ Rather than be endangered by the escalation and proliferation of standards, the Kenyan industry appears to have embraced the European standards and use them to competitive advantage, Jaffee argues.¹²⁹ A similar observation has been made regarding parts of the South African fishing industry.¹³⁰ However, as pointed out by Wilson, disentangling the trade-enhancing effects of food-safety regulations, and more generally SPS regulations, from other factors that may enhance trade, is difficult.¹³¹ Therefore a useful area of research would be to look at whether harmonization and transparency can actually improve trade and welfare. In any event, it appears doubtful whether Jaffee's findings may be given general application so as to apply also to other industries; not to mention to other developing countries. Indeed, Jaffee's observation that the Kenyan fresh vegetable industry used the escalation and proliferation of European standards to

¹²⁷ Wilson, *supra* note 33, at p. 437.

¹²⁸ Steven Jaffee, *From Challenge to Opportunity – Transforming Kenya's Fresh Vegetable Trade in the Context of Emerging Food Safety and Other Standards in Europe*, Agriculture & Rural Development Discussion Paper 1, The World Bank, 2003, p. 58.

¹²⁹ Jaffee, *supra* note 128, p. 59.

¹³⁰ Jooste et al, *supra* note 27, at p. 265.

¹³¹ Norbert Wilson, "A review of empirical studies of the trade and economic effects of food-safety regulation" in *New Approaches to Food-Safety Economic*, A.G.J. Velthuis, L.J. Unnvehr, H. Hogeveen and R.B.M. Huirne (eds), Kluwer Academic Publishers, Dordrecht 2003).

competitive advantage by definition implies that the standards led to a competitive disadvantage for other producers. Hence, whilst there may be cases where the European food safety regime constitutes a golden opportunity to some developing country food producers, it is likely to remain a daring challenge to other such producers; in particular the weakest thereof, i.e. small producers in LDCs.

5.2. A need for increased coordination, communication and cooperation

In order to improve on the situation outlined above it is submitted that the efforts should be aimed at three points, namely:

- Coordination
- Communication
- Cooperation

Over the last two decades food safety rules have grown considerably both in number and in scope. Some of these rules are formed by governments at the international, regional or national level. Others are drawn up by private undertakings or associations of private undertakings. A food business exporting a given food product to the European Community may thus have to comply with several different food safety requirements – some public others private. If the very same product is also exported to for instance the United States still other public and private food safety requirements are likely to apply. This multi-dimensional patchwork of regulatory measures places such pressure on the food businesses that in particular the weaker ones – such as small producers in developing countries – may be unable to meet the requirements. Indeed, not only developing country food businesses, but also retailers in industrialised

countries would prefer to have one global standard for food safety.¹³² Therefore, simplification of the fragmented standards through increased *coordination* between those issuing food safety requirements may be a significant improvement.

Not only are the developing countries faced with an extensive patchwork of regulatory food safety measures. Often food businesses and public authorities in the developing countries have only limited knowledge about the requirements they must comply with when exporting.¹³³ This may lead to substantial problems as is illustrated above in section 3.2 regarding Ghanaian pineapples which were rejected upon arrival in the European Community because the Community had reduced the MRL for a pesticide commonly used for de-greening pineapples without the Ghanaian producers being aware thereof. It follows that there is a need to improve the *communication* of the different food safety requirements together with specific information about how to best comply with these requirements. Whilst there seems to be a general need to improve communication in the field, arguably this need is particularly pronounced in the developing countries – *inter alia* due to the more restricted access to the relevant means of communication and to the linguistic and cultural differences *vis-à-vis* the European Community.

Finally, there is an apparent need for increased *cooperation* between those issuing the food safety requirements and food businesses and authorities in the developing countries. Such cooperation comprises technical assistance regarding how to best

¹³² OECD, *supra* note 32, p. 27.

¹³³ Wilson and Abiola, *supra* note 3, at p. xxxvi, and Henson et al, *supra* note 1, at p. 44-45.

comply with public and private food safety requirements and it comprises the need to design food safety requirements in a way that takes due account of the circumstances under which the food businesses work. Whilst the European Community and other donors provide technical assistance in the field of food safety to developing countries it appears that when drafting food safety requirements public regulators only have limited consideration for the situation in developing countries. This is unfortunate, not least because the incentive to circumvent the food safety requirements will be substantial where the requirements appear to be unrealisable, as has been shown by Ponte.¹³⁴ The European Community should therefore learn from the private standards which are often made in *cooperation* with the various stakeholders – including those in developing countries. In this way it will be more likely that the requirements will be workable – and thus accepted – by those who will have to work with them in practice.

5.3. What specific action may be taken – two immodest suggestions

Neither the purpose nor the limits of the present paper allows for a careful examination of what specific actions may be taken in order to mitigate the problems caused by food safety requirements when developing country food exporters export to the industrialised countries. Nonetheless, by way of illustration two immodest suggestions for specific actions are briefly outlined below.

Firstly, it is apparent that the standards fragmentation – i.e. the considerable number of heterogeneous food safety requirements – constitutes an important barrier to trade. The problem is centred on sales in

the industrialised countries. Increased harmonisation of these requirements will benefit all food businesses selling in the industrialised countries – and thus also those food businesses that are exporting from developing countries. Indeed, as argued in section 3.3 above the burden of complying with more different food safety requirements weighs more heavily on developing country food producers than on their counterparts in the industrialised countries. Therefore, reducing this burden is likely to particularly benefit the former.¹³⁵

Ideally, this harmonisation of public and private food safety requirements of the industrialised world should take place at the global level; for example in the Codex Alimentarius Commission. The question remains, however, whether the Codex Alimentarius Commission will be able to provide the desired results within a reasonable period of time. A better solution appears to be to set up a body that will be able to swiftly and efficiently harmonise food safety requirements in the industrialised countries. To this end access to participate in the body should be limited – for example to the OECD-countries only – and the body should be organised in such a way as to allow for efficient harmonisation. Moreover, in addition to harmonising the public food safety requirements, the body should also cater for the needs of private parties active in the field of laying down food safety requirements. In order to achieve these objectives, it would seem advisable to draw on the European Community's experiences based on Article 95 of the EC Treaty together with its experiences with

¹³⁴ Ponte, *supra* note 82, pp. 61, 63 and 64.

¹³⁵ CTA, *supra* note 26, p. 33, and Jaffee and Henton, *supra* note 45, p. 95. See also Henson et al, *supra* note 1, at pp. 71-73.

the so-called “New Approach”. Any harmonisation measure issued by this body must comply with the SPS Agreement and therefore in principle it will also have to conform to any Codex Alimentarius standard that has been adopted.

Creating this kind of ‘rich-countries-only’ body is likely to attract criticism. The important point to make is, however, that reducing the number of food safety requirements in the industrialised countries will be of particular benefit to food businesses in the developing countries. The more countries that participate in the body, the less effective it is likely to be and thus the less benefit for developing countries food businesses. Hence, whilst it would clearly be more ‘politically correct’ to have also the developing countries represented, a more limited and uniform membership is likely to lead to a much more efficient harmonisation; arguably a reflection of the best being the enemy of the good.

Secondly, in line with Article 178 of the EC Treaty, it is suggested that whenever proposing any new Community legislation in the field of food safety the European Commission should identify the consequences which the proposal will have on the developing countries. Moreover, the Commission should point out alternative ways of reaching an equivalent food safety level and should identify the consequences of this alternative both within the Community and in the developing countries. Admittedly, already today the Commission to a fair extent considers the consequences in developing countries that new food safety legislation may bring about. The proposal set out here however goes one step further by requiring, firstly, the Commission to consistently and openly consider this matter and, secondly, by requiring the Commission to consider alternatives. In this

regard it is possible to draw inspiration from the EFSA Opinion on aflatoxin in nuts referred to in section 4.1.2 above. The obligation proposed here would also imply that the Commission must point out differences between the proposed Community rule and rules regulating the same matter in other industrialised countries. For example, if the United States has laid down rules on what sampling plan must be applied to control the aflatoxin contents in groundnuts, the Commission when proposing a different sampling plan would be obliged to point out what consequences adopting either the proposed or the US sampling plan would have on food safety in the Community and on food businesses in the developing countries.

Similarly, where for example the Commission proposes to introduce a new (stricter) MRL for a pesticide that is used in developing countries, the Commission would have to point out the consequences of this proposal as well as those consequences that would occur if the developing countries were allowed a period of transition before the new MRL was to apply.

6. FINDINGS

Export of agricultural products to the European Community plays an important role for a considerable number of developing countries. Whereas earlier, to varying degrees, these countries were faced with high tariff barriers, today, metaphorically speaking, the tariff barriers have been replaced by extensive food safety requirements. That these requirements create new and extensive barriers is clearly reflected in the present working paper.

Whilst strict product requirements continue to present substantial hindrances to developing country exports, today it is in-

creasingly the process requirements that are hindering developing countries in accessing the European Community's market for food products. These process requirements place a heavy burden particularly on small and medium sized European enterprises, but the burden will normally be much heavier on food businesses in the developing countries where the available resources are appreciably scarcer. For developing country food businesses the marginal costs of complying with the process requirements are likely to be higher than the marginal costs for food businesses in industrialised countries and the high fragmentation of the food safety standards are likely to be more burdensome for the former food businesses than for the latter. Whilst compliance with European Community food safety standards may not always impose prohibitive costs on developing country food businesses and governments, it is likely to generally place them at a competitive disadvantage.

Perhaps the most important finding of the present examination is the confirmation that the devil is in the detail. Several studies have shown that making what may appear to be a minor change of a limit value of a given contaminant in food products may have considerable repercussions for developing countries' access to the European market. Likewise, many other – apparently minor – details may have wide-reaching consequences. For example the examination points out that if a limit value is set at the limit of determination (LOD) something as technical and apparently uncontroversial as improving the method of analysis is likely to be equivalent to a tightening of this limit value. Changing a sampling plan may have the same effect. It is also pointed out that in contrast to the regimes applying to additives and supple-

ments, an authorisation for a novel food product is not generic in nature, but gives only the applicant a right to market the 'novel food' in question. This constitutes an additional obstacle to the access of 'exotic' food products to the European market.

The situation could be much worse, however. For example, with regard to process requirements the European Community draws an important distinction between food products of animal and non-animal origin. If the non-animal origin food safety requirements were to be aligned with those applying to products of animal origin, this would mean a significant deterioration of developing countries' access to the European market. Equally, until now Community law has exempt primary producers from the obligation of introducing a HACCP system, though this may be a short respite. Indeed, there are even examples of the Community's food safety requirements being amended so as to provide better access for developing country food products – as is reflected in the proposed amendment of the Novel Food Regulation. If adopted, this amendment will improve 'exotic' food products' access to the European market.

When it comes to ways of remedying those problems presently facing the developing countries in the field of European Community food safety, there does not appear to be any 'easy fix'. Three measures are proposed to make the barriers more easily surmountable:

- Strongly increased harmonisation of the industrialised countries' food safety standards.

- When proposing new food safety legislation the European Commission should be obliged to set out the likely consequences the proposal may have on developing countries – and to identify alternative measures.
- Continued (and preferably increased) provision of technical assistance to the developing countries to enable them to comply with the food safety standards.

These measures might appear modest on paper, but in a political context the two first-mentioned are likely to go beyond what is politically feasible whilst the third measure is already in use today. In other words, things are likely to continue to be business as usual ...

REFERENCES

- Aloui, Omar & Lahcen Kenny. 2005. *The cost of compliance with SPS standards for Moroccan exports: A case study*. World Bank, Agriculture and Rural Development Discussion Paper.
- Bernauer, Thomas & Ladina Caduff. 2006. Food safety and the structure of the European food industry. In *What's the beef? The contested governance of European food safety* (Christopher Ansell & David Vogel, eds). Cambridge (MA): The MIT Press.
- Bhat, Ramesh V. & S. Vasanthi. 1999. Mycotoxin contamination of foods and feeds – an overview, Third Joint FAO/WHO/UNEP International Conference on Mycotoxins, Tunis, Tunisia, 3-6 March 1999.
- Bridges Weekly Trade News Digest. 2008. SPS Committee considers establishing working group on private sector standards. *Bridges Weekly Trade News Digest*, Vol. 12, Number 24, 2 July 2008.
- Broberg, M.P. 2000. The Court of First Instance's judgment in *Gencor v Commission*. *International and Comparative Law Quarterly* 49: 172-182.
- Broberg, Morten P. 2008. *Transforming the European Community's regulation of food safety*. Stockholm: SIEPS.
- Byron Nelson, Michael & David K. Leonard. 2005. *Pro-poor livestock policy initiative – a living from livestock – international rules, food safety and the poor developing country livestock producer* PPLPI Working Paper No. 25, FAO. www.fao.org/ag/againfo/programmes/en/pplpi/docarc/wp25.pdf
- Cato, J.C. 1998. *Seafood safety – economics of hazard analysis and critical control point (HACCP) programmes*. FAO Fisheries Technical Paper 381, Rome: FAO.
- Cerrex Ltd (UK). 2003. *Study of the consequences of the application of sanitary and phytosanitary (SPS) measures on ACP countries – Commissioned by CTA*.
- Coglianesi, Cary & David Lazer. 2003. Management-based regulation: prescribing private management to achieve public goals. *Law & Society Review* Vol. 37, No. 4: 691-730.
- COLEACP-PIP. 2005. *Diagnostic impact study of the new European regulation 882/2004 "official feed & food controls" and recommendations', Phase one / Final report*.
- Desta, Melaku Geboye . 2008. EU sanitary standards and Sub-Saharan African agricultural exports: a case study of the livestock sector in East Africa. *The Law and Development Review*, Vol. 1, Issue 1: 96-122.
- El-Tawi, Anwar. 2002. *An in-depth study of the problems by the standardizers and other stakeholders from developing countries – ISO/WTO regional workshops – Part 1*. Geneva: International Organization for Standardization.
- European Commission. 1997. *Commission decision 97/513/EC of 30 July 1997 concerning certain protective measures with regard to certain fishery products originating in Bangladesh*. [1997] OJ 214/46.
- European Commission. 1997. *The general principles of food law in the European Union – Commission green paper*. COM1997/176 (final).
- European Commission. 2000. *White paper on food safety*. COM 1999/719 (final).
- European Commission. 2000. *Written question E-2343/99 by Robert Evans (PSE) to the Commission. Aflatoxin fungus*. [2000] OJ 225E 109.
- European Commission. 2001. *2001/17/EC: Commission decision of 19 December 2000 on refusing the placing on the market of "Nangai nuts (" as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document number C(2000)*

- 3888). [2001] OJ L4/35.
- European Commission. 2003. *Commission decision of 5 June 2003 authorising the placing on the market of "noni juice" (juice of the fruit of Morinda citrifolia L.) as a novel food ingredient under Regulation 258/97*. [2003] OJ L144/12.
- European Commission. 2005. *Commission decision 2005/402 of 23 May 2005 on emergency measures regarding chilli, chilli products, curcuma and palm oil*. [2005] OJ L135/34
- European Commission. 2005. *Eurostat, structural business statistics*.
- European Commission. 2005. *The TSE road map*. (COM (2005) 322 final. Brussels 15 July 2005.
- European Commission. 2006. *Commission regulation 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs*. [2006] OJ L70/12.
- European Commission. 2006. *Guidance document – key questions related to import requirements and the new rules on food hygiene and official food controls*. Brussels.
- European Commission. 2006. *Guidance document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs*. Brussels 13 November 2006.
- European Commission. 2007. *Eurostat pocketbook – agriculture, main statistics 2005-2006*. Luxembourg.
- European Commission. 2007. *Bolivia country strategy paper 2007-2013*. 12.07.2007 (E/2007/1405), http://ec.europa.eu/external_relations/bolivia/csp/07_13_en.pdf.
- European Commission. 2007. *COM(2007)872 proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX (common procedure)*. COM(2007) 872 final.
- European Commission. 2008. *Commission decision of 27 June 2008 authorising the placing on the market of baobab dried fruit pulp as a novel food ingredient under Regulation 258/97*. OJ 2008 L183/38.
- European Commission. 2009. *Commission working document, third progress report on the strategy for simplifying the regulatory environment*. COM(2009) 17 final.
- European Commission. 2009. *Draft Commission regulation of 13 March 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC. SANCO/2697/2009 (POOL/E5/2009/2697/2697-EN.doc)*.
- European Commission, Health & Consumer Protection Directorate-General. 2007. *General guidance on EU import and transit rules for live animals and animals products from third countries*.
- European Community. 1964. *Directive 64/433/EEC on health problems related to intra-Community trade in fresh meat* OJ No P 121, 29/07/1964, p. 2012-2032.
- European Community. 1994. *Directive 94/35 of 30 June 1994 on sweeteners for use in foodstuffs*. [1994] OJ L237/3.
- European Community. 1994. *Directive 94/36 of 30 June 1994 on colours for use in foodstuffs*. [1994] OJ L247/13.
- European Community. 1995. *Directive No 95/2 of 20 February 1995 on food additives other than colours and sweeteners*. [1995] OJ L61/1.
- European Community. 1997. *Regulation 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients*. [1997] OJ L43/1.
- European Community. 2000. *Directive 2000/29 of 8 May 2000 on protective measures against the intro-*

- duction into the Community of organisms harmful to plants or plant products and against their spread within the Community.* [2000] OJ L169/1.
- European Community. 2002. *Directive 2002/46 of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.* [2002] OJ L183/51.
- European Community. 2002. *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.* [2002] OJ L31/1.
- European Community. 2004. *Regulation 852/2004 of 29 April 2004 on the hygiene of foodstuffs.* [2004] OJ L139/1.
- European Community. 2004. *Regulation 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin.* [2004] OJ L226/22.
- European Community. 2004. *Regulation 854/2004 of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.* [2004] OJ L226/83.
- European Community. 2004. *Regulation 882/2004, of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules,* [2004] L165/1.
- European Community. 2005. *Regulation 2076/2005, of 5 December 2005 laying down transitional arrangements for the implementation of Regulations 853/2004, 854/2004 and 882/2004 amending Regulations 853/2004 and 854/2004.* [2005] OJ L338/83.
- European Community. 2006. *Regulation 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.* [2006] OJ L364/5.
- European Community. 2008. *Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives.* [2008] OJ L33/1.
- Fischer, R. 1998. Regulation as a trade issue from a Chilean perspective. In *Regulatory reform in the global economy: Asian and Latin American perspectives*. Proceedings of the Conference on Trade Policies and Trade Regulations and International Openness. Paris: Organization for Economic Cooperation and Development (OECD).
- Fletcher, Anthony. 2007. Global concern over new EU novel food regs. *Nutraingredients.com, Europe*, 12 april 2007. www.nutraingredients.com/news/printNewsBis.asp?id=67019.
- Garcia Martinez, Marian & Nigel Poole. 2009. Ethical consumerism: development of a global trend and its impact on development. In *Standard bearers – Horticultural exports and private standards in Africa* (Adeline Borot de Battisti, James MacGregor & Andrew Graffham, eds). London: International Institute for Environment and Development (UK).
- Gilbert, John & Eugenia A. Vargas. 2005. Advances in sampling and analysis for aflatoxins in food and animal feed. In *Aflatoxin and food safety* (Hamed K. Abbas, ed.). Boca Raton (USA): Taylor & Francis.
- Graffham, Andrew. 2006. *EU legal requirements for imports of fruits and vegetables (a suppliers guide)*. Fresh Insights no. 1, DFID/IIED/NRI. www.agrifoodstandards.net/resources/global/fresh_insights_1_eu_legal_requirements_for_imports_of_fruits_and_vegetables
- Halliday, Jess. 2009. Illegal yellow prompts spate of spice recalls *FoodQuality news.com* 10 April

- 2009 (www.foodqualitynews.com/content/view/print/242937).
- Henson, Spencer & John Humphrey. 2008. Understanding the complexities of private standards in global agri-food chains. Paper presented at International Workshop on Globalization, Global Governance and Private Standards, Leuven.
- Henson, Spencer & Rupert Loader. 1999. Impact of sanitary and phytosanitary standards on developing countries and the role of the SPS Agreement. *Agribusiness*, Vol. 15, No. 3: 355-369.
- Henson, Spencer & Rupert Loader. 2001. Barriers to agricultural exports from developing countries: The role of sanitary and phytosanitary requirements. *World Development*, Vol. 29, No. 1: 85-102.
- Henson, S.J., R.J. Loader, A. Swinbank, M. Bredahl & N. Lux. 2000. *Impact of sanitary and phytosanitary measures on developing countries*, The University of Reading, Department of Agricultural and Food Economics, Centre for Food Economics Research (CeFER), www.reading.ac.uk/nmsruntime/saveasdialog.asp?IID=17696&sID=72895.
- Hirst, David. 2001. Recent developments in EU pesticides regulations and their impact on imports of tropical fresh produce, presentation given to Tropical Agriculture Association, London 27 March 2001. www.taa.org.uk/southeast/PaperDavidHirstmay2001.htm.
- Holland, Debra & Helen Pope. 2004. *EU food law and policy*. The Hague (the Netherlands): Kluwer Law International.
- Jaffee, Steven. 2003. *From challenge to opportunity – transforming Kenya’s fresh vegetable trade in the context of emerging food safety and other standards in Europe*. Agriculture & Rural Development Discussion Paper 1, The World Bank.
- Jaffee, Steven M. & Spencer Henton. 2005. Agro-food exports from developing countries: The challenge posed by standards. In *Global Agricultural Trade and Developing Countries*, (M. Ataman Aksoy & John C. Beghin, eds). Washington D.C.: The World Bank.
- Jooste, André Erik Kruger & Flip Kotzé. 2003. Standards and trade in South Africa – paving pathways for increased market access and competitiveness. In *Standards & Global Trade – A Voice for Africa* (John S. Wilson & Victor O. Abiola, eds). Washington D.C.: The World Bank.
- Josling, Tim, Donna Roberts & David Orden. 2004. *Food regulation and trade – toward a safe and open global system*. Washington D.C.: Institute for International Economics.
- Kinyua, Henry. 2009. How private standards designed for export produce also influence Kenyan domestic markets. In *Standard bearers – Horticultural exports and private standards in Africa*, (Adeline Borot de Battisti, James MacGregor & Andrew Graffham, eds). London: International Institute for Environment and Development (UK).
- Knudsen, Ib, Inge Søborg, Folmer Eriksen, Kirsten Pilegaard & Jan Pedersen. 2005. *Risk assessment and risk management of novel plant foods – concepts and principles*. TemaNord 2005:588. Copenhagen: Nordic Council of Ministers.
- Meulen, Bernd van der & Menno van der Velde. 2008. *European food law handbook*. Wageningen (the Netherlands): Wageningen Academic Publishers.
- Moorhead, Anne. 2007. *Missing the market – How exotic foods are being barred from the EU, Novel Food Regulation – joint paper prepared for UNCTAD, the CBI, GTZ, GFU and IPGRI*.
- Neville Craddock Associates (UK). 2005. *The EU Novel Food Regulation – impact on the potential ex-*

- port of exotic traditional foods to the EU: suggestions for revision*. Discussion Paper prepared for UNCTAD and CBI in cooperation with GTZ, GFU and IPGRI.
- Nyangito, Hezron Omare, Tom Olielo & David Magwaro. 2003. Improving market access through standards compliance – a diagnostic and road map for Kenya. In *Standards & global trade – A voice for Africa* (John S. Wilson & Victor O. Abiola, eds). Washington D.C.: The World Bank.
- OECD (Working Party on Agricultural Policies and Markets). 2006. *Final report on private standards and the shaping of the agro-food system*. AGR/CA/APM(2006)9/Final.
- Otsuki, Tsuchiro, John S. Wilson & Mirvat Sewadeh. 2001. Saving two in a billion: quantifying the trade effect of European food safety standards on African exports. *Food Policy* vol. 26: 495-514.
- Owuor, Apollo. 2009. The Kenya Horticultural Exporters Ltd experience of private voluntary standards. In *Standard bearers – horticultural exports and private standards in Africa*, (Adeline Borot de Battisti, James MacGregor & Andrew Graffham, eds) London: International Institute for Environment and Development (UK).
- Ponte, Stefano. 2005. *Bans, tests and alchemy: Food safety standards and the Ugandan fish export industry*. DIIS Working Paper no. 2005/19.
- Rebello da Silva, Gabriela & Lara da Silva Carrilho, 2003. Bridging the standards divide – A case study and action plan for Mozambique. In *Standards & global trade – a voice for Africa*, (John S. Wilson & Victor O. Abiola, eds). Washington D.C.: The World Bank.
- Roheim, Cathy A. 2005. Seafood: Trade liberalization and impacts on sustainability. In *Global agricultural trade and developing countries*, (M. Ataman Aksoy & John C. Beghin, eds). Washington D.C.: The World Bank.
- Rudaheeranwa, N., F. Matovu, & W. Musinguzi. 2003. Enhancing Uganda's access to international markets – a focus on quality. In *Standards & global trade – a voice for Africa* (John S. Wilson & Victor O. Abiola, eds). Washington D.C.: The World Bank.
- Schillhorn van Veen, Tjart W. 2005. International trade and food safety in developing countries, *Food Control* 16: 491–496.
- Scientific Panel on Contaminants in the food chain. 2007. Opinion of the Scientific Panel on Contaminants in the food chain on a request from the Commission related to the potential increase of consumer health risk by a possible increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products, Question N° EFSA-Q-2006-174, adopted on 25 January 2007. *The EFSA Journal* 446: 1-127. www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620761977.htm.
- Scott, Joanne. 2007. *The WTO Agreement on sanitary and phytosanitary measures – a commentary*. Oxford: Oxford University Press.
- SPS Secretariat. 2003. *World Trade Organization – Committee on Sanitary and Phytosanitary Measures, specific trade concerns – Note by the Secretariat – Revision*. G/SPS/GEN/204/Rev.3, 26 March 2003, <http://docsonline.wto.org/DDFDdocuments/t/G/SPS/GEN204R3.doc>.
- Standing Committee on the Food Chain and Animal Health. 2004. *Guidance on the implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) no 178/2002 on General Food Law, conclusions of the Standing Committee on the Food Chain and Animal Health*. http://ec.europa.eu/food/foodlaw/guidance/guidance_rev_7_en.pdf

- Stanton, Gretchen H. & Christiane Wolff. 2009. Private voluntary standards and the World Trade Organization Committee on Sanitary and Phytosanitary Measures. In *Standard bearers – horticultural exports and private standards in Africa* (Adeline Borot de Battisti, James MacGregor & Andrew Graffham, eds). London: International Institute for Environment and Development (UK).
- Starling, Shane. 2009. EU Novel Foods amendment proposal accepted. *FoodQualityNews.com*, 30 April 2009. www.foodqualitynews.com/content/view/print/245327.
- Taylor, Eunice & Kevin Kane. 2005. Reducing the burden of HACCP on SMEs. *Food Control* 16: 833–839.
- Tiviski. 2009. www.tiviski.com/index6-uk.html accessed 10 May 2009.
- Tridimas, Takis. 2007. *The general principles of EC law* 2nd ed. Oxford: Oxford University Press.
- Trienekens, Jacques & Jack van der Vorst. 2006. Traceability in food supply chains. In *Safety in the agri-food chain* (P.A. Luning, F. Devlieghere & R. Verhé, eds). Wageningen: Wageningen Academic Publishers.
- Unnevehr, Laurian & Nancy Hirschhorn. *Designing effective food safety interventions in developing countries*, <http://go.worldbank.org/Y0270X2TE0>, (unpaginated).
- Unnevehr, Laurian J. & Helen H. Jensen. 1999. The economic implications of using HACCP as a food safety regulatory standard *Food Policy* 24: 625-635.
- Wijnands, J.H.M., B.M.J. van der Meulen & K.J. Poppe (eds). 2006. *Competitiveness of the European food industry - an economic and legal assessment – 2007*. The Hague.
- Willems, Sabine, Eva Roth & Jan van Roekel. 2005. *Changing European public and private food safety and quality requirements – challenges for developing country fresh produce and fish exporters – European Union buyers survey*. The World Bank, Agricultural and Rural Development Discussion Paper 15, Cost of Compliance with SPS Standards.
- Wilson John S. & Victor O. Abiola. 2003. Executive summary. In *Standards & global trade – a voice for Africa* (John S. Wilson & Victor O. Abiola, eds). Washington D.C.: The World Bank.
- Wilson, John S. & Victor O. Abiola. 2003. Introduction. In *Standards & global trade – a voice for Africa* (John S. Wilson & Victor O. Abiola, eds). Washington DC: The World Bank.
- Wilson, John S. 2002. Standards, regulation and trade – WTO rules and developing country concerns. In *Development, trade, and the WTO – a handbook* (Bernard Hoekman, Aaditya Mattoo & Philip English, eds), The World Bank.
- Wilson, Norbert. 2003. A review of empirical studies of the trade and economic effects of food-safety regulation. In *New approaches to food-safety economics*, (A.G.J. Velthuis, L.J. Unnevehr, H. Hogeveen & R.B.M. Huirne, eds). Dordrecht (the Netherlands) Kluwer Academic Publishers.
- WTO. 2007. Sanitary and phytosanitary measures – private standards are a mixed blessing, committee hears. *WTO: 2007 News*, 28 February and 1 March 2007. www.wto.org/english/news_e/news07_e/sps_28feb_1march07_e.htm
- Yapp, Charlotte & Robyn Fairman. 2006. Factors affecting food safety compliance within small and medium-sized enterprises: Implications for regulatory and enforcement strategies. *Food Control* Vol. 17, Issue 1: 42-51.