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# Chemical and biological risk

## Study of regulatory regimes for managing chemical and biological risk in selected countries and implications for New Zealand

**Report to Ministry for the Environment**

**December 2011**

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# Executive Summary

This report surveys literature on the regulation of chemical and biological risks in selected countries, recent changes to those regulations and what has driven those changes. It provides a basis for further analysis of different regulatory approaches and their implications for New Zealand.

The countries selected for this review are Australia, Canada, United Kingdom; the United States, the European Union, Japan and China. This selection covers countries of varying sizes with different export orientation, and they also have quite different approaches to risk regulation for a variety of contextual reasons. The main focus has been on the United States and the European Union since this is where the best information is available on their regulatory regimes.

The literature surveyed includes some that is mainly descriptive of the different regimes, some that analyses the reasons for, and strengths and weaknesses of, the different regimes, and some that attempt comparative analysis of a number of the regimes, particularly between those found in the United States, the European Union, Japan, China, and the United Kingdom. These comparisons are made on the basis of different criteria, and further analysis will be required to compare across the comparative literature.

The literature reveals some distinct differences in approach to regulation:

- Chemical risk regulation is more likely to have a single overarching policy or act regulating introduction of new chemicals to a country, plus specific regulations of use in diverse laws on food safety, environmental protection, occupational safety and public health; whereas biological risk regulation has more diverse regulation of entry and quarantine, biosecurity, introduction of new organisms and genetic modification, plus specific regulations on food safety, pharmaceuticals and so on.
- In regulation of risks of biotechnology and genetic modification, there is a broad split between permissive regimes of large food exporting countries of Australia, Canada and the United States, and the more restrictive precautionary regimes in Europe and Japan where the regimes reflect both the lesser importance of food exports and public distrust of authorities arising from past food scares. Further, China has a different approach that broadly supports a permissive approach by Chinese companies but bans commercial farming of foreign GMO varieties.
- The European Union has recently reformed its regulation of chemical risks, largely driven by the need for harmonisation of laws across a common market of increasing member states; whereas the United States retains a 34 year old law which contains disincentives for replacing old chemistry with new more benign chemicals.

These various regulatory choices have implications for innovation, productivity and growth and also for New Zealand's capacity to trade and regulate efficiently. These are examined, particularly the trade aspect, in terms of New Zealand being a policy

taker, but also as a player who can influence agreements once framework for negotiations is set.

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# 1. Introduction

This report has been prepared by NZIER and URS New Zealand Limited for the Ministry for the Environment to provide information on approaches to biological and chemical risk management public policy and regulatory regimes in selected (comparable) countries together with an assessment of the impact of such approaches on innovation and economic development.

In accordance with the Ministry's RFP the following specific tasks were undertaken:

i A literature search on research and studies providing comparative analysis of selected countries' approaches to policy and regulation of chemical and biological risk.

ii A description of the regulatory frameworks for managing chemical and biological risks, identifying significant changes in recent years and what has driven them.

iii An outline of the policy rationale and principles underlying the approach taken by each of the countries examined.

iv Assessment of the impacts of each country's regulatory regime on innovation, productivity and economic development.

v Assessment of any impacts the selected countries' policy and regulatory regimes may have on New Zealand's ability to trade and to manage risk efficiently.

vi Identification of lessons for New Zealand from the experience above, taking account of differences in size or other characteristics that may affect applicability.

Scope of review:

- The countries selected for review were **Australia, Canada and the US, the EU and United Kingdom, Japan and China**, as these are New Zealand's major trading partners. (Where relevant information was obtained about other, smaller countries, this has been included for information).

- Biological risk includes risks arising from genetically modified organisms (GMOs) as well as non-GMOs.

- Radioactive materials are excluded from the scope, as is illegal or criminal use of biological agents.

- The focus of the review was regulations that relate to first entry of chemical substances or organisms, rather than internal management controls, as this is the step with the greatest implication for New Zealand (in respect of trade access for example).

- Specific regulations and controls regarding food and drug safety are excluded from the scope.

Most of the focus in this review is on countries who might influence New Zealand's regulatory regime either directly, or indirectly through international agreements and /or are major trading nations.

This Report is structured as follows:

- Section 2 sets up a framework for examining the drivers that influence regulation in each country;
- Section 3 provides information on the regulation of **biological** risks in each country;
- Section 4 provides information on the regulation of **chemical** risks in each country; and
- Section 5 presents an overview of the themes/trends, implications for innovation and productivity, a summary of policy positions and implications for New Zealand.

# 2. Framework for examining risk regulation

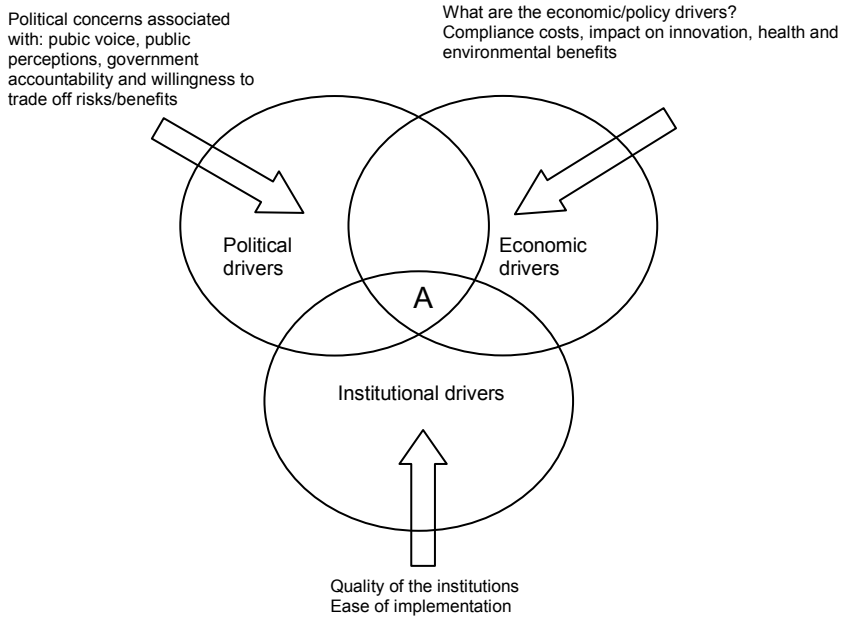
## 2.1 High level framework

To understand the current shape of each biological and chemical regulatory regime in each jurisdiction requires us to examine the interplay between the political, economic and institutional drivers.

Furthermore, it is how these political, economic, and institutional drivers reinforce each other in any particular biological and chemical regulatory regime that determines and informs the public policy and regulatory approaches to management of chemical and biological risk and the extent to which it assists efficiency, effectiveness, innovation and durability of the regime.

Figure 1 sets out one way of thinking about these drivers at a high level. The political, economic, and institutional drivers that need to be considered when examining biological and chemical regulatory regimes and how they have evolved.

***Figure 1: Political, economic and institutional drivers determine the shape of the regulatory regime***




Source: NZIER

At point A, all three drivers overlap and so there are no barriers to an agreement or agreed position in the short run. The three potential drivers can be considered:

- The political drivers: the background issues that drive political thinking:
  - A country's/region's overriding concerns that motivate politicians to take action or continue the status quo e.g. this could be driven by the effectiveness of lobby groups, general disquiet by voters about the state of the environment (as voters get richer), or "one-off" events that trigger a political response;
  - How biological and chemical regimes might impact on other trading/political relationships within and between countries over time;
  - The degree of domestic understanding of chemical and biological risk issues.
- The policy/economic drivers including:
  - The economic impact of any particular biological or chemical regime – positive or negative?
  - Are there any spillover effects (e.g. unforeseen impact on the market or other industries) from the biological or chemical regime?
- Institutional drivers including:
  - How do the arrangements work over time?
  - How arbitrary are the rules?

- What is the impact of incentives set up by the institutional approach? (The more likely that institutions will be less predictable in their decision making, reducing transparency and the ability of the economy to grow).

These matters of substance all play a part in the shaping the biological and chemical regimes are structured and also there durability.

# 3. Features of chemical risk regulation

Chemical production and use is widespread and growing, and while much of it has been concentrated in developed countries until recently, developing countries are becoming increasingly involved both in producing new chemicals and dealing with wastes (Bengtsson 2010). There is a long history of international co-operation in managing risks of chemicals, with over 100 international agreements, but their complexity means they are becoming increasingly difficult to manage.

There has recently been increased interest in consolidating or co-ordinating chemical regulations, giving rise to:

- The Strategic Approach to International Chemicals Management (SAICM), which is largely aimed at giving developing countries the sort of protections that developed countries have already achieved;
- the EU's chemical law reforms known as REACH (see below).

Increasing use of many different chemicals, increasing international trade and increasing awareness of types of hazard and their impacts on health and the environment has spurred United Nations initiatives to harmonise the classification and labelling of chemicals so as to give all regulatory structures a common language for deciding on chemical hazards. Chemical policy has also moved in part in response to the Agenda 21 goals derived at the 1992 World Summit on Sustainable Development in Rio de Janeiro. The increasing complexity of risks and international agreements does not make implementation easier and substantive changes can be slow to take effect.

Broadly chemical risk is regulated through two types of regulation:

- Specific regulations on the registration, assessment and use of chemicals in specific processes (i.e. point of entry or registration);
- "Environmental regulation" in a broad sense, which seeks protection of outcomes for people, communities, their health and livelihoods and the natural environment through controls on transport, storage, use and disposal.

This review focuses on the former – as this step has the greatest implications for trade and innovation.

### 3.1.1 International policy agreements

There are a number of international agreements that help shape national regulation of chemical risks. Some of these provide direction that necessitates amendment of

national policies to comply; others constrain what national policies can do (e.g. WTO measures to avoid undue restraint of trade). These include:

- WTO Agreement on Technical Barriers to Trade;
- Strategic Approach to International Chemicals Management (SAICM);
- Rotterdam Convention on Severely Hazardous Chemicals;
- UN Globally Harmonised System of Classification, Labelling and Packaging (GHS);
- Basel Convention on Control of Transboundary Movement of Hazardous Wastes;
- Stockholm Convention on Persistent Organic Pollutants;
- Montreal Protocol on Ozone Depleting Chemicals.

Bengtsson distinguishes two blocks of countries that dominate international negotiations: the EU and the "JUSCANNZ" block (Japan, US, Switzerland, Canada, Australia, Norway and New Zealand). Another group, G20 + China, contains mainly developing countries. Greater focus on life-cycle risks of chemicals, increasing involvement of all stakeholders with industry taking more responsibility, and increasing outreach to non-OECD countries have been driving chemical policies over recent decades. There has also been growing pressure to harmonise classification and hazard information for chemicals, due to increasing use of many different chemicals, increasing international trade and increasing knowledge of the risks to health and environment caused by chemicals.

In the next section, we set out the regime description and political, economic and institutional drivers for each region for chemical regulation.

## 3.2 European Union

### 3.2.1 Regime description

In the past five years the EU has undergone far reaching reforms of the way its chemicals are approved, placing the burden on businesses to prove their products are safe before they can be placed on the market. The system, called Registration, Evaluation and Authorisation of CHemicals (REACH), aims to make chemicals safer for human health and the environment and to stimulate innovation in the sector. It came into force in June 2007.

The key aim was a single set of controls for all chemicals. This included the 30,000 existing chemicals not subject to controls as well as the 2,700 "new" chemicals which have been put on the market since 1981 and that have been subject to strict controls. Under REACH manufacturers and importers of chemicals are required to submit hazard, use, exposure and risk data for identified uses of substances. Article 95 of the EC Treaty requires REACH to be uniformly applied across the whole Union. Furthermore, it applies to all chemicals manufactured or imported in quantities of one tonne or more. Other components included:

- The REACH system applies to all substances in any finished article even those that rarely resulted in adverse affects;
- It involves three elements: registration, evaluation, and authorisation.
  - The REACH requires registration for all substances, both new and existing subject to limited exceptions. Registration requirements include: summaries of all existing test data and other information; a description of all uses and related exposure scenarios; a chemical safety report that identifies all risks arising during a substance's lifecycle; and proposed risk reduction measures;
  - Evaluation includes compliance checks of registration dossiers, checking of testing proposals, and a substance evaluation that may require further information on the risk to human health or the environment
  - Full pre-market authorisation is required for substances that are banned in general use, however requests for authorisation of substances banned for general use can be considered under a defined risk management regime or where there is a socio-economic justification. Authorisation requests should also include a substitution plan and are also required to be renewed periodically.
- Four volume thresholds were set at 1, 10, 100, and 1,000 tonnes per year and per manufacturer. Below 1 tonne no additional tests are required; however for all substances produced in volumes over 10 tonnes per annum additional tests are required.

REACH replaced 40 different regulatory programmes with a single set of rules EU-wide. It requires industry to demonstrate the safety of chemical manufacturing and use and to go through a registration process. It applies to new chemicals immediately, but application to "old" chemicals is being phased in, with the most hazardous being treated first. The most dangerous chemicals will be phased out under REACH, to encourage their progressive replacement by safer ones. Phase in is scheduled for completion by 2018. REACH also employs a "tiered-testing" approach in that the data required for evaluation increases with higher volume of production.

In the following section we have used the framework set out in section **XX** to assess the political, economic and institutional drivers of the EU's approach. This section examines each of these drivers in turn.

### 3.2.2 Political drivers

The formation of the European Union approach to chemical regulation has been crucially dependent on the politics. It has set the tone, affected the aspirations and circumscribed what was achievable. Two important motivations are:

- "Voice", i.e. how voters' and other stakeholders concerns are manifested through the political process to make changes; and
- "Accountability" how voice has been translated into regulations that attempt to reflect voter concerns about the chemical regulatory regime.

Below we examine each of these issues in turn.

### *a) Voice*

The key driver for this change was mounting public concern over a lack of information on 99% of chemicals (around 100,000 'existing substances') that were placed on the market prior to 1981. This is because prior to that date, no stringent health and safety tests were needed for chemicals. On the market also are nearly 3,000 so-called 'new substances' which had to go through a more stringent safety screening after 1981.

The issue became politicised because of the rising incidence of diseases such as cancer and leukaemia that could potentially be linked to chemicals, creating a public perception that unrestricted chemical use was responsible. Blood tests in humans and animals have shown contamination by known toxic substances, raising questions as to how they enter the body and the extent of the damage that they could cause. Critics were quick to point out that many thousands of untested chemicals were in a large number of everyday consumer products. Numerous chemicals had already entered the food chain, and were found in breast milk as well as in the blood of polar bears in the Arctic regions.[1] It was strongly suggested by many environmental groups – without causal proof – that these substances were linked to cancer and other health problems, such as allergies, birth defects and reduced fertility as well as damaging wildlife and polluting the environment.[2] Coincidently there was another drive for reform of European chemicals regulations from the business sector, building on studies suggesting that the 7$^{th}$ Amendment of the European Scheme had led to a significant decline in new substances placed on the market compared with in the different US regime over the same period.[3] The primary concern was that regulation was causing a loss of competitiveness for EU industry, although a secondary issue was the slow down in replacing environmentally harmful chemicals with innovation with more benign chemicals.

However, the main public concern driven mainly out of Northern Europe[4] was with the safety for human health and environment and led to reports being commissioned

[1] http://archive.corporateeurope.org/docs/lobbycracy/BulldozingREACH.pdf

[2] Ibid.

[3] Fleischer M (1998) "Regulation and innovation in the chemical industry: the legislation of chemicals in the EU"; paper presented to IPTS workshop on *The Impact of Regulation on Innovation*, Sevilla, Spain, January.

[4] Of particular note is the role of Sweden in this development of a new regulatory regime. While we can not fully establish who was responsible for the development of REACH the following claim by the Swedish government seems to have an element of truth in it: "*in large measure the extensive EU chemicals legislation, REACH, which was adopted in 2006, has come about at the initiative of Sweden and with the assistance of Sweden's internationally recognised expertise in the area. In the negotiations on REACH Sweden has worked for stronger rights for consumers to information and for the continuous substitution of dangerous chemicals when research establishes substances or methods that are safer. Sweden is continuing to pursue these issues in the global chemicals negotiations, where REACH often serves as a model*" http://www.sweden.gov.se/sb/d/2951/a/17125

that uncovered deficiencies associated with the chemicals regulations. These identified two key issues[5]:

- A lack of available data on hazards and uses of existing chemicals, due to a lack of an obligation on industry to deliver such data. A study by Allanou et al (1998) showed that little data was available on high volume chemicals and without that data it was impossible to assess whether chemicals should undergo further evaluation or whether firms were carrying out responsibilities such as assessing risks to chemical workers; and
- An undue burden on the regulator to assess risks of existing chemicals. There was insufficient data to complete risk assessments and management studies.

Therefore, the driving political force was a concern for human health and environmental pollution (Warhurst, 2005). A secondary objective was to shift responsibility for testing from over-stretched tax-funded regulators to industries and importers closer to the chemicals, with a view to reducing transaction costs of undertaking hazard assessments and improving "innovation" by streamlining processes for "new chemistry" coming onto the market across a much enlarged EU.

Below we look at the response of the European Union to the perceived deficiencies.

### *b) Accountability*

### *The response to public concern*

Responding to the political pressures which led to REACH requires an understanding of the history of regulatory approaches to chemicals in the EU.

Regulation of chemical risks within what is now the European Union began in 1967 with the Directive on Classification, Packaging and Labelling of Dangerous Substances, a regulation primarily focused on occupational safety around chemicals and achieving harmonisation among the then six members of the EEC. Subsequent amendments have added to its scope. The 6$^{th}$ Amendment in 1979 introduced a requirement for pre-market notification of basic safety data for new chemicals, and also extended consideration to matters of environmental fate and safety. The 7$^{th}$ Amendment of 1992 required risk assessments to be carried out for notified substances, following a procedure published in 1993. Also in 1993 an Existing Substances Regulation sought information and assessments on the 10,000 substances that had been on the market before 1981 and which entered the market in volumes in excess of 10 tonnes per year.

These various requirements led to the establishment of two separate inventories of chemical substances on the European market: an inventory of information on new substances known as ELINCS, and one on existing substances known as EINECS. These were not linked so additions to ELINCS did not automatically lead to updating of EINECS. Notification of the manufacture or import of the substance was required before it entered the market in Europe.

[5] A report on Directive 67/548/EEC, Directive 88/379/EEC, Regulation 793/93/EEC and Directive 76/769/EEC. http://europa.eu.int/comm/environment/chemicals/pdf/report-4-instruments_en.pdf

In theory this system appeared to create a methodology for assessing and managing risks posed by chemicals.

### *The development of REACH*

A more focused debate developed between stakeholders as to how they were going to adequately control the chemical industry and the use of its products (Jeffs 2004). The debate resulted in the publication of a European White Paper in 2001 titled "Strategy for a future chemicals policy". This document is the foundation of the REACH approach.

Following feedback from stakeholders, the EU in 2003 adopted the REACH proposals set out in the 2001 strategy White Paper. The REACH proposals numbered some 1300 pages, were split into six volumes and included some 800 pages dealing with the test methods to be used in generating data on physical-chemical properties, toxicity, and ecotoxicity of all chemicals.

### *REACH philosophy*

REACH seeks to close a knowledge gap on the spread of chemicals and associated hazards by placing responsibility on importers and producers of chemicals to assess risks and provide appropriate safety information to professional users. It also puts obligations on producers to inform end users about the presence of the most hazardous substances in products. It requires companies that produce or import the same substance to participate in a Substance Information Exchange Forum intended to facilitate data exchange, avoid duplication of studies and reduce the number of studies on animals. REACH will also fulfil SAICM principles relating to knowledge and information on chemicals and chemicals management.

Compared to the previous situation in the EU, REACH has reduced the information requirements for new chemicals, required risk assessment of existing chemicals with increasing data requirements over time, and applied the idea of "no data, no market" for access to the EU (Karlsson 2010).

The European Union authorities have stated that a precautionary approach is the underlying basis of REACH. This principle advocates taking precautionary action when chemicals pose possible threats to human health (e.g. cancer) and the environment, rather than waiting for complete scientific proof of cause and effect This prevents damage while new information accumulates. Critics of this approach point out that it neglects the probability of an outcome (e.g. in contracting cancer from chemicals).

There are varying views of the strength of the precautionary approach being applied in REACH. However most of the literature (Bergkamp & Hanekamp 2003 for example) that represents views from a wide range of stakeholders (environmental groups, industry and government) suggest that REACH takes a very cautious approach to managing adverse effects. As "proof" they point to the banning of penta- and octa-bromodiphenylether (BDE) (a flame-retardant) in all products, the phase out

of deca-BDE in electronics and the use of linear non-threshold models (to extrapolate risks from high doses to very low doses) as evidence of a strong precautionary approach.[6] The intent is further underlined by drawing parallels between selected principles of the Rio Declaration on Environment and Development (1992) and the REACH approach set out in Table 1.

The overriding concern of European policymakers was to manage chemicals in a way that further safeguarded human health and the environment. The social and environmental objectives have been at the forefront of debate since the White Paper done in 2001. The focus on environmental and social considerations was backed up by a perceived strong precautionary approach.

Regulation of chemicals is a complex area and public opinion in different regions is strongly influenced by local events. Surveys in Britain suggest a mixed picture (Chemical Industries Association surveys) with a sharp divide amongst those responding. Pan European surveys carried out by the European Chemical Industry Council (Cefic) in 2010 suggested that most respondents (75%) wanted tougher controls and increased regulation, however the positive view of the chemicals industry (49%) outweighed the negative responses (44%). It was only in 2004 that the survey showed positives outweighing negatives for the first time. Public perception of the industry was worst in Sweden while Germany had the most positive views.

Public perceptions of the adequacy of existing enforcement regimes are mixed. The Cefic survey asks a number of questions around acceptance, trust and regulation. When asked if the industry should face tougher control, 77% of respondents agree with this statement. While this is high, the percentage agreeing has trended down over time, albeit slowly. When asked is this an industry I accept? 63% agree. This number has increased slowly over time. Two other questions that also have a bearing on attitudes to the chemical industry are:

- Does the industry deserve to be trusted? (50% agree); and
- Is this an industry I would work in? (34% agree).

Both of these numbers have slowly trended upwards over time.

[6] While these actions and methods have been adopted in the pre REACH period they signal the approach under the REACH regulation.

### *Table 1: REACH and the precautionary approach*

| Elements of the precautionary approach | REACH approach |
|---|---|
| The precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. (principle 15) | Precaution is the aim of regulators in Europe through the REACH regulations. Evidence exists to show this e.g. restrictions on BDE use and use of tests reinforce a conservative approach. |
| Environmental impact assessment, as a national instrument, shall be undertaken for proposed activities that are likely to have a significant adverse impact on the environment and are subject to a decision of a competent national authority. (principle 17) | REACH has set definite goals and time periods for registration, ensured that the industry assesses, communicates, and it manages risk under strong direction from regulators, putting financial responsibility on the registrant to prove that products are safe |
| To achieve sustainable development and a higher quality of life for all people, States should reduce and eliminate unsustainable patterns of production and consumption and promote appropriate demographic policies (principle 8) | As part of authorisation under REACH assessment of alternatives are required, particularly for hazardous chemicals |
| States should cooperate to strengthen endogenous capacity-building for sustainable development by improving scientific understanding through exchanges of scientific and technological knowledge, and by enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies (principle 9) | Required through the REACH registration and evaluation processes |
| Environmental issues are best handled with participation of all concerned citizens, at the relevant level (principle 10). | REACH reflects European views on chemicals |

Source: http://www.unep.org/Documents.Multilingual/Default.asp?documentid=78&articleid=1163

The willingness to trade off risk against perceived benefits depends on a number factors:

- Whether there has been an accident recently e.g. French public opinion was influenced by an accident in Toulouse (where 31 people lost their lives when a fertiliser factory exploded);
- Proximity to a chemical site - those who lived closer to chemical sites or who had friends and family working in the industry had the most positive opinion (German attitudes are influenced by the large petrochemical industry); and
- Other country-specific attitudes and beliefs.

However, with such a strong view that regulation should be tougher the willingness to trade off risk seems limited in Europe. If 75% of respondents to a reputable CEFIC industry survey continue to want stronger regulation then the perceived risks are seen as much higher than possible benefits.

The industry responses and opinions to REACH depend on the size of the company, who they are selling to (retail or trade customers) and the potential impact of REACH costs on their business.

Larger firms reacted in the first instance by commissioning studies to highlight the potential cost impact of REACH (Arthur D Little, Mercer Consulting, KPMG studies). Once they realised that REACH was going to be implemented, the focus of large companies shifted to how they could best manage the process at least cost. For example BASF, the world's largest chemical company, now predicts that its total REACH costs over the next 11 years will be between 500 – 550 million euros, equivalent to about 1% of its annual global chemical sales. BASF have some 250 employees working on REACH implementation.[7] Despite the costs, it is very hard to find either positive or negative comments about REACH from large firms in the post implementation period.

One window on how chemical firms are positioning on REACH has been set out by Syndex. The Syndex study (2005) pointed out that those industries that are most exposed to public opinion are the ones who will back REACH. Syndex suggest that:

> *"We are now in a phase [in 2005 onward] where the discussion on the various elements of REACH will start going round in circles, because all the arguments have already been repeatedly rehearsed and expanded on by the stakeholders. As a result, the players are starting to position themselves within the emerging new framework according to their own specific interests."* [8]

Therefore, those who sell chemicals to the general public such as Procter and Gamble, Marks and Spencer, Ikea, Unilever, Boots etc. will present a positive "spin" on REACH and be seen to be supporting it.

For SMEs there is real uncertainty because the costs vary so much from chemical to chemical. Cefic illustrate this by saying that the costs are too substance-specific to create an industry view.[9] Therefore, the opinions will vary depending on the specific cost to the firm. Having said that, ReachReady, an industry consulting firm, believe that administrative costs have been higher than expected because of the learning curve in compiling registration dossiers. But they add that these administrative costs are likely to fall in 2013 and 2018 when further registrations are required.[10]

However, the real costs are compliance costs associated with SMEs accessing data normally held by larger chemical companies. According to Milmo (2011) trade associations and consultancies are reporting that fees charged vary dramatically, depending on the safety of the chemical (between a few thousand euro and 500,000

[7] http://www.basf.com/group/corporate/en/sustainability/reach/organization

[8] http://hesa.etui-rehs.org/uk/newsletter/files/NWSL-28-EN-syndex.pdf p21

[9] Comments made by Cefic in Milmo (2011).

[10] http://www.reachready.co.uk/

euros). Most of the data has come from tests done over the past few decades by large companies. Crucially, under REACH, companies are allowed to charge fees that are equivalent to the cost of conducting the tests today. Few details are emerging about the exact levels of fees because of the confidentiality clauses. The UK Chemical Business Association suggests that:

> *"Our members are keeping very quiet about how much they are paying because they are worried that if they breach confidentiality rules their data access might be declared null and void"* [11]

While there is a lot of information about REACH from industry associations, how firms view REACH depends on the market situation they are confronted with. In most situations this is "core" to their business strategy and therefore they are unlikely to reveal how they are dealing with the situation.

#### *Other issues*

Related to REACH, in 2009 the CLP (Classification, Labelling and Packaging) Regulation came into force with the aim of aligning EU legislation with a Globally Harmonised System (GHS) developed by the United Nations (RPA 2009). CLP aimed to ensure a high level of protection of human health and environment, ensure free movement of chemical substances and enhance competitiveness and innovation. The GHS has similar aims, with an addition of providing a framework for countries without an existing system, reducing the need for repeat testing (including testing on animals) and facilitating trade in chemicals that have been properly assessed.

With almost a third of the global market, the EU is one of the world's largest producers of chemicals, and exerts an influence on outside producers wanting to export to it.

The expansion of the EU from 15 to 25 and then 27 member states added urgency to the adoption of common regulations and some centralisation of functions: the European Chemicals Agency (ECHA), based in Helsinki, has been set up to manage the day to day operation of REACH, including registration of chemical substances across the entire EU and EEA countries of Norway, Iceland and Liechtenstein. It also enables risk evaluation expertise to be focused in particular countries best placed to deal with risks of particular chemicals, thus enabling the EU at large to benefit from particular specialisations among its member states.

### 3.2.3 Economic drivers

The REACH is a radical departure from previous approaches to chemical regulation and an important legislative initiative. It is unsurprising therefore that REACH has been subject to an intense economic debate. We should note that most of the economic assessments have been done in the pre REACH implementation period

[11] http://www.chemical.org.uk/news/cbanews.aspx?p=4&ps=5

(prior to 2007). To date there have been at least 36 pre-implementation period studies examining REACH and its costs and benefits.

Two key caveats therefore need to be kept in mind:

- The assessments of the costs and benefits all have assumptions about how the new regime is going to operate – some are more valid than others. As expected the costs are up front and benefits take longer to occur; and
- The benefit estimates are more intangible than the costs since they involve areas that are usually much harder to estimate i.e. estimates of innovation, health and environmental benefits.

To obtain a flavour of these reports Table 2 sets out the findings of the various stakeholders. It reveals that there is a divided view on the impact of REACH.

The first group of arguments can be summarised as: the new regulation induces higher costs for industry which in turn might lower innovation, growth and productivity. Testing and registration costs will shift resources away from R&D and as some substances are removed from the market they will no longer be available for the formulation of new products. In particular this is likely to hit SMEs hard because of the high fixed costs of REACH (i.e. they will have to hire consultants to undertake registration and authorisation processes).[12]

The second group can be characterised by developing arguments that highlight the environmental, human health and business benefits. The business benefits include:

- Prevention of business risks related to liability claims. These benefits would be realised through the generation of new information on substance properties enabling the development and improved control of chemical products through the chemical safety assessment;
- More predictable chemical market conditions. This assumes that the pre-REACH market was insufficiently safeguarded from unpredictable events because it lacked systematic screening of eco-toxological consequences of chemicals. This unpredictability is stated to impair business performance;
- Reduced company costs related to occupational health issues. The benefit of REACH is seen in terms of identifying dangerous properties of substances in the registration process. The “improved” recommendation of safe conditions of use, within the registration process, will improve worker safety;
- More effective risk management at the enterprise level could benefit REACH resulting from lower expenses. The argument is that improved information will lead to better risk management measures;

[12] SMEs tend to be the driver of innovation in fine chemicals and specialties sectors. This sector is responsible for producing many key chemical ingredients and accounts for 20,000 SME manufacturers and blenders, representing 94% of all manufacturers and formulators in Europe. The fear is that higher costs are likely to push some of these SMEs out of the market. These SMEs provide the ‘building blocks’ for the European manufacture of dyes, inks, pigments, pharmaceuticals, surfactants, food additives, electronics, advanced materials, sensory products, etc. (http://www.reach-serv.com/index.php?option=com_content&task=view&id=72&Itemid=96).

- Reduced communication efforts through the introduction of standard procedures to facilitate communication on chemical safety along the supply chain. Potentially REACH could enhance strategic and risk management in the supply chain as an indirect benefit;
- Better conditions to innovate. A number of studies (Danish Eco Council, 2003 and European Commission, 2003) claim that under REACH the development of new substances as well as new uses for existing substances will be enhanced. However this is not quantified;
- Development of a level playing field with only one regulator. The benefits are focused on preventing fragmentation of the market with many national regulators; and
- Better market chances for safer substitutes. REACH could potentially motivate manufacturers to develop safer substitutes as substances of very high concern are withdrawn.

While a number of business benefits have been identified as a result of REACH (see above), according to Reihlen and Luskow (2007) the benefits remain abstract with regard to the actual cost and resource savings.

Expected environmental benefits for REACH are:

- Less environmental damage; and
- Less public spending for compensation of environmental damage and reduction of risk of exposure.

In all studies the estimation of benefits is heavily caveated since there was a lack of information on cause and effect, extent of damage already caused, the distribution of emissions, and a lack of monitoring data.

The approach taken to quantifying the benefits was through case studies, willingness to pay for surveys and the costs incurred for preventing substance related environmental damage. Some of the benefit calculations were as follows:

- Costs for repair of environmental damage, control of PCBs and other societal costs related to the use of PCBs in Sweden were summed up and extrapolated to the EU (based on inhabitants). Including adjustments to consumer price index and discounting of 4% over 23.5 years, savings were between 7 and 25 billion euros between 2005 and 2028 (ECORYS 2005);
- Sum of clean-up costs calculated. There is no statement on how much REACH would reduce the costs. Impact not specified (ECORYS 2005);
- Sum up of costs from historical damage as a per capita cost. PCB clean up valued at 25 billion euros and clean drinking water between 0.78 billion euros and 2.75 billion euros (DHI, 2005).

### *Table 2: Summary of findings of REACH assessments*

| Stakeholder | Findings |
|---|---|
| EU assessment published with the REACH proposals (2003) | Costs 2.3 billion euros over 11 years (max cost 5.2 billion euros)[13] Benefits (health) 50 billion euros |
| Arthur D Little and Mercer consulting (for industry) | Both studies found huge costs knocking several percent off GDP growth |
| German Environment Agency, German Advisory Council and Environment and Science Policy Research Unit | All produced reports highly critical of the industry studies |
| Nordic Council (2004) | Calculated that the changes in costs of REACH will not be significant relative to other business costs such as the exchange rate |
| Under the Dutch Presidency (2004) | A summary report was done on 36 assessments. The emphasis was on moving on from the impact assessment debate and focusing on workability What was outcome? |
| Industry studies funded by CEFIC and UNECE commissioned work by KPMG | Cost impacts were moderate and it focused on areas where cost could be minimised |

Source: Adapted from Reihlen and Luskow (2007) and http://www.chemicalspolicy.org/archives.reach.costsbenefits.php

Benefits for health can be divided into two areas:

- Benefits for occupational health including less spending on compensation damage and less incidence of occupational diseases. Specific benefits include:
  - Decreases in occupational diseases related to chemical exposure. Extrapolated from Germany to the rest of Europe valued at 40 million euros a year (Fraunhofer ISI, Ökopol, 2004);
  - Decreases in skin and respiratory diseases determined and the cases attributable to exposure to chemicals estimated as reductions of 88% for skin and 36% for respiratory diseases. A benefit of 3.433 billion euros over 10 years (School of Health and Related Research, University of Sheffield, UK, 2005).
- Benefits to public health that include less public spending for public health damage, less incidence of public diseases, and reduced risk exposures of general public. Specific benefits include:

[13] The costs included registration costs (500 million euros), testing costs (1,250 million euros), safety data sheet costs (250 million euros), authorisation procedures (100 million euros), reduced costs for new substances produced at under 1 tonne per year (benefit of 100 million euros) and agency fees (300 million euros). This totals 2.3 billion euros (over 11 years with a NPV of 3%). The cost of running REACH was estimated at 0.4 billion euros over 11 years. This cost will be meet by the fees paid by the industry (0.3 billion euros) and the remainder out of the EU budget. The downstream costs associated with withdrawal of chemicals from the market (higher price of testing being passed on, the need to find substitutes because of chemicals being withdrawn and the market power of fewer chemical companies) was estimated at between 2.8 and 3.6 billion euros. http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/eia-sec-2003_1171_en.pdf

- Historical damage from 4 substances was summed. Substances with similar risk profiles were identified and potential cost savings extrapolated (assumed 10% reduction in damage). A benefit of between 210 million and 2.5 billon up to 2017 (DHI 2005);
- Using the literature: 7% of general public in Germany quoted to be affected by contact allergies, treatment of which costed at 840 Euros per case. Costs for additional skin cancer cases (assumed reduction of between 1% and 10%). Between 0.5 and 5.2 euros per captia (Fraunhofer ISI, Ökopol, 2004).

### *Trade impacts*

As with other costs and benefits the REACH impact on trade is very unclear, so our approach has been to examine the arguments both for and against. Possibly, the most important impression regarding trade is how little it has been considered in estimating the REACH costs and benefits. In a study done by Reihlen and Luskow (2007) for the European Commission of 13 major studies on REACH benefits, trade is confined to an Appendix. In this respect, the trade benefit ascribed to REACH is focused on imports. All players in the market will have to abide by the same rules therefore European competitors will not be undercut by cheap foreign imports that do not have to go through the REACH process.

Possibly another benefit of REACH is that it sets a "gold standard" of excellence that will enhance the brand in third countries (Simpson, 2008). This is potentially an important benefit if other countries adopt REACH-like regulations because it puts those companies that have already adopted the REACH approach in a strong competitive position.[14]

In terms of trade costs, the two main trade fears are:

- That European chemical producers will become uncompetitive on international markets because of the high costs of the REACH process; and
- Innovation will be stifled.

The arguments are extensions of the debate canvassed above under the general economic costs associated with REACH.

### *Implementation phase of REACH*

In the implementation phase the main feedback has come from SMEs. This is because larger companies can absorb the cost more easily and have specialised staff to deal with REACH issues. Also the supposed benefits will not show up in the short and medium term.

SMEs are focused on the costs (Simpson 2008). The most burdensome are those associated with compiling dossiers for registration. The estimated costs are in the

[14] The best example if this is Heinz. With the signing of the 1907 Pure Food and Drug Act in the US, Heinz was one of the few companies that complied with the new regulatory standard. This had a major positive impact on Heinz's competitive position (http://www.fundinguniverse.com/company-histories/HJ-Heinz-Company-Company-History.html).

range of 100,000 to 200,000 euros which include hiring specialist help to navigate the registration process. Other issues include:

- Reduced opportunities to offset registration costs of lower value substances by cross-subsidising;
- Fewer producers so only limited opportunities to shatter potential data gaps;
- Lack of trained staff that understand REACH; and
- Regulators appear to be making it up as they go along – always in fire fighting mode.

To back up claims that regulators appear to be making things up as they go along, Simpson claims that not only are SMEs at a disadvantage under REACH but those SMEs exporting to the EU are discriminated against because they can not register directly. Unlike EU suppliers there is a requirement for a separate registration for each non EU supplier of the same substance. After submissions, this has now been changed so that a representative can represent a number of different importers into the EU. To complicate matters further some commentators are now claiming that regulators have tipped the balance in favour of foreign companies.[15]

Simpson suggests that for some companies there are opportunities to benefit from REACH since:

- REACH can be used in a positive manner, as a driver for internal innovation programmes;
- It has the potential to enhance brand reputation/industry leadership
- It can be used as a way to drive innovation in third countries through higher standards.

### 3.2.4 Institutional drivers

The regulation under REACH has involved strong direct government intervention setting up a new organisation, the European Chemicals Agency (ECHA) headquartered in Helsinki, Finland to oversee operations.

The setting up of a new approach (REACH) and a new institution (ECHA) to deal with chemicals involves some risk, particularly in the transition period. This is likely to cause disruption, which has not been factored into the costs.

[15] Critics claim that the stance means that a foreign company producing the same quantity of a substance as a European company with more than one EU establishment could end up paying lower fees e.g. an entity representing (1) a Japanese company exporting 3000 tonnes of a certain chemical and (2) a US company exporting 3000 tonnes of the same substance would make a single registration and pay one fee (31,000 euros). The representative could divide the fee between them – and could even spread the fees more thinly if it represented more companies for the same substance. However, an EU company making the same quantity as the Japanese company might have an establishment in France, Spain and Italy, each one manufacturing a bit more than 1000 tonnes. The EU company would have to make three separate registrations and pay the registration fee three times (93,000 euros or 69,750 euros in the case of joint submissions). http://www.wilmerhale.com/publications/whPubsDetail.aspx?publication=8230

At the moment it is unclear as to how smoothly the implementation process is progressing. Most firms are not talking publicly for a variety of different reasons (see discussion under the heading: The development of REACH). Some firms believe that REACH is a competitive advantage (Sydex, 2005), others suggest that the costs are higher than were expected (Milmo 2011) and Simpson (2008) focuses on the impact on potential costs for SMEs. What is clear is that the uncertainty around the total costs of REACH that existed prior to the pre registration phase remains, particularly for SMEs.

## 3.3 United Kingdom

As part of the EU, UK is subject to and in the process of implementing REACH. Therefore in this section we will consider where UK regulation and other factors differ significantly from the rest of the EU.

### 3.3.1 Regime description

With complete harmonisation there is no difference between the EU and UK regulatory approaches.

### 3.3.2 Political drivers

#### *a) Voice*

The UK appears to have gone through a similar process as in the rest of Europe. There is strong public support for further regulation in the chemicals sector driven by concerns about chemicals in the environment and their impact on human health. This has led to pressure on the political actors to support the REACH process.

#### *b) Accountability*

The UK was one of the first EU countries to start implementing REACH regulations.[16] Therefore, there does not appear to be any "foot dragging" by the UK government over the implementation of REACH.

In a recent report prepared for the British Government (RPA 2009) the pre-REACH regulatory system was described and particular note was made of the:

- Onus to undertake risk assessments and update as new information emerged which lay with regulatory authorities rather than the organisation marketing the chemical;
- Scope of information required for registration that did not fully address all toxicological and environmental factors; and
- Extensive burden on regulatory bodies to undertake risk assessments that slowed progress and limited the rate of progress in bringing forward new products.

[16] http://www.cosmeticsdesign-europe.com/Formulation-Science/UK-issues-consultation-on-enforcing-EU-chemicals-law

Public opinion polls such as Eurobarometer show little or no difference between UK and other European citizens when it comes to attitudes to chemical regulation. As in most European Union countries most consumers believed that further regulation of the chemical industry was required. Polling by the World Wild Life Fund (2001) showed a similar result.[17]

### 3.3.3 Economic drivers

In terms of size the UK chemical industry generates about 20% of European chemicals production[18], therefore it is not insignificant. Stakeholders within the UK have taken a keen interest in the REACH costs and benefits debate. The costs and benefits are similar to others within Europe.[19] As with the rest of Europe the business focus has been on SMEs and their ability to cope with REACH administrative and compliance costs.

### 3.3.4 Institutional drivers

While there were some computer glitches associated with data being transferred to ECHA these turned out to be temporary. Few other administrative issues in the UK have been encountered.[20]

## 3.4 United States

### 3.4.1 Regime description

In 1976, the Congress passed the Toxic Substances Control Act (TSCA) in part to authorize the Environmental Protection Agency (EPA) to regulate chemicals that pose an unreasonable risk to human health or the environment. TSCA addresses chemicals that are manufactured, imported, processed, distributed in commerce, used, or disposed of in the United States and authorizes EPA to assess chemicals before they enter use (new chemicals) and review those already in use (existing chemicals). TSCA excludes certain chemical substances, including among other things pesticides that are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and food; food additives; drugs; cosmetics or devices that are regulated under the Federal Food, Drug and Cosmetic Act (FFDCA).

TSCA addresses the production, importation, use, and disposal of specific chemicals including polychlorinated biphenyls (PCBs), asbestos, radon and lead-based paint.

Various sections of TSCA provide authority to:

[17] http://www.panda.org/detox

[18] http://www.cosmeticsdesign-europe.com/Formulation-Science/UK-issues-consultation-on-enforcing-EU-chemicals-law

[19] In reports published by the UK government (Defra 2006) costs of REACH are assumed to be 20% of total European Union costs. http://archive.defra.gov.uk/environment/quality/chemicals/documents/reach-partialria-commonposition.pdf

[20] http://www.rsc.org/chemistryworld/News/2008/June/17060801.asp

- Require, under Section 5, pre-manufacture notification for "new chemical substances" before manufacture.
- Require, under Section 4, testing of chemicals by manufacturers, importers, and processors where risks or exposures of concern are found.
- Issue Significant New Use Rules (SNURs), under Section 5, when it identifies a "significant new use" that could result in exposures to, or releases of, a substance of concern.
- Maintain the TSCA Inventory, under Section 8, which contains more than 83,000 chemicals. As new chemicals are commercially manufactured or imported, they are placed on the list.
- Require those importing or exporting chemicals, under Sections 12(b) and 13, to comply with certification reporting and/or other requirements.
- Require, under Section 8, reporting and record-keeping by persons who manufacture, import, process, and/or distribute chemical substances in commerce.
- Require, under Section 8(e), that any person who manufactures (including imports), processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment to immediately inform EPA, except where EPA has been adequately informed of such information.
- EPA screens all TSCA b§8(e) submissions as well as voluntary "For Your Information" (FYI) submissions. The latter are not required by law, but are submitted by industry and public interest groups for a variety of reasons.

Using its authority under TSCA, EPA has required testing for less than 200 of the over 62,000 chemicals that were already in commerce when EPA began reviewing chemicals in 1979. Since then, upon receiving notice of commencement that the company has begun manufacturing a chemical, EPA has added another 20,000 chemicals to its inventory after reviewing them under its new chemical review program. If EPA finds that a reasonable basis exists to conclude that a chemical presents or will present an unreasonable risk to human health or the environment, TSCA generally requires EPA to impose regulatory requirements. When doing so, EPA must apply the least burdensome regulatory requirement to adequately protect against a chemical's risk. EPA can promulgate a rule that bans or restricts the chemical's production, processing, distribution in commerce, disposal or use, or that requires warning labels be placed on the chemical. Canada and the European Union also maintain inventories of existing chemicals.

TSCA generally requires chemical companies to notify EPA at least 90 days before beginning production, manufacture, or import of a new chemical—or before manufacturing or processing a chemical for a use that EPA has determined by rule is a significant new use—by submitting a pre-manufacture notice.[3] Such notices are to provide information on the chemical's identity, production process, anticipated production volume, intended uses, potential exposure and release levels, disposal, and byproducts. A pre-manufacture notice is required for all levels of production or

import. In addition, companies are required to provide EPA any test data that they possess or control related to the chemical's effect on health or the environment and a description of any other data concerning the chemical's environmental or health effects known to or reasonably ascertainable by the companies. EPA has these 90 days to review the chemical information in the pre-manufacture notice and identify the chemical's potential risks. On the basis of this review, EPA makes a decision to (1) take no action; (2) after making certain findings under TSCA, require controls on the use, manufacture, processing, distribution in commerce, or disposal of the chemical pending development of test data; or (3) ban or otherwise regulate the chemical pending the receipt and evaluation of test studies performed by the chemical's manufacturer. As of June 2005, EPA's reviews resulted in some action being taken to reduce the risks of over 3,500 of the 32,000 new chemicals that companies had submitted for review.

### 3.4.2 Political drivers

#### *a) Voice*

In the last several decades, the US Congress has passed legislation to increase federal agencies' ability to determine the health and environmental risks associated with toxic chemicals and to address risk. Some of these laws, such as the Clean Air Act, the Clean Water Act; the Federal Food, Drug and Cosmetic Act; and the Federal Insecticide, Fungicide, and Rodenticide Act, authorize the control of hazardous chemicals in, among other things, the air, water, soil, food, drugs, and pesticides. Other laws, such as the Occupational Safety and Health Act and the Consumer Product Safety Act, can be used to protect workers and consumers from unsafe exposures to chemicals in the workplace and the home.

These laws were generally enacted in or before the early 1970s. Nonetheless, the Congress found that human beings and the environment were being exposed to a large number of chemicals and that some could pose an unreasonable risk of injury to health or the environment.

Preliminary work toward TSCA's enactment began in 1971 after the Council of Environmental Quality (CEQ) issued a report finding that existing regulations to control the potential toxicity of chemical substances were "inadequate" and that there was a "high priority need for a program of testing and control of toxic chemicals"[21]. CEQ was established within the Executive Office of the President by Congress as part of the National Environmental Policy Act of 1969 (NEPA) and additional responsibilities were provided by the Environmental Quality Improvement Act of 1970.

During the 1970s there were particular public concerns with high profile chemicals including vinyl chloride, arsenic, asbestos, mercury, lead, PCBs, and fluorocarbons. In 1976, the Congress passed TSCA to provide EPA with the authority to obtain more

[21] Council of Environmental Quality (1971): Toxic Substances, available online at http://www.whitehouse.gov/administration/eop/ceq/foia/readingroom.

information on chemicals and regulate those chemicals that pose an unreasonable risk to human health or the environment.

In 1987, the US EPA undertook a landmark study to understand how different environmental problems compare across different risk categories[22]. When compared to public surveys undertaken by the Roper Organisation, the EPA found that:

> *"EPA's priorities appear more closely aligned with public opinion that with estimated risks. Public polls … indicate that the public appears to be most concerned with chemical waste disposal, water pollution, chemical plant accidents and air pollution, in that order.*
>
> *Oil spills, worker exposure, pesticides and drinking water are rated as medium risks and indoor air pollution, consumer products, genetic engineering, radiation and global warming are ranked as comparatively low risks".*

Stakeholders have been critical of the current TSCA, for example, the Safer Chemicals, Healthy Families coalition [23] state that "TSCA has failed to protect human and environmental health from exposure to toxic chemicals" and highlights a number of problem areas:

- It fails to require the development of hazard data on chemicals in commerce: The EPA has only required testing on about 200 of the more than 82,000 chemicals that have been on or entered the market since the law passed in 1976.
- It does not require the EPA to identify chemicals of greatest concern to human health and the environment: The EPA has no obligation to assess chemicals in commerce to determine whether they are safe, and as a result has adequately scrutinized very few.
- It fails to restrict uses of the most toxic chemicals: Over the course of the 34 years since TSCA was enacted, EPA has succeeded in restricting only limited uses of five chemicals. The burden of proof TSCA places on the EPA to prove actual harm before it can regulate a chemical and to show its regulatory action is the least burdensome of all options is so onerous that it prevented the EPA from restricting asbestos, a known human carcinogen. The only full chemical ban enacted under TSCA, for PCBs, was mandated in the original legislation.
- It does not promote safer alternatives to toxic chemicals: TSCA perpetuates a chemicals economy that simply doesn't work. The market is ill-informed because producers are not required to develop even basic safety data for their chemicals. And because government cannot effectively act to control toxic chemicals, companies, institutions and individuals making or selecting chemicals or chemical products are unable to distinguish a safer one from a less safe one.

This is view of backed up by Dr. Richard Denison, Senior Scientist, Environmental Defense Fund: "By failing to identify, let alone control, the long and growing list of

[22] US EPA (1987): Unfinished Business: A comparative assessment of environmental problems, US EPA, Office of Policy Analysis.

[23] http://www.saferchemicals.org/resources/business.html

chemicals in everyday products that we now know can harm people and the environment, TSCA has forced states, businesses, workers and consumers to try to act on their own to address what should be a national priority".

Furthermore, Woolf (2006) sets out a number of areas where TSCA has failed to provide the EPA with the necessary tools to effectively evaluate chemicals:

- Few chemicals in commerce since 1979 have undergone EPA review;
- EPA lacks sufficient information to adequately evaluate new chemicals;
- TSCA's standard for restricting chemicals has proven unworkable;
- EPA's voluntary high production volume challenge is inadequate to protect human health.

The drive for reform is wider than problems with the framework or tools, for example:

- Modernisation is needed to prevent placing US-based global companies at a competitive disadvantage;
- New and emerging State laws are creating a patchwork of conflicting chemical regulations;
- Businesses are increasingly realising that there are profits in less toxic products;
- The need to promote public and investor confidence in nanotechnology creates a new driver for modernising TSCA.

### *b) Accountability*

The case for reform of TSCA and the approach to managing the risk of hazardous chemicals has gained momentum. Recent risk management changes include the 2008 Consumer Product Safety Improvement Act, which set new standards on such things as children's clothing and banned some chemicals from use in consumer products, and the Federal Hazardous Substances Act that requires labelling of chemical content and associated risks. The revised Act appears to be a partial response to REACH. Private US companies wanting to operate in Europe are investing considerable time and money in order to comply with REACH (pers comm., P Tyson, URS Birmingham).

TSCA is itself currently in a reform process, again, partly driven by the development of REACH in Europe[24]. The US EPA has set out a number of "Essential Principles for Reform of Chemicals Management Legislation", the principles present "Administration goals for updated legislation that will give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals":

- Principle No. 1: Chemicals Should be Reviewed Against Safety Standards that are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment;

[24] http://pubs.acs.org/cen/government/87/8711gov3.html

- Principle No. 2: Manufacturers Should Provide EPA with the Necessary Information to Conclude That New and Existing Chemicals are Safe and Do Not Endanger Public Health or the Environment;
- Principle No. 3: Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations;
- Principle No. 4: Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner;
- Principle No. 5: Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened;
- Principle No. 6: EPA Should Be Given a Sustained Source of Funding for Implementation.

The idea of the reform of TSCA has been around for many years, lawmakers have held a couple of hearings and introduced legislation to update TSCA in 2005 and 2008. That particular bill did not go anywhere. The Bush Administration, backed by the chemical industry, insisted that the statute was effective and needed no revision.

Driving the actions of the EU, Canada, and some US states is the science on chemicals that has emerged since TSCA was enacted. For example, in the 1990s, researchers began to find that at levels once thought to be inconsequential, some chemicals could interfere with the body's hormones. Such disruption may cause adverse changes during critical life stages, particularly fetal development. Meanwhile, the new field of bio-monitoring is detecting industrial chemicals in people's blood and urine, albeit often at trace levels. These findings challenge long-held assumptions that the general public has little or no exposure to many commercial substances.

In addition, a persistent push for a TSCA overhaul is coming from the Government Accountability Office. GAO critically assessed the statute in a 2005 report (GAO-05-458) and found the law wanting. GAO has since added TSCA to its list of federal programmes in greatest need of reform.

The push for REACH in Europe has fundamentally changed the chemical risk landscape (especially for exporters to Europe) and a reform Bill was released in April 2010 entitled the 'Safe Chemicals Act' which would:

- Ensure EPA will have information on chemical hazards, uses, and exposures sufficient to judge a chemical’s safety. The bill would require manufacturers to develop and submit a minimum data set for each chemical they produce. Under the bill, EPA would have the authority to require more data it believes is necessary to determine the safety of a chemical;
- Require EPA to use this information to categorize and prioritize chemicals, based on their hazard and exposure characteristics. EPA would identify and prioritize chemicals by their likely risk, based on the anticipated use, production volume, toxicity, persistence, bioaccumulation, and other properties that indicate risk;

- Ensure that expedited action is taken to reduce the use of or exposures to chemicals of highest concern. According to Lautenberg's summary, the bill calls for EPA "to act quickly on chemicals that clearly demonstrate high risk";
- Require all chemicals to be shown to be safe to remain in or enter commerce. The bill summary states:
  - The burden of proving safety rests on chemical manufacturers and users, not on government to show harm before it can act. All uses of a chemical must be identified, and the resulting aggregate exposure measured against a health-based safety standard set to protect both the general population and vulnerable subpopulations that may be more susceptible or more exposed to the chemical, such as children. If the safety standard is not met, the chemical cannot be marketed;
  - Ensure broad public, market, and worker access to reliable chemical information. The bill would establish a public database that would include chemical information submitted to EPA, and EPA's decisions regarding chemicals. The bill would also narrow the conditions under which data could be claimed as confidential business information (CBI), and would provide access to CBI by workers and local, state, tribal, and (in some cases) foreign governments, provided they protect its confidentiality; and
  - Promote innovation and the development and use of green chemistry and safer alternatives to chemicals of concern. EPA would establish a program to develop market and other incentives for safer alternatives, and a research grant program "targeted at priority hazardous chemicals for which alternatives do not presently exist." The bill would allow some new chemicals to enter the market, using an expedited process for reviewing safety.

A revised Bill was then introduced in April 2011 but with changes that respond to concerns raised by both industry and environmental groups. The Safe Chemicals Act would still require safety testing of all chemicals. Unlike the previous bill, this version would divide chemicals into three categories. The lowest category would include chemicals that are considered safe. The middle category would be for ones that need safety determinations, and the highest category would be for ones that require immediate action.

That top category would include chemicals that are persistent, bioaccumulative and toxic, meaning they don't break down in the environment and can build up in people and other living things.

The bill also requires the EPA to decide what minimum data is needed for each class of chemical in order to decide if they meet a safety standard. Some changes were also made related to claims of confidential business information, which in the past had shielded safety information about chemicals from being revealed. Under the proposed bill, any confidential information shared with states will stay confidential, and the EPA would be given the authority to strip confidential status away from information previously claimed as secret.

Industry has supported the concept of prioritisation but remains concerned about the confidential information aspects[25]). Although first introduced in 2010, progress has been slow and according to the Society of Chemical Manufacturers and Affiliates, reform "will take a backseat until the second half of [2011]"[26].

As is the case for greenhouse gas policy, many States have passed chemical safety laws that advance the reforms proposed in Congress. One example of this was to be California's Green Chemistry Initiative, initially proposed in 2008, and intended to require greater public disclosure and provide the California Department of Toxic Substances Control with greater authority to control chemicals and provide consumer information. Although part of this initiative was due to come into effect in 2011, changes to the draft legislation have been opposed by some stakeholders, and the programme has been postponed.

### 3.4.3 Economic drivers

The chemical industry has great importance to the US economy[27]:

- The United States is the world's largest chemical producer, in which there are approximately 170 major chemical companies;
- The industry annually contributes approximately 2.1% of the US GDP;
- The US chemical output is $400 billion a year;
- 36 million Americans work in businesses that rely on chemical products;
- The chemical industry directly employs over a million people in the US, with almost half working in chemical production and more than 90,000 chemists, engineers, and technicians employed in R&D;
- The chemical industry is also the second largest consumer of energy in manufacturing and spends over $5 billion annually on pollution abatement;
- The U.S., Europe, and Japan significantly increased chemical exports to developing nations such as China and Brazil in 2010.

There exist powerful economic drivers for the US to maintain a strong chemicals industry while balancing the costs and risks. As Woolf (2006) has noted, firms are increasingly seeing a reduction in hazardous chemical use as a business opportunity and much of this is driven by consumer demands and downstream business customers. This trend has reduced the chemical industry's resistance to reform of TSCA, especially in a post-REACH trade environment.

To control existing chemicals under TSCA, the US EPA must present substantial evidence that a reasonable basis exists to conclude that the chemical presents or will present an unreasonable risk to human health or the environment. The United States

[25] https://www.greenbiz.com/news/2011/04/14/congress-renews-debate-over-us-chemical-policy-reform

[26] http://pubs.acs.org/cen/government/89/8903gov5.html

[27] Sources: http://www.chemicalvision2020.org/pdfs/importance.pdf, http://pubs.acs.org/cen/coverstory/89/8927cover.html

Court of Appeals for the Fifth Circuit has stated that EPA must consider the costs of any proposed action in evaluating what risks are unreasonable. The EPA must also apply the least burdensome regulatory requirement. This is in contrast to European Union legislation where the costs of various controls are to be considered in deciding the particular control action to be taken, but these costs are not factors in determining whether to control a chemical.

Environment America released a report[28] that details how 14 businesses have removed harmful chemicals from their products, a process they call 'green chemistry.' The companies instead have used safer chemicals that cause little or no health or pollution risk and have all seen a benefit to their profitability. Additionally, a report by the Political Economy Research Institute[29] argues that contrary to chemical policy reform that will cost jobs and stifle innovation, innovation in sustainable chemistry presents new opportunities to reverse the job shedding trend. For example, if 20 percent of current production were to shift from petrochemical-based plastics to bio-based plastics, 104,000 additional jobs could be created in the U.S. economy.

### 3.4.4 Institutional drivers

The US chemical risk management framework is characterised by well-established and large institutions. There has been a noticeable shift in who leads the world in chemical regulation and the age of the institutions involved may reflect this difference. Selin and Van Deveer point out[30]:

> *"Whereas U.S. chemical policy in the 1970s and the early 1980s often acted as an inspiration for European policymaking, the EU has taken over the role as leader in chemical policy development. The EU is increasingly replacing the United States as the de facto setter of global product standards and the center of much global regulatory standard setting is shifting from Washington, DC, to Brussels."*

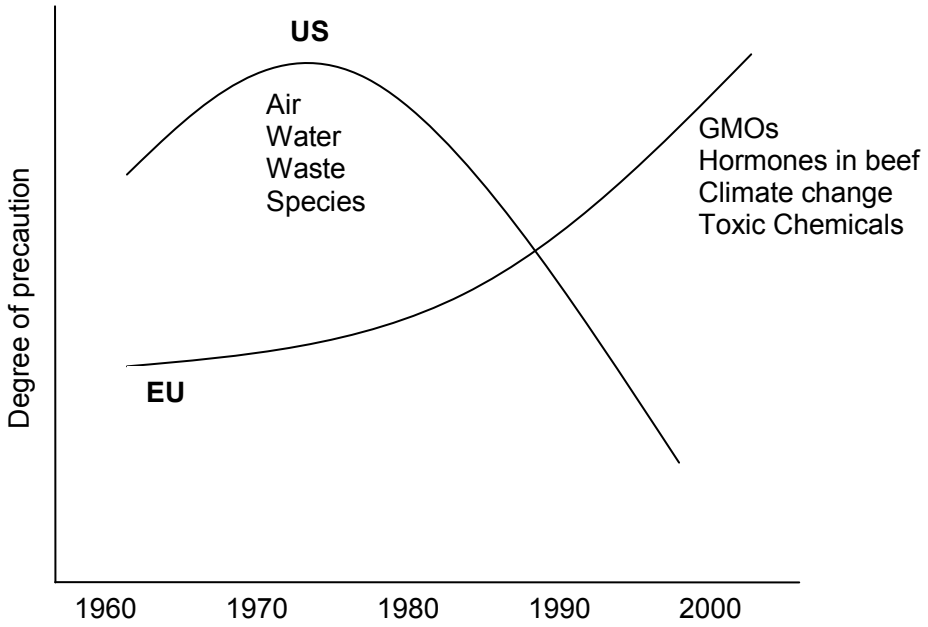
Wiener (2007) also picks up on this point and sees the US has having a less precautionary approach over time (in contrast to the European approach) as illustrated in Figure 1.

[28] Environment America (2011): Safer by Design: Businesses Can Replace Toxic Ingredients through Green Chemistry, http://www.environmentamerica.org/

29 PERI (2011): The Economic Benefits of a Green Chemical Industry in the United States: Renewing Manufacturing Jobs While Protecting Health and the Environment, http://www.peri.umass.edu/

[30] Henrik Selin & Stacy VanDeveer (2006) *Environment Magazine* 48(10) (Dec), p.14.

***Figure 2: Risk precaution over time***




Source: NZIER, adapted from Wiener (2007): Comparing risk reduction in the United States and Europe

The US EPA will face challenges as the reform process is completed especially if the result is a more REACH-like framework which would place greater emphasis at the front-end of the risk management process rather than relying on litigation at the end of the process. The 'end of pipe' litigation process may have led to the US taking a less precautionary approach with litigation used as the 'backstop'; this is contrasted to the EU approach which is essentially front-loaded to determine risks at the beginning of the process with no (or at least not formally part of the process) litigation

## 3.5 Australia

### 3.5.1 Regime description

In Australia, the Commonwealth government undertakes most hazard and risk assessments, implements international agreements and regulates international trade. The states and territories typically focus on control of use – including public health, workplace safety, transport, environmental protection and national security. Local government has some control over the location and operation of activities that discharge chemicals into the local environment.

The principal Commonwealth regulations for chemical risks cover industrial chemicals and agricultural and veterinary chemical products. Other regulation of chemical risks is provided by the Therapeutic Goods Administration (TGA), Food

Standards Australia New Zealand (FSANZ), the Australian Consumer and Competition Commission (ACCC) and the Customs Service.

Industrial chemicals are assessed by the National Industrial Chemical Notification and Assessment Scheme (NICNAS). NICNAS was established in 1990 under the Industrial Chemicals (Notification and Assessment) Act 1989 and associated regulations. Existing chemicals in use in Australia at the time of the Act were "grandfathered", but new chemicals have been assessed under the scheme since its establishment. The Australian Inventory of Chemical Substances (AICS) currently contains in the order of 40,000 chemicals.

NICNAS provides mainly non-binding risk management recommendations regarding public health, workplace safety and environmental issues to both national standard-setting agencies, and to states and territories, who then implement controls through a variety of agencies. All importers and manufacturers of industrial chemicals must register with NICNAS and fee revenue is collected annually (based on volume throughput) as well as through fees for registrations.

Agricultural and veterinary chemical products ("agvet") are assessed for registration by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The assessment covers risk to health, environment and trade, and reviews product efficacy. APVMA differs from NICNAS in that it combines risk assessment with risk management and standard setting, and the adoption of a common "Agvet Code" across states and territories has resulted in a more cohesive national approach than generally applies to industrial chemicals.

There is no comprehensive regulation covering all chemicals. However, when chemicals have multiple uses and one of those uses is industrial, the producer or importer must first register with NICNAS before introducing it into Australia.

A National Pollution Inventory (NPI) has been set up to facilitate the community's right to know what chemical discharges are made into the environment and where, to improve awareness of health and safety implications.

### 3.5.2 Political drivers

#### *a) Voice*

Although NICNAS and APVMA are broadly aimed at the public good of controlling risks to health and environment from the availability of chemicals, recent moves to improve these regulations have been largely driven by concerns about industry costs and competitiveness. In 2006 the Australian Productivity Commission commenced a review of chemicals and plastic regulations, driven by the desire for the Federal Government to consolidate regulatory powers within the Federal system.

Building on the Commission's report, the Government's Regulatory Task Force report, *Rethinking Regulation* (2006), developed recommendations to streamline and harmonise national regulatory systems across a broad range of sectors, including

chemicals and plastics. The Task Force estimated 144 pieces of Commonwealth, State and Territory legislation regulated use of chemicals and plastics, and in the submissions it received from affected industries and users, recurring themes were:

- Overlap and duplication between different agencies in their information requirements and areas of responsibility (with some ambiguity at the margins)
- Delays and costs incurred in obtaining assessments and approvals from authorities
- Industry desire for more timely and cost effective assessment/approval processes
- Industry desire for more consistency with international standards, including
  - greater use of assessment results done overseas, where relevant
  - less use of Australian-specific add-ons to international regulatory requirements, unless there is a clearly demonstrable case for them.

The Taskforce identified as problematic a growing 'risk aversion' in many spheres of life, and a tendency to lay at government's door for a regulatory fix any adverse effect on life or wealth. Vocal business interests seek to roll back this tendency and concentrate on critical risks beyond the capability of individuals to control.

Public health and safety concerns have been directed more at agricultural chemicals than industrial chemicals. Press reports have highlighted the use in Australia of chemicals that have been banned elsewhere, that chemicals may take up to 16 years to review, and that the system is not keeping pace with changes in public expectations, changes in science, and best practice regulation observed in other countries.[31] There are also concerns that the APVMA's budget is inadequate for what it is required to do, reflecting common international concern that placing the onus of assessing chemical safety on regulatory bodies is not particularly efficient.

### *b) Accountability*

In light of these concerns expressed by the public and industry there is interest in transferring more chemical regulatory powers to the Federal government so that a more consistent approach can be taken to applying the chosen regulatory approach, reducing costs and increasing efficiency. Various other measures have be enacted or proposed in response.

The *Agricultural and Veterinary Chemicals Code Amendment Act 2010* made five amendments to the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, covering such things as labels, approved persons and minor product variations.[32] Also in 2010 changes were proposed to the NICNAS, including transferring some chemicals from the TGA's jurisdiction, requiring new assessment procedures for new active ingredients for sunscreens, providing for screening

[31] See August 2010: http://www.news.com.au/features/environment/australia-is-lagging-behind-the-majority-fo-the-developed-world-when-it-comes-to-chemicals/story-e6frflp0-1225903069771

[32] http://www.apvma.gov.au/about/legislation/amendments_2010.php

assessments for all new chemicals, and other minor changes in line with international best practice.

In November 2010 the Commonwealth government issued a policy discussion paper, *Better Regulation of Agricultural and Veterinary Chemicals*, with recommendations aimed at better protecting human health and environment and increasing the Authority's effectiveness and efficiency. Specific recommendations were intended to improve review arrangements, make more use of overseas assessments, establish an independent science panel and make more use of expert advice, improve compliance enforcement and using a tiered and targeted approach for reapplication, review and re-registration of existing chemicals.

These changes address a number of the issues raised in public consultation. The Gillard government has made a pre-election commitment to continue with regulatory reform and shift responsibility for proving products are safe from regulatory agencies to importers and producers.

### 3.5.3 Economic drivers

The Regulatory Task Force (2006) found that chemicals and plastics accounted for about 10% of Australia's output and employment, and that 70% of the sector's outputs are used as intermediate inputs into other industries such as automotive, building and packaging industries. Chemicals and plastics comprise significant sectors for Australia and regulations are required that do not unduly impede them.

The Productivity Commission (2006) found that firms incur significant costs on both NICNAS and APVMA, and that the small size of the Australian market was considered a deterrent to the introduction of new chemicals. Such findings are echoed in concerns from farming interests that increasing requirements for registration would make it not worthwhile for companies to go to the expense of registering new chemicals for small Australian markets (e.g. horticulture with specific chemical requirements). This would limit farmers' choices over how to control weeds and pests, and raising the risk of increased pest resistance developing over time to the fewer chemical products available.[33]

The Commission recommended allowing greater recognition of international testing results and utilisation of modelling tools (rather than laboratory tests), as a means to expedite assessment of low regulatory concern chemicals. NICNAS has recently (23 May 2011) signed a Memorandum of Understanding with ECHA (EU Chemicals Agency) and has existing MOUs with the US EPA (December 2008) and Canadian EPA (August 2007).

### 3.5.4 Institutional drivers

The institutional structures for chemical registration in Australia have not come if for serious criticism, but there is recognition that placing responsibility for assessments

[33] See farmonline.com.au 12/5/2011.

on regulatory agencies can overstretch the resources available to them. The recommendations in the 2010 paper on *Better Regulation of Agricultural and Veterinary Chemicals* are mostly about changes in process, with the exception of building capacity in enforcing compliance.

While the Productivity Commission (2006) considered current provisions more effective in managing risks to health and safety than they are to managing risks to environment and national security, it considered the effectiveness of both NICNAS and APVMA schemes rather limited, given existing chemicals were grandfathered, and these constitute the majority of 'approved' chemicals (both industrial and agvet). The Commission recommended that reassessment be accelerated, and this is currently underway, with NICNAS implementing reforms to the Existing Chemicals Program. Their approach mirrors the Canadian approach – applying a screening level review first to determine those most hazardous to human health and the environment. This framework is currently in development, and the cost for completing this work (estimated to be in the order of $A30 million over the next 7-10 years[34]), will be recovered from industry through annual fees.

The Commission concluded that chemical assessment should be a statutorily independent process conducted at national level, that utilises international data where possible. It also recommended deferring adoption of the Globally Harmonised System of Classification and Labelling until benefits for trade can be demonstrated to be commensurable with the costs incurred by GHS. This recommendation has been taken up by Workplace Australia who are now in discussions with the Department of Agriculture, Fisheries and Forestry (DAFF) as to how they might implement a hazard based GHS process alongside the risk regulations already in operation.

## 3.6 Canada

### 3.6.1 Regime description

Canada implemented a review of its chemical control regulations some time before the EU and, similarly, implemented a sweeping reform of the regulatory structure. The changes aimed to prevent pollution before it happened in order to create sustainable economic development. The new system was passed into law as the Canadian Environmental Protection Act, 1999 (CEPA 1999).

CEPA is similar to the EU's new regulations, REACH, in that:

- The industry must supply data and propose safety measures for assessment;
- It is both precautionary and polluter-pays in philosophy;
- Priorities are set based on a risk assessment;
- Industries are required to manage risk; and
- The public is informed about high risk substances.

[34] Personal Communication, John Issa, Cintox Australia (Consultant), May 2011.

The main goal of CEPA is to ensure that all chemicals, both existing and new, are assessed under the same criteria. CEPA requires every new chemical substance made in Canada or imported from other countries since 1994 to be assessed against specific criteria. In addition, the legislation required every one of the 23,000 existing chemicals to be categorised according to criteria that include:

- The potential for human exposure;
- The level of persistence or bioaccumulation of the substance; and
- The toxicity of the substance to humans and non-human organisms.

Canada completed categorisation of all existing substances in 2006 and identified 4,300 existing substances that requiring further action. For most of those 4,300 substances the next step will be a scientific assessment to determine if there is a risk to human health and/or the environment. All new substances are subjected to the same categorisation and risk management processes. However, the nature of the risk management process has yet to be clearly identified.

The CEPA is based on a set of clear, guiding principles. Key among them are:

- Sustainable development: The Government's environmental strategy is driven by a vision of environmentally sustainable economic development. Strong chemical regulation is a key element of that
- Pollution prevention: CEPA focuses on preventing pollution rather than managing pollution after it has been created
- Virtual elimination: CEPA requires the virtual elimination of releases of man-made substances that are persistent, bioaccumulative or toxic
- Precautionary principle: CEPA requires the government to be guided by the precautionary principle
- Polluter pays: CEPA requires that users and producers of pollutants should bear the cost of their actions.

Based upon these principles the CEPA legislation was created to replace the previous iteration.

### 3.6.2 Political drivers

#### *a) Voice*

In an Environics (2007) survey, indicated that 59% of respondents thought that the Federal government was not doing enough to manage chemicals. Most concern is about how chemicals might impact on health and the health of their families rather than the environment. Other public opinion surveys support this e.g. Ekos (2007) only gave the Federal Government 22% positive rating for controlling and releasing chemicals into the environment.

In recent times, indications of how sensitive Canadian are becoming is illustrated by the controversy around Bisphenol A. In 2010, Canada became the first jurisdiction in

the world to declare the everyday plastic-making compound bisphenol A to be toxic. Bisphenol A is used in nearly all food and beverage cans sold in Canada.

In reaction to the CEPA, environmental groups have had a relatively positive response. Some of suggested that the chemicals management plan is "cutting edge".[35] In support of this contention environmental groups point to the dozens of substances, formerly deemed safe, that have been added to the Toxic Substance List.

### *b) Accountability*

CEPA (1999) replaced the previous CEPA legislation following an extensive Parliamentary review. It attempted to address the concerns raised about the previous legislation by adopting a more precautionary approach that emphasised the sustainable use of chemicals. To that end, it made pollution prevention the cornerstone of the new legislation and attempted to prevent future release of chemicals that may accumulate in the environment.

It also placed the onus on users and producers to prove the safety of their chemical products once they have been challenged by the government during categorisation. In this, CEPA is similar to REACH but stands in stark contrast to the US approach (Erica Crawford & Tim Williams 2006).

In taking a more precautionary approach CEPA also attempts to circumvent criticisms that too little is known about many chemicals to accurately assess the hazards that they pose to the environment. Rather than waiting for the chemicals to be proven toxic the government can move to manage the risk that they may pose when users and producers are unable to demonstrate that the chemicals are not a risk.

CEPA replaced legislation, which was passed in the 1980s. It was seen as weak in its controls on existing chemicals, lacking in a clear mechanism for prioritising action and lacking in government accountability (Wordsworth A 2004). However, in contrast with the EU experience, these concerns were voiced primarily by industry participants and observers.

The primary goals for the revisions of CEPA in the late 90s were to ensure:

- Equal treatment of new and existing chemicals to remove the disincentive to introduce new chemicals. There was a feeling prior to the new CEPA that innovation was discouraged by legislation that was more stringent on new chemicals than it was on existing ones
- Strengthen the existing regime and set priorities through categorisation. This was a response to the concern that the government had no clear way to rank priorities for dealing with hazardous or risky chemicals

[35] http://www.cbc.ca/news/technology/story/2011/07/07/pol-chemical-report.html

- Integrate government activities to reduce overlap between Acts. There was previously a lack of co-ordination between the CEPA, food and pest control legislation that hampered effective responses.
- Increase accountability of the government's actions to ensure that Canadians are informed about risky substances.

While it is difficult to know whether the Canadian approach is "tougher" than the European REACH regulations, CEPA does move Canada further away from the US and closer the European chemicals regulation. As part of this process the precautionary approach has been applied more stringently than before.

### 3.6.3 Economic drivers

In constructing the CEPA the government had an eye to ensuring that it did not become overly burdensome for industries. To ensure that is the case CEPA allows decisions and processes to manage toxic substances only insofar as they are cost-effective. Thus, activities that generate toxic chemicals but which are of little cost may not be subject to management because of the lack of cost-effective methods of reducing the small harm. This inclusion has drawn the ire of environmental groups who accuse the government of inappropriately trading social costs for businesses' profits (Canadian Environmental Network 2006).

To minimise the costs associated with a comprehensive and systematic review of all existing chemicals Canada has engaged in extensive collaboration with the OECD, WHO and UN to share information. For example, Canada has been very active in supporting the OECD's 'Mutual Acceptance of Data' program whereby member nations accept each other's assessment of the safety of various chemicals. A similar system exists under the auspices of the UN and is also supported by Canada. Indeed, the process of co-operation is enshrined within the CEPA in order to minimise the costs and maximise the benefits of information sharing.

However, the CEPA does not go as far as REACH in reducing costs by requiring users to provide evidence of the safety of chemicals when they are first brought to market. The initial categorisation of chemicals draws upon all data sources available to the government, including international reports and modelling data (NICNAS n.d.). That reduces the social cost of categorisation but also increases slightly the risk that chemicals known to be harmful will be submitted for categorisation without appropriate risk management procedures first being developed.

On the business side there have been concerns expressed by some that the process introduces additional business risk for heavy users and producers of chemicals (Michael Teeter 2001). Because the government controls the categorisation of chemicals, Teeter suggests that business users may have chemicals they use labelled as toxic before they have had the chance to rebut the science. However, CEPA has strong consultation mechanisms built in and this seems to be an unavoidable problem when managing potentially toxic substances.

The net economic impact of CEPA is highly unclear, although it may be hard to assess in the short run. Given that CEPA is designed to reduce long-term chemical accumulation in the environment it might be some time before its effects can be accurately assessed.

### 3.6.4 Institutional drivers

As discussed above, the present CEPA legislation is an evolution of the previous CEPA. Thus, is an evolution and was not constructed from a blank slate. Consequently, there was familiarity with the concept of a CEPA and the bodies involved before the latest revisions became law.

Particular institutional bodies that needed to be created for the new revisions were the Advisory Panels of experts that review applications of the precautionary approach and weigh the evidence to determine categorisation. While the government retains all final decision-making power, it felt that independent review and public consultation was an important part of a successful CEPA and instituted these panels.

The CEPA also creates a national Environmental Registry to encourage dissemination of information that is collected during the assessment and categorisation process. To ensure that citizens can act upon a harm that they find the government also created an Environmental Protection Action that allows citizens to sue companies for breaches of CEPA. However, in the six years leading up to the 2007 review of the Act the power was used only once, which suggests that the efforts at community engagement may not have bee wholly effective.

## 3.7 China

### 3.7.1 Regime description

Until recently China's chemical regime was spear-headed by the Provisions on the Environmental Administration of New Chemical Substances but in 2010 this was superseded by "Measures on the Environmental Management of New Chemical Substances". These new Measures, which have been dubbed "China REACH" and have been issued by the Ministry of Environment Protection of China (MEP), move in the direction of the European REACH but also contain provisions that impact on foreign companies and may place them at a significant disadvantage.

The new measures include:

- Requirement of a risk assessment report for new chemicals
- Notification of new chemicals, which can only be processed by a registered Chinese entity and use eco-toxicological data from a select list of pre-approved labs in China
- Classification of chemicals into three categories: general, hazardous and chemicals of environmental concern

- Requirement for general notification of new chemicals imported or produced in China, with a principle of "higher volume, more information requested"
- Simplified notification of new chemicals required even if the volume imported or produced is less than 1 tonne per year in China
- A foreign company can not register a totally new to the market chemical in China, before registering overseas data is required.

The provisions most problematic for foreign chemical manufacturers or exporters are those that specify only data generated in specific Chinese labs are acceptable for registration, and another that under Article 16, joint-notification is only acceptable by Chinese entities, so a foreign company must partner with a Chinese company to register new chemicals and may face difficulty in protecting confidential information. A late change to the new measures also raised the capital requirement for a Chinese legal entity to be able to notify a new substance, from €110,000 to €330,000, raising a hurdle for Chinese small enterprises and consultancies to act on behalf of their foreign partners. The information requirement for notification under the new Measures has been raised, increasing the costs and effort required for registration of new chemicals.

The new Measures only apply to new substances not listed on the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC). There are currently around 45,355 substances in this inventory, which compares with 80,000 on the US TSCA inventory and 110,000 on the register at the EU's ECHA, so there is potential for many substances approved elsewhere to require new registration if introduced into China.[36]

### 3.7.2 Political drivers

#### *a) Voice*

There are two forces at work in the Chinese chemical sector that have had an impact on the new regulation:

- Concerns about environmental pollution with protests by the green movement and general public; and
- The ineffectiveness of Chinese legislation.

Below we look at these two issues in turn.

#### *Pollution concerns*

Public concerns about chemicals have had some effect on Chinese regulations regarding chemicals. Possibly the main reason for this is the ability to connect cause (a chemical accident or poisoning incident) and effect (hospitalisations and death). As a fast growing economy, China is also one of the world's most polluted nations. Pollution from a variety of sources has created new health and environmental issues.

[36] REACH24H Consulting Group (2010) Issue 2 InFocus on china New Chemical Notification, www.reach24h.com

In 2008, there was widespread public anger in China about toxins in food and consumer products, and chemicals used in mining and other industrial workplaces. In response the Chinese media are bringing the scandals to national — and sometimes international — attention.[37]

Signs that some headway is being made include:

- Authorities in Hunan in southern China shut a manganese smelter down near Wuganag and two executives were detained after more than 1,000 people protested when 1,300 children fell ill from lead poisoning;
- Three smelters were shut in Jiyuan, the world's leading centre for manufacture of the metals used in batteries;
- Villagers blocked a major road in Fujian in eastern China. They were protesting the discovery that 121 children out of 287 tested in three communities were suffering from lead poisoning, apparently a result of pollution from the local battery factory;
- Doctors diagnosed 509 inhabitants of Liuyang and Zhentou suffering from cadmium poisoning, which causes kidney and liver damage, and even cancer. Two residents had died before it was uncovered. Locals blamed the Changsha Xianghe plant, which opened in 2003 to manufacture zinc sulphate, an additive in animal feed;
- The state-owned Dabaoshan mine, discharges acidic water laced with metals such as cadmium, killing most life in the Hengshi River, a major waterway in the area. Villagers near the mine drink and irrigate their rice crops with well water contaminated with cadmium and zinc. A 2009 study by Ping Zhuang, of the South China Botanical Garden at the Chinese Academy of Sciences in Guangzhou, confirmed dangerous levels of the metals in paddy soils and local food.

Faced with an alarming increase in public concern, in 2009 the central authorities in China launched a Pollution Source Census, demanding that the estimated 15,000 polluting factories, as well as mines and farms, come clean about their emissions, which often exceed formal license limits. The government insisted the aim was to evaluate rather than prosecute, and that legal action would only follow if companies continued the cover-up. The census results revealed twice as much water pollution as previously recognised.

### *Ineffectiveness of previous legislation*

Possibly even more alarming for Chinese authorities was the complete lack of any regulatory oversight despite regulations being in place. The existing legislation (prior to the 2010 change) had been in effect for seven years, but according to some news reports[38] most chemical manufacturers in China were unaware of its existence. According to a report by China Chemical Industry News, more than 100,000 chemical

[37] http://e360.yale.edu/feature/as_chinas_pollution_toll_grows_protesters_and_media_push_back/2254/

[38] http://www.rsc.org/chemistryworld/News/2010/April/01041001.asp

substances are commercially used worldwide. And even though most of those are used in China, so far only 40,000 are recorded on the IECSC.[39]

Even during 2009 when registrations were at their peak, only about 4,500 of the tens of thousands of organisations in China registered their chemical substances with the MEP, and most were foreign-backed firms, says Zhou Houyun, editor in chief of the Chinese journal *Chemical Safety and Environment*, who has been working closely with industry on the chemicals regulation.

As most Chinese chemical producers do not have the capacity to develop new chemicals, they are not aware of the need to register them. Also, insufficient publicity, lack of sanctions and low participation of local environmental agencies all contribute to low engagement of the Chinese chemical sector with the regulations.

> *"But [European] Reach has increased awareness, and in the new rules, a greater law enforcement role has been given to local environment watchdogs, promoting them to implement the measures more actively,"* Zhou told Chemistry World. [40]

### *b) Accountability*

Guiding principles around the recent changes include:

- Changing government administration towards more environmental-protection oriented economic growth;
- Change from a situation of treatment after pollution to simultaneous treatment and reduction of risk; and
- Extending the comprehensive use of laws, technology, economics and administration to solve environmental problems.

China's new chemical law appears to be a direct response to the EU's REACH and the globalised nature of the chemicals industry. The new measures have expanded China's existing regime for new chemical substances, increasing the volume and complexity of data that must be supplied to authorities, with a view to maintaining the acceptability of Chinese manufactured chemicals for access to the EU. It also reflects recognition that Chinese products were facing Technical Barriers to Trade in other countries around the matter of chemical residues, which was related to China's existing chemicals environmental management being relatively weak. In particular, the recent new measures address the perception that Chinese chemicals management cannot meet the requirements of modern environmental protection and public health and safety requirements because of:

- A lack of clarity in national chemicals environmental management policy and strategy;
- Incompleteness in regulations;

[39] Ibid.

[40] Ibid.

- Lack of institutional capacity, and enforcement capabilities are weak;
- Lack of public participation in formulating policies and strategy;
- Limitations in management support systems and integration of management measures (and a lack of third party regulatory service agencies).

### *Driving philosophy*

While it is difficult to know how new laws will be implemented or, indeed, whether the chemical industry takes any notice of the new regulations, the motivation behind the introduction of the regulations seems to be a combination of mounting public concern because of the large number of accidents, a lack of understanding about existing regulations, and international trends chemical regulation (including the new REACH legislation in Europe).

While a number of papers and articles[41] describe the new measures being undertaken in China as "China REACH"[42] there is little discussion as to whether China is taking a precautionary approach to chemicals. A number articles[43] suggest that it is more likely Chinese authorities are attempting to put a brake on unrestricted use of chemicals. Furthermore, given previous experience, the chances that the legislation is likely to be effective in the ways that authorities want is an open question. It is also possible that Chinese authorities will not be able to stop unrestrained chemicals use.

## 3.7.3 Economic drivers

Economic drivers seem not to have been a part of the introduction of the new chemical measures in China. The main reason for the new legislation, it seems, is to restrain the use of chemicals in what is an unrestrained chemical environment. Potentially there could be economic, health and environmental benefits from doing this. These could include:

- Improving the use of chemicals by using them more efficiently;
- Health benefits through reducing the number of poisonings associated with chemical production and release into the atmosphere. There have been huge increases in cancer within China over the last twenty years. Not only have cancer rates risen but at least 400,000 people die each year in China of respiratory disease[44]; and
- Environmental benefit through less contamination. In some parts of China the environmental problems have become so bad that water cleaning systems are necessary, since drinking water is also polluted and is dangerous to drink; people

[41] http://www.rsc.org/chemistryworld/News/2010/April/01041001.asp

[42] Known as *Measures on Environmental Management of New Chemical Substances*, otherwise known as Order 7.

[43] REACH24H Consulting Group (2010) Issue 2 InFocus on china New Chemical Notification, www.reach24h.com

[44] http://www.china-family-adventure.com/pollution-in-china.html

have to be cautious when they choose what food they eat, since it can also be polluted, and people choose to limit their time spent outside to reduce their risks.[45]

### *Trade impacts*

The main trade impact for China is that its domestic standards fall in line with international standards. Recent developments in Europe may have had some influence on the thinking of Chinese authorities. However, commentators industry people point to the fact that China is scrambling to catch up and is taking advice from a large range of sources. So the challenge is to integrate the advice being sought into a workable chemical regulatory regime. This will take time and will not be easy to achieve.

On the exporting side, foreign companies are reluctant to put new chemistry on the market in China because of the possibility that it will be copied and sold in other nations that do not recognise the international patent for that chemistry (Colin Sharpe Dow Chemical Company pers comm). In this respect, foreign firms have to weigh the potential the costs (patent infringements) and benefits (very large market). Possibly, this could put Chinese agriculture and other sectors at a disadvantage because they do not get access to the latest chemicals.

### 3.7.4 Institutional drivers

A key problem is institutional strength and whether or not the Chinese authorities can restrain chemical companies. In the short run, the new measures are likely to make some difference because there is a focus on chemical use. However over the long run, uneven application of regulatory process and the devolved enforcement responsibility to the district level seriously hamper the ability of authorities to control chemicals as specified in the new Measure.

We are likely to see a similar situation as existed prior to the new Measure being introduced: scandals/scares/accidents occurring every now again, coupled with inconsistent application of regulation. In short - business as usual, but possibly with more awareness of the laws enacted.

## 3.8 Japan

### 3.8.1 Regime description

The Japanese system for regulation of chemical substances has, like many systems around the world, been recently revised and updated. It is anchored by the Chemical Substances Control Law (CSCL), which was amended in May 2009 to ensure consistency with recent international agreements. In particular, the legislation, which had previously been amended in 2003 needed to be updated to comply with the Global Harmonized System of Classification and Labelling of Chemicals (GHS)

[45] Ibid.

established by the 2002 World Summit for Sustainable Development and the 2006 Strategic Approach to International Chemicals Management.

The new system covers all industrial chemicals. It includes a move from hazard-based to risk-based management and risk assessment, in line with the changes implemented by Canada and the EU over the last decade. There is also partnership between the government, and manufacturers and importers as the law now requires reporting of annual amounts of use and exposure each year. It covers all industrial chemicals and includes development of a priority list for precise risk assessment, in partnership with industry and importers.

For existing chemicals, a three-stage approach is planned: risk characterization; primary risk assessment; and precise risk assessment. The Japanese government will conduct the risk assessments. Manufacturers and importers will be encouraged to work with the government, which will gather hazard and use/exposure information from them under a mandatory system. The government will also request information from downstream users to inform its assessments (Banerjee 2010).

While the amendment aims for some similarities to REACH, there are differences in risk evaluation processes.

### 3.8.2 Political drivers

#### *a) Voice*

Japan has a chequered and reactive history of chemical regulation. Standing out in that history are the great pollution disasters of the mid-20$^{th}$ century: mercury poisoning from 1932-1968, Cadmium poisoning from mining in 1912, asthma-causing air pollution in Yokkaichi in 1961, PCB pollution in 1967, and then arsenic poisoning in the early 1970s. The string of serious, widespread outbreaks of chemical poisoning galvanized public opinion and sowed distrust of the government's ability to control such disasters. Each of these prompted grass roots movements calling for reform to generate changes in the law (Almeida & Stearns 1998).

The well-known Consumers Union of Japan (CUJ) was founded in 1969 to represent the interests of the public and immediately commenced activism to push for tighter environmental regulation. In recent times the CUJ has been a notable opponent of GMOs in Japan.

More recently the Japanese Environmental Agency issued a White Paper in 1989 that surveyed citizens on environmental issues. It showed that 75% of Japanese had some concerns about the environment and believed that Japan should take leadership to rectify environmental problems (Environmental Agency 1989). The same survey, administered in 2007, indicated that 32% of the populace believe that environmental issues are more important than economic issues. Indeed, 23% even suggest that environmental issues should be addressed even when it will result in a hindrance to the economy.

The groundswell of support in Japan for environmental regulation is thus long-term and persistent. It also comes on the back of a history of chemical disasters that generated the formation of consumer advocate groups such as the CUJ.

### *b) Accountability*

The response of the government to that public support has been patchy until recently. Historically, the government tended to respond to major disasters with tighter regulation but do little in between. However, the string of disasters in the 1960s forced their hand and they began to reform Japan's environmental regulations pertaining to chemical substances.

The Basic Law for Environmental Pollution Control was passed in 1967 and was quickly followed by others, including the Water Pollution Control Act in 1970 and the original Chemical Substances Control Law in 1973. The latter arose in response to the PCB pollution crisis and focussed on persistent, bio-accumulating and toxic chemicals initially (Takemoto 2010).

Continued public pressure encouraged the government to persist with reform and, in 1986 the CSCL was amended to introduce chemical production reporting and labelling systems. That was followed in 1999 by the instigation of a Pollutant Release and Transfer Register, in line with the OECD's 1996 recommendations. This law marks the rise in importance of global institutions for driving changes in Japan's chemical regulation system.

The most recent amendments to CSCL were completed in 2009 and have a threefold purpose: two of the purposes are related to international goals and conventions but neither leads the list provided by Japanese government agencies. The first reason cited for reviewing CSCL is the increased public interest in safety and security of chemical substances (Tamura 2010). It seems likely that, as in the case of biological regulations, at least some of the change has arisen not in the public's interest but in the official recognition of it.

## 3.8.3 Economic drivers

The primary economic motivation of the Japanese government in the latest round of revisions to CSCL has been to smooth trade and investment across borders (Tamura 2010). The harmonisation with emerging global standards and the similarity of the scheme's philosophy to REACH and CEPA are at the heart of creating those trade benefits. The similarity of schemes across trading partners should reduce transaction costs and encourage information sharing that will allow trade in chemicals to occur more easily.

However, there are also costs envisaged by the government. Chief among those is the direct cost of implementing the scheme. The new CSCL scheme will require the review and prioritisation of all existing and new substances, which comes at a considerable financial cost to the government. The government is also concerned that the more stringent requirements of industries to provide information and

reporting may discourage firms from investing in local chemical plants. The proximity of Japan to other major industrial manufacturers in Asia with less onerous chemical regulations may put them at a disadvantage when it comes to attracting such investment.

### 3.8.4 Institutional drivers

The section above on accountability deals with the primacy of public outrage in driving policy responses to major chemical disasters. Since the introduction of effective legislation those disasters have been absent for contemporary Japanese. As a consequence the environmental concerns of modern Japanese now focus more on the risks of nuclear power, for instance. That has meant chemical regulations now develop not solely as demanded by exigent circumstances but more as a response to international agreements and developments.

As an example, Tamura (2010) cites achievement of the World Summit on Sustainable Development 2020 (WSSD) target of minimising significant adverse effects as an important motivation for CSCL's 2009 amendment. Similarly, he points to harmonisation with the Stockholm Convention as another motivation. Since these comprise two-thirds of the reasons he cites for implementing the recent reforms it can be seen that the Japanese government is now looking outward for guidance on chemical regulation.

Naiki (2010) has analysed the genesis of the last decade of reforms to CSCL and believes that the Canadian regulations, as well as the EU's REACH, have both had a significant impact on Japan's legislative development. The introduction of risk-based assessments and the prioritisation of risk assessments, in particular, echo the Canadian CEPA legislation.

The evidence suggests that Japan is moving away from a reactive regime for controlling chemical substances towards one that focuses on harmonisation with overseas systems. In doing so it also satisfies the broad, public desire to see Japan take a leadership role in tackling environmental issues.

## 3.9 Overview of current approaches

Karlsson (2010) identified chemical regulation in most countries as facing similar problems: limited data, a distinction between new and existing chemicals that sometimes impeded innovation, unconsolidated legislation, ineffective risk assessment and enforcement and weak incentives for substitution. The TSCA in the US epitomises this approach and appears outdated.

The European REACH addresses most of these problems. Initial arguments against REACH – that it is high cost and impedes competitiveness – have yet to be substantiated at this early stage of its implementation. The architects of REACH clearly envisage this as being a model for others to emulate, a bid to establish a global standard for chemical regulation.

The chemical control laws in the US, Japan and EU represent a range of common regulatory frameworks employed across different countries. The discretion-based testing approach in the US is claimed to face fewer difficulties in accommodating new substances and new evaluation techniques than those that require a prescribed base data set (such as Japan's CSCL). The EU's REACH is the most comprehensive chemical control law to date and it allows alternative testing strategies to evaluate specific endpoints although it is still unclear how ECHA regulators will incorporate these in all aspects of its implementation (Stedeford and Banasik 2010).

Because countries have different testing requirements, manufacturers seeking to register a new chemical globally typically do so in a staggered fashion, first filing registrations in jurisdictions with discretion-based requirements (e.g. US) and last in those requiring data rich registration (e.g. Japan). International harmonisation of laws would impose more requirements on those who only register in countries with discretion-based testing, such as small industries and those operating in limited markets (Stedeford and Banasik 2010). The tiered approach of the EU's REACH is an attempt to lessen the impact on low volume producers.

While non-EU countries like Norway have assimilated with REACH, countries outside Europe are unable to gain the full benefits of supra-national co-ordination of those in Europe, and less likely to go to full assimilation. But they can shift domestic legislation to be more compatible with REACH, for instance aligning data collected for their own assessments and registrations to match that for REACH. This would ease the process for new chemicals developed in those countries to penetrate the large European market.

Bowman and Hodge (2007) note that to date no specific regulations have emerged to control emerging nano-technologies, and regulation of any risks depend on triggering clauses in regulation of new chemicals. Existing chemicals produced at nano-scale are not considered to be new chemicals. The WTO's SPS, TBT and TRIPS provide the international framework within which nano-specific measures must be viewed. The international standards organisation is working on establishing a common language for nano-technology concepts, and the OECD is considering international ramifications. Amongst Australia, Japan, UK and the US, the UK appears most advanced in developing regulation for risks specific to nano-technology, although this is at a very early stage.

One of the recurring principles guiding chemical risk regulation is reference to a precautionary principle, but there is not common set of guidelines for how this is to be implemented. Briand (2010) draws distinction between the "traditional" interpretation of the precautionary principle in not letting lack of certainty prevent precautionary measures being taken, against the a more novel approach in the EU's REACH which employs a form of "reverse onus", which shifts the burden of proof that a substance is safe for authorisation from the risk mitigators (government) to the risk generators (industry).

Karlsson (2010) compares REACH to US chemicals policy, which has not explicitly embraced the precautionary principle but contains some scope for precautionary

action. Overall, however, Karlsson suggests the US TSCA places too much onus for assessing safety on the regulator, the EPA, which has limited resources to do so, and characterises this as an old style regulation which has difficulty working effectively with the multiple risks of modern chemicals. That may also reflect the strong tradition of litigation and compensatory remedies in the US – front end precautionary regulation is relatively light as it relies on the threat of after the event liability to strengthen incentives on market participants to manage risks appropriately (although it also creates incentives to avoid such liability by outsourcing most risky activities to small "judgment-proof" companies without the deep pockets to provide for remediation when things go wrong). US legislation addresses these deficiencies in litigation by making liability strict, joint and severable which means that any party that is associated with a chemical hazard event can be held liable for the clean up – an approach that is now well established in the CERCLA "Superfund" law with respect to clean up of hazardous sites.

# 4. Features of biological risk regulation

Biological risk regulation is a broad sector, encompassing:

- Agriculture and food, including GMOs for food production, agricultural compounds and veterinary medicines;
- Pharmaceuticals and health care products;
- Industrial processes, including use for bio-remediation of environmental damage, and for enabling cleaner production processes;
- Security concerns, including bio-terrorism and natural disease pandemics.

The literature on regulation of biological risks mostly focuses on one aspect of a diverse sector. For this study, we focus on those regulations that relate to first entry of substances or organisms (which may be used in food or drug manufacture), but we do not review in detail food and drug safety programmes per se.

Many countries have long standing quarantine arrangements in place to protect against the importing of diseased livestock or plant matter that could cause a threat to human health, agricultural production or environmental quality. Some countries have formalised this into a biosecurity policy controlling both deliberate introduction of organisms and providing response for accidental introduction of an unwanted organisms. Others have biosafety policies, which may be as narrow as the handling of restricted materials within laboratory settings and their release into the environment.

## 4.1 International regulatory setting

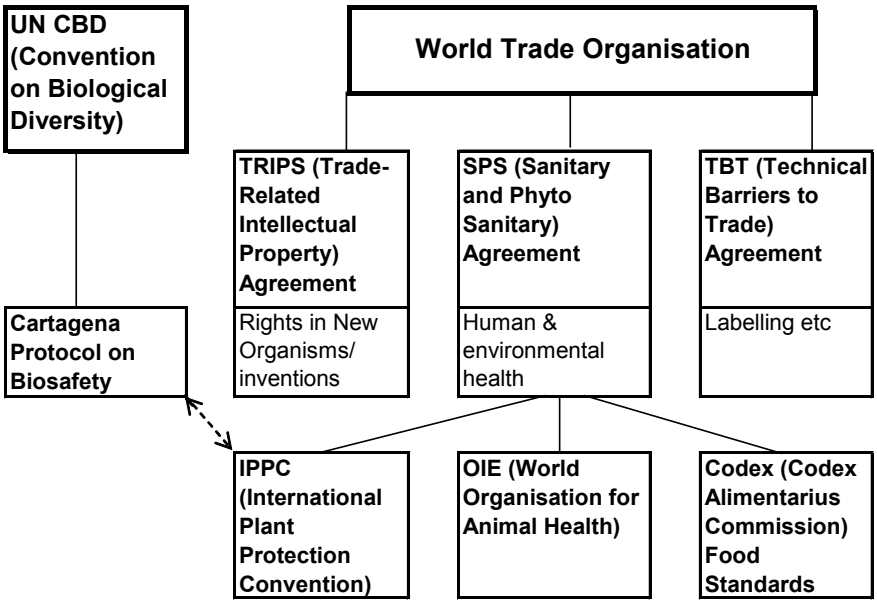
International agreements set the framework for national legislation and regulation in signatory countries. The principal international agreements relating to biological risk management are:

- World Trade Organisation (WTO) agreements on:
  - Technical Barriers to Trade (TBT);
  - Sanitary and Phyto-sanitary measures (SPS);
  - Trade-related Intellectual Property (TRIPS).
- World Health Organisation:
  - International Health Regulations;
  - Codex Alimentarius Commission;
  - OIE Animal Health Codes on cross-border movement of animals.
- UN Food and Agriculture Organisation:
  - International Plant Protection Convention.
- UN Convention of Biological Diversity:
  - Cartagena Protocol to protect biodiversity and human health from risks arising from new organisms.

The WTO agreement provisions are intended to prevent restriction of trade that could be a guise for industry protectionism, limiting trade impacts to those where there are sound scientific reasons to do so for the protection of health or the environment. The UN agreements work in the opposite direction to those of the WTO, as they provide justification for restricting movements of animals and plant matter to reduce risks of adverse effects, described further in the following discussion. The Cartagena Protocol is a point of difference between countries, which many major food exporting countries have resisted ratifying because of uncertainty over how compliance may affect trade in GM products.

The WTO has a central position in defining the scope within which national rules and regulations can be applied, with its subsidiary agreements providing the tools within which regulations for environmental and health benefits are framed. Of particular relevance to biological risks is the SPS agreement, which recognises three bodies for setting international standards and guidance for regulation – the IPPC, OIE and Codex. The work of these bodies, in particular the IPPC, overlaps with that being developed under the Cartagena Protocol, so there is communication and collaboration on standards setting between these bodies (Manzella & Vapnek 2007). This is illustrated in the diagram below.

***Figure 3: International agreements and bodies***




Source: NZIER

The SPS Agreement aims to prevent the use of sanitary and phytosanitary measures as disguised barriers to international trade, and is binding on all WTO members. The Agreement allows countries to set their own level of protection based on assessment of risks to human, animal and plant life and health, and these are presumed to be

consistent with the provisions of the SPS if they employ international standards in their formulation. Countries may adopt measures with a higher level of protection than that offered by international standards, but may be asked to provide scientific justification before the WTO.

The International Plant Protection Convention (IPPC), adopted in 1951 and revised in 1979 and again in 1997, is a multilateral treaty intended to secure "common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control". Pest is defined broadly as any species, strain or biotype potentially injurious to plants or plant products. The IPPC embraces phyto-sanitary concepts and principles (such as pest risk analysis) that align it with the SPS Agreement, and there is also overlap and growing co-operation with implementation of the Convention on Biodiversity (CBD).

The CBD provides guidelines on the systematic control of invasive alien species, including priority attention to preventing the entry of invasive species both between and within states, prevention of establishment and spread of invasive species once entry has occurred, and aiming for eradication at the earliest possible stage or, if not feasible or cost effective, the use of long term control measures. The CBD defines biotechnology as any technological application that uses living organisms to make or modify products or processes for specific uses, and it requires member countries to take all practical measures to give priority access to the beneficial results that come from biotechnologies based on genetic resources.

However, the development and transport of living modified organisms into new environments presents some risks. The Cartagena Protocol has been established under the CBD to promote biosecurity by setting rules for safe transfer, handling and use of living modified organisms, focusing on trans-boundary movements. The Cartagena Protocol provides for advanced information agreements between states exporting and importing living modified organisms, to enable the importing or recipient state to make an informed decision on regulatory requirements within a specified timeframe. It may refuse entry on the basis of risk assessment according to an Annex in the Protocol, and failure of an importing country to respond to notification does not imply entry is permitted by default. The potential uncertainty and costs this may add to trade in modified organisms has been a point of contention and some countries have not signed or ratified the Protocol.

The Protocol has also set up a Biosafety Clearing House as an information exchange to facilitate sharing of scientific, technical and legal information on experience with living modified organisms. Governments that approve such organisms for import or domestic use are required to communicate the decision-related information to the Biosafety Clearing House, and any other data about their laws, regulations and guidelines relevant to biosafety (Manzella & Vapnek 2007).

There are other international requirements that affect regulation of biological risks. Rhodes (2007) identified 36 international regulations applicable to the control of biotechnology but concluded they did not form a coherent regulatory set. This was

because they have little commonality in terms of how they were formed, have few common principles and no shared history of development, having been implemented over 80 years and originating in very different contexts. “Stickiness” in the incremental evolution of each regulation and differences in their interpretation by countries creates a high likelihood of inconsistency in implementation.[46]

In the following section, we examine the approaches being taken in relevant regions.

## 4.2 European Union

### 4.2.1 Regime description

The agri-food sector is of major importance for the European economy with annual production that equates to 15% of total manufacturing output. The EU is the largest producer in the world of food and drink products. The importance of food is underlined by the formation of the Common Agricultural Policy (CAP). The CAP has been a central part of the European agricultural system since 1962 and its aim has been to provide farmers with a reasonable standard of living, consumers with quality food at fair prices and to preserve rural heritage.

In the 1990s the CAP was approximately 50% of the EU budget.[47] In reality the economic food production incentives dominated the CAP despite what seemed to be tight regulatory practices.[48] However, the food scandals of the 1990s, most notably the BSE scandal, prompted a re-think by politicians and regulators. According to Hoffman (2010) behind the current crises lie economic and technological transformations in both food and the food supply system. Institutions are rushing to catch up with the implications these changes have for public health risks.

In the case of the European Union the prime aim has been to restore confidence in the food system, its science, law, and controls. To this end, a White Paper (2000) was produced that recommend the formation of the European Food Safety Authority (EFSA). The White Paper on Food Safety recognised that a European agency responsible for the scientific assessment of risks in the food chain with the ability to communicate independently on these risks would provide a basis for improvements in the food law system and help enhance confidence in the European food supply, the internal market and international trade.[49]

[46] By stickiness we mean that once a clause or a piece of regulation finds its way into statues or regulations it is difficult to remove it because of policy inertia.

[47] As a percentage of the total EU budget the CAP is declining (projected to be 32% by 2013), although regional development has doubled (from 17% in the 1990s to 36% in 2013).

[48] Therefore we have a political drive to protect farmers clashing with economic incentives to produce as much food as possible.

[49] EFSA’s advice frequently supports the risk management and policy-making processes. These may involve the process of adopting or revising European legislation on food or feed safety, deciding whether to approve regulated substances such as pesticides and food additives, or, developing new regulatory frameworks and policies, for instance in the field of nutrition. EFSA is not involved in these management processes, but its independent advice is from a scientific foundation. http://www.efsa.europa.eu/en/aboutefsa/efsawhat.htm

However, the highly sensitive nature of food production in Europe means there is no European wide view and EFSA advise the European Commission and national governments but does not set policy. A good example is the evolving management regime of genetically modified organisms (GMOs):

- Long history of regulation starting in the 1970s, although in this early period the EU tried to avoid statutory commitments;
- In the period between 1983-86 attempted to address regulatory issues in terms of biological safety, the consumer and bio-industry and the regulation of products;
- 1986-1991 regulations became more restrictive with specific directives on contained use and deliberate release. Comments made that restrictive approaches were “exceptionally forthcoming”;
- 1992 - 2001 a de facto moratorium existed of GMOs as European nations retreated further from their already restrictive approach in the 1980s;
- 2001 – 2010 period. The de facto moratorium was lifted in 2001, however it took some time before all member countries complied. What emerged were real differences in approach from country to country;
- 2010 Commission proposals aim to allow member states to enact restrictive measures on cultivation of GM crops based on broadly scoped non-scientific criteria;
- The current approach was crystallised in a meeting of the Environment Council in Dec 2008 which called for work to be done on the long term impacts effect of GMOs to be assessed on the EU environment. A subsequent meeting put forward a proposal to allow countries to determine their own approaches;
- The Commission proposed that member countries could make up their own minds as to whether GM plants are prohibited or cultivated and that members could use any ground to do so.
- Other issues include:
  - How to achieve orderly “co-existence” of biotechnology and organic farming across the continent. Member states are currently implementing or developing both ex ante co-existence regulations and ex post liability schemes to ensure both GM and non-GM crops can be cultivated in the EU (Dement et al 2010). Such regulation may hamper the adoption of GM crops unless the regulatory burden can be reduced and flexibility increased from what has been the case.
  - The EU has issued Regulations binding on its member states regulating novel foods, trans-boundary movements of GMOs, GM food and animal feeds, and the traceability and labelling of GM content in products. The principal agency overseeing this is the EFSA.

It should also be noted that EU regulation requires the traceability and labelling of all GM food and feed products derived from GMOs, regardless of the presence or absence of GM material in the final food or feed product. Two exemptions from the traceability and labelling requirements exist:

- Conventional products with accidental presence of authorised GM products are not subject to these requirements if the GM content does not exceed the threshold of 0.9%; and
- Products obtained from animals fed with GM feed or treated with GM medicinal products, such as meat, milk or eggs.

### 4.2.2 Political drivers

#### *a) Voice*

The recent history around food, feed, and biological controls have had a major impact on consumer views of the European food system. These include:

- In general views formed in Europe have been influenced by the corruption of the food system in the 1990s; and
- Mistrust of institutions and governments and, to some degree, of scientists. Although the most recent Eurobarometer (2010a) report on food related risks suggests that:
  - There is broad agreement that public authorities do ensure food is safe (increased since 2005);
  - Opinion is more divided about whether scientific advice and public authorities are independent from other interests e.g. 46% believed that public authorities viewed health of the consumer as being more important than profits, 42% did not, and 12% did not know;
  - Almost 80% believed that authorities could do more to protect the public to ensure food was healthy.

Overall there is uncertainty about "new" foods and biological risk. However from the articles read there has been a shift in perceptions from "total opposition" to a "wait and see" attitude and this is reflected in the Eurobarometer polls (2010b) which talk about "Winds of change?" as Europeans appear to be more accepting of nanotechnology, biofuels, synthetic biology and GM foods, albeit with a question mark (and with GM foods still having the lowest acceptance rates).

However, there are a wide variety of views throughout Europe for example:

- There is a very high demand for more information - only a small proportion of EU consumers have made up their minds. Of those that had a decided opinion 40% spoke positively of eating GMO based food;
- Acceptance of "new technology" had increased since 1999, particularly for medical applications. Medical applications developments attract considerable support across Europe. Of the respondents 68 per cent approve of stem cell research and 63 per cent approve of embryonic stem cell research. Levels of approval for gene therapy are similar, at 64 per cent. Xenotransplantation – an application long subject to moratoria in various countries – now finds approval with 58 per cent of respondents. And the solid support for medical applications of biotechnology spreads over to non-therapeutic applications. Moving from repair to improvement, we find that 56 per cent of the European public approves of

research that aims to enhance human performance. However, support for regenerative medicine is not unconditional. Approval is contingent upon perceptions of adequate oversight and control (Eurobarometer, 2010b);

- Some suggestion that consumer behaviour inside supermarkets is different from concerns expressed outside the supermarket (Euro Compass) In some cases – where GM products were lower priced - they had dominated the market;
- INRA quote polls that suggest: -+30% are for GM foods, -+30% are against and +-30% have taken a wait and see approach;
- Other voice factors shaped by the nature of products and how they are produced and consumed:
  - Cultural issues important – a threat to the traditional way food is grown and sold i.e. their national food traditions (really important in countries such as Greece, France, Germany and Austria). Are attitudes to biotechnology any different than free trade in agricultural products?
  - Amplification of GMOs issues by supermarkets;
  - If GMOs are harmful to the environment and to human health the impacts are long term impacts. Unlike a chemicals accident, the links in consumer minds is not instantaneous.

It is not surprising therefore that politicians are taking a wait and see approach to developments right across the biological risk spectrum. Possibly the most sensitive issues are those associated with GMOs. The best way of understanding these issues is through case studies on Bt maize (set out in Morris and Spillane, 2010).

Case study 1: Attempts to grow Bt maize in Germany
In April 2009 the Germany government suspended the commercial growing of the genetically modified maize varieties containing the Bt insect-resistance trait MON810 based on (alleged) fresh data showing negative environmental impacts of these varieties. Meanwhile, the German Central Committee on Biological Safety (ZKBS) concluded in July 2009 that based on all available scientific information available the cultivation of MON810 poses no risk to the environment. Subsequent analysis of the case has clearly shown the German government selected several individual studies to justify their political U-turn while ignoring the vast majority of research relating to Bt maize expressing the Cry-1Ab protein.

### *b) Accountability*

### *Philosophy*

According to Hoffman (2010) the most fundamental change in the E.U. system has been recognition of the central role that food safety and consumer protection play in integration of the European food market and with this adoption of risk analysis as a structure to shape and bring transparency to conflicts between the goals of integration and maintenance of diverse food cultures and other local and national values.

The EFSA has responsibility for conducting scientific assessment of new food safety policy, but national competent authorities do as well. While both the EC and national

authorities are required to take account of EFSA scientific assessment, they are not bound by it. While many food safety issues are now addressed by EU-wide regulation, not all are and in the absence of EU-wide regulation, food is deemed safe and marketable across the EU if it meets the national safety requirements. As Alemanno (2006) p254 points out:

> *"a claim by a domestic food authority that a certain good is safe or unsafe is likely to involve not only an assertion about science, but also about the willingness of this country to bear or not bear the level of risk considered acceptable in order to continue or reject a certain local tradition".*

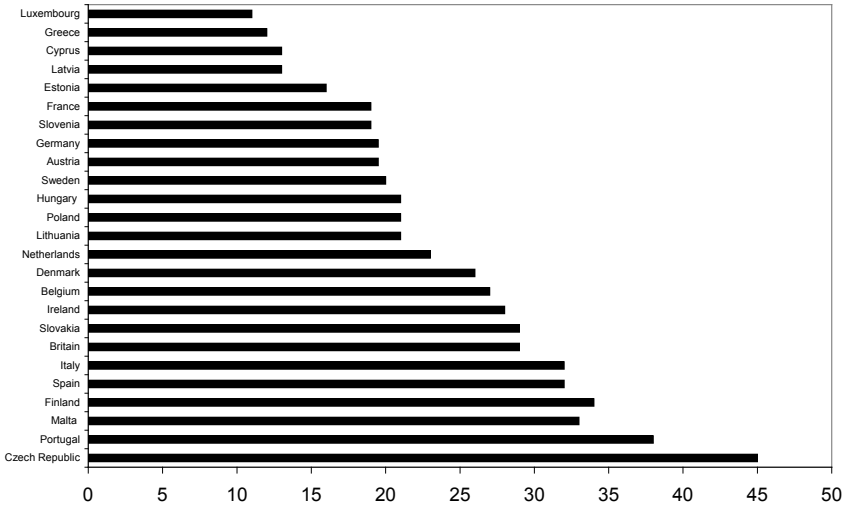
Of course, national decisions may also be driven by a desire to protect local economic interests. In the case of conflicting scientific opinion, it will be up to the European Court to determine the balance between local, national and Europe-wide interests. It remains to be seen what balance is ultimately worked out between national and EU concerns.

Biological risk issues will be treated differently in each region depending on public opinion, economic incentives and perception of harm caused by the specific issue or even other food scares. Whether a precautionary approach is taken will depend on:

- Whether or not the country is a agricultural exporter, particularly outside of the EU;
- Attitudes towards growing and consuming GMO crops. The Eurobarometer surveys (2010a, 2010b, the case studies, and GMO compass) indicate that the level of tolerance for farming GMO crops is much lower than eating GMO foods;
- The influence of cultural factors in each country. The attachment of consumers to their national food traditions is seen as an important factor in the process of acceptance of food technology (Menrad, 1999);
- The details of each country's legislative approach;
- The economics of growing GMO vs non GMO crops and whether a market advantage can be gained.

Possibly the best way to understand this is to examine how consumers in each region view GMOs or the introduction of biotechnology as tool for producing food (see Figure 1).

***Figure 4: Support for consuming GMO based foods***
Percent, 2006




Notes: 25,000 citizens polled - approximately 1,000 in each country
Source: Eurobarometer

Case study 2 Attempts to grow Bt maize in France

In October 2007, the French government temporarily suspended the cultivation of maize MON810. In December 2007 the French Ministry of Ecology created a committee composed of 34 experts (including 15 scientists) entitled the Comité de Préfiguration pour une Haute Autorité sur les OGM (CPHA) to examine the impact of MON810 on the environment. On 7th January 2008, French President Nicolas Sarkozy stated he was willing to invoke a safeguard measure prohibiting the cultivation of maize MON810 if the committee raised "serious doubts" concerning the safety of MON81039. The next day, the CPHA's report was submitted to the French government. Within twenty-four hours the French government quickly announced to the press that the CPHA had found that "new scientific studies ... establish serious doubts about the effects of MON 810 maize". On 11th January 2008 twelve of the 15 CPHA scientific experts protested publicly as the report was supposed to be only a draft and did "not contain the words 'serious doubts', nor does it qualify the new scientific evidence as "negative'". On February 7, 2008, the French government formally suspended the authorization of MON810 cultivation. Subsequently, the French Food Safety Agency (AFSSA) and the European Food Safety Authority (EFSA) both found the claims used by French political leaders to justify the safeguard clause had no scientific basis. Both organisations confirmed their earlier findings that MON810 was safe for human consumption. The French Ministry of Ecology then justified keeping the safeguard clause, not based on health concerns but on environmental grounds. However, this environmental basis was again rejected by EFSA when it renewed approval for MON810 to be used as seed for cultivation on June 15, 2009. Despite this, growing Bt Maize still remains banned in France in 2011. Several journalists have suggested that the French Government's U-turn on MON810, the only GM crop in commercial use in France, was as a result of a 2007 political agreement with environmentalists that ensured the French nuclear industry was not targeted in France's national environment debate (the "Grenelle de l'environment") in return for action against GM crops. Indeed, French Prime Minister François Fillon has admitted that the decision to start the procedure for the approval suspension of GM maize MON810 was based on a "compromise sealed in the 'Grenelle de l'environment'".

Revealed preference possibly means that acceptance of GMOs is higher than anticipated as the following two studies suggest:

- European Commission funded research project "Consumerchoice", polls were conducted on this topic in 2006 and 2007. In countries in which GM products were available in shops at the time of the polls (the Czech Republic, the Netherlands, Poland and Spain), only 20% of buyers actively avoided such products. The authors of the study therefore regard it as likely that in many European countries GM products would be bought if they were offered for sale;
- An Institute of Grocery Distribution study in the UK in 2008 found that more than half (53%) of respondents claimed not to think about GM when shopping. Only 21% claimed to check food labels to ensure that food was non-GM.

The European approach to GMOs and biotechnology in general is in a state of flux, highly dependent consumer views at given point in time and the attitudes of stakeholders.

### 4.2.3 Economic drivers

#### *a) Business costs and benefits*

##### *Costs*

There are a number of potential costs associated with individual countries developing their own policy associated with food, feed, biological controls and approaches to technologies such as nanotechnology. These include:

- Lack of certainty and lack of policy coherence across the EU single market. Possibly this could lead to an unstable fractured market for different products (e.g. GMOs and non GMOs). This bifurcation of the market might possibly be based on a myriad of inter-jurisdictionally unaligned opt out criteria (particularly if members apply their respective cultivation regulations);
- An unstable (and possibly fluctuating over time) legislative environment will mean innovation suffers (highlighted by the case studies);
- Flight of R&D capital and expertise is possible. Apart from assertions by different groups it is hard to establish a true picture of R&D flight since we are unsure what the baseline would be if GMOs could be planted freely in Europe. Having said that the European Commission are clearly worried that its approach to biotechnology risks has hindered the development of its industries and technological capabilities: a 2006 report from the European Parliament expressed regret that Europe had fallen behind with development of GM crops (Cantley 2007).

Possibly it is too early to tell what the impact of the first two points will be on the food system since we do not know how closely aligned European regions will be on issues such as GMOs over time. As for R&D capital expertise flight the European Commission is worried that this has been happening for some time.[50]

[50] http://ec.europa.eu/research/press/2004/pr2304en.cfm

### Benefits

In terms of business benefits, preserving (current) cultural practices in some parts of the market is the main benefit. While this "value" does not go through any market it does have an important economic value and needs to be considered.

## b) Environmental and health benefits and costs

### Costs

There are no environmental or health costs associated with adopting a risk adverse position to producing GMOs. Possibly there will be such costs for banning GMOs for medical use but it unlikely – given relatively strong consumer support for medical GMOs (Eurobarometer, 2010b) – that use and possibly production of GMOs for medical use will be banned.

### Benefits

Avoid possible long term health and environmental impacts of GMO products.

## c) Trade benefits and costs

The first commercial GMO crops were planted in 1994. In 2008, GMO areas reached 125 million hectares in 25 countries. The US is the main producer country with 50% of the total areas, followed by Argentina (16.8%), Brazil (12.6%), Canada (6.1%), India (6.1%), China (3.0%) and Paraguay (2.2%).

All other countries cultivate GMO crops on less than 2 million hectares. Furthermore, almost 44% of GMO crops are produced in developing countries. Main GMO products are soybeans, maize, cotton and oilseed rape. In 2008, GMO soybeans accounted for 53% of global GMO crop area, followed by maize (30%), cotton (12%) and oilseed rape (5%) (Clive, 2008). In terms of the share of global plantings for these four crops, GMO traits account for 59% of soybean plantings in 2005. The shares are 13% for maize, 27% for cotton and 18% for oilseed rape (Brookes and Barfoot, 2006). According to Friends of the Earth[51] the land in Europe planted with GMOs is very small, some 0.05% of the total agricultural land.

### Costs

The costs relate to:

- Inability to access possibly cheaper food and feed and associated flow on impacts;
- Inability to grow large volumes of GMOs crops to compete on world markets and associated flow on impacts;

[51] http://www.foeeurope.org/press/2010/Feb23_new_report_GM_crops_failing_to_tackle_climate_change.html

- Trade disputes, in particular the 2006 ruling that the moratorium on GMO trade is illegal. Since that time the European Commission has been working out how it can implement GMO trade.

### *Benefits*

The trade benefits are the same as the business benefits i.e. preservation of (current) cultural practices in some parts of the market.

## 4.2.4 Institutional drivers

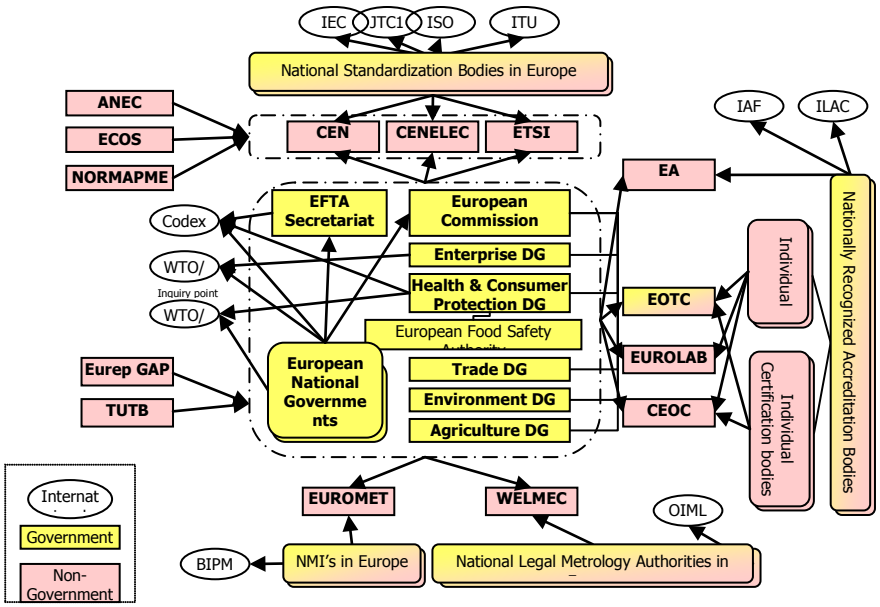
Trust in officials and scientists is starting from a very low base. Mistrust has its origins in the focus on production associated with the Common Agricultural Policy- a focus that led to some unusual practices in the food system in the 1990s. The attempts to rebuild this process have led to the formation of the EFSA.

The rebuilding of public confidence in EFSA is based around:

- Legal independence. The risk assessment and risk communication work carried out by EFSA is underpinned by strict legal criteria. EFSA has its own legal personality and while funded from the Community budget, it operates independently of the community institutions such as the European Commission and the Parliament;
- No political interference. The Executive Director, who runs EFSA, is answerable to an independent Management Board not the European Commission;
- A commitment to openness and transparency. In addition the Authority is bound by European Union legislation on issues such as public access to documents i.e. EFSA is legally obliged to publish on its website outcomes of its scientific work as well as main management documentation such as budgets, accounts and contracts.

Figure 2 sets out the web of European authorities that focus on standards conformity. The point of setting out this diagram is to illustrate that the system of conformity is an intricate web of interactions that has been developed since the early 1980s. The complex interrelationship highlights that different entities, actors, pan European bodies or national governments can, at any particular point to the process, have a major impact on the food and feed system.

***Figure 5: The development of Food Standard in Europe***




Source: The American National Standards Institute(www.ansi.org)

## 4.3 United Kingdom

Below we examine the response to biological risk in United Kingdom where it differs from the European wide experience.

### 4.3.1 Regime description

The responsibility for implementing biological regulation is largely spread across existing agencies, principally:

- Health and Safety Executive (HSE) regulates use of GMOs in contained settings;
- Department of Environment, Food and Rural Affairs (DEFRA) authorises controlled releases of GMOs;
- Food Standards Agency (FSA) assesses safety of GM content in foods, and also tracks changes in public attitudes towards novel foods;
- Advisory Committee on Releases to Environment (ACRE) and an Advisory Committee on Novel Foods and Processes (ACNFP) assist the other agencies in evolving their policies.

HSE is currently working on the development of new legislation, the Biological Agents and Genetically Modified Organisms (Contained Use) Regulations 2011. Scheduled to come into force in April 2011, this will provide a single regulatory framework to cover all work with human and animal pathogens and genetically modified organisms (GMOs) in containment, such as research laboratories or

biotechnology production facilities. These new regulations are in response to the recommendations from the Callaghan Report.[52]

### 4.3.2 Political drivers

#### *a) Voice*

In Eurobarometer, (2010b) surveys UK respondents are just as split as other Europeans on their views of biotechnology, nanotechnology and specific issues such as eating GM food. They tend to be towards the less sceptical end of the spectrum and are relatively positive about new technology and specifically biotechnology (see Table 1).

***Table 3: Trends in optimism for biotechnology***

Index numbers

| | 1991 | 1993 | 1996 | 1999 | 2002 | 2005 | 2010 |
|---|---|---|---|---|---|---|---|
| Spain | 82 | 78 | 67 | 61 | 71 | 75 | 74 |
| France | 56 | 45 | 46 | 25 | 39 | 49 | 46 |
| Germany | 42 | 17 | 17 | 23 | 24 | 33 | 12 |
| UK | 53 | 47 | 26 | 5 | 17 | 50 | 50 |

Source: Eurobarometer (2010b)

The startling fact about Table 1 is that UK views on biotechnology in general are roughly the same as they were in 1991. However, in between these two dates public opinion has plummeted and then recovered, presumably because of concerns about BSE and other food related scares.

#### *b) Accountability*

Possibly the most dramatic public sector response to the food scares of the 1990s was the dissolution of the Ministry of Agriculture, Fisheries and Food (MAFF) with most of its activities being taken over by the Department of Environment, Food and Rural Affairs (Defra).

MAFF, created in 1889, was widely criticised for its handling of the outbreak of BSE and later the outbreak of foot and mouth disease in 2001. One of the reasons for its dissolution was MAFF's excessive secrecy and obstruction during the BSE crisis (Economist, 28th Nov 1998). This was at a time that public confidence was at an all time low (see Table 1).

It is very unclear how the UK government will react to changes that allow European governments to take their own stance on controlling biological risk. Possibly over

[52] http://www.hse.gov.uk/biosafety/callaghan.htm

time the approach might be one of caution[53] rather than applying the precautionary approach, although this remains to be seen. Any moves are likely to further allow more tolerance of biotechnological research, development, and eventual production will depend on continuing trends evident in the the Eurobarometer (2010a, 2010b) reports. This is unlikely to be a fast process.

### 4.3.3 Economic drivers

The economic and trade drivers are similar to those of the rest of the European Union.

### 4.3.4 Institutional drivers

Defra has a very big challenge to balance the strongly divided opinions of many UK residents and the economic pressures of increased trade in GM products and possible loss of research jobs (widely talked about but difficult to value).

Defra also has to take into account the complex web of European agencies that potentially have a bearing on decision making processes.

## 4.4 United States

### 4.4.1 Regime description

In 1974 the National Institute of Health established a Recombinant DNA Advisory Committee which guided a consultative process that framed subsequent law on biotechnology applications. The outcome of this debate in the 1970s and 1980s was a conclusion that products of new technology could be handled by existing federal agencies and their existing legal powers.

This means that there is currently no single statute and no single federal agency to govern the regulation of agricultural biotechnology products in the US. Regulation of biotechnology products currently falls primarily under the jurisdiction of three regulatory agencies: the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA):

- FDA has responsibility for the safety of food and animal feed, and for the safety and efficacy of human drugs and animal drugs. Within the FDA, there are four centers with responsibilities for biotechnology products: the Center for Food Safety and Applied Nutrition (CFSAN); the Center for Veterinary Medicine (CVM); the Center for Drug Evaluation and Research (CDER), and the Center for Biologics Evaluation and Research (CBER);
- EPA has responsibility for the use of pesticides and setting allowable levels (tolerances) of pesticide residues in food, and for the regulation of non-pesticidal toxic substances, including microorganisms;

[53] Caution in this case means providing not just scientific evidence but also socio-economic evidence that shows acceptance of biotechnological techniques Myher (2010).

- USDA has responsibility for the safety of meat, poultry and egg products; for regulating potential agricultural plant pests and noxious weeds; and for the safety and efficacy of animal biologics. Within USDA, the Animal and Plant Health Inspection Service (APHIS) has the major responsibility for biotechnology regulation, with additional possible responsibilities for the Food Safety and Inspection Service (FSIS).

These agencies regulate across a number of pieces of legislation:

- The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (EPA);
- The Toxic Substances Control Act (TSCA) (EPA);
- The Food, Drug and Cosmetics Act (FFDCA) (FDA and EPA);
- The Plant Protection Act (PPA) (USDA);
- The Virus Serum Toxin Act (VSTA) (USDA);
- The Public Health Service Act (PHSA)(FDA);
- The Dietary Supplement Health and Education Act (DSHEA) (FDA);
- The Meat Inspection Act (MIA)(USDA);
- The Poultry Products Inspection Act (PPIA) (USDA);
- The Egg Products Inspection Act (EPIA) (USDA);
- The National Environmental Protection Act (NEPA).

A summary of the regulatory responsibilities associated with GMOs in the US is set out in Table 1.

With such an array of agencies involved in the management of GMO's and GMO-containing products, the White House Office promulgated in 1986 the 'Coordinated Framework for Regulation of Biotechnology' which established principles for the regulation of biotechnology and clarified the roles and responsibilities of the agencies involved. Of particular interest is that the Framework envisaged a review of arrangements as technology developed; this is a particular challenge for the agencies involved and it is not clear from the literature how successful this has been in responding to new risks.

In 1992, the Bush Administration's OSTP completed its deliberations on appropriate agency approaches to GM technology and published a Final Statement of Scope. This document reiterated the approach to regulation:

> *"oversight will be exercised only where the risk posed by the introduction is unreasonable . . . that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed".*[54]

[54] 57 Fed. Reg. 6753 (February 27, 1992).

The Final Statement of Scope explained that this approach to risk was chosen because it "is scientifically sound, properly protects public health and the environment against risk, and avoids hindering safe innovations."

### *Table 4: Summary of GMO regulatory responsibilities in the US*

| **Regulation of Genetically Modified Organisms** | | |
|---|---|---|
| *Genetically Modified Product* | *Responsible agency* | *Applicable legislation* |
| Plant Pests | USDA-APHIS | PPA |
| Plant-Incorporated Protectants | EPA | FIFRA |
| Plants producing toxic substances | EPA | TSCA |
| Animals | FDA | FFDCA |
| Animals producing toxic substances | EPA | TSCA |
| Microorganisms | EPA | TSCA |
| Microorganisms if plant pest | USDA-APHIS | PPA |
| **Regulation of Products Derived from Genetically Modified Organisms** | | |
| Plants (*i.e.*, vegetables, fruits) | FDA – CFSAN | FFDCA |
| Meat, Poultry and Eggs | USDA – FSIS | MIA; PPIA; EPIA |
| Food Additives | FDA – CFSAN | FFDCA |
| Dietary Supplements | FDA – CFSAN | DSHEA |
| Animal Feed | FDA – CVM | FFDCA |
| Human Drugs | FDA – CDER | FFDCA |
| Human Biologics | FDA – CBER | PHSA |
| Animal Drugs | FDA – CVM | FFDCA |
| Animal Biologics | USDA – APHIS | VSTA |
| Cosmetics | FDA – CFSAN | FFDCA |
| Pesticides | EPA | FIFRA |
| Other substances if toxic | EPA | TSCA |

Source: NZIER, adapted from Pew Initiative on Food and Biotechnology (2001): Guide to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products

The scientific principles outlined in the Final Statement of Scope are the clearest statement of the Administration's tenets on GM foods. The five policy principles listed are:

- The same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods;
- Information about the process used to produce a GM organism is . . . not a useful criterion for determining whether the product requires less or more oversight;

- No conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques;
- Crops modified by molecular and cellular methods should pose risk no different from those modified by classical methods for similar traits; and
- In many respects, molecular methods resemble the classical methods for modifying particular strains of microorganism, but are even more useful than the classical methods.

The resulting framework means that the US adopts a product-based approach (which is in contrast to the EU process-oriented approach). This negates the need for GM-specific legislation and has proved adequate for domestic needs but problematic in an international trade context.

The are now a number of GM crops approved for sale in the US (including soybeans, corn, canola, papaya, potatoes and tomatoes) and a number of approved GM products (including yellow crook-neck squash, red-hearted chicory, cotton, dairy products from cows injected with genetically altered hormone and recombinant bovine growth hormone).

The labelling of GM foods in the US is necessary only when the product is materially different from its non-GM equivalent. For example, consideration would be given to whether the use of biotechnology has changed the quality, safety or nutritional composition of a food product. This test for 'substantial equivalence' is a cornerstone of regulation in the US and has been criticised internationally for not being rigorous or scientific enough.

### 4.4.2 Political drivers

#### *a) Voice*

Perhaps as a result of the success of industry self-regulation of rDNA, there was very little public discussion of GM products in the 1980s and early 1990s. Consumer and environmental groups in the US paid little attention to the technology at the time of its initial introduction into the US market.

Measurable public concern about the technology did not emerge in the US until the late 1990s – well after varieties of soy, cotton, and corn had been introduced into American agriculture – and only after the issue had become a political force in Europe. This concern however, is limited and has not grown much over the past years.

A survey report from the US-based Pew Initiative on Food and Biotechnology has found that opinions among U.S. consumers about the safety of genetically modified foods remain mixed and have not changed significantly. The survey, conducted in late September 2004, consisted of telephone interviews with a representative sample of 1,000 US consumers. Thirty percent of those interviewed said that GM foods are "basically safe," (as opposed to 29 percent in 2001). Twenty-seven percent said that the foods were "basically unsafe," up from 25 percent in 2001. Opposition to

"introducing genetically modified foods into the US food supply," declined significantly, however, from 58 percent in 2001 to 47 percent in 2004. Emergent opposition has also come from the agricultural sector, where there are concerns about economic and health implications of GM technologies.

In addition, natural food organisations have taken an interest in the implications of the technology for healthy food and organic products. Environmental groups also raise questions about long term ecological and health consequences of GM products.

Consumer comments, petitions and lawsuits have forced the agencies to address safety and labelling issues, and to be responsive to consumer and the public interest. However, even in the face of such challenges, US regulators have remained largely faithful to the tenets of policy laid out in the Coordinated Framework and associated Scope documents. Opposition groups have not slowed the flow of new products into the U.S. market.

The slow development of US opposition to GM food and agriculture stands in marked contrast to the trajectory of the GM issue in Europe. There, the technology was the focus of intense public opposition even before it was introduced and the resulting debate has led to a moratorium on the introduction of GM products and stringent regulations on labelling. The reason for this difference has been much debated but remains unclear.[55]

Some hold that the threshold for European objection to a new food technology was much lower because of the rash of food scares there, including the Bovine spongiform encephelopathy ("BSE" or “mad cow disease”) epidemic, and issues with dioxin tainted products.[56] Others explain the European objection as a function of more enduring ties between urban populations and agriculture and food products.[57] Still others rationalize that the response to GM technology in Europe was simply an indirect route for rejecting American corporate arrogance.[58] Another view is that politicians with strong views on the propriety of GM technologies were able to find a voice in European governments as a result of the system of proportional representation, whereas such voices have been largely muted in the U.S. first-past-the-post political system. It is likely that all of these factors are contributors to the distinct European reaction to the technology.

By the late 1990s, public awareness of GM foods reached a critical level and a number of public interest groups emerged to focus on the issue. One of the early groups to focus on the issue was Mothers for Natural Law ("MFNL"), an Iowa based

[55] See for example., “Consumers in Europe Resist Gene Altered Foods,” New York Times, February 11, 2003, at A3.

[56] George Gaskell, Martin Bauer, John Durant and Nicholas Allum, “Worlds Apart? The Reception of Genetically Modified Foods in Europe and the U.S.,” 285 Science 384 (July 16, 1999).

[57] Marsha A. Echols, "Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws,” 4 Colum J. Eur. L. 525 (1998).

[58] See C. Heeler, “From Scientific Risk to Paysan Savoir-Faire: Peasant Expertise in the French and Global Debate over GM Crops,” 11 Science as Culture 7 (2002).

organisation that aimed to ban GM foods from the market. In July 1996, Mothers for Natural Law launched a national public awareness campaign on the dangers of genetically engineered foods. In addition, the group promoted an initiative to secure rigorous pre-market safety testing, mandatory labelling and even a moratorium on these foods.

In 1998 and 1999, MFNL undertook a grass roots petition drive to call for labelling of GM products and it generated nearly 500,000 signatures. This petition was distributed through health food stores, regional coordinators and on university campuses, as well as tens of thousands of signature gatherers all over the country.

The Union of Concerned Scientists ("UCS"), an alliance of 50,000 citizens and scientists, has been another prominent voice on the issue. UCS relies on its scientific expertise and publicly questions the basis for FDA's regulatory process. UCS has urged FDA to require safety testing – on the level of food additive petitions – prior to allowing GM foods on the market and has also consistently urged the agency to require labelling of these products. As the pace of GM products entering the market increased in the 1990s, UCS became a vocal critic of what it saw as the agency's collusion with industry and failure to fully take account of allergenicity and other safety issues.

The Center for Food Safety ("CFS"), a public interest organization dedicated to strict regulation of GM foods, organics and other novel technologies, is also a prominent voice on the issue. In 2000, CFS filed a citizen petition with FDA outlining safety concerns associated with GM foods. Signers of the CFS petition included a range of NGOs, from environmental organizations to health food concerns to representatives of traditional family farms. Collectively, the signers accused FDA of a too permissive position on GM foods and asked that the agency institute mandatory food additive petitions for these products.

In its report "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects"[59], the National Academy of Sciences stresses the potential dangers for human health of genetic engineering. While stressing that the process of genetic engineering has not been shown to be inherently dangerous, it states that any gene altering technique, including genetic engineering, carries the potential to result in unintended changes in the composition of food, which changes may bring negative health effects. The report ranks different techniques and the likelihood that these techniques bring unintended effects, including health effects. Three 'varieties' of GM[60] are ranked second, third and fourth highest, right behind mutation breeding, chemical mutagenesis and ionizing radiation.

[59] "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects", July 2004.
[60] 'rDNA biolistic, transfer of genes from closely related species', 'rDNA via Agrobacterium, transfer of genes from distantly related species' and 'rDNA biolistic, transfer of genes from distantly related species' See http://www.nap.edu/html/ge_foods/ge-foods-reportbrief.pdf

### *b) Accountability*

### *FDA's Framework for GM Products*

FDA is the most central of the three agencies involved in oversight of GM products and is charged with ensuring the safety of human food and animal feeds. FDA's statutory framework for conventional foods is based on the approach that in the absence of identifiable risks, a manufacturer may place a product on the market without securing regulatory authorization. However, under the Federal Food, Drug and Cosmetic Act ("FFDCA"), the manufacturer bears responsibility for ensuring that a product is not adulterated or misbranded. A finding by FDA that a product is in violation of these sections can result in recalls, market withdrawals, or seizure.

FDA did not initially offer any guidance to industry as to how this framework would apply to GM products after the publication of the Coordinated Framework. The agency issued its "Statement of Policy: Foods Derived From New Plant Varieties," ('1992 FDA Policy'), to "… clarify its interpretation of the [FFDCA] with respect to human foods and animal feeds derived from new plant varieties, including but not limited to plants developed by new methods of genetic modification."

The 1992 FDA Policy defined genetic modification in a manner that facilitated the view that the risks associated with the technology were no different in kind than those posed by traditionally produced foods. FDA explicitly positioned its policy in this context, stating that genetic modification included the alteration of the genotype of a plant using any technique, new or traditional (*e.g.*, hybridization, etc.):

'Modification' is used in a broad context to mean the alteration in the composition of food that results from adding, deleting or changing hereditary traits, irrespective of the method. The agency re-emphasized that the approach was consistent with a product based approach:

> *"… the method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used."*

In a 1997 FDA document, "Guidance on Consultation Procedures for Foods Derived from New Plant Varieties" the agency outlined the types of information that agency scientists would want to see in a consultation proceeding. This list includes:

- the name of the food and the crop from which it is derived;
- a description of the applications or uses of the food;
- information concerning the sources, identities and functions of introduced genetic material;
- Information on the purpose or intended technical effect of the modification and its expected effect on the food;

- Information concerning the identity and function of expression products encoded by the introduced genetic material;
- Information on any known or suspected allergenicity;
- Information comparing the GM food to that of natural or commonly consumed varieties;
- A discussion of whether potential for allergic response has been altered by the genetic modification; and
- Any other information that is relevant to the safety of the GM food. The consultation would then involve a meeting with the agency and continued discussion on any outstanding issues.

In 1998, FDA faced a legal challenge over the legitimacy of its 1992 policy. In Alliance for Bio-Integrity v. Shalala, the agency was sued by a group of concerned citizens over its position on GM foods. The lawsuit alleged that GM food was unsafe because of a range of secondary changes that could occur in products as a result of genetic modification, including unwanted, unpredictable new toxins and/or carcinogens or degradation of nutritional quality. The plaintiffs sought to make GMOs subject to the same testing and safety evaluations as food additives, and to require labelling of foods that they had been "materially" changed. The District Court of the District of Columbia rejected each of the plaintiffs' arguments.

In light of the heightened focus on GM products:

- In January 2001, FDA proposed a new rule that would *require* manufacturers of "plant-derived, bioengineered foods and animal feeds" [GM foods] to notify FDA at least 120 days before the products are marketed in a "Premarket Biotechnology Notice" or "PBN". In essence, FDA's proposed rule would make the 1992 voluntary consultation process mandatory. FDA characterised the proposed rule as a proactive measure to ensure that it stayed current with developing technology, and the agency restated its belief that the existing food safety rules were adequate to ensure the safety of GM products.
- In January 2003, the Center for Science in the Public Interest ("CSPI") released a report based on its review of fourteen FDA GM product consultations obtained through a Freedom of Information Act request to the agency. According to CSPI, in six of the consultations FDA requested additional information, and in three of those cases, the companies refused FDA's request. CSPI also claims that FDA overlooked factual and scientific errors in documents submitted to the agency. For example, a developer of GM tomatoes and cantaloupes, Agitope Inc., claimed its products posed little risk because humans were already naturally exposed to the protein they were engineered to make, but the scientific papers submitted to prove this point did not support that claim.[61] The company said that FDA never raised the issue and that the product was dropped.[62]

[61] Center for Science in the Public Interest, "Holes in the Biotech Safety Net: FDA Policy Does Not Assure the Safety of Genetically Engineered Foods," available at www.cspinet.org

[62] Leila Aboud, "Modified-crop Makers Faulted on Safety Data Sent to FDA," Wall Street Journal, January 7, 2003.

The issue of containment poses the latest challenge to FDA, and may result in the agency having to move away from its product-based approach, and perhaps even reliance on existing statutory law. Containment aims to prevent GM plants/seeds from cross-fertilizing neighbouring crops or from contaminating non-GM foods.

From the first discussions of GM foods, scientists have pointed to the potential risks from altered genomes spreading into other plants and the environment, but FDA has not explicitly addressed the issue or defined a tolerance level for GM contamination. Contamination issues are occurring with greater frequency both in the U.S. and internationally, and FDA appears on the verge of issuing a guidance on the subject.

At present, FDA only reviews GM products that are intended for food uses under its consultation program. Containment issues could mean that the agency would need to consider potential food presence of GM products that were not intended for use as foods. As such, the agency would be forced to move beyond its product based approach.

### *U.S. Department of Agriculture*

Both USDA and EPA share significant authority over GM foods with FDA. Like FDA, each of these agencies focus their policies around the three-part approach developed by the White House and OSTP.

USDA and EPA have responded to the three regulatory principles in different ways. Thus, while USDA explicitly stated that it agreed that existing statutory frameworks and risk-based regulation were priorities, the department initially took a more precautionary approach to the technology. It extended its pre-introduction permit requirement to *any* GM product that was deemed to have the potential to spread or cause injury in other plants. Only after several years of experience did USDA conform to OSTP policy and presume minimal levels of risk.

EPA, in contrast, has remained largely consistent in its approach, stating its statutory framework was written broadly enough to include GM products, and that its existing product-focused approach would apply. In recent years, this perspective has been subject to criticism in response to growing concerns that EPA has not fully considered environmental risks and lacks the capacity to monitor them.

The Coordinated Framework directed USDA to oversee the introduction of GM plants into agriculture and their transport around the U.S. USDA stated that such oversight would be conducted under the existing statute, the Federal Plant Pest Act ("FPPA"), which directs the agency to monitor the introduction and transport of new agricultural organisms. The FPPA specifically empowers USDA to regulate imports and the movement of "plant pests" (*e.g.,* microorganisms, plants or insects), to maintain the health and sustainability of U.S. agriculture.

In a sharp divergence from FDA, USDA initially chose to take a precautionary approach under this existing statutory regime. Instead of presuming that existing regulations were adequate for GM products, USDA promulgated regulations specific

to GM products: not all GM products would be subject to the FPPA, but GM products that *could* be considered to be "plant pests" under the existing definition would be subject to mandatory pre-release permitting. As of 1999, USDA had completed more than 6,700 permits for more than 20,000 locations under this system.

### *US EPA*

EPA is the third agency with major responsibility for oversight of GM products, with authority to ensure that any such products are safe for the environment and safe for human uses. Following the Coordinated Framework, EPA took the position that its existing statutory and regulatory framework under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") would be adequate for GM products.

Under FIFRA, a pesticide is defined broadly to include any substance “intended for preventing, destroying, repelling, or mitigating any pest” or “intended for use as a plant regulator, defoliant, or dessicant. To obtain a registration for a pesticide, the registrant must demonstrate that when used in accordance with widespread and commonly recognized practice, the pesticide will not generally cause unreasonable adverse impacts on the environment. In general, this requires the registrant to submit extensive information on the pesticides’ identity, its environmental fate, potential toxicity to humans and animals, and its potential for ecological disruption.

EPA has additional authority under the FFDCA, as amended by the 1996 Food Quality Protection Act, to set “tolerances” -- or permissible levels -- of pesticide residues on food. Statute directs EPA to set tolerances such that there is “reasonable certainty that no harm will result” from aggregate exposure over a lifetime.

Following the publication of the Coordinated Framework, EPA made clear that it would rely on existing regulations promulgated under FIFRA to ensure the safety of GM plants with pesticidal properties. However, after receiving numerous inquiries as to the data required under FIFRA for registration of GM plants, EPA issued a proposed policy statement in 1994 to clarify the regulatory status under FIFRA and FFDCA as GM plants became a market reality.

In the proposed policy, EPA coined the term “plant-pesticide” to refer to GM products under EPA authority. By definition, ,a “plant-pesticide” was a “pesticidal substance that is produced in a living plant and the genetic material necessary for the product of the pesticidal substance where the pesticidal substance is intended for use in the living plant.”[63] Like FDA, EPA stated that its approach would be product based: “EPA indicates that it proposes to focus its regulatory attention on the plant-pesticide and not on the plant per se.”

To focus the agency’s resources where there was greater risk, EPA’s 1994 proposed policy exempted a number of products for which the risks were deemed negligible.[64] Exemptions included plants that already contained some level of the incorporated

[63] 59 Fed. Reg. 60496 (1994).

[64] Id. at 60501.

pesticide, plants that were sexually compatible with another plant containing some level of the incorporated pesticide, and those modifications that only affected the plant itself.

In 2001, EPA published a rule finalising elements of the 1994 publication, changing the name of the regulated element from “plant pesticide” to “plant incorporated protectant” in order to clarify that a regulated GM plant was one *intended* to have pesticidal properties. The definition excludes plants with chance pesticidal modifications.

The 2001 rule also affirmed the exemptions contained in the 1994 proposal and reiterated EPA’s focus on the pesticidal aspects of the plant and not on the plant itself, remaining consistent with White House policy.

As of 1999, EPA had registered twelve plant pesticide GM products under FIFRA and had exempted all plant pesticides registered for food (as opposed to animal) from the FFDCA tolerance requirement. The agency’s justification in each case was that the pesticidal proteins originated from sources not known to be food allergens, and that the plant pesticides were therefore not expected to be food allergens.

The monarch butterfly quickly became the motif of protests against the introduction of GM foods. At the 1999 hearings held by FDA, for example, protesters dressed as monarch butterflies paraded outside the hearing sites. In June 1999, the Environmental Defense Fund ("EDF") called on EPA to require 60-foot buffer zones around fields planted with genetically modified corn to protect butterflies. According to EDF, such borders would dramatically reduce flow of corn pollen.

EPA scientists said that they were aware that the Bt pollen could kill insects but did not believe the butterflies would be exposed to the toxin. EPA stated that the subsequent discrediting of the monarch study validated its approach. Nonetheless, in January 2000, EPA issued new planting restrictions on genetically modified corn which would require that the crops be mixed with conventional varieties in part as a response to the type of concerns raised in the monarch study. The mixing was intended to prevent insects from becoming resistant to the Bt toxin and to reduce the exposure of other organisms, such as the butterfly. The new restrictions, which EPA drafted jointly with industry, require farmers to plant at least 20 percent conventional corn in most regions, and 50 percent where cotton is grown.

The National Academy of Sciences published a report in April 2000 titled “Genetically Modified Pest-Protected Plants: Science and Regulation”, which stated that EPA and other agencies needed to coordinate their regulatory authority over GM plant pesticides to ensure that there were no adverse effects on human health and the environment. The NAS report took issue with exemptions for certain transgenic plant pesticides in EPA’s 1994 Proposed Rule and urged EPA to reconsider potential environmental impacts of these varieties. It also recommended the development of a strategy for monitoring long-term impacts of plant-protectant pesticides on human and environmental health.

### *The StarLink corn crisis*

StarLink is the trade name for genetically modified corn hybrids that contain a plant pesticide protein (Cry9C) derived from a common soil microbe Bacillus thuringiensis ("Bt") which kills destructive pests of corn such as the European corn borer.

In May 1998, StarLink corn was registered under FIFRA with EPA by the originator of the technology, Plant Genetic Systems Inc., and subsequently transferred to AgrEvo USA and then to Aventis CropScience USA LP. At the time of the registration, Plant Genetic Systems had presented health and safety tests that it believed indicated that the Cry9C protein contained in StarLink did not resemble any known allergens. But the science of identifying potential allergens is inexact, and despite the company's protestations, EPA's Scientific Advisory Panel concluded that results did not rule out the potential for allergenicity, because tests showed that Cry9C protein could survive cooking or processing and is hard to digest.[65]

Despite the uncertain data, EPA took the unusual step of issuing a "split registration," which limited use of the product to animal feed or industrial purposes -- and restricted it from human use. This required that systems be in place to prevent StarLink from entering the human food supply. Although StarLink corn was only grown on a small portion of the nation's corn acreage, in September 2000, Genetic ID, an independent testing laboratory hired by a coalition of consumer and environmental groups found traces of StarLink in Kraft taco shells that were widely sold under the brand name Taco Bell. As publicity mounted, StarLink was detected in a range of other food products in the US and Japan. FDA and USDA recalled contaminated food products and offered compensation to farmers to sell their remaining StarLink products to the government. Ultimately, under pressure of negative publicity, the company voluntarily withdrew its registration so that StarLink would no longer be commercially used.

The StarLink crisis created a public challenge to the adequacy of EPA's approach to GM products. The approach adopted following split registration for StarLink was implemented without consideration of whether planting restrictions would be adequately communicated to farmers, and whether agency enforcement was available. Many pointed out that contamination was inevitable given the lack of enforcement capacity at EPA. The incident resulted in public calls for validated testing procedures and mandatory pre-market reviews by experts *outside* the government.[66]

## 4.4.3 Economic drivers

Interesting tensions exist within the US regarding economic drivers for the development of GM-related food and products. On the one hand there is the potential for innovation, development of intellectual property and productivity gains. On the

[65] See the discussion of the history of the allergenicity assessment at 64 Fed. Reg. 71452.

[66] Alejandro E. Segarra and Jean M. Rawson, "StarLink Corn Controversy: Background," CRS Report for Congress, January 10, 2001, *available at* www.cnie.org/nle/crsreports/agriculture/ag-101.cfm

other hand, there is resistance internationally to GM products (and products that contain GM material) meaning that exports can come under pressure.

The current EU-US trade dispute presents such a tension. The EU and US are each other's main trading partners. The EU is the fourth largest market for US agricultural exports. The main export products are soybeans, tobacco and animal feed.

***Table 5: US agricultural exports to the EU-25***
US dollars

| | |
|---|---|
| 1998 | $8.21bn |
| 1999 | $6.83bn |
| 2000 | $6.48bn |
| 2001 | $6.63bn |
| 2002 | $6.34bn |
| 2003 | $6.66bn |
| 2004 | $6.81bn |

Source: USDA

Starting in 1997, the US mostly stopped shipping bulk commodity corn to the EU as it was typically comingled corn from many farms, including GM varieties not approved by the EU. By 2004, the EU share of the total corn export market for the US had fallen to less than 0.1 percent (from 4% in 1998). The largest market for US corn exports are Asia and Africa. The trade of corn by-products (such as corn gluten used in animal feed) have so far been unaffected by EU regulation of GM products.

In 1998, a number of EU states agreed to block further approval of GM crops unless existing labelling and safety regulations were tightened. This meant that no new GM crops were approved from 1998 to 2004 - a de facto moratorium, which became a formal complaint to the World Trade Organisation.

Given this export shock, US farmers have been reluctant to introduce new GM varieties (especially soybean) that have not been approved for the EU market. It is likely that the soybean market is driven by price considerations rather than opposition to GM products (Brazil's exports of soybean to the EU have more than doubled, reflecting its lower costs).

In 2004, the EU introduced new GM legislation which expanded current labelling requirements and introduced the concept of 'traceability' (essentially being able to trace the GM product from farm gate to consumer). US farmers, food manufacturers

and exporters have been working to comply with the new regulation, while politicians have objected to the (potentially costly) rules.

In a survey conducted in New Zealand in 2004[67] it was found that current GM producing countries have not faced significant image problems in relation to the export of GM crops or food:

> *" … none of the respondents considered that countries such as the USA, Argentina, Canada, and Australia that already produce GM crops had suffered any loss of country image as a high quality food producer from having done so. … The results of this study would suggest that these countries will not face any damage to perceptions of non-GM food products which they produce."*

Over the longer term therefore, there appears to be little evidence of a sustained impact on food or crop exports and producers seem to be meeting the expectations of regulators to ensure export markets are maintained.

### 4.4.4 Institutional drivers

The US has one of the biggest GMO/biotechnology sectors in the world and is characterised by large companies, well established regulatory institutions and consumers who are generally accepting of GM products. The product-based framework creates an environment that is conducive to the further development and use of GM and biotechnology, both in terms of production and end-use.

The regulatory environment has developed over time, sometimes as the result of court action and sometimes the result of incident's (the most prominent being the StarLink corn case). The StarLink case did begin to see calls for more independent scientific testing of GM products rather than within industry or government, however there seems to be gradual evolution in the regulatory system rather than any plans for significant change.

## 4.5 Australia

### 4.5.1 Regime description

Australia is an agricultural exporting country with an interest in both controlling risks to its natural production base and also taking advantage of biotechnological developments in that base. It has neither signed nor ratified the Cartagena Protocol.

Principal legislation governing the import and/or release of biological organisms is the Quarantine Act 1908, administered by the Department of Agriculture , Fisheries and Forestry (DAFF), and the Environment Protection and Biodiversity Conservation Act 1999, managed by the Department of the Environment and Heritage (DEH).

[67] Knight J 2004 Impact of Genetically Modified Organisms on Perceptions of Country Image: Implications for Food Exporters, Marketing Department, Otago School of Business, Dunedin.

These two agencies have different perspectives. DAFF is primarily responsible for managing risks to primary industries and agriculture. A separate body within DAFF, Biosecurity Australia, undertakes import risk assessments on deliberate introductions and provides policy on responding to biosecurity incursions, collaborating with similar agencies within each state (Binder 2002). DEH focuses on managing risks to the environment, and applications for release and import are made available for public comment during the application process. The process for applicants is streamlined however by the use of one common application form with common/aligned information requirements (Hauschild, 2006).

One further Act can be used specifically in relation to biological control agents – the Biological Control Act 1984 (and equivalent state-specific acts). These Acts are used only for projects considered to be of high interest, or generating high costs and benefits (initiating public consultation), or where a conflict of interest applies. To date this has been used only in one case.

For both GMOs and other organisms, the first import into Australia must be into a controlled facility, overseen by the Australian Quarantine Inspection Service (AQIS) (part of DAFF). AQIS provides operational functions in controlling trans-border movement of organisms.

The Gene Technology Act 2000 provides the regulatory framework for biotechnology. This act established the Office of the Gene Technology Regulator (OGTR), responsible for assessing, regulating and licensing GMOs in Australia. A Ministerial Council for Gene Technology represents various ministries and oversees and advises OGTR on various matters, along with an Advisory Committee, Ethics Committee and Community Consultation Committee. The Gene Technology Act 2000 arose out of the Government's Biotechnology Strategy issued the same year, with the intention of instituting a system that ensures potential risks from introduction of GMOs are accurately assessed and effectively managed.[68] Thus regulation has gone hand in hand with promotion of biotechnology, with another agency, Biotechnology Australia, set up to improve public awareness of biotechnology.

To use or grow a GMO out of containment (described as an intentional release), an application for release must be made to the OGTR who, in granting the application, will specify controls in a Risk Assessment and Risk Management Plan (including location, fencing, notification and post-harvest requirements, and audit/inspection requirements for example). In general, limited and controlled applications are made first, before an application for general release. All applications must be reviewed/supported by the Institutional Biosafety Committee (IBC) and supporting information provided in the application by the IBC. Application turnarounds specified by OGTR range from 90 working days (non-release) to 150 days (limited and controlled release) to 255 days for general release.

[68] http://www.cbd.int/doc/measures/abs/msr-abs-au4-en.pdf

In general, the greatest volume of applications for intentional release are for limited controlled releases or field trials primarily for research purposes. Only a few GMOs have been approved for general release in Australia – including some flowers (carnations and roses), cotton, canola and sugar cane (currently in progress).

Apart from OGTR, Food Standards Australia New Zealand (FSANZ) is required to assess and authorise food stuffs with more than 1% GM content, and requires labelling of such foods. The Therapeutic Goods Administration has similar responsibilities with respect to therapeutic products with GM content.

### 4.5.2 Political drivers

#### *a) Voice*

There is a natural tension between the precautionary approach to novel organisms sought by members of environmental organisations and some in the public, and the desire of the agricultural industry in Australia to take advantage of technological advances to better compete on the world market. Concern about the possible consequences of the spread of GMOs provided the impetus for the Gene Technology Act in 2000, but this act specifically focuses on risks to health and environment and excludes consideration of economic risks, such as impacts on incomes and the marketability of GM crops. This issue of economic risk was to become a focus of public concern in the early 2000s, particularly over the marketability of non-GMO products produced in proximity to GM crops. This effectively split farming industry opinion between pro- and anti-GM camps, as well as fanning opposition to GM crops in the general public.

Stakeholder consultation during the development of the 2000 *Biotechnology Strategy* reinforced the importance of consumer attitudes to the success of agribiotech. An impediment to consumer acceptance at that time was that consumers were not seeing the benefits (such as improved quality, new products or lower prices) as much of the agribiotech work at that time focused on reducing costs to producers. A later survey of community attitudes in 2007 found there had been significant increase in awareness of, and support for, biotechnology's use in agriculture and food, but there was still a level of suspicion in the community about the regulation of biotechnology (in particular GM).[69] While bodies such as CSIRO were consistently nominated as a trustworthy and independent source of scientific advice for decision-making, there was also expressed concern at keeping evaluation of safety of GM applications protected from political or commercial influence (Eureka 2007 p12).

#### *b) Accountability*

A fundamental issue for accountability in Australia is the inter-play between different levels of government, in particular between Commonwealth and State governments. In 2003 the OGTR approved two applications to release GM Canola on the basis that

[69] Eureka Strategic Research (2007) "Community attitudes to biotechnology report on regulation"; Eureka Project 4001, prepared for Biotechnology Australia.

it would pose no unmanageable risk to human health or the environment, but before any commercial planting took place, all states and territories except Queensland and NT had imposed an effective moratoria that prohibited release of these two crops. The Victorian government justified its decision on its responsibility to consider market implications for its exporters, and duly set the moratorium for 4 years, after which market trends should become clearer. Similar justifications were made in other states. During this time, agricultural exports of canola to Japan were severely constrained due to competition from GMO crops, primarily from Canada (pers comm, Dr Geoff Smart, private consultant, Australia). In late 2007 the Victorian government allowed the moratorium to expire, and other states soon followed, although NSW retained the right to approve release of OGTR licensed GM crops.

In response to expressed concerns, in 2003 the Gene Technology Ministerial Council issued a policy principle under subsection 21(1) of the Act to recognise areas designated under State or Territory law where the separate identity of GM and non-GM crops would be preserved for marketing purposes. In 2006 a Statutory Review of the Gene Technology Act 2000 was undertaken and found that the Act was generally working well, and made recommendations for only minor changes to it.

A review of the Gene Technology Act 2000, undertaken every five years, is currently underway (submissions closed in June 2011)[70]. The review will investigate:

- Emerging trends and international developments in biotechnology and its regulation;
- The efficiency and effectiveness of the Act nationally across Australia;
- The interface between the Act and other schemes.

### 4.5.3 Economic drivers

The principal economic driver for uptake of GM crops has been producers' desire to increase yields and reduce unit costs of production so as to better compete with suppliers on international markets, some of whom will also be using GM crops (e.g. Canada). There may also have been some produce quality improvements in the form of greater resistance to pest and drought damage, but since most of the output of affected crops is destined for export markets and receives international prices, there has been negligible benefit to Australian consumers to date.

The moratoria are thought to have had a significant effect on Australia's attactiveness as a place to invest in biotechnology. CropLife Australia, which represents registrants, formulators and manufacturers of GMOs, claim they have had significant negative effects on plant breeding across Australian agriculture, and cite OGTR figures that cases lodged on intentional release of GMOs into the environment fell from 57 in the 2001-2004 period (14 per year) to 15 over 2005-2007 (5 per year).

[70] http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review (accessed 2 June 2011).

### 4.5.4 Institutional drivers

There remains a belief that Australia has many strengths for development of its biotechnology industry, including a capable workforce, proximity to Asia, a diverse range of agricultural enterprises and research institutions and strong regulation and risk management.[71] But Australia also has relatively low R&D expenditure in the biotechnology area, both in absolute terms relative to countries like USA or Germany, and also in relative terms of R&D as a percentage of value added, in which it ranks behind small countries like Israel, New Zealand and Denmark.

## 4.6 Canada

### 4.6.1 Regime description

The story of the past two decades of biological risk control in Canada is primarily about genetically modified organisms (GMOs). Canada has been at the forefront of dealing with the introduction of GMOs for the past decade as its farmers plant increasing quantities of GM crops. Genetically engineered (GE) canola was first introduced to Canada in 1995 and has taken off since then. Nearly all canola grown in Canada is now GM, along with much of the corn and soybean.

In Canada, GMOs used as food or animal feed must be approved before gaining access to the market. The approval process is covered by numerous regulations and is done by Health Canada for foods, the Canadian Food Inspection Agency (CFIA) for seeds and livestock feed, and Environment Canada for new substances intended for environmental release. Since 1993 the process has been conducted within the Federal Biotechnology Regulatory Framework, which replaced the previous National Biotechnology Strategy.

In order to gain approval for a new product the creators must provide the relevant authority with detailed information on numerous aspects of their product:

- The identify and origins of the product;
- The novel gene and breakdown products;
- Activity of the gene product and by-products in the plant;
- Activity of the gene product in the environment;
- Ather DNA sequences that have been inserted into the product (Canadian Food Inspection Agency 2000).

Approval is required for both locally produced and imported products.

[71] http://www.daff.gov.au/agriculture-food/biotechnology/reports/biotechnology_and_australian_agriculture_-_towards_the_development_of_a_vision_and_strategy_for_the_application_of_biotechnology_to_australian_agriculture/4_what_are_the_strengths_and_weaknesses_of_australian_agricultural_biotechnology_how_will_australia_be_able_to_respond_to_the_key_drivers

Biotechnology regulation in Canada has two important characteristics. First, regulation is based on the product, not the process, and, secondly, regulation is based on 'sound science' rather than a precautionary approach (Andree 2006).

In Canada, a genetically engineered plant is considered to be a plant with a novel trait. Plants falling into this category are regulated on the basis of the characteristics of the product, not the specific process by which the product is made. The primary trigger of the regulatory process is the novelty of the plant species, so products of traditional breeding as well as GM products may be considered novel and regulated. A novel plant is referred to as a Plant with Novel Traits (PNT).

Product-based regulation of PNTs assumes that all organisms, including those that are genetically modified, have similar safety risks. Consequently, regulation of PNTs is based on the concepts of familiarity and substantial equivalence. Familiarity applies to the knowledge of the characteristics of a plant species and experience with the use of that plant species. Substantial equivalence refers to the determination of potential alteration of environmental interactions. The implication of these tests is that PNTs that largely resemble known species will be adjudged to be safe.

All PNTs are evaluated for possible safety concerns with respect to humans, animals, and the environment. The safety assessment of a PNT takes between 7 to 10 years and focuses on the differences that are identified between a PNT and its conventional counterpart. Most of the conventional food consumed is not required to undergo safety assessments as they are assumed safe due to a long history of safe use.

The second key element of the system is the reliance on 'sound science'. Essentially, this means that PNTs are assumed to have the same risks as their conventional counterparts if there is no sound scientific evidence to the contrary. That stands in marked contrast to the precautionary approach taken by the Europeans (Gupta et al. 1999; Andrée 2005).

A final, notable characteristic of the Canadian system is that there is no requirement for labeling of GM foods, unless there is a health or safety risk that can be avoided through a warning on the label. In 2002, the Canadian Parliament introduced a law that would require labelling of foods containing GE ingredients, but the bill failed to garner the support it needed to pass.

### 4.6.2 Political drivers

#### *a) Voice*

Since the widespread introduction of GMOs in Canada there has been a significant reaction from both the public and interested parties. We deal with each of these in turn.

The public reaction to GMOs has been one of cautious acceptance. While 90% of Canadian consumers want to see labelling of GM products (Environics 2000) only

half see GM foods as more than a slight risk (Veeman et al. 2007), although that number appears to be rising. Surveys show similar results for animals fed with GM feed: about half of Canadians see it as a significant risk to their health (Zoia Komirenko 2010).

On the side of experts in the field the concerns are more explicitly articulated. In 2000 the Royal Society of Canada (RSC) was asked to convene an expert panel on the future of food biotechnology by Environment Canada, Health Canada, and the Canadian Food Inspection Agency. The panel's report, entitled "Elements of precaution: recommendations for the regulation of food biotechnology" was published in 2001. The main bone of contention articulated in it was the lack of precautionary measures embodied in the regulation of GMOs in Canada (Barrett et al. 2001).

As its title suggests, the report offered a precautionary perspective on how Canada's regulatory system could be improved. As an example, the panel called for a revision of the concept of substantial equivalence. They believed that some decisions by regulators to determine whether a new GMO could be considered substantially equivalent to a conventional counterpart allowed PNTs to escape more detailed regulatory scrutiny and were rather superficial.

This has been reinforced by academic critiques of the concept of substantial equivalence and the reliance on sound science, rather than precaution (Andree 2006).

#### *b) Accountability*

The government's response to the RSC's report was to acknowledge the concerns and move to address them. This signalling a potential shift towards the acceptance of a more precautionary approach to GMOs. However, analysis of the measures since taken by the government suggests that they fall well short of the recommendations of the RSC's expert panel (Andree 2006). Some recommendations were partially implemented, while others were ignored entirely. However, the government's "Framework for the application of precaution in science-based decision making" suggests that they have taken some of the criticism levelled at them seriously (Privy Council Office 2003).

### 4.6.3 Economic drivers

The economic drivers of regulation of GMOs and other biotechnology have to balance competing concerns. On the one hand, biotechnology offers potential benefits for growers, consumers and the environment. Consumers gain fresher, tastier, more nutritious food. Producers gain greater yields from the same land area with fewer concerns about pest management and weed control. For the environment, direct seeding reduces soil erosion and loss of topsoil (Crop Protection Institute of Canada n.d.).

However, there are also drawbacks to lax regulation of GMOs. For example, Ian Mauro and Stéphane McLachlan at the University of Manitoba, Winnepeg, surveyed

farmers between 2002 and 2003 to identify the key risks to their crops from GMOs. They found that farmers have been placed at risk primarily by the wind-borne spread of GM crops into fields that are not intended to have any GM content. Smaller farms and those with a longer history of GM use were at highest risk (Mauro & McLachlan 2008).

In addition, the Canadian Wheat Board has spoken out against GE wheat, which is not yet widely used in Canada, stating it is opposed to its introduction until there is a positive payoff for farmers and widespread market acceptance. According to a study prepared for the Board, customers representing over 80% of Canadian wheat markets are concerned about GM wheat and some customers, particularly those in Asia and Europe, have said that if Canada or the US introduce GM wheat, they will find new markets.

This highlights the trade concerns that European nations have when trading with nations that do not take a precautionary approach to control of GMOs. It suggests that an approach more aligned with the RSC panel's recommendations may have benefits for the nation' farmers. However, Andree (2006) suggests that the main reason why the government has not moved to implement the extensive testing, monitoring and surveillance called for by the RSC expert panel is because of the significant cost involved in all of these actions.

### 4.6.4 Institutional drivers

In the discussion over whether to favour a precautionary or sound science-based approach, it has been suggested that a key factor in sticking with the latter has been a culture within the Canadian regulatory system that simply does not recognize the value of the more precautionary approach (Andree 2006). For example, in the "Framework for the application of precaution in science-based decision making" previously mentioned there is an allowance for precautionary decision in cases of scientific uncertainty, but no requirement for a precautionary approach to be taken in risk assessment.

If this assessment of the government's culture is accurate then it must be limited to the regulation of biotechnology since the CEPA reviewed above shows a highly precautionary approach to chemical regulation. It will be interesting to see whether future revisions to either regulatory framework lead to a more consistent approach.

## 4.7 China

### 4.7.1 Regime description

Biotechnology is governed by State Council regulations: these include "Food and Agriculture Import Regulations and Standard" and "Agricultural Genetically Modified Organisms Safety Administration Regulations 2001" and implemented by the Ministry

of Agriculture under Ministerial Decrees.[72] These cover domestic approval, import approval and labelling.

New biotech products on first entry into China need:

- To apply for bio-safety certificates from the Ministry of Agriculture;
- To obtain approval, in many cases, at the provincial level;
- A product to be fully approved in the originating country before an application can be filed for approval in China;
- Since 2002, to comply with mandatory labelling – this includes seeds, animal feed and food products; and
- Deal with other impediments including weak protection for intellectual property rights, a low level presence threshold of 0% and lack of policy allowance for "stacked events".

The main agencies in China's regulatory structure are:

- Ministry of Agriculture for approval of biotech agricultural crops for import and domestic production;
- Ministry of Environment Protection for implementation of the Biosafety Protocol, which China ratified in 2005; and
- the General Administration of Quality, Inspection and Quarantine and its local inspection and quarantine offices which oversee quarantine of biotech products entering or leaving the country.

A National Biosafety Committee is a multi-disciplinary team of 74 experts that oversees the evaluation of domestic and foreign applications for biosafety certificates. A National Technical Committee for Standardisation of Biosafety Management of Agricultural GMOs includes 41 experts and administrative officials and is responsible for drafting technical standards.

China has commercialised six genetically modified plants since 1997, but as at 2010 no foreign biotech crops for domestic commercial production had been approved. In addition to bio-safety certification, products must complete a plant variety registration before being commercialised, which may take 2-3 years or longer in the case of GM plants. Most of the GM plants approved for commercial production are not currently being produced because their biosafety certificates expired and were not renewed because of lack of a commercial market.

Currently, the dominant GM crop production is Bt cotton, with 5.2 million acres planted in 2002 (USDA FAS, 2003a). China has not approved the adoption of other major GM agricultural commodities, such as soybeans, corn, rice, or wheat.

[72] GAIN (2011) "China – Biotechnology – GE Plants and Animals", Global Agricultural Information Network, USDA.

### 4.7.2 Political drivers

#### *a) Voice*

It is difficult to get a national picture of public opinion associated with biotechnology within China. This is complicated also by the government owned national media which is pro technology, particularly Chinese technology.[73] The pro technology stance also extends to biotechnology.

According to Environics International (1999) in a survey of ten countries it found that Chinese consumers were the strongest supporters of agricultural biotechnology research, followed closely by the United States. Chinese respondents also had the most trust in independent health and scientific experts.

Supporting this Li et al concluded that Chinese consumers, on average, were willing to pay a 16% premium for GM soybean oil and a 38% premium for GM rice over the non-GM alternatives. Curtis (2004) found that Chinese consumers, on average, were willing to pay a 35% premium for GM processed potato products such as fries, mashed potatoes, and potato chips.

Despite this, Chinese consumers have had little information about GMOs through Chinese newspapers. Prior to 1998 few reports of GMOs occurred in Chinese newspapers (Zhong et al., 2003). It only has been after that time that media reports have increased.

Typically, the government controlled media coverage on biotechnology has been relatively positive. Zhong comments that some surveys indicated that television is the major information source concerning GM foods, with peer discussion and radio following in second and third places. The biosafety benefits and risks from GM crops have been relatively underreported compared to the relevant issue of food safety.

With the data of newspapers collected from 1995 to 2001, Zhong et al., (2002) found that attitudes in reporting GM foods were different among major government official newspapers and popular evening papers. They also suspected that there might be some reporting differences between the coastal and inland areas of China.

The positive nature of support is reinforced by the Chinese consumer being prepared to pay a premium for GM food. When asked why they would be willing to pay a premium for GM foods, many responded that they felt positively about science, were willing to try new products, or the price change was not enough to keep them from purchasing the products, even enhancing their choice (Zhong et al., 2006).

Xi and Harris (2006) set out a comparison between the US and China on risk perceptions towards biotechnology (see Table 1).

[73] Possibly, Chinese nationalism is a component this process.

**Table 6: Evidence of biotechnology risk perceptions**

| | Trust in Government | Attitudes towards Science & Technology | Risks regarding health and environment | Media coverage |
|---|---|---|---|---|
| China | ++ | ++ | ++/- | ++/- |
| US | + | + | +/- | +/- |

Source: Xi and Harris (2006)

### *b) Accountability*

While it is unclear whether there is a concerted approach to putting a positive spin on biotechnology within the national Chinese media there does appear to be a dual approach:

- Very much a precautionary approach to foreign developed GMOs with no foreign developed GM products being grown in China; and
- Heavy domestic investment in biotechnology to the point where China will spend more than US $3 billion over the next five years on biotechnology.

This ranks only second to the US in terms of public sector investments in biotechnology. Chinese officials have said that biotechnology will be one of the country's priorities which will lead to jobs and innovations and underpin standards of healthcare, nutrition, drug safety and disease diagnosis.[74]

This suggests that China is pushing forward as hard and fast as possible on both agricultural and medical biotechnology, however it is doing so on its own terms and without foreign assistance.

To this end, the numbers of both national and provincial biotechnology programmes and institutes continue to increase.[75] China is even considering establishing a new national agricultural biotechnology research centre—a megaresearch centre over the current 150 agricultural biotech laboratories. Based on these developments, if there have been shifts in China's biotechnology developmental plan, it is towards pro-biotechnology research.

Xi and Harris (2006) believe that heavy investment in biotechnology is driven by the following risk perception matrix (Table 2). That is, relative to the other countries, the Chinese see biotechnology, in all its forms, as a small risk and a large opportunity.

[74] http://www.idbs.com/data-management-news/industry-news/article.asp?news-id=800603348

[75] http://www.agbioforum.org/v5n4/v5n4a01-huang.htm

***Table 7: Risk benefit perception matrix***

| | | Opportunity | |
|---|---|---|---|
| | | Large | Small |
| **Danger** | Large | Balanced | Better safe than sorry (EU) |
| | Small | Waste not want not (China) | Indifference (US) |

Source: Xi and Harris (2006)

According to Huang (2010)[76] the main strategy for development has been to:

- Build capacity in biotechnology across the spectrum of activities. This includes recruiting the talent to drive R&D, improving the laws and regulations associated with biotechnology, and prioritising investments to ensure they have maximum impact; and
- Establishing biotechnology parks to develop and maintain an innovative approach to biotechnology.

Interestingly, Huang argues that for China to develop its biotechnology industry to its full potential it will need to encourage foreign investments, something that it has, to date, been reluctant to do.

### 4.7.3 Economic drivers

A major economic driver for biotechnology is to support the growth of the Chinese economy and to ensure that it has enough food to support a growing population. China currently has almost 1.3 billion people and is likely to exceed 1.4 billion by 2050.

Finding more efficient ways of producing food with less land is a top priority for the Chinese government. Biotechnology in agriculture is one avenue that has been embraced to do this. More than a dozen GM crops have been approved for development in China (Huang, Rozelle, Pray, & Wang, 2001).

James and Krattiger (1996) estimate that biotechnology may increase rice production in Asia alone by 10-20% in the next decade. As an example, the use of insect-resistant Bt cotton in China reduced production costs by 14%-33% (Pray, 2000). Reduction in production costs also meant lower prices for Chinese consumers.

Demand side trends also need to be considered. Increased incomes mean more demand for western diets. Convenience foods such as potato chips and pre-packaged meals means that biotechnology will have a major role to play in supporting the diet changes of Chinese consumers either by increased imports or locally grown food.

[76] http://www.apo-tokyo.org/00e-books/AG-19_BusinessPotential/AG-19_BusinessPotential.pdf

The perceived economic benefits (relative to the US) are set out in Table 3. According to Xi and Harris (2006) the perception is that biotechnology will assist in food availability and nutrition, and also provide China with an economic advantage.

***Table 8: Perceived benefits of biotechnology***

| | Food availability | Nutrition | Economic advantage |
|---|---|---|---|
| China | ++ | + | ++ |
| US | Na | Na | ++ |

Source: Xi and Harris (2006)

### *Trade impacts*

To date, Chinese authorities have been inconsistent in their approach to GMO trade. On the one hand they are spending large amounts of money in developing their own biotechnological capacity and also importing large amounts of GM crops, but they are not allowing GM crops to be planted in China that have been developed elsewhere.

It is uncertain how this will change over the coming years. Possibly, it will depend on how successful the biotechnology industry is without foreign assistance. It is also possibly as Huang (2010) suggests - that foreign assistance will be required for China to maximise its own biotechnology potential.

Another interesting area will be China's impact on international agreements in the area of biotechnology (such as the Cartagena Protocol). Like trade in industrial goods, we expect China, at some stage, to have a major impact on the trade of goods that have been made with the help of biotechnology process.

If these agreements have not been developed in a way that reflects Chinese views or without significant Chinese participation in the process then these agreements are likely to be subject to significant change over time. At this stage it is very difficult to know how this will play out.

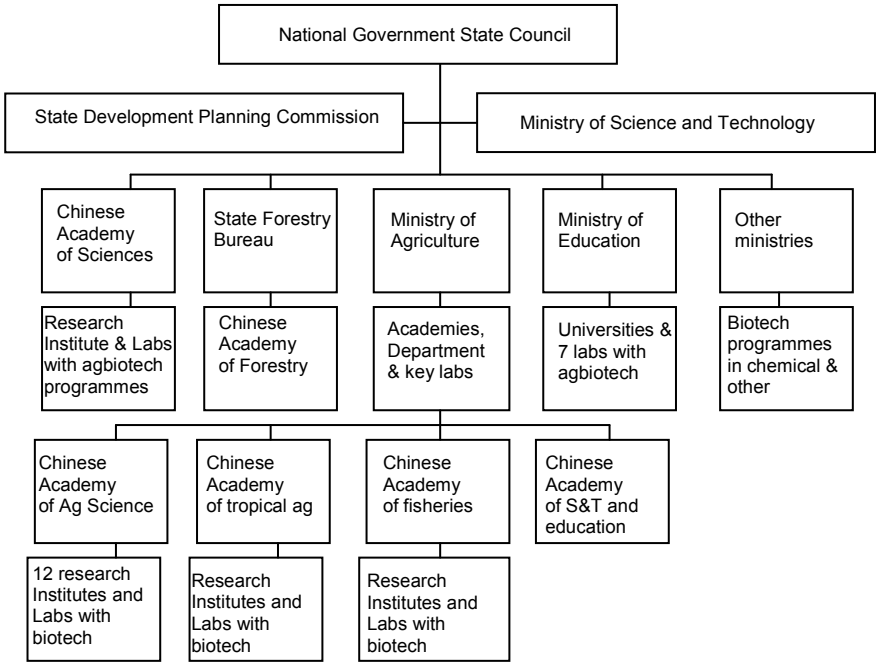
## 4.7.4 Institutional drivers

The Ministry of Science and Technology (MOST) is mainly responsible for biotechnology research in China. However the Ministry of Agriculture is the primary institution in charge of the formulation and implementation of biosafety regulations on agricultural GMOs and their commercialisation, particularly since 2000.[77]

To incorporate representation of stakeholders from different ministries, the State Council established an Allied Ministerial Meeting comprised of leaders from the Ministry of Agriculture, MOST, the Ministry of Public Health, the Ministry of Foreign Economy and Trade (MOFET) and other ministries (see Figure 1).

[77] http://www.agbioforum.org/v5n4/v5n4a01-huang.htm

***Figure 6: Chinese agricultural biotechnolgy research structure***




Source: http://www.agbioforum.org/v5n4/v5n4a01-huang.htm

In this system the MoA has a great deal of power (Huang, 2010) in what is a “top down” corporate structure. They are more familiar with, and have more expertise in, agriculture and agricultural GMOs than any other ministries. MoA are also in charge of pesticide use and its environmental assessment in agricultural production – MoA is a major player in China's agricultural biosafety management.

Two key issues are important. The top down structure leaves little room for participation from other stakeholders. This possibly means that the system reacts to rather than anticipates problems.

Secondly, how do Chinese authorities react to issues/problems where according to Winters and Yusf (2007) the institutions are much weaker than those of more developed nations. While it is recognised that some Chinese institutions are extremely strong and have world best practice they are undermined by the weak application of the law.

From this type of system we would expect an uneven and reactive response to issues/problems as they arise, such as occurred in the recent case of the melamine milk scandal.

## 4.8 Japan

Japan spends more of its gross domestic product on research than any other country, and biotechnology spending is a high priority. However, agricultural applications have been slow to develop, with few field releases of GMOs in Japan and no approved production so far. There are guidelines to assess applications for GM foods but most of the foods accepted by the regulatory committee are foreign imports. Given Japan's low self-sufficiency of food (40%) today, it has been suggested that Japan has become one of the world's largest importers of genetically modified crops.

### 4.8.1 Regime description

Japan has a heavily subsidised agricultural sector and has ratified the Cartagena Protocol, but it also has a strong tradition in technological research and development. In Japan, the use of GMOs is regulated by the Cartagena Domestic Law and the Food Safety Basic Law (FSBL) (Shineha & Kato 2009).

With close ties to the US it does allow imports of food with GM content. Indeed, over 70% of corn and 85% of soybeans imported into Japan are believed to contain GMOs. Gaining approval for import requires the explicit approval of the relevant Ministry and imports without that approval are illegal.

It also has a relatively high rate of authorisation of GMO release for field trials. As of 2008 there were over 115 approvals cultivation of GMOs without containment measures, both in field trial and commercial cultivation. However, there were still no instances of commercial cultivation of GMOs.

The principal agencies involved in regulating risks around biotechnology are:

- Ministry of Agriculture, Forestry and Fisheries oversees the safety of animal feeds and effects on the environment
- Ministry of Health, Labour and Welfare has responsibility for food safety and biotechnology applications
- Food Safety Commission (FSC) undertakes assessments of the overall safety of GM foods, GM animal feed, and GM additives for the other two agencies. Safety evaluations are based on standards created by the FSC's Genetically Modified Foods Expert Committee.

Labelling is mandatory for foods derived from biotechnology applications. To date no field trials of GMOs for food crops for domestic consumption have been authorised because of concerns of consumer backlash, among retailers as well as regulators.

The ministries have set up various guidelines for assessing risks of GM plants at differing levels of technology development and application in agriculture. The principles translated in these guidelines are based on the concepts of familiarity and substantial equivalence agreed upon by the OECD member states in 1993. In this, it

follows a similar approach to Canada and distinct from the precautionary approach of Europe.

### 4.8.2 Political drivers

The most interesting aspect of Japan's regulation of biotechnology, and GMOs in particular, has been the development of the public debate and the way in which it has influenced government policy.

#### *a) Voice*

Early public opinion in Japan was very positive towards biotechnology. In the 1993 International Bioethics Survey (D. R. J. Macer 1994), when asked about specific developments of technology, 74% of Japanese saw biotechnology as worthwhile. In addition, 37% said that they had no worries about its development; indeed, 30% of those who cited it as beneficial said it would help humanity.

In the 1997 surveys there was less optimism about biotechnology and genetic engineering in Japan: only 62% thought that biotechnology would improve the way we live in the next twenty years, 12% thought it would make things worse and 4% said no effect, with 54% seeing genetic engineering as worthwhile. In contrast, the 1991 survey showed 76% of Japanese thought that genetic engineering would be worthwhile (D. Macer et al. 1997).

It may be that the early, positive attitudes were reflected in a general complacence about the impact of GMOs in Japan. Indeed, GM foods drew little attention from the Japanese public at first. However, the public showed increased concern about the growing number of GM crops imported to Japan from early 1997. Numerous anti-GM food campaigns were launched by consumer groups that perceived GMOs as a threat (Nishizawa & Renn 2006).

A major turning point in the public debate came in 1999 when a consumer group, the Consumers Union of Japan, claimed that it had traced a non-accredited type of GMO to corn snacks manufactured by big Japanese food processing companies and sold domestically. Despite repeated denials and investigation by the responsible Ministries the incident led to the government introducing mandatory labelling and certification of GM crops in 2000.

Following these incidents McCluskey et al. (2003) estimated Japanese consumers willingness to pay to avoid GM food. In marked contrast to the studies a decade earlier, they found that a consumery would require a 60% discount in order to be persuaded to purchase GM noodles over their conventional counterpart. Similarly, GM tofu would have to be discounted by 62% to be chosen over conventional tofu. These figures demonstrate the shift in public perceptions of GMOs in Japan over the last twenty years.

### *b) Accountability*

The response of central government to the demands of consumers for greater openness and inclusiveness in policy debates has been muted. Initially, in the 1996-1998 period, the central government was prepared to ignore consumer advocates' demands for regulatory control and rejected calls for an immediate policy response. In the food safety discussions within Japanese ministries prior to 2001, issues of public engagement in policy development were seldom discussed (Shineha & Kato 2009).

The shifts in public opinion convinced Japanese bureaucrats of the need for increased public consultation on policy issues, particularly with relation to GMOs. To facilitate that a number of Ministries convened a consensus conference on GMO in 2000 to discuss future policy settings. The conference attracted much attention from researchers, policy-makers, and advocates and was repeated again in 2007 to discuss GM crops.

Despite the attempts at consultation, there was little response to the public concerns until after 2000. The turning point for Japanese policy consultation on GMOs occurred around 2001, following the corn snacks incident, after which public engagement was included in the development of policies developed by the Japanese science and technology agencies. The importance of public engagement in policy development is now accepted by Japanese policy-makers. However, Shineha and Kato (2009) suggest that effective public engagement in policy-making does not yet exist in Japan. They claim that, despite repeated emphasis on the importance of public engagement, "policy decisions are still not seen as adequately reflecting the outcome of consensus conferences. Therefore, it seems that most of attempts at public engagement in Japan are concerned with one-way communication."

Nishizawa and Renn (2006) suggest that the change in the government's approach to biotechnology regulation was brought about in part by growing dislike of GMOs among consumers and, eventually, the government's acknowledgement that consumer opinion mattered for policy development. However, they also caution that this seemingly reactive approach to policy and governance arose in the context of a broader shift in the Japanese government's handling of stakeholder consultation. At around the same time as public disillusionment with GM foods was growing there was also a backlash against the government's reliance on cliques of experts. No doubt this also influenced the government to hasten the implementation of regulations on GMOs in response to public opinion.

## 4.8.3 Economic drivers

The view of those in industry seems directly opposed to that of the general public in Japan. Whereas the Japanese public became increasingly concerned by the lax regulation of GMOs and pushed for labelling and tighter controls, industry participants and scientists often claim that the regulations have inhibited innovation (D. R. Macer 2000). Their claim has two parts to it: first, they point to the fact that there is no central law governing all biotechnology in Japan but, rather, a series of

interlocking and overlapping regulations governed by a number of different Ministries. That introduces significant transaction costs for industry participants hoping to gain approval for domestic field trials or release.

Secondly, they point to the lack of authorisations given to domestic GM foods: none so far. Industry participants claim that the lack of approvals for such GMOs is indicative of pandering to public opinion, which casts some doubt upon Shineha and Kato's claim that public consultation does not involve the Ministries listening to the views of the Japanese public.

### 4.8.4 Institutional drivers

The slow pace of institutional change in Japan and its sudden reversal can be largely attributed to the institutional arrangements of the nation. In general the culture of the public service has been to have limited public consultation and a paternalistic political culture where challenges to state authority are not encouraged (Buruma 2003; Pharr 1990). The consensus conference on GM crops hosted by the Ministry of Agriculture, Forestry and Fisheries (MAFF) of Japan in 2000, for example, was a novel event in Japanese politics. That illustrates how groundbreaking the policy movements generated by an upswell in public opinion about GMOs were.

The lack of consultation and reliance on small groups of scientists has lead to another challenge for Ministries in generating stakeholder engagement with biotechnology regulation. In a 1997 survey, when given a range of bodies, international organisations like the UN and WHO were considered the best placed bodies to regulate modern biotechnology by 62% in Japan, compared to just 34% in Europe (D. Macer et al. 1997). The lack of public trust in the institutions of government to make the right decisions may be another reason why progress on domestic production of GMOs has been slow.

## 4.9 Overview of current approaches

The literature reveals a clear divide in countries' approaches towards regulation of biological risk, which is particularly apparent in the policy towards biotechnology. In this area the two views on regulation – necessary protection against risk or undue impediment to innovation and growth – are sharply distinguished. There is a tension in the literature (and in countries' policies) between those who view biotechnology as simply on a continuum from other forms of conventional genetic manipulation (such as selective breeding) and requiring no special treatment, and those who in contrast regard biotechnology as presenting new risks requiring a precautionary response and ad hoc special regulations. That same tension can be viewed as a distinction between emphasis on the product attributes and a focus on the processes by which it is produced. Of the countries selected in this review, Australia, Canada and USA can be placed in the former group in seeing little need for special treatment of biotechnology products (including genetically modified organisms) and having approved commercial release and use of such products, whereas the European countries, and Japan have adopted a more cautious approach. The Chinese have

adopted a permissive approach for domestic companies and banned foreign GMOs from being grown in China.

New Zealand is unusual in that food exports are a major part of its economy, but its regulatory stance resembles that of European countries more than that of other major food exporters, having ratified the Cartagena Protocol (hesitantly, according to Cantley 2007, to exert some influence on the Protocol's evolving implementation), and has yet to approve widespread release of GMOs into the environment.

Reporting for the OECD, Cantley (2007) questions the underlying assumption in the European position that GMOs are inherently more hazardous than other genetic technologies: a focus on perceived or conjectural risks is inherently unfavourable to innovation, and the diversion of political attention and resources to such matters is blocking application of biotechnology to solving real problems. Menrad (2004) contrasts the EU with the situation in the USA, where GM crops are distinguished from other crops by the ability of owners to hold property rights and patents in them, and GM release into the environment is based on an assumption of "substantial equivalence" with other organisms unless proven otherwise. The EU takes an opposite position: GM crops are protected by the same breeder rights as all other crops, and release to the environment follows a rigorous precautionary approach with different, more complex procedures that add time and cost to development of GM products in Europe. Menrad cites other studies that suggest the EU's *de facto* moratorium on GM had a negative impact on pre-market innovation with GMOs; that an unclear legal situation over intellectual property in the 1990s led to reduced biotechnology activities in Europe; and that no significant consumer purchase aversion to GM products has been measured, the principal determinant being price.

A case study of the registration of a plant protection product based on a single-strain organism demonstrates the difference between US and EU approaches (Hauschild et al 2006). While the initial data dossier submitted to each agency was virtually the same, registration in the USA was achieved 21 months from the submission of the application; approval from the EU had not been received after 58 months, during which time further information had been demanded of the applicant. Hauschild reports that, in general the EU registration authorities take more responsibility when they register a substance, while in the USA, the responsibility stays largely with the applicant. In addition, EU registration is a two tiered approach – with the active substance evaluated at EU level (referred to as Annex I of Directive 91/414), followed by registration of the product at national level – which may involve a number of country-specific registrations.

While some commentary hails the US approach as far-sighted and rational, others have been more critical. Pelletier (2006) argues that the US FDA's current policy established in 1992 responded to political pressure for a permissive regulatory approach, by exploiting gaps in scientific knowledge, creatively interpreting existing food laws and limiting public involvement in the policy's development.

Kuzma and Todd (2010) discuss regulatory oversight of synthetic biology, finding biosecurity issues most well defined but other societal implications around biosafety, intellectual property and ethics to be less well explored. Developing a typology of potential synthetic biology applications they argue that there may not be an appropriate "one size fits all" regulatory approach and that different regimes may be necessary for different types of risk.

Gupta (2010) identifies information disclosure as central to current efforts to govern biosafety and safe trade in GMOs. But Gupta concludes that current approaches to disclosure may not be assisting countries' right to know and choose before admitting trade in GMOs, because the burden of disclosure and evaluation currently rests largely on the importing countries.

# 5. Implications for New Zealand

## 5.1 Round-up from the literature

Chemical risk regulation is less fragmentary than biological risk regulation in the countries surveyed. Most countries have an overarching regulatory structure governing risk assessment and introduction of new chemicals to a territory, as well as references to chemicals uses in specific legislation on food, health, safety and environmental protection. The major recent developments in chemical risk regulation are overhauls of regulations in Europe and Canada in an attempt to simplify early laws that have become unwieldy and to remove the paradoxical disincentive for innovation and cleaner chemicals from assessments of new chemicals that are more stringent than those for existing chemicals.

Biological risk regulation is divided between a range of different fields: traditional quarantine arrangements to exclude disease and pest bearing organisms from entering a country, broader biosecurity arrangements for both pre-emption and response to biological incursions, biosafety measures that may narrowly focus on the safe handling of biological agents in laboratories and hospitals but may also be more widely aimed at public safety, and measures specific to risks around biotechnology and its release into the environment.

There are broad divisions in approaches across countries and no sign of universal convergence. Even with international agreements, countries can choose to adopt or reject adherence to instruments like the Cartagena Protocol. Those in the EU and Europe more generally, are pushing chemical regulation to a new level of uniformity, partly driven by the European project of harmonisation of laws to reduce transaction costs of doing business across the EU's member states. Canada has been moving to rationalise its regulations for its own purposes but the US retains a relatively old law with some disincentives for innovation to replace older chemicals with newer ones.

In biological risk regulation the big difference is in the field of biotechnology regulation, where food exporters like Australia, Canada and the US have all retained

a relatively liberal regime to introduction of genetic modification applications in food crops, whereas Europe and the UK have been more precautionary with fewer approvals for release.

In both Europe and North America the main focus has been on GM uses in agriculture for food production, as there is less public concern around GM in pharmaceuticals where the risk of irreversible escapes into the environment is less apparent. In Asia, interest in biotechnology is more focused on responding to infectious diseases such as SARS or avian flu which have surfaced there in recent years, so the risk regulation is more focused on biosafety in hospitals and laboratories than on food crops. However, there is still resistance to GM food in Japan where, as in Europe, public trust in authorities to protect the food chain is low.

## 5.2 Recent trends in regulation of risk in general

Literature on regulation in general highlights a shift since the 1980s away from prescriptive command and control regulation towards more outcome or performance based regulation. The reasons for this change are primarily:

- The task of keeping up with and ahead of new developments was costly for regulatory agencies, and inhibiting to innovation because of delayed regulatory decisions;
- Prescriptive regulations also inhibit innovation by making it harder for new and better processes to be implemented, to the detriment of both economic activity and in some cases risk to environment and public health where older, more risky technologies remained in operation after newer more benign approaches became available;
- By shifting responsibility for risk management from regulators to those controlling activities or the use of materials, incentives for sound practice are sharper and new innovation is more likely when desired outcomes can be defined and process managers can get on with finding the best way of achieving those outcomes.

Outcome based regulation inevitably needs to take explicit account of risk, through a risk-based or risk-informed approach to managing hazards (Hutter 2005, Heyman 2010). Other variants around these approaches include “responsive regulation” with flexibility to adapt to changing circumstances (Black and Baldwin 2010) and “smart regulation” that customises a mix of instruments to the characteristics of the risk being managed, characterised by an enforcement pyramid that ranges from measures of soft persuasion to hard sanctions like fines and licence suspension to deter breaches of regulatory requirements (Gunningham and Grabovsky 1998).

The literature also distinguishes ways of dealing with different degrees of scale and severity of risk. Quantified risk assessment works well with known risks, but the greater the complexity, ambiguity or uncertainty associated with potential outcomes, the more likely it is for quantified assessment to be guided by principles or measures of risk tolerance drawn from engagement with the affected parties (e.g. industries and public). This approach has been encapsulated in a risk escalator model, which

differentiates risks and their treatment by successive levels of complexity or uncertainty (Renn 2006). There can be trade-offs between industry and public preferences towards risk, which can be informed by weighting preferences according to market and non-market valuation principles, or other weighting processes feeding into multiple-criteria analyses. The extent to which these processes are extensively and consistently used in practice is unclear from the current literature, and the experience of several countries surveyed here suggests there is a wide divergence from this approach.

Since the 1990s there has been some movement to rolling back regulatory restrictions on the grounds that too much red tape is inhibiting to industry and other activity. This is exemplified by the UK's Better Regulation Task Force (1998), which gave rise to the Better Regulation Commission (2006) and Better Regulation Executive (2009), but it is also reflected in most other OECD countries. The Netherlands in 2001 began applying a Standard Cost Model to identify unnecessary administrative costs from regulations with a view to reducing them, and most other countries in Europe and some elsewhere have since followed their lead (SNM Network 2006). Australia and New Zealand have developed and trialled their own Business Compliance Cost Model to fulfil a similar function, but expanded to reflect the compliance costs for regulated entities (e.g. the costs of equipment to comply with regulations) as well as administrative costs (e.g. reporting and certification).

There has also been interest in standardisation or harmonisation of approaches to regulation across nations. Swann (2010) scans empirical studies of international standards in practice, and finds harmonisation of standards tends to favour trade, and that a country's total stock of standards (both international and national) tends to be positively related to productivity, economic growth, wages, employment and foreign direct investment. Both international and national standards tend to have a positive (or at least neutral) effect on export performance, but with regards to imports, adopting international standards tends to increase imports whereas national standards tend to decrease imports. By reducing variety in pursuit of economies of scale or lower transaction costs standards can reduce trade, but they also act as a signal of quality that can support competitiveness in those striving to attain them.

Given this, recent regulatory trends that can be seen also in chemical and biological risk regulation have been:

- Moves to explicit risk-informed regulation for outcomes that puts more responsibility on those in control of risky activity, away from prescription by regulators;
- Categorising risks on scale and severity, and tailoring regulatory responses that are proportionate to them; and
- Rolling back regulatory characteristics that impose undue cost on regulated activities in pursuit of encouraging innovation and competition.

These are all broadly informed by the notion of achieving regulation where the benefits of reduced risk exceed the costs imposed by regulation, as revealed through

cost benefit analysis (CBA) or regulatory impact analysis (RIA). However, detailed RIAs are only practical for certain types of risk where reliable information is available, and there is wide variation in the manner in which they are undertaken (Renn 2008).

## 5.3 Regulatory choices and innovation, productivity and growth

Regulation of chemical and biological risks is about reducing the probability of bad things happening, so assessing the effects of different regulatory regimes depends on defining the counter-factual: what would have happened under a different set of circumstances. To the extent that a regulatory regime is successful in reducing the incidence of costly risk events it will support productivity and growth over time: just defending current production as a basis for growth is good for the economy, and may be good for the environment as well if it reduces the damage to natural features.

There is a voluminous literature on innovation but no universally agreed definition.[78] The basic idea is of novelty, but distinction can be drawn between innovation in products and innovation in processes. Product innovation tends to be more visible and there is a tendency for consideration of innovation to focus on breakthrough new products with the power to transform some aspect of economic or social activity, but most innovation is less spectacular and lies in process as much as in products.

Innovation with respect to products is sometimes viewed as an intermediate stage in a chain of events from invention, research and development through to taking products to market: it is the stage at which entrepreneurial companies convert research outputs into commercially valuable propositions. It can also be viewed as encompassing the whole process from invention to marketing. The innovation process has a high attrition rate, with very few inventions actually reaching the marketable stage, and fewer still establishing a lasting presence on the market.

Measures of the level of innovation in an economy include such indicators as:

- Expenditure (or employment) in research and development activities;
- A count of innovations from particular countries or companies (e.g. the number of patents filed or number of market introductions of new products);
- Productivity in patent output or R&D activity; and
- Value of innovative market introductions.

All such measures have limitations in what they cover and reliability of available data and are more oriented to innovation in products than in processes. In practice these measures tend to focus on the rate of innovation, but it is also important to consider the direction of innovation which may be more directly affected by market influences such as regulation.

[78] Kemp R (1998) "Environmental regulation and innovation – Key issues and questions for research", Paper t IPTS-DG III project on *Innovation and Regulation.*

Regulations may be viewed as a drag on economic activity, and as inhibiting innovation, productivity and economic growth. However, there is a wider debate about whether environmental regulation can stimulate competitiveness and business performance, as expounded by Porter and van de Linde (1995), or whether it conforms to the traditional economic paradigm of regulation diverting capital away from productive investment.

There is a broad debate on the effect of regulation on innovation and productivity, with literature ranging from the view that regulation is generally negative in stifling innovation (Widavsky 1987)[79] and a more positive view that regulation can stimulate innovation and point it in new directions (Porter and Linde 1995)[80]. The "anti-regulation" arguments centre on companies shifting resources away from R&D to comply with resources, the introduction of new rules increasing the risk of innovation and making companies less likely to innovate, and on regulation bearing more heavily on smaller enterprises that are more innovative than larger organisations. The "pro-regulation" arguments are that regulation may open new market opportunities, that innovation triggered by regulatory compliance enables cost savings for business activity, that companies or economies can obtain "first mover advantage" in developing means of complying with the regulation (Porter & Linde 1995) and that well-designed regulation can reduce uncertainties for market participants.

Empirical studies tend to give mixed results, although do tend to confirm Wildavsky's view in one respect (Wolf & Delgado 2003). Studies stimulated by that debate have provided empirical support for a weak Porter hypothesis (that stricter regulation leads to more innovation), more mixed results for the strong Porter hypothesis (that stricter regulation leads to improved business performance), and shown that the positive effects are stronger when allowance is made for time-lag between regulatory stimulus and innovation put into effect (Ambec et al 2011).[81]

### 5.3.1 Innovation and productivity effects of regulation

The presumed impacts of regulation on innovation have had a significant influence on recent chemical regulation, with a number of influential papers drawing distinction between the regulatory regimes in the EU, US and Japan in the period when the European REACH was being designed. Fleischer et al (2000)[82] summarise the regulatory systems in Europe, Japan and US as being similar in including a threshold concept, a number of specific exemptions and an inventory against which substances can be classified as new, but they also note distinction between the Japanese and

[79] Wildavsky A (1987) *Searching for safety*, Transaction Publishers, New Brunswick & Oxford.

[80] Porter MA & Linde C van der (1995) "Toward a new conception of the environmental competitiveness relationship", *Journal of Economic Perspectives* 9(4) 97-118.

[81] See Ambec S, Cohen MA, Elgie S & Lanoie P (2011) "The Porter Hypothesis at 20"; RFF DP 11-01, Resources for the Future, Washington DC, January 2011 www.RFF/Documents?RFF-DP-11-01.pdf

[82] Fleisher M, Kelm S & Palm D (2000) "Regulation and innovation in the chemical industry" EUR19735en, European Commission, Sevilla.

US systems which may be described as risk-contingent and the then European system which prescribed comprehensive data for assessment irrespective of risk to environment or human health. The European system had the advantage of predictability over what is required, but at the expense of inflexibility in the volume of data to be assembled.

Fleischer et al viewed chemical regulation in Europe to be dominated by a "sunk cost effect" in which the use of existing production infrastructure impedes the development of new production pathways, and a "replacement effect" in which innovation pays off as soon as the variable costs are lower than for processes already in use. A third "efficiency effect", in which established companies are incentivised to innovate because they have more to lose than new market entrants might win is less important in Europe, but has more influence on the US notification system. Fleischer et al observe that innovative activity in chemicals in recent decades has shifted away from development of new chemicals requiring notification and also that there is evidence that R&D processes have been transferred abroad. Their study reinforced the view among some in the industry that regulation was putting the chemicals industry in Europe at a competitive disadvantage and needed reform.

Berkhout et al (2003)[83] take issue with that view, noting that Fleischer and other studies define the economic impact too narrowly and do not explicitly take into account the environmental and health consequences of the different regulatory approaches. These earlier studies tend to stress the effects on rate of innovation by reference to incomplete and sometimes ambiguous measures, and omit consideration of the effect of regulation in shifting the direction of innovation into areas that can create long term market advantage. The innovation rate in the chemicals industry may decrease initially under implementation of REACH, but this is temporary and later recovered by new directions for innovation.

In the UK, the Royal Commission on Environmental Pollution (RCEP 2003) examined similar ground, on the premise that the chemical industry is in a process of permanent change and innovation, regardless of innovation. It argues that the available information provides no evidence that Europe lags behind in innovation in chemicals, and that on the contrary on some measures, the notification rate for new substances appears to have risen. It concludes that the existing regulation does not hamper innovation as is so often claimed by industry, but neither is their evidence of it assisting innovation, so the new chemicals regulation is to be supported as a way of finding improvements over the current approach.

Wolf and Delgado (2003)[84] note that the application of the Porter hypothesis to the chemicals sector is difficult because of the diverse structure of the industry, in which big companies tend to produce basic bulk chemicals whereas refined or niche

[83] Berkhout F, Iizuko M, Nightingale P & Voss G (2003) "Innovation in the chemicals sector and the new European Chemical Regulation", University of Sussex SPRU.

[84] Wolf O & Delgado L (2003) "The impact of REACH on innovation in the chemical industry", Report EUR 20999 EN for the European Commission, Institute for Prospective Technology Studies.

chemicals are more likely to be developed by small or medium enterprises. One of Wildavsky's arguments is confirmed by experience that the need to register new chemicals can be a barrier to innovation in the sense of new substance introduction, and prompt established companies to concentrate on reformulating old substances that are already on the existing chemicals inventories.

The perception that regulation has adverse effects on innovation and competition has clearly been a driving influence on reform of chemicals regulation in Europe, and aspects of REACH such as raising the tonnage thresholds at which more involved risk assessments are required is an explicit response to this perception.

### 5.3.2 Innovation and productivity effects of biological regulation

In biotechnology there is in addition the prospect of new techniques not only protecting current production but also raising it to new levels. In this area there is commentary to the effect that the EU's precautionary approach has impeded innovation and its capabilities in biotechnology developments, compared to the more permissive regulatory approach in North America. The Europeans are also trying to regulate for "co-existence" between GM and non-GM agriculture, the details of which, and effects of, bear closer examination.

## 5.4 Regulatory regimes and impacts on New Zealand

In this section we set out the implications for New Zealand of regulatory regimes being developed in industrialised nations and major markets. Our approach is to examine the New Zealand context, the international context and the implications for New Zealand.

### 5.4.1 New Zealand context

A small country like New Zealand is effectively an international policy taker. One of the misconceptions that New Zealand commentators have is that New Zealand's voice is listened to on the international stage because it can set an example of how others should behave/regulate. It is thought that New Zealand is able to use the "high moral ground" thus gained to somehow persuade, browbeat, or otherwise obtain concessions from larger, more powerful nations.

This could not be further from the truth. New Zealand has no real power to set the international agenda, however it can influence the final consensus. It does this by bring other parties together and being useful to the process. Therefore New Zealand's influence is more "behind the scenes" positioning that is inevitable when international negotiations are being conducted.

Therefore introducing "world first" regulatory approaches, particularly those that are unfamiliar other regulators, is a highly risky approach that can lead to increased compliance costs and in some cases a loss of competitiveness of products and services.

Regulators need to be aware that they are an integral part of New Zealand's competitive advantage. Their ability to see the bigger picture and move adroitly to solving issues as they arise relative to other jurisdictions can be highly advantageous to New Zealand businesses.

### 5.4.2 International context

Many international organisations are committed to harmonising international regulations because of the obvious economic benefits of doing so. In particular, it increases certainty and possibly the simplification of processes help to reduce transaction costs e.g. the OECD, WTO, WHO, FAO and OIE all have well advanced programmes that focus on harmonising regulatory regimes.

However, individual countries focus on their own interest first before considering the implications of how their actions might impact on others. This is reinforced by:

- the political environment in which they operate and the forces that act on them to craft the political actions in the form of regulations
- the institutional framework in which they operate. Many of the big players have thousands of employees whose job is to examine one specific part of the regulatory regime. These organisation do not move quickly and do not see the bigger picture of how their actions fit into a wider international context
- economic considerations such as whether the region is an exporters of chemicals, the size of the domestic market, and the size of agricultural exports.

While countries pay attention to international trends, the reality is – particularly in the US and EU – that domestic considerations are more important and determine the regulatory approach. The way these domestic concerns manifest themselves in a local context include food scares and mistrust of authorities in Europe and Japan's driving attitudes on GM food.

Having said that, the dominance of the EU and the US potentially over national and international regulatory regimes is likely to be weakened over the next twenty years. In this respect, there parallels to world trade. China has "warped" world trade in a way that has shaped and re-shaped trading patterns. Given the growing economic power of China, this same pattern could also occur in terms of international regulatory settings associated with managing chemical and biological risk. As with trade, the impact of China on regulatory regimes is likely to be dramatic and also highly uncomfortable for major players. It will offer opportunities for smaller players, such as New Zealand, who will be able to move quickly enough to capitalise on opportunities as and when they arise.

### 5.4.3 Implications for New Zealand

Considering the way in which New Zealand should respond to the changing regulatory approach in other countries depends on:

- The direct impact of other regulatory regimes on New Zealand;

- The indirect impact of other regulatory regimes on international agreements associated with managing biological and chemical risk; and
- The impact of these regulatory regimes on New Zealand land based agricultural trade.

Unfortunately, in judging the strength of these impacts on New Zealand there is no orderly shift or causal factor that New Zealand regulators might put their finger on and say this will be important. Furthermore, the full impacts of any particularly regulatory approach may take time to be fully understood.

Table 1 sets out a way of approaching offshore regulatory change and how New Zealand could respond. To judge whether we should be a slow adopter, fast follower or a leading player it is possible to think about the process in the following way:

- How simple is any particular response? Are there ways that we can navigate around the issue in a relatively costless way if it is a problem?
- How much certainty is required in a New Zealand response? The more certainty that is required then more formal arrangements are required;
- Can we influence the decision making process either before or after the fact in a way that mitigates compliance costs? If this is possible, formally or informally then it will dictate the way New Zealand develops a response;
- How much flexibility is required in New Zealand's response and how will other regulators react? Can we delay any action, particularly if it is highly uncertain how a particular regulation might work over time?
- How feasible is the option that we propose? What sort of impacts will it have on New Zealand – directly? Indirectly?

As an example we have used the European Union REACH regulations to show how we would think about the direct, indirect and trade implications for New Zealand.

***Table 9: Factors that dictate New Zealand's response to regulatory change: Example of REACH***

| | Simplicity | Certainty | Influence | Flexibility | Feasible |
|---|---|---|---|---|---|
| Direct impact | The regulation is complex | It does provide some certainty | None in its formation | None | It's complexity and high compliance costs may make it less relevant |
| Indirect impact | Its complexity may not help its influence | Certainty of process may help influence international agreements | Takes no account of others – major drawback | None also a drawback | Difficult to implement |
| Trade | Complex increase transaction costs | Very clear you comply or do not trade | While NZ had no influence on its formation it remains to be seen if we can have some influence on its implementation | Does not appear to be flexible | Possible reduction in trade if non complying |

Source: NZIER

Each of these regulatory questions will be different and therefore will have to be examined on its own merits. In answering these questions in a structured way means that a lot more thought into the development of policy responses is required than has previously the case. Examples of "front ending" any response include:

- The EU's new REACH regime for new chemical substances has implications for New Zealand businesses seeking to introduce new products into the European market, in that they will need to conform to the information requirements of the new regime. If those are substantially different from those needed in other markets there could be duplication of costs and possibly exclusion from the market, but how significant that would be is a question for empirical research;
- Signing international agreements will require more research as to what the implications are for New Zealand. Too often in the past we have signed up to international agreements and not understood the ramifications of what we were signing;
- Understanding more fully the costs and benefits of changing New Zealand's regulations so that they:
  - Align their information requirements to those of other countries or trading areas, to reduce the costs of trading into those areas;
  - Shed light on whether New Zealand should support one or other country's regimes as a model for global harmonisation, in light of the costs and benefits from common standards across countries.

The movement from a generic approach to a more specific approach to understanding international changes to chemical and biological regulation will require

some stretch by government, however, adaptability and learning from its mistakes are major strength of New Zealand's regulatory system relative to other bureaucracies who find it hard to change.

# 6. Bibliography


Allanou, R., B.G. Hansen, and Y. van der Bilt, (1999), Public availability of data on EU High Production Volume chemicals 1999, European Chemicals Bureau: Ispra, Italy.http://ecb.jrc.it/existingchemicals/PUBLIC_AVAILABILITY_OF_DATA/

Ambec S., M.A. Cohen, S. Elgie and P. Lanoie, (2011), The Porter Hypothesis at 20, Discussion Paper 11-01, Resources for the Future (RFF), Washington DC. www.RFF/Documents?RFF-DP-11-01.pdf

Almeida, P. and L. B. Stearns, (1998), Political opportunities and local grassroots environmental movements: The case of Minamata, *Social Problems*, 45 (1) 37-60. Available at: [Accessed July 19, 2011].

Ambec S., M.A. Cohen, S. Elgie and P. Lanoie, (2011), The Porter Hypothesis at 20, Discussion Paper 11-01, Resources for the Future (RFF), Washington DC. www.RFF/Documents?RFF-DP-11-01.pdf

Andree, P., (2005), The Genetic Engineering Revolution in Agriculture and Food: Strategies of the Biotech Bloc in *The Business of Global environmental Governance*, p.135–166.

Andree, P., (2006), An analysis of efforts to improve genetically modified food regulation in Canada, *Science and Public Policy*, 33(5), 377–389.

Banerjee, S., (2010), Reach-like regulations enacted globally, *ICIS.com*. Available at: http://www.icis.com/Articles/2010/05/31/9362538/reach-like-regulations-enacted-globally.html [Accessed July 20, 2011].

Barrett, S.C.H. et al., (2001), *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, The Royal Society of Canada, Ottawa.

Binder, Monika, (2002), The Role of Risk and Cost-Benefit Analysis in Determining Quarantine Measures, Staff Research Paper, Australian Productivity Commission, Melbourne.

Bengtsson, Gunnar, (2010), 'Global trends in chemicals management' in *Regulating Chemical Risks: European and Global Challenges*, J. Eriksson et al (eds), Springer: Science+Business Media.

Better Regulation Commission (BRC), (2008), *Public Risk - The Next Frontier for Better Regulation*.

Better Regulation Commission (2006), Risk, Responsibility and Regulation – Whose Risk is it Anyway?

Better Regulation Executive (BRE), (2009), *Striking the Right Balance: BRE Annual Review 2009*. United Kingdom Government.

Better Regulation Task Force (BRTF), (1998) *Principles of Good Regulation* (Cabinet Office) p 1; and http://www.berr.gov.uk/whatwedo/bre/ (last visited 27 June 2010).

Black, J. and R. Baldwin, (2010), Really responsive risk-based regulation, *Law and Policy* 32 (2) 181 – 213.

Bowman, Diana and Graeme Hodge, (2007), A small matter of regulation: an international review of nanotechnology regulation, *Science and Technology Law Review* VIII 1-36.

Briand, Adam, (2010), Reverse onus: An effective and efficient risk management strategy for chemical regulation, *Canadian Public Administration* 53 (4) 489-508.

Buruma, I., (2003), *Inventing Japan*, Modern Library.

Canadian Environmental Network, (2006), *Review of the CEPA 1999: Perspectives of NGOs*.

Canadian Food Inspection Agency, (2000), *Assessment criteria for determining environmental safety of plants with novel traits*.

Cantley, Mark, (2007), *An Overview of Regulatory Tools and Frameworks for Modern Biotechnology: A Focus on Agro-food*, OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda", OECD, Paris. http://www.oecd.org/dataoecd/11/15/40926623.pdf

Chataway, David, (2006), The governance of agro- and pharmaceutical biotechnology innovation: Public policy and industrial strategy, *Technology Analysis and Strategic Management* 18 (2), 169-85.

CIOA, (2005), *Biosafety Legislation in Selected Countries: A Comparative Analysis*, Consumers International Office for Africa, Harare.

Crawford, Erica and Tim Williams, (2006), *International Management of Chemicals*, Canada: Parliamentary Information and Research Service.

Crop Protection Institute of Canada, (n.d), *Plant biotechnology in Canada*, Canada, Ontario: Crop Protection Institute of Canada.

Curtis, K. R., J. J. McCluskey, and T. I. Wahl (2003), Westernization in China: A case study in processed potatoes, IMPACT Center Technical Working Paper, Pullman, WA: Washington State University.

Curtis, K. R., J. J. McCluskey, and T. I. Wahl, (2004), Consumer acceptance of genetically modified food products in the developing world, *AgBioForum*, *7* (1&2), 70-75. Available at: http://www.agbioforum.org

Dahlstrom, Alisha, Chad L. Hewitt, and Marnie L. Campbell, (2011), A review of international, regional and national biosecurity risk assessment frameworks, *Marine Policy* 35 (2) (March).

Danish Eco-council, (2004), REACH – a leap forward for industry, Nordic Council of Industry.

Demont, M, Y. Devos and O.Sanvido, (2010), Towards flexible co-existence regulations for GM crops in the EU, *Euro Choices* 9(2) 18-24.

DHI, (2005), The impact of REACH on the environment and human health.

Doria, Maria, (2007), *Regulation and the Chemical Industry,* A report to the Royal Commission on Environmental Pollution (RCEP). http://www.rcep.org.uk.

Duncan, S., (2009), International Comparisons to the Hazardous Substances and New Organisms Act 1996, Summer Intern Paper, New Zealand Treasury.

ECORYS & Opdenkamp Adviesgroep, (2004), REACH – The Impact of REACH - overview of 36 studies on the impact of the new EU chemicals policy (REACH) on society and business.

Ehlers, Ralf-Udo (ed.), (2011), *Regulation of Biological Control Agents,* Springer. http://www.springer.com/life+sciences/agriculture/book/978-90-481-3663-6.

Ekos Research Associates, (2007), *Public Opinion on Chemicals and Consumerism,* for Environment Canada.

Enemark, Christian, (2010), Preventing Accidental Disease Outbreaks: Biosafety in East Asia, http://www.nautilus.org/publications/essays/apsnet/policy-forum/2006/0631a-enemark.html

Environics, (2007), Chemicals Management and Environmental Health Issues Baseline Survey Ottawa: Environics.

Environics, (2000) Results of Environics poll on Canadian consumer attitudes to genetically engineered foods, Ottawa: Environics.

Environics International, (1999), Attitudes toward biotech crops in various countries *The Washington Post*, October 16 1999 p. A19.

Environmental Agency, (1989), *Quality of the Environment in Japan 1989*, Japan: Environmental Agency.

Eriksson, Christina (ed.), (2010), *Regulating Chemical Risks: European and Global Challenges*. Dordrecht; New York: Springer. http://www.springer.com/law/environmental/book/978-90-481-9427-8

European Commission, (2010a), Special Eurobarometer 354 Food related risks, June 2010.

European Commission, (2010b), Europeans and Biotechnology in 2010 Winds of Change? October 2010.

European Commission, (2009), *Towards 2020 : Making Chemicals Safer: the EUs Contribution to the Strategic Approach to International Chemicals Management,* Luxembourg: Office for Official Publications of the European Communities. http://ec.europa.eu/environment/chemicals/reach/pdf/SAICM_09%20_en.pdf.

European Commission, (2003), Extended Impact Assessment, Staff working paper.

European Commission, (2000), White Paper on Food Safety, Brussels 12th January 2000 Com (1999) 719 final.

Fleischer M., (1998), Regulation and innovation in the chemical industry: the legislation of chemicals in the EU, paper presented to IPTS workshop on *The Impact of Regulation on Innovation*, Sevilla, Spain, January.

Fraunhofer ISI and Ökopol, (2004), Analysis of the costs and benefits of the new EU chemicals Policy – An examination based on selected sectors taking into account effects on competitiveness, innovation, environment, and health, Research project commissioned by the German Federal Environmental Agency.

GAO, (2007), Chemical Regulation: Comparison of US and Recently Enacted European Union Approaches to Protect Against the Risks of Toxic Chemicals, Government Audit Office, Washington DC.

GDEI, (2005), Surviving REACH - A guide for companies that use chemicals, Chemsec.

Gunningham, N., P. Grabosky and D. Sinclair, (1998), *Smart Regulation: Designing Environmental Policy,* Oxford: Oxford University Press.

Gupta, A., (2010), Transparency to what end? Governing by disclosure through the biosafety Clearing House, *Environment and Planning C: Government Policy* 28 (1) 128-44.

Gupta, A., (1999), *Framing 'Biosafety' in an International Context: The Biosafety Protocol Negotiations*, Discussion Paper E-99-10, Kennedy School of Government, Harvard University.

Hampton, P., (2005), *Reducing Administrative Burdens: Effective Inspection and Enforcement* London: HM Treasury.

Hauschild, R., (2006), Microbial biocontrol agents, data requirements and registration: international outlook, paper to REBECA Conference on *Regulation of Biological Control Agents*, Brussels.

Heymann, T., (2008), Improving the effectiveness of regulation through better risk management – a view from the UK's Risk and Regulatory Advisory Council, presentation to the Group on Regulatory Policy, OECD, Paris.

Heyvaert, Veerle, (2010), Regulating chemical risk: REACH in a global governance context" in *Regulating Chemical Risks: European and Global Challenges*, J. Eriksson et al (eds), Springer Science+Business Media.

Hoffman, S., (2010), Food Safety Policy and Economics: A Review of the Literature, discussion paper 10-36, Resources for the Future (RFF), Washington D.C.

Huang, J., S. Rozelle, C. Pray and Q. Wang, (2001), Plant biotechnology in the developing world: The case of China, REAP working paper, Davis, CA: University of California-Davis.

Hung, W., (2007), The Business Potential and Development Strategy for Agricultural Biotechnology Products in the Republic of China, in *Business Potential for Agricultural Biotechnology Products,* Asian Productivity Organization Tokyo.

Hutter, B., (2005), The Attractions of Risk-Based Regulation: Accounting for the Emergence of Risk Ideas in Regulation, Discussion Paper No. 33, London School of Economics and Political Science, London.

James, C., and A. Krattiger, (1996), Global Review of the Field Testing and Commercialization of Transgenic Plants, 1986 to 1995: The First Decade of Crop Biotechnology, ISAAA Brief 1-1996, Ithaca New York: ISAAA.

Jeffs, M., (2004), European chemicals legislation will reach all parts of the PU industry, *Urethanes Technology* October/November 2004.

Just, David (ed), (2006), *Regulating Agricultural Biotechnology,* Springer. http://www.springer.com/economics/agricultural+economics/book/978-0-387-36952-5.

Karlsson, Mikael, (2010), The precautionary principle in EU and US chemicals policy: a comparison of industrial chemicals legislation" in *Regulating Chemical Risks: European and Global Challenges*, J. Eriksson et al (eds), Springer Science+Business Media.

Komirenko, Zoia, Michele M. Veeman, and James R. Undershultz, (2010), Do Canadian Consumers have concerns about genetically modified animal feeds? *Agbioforum* 13 (3) article 3, Available at: http://www.agbioforum.org/v13n3/v13n3a03-komirenko.htm [Accessed July 18, 2011].

Krattiger, Anatole F., (2000), Food Biotechnology: Promising havoc or hope for the poor? *Proteus: A Journal of New Ideas*, 17: 38.

Kuzma J. and T. Todd, (2010), Unpacking synthetic biology: Identification of oversight policy problems and options, *Regulation and Governance* 4(1) 92-112.

Kvakkestad, V. and A. Vatn, (2008), Regulating the release of GMOs: Contrasts between the European Union and Norway, *Environment and Planning C: Government and Policy* 26 (5) 968-981.

Lin, W., A. Somwaru, F. Tuan, J. Huang, and J. Bai, (2006), Consumers' willingness to pay for biotech foods in China: A contingent valuation approach, *AgBioForum*, *9*(3), 166-179. Available at: http://www.agbioforum.org.

Liou, P., (2007), Marching Towards the Market: The Business Potential of Agricultural Biotechnology Products in the Republic of China, in *Business Potential for Agricultural Biotechnology Products,* Asian Productivity Organization Tokyo.

Macer, D. R., (2000), International Aspects: National Profiles, Japan, in *Encyclopaedia of Ethical, Legal, and Policy Issues in Biotechnology,* T. J. Murray & M. Mehlman, (eds) John Wiley & Sons, 722-31.

Macer, D. R. J., (1994), *Bioethics: For the People by the People*, Eubios Ethics Institute.

Macer, D. et al., (1997), Attitudes to biotechnology in Japan and New Zealand in 1997, with international comparisons, *Eubios Journal of Asian and International Bioethics*, 7, 137–151.

Manzella, Daniele, and Jessica Vapnek, (2007), *Development of an Analytical Tool to Assess National Biosecurity Legislation,* FAO Legislative Study 96, Rome: FAO.

Mauro, I. J. and S. M. McLachlan, (2008), Farmer knowledge and risk analysis: Post release evaluation of herbicide-tolerant canola in Western Canada, *Risk Analysis* 28 (2), 463–476.

McCluskey, J. J. et al., (2003), Consumer response to genetically modified food products in Japan, *Agricultural and Resource Economics Review*, 32 (2) 222–231.

Menrad, Klaus, (2004), The regulatory regime and its impact on innovation activities in agro-food biotechnology in the EU and USA, paper to the conference, *Seeds of Change: Intellectual Property Protection for Agricultural Biotechnology*, University of Illinois, Urbana-Champaign, USA.

Migone, A. and M. Howlet, (2010), The public management of new technologies: (Gen)'omics and regulation, submitted to IRSPM-Berne April 2010, http://www.irspm2010.com/workshops/papers/I_thepublicmanagement.pdf

Milmo, S., (2011), *REACHing for a price tag,* Society of Chemical Industry (SCI).

Morris, S. H. and C. Spillane, (2010), EU GM Crop Regulation: A road to resolution or a regulatory roundabout? *EJRR* 4.

Myhr, A. I., (2010), A precautionary approach to genetically modified organisms: Challenges and implications for policy and science, *J Agric Environ Ethics* 23, 501–525.

Naiki, Y., (2010), Assessing policy reach: Japan's chemical policy reform in response to the EU's REACH Regulation, *Journal of Environmental Law* 22 (2), 171 -195. Available at: [Accessed July 19, 2011].

NICNAS, (n.d.), *Overview of Overseas Existing Chemicals Programs*, Australia: NICNAS, http://www.nicnas.gov.au

Nishizawa, M. and O. Renn, (2006), Responding to public demand for assurance of genetically modified crops: Case from Japan, *Journal of Risk Research* 9 (1), 41–56.

Nixon, C. and Yeabsley J, (2011), Australia New Zealand Therapeutic Products Authority, paper prepared for the Law Commission.

Nixon C and Yeabsley J (2011), The challenges of conformity in the wider Asia – Pacific context – Tiny steps on a long road, paper prepared for the Law Commission.

Nixon, C. and J. Yeabsley, (2002), *New Zealand's Trade Policy Odyssey: Ottawa, via Marrakech, and on,* NZIER Research monograph No 68, Wellington: NZIER.

Nixon C (forthcoming), Taxi markets in ASEAN + 6 markets, Wellington: NZIER.

OECD, (2010), *Risk and Regulatory Policy: Improving the Governance of Risk,* Paris: OECD.

OECD (2002), Technical Guidance Document On The Use Of Socio-Economic Analysis In Chemical Risk Management Decision Making, OECD Environmental Health and Safety Publications Series on Risk Management No. 14, Paris: OECD.

OECD (2000), Framework for Integrating Socio-Economic Analysis in Chemical Risk Management Decision Making, OECD Environmental Health and Safety Publications Series on Risk Management No. 13, Paris: OECD. http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono%282000%295&doclanguage=en.

Pelletier, D.L., (2006), FDA's regulation of genetically engineered foods: scientific, legal and political dimensions, *Food Policy* 31(6) 570-591.

Pharr, S. J., (1990), *Losing face: Status politics in Japan*, Univ of California Pr.

Porter, M. and C. van der Linde, (1995), Toward a new conception of the environment-competitiveness relationship, *Journal of Economic Perspectives* 9 (4) 97-118.

Pray, C., D. Ma, J. Huang, and F. Qiao, (2000), Impact of Bt Cotton in China, presented at *4th International Consortium on Agricultural Biotechnology Research* in Ravello, Italy, August 24-28, 2000.

Privy Council Office, (2003), *A Framework for the Application of Precaution in Science-Based Decision Making about Risk,* Canada: Privy Council Office, http://www.pco-bcp.gc.ca

Productivity Commission, (2008), *Chemicals and Plastics Regulation,* Research report, Melbourne: Productivity Commission, http://www.pc.gov.au/projects/study/chemicalsandplastics/docs/finalreport.

Productivity Commission (2009), *Chemicals and Plastics Regulation: Lessons for National Approaches to Regulation: Supplement to Research Report*. Melbourne: Productivity Commission, January. http://www.pc.gov.au/__data/assets/pdf_file/0004/85297/chemicals-plastics-supplement.pdf.

Ravenberg, Willem J., (2011), Registration of Microbial Pest Control Agents and Products and Other Related Regulations, in *A Roadmap to the Successful Development and Commercialization of Microbial Pest Control Products for Control of Arthropods: Progress in Biological Control, 2011,* Volume 10, 171-233. Springer. http://www.springerlink.com/content/j5k608w002523332/.

Reihlen, A. and H. Luskow, (2007), Analysis of Studies Discussing Benefits of REACH, report to the European Commission.

Renn, O (2006), Risk Governance – towards an integrative approach, White Paper No 1, International Risk Governance Council, Geneva, www.irgc.org

Renn, O (2008), *Risk Governance – Coping with uncertainty in a complex world,* London: Earthscan Books.

Rhodes, Catherine, (2007), International regulation of biotechnology – flawed but vital, paper presented to the Egenis Conference on *Governing Genomics – Interdisciplinary Perspectives on the Regulation of Biosciences*, University of Exeter, United Kingdom.

RPA, (2009), Scoping Study for the Evaluation of EU REACH and CPL Regulations, Report to the Department of Environment, Food and Rural Affairs, United Kingdom.

SAICM, (2006), Strategic Approach to International Chemicals Management: Comprising the Dubai Declaration on International Chemicals Management, the Overarching Policy Strategy and the Global Plan of Action. http://www.saicm.org/documents/saicm%20texts/SAICM_publication_ENG.pdf

SAICM (2009), Guidance for developing SAICM Implementation Plans.

School of Health and Related Research University of Sheffield, (2005), The impact of REACH on occupational health – with a focus on skin and respiratory diseases, September 2005.

SCM Network, (2006), Measuring and reducing administrative burdens for businesses, International Standard Cost Model Network, www.administrative-burdens.com

Shineha, R. and K. Kato, (2009), Public engagement in Japanese policy-making: A history of the genetically modified organisms debate, *New Genetics and Society*, 28 (2), 139–152.

Stedeford, T. and M. Banasik, (2010), International Chemical Control Laws and the Future of Regulatory Testing for Risk Assessment, *Georgetown International Environmental Law Review,* 619.

Swann, G. M. Peter, (2010), International standards and trade: a review of the empirical literature, OECD Trade Policy Working Paper No 97.

Swinnen, Johan F. M. and Thijs Vandemoortele, (2011), Policy Gridlock or Future Change? The Political Economy Dynamics of EU Biotechnology Regulation, *Agbioforum* 13 (1) article 1, http://agbioforum.org/v13n4/v13n4a01-vandemoortele.htm

Syndex, (2005), REACH, lever for a sustainable chemical industry: on what basis and how? www.etui-rehs.org/hesa.

Takemoto, K., (2010), Practical approach in chemicals legislation - Japan's experience.

Tamura, S., (2010), Newly Amended Chemical Substances Control Law - Japan.

Teeter, Michael, (2001), The Implementation of Canadian Environmental Protection Act 1999: Why Industry should care! *Hillwatch,* Available at: http://www.hillwatch.com/Publications/Policy_Briefs/Implementation_of_Canadian_Environmental_Protection_Act.aspx [Accessed July 18, 2011].

UNEP-GEF Biosafety Unit, (2006), *A Comparative Analysis of Experiences and Lessons From the UNEP-GEF Biosafety Projects,* UNEP-GEF Biosafety Unit. http://www.unep.org/biosafety/Documents/UNEPGEFBiosafety_comp_analysisDec2006.pdf.

Veeman, M. et al., (2007), *Investigating Changes in Canadian Consumers' Food Safety Concerns, 2003 and 2005*, Dept. of Rural Economy, Faculty of Agriculture & Forestry, and Home Economics, University of Alberta.

Warhurst, M., (2005), REACH, A new approach to Chemicals Regulation in Europe, *JEEPL* 3.

Winters, L. A. and S. Yusuf, (2007), *Dancing with Giants,* Institute of Policy Studies and the World Bank.

Wordsworth, A., (2004), Within REACH: An agenda for improving the Canadian Environmental Protection Act, 1999, prepared for the Canadian Environmental Network Toxics Caucus.

Xi, C. and R. Harris, (2006), Consumer Attitudes toward Genetically Modified Foods A U.S.-China Risk-Benefit Perception Comparison. http://web.cenet.org.cn/upfile/92230.pdf

Zhong, F., M. A. Marchant, Y. Ding, and K. Lu, (2003), GM foods: A Nanjing case study of Chinese consumers' awareness and potential attitudes, *AgBioForum*, 5(4) 136-144.

Zhong, F., X. Chen and Y Xijun, (2006), GM food labeling policy and consumer purchasing behavior—A Nanjing case study of consumers' actual edible oil purchasing in supermarkets, *China Economic Quarterly*.