

Bisphenol A: A Critique on the Law's Failure to Protect the Public from Toxic Exposure

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[I] INTRODUCTION

Bisphenol A (BPA) is a ubiquitous chemical used in a variety of consumer products including polycarbonate bottles, plastic containers, flame retardants, compact disks, thermal receipts and canned food lining.¹ There is also a 93 per cent chance that this chemical is inside your body right now.²

BPA is an endocrine disruptor; that is, a chemical that interferes with the normal functions of hormones.³ Exposure to endocrine disruptors may affect the expression of genes inside the body. So far, there has been no conclusive evidence on BPA's health effects, although a mounting body of research suggests that it may be causing reproductive and developmental problems.

Scientific uncertainty over BPA's effects has made it difficult for governments to take action. In most cases, the law places the burden of proof on regulatory authorities to show that a chemical is unsafe. This paradigm is particularly dicey for BPA as its effects are most likely to be felt during the early stages of development. Unless governments restrict this chemical, the developing fetus and young children are at increased risk of lifelong disease.

This paper argues that current laws are incapable of protecting our most vulnerable population from hazardous chemicals such as BPA. Thus, it is suggested that a more precautionary approach is needed to control substances that could interfere with the hormonal system. This paper will be divided into four parts. Part I discusses the science behind the developmental origins of disease and how BPA may be causing irreversible harm. Part II critically evaluates the law's response to the BPA controversy, using examples from various jurisdictions. Part III investigates the precautionary principle and its role in the regulation of BPA. Finally, Part IV concludes that New Zealand should adopt a more precautionary approach towards BPA.

¹ The annual production of BPA has been estimated at 2.2 million tonnes Tadeus T Shug and others "Bisphenol A" in *Dioxins and Health* (John Wiley & Sons, Inc, Hoboken, 2012) at 382.

² Kelli Whitlock Burton "Shiny Plastic People" (2008) 319 *Science* at 1019.

³ Terri Damstra and others *Global Assessment of the State of the Science of Endocrine Disruptors* (International Program on Chemical Safety 2002).

[III] SCIENCE

[A] Epigenetics

Every cell inside the human body is encoded with an identical sequence of DNA, which is known as the genome.⁴ Although our DNA does not change, it is expressed differently across the body's various cell-types. This process is known as epigenetics.⁵ Essentially, epigenetics is what makes a lung cell different from a brain cell or a kidney cell different from a liver cell. This record of cellular differentiation is known as the epigenome.⁶

[B] Development

Development is by definition, epigenetic.⁷ During the early stages of development, epigenetics plays a vital role in cell production and differentiation. This is an essential process for the normal growth of tissues, organs and systems.⁸

However, the epigenetic process is also incredibly sensitive to endocrine disruptors in the environment.⁹ Endocrine disruptors can cause permanent changes in the epigenome, which may then be passed down to offspring. BPA is one type of endocrine disruptor that may affect the epigenetic process.¹⁰ To understand how endocrine disruptors work, it is important to first consider some basic features of the endocrine system.¹¹

[C] The Endocrine System

The endocrine system is made up of a network of glands that secrete hormones into the blood stream. These hormones are then transported through the blood

⁴ W Wayt Gibbs "The Unseen Genome: Beyond DNA" (2003) 289(6) *Scientific American* at 108.

⁵ Alex Eccleston, Natalie DeWitt, and Chris Gunter "Epigenetics" (2007) 447 *Nature*.

⁶ National Humane Genome Research Institute "Epigenomics" (2012) at www.genome.gov (last accessed 11 June 2013).

⁷ Wolf Reik "Stability and Flexibility of Epigenetic Gene Regulation in Mammalian Development" (2007) 447 *Nature* at 425.

⁸ Carl F Cranor *Legally Poisoned* (Reprint ed, Harvard University Press, 2013) at 122.

⁹ Louis J Guillette Jr and Taisen Iguchi "Life in a Contaminated World" (2012) 337 *Science Magazine* at 1614.

¹⁰ Sher Singh and Steven Shoei-Lung Li "Epigenetic Effects of Environmental Chemicals Bisphenol A and Phthalates" (2012) 13 *Int J Mol Sci* 10143.

¹¹ Åke Bergman *State of the Science of Endocrine Disrupting Chemicals 2012: Summary for Decision-Makers* (2012) at 4.

stream to their target cells. If the incoming hormone is a match, it will fit inside the cells' receptors like a lock-and-key.¹² This receptor-hormone interaction signals the cell to start producing new proteins, which can then be used for the normal functioning of tissues and organs.

[D] Endocrine disruptors

Endocrine disruptors compete with the body's natural hormones by latching on to the target cell's receptors.¹³ Once an endocrine disruptor has reached the target cell, it will either promote or inhibit very specific parts of the DNA.¹⁴ Thus even in very small concentrations, these chemicals can have a profound impact on the developing organs, tissues and systems.

Synthetic estrogens are one particularly potent class of endocrine disruptor. These substances mimic the functions of natural estrogen - the female sex hormone. Estrogen is important for regulating the onset of puberty, breast tissue growth, menstruation and menopause in women; although it also plays a vital role in male reproduction.¹⁵

BPA was first discovered to be a synthetic estrogen in 1936.¹⁶ While it was originally thought to be weakly estrogenic, recent findings suggest that BPA could be far more potent.¹⁷

[E] Bisphenol A

Hundreds of animal studies have linked BPA to a variety of health problems including declines in sperm count, abnormal penial and urethra development in males, early sexual maturation in females, neuro-behavioural problems, type-2 diabetes and immune system disorders.¹⁸ In addition, BPA has been shown to

¹² Kevin T Patton and Gary A Thibodeau *Anatomy and Physiology* (7th ed, Mosby Elsevier, St Louis, 2010) at 538.

¹³ Scott F Gilbert *Developmental Biology* (7th ed, Sinauer Associates Inc, Sunderland, 2003) at 698.

¹⁴ Olov Sterner *Chemistry, Health and Environment* (2nd ed, Wiley-Blackwell, Weinheim) at 230.

¹⁵ Arthur C Guyton *Textbook of Medical Physiology* (W B Saunders, Philadelphia, 1986) at 876.

¹⁶ Nancy Langston *Toxic Bodies* (Yale University Press, New Haven and London, 2010) at 124.

¹⁷ Sarah A Vogel *Is it safe?* (University of California Press, Berkeley, 2013) at 183.

¹⁸ Mr John Wargo *Green Intelligence* (Yale University Press, 2010) at 275.

cause chromosomal damage in mice offspring, suggesting that its effects could be intergenerational.¹⁹

Due to ethical and legal constraints, it is not possible to directly test the effects of BPA on humans.²⁰ Nevertheless, epidemiological studies have linked high concentrations of BPA with cardio-vascular disease and diabetes.²¹ In addition, occupational exposure to BPA has been shown to decrease sperm quality and sexual function in men.²²

[F] Bisphenol A and Early Childhood Development

There are a number of reasons why children are particularly vulnerable to BPA's effects.

Firstly, the timing of exposure is a crucial factor. During the early stages of development, the body uses hormones to regulate the growth of organs, tissues and systems. If an endocrine disruptor is present during this period, it can interrupt the body's normal hormone levels.²³ The history of Diethylstilbestrol (DES) highlights this danger all too well. DES is a potent estrogen that was prescribed as an anti-miscarriage drug in the 1940-60s. Years later, it was discovered that exposure to DES inside the womb had caused many of the so called "DES daughters" to develop a rare form of vaginal cancer.²⁴ Although BPA might not be quite as potent as DES, children are more likely to be exposed to BPA on a daily basis.

Secondly, children have lesser defences than adults. Both the immune system and liver have not fully matured and cannot metabolize BPA efficiently.²⁵

Thirdly, children are more likely to have a higher dietary exposure to BPA as they tend to eat more food per body weight than adults.²⁶

¹⁹ Mark Alpert "Fighting Toxins in the Home" (2008) 108 *Scientific American* at 46.

²⁰ Nancy Langston, above n 16, at 126.

²¹ Alison Motluk "Plastic Linked to Heart Disease and Diabetes" (2008) 199(2674) *New Scientist* at 7.

²² Taddeus T Shug and others, above n 1, at 390.

²³ Åke Bergman, above n 11, at 12.

²⁴ World Health Organization *Endocrine Disruptors and Child Health* (2012) at 1.

²⁵ Muna S Nahar and others "Fetal Liver Bisphenol A Concentrations and Biotransformation Gene Expression Reveal Variable Exposure and Altered Capacity for Metabolism in Humans" (2013) 27 *J Biochem Mol Toxicol* 116.

Finally, a large number of children's products contain BPA. For example, polycarbonate baby bottles are known to leach high concentrations of BPA when sterilised under hot water.²⁷ BPA is also used in plastic lunch boxes infant formula cans and toys – products used almost exclusively by young children.

[G] Science - Summary

In sum, BPA is likely to affect the epigenetic process and could be causing serious harm. For this reason, BPA has caught the attention of regulators over the last few years. The following section will discuss how the law regulates toxic chemicals in relation to the BPA controversy.

[II] Law

[A] International Environmental Law

International Environmental Law has responded to the growing risk of contamination from pesticides and other industrial chemicals. Although a number of conventions regulate the trade in toxic chemicals, two of the most important agreements will be considered here; namely, the Stockholm Convention on Persistent Organic Pollutants and the Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals.

[1] Stockholm Convention

The Stockholm Convention aims to eliminate the use and production of certain persistent organic pollutants (POPs). These substances raise a number of health concerns including cancer, immune system disorders and reproductive problems.²⁸

The Stockholm Convention obliges parties to reduce, and in some cases completely eliminate, a group of POPs; collectively known as the “dirty

²⁶ ATSDR “ATSDR - Principles of Pediatric Environmental Health - Factors Affecting Children's Susceptibility” at www.atsdr.cdc.gov (last accessed 12 June 2013).

²⁷ Anon “Be Careful which Bottles You Sterilise” (2008) 197(2641) *New Scientist* at 15.

²⁸ Ulrich Beyerlin and Thilo Marauhn *International Environmental Law* (Hart Publishing, Oxford, 2011) at 221.

dozen”.²⁹ Parties are required to develop their own Implementation Plan to demonstrate how they will fulfil their obligations.³⁰ The Convention also establishes a rigid compliance and enforcement regime.

New chemicals can be added under the Stockholm Convention as long as they qualify as POPs. By definition, these chemicals share the following properties:³¹

- 1) They are highly toxic and persistent;
- 2) They are capable of being transported across international boundaries;
and
- 3) They bio-accumulate in fatty tissue.

Based on the above criteria, BPA does not meet the definition of a POP. Although there is now evidence to suggest that BPA could be highly toxic, it does not persist in the environment nor does it bio-accumulate.³² For this reason, the Stockholm Convention is not the appropriate mechanism for controlling this chemical.

[2] The Rotterdam Convention

The Rotterdam Convention is based on the idea of prior informed consent (PIC). This process prevents the exportation of hazardous chemicals unless the importing party gives its consent before accepting them.³³

The Rotterdam Convention requires parties to disclose their position for all chemicals covered by the PIC list.³⁴ These decisions are compiled into a report and distributed so that all the parties are kept up to date with any restrictions.

²⁹ Article 3(1)(a).

³⁰ Julie B Truelsen “Developments in Toxics in 2004: The Ratification of the Stockholm Convention and the Rotterdam Convention” (2005) 16 Colorado Journal of International Environmental Law and Policy at 222.

³¹ UNEP *Ridding the World of POPs: A Guide to the Stockholm Convention on Persistent Organic Pollutants* (2010) at 5.

³² BPA is quickly metabolized inside the human body - Wolfgang Völkel and others “Metabolism and Kinetics of Bisphenol A in Humans at Low Doses Following Oral Administration” (2002) 15 Chem Res Toxicol 1281.

³³ UNEP “How it Works” (2013) at www.pic.int (last accessed 1 June 2013).

³⁴ Art 10(7).

Importantly, parties must not export any of the PIC chemicals if this would contravene the decision of another party.³⁵

The scope of the Rotterdam Convention is quite narrow as it is mainly concerned with pesticides and industrial chemicals. For this reason, BPA has not yet been added to the PIC list. Even if BPA was covered by the Rotterdam Convention, the PIC procedure would become quite difficult as BPA is one of the most ubiquitous chemicals on the international market. Therefore, it is unlikely that BPA will be added to the PIC list any time soon.

[B] Regional Regulation of Chemicals: The European Union

[1] Overview of REACH

The EC's Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) came into force in 2007. REACH provides a regulatory overhaul for all chemicals manufactured and imported into Europe.

Prior to REACH, chemicals were regulated under a patchwork of different laws and policies.³⁶ The old system 'grandfathered in' all chemicals that were already on the European market— even though there was little or no data on their risks.³⁷ In contrast, companies had to carry out extensive testing and provide data for new chemicals.

This data gap is now beginning to close as REACH now requires premarket testing for all chemicals. The philosophy behind REACH is that no chemical should be placed on the market, unless the industry can provide sufficient documentation.³⁸ In other words, REACH adopts a "no data, no market" approach.

³⁵ Art 11(1)(b).

³⁶ Environment Directorate General *REACH in Brief* (2007) at 3.

³⁷ Cranor, above n 8, at 198.

³⁸ European Commission *Chemicals in the Environment and their Health Implications* (2012) at 4.

[2] How REACH Works

(a) Registration

Before a company can gain access to the market, it must register its chemicals with the European Chemicals Agency (ECHA). The registration process will depend on the chemical's annual production volume – in general the higher the tonnage, the more stringent the requirements.³⁹ For high production chemicals (>10 tonnes per annum), a chemical safety report (CSR) will be required. The purpose of the CSR is to provide information on a substance's hazards. If the substance is identified as hazardous, the CSR must include information on exposure scenarios and a risk management plan.⁴⁰ A CSR is also required for substances that are reasonably expected to be released from products during their normal use.⁴¹

The registration process has some important implications for BPA. As BPA is a very high production chemical, companies wishing to manufacture or import this chemical into Europe will have to submit a CSR.⁴² In addition, companies planning to sell large amounts of polycarbonate plastics will also have to submit a CSR as BPA is “reasonably expected” to be released from these products.

(b) Evaluation

ECHA is also responsible for evaluating the CSRs. If a chemical is found to pose a significant risk to human health and safety, ECHA can order companies to submit more data or conduct further testing.⁴³ If ECHA discovers that a

³⁹ Ohandja Dieudonné-Guy and others “Regulatory Systems and Guidelines for the Management of Risk” in *Pollutants, Human Health and the Environment* (Wiley-Blackwell, West Sussex, 2012) at 30.

⁴⁰ Bjorn Hansen and Mark Blainey “Registration: The Cornerstone of REACH” (2008) 17 *Review of European, Comparative & International Environmental Law* at 120.

⁴¹ Environment Directorate General, above n 36, at 9.

⁴² 1 million tonnes of BPA is used in Europe each year. European Commission Joint Research Centre *European Union Risk Assessment Report - Bisphenol A* (2010) at 22.

⁴³ Bjorn G Hansen and Mark Blainey “REACH: A Step Change in the Management of Chemicals” (2006) 15 *Review of European, Comparative & International Environmental Law* at 276.

substance is particularly hazardous, it may decide to take further action under REACH's authorisation and restrictions procedures.⁴⁴

(c) Authorisation

The authorisation process imposes tough restrictions on so called 'substances of very high concern' (SVHC). This includes any substance that is: carcinogenic, mutagenic and reprotoxic (CMRs); persistent, bio-accumulative and toxic (PBT); very persistent, bio-accumulative and toxic (vBvP), as well as certain types of endocrine disruptors.⁴⁵ Companies cannot produce these chemicals unless they obtain authorisation from the European Commission (EC).

The EC may grant authorisation under two separate grounds: 1) where exposure to a substance can be adequately controlled or 2) where the socio-economic benefits outweigh the risks, taking into account any alternative substances.

To date, BPA has not been classified as a SVHC.⁴⁶ In the event that BPA is so classified, it is unlikely that the EC would grant authorisation under the first ground, as it would be difficult to control exposure to BPA. However, companies could still argue that the socio-economic benefits outweigh the potential risks. For example, epoxy resin made with BPA prevents contamination in tinned food— a clear benefit; whereas the risks associated with BPA exposure are still equivocal.

⁴⁴ Steffen Erler, ebrary, Inc *Framework for Chemical Risk Management under REACH Regulatory Decision-Making* (1st revised ed ed, Smithers Rapra Technology, Ltd, Shrewsbury, 2009) at 72.

⁴⁵ Environment Directorate General, above n 36, at 12.

⁴⁶ PlasticsEurope "Bisphenol-A and REACH" (2013) at www.bisphenol-a-europe.org (last accessed 8 May 2013).

(d) Restrictions

Finally, the EC may impose community-wide bans and restrictions whenever a substance or article presents an ‘unacceptable risk’.⁴⁷ So far, thousands of substances have been restricted under the process.

It is interesting to note that DEHP is listed as a restricted substance. Like BPA, DEHP is a known endocrine disruptor and is also a common ingredient in plastics.⁴⁸ Unlike BPA however, DEHP is strictly controlled by the REACH program.

[3] The European Approach to BPA

While REACH now applies to virtually all chemicals in Europe, a few types of chemicals are regulated under separate regimes. For example, chemicals used in food packaging and containers are regulated under the EU’s Regulation on Food Contact Materials. The European Food Safety Authority (EFSA) is responsible for upholding this Regulation and setting the appropriate safety standards. As such, the EFSA plays a vital role in the regulation of BPA.

The EFSA approved BPA as a food contact material in 2002,⁴⁹ and set its first safety standard in 2006.⁵⁰ However following new evidence over BPA’s effects, a few members of the EU decided to adopt their own national measures. Thus in 2010, France banned BPA from all baby bottles, with Denmark taking a step further and banning BPA from all food products intended for children.⁵¹ With these restrictions in place, the EC asked the EFSA to reconsider the 2006 safety level.⁵² After months of consultation, the EFSA decided that the recent evidence on BPA’s effects did not warrant a new safety standard.

⁴⁷ Cyril Jacquet “The Effect of REACH on the Supply of Chemicals” (REACH 2007, Brussels, Belgium, 17 April 2007) at 7.

⁴⁸ Wargo, above n 18, at 278.

⁴⁹ European Commission Directive 2002/72, 2002 O.J. (L 220) 18 (EC).

⁵⁰ Tolerable Daily Intake is currently set at 00.5mg/kgBW/day Emilie H Leibovitch “European Union Food Law Update” (2010) 6 Journal of Food Law & Policy at 347.

⁵¹ Taddeus T Shug and others, above n 1, at 401.

⁵² At 400.

Unsatisfied with the EFSA's response, the EC decided to impose a community-wide ban on the use of BPA in baby bottles.⁵³ The decision was a victory for public health agents and worried parents across Europe. However, their enthusiasm was not shared by the plastics industry. Shortly after the announcement, the European Plastics Association issued a public statement claiming that European BPA producers were "deeply disturbed by the EC's Proposal to ban polycarbonate baby bottles" and that it had "ignored the weight of scientific assessments".⁵⁴

Although the EC has banned BPA from polycarbonate bottles, there are currently no plans for further restrictions.

[C] United States of America

[1] Overview

Over the last few decades, the law has failed to protect the American public from toxic exposure. Two of the main culprits will be considered here; namely, the Toxic Substances Control Act 1976 and the Federal Food, Drugs and Cosmetics Act 1938. Both of these Acts are at the centre of the BPA debate in the USA.

[2] The Toxic Substances Control Act 1976

(a) History

In 1976, Congress passed the Toxic Substances Controls Act (TSCA) to fill in the gaps of previous legislation that had traditionally focused on one pollutant at a time.⁵⁵ To achieve this end, Congress authorised the Environmental Protection Agency (EPA) to enforce the Act and develop its own regulations.⁵⁶

⁵³ European Commission - Press Release *Bisphenol A: EU Ban on Baby Bottles to Enter into Force Tomorrow* (2011) at 1.

⁵⁴ PlasticsEurope *Statement Regarding the European Commission's Announced Measure to Ban Polycarbonate Baby Bottles in Europe* (2010).

⁵⁵ Cranor, above n 8, at 134.

⁵⁶ Miriam V Gold and Jean Warshaw *The Toxic Substances Control Act - A Practical Guide* (Oxford University Press, Oxford, 2010) at 3.

(b) 'New' and 'Existing' Chemicals

TSCA aims to provide a single regulatory process for all chemicals. In practice however, the Act contains separate rules for 'existing' and 'new' chemicals. Chemicals listed under the TSCA inventory are referred to as 'existing' chemicals and do not require any data or testing. Conversely, all chemicals not covered by the TSCA inventory are referred to as 'new' chemicals. Before 'new' chemicals can be listed, companies must submit a pre-manufacture notice outlining all the information they have on the chemical.⁵⁷

When TSCA first came into force in 1976, it 'grandfathered-in' the vast majority of chemicals on the US market - despite little being known about their risks.⁵⁸ As a result, BPA and some 62,000 other chemicals were added to the inventory overnight.⁵⁹

In theory, the EPA may still restrict existing chemicals where they are found to present an "unreasonable risk". In this case, companies will have to provide further information on their chemicals. But unless the EPA had some data from the outset, it will be very difficult to provide any evidence of the chemicals' risks.⁶⁰ It is precisely this regulatory 'Catch 22' situation that has left the EPA powerless in the battle against BPA.

(c) BPA and TSCA

Following the devastating effects of DES in the 1970s, the US National Toxicology Program (NTP) began to test a number of endocrine disruptors. However, traditional toxicology methods were based on the idea that "the dose makes the poison". Thus it was assumed that BPA's reproductive effects would diminish with dose. By measuring toxicity in this way, the NTP failed to account for one other crucial variable – the timing of exposure.

⁵⁷ Toxic Substances Control Act, 5 USC s 5 (1976).

⁵⁸ Sarah A Vogel, above n 17, at 196.

⁵⁹ Susan Freinkel *Plastic* (Houghton Mifflin Harcourt, 2011) at 106.

⁶⁰ At 106.

The EPA set the first safety standard for BPA in 1988 at 0.05 mg per kg of bodyweight per day.⁶¹ To this day, the EPA has never updated the safety standard, despite new evidence that BPA could be harmful at much lower concentrations.

Furthermore, the EPA has not taken any action under TSCA as it still cannot decide whether BPA presents an “unreasonable risk”.⁶² Instead of proceeding with precaution, the EPA prefers to wait for unequivocal evidence that low dose exposure to BPA ‘causes’ adverse health effects - a conclusion that is unlikely to be reached any time soon.

While TSCA applies to most chemicals, it contains exceptions for substances already regulated under other statutes.⁶³ For this reason, the BPA debate will also be assessed under the USA’s food safety legislation.

[3] Federal Food Drug and Cosmetics Act

(a) Overview

Congress passed the Federal Food Drug and Cosmetics Act (FDCA) in 1938. The FDCA authorises the Food and Drug Administration (FDA) to regulate food safety standards in the USA.

(b) Food Additives

In the decades following the passage of the FDCA, the food additives industry began to explode.⁶⁴ Congress soon recognised the need for tougher restrictions on these chemicals and passed the Food Additives Amendment in 1958.

The Amendment requires all companies to prove that their food additives will be safe. Section 201(s) of the FDCA defines ‘food additives’ quite broadly and

⁶¹ The NTP estimated the lowest observed effects would be around 50mg/kgBW/day. This figure was then divided by one thousand to account for uncertainties with the estimate and differences between animals and humans. Sarah A Vogel, above n 17, at 89.

⁶² Karen Boswell “Bisphenol A (BPA) Action Plan Summary | Existing Chemicals | OPPT | US EPA” (2013) www.epa.gov (last accessed 17 June 2013).

⁶³ Toxic Substances Control Act, § 3(2)(B)(vi).

⁶⁴ Kenneth R Piña and Wayne L Pines *A Practical Guide to Food and Drug Law and Regulation* (3rd ed, Food and Drug Law Institute, Washington, 2008) at 242.

includes any substance that is “reasonably expected” to directly or indirectly become part of the food.⁶⁵ Although BPA is not directly used as a food additive, it is “reasonably expected” to migrate from plastic packaging and is therefore an ‘indirect food additive’. However the statutory definition of ‘food additives’ excludes any substance that is ‘generally regarded as safe’.⁶⁶ Thus in 1963, the FDA approved BPA for use in food containers as it was not known to cause any ill effects.⁶⁷ This approval meant that companies could use BPA in all types of food packaging.

(c) The Delaney Clause

The 1958 Amendment also contains an absolute prohibition on the use of carcinogens in food.⁶⁸ This rule became known as the Delaney Clause, named after Congressman James Delaney who originally proposed the Amendment. In essence, the Delaney Clause states that the FDA must not approve any food additive that is known to cause cancer.⁶⁹

Upon coming into force, the 1958 Amendment sent the chemicals industry into a frenzy. Companies were worried that if the Delaney Clause was given a strict interpretation, a number of pesticides and other chemicals would become banned overnight. Instead, the Delaney Clause was given a liberal interpretation so that it would only apply to ‘quantifiable’ amounts of carcinogens. Thus if the carcinogen could not be detected, there was no need to regulate it.

Today, this *de minimis* exception fails to account for BPA’s low dose effects. BPA defies the rules of toxicology; that is, its low dose effects are often more

⁶⁵ At 243.

⁶⁶ James O’Reily *Food and Drug Administration* (3rd ed, Thomson/West, St Paul, 2007) at ch 113.

⁶⁷ Cranor, above n 8, at 40–41.

⁶⁸ James O’Reily *Food and Drug Administration* (3rd ed, Thomson/West, St Paul, 2007) at ch 3.6.

⁶⁹ Federal Food, Drug, and Cosmetic Act 1938, s 409.

potent than its high dose effects.⁷⁰ Thus, BPA might still be hormonally active even at non-detectable concentrations.⁷¹

Another problem is that the Delaney Clause only prohibits carcinogenic food additives. As there is no substantial evidence to show that BPA acts as a direct carcinogen, it cannot be prohibited under this Clause.

[4] The Contemporary BPA Debate and Food Safety

For some thirty odd years, BPA managed to stay out of the regulatory spotlight. However all of that changed in the early 1990s when Theo Colborn released her timeless novel “Our Stolen Future”, outlining the effects of endocrine disruptors on early childhood development.⁷² The book’s success helped move the topic of endocrine disruption away from the scientific community and into the public forum.

In 1997, a crucial discovery was made by Frederick vom Saal - one of BPA’s most outspoken critics. Vom Saal discovered that low level exposure to BPA harmed the prostate of male rats.⁷³ This finding provided an impetus for further research and over the next 10 years, hundreds of studies began to link BPA with a variety of illnesses.

By the mid-2000s, consumer protection groups started to target children’s products as unnecessary sources of BPA.⁷⁴ These product campaigns helped decrease the public’s confidence in BPA and created a demand for safer alternatives.

However the real tipping point came in September 2008 when the NTP released its report on BPA; expressing “some concern” over its effect on prostate development and the behavioural effects in fetuses, infants and young

⁷⁰ Nancy Langston, above n 16, at 128.

⁷¹ Antonia Calafat “Background Paper on BPA Biomonitoring and Biomarker Studies” [2011] World Health Organization.

⁷² See Theo Colborn, Dianne Dumanoski and John Peter Meyers *Our Stolen Future* (Plume, 1997).

⁷³ Frederick S vom Saal and others “Prostate Enlargement in Mice due to Fetal Exposure to Low Doses of Estradiol or Diethylstilbestrol and Opposite Effects at High Doses” (1997) 94 Proc Natl Acad Sci U S A 2056.

⁷⁴ Sarah A Vogel, above n 17, at 174.

children.⁷⁵ This was the first time that a US government agency had formally questioned the safety of BPA. Just two weeks later, the results of a groundbreaking epidemiological study were released. The Lang Study linked high urinary concentrations of BPA with cardio-vascular disease, types-2 diabetes and liver deficiencies.⁷⁶ In many ways, the NTP's report and the Lang Study confirmed what many had always suspected – that BPA was not harmless at all.

By 2009, demand for BPA-free products was so high that all major baby bottle producers agreed to remove the chemical from their products.⁷⁷ Major retailers like Wal-Mart followed suit and announced that they would no longer stock BPA baby bottles; while Sunoco - one of the largest producers of BPA - revealed that it would not sell the chemical to manufacturers of children's products. Although the polycarbonate baby bottle was now commercially dead, the voluntary ban did not stop manufacturers from using BPA in other consumer products.

By 2011, the whole country was affected by the voluntary ban and 11 states had taken legislative action against the use of BPA in baby bottles. To prevent any further restrictions, the plastics industry petitioned the FDA to formally ban BPA from baby bottles.

On 2 July 2012, the FDA announced that BPA could no longer be used in baby bottles. Shelley Burgess, a spokeswoman for the FDA, stated that the decision was not based on any concern for public health and that the FDA “continues to support the safety of BPA for use in products that hold food”.⁷⁸ The FDA's

⁷⁵ NTP-CERHR *Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A* (08-5994 2008).

⁷⁶ Iain A Lang and others “Association of Urinary Bisphenol A Concentration with Medical Disorders and Laboratory Abnormalities in Adults” (2008) 300 JAMA 1303.

⁷⁷ Michelle Crozier-Haynes “Keeping BPA from Baby: Why the Endocrine Disruptor Bisphenol-A Should be Banned from Products for Infants and Children” (2010) 21 Colorado Journal of International Environmental Law and Policy at 169.

⁷⁸ “FDA Officially Bans BPA, or Bisphenol-A, from Baby Bottles” (2012) at www.usatoday.com (last accessed 26 April 2013).

decision was heavily criticised, with one NGO calling the ban “purely cosmetic”.⁷⁹

Currently, there are no further plans to limit the public’s exposure to BPA. While the FDA concedes that more research is needed, it continues to uphold the safety of BPA.⁸⁰

[D] Domestic Regulation of Chemicals: China

[1] China’s New Chemical Program

In 2009, the Chinese government passed the New Chemical Substance Regulation (New Chemicals Regulation), colloquially known as China REACH.⁸¹

The New Chemicals Regulation requires companies to file an application with China’s Chemical Registration Centre. Each application must include general information on the chemical, test reports and a risk assessment. The application is then sent to the Expert Assessment Committee, which assigns the appropriate risk category and controls.⁸² If the chemical is approved, a Registration Certificate is issued outlining basic information on the chemical’s production volume, risk management category and control measures.

Unlike the EC’s REACH program, the New Chemicals Regulation only applies to ‘new chemicals’; namely, substances that are not listed under the Inventory of Existing Chemical Substances in China (IECSC).⁸³ When the New Chemicals Regulation came into force in 2009, it ‘grandfathered in’ all chemicals that had entered China before 15 October 2003. As BPA had been used in China for a number of decades, it did not require any data or testing and was automatically added to the IECSC list.

⁷⁹ “FDA to Ban BPA from Baby Bottles; Plan Falls Short of Needed Protections: Scientists” (2012) at www.commondreams.org (last accessed 3 May 2013).

⁸⁰ Office of the Commissioner “Public Health Focus - Bisphenol A (BPA): Use in Food Contact Application” (2013) www.fda.gov (last accessed 25 April 2013).

⁸¹ Dr Paul Goodman *Chinese Chemicals Legislation - “China REACH”* (2011).

⁸² Charles McElwee *Environmental Law in China* (Oxford University Press, USA, 2011) at 294.

⁸³ New Chemical Substance Regulation 2009, art 16.

[2] Hazardous Chemicals

In 2011, the Chinese government passed the Regulations on Safe Management of Hazardous Chemicals. The Hazardous Chemicals Regulation imposes tough restrictions on all substances listed under the Catalogue of Hazardous Chemicals. Although the Catalogue had not been updated since 2002,⁸⁴ a new version was released on 10 April 2014.⁸⁵ The new catalogue has some important implications for BPA as China's Ministry of Health recently announced that BPA would be added to the 'Hazardous Chemicals of Priority Environmental Concern (HCPEC) list.⁸⁶ Once the new catalogue comes into force, BPA will be regulated under a strict licensing and controls regime.

It is important to note that the Hazardous Chemicals Regulation contains an exclusion clause for chemicals already covered by other legislation.⁸⁷ For this reason, China's food safety laws will continue to regulate BPA as a food contact additive.

[3] Food Contact Legislation

In 2009, China's Ministry of Health revised the Hygienic Standard Uses of Additives in Food Containers and Packaging Materials.⁸⁸ The Standard provides a list of authorised food contact additives and the circumstances in which they may be used. For example, if a food contact additive exceeds its specific migration level (SML), it can no longer be used in food production.⁸⁹ Currently BPA is authorised for use in food contact coatings and adhesives,

⁸⁴ Andy Burgess "Chemical Watch Webinar - China Chemical Regulation" (Chemical Watch, 31 May 2012) at 8.

⁸⁵ CIRS "China MEP Issues the Catalog of Priority Hazardous Chemicals for Environment Management" (2014) <http://www.cirs-reach.com/news/China_MEP_Issues_the_Catalog_of_Priority_Hazardous_Chemicals_for_Environment_Management.html>.

⁸⁶ Ministry of Environmental Protection (China) *12th Five-Year Plan for the Environmental Risk Control on Chemicals* (2013).

⁸⁷ At Article 97.

⁸⁸ "China Publishes List of New Additives Authorized for Use in Food Packaging" (2009) www.khlaw.com (last accessed 10 May 2013).

⁸⁹ "Food Additive Laws and Food Safety Standards in China" (2012) at www.cirs-reach.com (last accessed 10 May 2013).

subject to a SML of 0.6mg/kg.⁹⁰ As there has been little research on dietary exposure to BPA in China,⁹¹ it is unclear whether the current SML is sufficient.

The Standard also contains a list of substances that cannot be used in food packaging. In 2011, BPA was added to the list so that it may no longer be used in baby bottles.⁹² Whether China will ban BPA from other products in the near future remains to be seen.

[E] New Zealand

[1] Hazardous Substances and New Organisms Act 1996

The main tool for regulating toxic chemicals in New Zealand is the Hazardous Substances and New Organisms Act 1996 (HSNO). Before the HSNO came into force, toxic chemicals were regulated under different statutory regimes such as the Pesticides Act 1979 and the Toxic Substances Act 1979.⁹³ Nowadays, the HSNO provides a single process for controlling all hazardous substances.⁹⁴

The purpose of the HSNO is to “protect the environment, health and safety of the community from the adverse effects of hazardous substances”.⁹⁵ Section 2(1) defines a “hazardous substance” as any substance possessing one or more of the following properties: explosiveness, flammability, capacity to oxidise, corrosiveness, toxicity, and eco-toxicity.

A substance will only be deemed “hazardous” if it exceeds the threshold levels prescribed by the HSNO regulations.⁹⁶ If the substance exceeds the relevant

⁹⁰ “China Latest Country to Ban BPA in Baby Bottles” (2011) at www.packaginglaw.com (last accessed 10 May 2013).

⁹¹ YQ Huang and others “Bisphenol A (BPA) in China: A Review of Sources, Environmental Levels, and Potential Human Health Impacts” (2012) 42 *Environment International* 91.

⁹² Lu Feiran “China to ban plastic bottles to feed babies” *ShanghaiDaily.com* (Shanghai, 5 May 2011) at www.shanghaidaily.com (last accessed 11 May 2013).

⁹³ Simpson Grierson and URS New Zealand *A Practical Guide to the Hazardous Substances and New Organisms Act* (DSL Publishing, Auckland, 2005) at 1.

⁹⁴ Department of Labour “HSNO and hazardous substances” [2005] Safeguard at 34.

⁹⁵ Hazardous Substances and New Organisms Act 1996 s 4.

⁹⁶ *Hazardous Substances (Minimum Degrees of Hazards) Regulations 2001*.

threshold level, it will be categorised according to its hazardous properties.⁹⁷ For example, BPA is currently categorised under Class 6 and Class 9, due to its toxic and eco-toxic properties.⁹⁸

The HSNO regulations provide a series of controls to minimise the risks associated with each type of hazardous substance.⁹⁹ For substances categorised under Class 6 (toxic), an acceptable daily exposure (ADE) level must be set; that is, the amount of a hazardous substance that would be unlikely to cause adverse health effects, given a lifetime of daily exposure.¹⁰⁰ Currently there are no safety standards for BPA, even though the regulations state that an ADE must be set in accordance with international standards.¹⁰¹ At the very least, New Zealand's Environmental Protection Authority could have adopted the same safety levels used in Europe or the USA. To date, the Environmental Protection Authority has only banned BPA from cosmetic products.¹⁰²

Although HSNO covers most hazardous substances, it will not apply if an otherwise 'hazardous substance' has been incorporated into food or used as a food additive. For this reason, the BPA is also subject to New Zealand's food safety laws.

[2] Australian New Zealand Food Standards Code

The Australian New Zealand Food Standards Code (the Code) authorises the Ministry of Primary Industries (MPI) to regulate food safety standards in New Zealand.¹⁰³ Two features of the Code are relevant to the BPA debate; namely, Part 1.2 (labelling requirements) and Part 1.4 (contaminant and residue standards)

⁹⁷ Environment and Business Group and others *Your Guide to the Hazardous Substances & New Organisms Act* (Ministry for the Environment, Wellington, NZ, 2001) at 51.

⁹⁸ "Hazardous Substances (Chemicals) Transfer Notice 2006" (28 June 2006) 72 *New Zealand Gazette* 1655 at 1733.

⁹⁹ Derek Nolan *Environmental and Resource Management Law* (4th ed, LexisNexis NZ, Wellington, 2011) at [11.43].

¹⁰⁰ Simpson Grierson and URS New Zealand, above n 94, at 35.

¹⁰¹ Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001, r 12.

¹⁰² "Cosmetic Products Group Standard 2006" (2010) at www.epa.govt.nz (last accessed 10 May 2013).

¹⁰³ In August 2012, the New Zealand Food Safety Authority (NZFSA) merged into the Ministry of Primary Industries. All policies are now published on the Ministry of Primary Industries' website.

(a) Labelling

Standard 1.2.3 of the Code provides for mandatory warnings and advisory statements in relation to certain foods and foods containing particular substances. These labelling requirements are normally used to warn consumers about any harmful substances that could be present in the food.¹⁰⁴ For example, foods containing phytosterols must include an advisory statement that the product might not be suitable for young children or pregnant women.¹⁰⁵ Currently, the Standard does not require any warnings or advisory statements for products containing BPA.

(b) Contamination

Standard 1.4.1 outlines the maximum levels of toxins that may be present in food as a result of contact with the packaging. For example, the maximum amount of tin that may be present in canned foods is set at 250mg/kg.¹⁰⁶ Again, the Standard makes no explicit mention of BPA. When questioned on this, the MPI stated that:¹⁰⁷

“it is very aware and sensitive to the public concerns about the potential adverse health effects of exposure to Bisphenol A but remains in the opinion that there is no health risk for consumers, including infants”.

To date, New Zealander’s dietary exposure to BPA is estimated to be much lower than the maximum levels set by the EFSA and FDA.¹⁰⁸ Despite the fact that there is now good reason to believe that BPA could still be harmful at very low doses, the MPI has chosen to ignore the weight of the evidence.¹⁰⁹ Instead, it prefers to follow the same myopic approach taken by EFSA and the FDA.¹¹⁰

¹⁰⁴ Bill Bevan, Bob Dugan and Virginia Grainer *Consumer Law* (LexisNexis NZ Limited, Wellington, 2009) at 521.

¹⁰⁵ Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations, cl 2.

¹⁰⁶ Standard 1.4.1 Contaminants and Natural Toxicants, cl 4.

¹⁰⁷ “Bisphenol A in New Zealand” (2012) at www.zerowaste.co.nz (last accessed 7 May 2013)

¹⁰⁸ Exposure levels are estimated at 0.008mg/kg body weight per day Barbara Mary Thomson “Human Health Implications of Exposure to Xenoestrogens from Food” (University of Canterbury, 2005).

¹⁰⁹ *NZFSA Response to Studies Cited as Evidence that BPA May Cause Adverse Effects in Humans* (2011).

¹¹⁰ *NZFSA Bisphenol A - Information Sheet* (2012) at 3.

[3] New Zealand market response

Recently, all of New Zealand's major baby bottle suppliers have started to phase-out polycarbonate bottles.¹¹¹ Other companies like Watties have taken a step further and completely removed the chemical from all baby-food products.¹¹² Despite these individual efforts, products containing BPA are still pervasive across stores in New Zealand.¹¹³ For example, Foodstuffs (owner of Pak'nSave and New World) has stated that it has no plans to withdraw products containing BPA; whereas Progressive Enterprise (owner of Countdown and Woolworths) has revealed that it would not be taking any action, although it does support its suppliers' voluntary phase-out.¹¹⁴ Furthermore, the New Zealand Food and Grocery Council maintains that the voluntary phase-out is a mere response to consumer demand and does not concern any issues of product safety.¹¹⁵

[F] Conclusion on Law

There is now strong evidence to suggest that BPA may be causing serious damage, particularly in young children. But because BPA defies the rules of classical toxicology, scientists have been unable to establish a clear link between exposure and subsequent harm.¹¹⁶ This is problematic as the law tends to treat chemicals as safe, until proven otherwise.¹¹⁷ Unless some precautionary measures are put into place, the population will continue to be exposed to BPA.

¹¹¹ "The BPA Debate" (2011) at www.consumer.org.nz (last accessed 7 May 2013).

¹¹² "Wattie's to Phase Out BPA in Baby Food Packaging" (2010) at www.heinzwatties.co.nz (last accessed 7 May 2013).

¹¹³ Peter Griffin "Crunch time in Bisphenol-A debate" *The New Zealand Herald* (15 September 2010).

¹¹⁴ "Voluntary Phase-Out of BPA bottles" (2010) at www.consumer.org.nz (last accessed 7 May 2013).

¹¹⁵ "Bisphenol A (BPA)" (2013) at www.nutritionfoundation.org.nz (last accessed 8 May 2013).

¹¹⁶ Rachael Rawlins "Teething on Toxins: In Search of Regulatory Solutions for Toys and Cosmetics" (2009) 20 *Fordham Environmental Law Review* at 40.

¹¹⁷ Freinkel, above n 60, at 106.

[IV] Solution – Precautionary Measures

[A] What is Precaution?

Precaution is the linchpin of environmental law and policy. Essentially, precaution is what guides regulators to act whenever the harmful effects of a proposed activity are uncertain.¹¹⁸

Precaution can be implemented on a scale ranging from weak (the precautionary approach) to strong (the precautionary principle). For example, where a chemical is suspected of causing harm, a precautionary approach might require further studies into its effects; whereas the precautionary principle might call for a total ban.¹¹⁹

Where there is a risk of irreversible and serious harm, the precautionary principle will normally be the preferred option. The Wingspread Conference of 1998 provides a useful definition:¹²⁰

When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof.

This articulation of the precautionary principle is useful for assessing the risks posed by BPA. As it is difficult to establish a causal relationship between exposure to BPA and subsequent harm, the precautionary principle would allow for a moratorium until more is known about this substance.

¹¹⁸ Neil A Manson “Formulating the Precautionary Principle” (2002) 24 *Environmental Ethics* at 264.

¹¹⁹ Joel Tickner and others *The Precautionary Principle in Action* (Science and Environmental Health Network Windsor, North Dakota, 1999) at 5.

¹²⁰ The Global Development Research Center “The Wingspread Conference on the Precautionary Principle” (1998) at www.sehn.org/wing (last accessed 18 May 2013).

The following section will discuss how the international community, regional bodies and national jurisdictions have viewed the precautionary principle in relation to the BPA controversy.

[B] International Environmental Law

[1] The Stockholm Convention

The preamble of the Stockholm Convention states that the parties are “mindful of Principle 15 of the Rio Declaration” – the most famous statement of the precautionary principle.¹²¹ In practice, however, the scope of the Stockholm Convention is quite narrow and only restricts a few types of POPs. Moreover, parties wishing to add new POPs are required to provide extensive scientific data.¹²² For these reasons, the Stockholm Convention applies a very general and weak version of the precautionary principle.

[2] The Rotterdam Convention

The Rotterdam Convention does not expressly refer to the precautionary principle - although the PIC procedure does contain some precautionary elements.¹²³ When it comes to adding new chemicals, however, the Convention wears thin on precaution. Before a chemical can be added to the PIC list, at least two countries from two different regions must file a notification. Upon receiving the notification, the Chemicals Review Committee must carry out an extensive scientific risk evaluation.¹²⁴ Finally, any recommendation to add a new chemical must be approved by a majority vote at the Conference of the Parties.¹²⁵ This prolonged and arduous process makes it difficult for parties to exercise precaution when adding new chemicals to the PIC list.

¹²¹ David L VanderZwaag “The Precautionary Approach and the International Control of Toxic Chemical’s: Beacon of Hope, Sea of Confusion and Dilution” (2010) 33 *Houston Journal of International Law* at 615.

¹²² At 619.

¹²³ Arie Trouwborst *Evolution and Status of the Precautionary Principle in International Law* (Kluwer Law International, Hague ; London, 2002) at 80.

¹²⁴ FAO and UNEP *PIC Chemicals* (2010) at 4–5.

¹²⁵ Julie B Truelsen, above n 30, at 228.

[C] Europe

The European Union is one of the most outspoken champions of the precautionary principle.¹²⁶ In particular, Article 191 of the EC Treaty expressly states that European environmental policy should be based on the precautionary principle.¹²⁷

[1] REACH

The REACH regime is directly related to the precautionary principle.¹²⁸ REACH places the burden on companies to test their chemicals and submit the relevant data. This registration process, however, does not require companies to prove that their chemicals will be safe. Rather, companies must provide the relevant information so that ECHA can conduct its own risk assessment.¹²⁹ If the chemical's effects are uncertain, ECHA will normally carry out its own testing and decide if any restrictions are needed. Thus, ECHA will ultimately have to show that BPA is a SVHC before it can take any action. For this reason, REACH does not apply a strong version of the precautionary principle.

[2] European Food Law

Article 7 of the Basic Regulation on Food Law states that the EFSA must have regard to the precautionary principle whenever there is scientific uncertainty. However, the precautionary principle is just one of a number of factors to be considered.¹³⁰ In making its decision, the EFSA must also weigh up the economic, social and political consequences.¹³¹ Thus, it is unlikely that the

¹²⁶ Joakim Zander *The Application of the Precautionary Principle in Practice* (Cambridge University Press, Cambridge, 2010) at 76.

¹²⁷ The Treaty on the Functioning of the European Union (Lisbon Treaty) [2010] OJ C83/49.

¹²⁸ Milieu (Belgium) *Considerations on the Application of the Precautionary Principle in the Chemicals Sector* (2011) at 12.

¹²⁹ Ortwin Renn and E Donald Elliott "Chemicals" in *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe* (Earthscan, London, 2011) at 242.

¹³⁰ Rudolf Streinz "Risk Decisions in Cases of Persisting Scientific Uncertainty: The Precautionary Principle in European Food Law" in *Risk and the Law* (Routledge-Cavendish, Oxon, 2012) at 63.

¹³¹ Nicolas de Sadeleer "The Precautionary Principle in EC Health and Environmental Law" (2006) 12 *European Law Journal* at 147.

EFSA will ban BPA any time soon, as even slight restrictions could have a huge impact of the EU's trade market.¹³²

[3] The EC's 2011 Ban

It is safe to assume that the EC's ban on polycarbonate bottles was motivated by the precautionary principle. In any event, the bottle ban highlights a missed opportunity for the EC to impose tighter restrictions on the use of BPA.

[D] United States of America

Traditionally the USA has viewed the precautionary principle as an unjustified restraint on economic growth.¹³³ Instead, government agencies must generally show that there is an 'unreasonable risk' before they can take action against a product or proposed activity.¹³⁴

[1] Toxic Substances Controls Act

TSCA is no exception to this way of thinking. In theory, s 6 allows the EPA to restrict any substance that presents an "unreasonable risk". This seemingly precautionary language, however, fails to reflect the strong evidential burden that the EPA must satisfy.¹³⁵ Because manufacturers are not required to test their chemicals, the EPA will often have to conduct its own testing or simply wait until some harm has occurred.¹³⁶ By the time the EPA has discovered an "unreasonable risk", it will generally be too late to protect the public from toxic exposure. This problem is particularly acute for BPA as it can take a number of years for its effects to become manifest.

Even if the EPA finds that a substance presents an "unreasonable risk", its decision can still be challenged in court. In *Corrosion Proof Fittings v EPA*,

¹³² Tessa Fox and others "Regulating the Use of Bisphenol A in Baby and Children's Products in the European Union: Current Developments and Scenarios for the Regulatory Future" at 33.

¹³³ Samuel Loewenberg "Precaution Is for Europeans" *The New York Times* (New York, 18 May 2003).

¹³⁴ Noah M Sachs "Rescuing the Strong Precautionary Principle from its Critics" (2011) 2011 *University of Illinois Law Review* at 1288.

¹³⁵ Ortwin Renn and E Donald Elliott, above n 130, at 254.

¹³⁶ John Kvinge "Morally Hazardous Chemical Regulations: Why Effective Reform of the TSCA Requires Reduction of the Toxic Data Gap" (2012) 12 *Minnesota Journal of Law, Science & Technology* at 328.

the Fifth Circuit Court of Appeal overturned the EPA's ruling on asbestos.¹³⁷ The Court held that the EPA did not have sufficient proof that each and every use of asbestos would cause actual harm. If the EPA could not successfully ban asbestos - an undisputed carcinogen – the chances of a similar ban against BPA being upheld are incredibly slim.

[2] Federal Food, Drugs and Cosmetics Act

The FDCA provides an early example of the precautionary principle.¹³⁸ The Act prevents the use of all food additives, unless the manufacturer can show that the proposed food additive will be safe.¹³⁹ In most cases, 'safety' will be based on what the pertinent scientific community 'generally regards as safe'.¹⁴⁰ Prima facie, the FDA could restrict BPA in the interests of public safety; given that the vast majority of studies have expressed concern over this chemical.¹⁴¹ Instead, the FDA has ignored most of these studies for failing to comply with its regulation on Good Lab Practice (GLP). While GLP assures consistency in safety data, it also encourages the use of out-dated techniques that simply cannot account for BPA's low dose effects.¹⁴² To date, the FDA has given more weight to a handful of GLP industry-funded studies than to hundreds of independent studies. Ironically, none of the industry-funded studies were able to replicate BPA's low dose effects.¹⁴³ By demanding strict compliance with GLP, the FDA has disregarded some of the most compelling evidence against BPA.

¹³⁷ *Corrosion Proof Fittings v EPA* 947 F.2d 1201 (5th Cir 1991).

¹³⁸ Nathaniel Garrett "Life is the Risk We Cannot Refuse: A Precautionary Approach to the Toxic Risks We Can" (2004) 17 *The Georgetown International Environmental Law Review* at 541.

¹³⁹ Trouwborst, above n 124, at 192.

¹⁴⁰ Kenneth R Piña and Wayne L Pines, above n 65, at 247.

¹⁴¹ Ryan J Carra "It's in Our Blood: A Critique of the FDA's Reluctance to Regulate the Use of Bisphenol A in Food Supply" (2011) 14 *Journal of Health Care Law & Policy* at 173.

¹⁴² John Peterson Myers and others "Why Public Health Agencies Cannot Depend on Good Laboratory Practices as a Criterion for Selecting Data: The Case of Bisphenol A" (2009) 117 *Environ Health Perspect* 309.

¹⁴³ "Timeline - Key dates for BPA" (2013) at www.jsonline.com (last accessed 29 May 2013).

[3] FDA's 2012 Ban

The FDA's decision to ban BPA from all baby bottles was in no way motivated by precaution. Instead, the ban merely reflected what companies were already doing in response to public pressure.¹⁴⁴ If the FDA was truly concerned about protecting young children from BPA, it would have banned the chemical from all food products intended for children.

[E] China

In recent years, the Chinese government has started to confront the environmental costs of rapid economic growth.¹⁴⁵ While China's environmental law regime is still in its infancy, a few key concepts are now beginning to emerge; namely, the 'prevention-first' principle.¹⁴⁶ This concept holds that pollution should be prevented at its source in preference to being controlled after it is released.¹⁴⁷ While 'prevention first' may be useful policy for controlling China's pollution problems, it cannot be used to prevent toxic exposure more generally. For this reason, the precautionary principle is a useful tool for filling in the gaps of China's environmental law regime.¹⁴⁸

[1] New Chemicals Regulations

In the last few years, China's chemical regulations have moved in the direction of REACH.¹⁴⁹ Much like its European counterpart, China's New Chemicals Regulation requires companies to provide test data and assessments. However, the New Chemicals Regulation does not require companies to prove that their chemicals will be safe. Instead, companies only have to submit data so that the Expert Assessment Committee can carry out its own investigations and assign

¹⁴⁴ Mitchell S Tucker "Banning BPA in the United States and Canada: Epigenetic Science, the Precautionary Principle, and a Missed Opportunity to Protect the Fetus" (2012) 8 *Journal of Health and Biomedical Law* at 209.

¹⁴⁵ McElwee, above n 83.

¹⁴⁶ Environmental Protection Law (China), art 1.

¹⁴⁷ Stefanie Beyer "Environmental Law and Policy in the People's Republic of China" (2006) 5 *Chinese Journal of International Law* at 200.

¹⁴⁸ Li Shuo "When it Comes to Environmental Talks, Don't Give Up on China" (2013) at www.greenpeace.org (last accessed 31 May 2013).

¹⁴⁹ URS New Zealand *Chemical and Biological Risk* (2011) at 37.

the appropriate controls. Accordingly, the New Chemicals Regulation only applies a weak form of precaution.

[2] Hazardous Chemical's Regulations

In contrast, China's Regulation on Hazardous Chemicals applies a strong version of precaution.¹⁵⁰ The Regulation prohibits all substances listed under the Hazardous Chemicals Catalogue, unless a company obtains a production license. In any event, a license will only be granted after the company has carried out a plethora of tests and provided numerous safety reports.¹⁵¹ The Ministry of Health's recent decision to include BPA on the HCPEC list is also a promising step. While scientists continue to debate BPA's risks, China has chosen to treat BPA as a highly toxic substance.

[3] China's 2011 Ban

China's decision to ban BPA from baby bottles could set the scene for further restrictions. Once the HCPEC list comes into force, tough restrictions on the production of BPA might encourage manufacturers to look for safer alternatives.

[F] New Zealand

Since 1992, New Zealand has applied the precautionary principle to a number of its environmental policies.¹⁵² In most cases, the importance of precaution is implicit; as with the Resource Management Act 1991.¹⁵³ In other cases, precaution is dealt with more explicitly.

¹⁵⁰ Article 4 states that "the safe management of hazardous chemicals should abide by the policy of 'precaution mainly'".

¹⁵¹ Yunbo Shi "The Measures for Environmental Administration Registration of Hazardous Chemicals" (2013) at www.cirs-reach.com (last accessed 4 June 2013).

¹⁵² Linda Cameron *Environmental Risk Management in New Zealand – Is There Scope to Apply A More Generic Framework* (2006) at 15.

¹⁵³ Alexander Gillespie "Precautionary New Zealand" (2011) 24 *New Zealand Universities Law Review* at 375.

[1] HSNO

Precaution is an inherent part of the HSNO. Section 7 of that Act explicitly refers to the “precautionary approach”:¹⁵⁴

“All persons exercising functions, powers and duties under this Act...shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects”

When the HSNO first came into force in 2001, s 7 was given quite a narrow interpretation.¹⁵⁵ Nowadays, the Courts appear to be taking a more liberal approach. An example of this was seen in the 2007 case of *National Beekeepers v Chief Executive of the Ministry of Agriculture*.¹⁵⁶ After reviewing the legislative history of s 7, the Court of Appeal noted that:¹⁵⁷

“[in adopting] the precautionary principle... Parliament was concerned to ensure a high standard of environmental protection was the overriding goal of the new legislation”

Section 7 clearly shows that Parliament intended to place a high value on precaution.¹⁵⁸ To achieve this end, the section requires the Environmental Protection Authority to adopt a precautionary approach in protecting the public from hazardous substances. While BPA has been categorised as a toxic and ecotoxic substance, the Environmental Protection Authority has failed to lay down any safety standards. It makes little sense to categorise a substance as hazardous if there are no corresponding controls to minimise the risks of harmful exposure. For this reason, the Environmental Protection Authority has not taken a precautionary approach in protecting the public from BPA.

[2] Australia New Zealand Food Standards Code

The MPI has also failed to adopt a precautionary approach. According to its mandate, the MPI aims to base its risk management decisions on “sound

¹⁵⁴ Hazardous Substances and New Organisms Act 1996 s 6.

¹⁵⁵ *Bleakley v Environmental Risk Management Authority* [2001] 3 NZLR 213 (HC).

¹⁵⁶ *National Beekeepers v Chief Executive of the Ministry of Agriculture* [2007] NZCA 556.

¹⁵⁷ At 25.

¹⁵⁸ Alexander Gillespie, above n 154, at 377.

science” and apply “a precautionary approach when faced with scientific uncertainty”.¹⁵⁹ In doing so, the MPI may require mandatory labelling or establish acceptable daily intakes for chemical residues in food.¹⁶⁰

Despite widespread uncertainty over BPA’s effects, the MPI has chosen not to take any action. Its current position is that there is simply not enough scientific evidence to conclude that low level exposure to BPA poses any kind of health concerns.¹⁶¹ Instead of adopting a precautionary approach, the MPI prefers to wait for some concrete proof on BPA’s low dose effects.

[V] Conclusion: Where to from here

Although some questions remain, there is now arguably enough evidence to conclude that BPA may cause serious health problems. In the absence of certainty, precautionary measures are needed to protect the public from this chemical.

So far, however, the precautionary principle has failed to carry the day. In weighing up BPA’s risks, regulators continue to overlook a number of crucial factors such as the timing of exposure, low dose effects and the delayed onset of harm. By the same token, the law tends to place the burden of proof on regulators to show that a chemical is unsafe.¹⁶² Unless regulators can satisfy this high scientific and evidential burden, companies will continue to expose the population to BPA.

In any event, the BPA controversy highlights an even greater issue. New Zealand needs to make better use of the precautionary principle, not just for BPA, but in the way we regulate all chemicals. Currently our HSNO permits the use of hazardous substances, provided that they can be adequately controlled. Yet BPA is not adequately controlled. New Zealand must adopt a

¹⁵⁹ NZFSA *Making Sure New Zealand’s Food is Safe* (2009) at 4.

¹⁶⁰ NZFSA *New Zealand’s Food Safety Risk Management Framework* (2010) at 23.

¹⁶¹ Ministry of Primary Industries “BPA (Bisphenol A)” www.foodsmart.govt.nz (2013) (last accessed 7 June 2013).

¹⁶² Carl F Cranor “Do You Want to Bet Your Children’s Health on Post-market Harm Principles? An Argument for a Trespass or Permission Model for Regulating Toxicants” (2008) 19 *Villanova Environmental Law Journal* at 252.

prohibitive policy and require companies to prove that their chemicals will be safe. Alternatively, New Zealand could phase-out all hormonally active chemicals from consumer products.¹⁶³

The time is also right for the MPI to ban BPA from all food and beverage products. Although the recent controversy has caused some suppliers to phase out polycarbonate bottles, BPA is still found in food containers, tinned foods and infant formula cans. For this reason, a blanket ban is necessary to eliminate all routes of dietary exposure.

In sum, it is unlikely that science will deliver any neat and clear cut answers on BPA anytime soon.¹⁶⁴ So should we wait and risk harming our own health, and more importantly, our children's health? Or should we take some basic precautionary measures? By now the answer should be clear. Assuming that BPA is not harmful would be a poor bet to make. For this reason, New Zealand should invoke the precautionary principle and take immediate action against BPA.

¹⁶³ John Wargo "14 The Quiet Revolution in Plastics" (12 March 2011) at www.youtube.com (last accessed 9 June 2013).

¹⁶⁴ Freinkel, above n 60, at 106.

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