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Options to Limit Consumer Exposure to Hazardous Azo Dyes in Certain Clothing, Textiles and Leather Goods

Draft Regulation Impact Statement

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Contents

	Options to Limit Consumer Exposure to Hazardous Azo Dyes in Certain Clothing, Textiles and Leather Goods.....	- 1 -
1.	Introduction.....	- 3 -
2.	The problem	- 5 -
3.	Is Government action needed?	- 15 -
4.	Policy options under consideration.....	- 16 -
4.1	Option 1: Status quo (continued industry self-regulation).....	- 17 -
4.2	Option 2: Increased education and on-going ACCC surveys.....	- 17 -
4.3	Option 3: Regulation via a mandatory safety standard or permanent ban..	- 18 -
4.4	Option 4: Provision of information to consumers	- 19 -
5.	The likely net benefit of each option.....	- 20 -
5.1	Option 1: Status quo (continued industry self-regulation).....	- 21 -
5.2	Option 2: Increased education and on-going ACCC surveys.....	- 23 -
5.3	Option 3: Regulation via a mandatory safety standard or permanent ban..	- 25 -
6.	The preferred option	- 31 -
7.	Implementation and evaluation	- 32 -
8.	Form of possible regulation.....	- 32 -
9.	Submissions	- 32 -
Attachment 1:	Summary of comments from June 2014 call for information	- 34 -
Attachment 2:	Development of the existing product safety system in Australia	- 35 -
Attachment 3:	The cost of benzidine-based dye exposure	- 37 -
Attachment 4:	Chemicals and textiles	- 39 -
Attachment 5:	Identifying hazardous aromatic amines in goods.....	- 41 -
Attachment 6:	Constraints and barriers	- 42 -
Attachment 7:	International controls.....	- 44 -
Attachment 8:	Determination of the estimated additional costs to business of option 3.....	- 46 -
Attachment 9:	List of 22 aromatic amines and their safe limits.....	- 55 -

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1. Introduction

This draft Regulation Impact Statement (RIS) has been prepared by the Australian Competition and Consumer Commission (ACCC). The RIS should assist stakeholders consider possible options available to manage the potential hazards associated with consumer exposure to chemicals in clothing, textiles and leather goods that are in direct and prolonged contact with the skin (**referred to in the remainder of this RIS as ‘direct and prolonged contact articles’**).

Every policy proposal designed to introduce or abolish regulation must now be accompanied by an Australian Government RIS. *The Australian Government Guide to Regulation*¹ sets out the process for developing a RIS. The RIS process provides for careful, transparent and accountable assessment of every policy option, their likely impacts and any associated costs.² In considering the policy options it is important to note that regulation cannot eliminate risk entirely and the RIS process can provide advice to governments about levels of risk, consequences and how much it will cost the community to reduce that risk.³ The Office of Best Practice Regulation (OBPR) is required to assess and determine if the RIS complies with government requirements. A copy of this draft RIS has been provided to OBPR for ‘Early Assessment’. Early Assessment of a RIS by OBPR is one of the key steps in developing a final RIS.⁴

The ACCC’s recent work on hazardous azo dyes in consumer goods was prompted by a recommendation from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Following publication of the NICNAS human health assessment on benzidine-based dyes, the ACCC conducted a survey and commissioned testing of direct and prolonged contact articles. While the majority of articles tested did not raise safety concerns, a number of articles were found to have unacceptable concentrations of certain aromatic amines (including benzidine), which are carcinogenic chemicals derived from a small number of hazardous azo dyes. Both the NICNAS recommendation and details of the ACCC survey are discussed in more detail in this draft RIS.

Azo dyes are a large class of effective colorants used in a variety of consumer goods including direct and prolonged contact articles. The majority of azo dyes do not break down to hazardous aromatic amines and are not associated with the problem outlined below. The small number that do break down are referred to in this draft RIS as ‘hazardous azo dyes’. The risk of exposure depends on factors such as the concentration and type of dye, the type of material, the size of surface contact area and duration it is in direct contact with the skin. Body heat, sweat or saliva exacerbates exposure.

While exposure to a carcinogen does not mean cancer will necessarily result, avoidable exposure should be minimised as the personal, community and medical costs of any avoidable case of cancer is high. All reasonable efforts to prevent avoidable exposure should be pursued. This draft RIS contains discussion on the risks and costs of cancer.

Globally there are a range of controls applied by different countries to address exposure to hazardous azo dyes. These controls are discussed in ‘the problem’ section and Attachment 7 of this draft RIS.

¹ *The Australian Government Guide to Regulation* is available on the cutting red tape website - http://www.cuttingredtape.gov.au/sites/default/files/documents/australian_government_guide_regulation.pdf.

² *ibid.*, p. 4.

³ *ibid.*, p. 19.

⁴ *ibid.*, p. 5.

In June 2014, Australian suppliers of clothing textiles and leather articles were asked to provide estimates of additional costs they would incur for both the regulatory and non-regulatory options under consideration at the time. Some suppliers provided confidential information, so individual suppliers have not been identified. A summary of the themes raised in submissions are included in Attachment 1. While those costs have been considered in the development of this draft RIS, the responses the ACCC received were small in number and suppliers did not provide sufficiently detailed estimates that were specifically attributed to any additional activity that might need to be undertaken in response to each option. To the extent possible, costs provided by business have been used to develop preliminary estimates of additional costs under the regulatory and non-regulatory options.

Consumer protection laws have for some time provided a product liability framework which gives consumers who are injured as a result of a defective product a right to compensation without the need to prove negligence on the part of the manufacturer.⁵ Goods are considered defective if they do not have the degree of safety which people are entitled to expect in all circumstances.⁶ These requirements are known, generally, as the *defective goods regime*.

The Australian Consumer Law (ACL) took effect on 1 January 2011. The ACL strengthened the product safety provisions to enhance consumer protection. The ACL also included a number of general provisions intended to ensure that businesses supply safe goods; for example, suppliers give statutory guarantees to consumers that goods are of acceptable quality, including that they are safe. More information on the development of the product safety regime in Australia is included in Attachment 2.

The definition of the term 'supplier', which is used throughout this draft RIS is consistent with the definition in the ACL that is:

supply, when used as a verb, includes:

- (a) in relation to goods—supply (including re-supply) by way of sale, exchange, lease, hire or hire-purchase; and
- (b) in relation to services—provide, grant or confer;

and, when used as a noun, has a corresponding meaning, and *supplied* and *supplier* have corresponding meanings.

Consultation

Stakeholder consultation provides an opportunity to shape government policy decisions. All stakeholders – including consumers, medical professionals, advocates, industry associations, importers, wholesalers, manufacturers and suppliers are invited to make submissions on any issue canvassed in this draft RIS. The ACCC also seeks additional information to consider the benefits and costs associated with the options outlined below, and has posed specific questions in this draft RIS for that purpose.

Consultation commences on Tuesday 24 February 2015 and closes on Friday 10 April 2015. The ACCC's preferred method of receiving submissions is via the Consultation Hub at: <https://consultation.accc.gov.au/>.

⁵ The Parliament of the Commonwealth of Australia, Senate, *Trade Practices Act Amendment Bill 1992, Explanatory Memorandum*, p. 2.

⁶ *ibid.*, p. 2.

2. The problem

Some azo dyes used in the manufacture of direct and prolonged contact articles can unnecessarily and involuntarily expose consumers to aromatic amines which are known or suspected to be carcinogens. The ACCC considers that direct and prolonged contact articles are unsafe if they contain aromatic amines in excess of the European Union's (EU) acceptable limit of 30 mg/kg (30 parts per million). Consumers cannot detect this hazard when purchasing articles.

The ACCC survey

In late 2013 the ACCC commissioned the testing of 199 direct and prolonged contact articles selected from mainstream suppliers in Australia.⁷ The articles purchased were readily available and likely to be worn in direct and prolonged contact with the skin. The ACCC conducted further testing of an additional 28 articles which were related variants of the articles where hazardous aromatic amines were initially detected. Subsequently, the ACCC surveyed a further tranche of 79 articles of the same product categories where hazardous aromatic amines had been detected earlier. These were predominantly coloured jeans and pillow slips.

The majority of the first tranche of randomly selected articles (approximately 97 per cent) passed testing with either no detection or low detection of hazardous aromatic amines. However, a number of articles recorded concentrations in excess of the EU's acceptable limit of 30 mg/kg. Washing did not resolve the detections. Given the subsequent tranches were more targeted to identified risk profiles, a modest increase in the rate of failure at testing was expected and did occur.

As a result of testing by the ACCC and suppliers, 37 product lines of clothing and textiles from nine suppliers were voluntarily recalled. Nearly 208 000 individual articles were identified for recall. In all cases where hazardous aromatic amines were detected the articles had been imported into Australia.

The cost of product purchase, testing and ACCC staff time to manage the survey and liaise with suppliers on survey results and recalls was approximately \$140 000.

Aromatic amine exposure and the risk of cancer

Expert authorities, such as the International Agency for Research on Cancer (IARC), which operates under the World Health Organization (WHO), have classified some of these aromatic amines as known or suspected human carcinogens.⁸ A carcinogen is a substance that is capable of causing cancer. Exposure to a carcinogen does not mean cancer will necessarily result.

In the case of benzidine, the primary human health risk associated with exposure is cancer. The IARC classifies benzidine as a Group 1 carcinogen – a known human carcinogen.⁹ IARC Group 1 classification means that there is sufficient evidence that the chemical is capable of causing cancer in humans if there is sufficient exposure.

⁷ This first tranche of randomly selected goods had a construction or use pattern that could lead to exposure.

⁸ These aromatic amines are either known human carcinogens or suspected to be human carcinogens because they are known to be carcinogenic in animals.

⁹ International Agency for Research on Cancer, *Monographs on the Evaluation of Carcinogenic risks to humans, List of classifications by alphabetical order*, last updated 31 March 2014, viewed 21 August 2014, <http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf>.

The IARC classifies other aromatic amines like 3,3'-dimethoxybenzidine and p-aminoazobenzene as Group 2B carcinogens.¹⁰ The Group 2B classification is the highest available to the IARC when the carcinogenic effect is evident in animal studies but there is insufficient human data to assess the carcinogenicity to humans. It should not be taken to mean that the chemical is a less potent carcinogen than those classified in Group 2A or Group 1.

It is important to make a distinction between a product, the usage of which can be characterised as causing cancer as a result of being used (for example tobacco) and a product, the usage of which can be characterised as resulting in some level of exposure to a carcinogen. By wearing clothing containing dyes that can be metabolised or reduced to benzidine is an example of consumers being exposed to a carcinogen. Studies have shown that consumers can be exposed to carcinogens when aromatic amines, including benzidine, migrate from direct and prolonged contact articles and are absorbed through the skin.

The European Scientific Committee on Toxicity, Ecotoxicity, and Environment (CSTEE) has completed a multinational assessment of the risk of cancer caused by articles coloured with certain azo dyes (including benzidine-based dyes). The conclusion was that while consumer exposure is likely to be very low, the associated cancer risks give cause for concern. As a result, exposure to certain azo dyes, including benzidine-based dyes, should be minimised or eliminated,¹¹ which avoids unnecessarily heightening the cumulative risk of cancer in any individual circumstance. Avoiding any increase of cumulative risk, especially through avoidable exposure, remains relevant even though there is no specific evidence available to the ACCC that exposure to aromatic amines through this mechanism specifically or directly causes cancer. This also means that there is no quantifiable cancer burden in the population *definitively attributable* to this source of exposure.

While the very low levels of involuntary exposure to hazardous aromatic amines from these articles may give rise to a correspondingly very small increased risk of cancer, the increased risk cannot realistically be quantified. The absence of strong data sets would necessarily lead to estimation involving many assumptions and estimates of variables such as the dye concentration in articles, rate of reduction of dyes to aromatic amines, dermal absorption efficiency and the area and duration of skin contact. These uncertainties are likely to lead to debate over the quantum of risk rather than focusing on the involuntary consumer exposure to these compounds being unnecessary and needing to be minimised or avoided. Minimising or avoiding unnecessary exposure to carcinogens is well supported by cancer experts.

Critical health effects for 11 benzidine-based dyes include systemic long term effects including carcinogenicity, reproductive toxicity and developmental toxicity.¹² In their report NICNAS recommended that the ACCC “*consider mechanisms to restrict the supply of textiles and leather articles which may come into direct and prolonged contact with the human skin, that may plausibly result in human exposure to these chemicals at unacceptable concentrations*”.¹³

¹⁰ ibid.

¹¹ National Industrial Chemical Notification and Assessment Scheme, 6 June 2013, *Inventory Multi-Tiered Assessment and Prioritisation Human Health Tier II Assessment for Benzidine-Based Dyes*, viewed 21 July 2014, http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=513.

¹² ibid.

¹³ ibid.

The impacts of cancer

There is significant global concern about exposure to carcinogens and the cumulative risk of cancer. Even a small increased risk of cancer to individual consumers and the population as a whole is undesirable if that increased risk comes with no appreciable benefit and is avoidable. Should a small increased risk of cancer translate to a small additional number of cancer cases in the community, then there are clearly direct and intense adverse impacts, and additional costs to those individuals and the community.

According to 2010-11 statistics published by the Cancer Council Australia, cancer costs more than \$3.8 billion in direct health care costs in Australia. This equates to 7.2 per cent of the overall cost of the health system.¹⁴

The Cancer Council of NSW commissioned Access Economics to compile an independent report to determine the true cost of cancer to affected individuals, their families and the community. Access Economics considered the costs in terms of the financial costs to individuals, family/friends, federal and state government, employers and the community, and non-financial costs known as the burden of disease which include the pain, suffering and premature death that result from cancer.¹⁵ Together, financial costs and the burden of disease make up the economic cost of cancer.

Access Economics found the most costly cancers in terms of economic burden were lung, colorectal, breast, stomach, liver and pancreatic cancer while the least costly were bladder, kidney and brain cancer. Bladder cancer has been associated with exposure to benzidine. The total cost of bladder cancer and an average of the total cost of all cancers are provided in Attachment 3. The total lifetime economic cost of bladder cancer calculated by Access Economics in 2005 dollars was \$813 500. When this figure is escalated to 2014 dollars using relevant CPI data, the total lifetime economic cost of bladder cancer is estimated to be a little over \$1.0 million per case of cancer. This figure includes the value of the burden of disease and total financial costs and therefore represents the economic cost of cancer. Further information about the cost of exposure to benzidine-based dyes is available in Attachment 3.

The market failure

The textiles sector produces clothing and other textiles that almost all consumers come into contact with. However, significant negative externalities¹⁶ and information asymmetries exist in relation to the risks associated with hazardous chemicals in clothing and textile products. In this case consumers are unable to determine if coloured articles contain hazardous dyes, and nor can they detect the presence and concentration of hazardous aromatic amines when articles are in contact with skin. This means consumer exposure is involuntary and consumers may be buying goods that they would not buy if they were aware of the associated hazards.

Over recent years there has been a general increase in consumer awareness and concern in relation to chemicals used in the textiles sector and the possible harm they may cause.

¹⁴ Cancer Council Australia, *Facts and figures cancer in Australia*, viewed 2 September 2014, <http://www.cancer.org.au/about-cancer/what-is-cancer/facts-and-figures.html>.

¹⁵ Access Economics, *Cost of Cancer in NSW – A report by Access Economics Pty Limited for the Cancer Council NSW*, 2007, Executive Summary, viewed 2 September 2014, : http://www.cancercouncil.com.au/wp-content/uploads/2010/11/costofcancer_summary.pdf.

¹⁶ Negative externalities occur when production and/or consumption impose external costs on third parties outside of the market for which no appropriate compensation is paid. Common negative externalities include pollution and exposure to hazardous chemicals.

The ACCC's work on hazardous azo dyes in direct and prolonged contact articles and the subsequent recalls drew significant media interest and was an issue of community concern. There were over 50 media articles immediately following the recalls and the ACCC conducted 11 media interviews between March and May 2014. The ACCC's call centre received 94 phone calls in relation to the recalls and the hazards associated with certain azo dyes. It appears consumer confidence in the clothing and textile industry has fallen since hazardous azo dyes were found in articles.

A recent survey by the European Union¹⁷ indicated that the majority of consumers believe that it is not possible to completely eliminate chemical substances in daily life. Other European studies¹⁸ show that consumers believe that exposure to even a small amount of a hazardous chemical to be potentially harmful. Attachment 4 includes more details on the use of chemicals and consumers' concerns about their safety.

Consumers are becoming more aware of, and concerned about not being able to identify products containing harmful chemicals and not being able to respond by avoiding exposure. The only way to detect the presence and concentration of harmful aromatic amines is to conduct product testing which involves the destruction or significant degradation of the product. Information on test methods is provided in Attachment 5.

This information asymmetry suggests that intervention may be required to either:

- remove the hazard from the goods to prevent consumer exposure
- ensure consumers are warned about the hazards in individual goods so they can choose to not purchase them.

There is also a public good argument that protection of public health is underprovided by the private sector.¹⁹ Health has been identified as one of four significant areas of public policy concern that relate to the hazardous nature of some chemicals.²⁰

In all cases where the ACCC survey identified use of hazardous azo dyes, the articles were manufactured overseas. While many suppliers have advised the ACCC that they have quality control processes in place to prevent the use of hazardous azo dyes and claimed to be the victims of 'dye substitution', the survey results indicate that whatever the cause of the presence of hazardous dyes, quality control processes are at times ineffective.

Who is best placed to prevent exposure?

There are a number of ways Australian suppliers can manage quality risk including monitoring output and ensuring that manufacturers understand the threshold for a quality product.²¹ Output management may be achieved by testing finished goods or, preferably via supply chain monitoring with auditing and testing.

¹⁷ European Commission, Flash Eurobarometer 361, *Chemicals Report*, 2013, p. 8.

¹⁸ United Nations Environment Program DTIE / Chemicals Branch, *The Chemicals in Products Project: Case Study of the Textiles Sector*, 2001, p. v.

¹⁹ Productivity Commission, *Chemicals and Plastics Regulation, Productivity Commission Inquiry Report, Overview*, July 2008, p. xxvi.

²⁰ *ibid.*, p. xxv.

²¹ *How to manage and mitigate offshore risks*, available: <http://outsourcing-center.com/2009-06-how-to-manage-and-mitigate-offshore-risks-article-37409.html>.

Other controls may include:

- Australian suppliers specifying in their contracts with overseas suppliers or intermediaries that hazardous azo dyes are not to be used in direct and prolonged contact articles
- specifically ensuring that raw materials used to manufacture finished goods meet specifications, which may require representatives from Australian suppliers visiting overseas factories and selecting raw materials from the production line to send for third party testing
- testing samples from batches of finished goods prior to the Australian supplier accepting delivery of a consignment (ideally, before goods have left the overseas manufacturing facility)

A comprehensive quality assurance system involving established quality systems such as ISO 9000 and factory audits in conjunction with some input and output testing is generally thought to be a robust and efficient approach. Such third party certification schemes are available at a cost to suppliers, but they are not infallible.

Attachment 6 includes more discussion on the constraints and barriers for business when considering an appropriate compliance program.

International trade and regulation

Over recent decades, there has been a general trend to manufacture and source finished goods from countries with lower production costs, commonly known as 'off-shoring'. While there may be cost benefits associated with this trend there are also hidden costs in moving production a long way from the intended market for supply.²² Product quality failure is just one of the hidden costs associated with off-shoring.²³

As a result of this trend to source goods from overseas, output from the Australian manufacturing industry for clothing and textiles has declined over time.²⁴ Quantifying this decline is difficult due to the diversity of the industry although the Australian Bureau of Statistics estimates of the level of textiles, clothing and footwear manufacturing activity are understated.²⁵ However, there is no doubt the clothing and textiles sector in Australia has declined over many years.²⁶

A number of countries including China, Japan, the United States and countries in the EU have restrictions in place for certain azo dyes and hazardous aromatic amines. These restrictions vary from voluntary standards to specific limits. For example, in the EU, the use of hazardous azo dyes in clothing and textiles has been restricted since 2003. Despite these restrictions, clothing containing hazardous azo dyes is still found in countries where regulations are in place. Further information on international regulations is provided at Attachment 7.

²² The Economist, *Reshoring manufacturing, Coming Home*, 19 January 2013, viewed 15 September 2014, <http://www.economist.com/node/21569570/print>.

²³ K. Chubb, *Going Abroad? Don't Forget Supply Chain Safety Risks*, 8 July 2014, Viewed 10 October 2014. Available: <http://www.industryweek.com/transportation/going-abroad-dont-forget-supply-chain-safety-risks>.

²⁴ Department of Industry, *Textiles Clothing and Footwear (TCF) Industry Capability Map: Textiles*, 2013, and Productivity Commission, *Trends in Australian Manufacturing* Commission Research Paper, AusInfo, Canberra, p. 52, 2003, viewed 14 August 2014, http://www.pc.gov.au/data/assets/pdf_file/0005/8447/tiam.pdf.

²⁵ Department of Industry, *Textiles Clothing and Footwear (TCF) Industry Capability Map: Textiles* 2013.
²⁶ *ibid.*

Between 2005 and 2014, there have been 126 recalls notified on the EU's RAPEX alert system²⁷ for products containing hazardous aromatic amines that exceed the maximum limit of 30 mg/kg. The majority of recalled articles originated from China (approx. 52 per cent) and India (23 per cent). Recalled articles included scarves and gloves (28 per cent), children's clothing (14 per cent), women's clothing (13 per cent), and shoes (9 per cent).

Recently, school uniforms containing hazardous aromatic amines were discovered in China, despite a ban on their use for clothing supplied for use within China.²⁸

The causes of these breaches are unknown but they are likely to be due to intentional or unintentional substitution of dyes. It is reasonable to assume that the risk of breach recurrence will remain for as long as stockpiles of hazardous azo dyes exist and the opportunity for substitution continues. In order to prevent unsafe goods from being supplied in Australia, Australian suppliers may need to improve quality control processes and step up monitoring of finished goods.

How might the problem be corrected?

Self-correction

The risks associated with certain hazardous azo dyes have been well documented and known for some time. There are reports that the use of hazardous azo dyes is dwindling and manufacture is being phased out internationally as large markets such as the EU have restrictions in place and safer dyes are being developed to replace hazardous ones.²⁹

The declining availability of hazardous dyes combined with any increased Australian supplier compliance activities may see the use of hazardous azo dyes in direct and prolonged contact articles fall and the problem self-correcting.

However, information provided by stakeholders suggests that increases to the world oil price correspondingly results in dyestuff price increases. Many azo dyes are derived from petrochemicals, so an increase in oil prices can increase the price of new safer azo dyes. Stakeholders suggest that in these circumstances less scrupulous manufacturers may turn to stockpiles of older less safe dyes (or stockpiled fabrics dyed with unsafe dyes) in order to keep manufacturing costs down.³⁰

Stakeholders provided comments to the ACCC in June 2014. Since then the oil price has fallen significantly. On 30 June 2014 West Texas Intermediate (WTI), a grade of oil used as a benchmark for the oil price sold for USD 106.07 per barrel.³¹ On 12 January 2015, WTI sold for USD 46.06 per barrel. While these prices are likely to be part of the oil price cycle

²⁷ RAPEX is the EU's rapid alert system that facilitates the rapid exchange of information between member states and the European Commission.

²⁸ M Bennett-Smith, 'Chinese School Uniform Ban: Cancer-Causing Dyes Possibly In Students' Clothes', (2013), viewed 2 September 2014, http://www.huffingtonpost.com/2013/02/20/chinese-uniforms-dyes-cancer_n_2720399.html.

²⁹ *Draft Screening Assessment Aromatic Azo and Benzidine-based Substance Grouping Certain Azo Solvent Dyes*, Environment Canada/Health Canada, November 2013, viewed 1 September 2014, <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=AB88B1AB-1#toc31>.

³⁰ Based on one stakeholder comment made in a submission to the 'call for information' paper in June 2014.

³¹ United States Energy Information Administration, accessed 18 January 2015, available: <http://www.eia.gov/dnav/pet/hist/LeafHandler.ashx?n=PET&s=RWTC&f=D>

(prices fell to USD 40 in late 2008)³², if sustained, the price of new safer azo dyes should fall at least in the short to medium term.

Manufacturers turning to less safe dyes may be more of an issue at the cheaper end of the market (i.e. discount shops) where price, rather than the latest fashion is the main driver for both supplier and consumer purchasing decisions. Suppliers may be tempted to source articles from sources which use unsafe cheaper dyes particularly in circumstances where other jurisdictions have acted to prevent their use.

With restrictions introduced in the EU over 10 years ago, Australian suppliers have had ample opportunity to inform themselves of the risks associated with the use of some azo dyes and taken steps to prevent their use in the supply chain and monitor supply chain output. Based on the survey results, not all suppliers have done this and without added incentive, it is reasonable to assume they will not do it in the future.

If suppliers voluntarily put effective mechanisms in place to ensure hazardous azo dyes are not used in direct and prolonged contact articles, government intervention may not be required. Based on ACCC discussion with Australian suppliers, some but not all, businesses have initiated quality control measures and commenced testing to monitor direct and prolonged contact articles for hazardous azo dyes. This activity will need to be sustained and undertaken by all suppliers for self-correction to occur and continue in the long term.

While self-correction is desirable and arguably the most efficient solution to the use of hazardous azo dyes in direct and prolonged contact articles, as described above there are a number of impediments to self-correction. Where self-correction is unlikely or unsuccessful, additional controls, such as those outlined as options in this document, can be implemented to complement the ACL's general product safety provisions to provide further incentive to supply safe consumer goods.

Managing online supply - increased liaison with border protection agencies and international regulators

Domestic suppliers and consumers are increasingly purchasing products online from both domestic and international suppliers. All businesses supplying products to Australian consumers have obligations to supply safe products and comply with the ACL. This includes domestic companies, online suppliers and businesses operating outside Australia that supply products either to Australian retailers for resupply or directly to consumers.

The ACCC is committed to enforcing the ACL and mandatory product safety regulations for products supplied in Australia, regardless of whether those products are supplied by businesses in Australia or overseas.

Online sales platforms can be hard to identify and engage with, making it more difficult (relative to other traditional sales platforms) for regulators to promote compliance with the ACL. While domestic online suppliers and traditional 'bricks and mortar' style businesses are well within reach of Australian consumer protection regulators, managing compliance in the international arena is more challenging. Nevertheless, there are several approaches available to the ACCC to managing and overcoming these challenges including:

³² M. Phillips, *Goldman's Oil Guru: The \$50 Barrel Is Right on Time*, published 7 January 2015, accessed 18 January 2015, available: <http://www.businessweek.com/articles/2015-01-07/oil-falls-below-50-goldmans-guru-says-the-crash-is-right-on-time>

- engaging with the Australian Customs and Border Protection Service and Australia Post to identify and prevent the importation of unsafe goods
- using various government intelligence gathering agencies to identify unscrupulous international suppliers
- using existing relationships with international regulators to share intelligence and where possible take action against non-compliant international suppliers
- alerting Australian consumers to the risks associated with buying direct and prolonged contact articles directly from overseas suppliers and highlight that the consumer rights they enjoy when purchasing in Australia may be more difficult to exercise when purchasing directly from overseas

The view of the ACCC is that all businesses supplying products to Australian consumers, including online businesses, must comply with the ACL. This includes both Australia's product safety laws (including bans and mandatory safety standards, product recalls, mandatory reporting of product-related illness, injury or death) and other important consumer protection laws (including consumer guarantees, laws against misleading or deceptive conduct and false or misleading claims).

What is the likelihood that the problem will be completely solved?

Despite the best efforts of both regulators and suppliers, it is possible that a small number of direct and prolonged contact articles will continue to be supplied containing hazardous azo dyes. Quality control processes can fail and it is impractical to test every article before supply. Therefore, it may not be possible to ensure that all articles supplied are free of hazardous azo dyes. It is the ACCC's experience with surveillance of other regulated goods that there are instances where, for a number of reasons, products continue to fail to meet regulatory requirements.

RAPEX recall data provided earlier in this paper and the identification of school uniforms dyed with hazardous dyes in China highlight that clothing and textiles containing hazardous dyes are still identified in Europe and China despite regulation in both those jurisdictions.

Even with additional controls in place in Australia, it is unlikely that the problem will be completely solved. However, it may be possible to further reduce the likelihood of consumer exposure to hazardous azo dyes in direct and prolonged contact articles via the options discussed in this draft RIS.

Additional legislative controls

In the event that Australian suppliers, for whatever reason, are unable to rectify the problem through industry self-regulation, other measures may be required to protect consumers.

Governments worldwide develop laws and regulations to deal with negative externalities³³ by regulating the activity, regulating production processes and inputs and directly regulating the externality.³⁴ In this case the externality is the unnecessary and avoidable exposure to hazardous aromatic amines via direct and prolonged contact articles.

³³ Negative externalities occur when production and/or consumption impose external costs on third parties outside of the market for which no appropriate compensation is paid.

³⁴ P Abelson, *Public Economics: principles and practice*, second edition, McGraw-Hill Australia, 2008, pp. 240-241.

Regulating the activity that creates the externality and regulating production processes and inputs is, in this case, impractical as these activities are conducted outside of Australia and successfully applying the ACL to these entities may be difficult.

Where regulation is necessary, directly regulating the externality addresses the problem by setting or prescribing limits and would allow each Australian supplier to decide how to comply with regulation to minimise consumer exposure.

Consumer willingness to pay for any additional cost of regulation

Additional regulatory costs may be passed on to consumers, and studies of consumer behaviour consistently show that price is a major purchasing criterion and consumers are very sensitive to price changes.³⁵ However, some consumers are also prepared to pay more for perceived benefits. Whether Australian consumers are willing to pay more for articles that are subject to additional controls aimed at reducing the likelihood of consumer exposure to carcinogens, has not been canvassed.

One large Australian retailer estimated that increased testing of relevant articles would add 10 cents to the retail price of each article. Other businesses estimated mandatory requirements would add substantially to their sourcing costs but did not provide an estimate of the effect on retail price. It is expected the consultation on the draft RIS can provide further information on the impact of regulation on retail prices.

There are a number of certification schemes already operating in the clothing and textile field that claim to ensure residues or hazardous aromatic amines are below published limits. The most common of these are:

- Oeko Tex
- GreenGuard
- Cradle 2 Cradle by McDonough Braungart Design Chemistry (MBDC)
- Global Organic Textile Standard
- Global Recycle Standard
- SMART Sustainable Textile Standard.

These certifications vary significantly, with different cost structures and specifications.

Probably the most widely recognised of the certifications is Oeko Tex, which is an independent third party certifier offering two certifications for textiles. Oeko Tex was founded in 1992, by the Austrian Textile Research Institute (OTI) and the German Research Institute Hohenstein, with the aim of providing an objective and reliable product label for consumers.³⁶ Chemical residues are the main focus of the certification. The certification can apply to production sites/factories (Oeko-Tex 1000) or to the products themselves (Oeko-Tex 100). The cost structure for the Oeko Tex certification is quite complex and varies according to the production facilities involved and the volume of articles.

³⁵ F Perreau, *The criteria that lead consumers to brand switching*, 2014, viewed 18 September 2014, <http://theconsumerfactor.com/en/criteria-lead-consumers-brand-switching/>.

³⁶ See <https://oecotextiles.wordpress.com/category/certifications-2/oeko-tex-certifications/> for further information.

A survey of 2 090 people in the United Kingdom indicated 42 per cent of respondents were willing to pay more for textiles that had been tested for harmful substances.³⁷ Other surveys indicate the price/quality ratio is of high importance to consumers and people are willing to pay more for better products.³⁸

In March 2012, Oeko Tex conducted an online survey in 13 countries.³⁹ The survey identified 9 out of 10 consumers wanted to be able to choose between more certified clothes and textiles in the future.

These survey results are indicative of some level of consumer willingness to pay additional costs for better quality/safer clothing.

³⁷ Reported in Oeko-Tex News, Edition 2/2008, p. 8, viewed 15 September 2014, https://www.oeko-tex.com/media/downloads/OEKO_TEX_NEWS_2008-2_EN.pdf.

³⁸ S Bramel 'Ethics and manufacturing social responsibility in apparel sourcing' , viewed 7 October 2014, <http://www.performancedays.eu/ethics-manufacturing-social-responsibility-in-apparel-sourcing.html>.

³⁹ B Willmann, and J Groten, *20 years of Oeko-Tex® Standard 100: Project Report of a worldwide Consumer-Survey*, 2012, viewed 18 September 2014, https://www.oeko-tex.com/media/downloads/OETS_100_Consumer-Survey_2012_en.pdf.

3. Is Government action needed?

Objective

The broad objective of any intervention is to prevent unnecessary and avoidable exposure to hazardous aromatic amines in direct and prolonged contact articles. If successful, this is likely to remove any addition to cumulative cancer risks, make existing controls and laws more effective in responding to this issue and improve consumer confidence in the market.

While it is not possible to quantify the increased risk of developing cancer due to additional exposure to hazardous aromatic amines from these articles, each individual case of cancer has direct impacts and cost on individuals, the community and government.

The results of the ACCC survey described above, which revealed that approximately three in every 100 items tested contained levels of hazardous azo dyes considered unacceptable, together with growing public concern about this issue, suggests that the current legislative framework may not be providing Australian suppliers a sufficient incentive to ensure that the clothing and textile products they are distributing in Australia meet appropriate standards and are safe.

For this reason, this draft RIS suggests consideration be given to additional measures to complement the general provisions of the ACL to provide further incentive to supply safe consumer goods.

The alternative to government intervention is to adopt option 1 as set out below and allow the industry to self-regulate. The previous section included discussion on problem self-correction. While self-correction is a possibility, there are a number of impediments to it as described above. Additionally, the restrictions in the EU have been in place for some time and it is therefore reasonable to expect Australian suppliers to be aware of them and to act to ensure the supply of safe goods in Australia. Based on the ACCC's survey results, it appears this has not happened in all cases.

The previous section also includes discussion on the likelihood that the problem will be completely solved. While there is an argument that eliminating the problem may be difficult, given the risks to consumers due to exposure, it seems reasonable for government to attempt to eliminate exposure or at least reduce it to the point where it is as low as reasonably achievable.

The legal framework

Supply of safe goods under the Australian Consumer Law

As discussed briefly in the introduction and more extensively in Attachment 2, the defective goods regime, a number of general provisions of the ACL and the common law provide, in most circumstances, sufficient incentives for business to supply safe goods in Australia. The ACL also includes provisions for the compulsory recall of unsafe goods where, among other things, the goods will or may cause injury to any person. Voluntary or compulsory recalls are costly for suppliers and can be damaging to a supplier's reputation, so the prospect of conducting a recall also acts as an incentive to supply safe goods.

However, the survey results discussed above indicate that these incentives may not be sufficient in relation to the supply of clothing and textiles containing hazardous azo dyes.

In these circumstances, the ACL includes provisions for the Commonwealth Minister to develop specific regulation of consumer goods. Development of regulation has been used successfully in the past to prevent the supply of unsafe consumer goods.⁴⁰ The ACCC and state and territory product safety regulators regularly conduct both consumer and supplier education campaigns, surveillance activities on regulated and non-regulated goods and where necessary take action against suppliers of unsafe goods. However, the scope and scale of direct and prolonged contact articles available in the market means that regulators cannot assess the safety of each article. Further, the funds available for testing are not unlimited and there is an opportunity cost in focussing resources on one hazard at the expense of another. This represents a potential barrier to achieving the goal of eliminating the problem.

Current Australian regulation of hazardous azo dyes via the Poisons Standard

In addition to the general provisions of the ACL, there are specific controls for other goods through various legislative instruments and regimes. Controls have been put in place to restrict the importation and use of hazardous azo dyes in Australia including their use in cosmetics through the *Standard for the Uniform Scheduling of Medicines and Poisons* (legally referred to as the Poisons Standard) which is enforced by state and territory health agencies.

A recent amendment to the Poisons Standard, which stemmed from a NICNAS recommendation on the risk to public health and safety, took effect on 1 June 2014.⁴¹ This amendment will assist in controlling the supply, manufacture and use of the specific hazardous dyes. It will not prevent the supply of already dyed direct and prolonged contact articles. This is because the *Poisons Standard* does not have the reach to control the full range of consumer goods that may contain hazardous chemical contaminants.

The ACL remains the most appropriate legislative framework for controlling hazardous chemicals in most *finished* consumer goods, as it specifically provides a range of general and specific provisions that can be used to address unsafe finished consumer goods. This includes recall powers and the option to develop specific regulation to control the supply of unsafe consumer goods.

4. Policy options under consideration

There are four options identified below, of which three are discussed in more detail in the analysis of costs and benefits section below. Two of the options are non-regulatory, and could be established on an interim basis to ascertain whether the market can self-correct without further regulatory intervention. This approach accords with the idea of *responsive regulation*.⁴² Responsive regulation is a strategy which considers:

⁴⁰ The ACCC administers 42 mandatory safety standards and 22 permanent bans on consumer goods. These bans and standards were made under the provisions of the Australian Consumer Law or the previous *Trade Practices Act 1974*.

⁴¹ See ComLaw: <http://www.comlaw.gov.au/Details/F2014L00566>.

⁴² R Sarre and R Johnstone. *Regulation: Enforcement and Compliance*, Research and Public Policy Series No. 57, Australian Crime Commission, 2004, viewed 1 August 2014, <http://www.aic.gov.au/documents/B/A/0/%7BBBA0FC2D0-B43E-4CB6-A5AD-95ACE70542AA%7DRPP57.pdf>.

*“...that regulation should respond to industry conduct, to how effectively industry is making private regulation work. The very behaviour of an industry or the firms therein should channel the regulatory strategy to greater or lesser degrees of government intervention”.*⁴³

Any regulatory intervention could also be subject to a sunset clause. This is relevant given the earlier discussion about the decline in manufacture of hazardous azo dyes (and therefore the possible decline in their use), meaning the problem may be finite. The policy options are outlined in this section of the draft RIS.

4.1 Option 1: Status quo (continued industry self-regulation)

Under option 1, business would manage the supply of direct and prolonged contact articles in the same manner as it has done both before and after the ACCC survey. Following the survey, the ACCC published guidance on safe concentrations of particular chemicals (SCoC) in consumer goods on the Product Safety Australia website.⁴⁴ The SCoC provides guidance on safe concentrations of aromatic amines in direct and prolonged contact articles and is voluntary. The SCoC is based on the best available scientific evidence cited by relevant expert authorities and should assist business in the supply of safe direct and prolonged contact articles in Australia.

The ACCC regards these safe concentrations of particular chemicals as being the levels at which consumer goods are safe and fit for purpose. The SCoC clarifies the thresholds at which consumer goods would be considered defective (i.e. *not* safe and *not* fit for purpose), based on the most authoritative scientific information available. In the case of hazardous azo dyes, these thresholds are modelled on the EU limits for which there is an established and accredited testing methodology.

The general provisions of the ACL would still apply. However, it would not be an offence to exceed a SCoC, and there would not be any specific financial penalty for doing so. This may be seen by some stakeholders as not providing sufficient incentive to improve compliance.

4.2 Option 2: Increased education and on-going ACCC surveys

Under option 2, the ACCC would increase industry and consumer education on the established SCoC. The ACCC would also conduct regular surveys of direct and prolonged contact articles.

Industry education would increase awareness of suppliers' obligations under the general provisions of the ACL and ensure business is aware of the SCoC. Information could be provided to business in a variety of ways including:

- online via the Product Safety Australia website
- ACCC staff attending and participating in industry forums and
- proactive engagement with industry associations

This option would also involve the ACCC conducting further surveys of direct and prolonged contact articles. Articles could be purchased and sent to an accredited test laboratory for

⁴³ *ibid.*, p. 5.

⁴⁴ See: <http://www.productsafety.gov.au/content/index.php/itemId/1009938>

testing against the SCoC. If unacceptably high concentrations of hazardous aromatic amines are detected, the ACCC would act to remove unsafe goods from supply.

4.3 Option 3: Regulation via a mandatory safety standard or permanent ban

The ACL allows the Commonwealth Minister to make a mandatory safety standard, or impose a permanent ban, on certain consumer goods. Safety standards and permanent bans are legislative instruments and enforceable under the provisions of the ACL. All such legislative instruments are centrally recorded on the Federal Register of Legislative Instruments (FRLI), and would be accessible to suppliers and their legal advisers. FRLI is also an obvious point of reference for overseas suppliers.

Regulation would specify limits for certain aromatic amines in direct and prolonged contact articles and compliance with that limit would be mandatory. It would be based on the best available scientific evidence cited by relevant expert authorities. As any regulation is likely to be constructed to permit supply if goods are within an acceptable level, a safety standard may be more appropriate than a permanent ban.

If this option were pursued, any regulation would likely be structured to effectively require adherence to the key elements of the EU standard and testing methodology. This element of overseas equivalence should both provide additional consumer protection and enhance supply options as it does not impose unique Australian requirements and the testing capability is already established. While test houses in Australia are not currently accredited to test to the EU requirements, there is suitable availability overseas and there is no barrier to Australian test laboratories becoming accredited if a market for those services develops.

Any regulation under the ACL would be enforced by the ACCC and state and territory fair trading agencies. There are already a number of mandatory standards and bans in place that the ACCC and other regulators actively enforce by surveying retail outlets and websites, conducting testing, responding to complaints and by acting promptly against offending suppliers.

Under the ACL, the onus is on suppliers to ensure they supply safe products whether specific regulation has been developed or not. Where a mandatory standard is in force, there is no requirement for suppliers to routinely demonstrate to the ACCC or state and territory fair trading agencies that their goods comply with that standard. Prudent suppliers maintain good records which demonstrate the effort taken to comply with a mandatory standard and the general provisions of the ACL. Where a regulator identifies goods that do not comply with regulation, the supplier of those goods is generally asked to provide documents that they have relied upon to satisfy themselves that their goods comply with regulation.

The most efficient way to manage compliance with regulation is likely to ensure good quality control processes are developed and maintained. Suppliers can monitor the effectiveness of these processes by testing some finished goods. The scope of testing across each supplier's product range and the test frequency will depend on each supplier's confidence in their quality control processes. Estimates for these costs have been included under section 5 and relevant attachments. While the ACCC is committed to enforcing the ACL and mandatory product safety regulations for products supplied in Australia, the ACCC exercises its discretion to direct resources to the investigation and resolution of matters that provide the greatest overall benefit for competition and consumers. Use of this discretion is set out in the

ACCC's Compliance and Enforcement Policy.⁴⁵ Where companies have strong compliance cultures and good supporting systems in place, and/or strong stewardship processes exist, the ACCC is unlikely to pursue matters that are isolated events.⁴⁶

All businesses supplying products to Australian consumers already have obligations to supply safe products and comply with the ACL. This includes domestic companies, online suppliers and businesses outside Australia that supply products to Australian retailers for resupply. With consumers increasingly turning to online sales platforms in both Australia and overseas, the enforcement of regulation is more challenging. As discussed in section 3, the ACCC takes several approaches to promoting compliance with the ACL and specific regulation. Despite these strategies, the effectiveness of regulation for online suppliers may be less than for products supplied via traditional 'bricks and mortar' businesses. Whilst the extent to which it may be less effective is not certain, there is nothing to suggest it would be significantly different to other categories of consumer goods specifically regulated by the ACCC.

Regulation combined with the general provisions of the ACL should maximise the incentive to source fully compliant goods. Generally speaking, increased consumer protection and associated improved confidence in purchasing decisions are expected to encourage consumer demand and increase competition.⁴⁷

4.4 Option 4: Provision of information to consumers

Another option is to require suppliers to provide information to consumers that explains whether they may be exposed to hazardous azo dyes as a result of purchasing/using particular direct and prolonged contact articles. For example, clothing labels could provide a simple statement that declares that hazardous azo dyes may be present in the article in a similar fashion to foods carrying the 'may contain traces of nuts' statement. Alternatively, the label might carry detailed information specifying the concentrations of aromatic amines found in a typical analysis for the batch (it is not possible to test each article prior to supply) or declare that a typical analysis has found the batch complies with an acceptable limit.

The provision of information could reduce the extent that exposure to hazardous azo dyes was involuntary as it would enable consumers to manage their potential exposure from such articles.

Depending on the form that a mandatory information requirement takes, this option would mean:

- Where unauthorised substitution of dyes has occurred during production, a label which specifies the concentrations of azo dyes are acceptable will be incorrectly applied to the article, unless the fraud is discovered. The Australian suppliers will still act under the erroneous belief that their specifications are being met and consumers would still be exposed to hazardous aromatic amines.
- Where a label specifies that the concentrations of hazardous azo dyes have been tested and are found to be acceptable, those suppliers will incur the same costs as

⁴⁵ ACCC, Compliance and Enforcement Policy, available: <https://www.accc.gov.au/about-us/australian-competition-consumer-commission/compliance-enforcement-policy>

⁴⁶ Available on the ACCC website: <http://www.accc.gov.au/about-us/australian-competition-consumer-commission/compliance-enforcement-policy>.

⁴⁷ Productivity Commission, *Review of Australia's Consumer Policy Framework, Productivity Commission Inquiry Report, Volume 2 Chapters and Appendices*, No. 45, 30 April 2008, p. 23, viewed 10 September 2014, <http://www.pc.gov.au/data/assets/pdf_file/0008/79172/consumer2.pdf>.

they would have under regulatory option 4.3 above, as well as any additional cost of producing the labels with the information. So industry and/or consumers would incur additional costs for labelling with little or no tangible benefit compared to regulatory option 4.3.

- The potential penalties for making false or misleading representations could be applied, to cases where the information on labels is untrue. This may provide suppliers with added incentive to test products so they are not making false or misleading representations. However, regulatory option 4.3 also provides a similar incentive to test products.
- Labelling that certain aromatic amines will not be present in dyed articles is a message that cannot be simply translated into a simple risk message to consumers. It may however, allay the fears of some consumers if they were previously concerned and they believe the labelling to be truthful. It may not have significance to many consumers who already assume that suppliers attend to safety issues and that they would not use toxic chemicals where there are safer alternatives.
- Suppliers may decide not to test their products and simply apply a label to say so. In this case consumers are no better off than under option 1 above (the 'status quo' option) but suppliers will incur the additional cost of applying a label (and potentially risk breaching the misrepresentation provisions of the ACL).

This option is *not considered further* because there would be few if any quantifiable benefits for consumers over the regulatory option outlined in the section above, and it would result in additional costs for suppliers.

5. The likely net benefit of each option

This section of the draft RIS assesses the likely benefits and costs of each option. *The Australian Government Guide to Regulation* requires any new regulation to be offset by a reduction in existing regulatory burden.⁴⁸ For the regulatory option below (option 3), a regulatory offset has been identified from within the Treasury portfolio, relating to the 'MyTax' reforms.

To estimate costs to industry, the ACCC sought input from Australian suppliers about the current cost of their quality control and testing arrangements used to monitor for the use of azo dyes in their products. The suppliers were then asked to estimate any additional costs of complying with regulation which mirrored EU restrictions. Costs to suppliers in controlling the use of azo dyes were attributed to:

- the costs of negotiating the nature of dyes that may be used in the products
- salary and overhead costs for quality control staff
- costs of testing and reporting
- delays in stock delivery to the next stage of the supply chain due to quarantine of stock pending testing results.

⁴⁸ *The Australian Government Guide to Regulation* defines an offset to be 'A reduction in existing regulatory burden to ensure the regulatory cost of new regulation is negated'. The ACCC falls under The Treasury portfolio.

Costs associated with negotiating the use of safe dyes in direct and prolonged contact articles should already be being done in order to comply with the general provisions of the ACL. Other costs identified by suppliers may be seen as additional costs which are more likely to arise under the regulatory option.

Most suppliers already comply with the EU limits of less than 30 mg/kg aromatic amines in direct and prolonged contact articles. This is achieved through commercial arrangements with suppliers of raw materials and manufacturers and materials testing at various points along the supply chain. These suppliers have been able to provide limited information about the cost of testing.

Some suppliers also indicated they had increased the frequency of testing for aromatic amines in response to the detections in the ACCC's chemical survey.

Other suppliers advised that testing is not currently performed and that introduction of testing would be an additional product stewardship cost. Some suppliers noted that the extent of the additional cost would depend on the frequency of testing that was required.

However, some of the costs immediately give rise to benefits. For example, testing for aromatic amines represents an up-front cost to suppliers, but also a benefit to the same suppliers because the legal and reputational risks of discovery of supplied goods containing hazardous azo dyes are avoided, together with avoiding the costs of voluntary recall action.

The cost to government was determined using estimates of the cost of ACCC staff and testing that would be applicable under the three options.

The costs and benefits for options 2 and 3 are considered against those for option 1 – maintaining the status quo.

5.1 Option 1: Status quo (continued industry self-regulation)

Option 1 represents the 'status quo' option against which the benefits and costs of the other options are measured.

Benefits

Publishing SCoC based on the best available scientific evidence in a clear and concise format on the Product Safety Australia website has made them visible to both suppliers and consumers. This has enabled Australian suppliers to direct overseas suppliers, manufacturers and intermediaries to information to help them understand Australian expectations, it avoids search costs for manufacturers wishing to distribute products in Australia and it references an internationally accepted and familiar limit.

Suppliers are ultimately responsible for the safety of products they supply. The publication of a SCoC reminds suppliers of their responsibilities and encourages them to supply safe goods consistent with the requirements under the general provisions of the ACL. The ACCC has evidence that suppliers of clothing and textile products are inclined to support published SCoC.

As well as assisting industry, consumers who are aware of the SCOC will be able to ask suppliers for assurances that direct and prolonged contact articles of interest have not been dyed with hazardous azo dyes.

This option does not create additional regulatory costs for suppliers and government in circumstances where the manufacture and use of hazardous azo dyes appears to be in decline and the problem may therefore be resolved within a reasonable period.

Costs

The ACCC is aware that the extent of supplier efforts to reduce consumer exposure to hazardous azo dyes is variable, even among those that are aware of the potential health risks from these chemicals. While some suppliers indicate they conduct finished product testing, others rely on statements of compliance by manufacturers (or sourcing agents) and do not commission their own compliance testing.

Continued industry self-regulation may not result in any significant change in the presence of hazardous azo dyes in clothing and textile products made available to Australian consumers. Given that the ACCC's survey detected hazardous aromatic amines in three out of every 100 products tested, the cost to consumers of this option is the continuing prospect of exposure to hazardous azo dyes and their aromatic amines via direct and prolonged contact articles, particularly if recent detection levels remain constant.

The effectiveness of this option in addressing the problem of exposure relies on an ongoing voluntary effort by suppliers to conduct supply chain monitoring and continuous testing to detect dye substitution, without government involvement. The ACCC has not been able to establish whether self-regulation through supply chain checking and testing is likely to be industry-wide or enduring.

While the current state of the market does not indicate a widespread problem, recent media coverage has generated significant consumer interest and concern about consumer exposure to known carcinogens. There was an apparent loss of consumer confidence in the safety of a range of direct and prolonged contact articles. However slight, exposure to a known carcinogen increases each exposed individual's aggregate risk.

The main health problem associated with exposure to aromatic amines is bladder cancer. The current lifetime economic cost (including medical and community costs) of treating bladder cancer is \$1 million per case. It is not possible to attribute a particular number of cases of bladder cancer to exposure to azo dyes, nor is it possible to quantify the increased risk of developing cancer due to exposure to aromatic amines from these articles. Therefore, it is not possible to quantify the cost of treating any cases of bladder cancer that occur as a result of exposure to azo dyes. However, as viable alternative dyes without such risks exist, it is prudent to avoid unnecessary exposure to aromatic amines which are known or suspected carcinogens.

From a supplier's perspective, assuming that the incentives to supply products free from hazardous azo dyes remain unchanged, this option does not impose any additional costs.

Finally, it is unclear if continued self-regulation will sufficiently restore consumer confidence and manage broader stakeholder concerns about exposure to azo dyes in direct and prolonged contact articles.

5.2 Option 2: Increased education and on-going ACCC surveys

Benefits

This option has the same benefits as option 1 (i.e. the provision of a clear public guidance on SCoC), with the additional benefit of increasing supplier awareness of both the problems associated with hazardous azo dyes and appropriate concentration levels for the provision of safe products. Educational activities may also assist suppliers to develop improved compliance and testing regimes to increase detection.

Regulatory theory suggests most businesses will meet requirements if they are aware of them and they are not unduly difficult or expensive to achieve. Publishing SCoC and providing educational information to support suppliers to comply with SCoC is expected to result in reduced detections of aromatic amines in consumer products and a related reduction in levels of exposure of consumers to these chemicals.

Given that the ACCC website would be the central information tool to provide increased education to suppliers, this activity would not be considerably resource-intensive. Education initiatives can be readily adapted and tailored to target particular sectors or sub-issues where there is evidence that general education campaigns are not eliciting the intended outcome.

Consumer education on the ACL and the SCoC would also be beneficial. By knowing their rights consumers can demand safer products and services.⁴⁹ In this case consumers could ask sellers if goods of interest had been manufactured without use of the hazardous azo dyes. The appropriateness of regulators working to raise awareness of consumers and suppliers about the statutory rights and responsibilities conferred by consumer law has previously been noted by the Productivity Commission.⁵⁰

This option would also include ongoing ACCC product survey activity to identify articles with high concentrations of certain aromatic amines and remove these from the market, reducing the likelihood that consumers would be exposed to these carcinogens. Additional ACCC product surveys could be random or programmed, announced or unannounced. These additional surveys are expected to further encourage supplier vigilance.

Under this option suppliers may be more willing to engage with Australian regulators and discuss adverse test results as this option does not include a specific penalty for having unsafe levels of aromatic amines.

Costs

The difference between this option and option 1 is that under this option, suppliers are more likely to become aware of the SCoC and appropriate concentration levels, and the problems associated with hazardous azo dyes.

However, the importation and supply of direct and prolonged contact articles is already governed by the general provisions of the ACL and the defective goods regime, a series of industry standards and various contractual arrangements. This option will not change the requirements of those regulatory regimes, or make the process of importing dyed articles

⁴⁹ The Australian Consumer Law and Your Safety, viewed 8 July 2014, http://www.consumerlaw.gov.au/content/Content.aspx?doc=fact_sheets/safety.htm.

⁵⁰ Productivity Commission, *Review of Australia's Consumer Policy Framework, Productivity Commission Inquiry Report, Volume 2 Chapters and Appendices*, No. 45, 30 April 2008, pp. 176-177.

noticeably more complex. Any additional costs to improve quality control processes which otherwise could be attributed to this option should be being incurred already in order to comply with the general provisions of the ACL. Additional costs (such as testing costs) incurred under this option would be voluntarily incurred by suppliers and would likely be due to suppliers better understanding their existing obligation to supply safe goods. This option is non-regulatory and therefore there are no penalties associated with it.

Under this option consumers may still be exposed to potentially carcinogenic chemicals in direct and prolonged contact articles from those suppliers that choose to not invest in supply chain monitoring and testing. The extent of this exposure is not clear because it is uncertain to what extent suppliers as a whole will change their current practices.

This option also involves the conduct of future product surveys of the market. The 2013 product survey cost \$140 000, which included the purchase and testing of 300 clothing and bedding items. The extent and frequency of future ACCC product surveys could be adjusted to reflect the degree to which suppliers meet the SCoC as observed in earlier surveys. The ACCC expects to allocate a proportion of its budget to staff and testing costs in relation to azo dyes on an ongoing basis (approximately \$50 000 for staff and testing per year). This expenditure comes with an opportunity cost as it may reduce expenditure assessing the safety of other goods.

Where unsafe direct and prolonged contact articles are identified during a product survey, suppliers will be contacted and given the opportunity to voluntarily recall those goods. The ACL includes an option for the Minister to issue a compulsory recall notice.

Any additional costs for maintenance of the ACCC (Product Safety Australia) website, education and surveys to complement publications of the SCoC would be modest and these costs are expected to be absorbed by the ACCC.

It is unclear if maintaining the status quo combined with supplier education is likely to reduce the use of hazardous azo dyes in direct and prolonged contact articles sufficiently to restore consumer confidence in the safety of these products. Consequently, some stakeholders may see this option as an inadequate response.

A regulatory burden and cost offset estimate (RBCOE) table must be populated and reproduced for every viable option in a RIS. Table 5.1 sets out the RBCOE for this option.

Table 5.1: Regulatory burden and cost offset estimate for option 2

Average annual regulatory costs (from business as usual)				
Change in costs (\$million)	Business	Community Organisations	Individuals	Total change in cost
Total, by sector	\$0	\$0	\$0	\$0
Cost offset (\$ million)	Business	Community organisations	Individuals	Total, by source
Agency	\$0	\$0	\$0	\$0
Within portfolio	\$0	\$0	\$0	\$0
Outside portfolio	\$0	\$0	\$0	\$0
Total by Sector	\$0	\$0	\$0	\$0
Are all new costs offset?				
<input checked="" type="checkbox"/> Yes, costs are offset <input type="checkbox"/> No, costs are not offset <input type="checkbox"/> Deregulatory—no offsets required				
Total (Change in costs – Cost offset) (\$million) = \$0				

5.3 Option 3: Regulation via a mandatory safety standard or permanent ban

Benefits

This option is, of all the options presented, most likely to result in a complete, consistent and integrated set of controls that would provide an incentive for suppliers to take steps to eliminate the use of hazardous azo dyes in direct and prolonged contact articles that they supply. This is because regulation would likely provide an incentive for suppliers to adopt some form of enhanced supply chain vigilance as they may face penalties for breach of regulation. The maximum penalties for breaching a safety standard or permanent ban are significant.⁵¹

When compared to other options, regulatory theory suggests this option could be expected to be effective across the widest number of businesses in addressing the problem and lowering the risk of exposure. This is because it provides specific remedies including penalties for dealing with non-compliance. However, it may still take time for whole-of-industry practices to change sufficiently so that detections do not occur.⁵²

Australian suppliers would have choices about how they enhance their supply chain vigilance. They could generally improve compliance processes, institute supply chain auditing, implement product testing prior to offering products for sale or negotiate contracts with manufacturers that fully encourage the sourcing and use of safe components.

⁵¹ Maximum penalties are \$1.1 million for a corporation and \$220 000 for an individual.

⁵² Europe has regulated these dyes since 2003, and non-compliance is still detected during surveys - see discussion in Section 2.

Under this regulatory option all suppliers of the Australian market, regardless of their size, would need to meet the same requirements. Suppliers will know that their competitors face the same regulatory regime. Assuming businesses ensure products are within the limits prescribed in regulation, the risk of consumer exposure to carcinogens should be practically eliminated.

Under this option, the ACCC would include a link to the Federal Register of Legislative Instruments and a plain English explanation of the regulation on the Product Safety Australia website. This would make the regulation readily accessible to consumers and both new and existing suppliers of direct and prolonged contact articles.

If exposure to carcinogens is reduced or eliminated under this option, there may be a fall in the number of cases of bladder cancer in Australia, and therefore a reduction in the economic burden of bladder cancer (which has previously been identified to be \$1 million per case). However it is not possible to estimate the number of avoided cases of bladder cancer under this option.

Following the announcement of recalls of clothing and textiles with unacceptably high levels of hazardous aromatic amines there was significant media interest with some stakeholders openly calling for government intervention. Regulation may have the additional benefit of restoring consumer confidence and allaying stakeholders concerns.

Costs

This option is likely to increase the incentives for suppliers to take steps to eliminate the use of hazardous azo dyes in direct and prolonged contact articles that they supply.

However, for those suppliers who currently have appropriate monitoring for azo dyes in their supply chain and end-products there is unlikely to be any significant additional cost. The ACCC is also aware that following the survey, a number of suppliers have already increased their effort in prevention or detection of the use of hazardous azo dyes in their products by conducting more testing.

Despite being an additional cost to suppliers, this testing results in reducing or eliminating consumer exposure to hazardous azo dyes, which should improve consumer confidence and in turn should ultimately benefit the industry.

Current situation

A number of Australian suppliers reported they already specify to their manufacturers and sourcing agents that dyed articles must meet the EU requirements. The extent to which end product testing is undertaken to verify that specifications are being met would vary, but it is not routine for all businesses. The results of the recent ACCC survey indicated that at a point in time, the approach was not able to prevent all consumer exposure to articles dyed with hazardous azo dyes. The failure rate for the first tranche of testing (randomly selected articles) was approximately 3 per cent. Since then, more businesses have commenced routine end-product testing.⁵³

The recent ACCC survey has motivated a number of suppliers to improve their testing for compliance with their specifications. While this may be the case for many suppliers, the ACCC is yet to establish if this is likely to become industry-wide or enduring. As discussed

⁵³ Based on ACCC discussions with clothing and textile suppliers.

earlier, general provisions of the ACL and the defective goods regime can be used where, under the current situation, unacceptably high concentrations of hazardous aromatic amines are detected in a chemical survey.

Cost to suppliers

As discussed above, the establishment and maintenance of robust quality control processes are not an additional cost of regulatory compliance as these processes should already be in place in order to comply with the general provisions of the ACL, the defective goods regime and any existing industry standards.

To the extent that suppliers are motivated to improve their compliance and monitoring regimes as a result of the potential for exposure to pecuniary penalties, the quantum for each business will vary depending on:

- the number of direct and prolonged contact articles supplied
- the nature of the supplier's quality control processes
- the level of trust in manufacturers and sourcing intermediaries
- other non-azo dye related quality issues
- the frequency and intensity of testing.

All 19 stakeholders that provided a submission on the call for information paper indicated awareness of the safety concerns with certain azo dyes, and the majority of suppliers indicated that they voluntarily adopt the EU requirements and expect their manufacturers to do the same. A small number of the 19 suppliers have a zero tolerance for the 22 hazardous aromatic amines; that is, the aromatic amines must not be present at any concentration.

Several suppliers estimated the cost of additional testing for their business as a result of the introduction of a mandatory standard for azo dyes. These estimations varied greatly, as did the expected frequency and scope of testing:

- Some suppliers did not expect a significant increase in testing costs, while others expected a large increase based on extreme estimations of the scope and frequency of testing they expected would be necessary to demonstrate compliance.
- One supplier noted that the additional testing would also need additional emphasis on record-keeping and administration, which also represents additional costs.
- One major supplier stated that an extreme approach to compliance would be to test a sample of every stock keeping unit (SKU) from every purchase order. The ACCC does not consider this example to be realistic or represent the additional costs to the supplier, as not every SKU will relate to direct and prolonged contact articles and it fails to recognise the existing product safety obligations under the general provisions of the ACL, the defective goods regime and the series of industry standards. Further, testing of every SKU would seem unnecessary if suppliers know their products and are certain that the same raw materials are used across a range of sizes or variants of clothing. In these circumstances, it may be appropriate to test one product to ensure several product lines meet the requirements.

- Another major retailer stated it would need to conduct additional testing for a small percentage of its product range at an approximate cost of \$500 000 per year. It also stated that regulation would create a significant increase in costs for the remaining 95 per cent of its product range to monitor the conduct of its suppliers and implement procedures and policies to better ensure compliance.
- Another significant supplier stated that it was unlikely to incur any additional costs as a result of regulation.

Given the wide range of estimated additional costs from such a small sample of a large industry (as set out in Attachment 6), accurately estimating the total additional industry costs due to regulation is difficult. However the ACCC has, for the purposes of this draft RIS, prepared estimates of the additional costs based on the number and size of affected retailers, the cost of product testing, the number of tests suppliers may need to conduct (an estimate of the minimum, maximum and midpoint between minimum and maximum), the additional costs for record keeping, reporting and the cost of delays in getting goods to market.

Additional costs have been estimated and *averaged* over the 10 year default period as required by OBPR.⁵⁴ The estimation of additional costs results in a minimum cost of \$8 million each year, a maximum cost of \$29 million each year and a midpoint cost of \$18 million each year.

The midpoint estimate of \$18 million per annum represents the estimate of total additional costs under this option. Table 5.2 sets out these figures and Attachment 8 provides details on how this estimate was calculated.

Table 5.2: Estimate of total costs for option 3, averaged over 10 years, \$m

Range of estimated costs	Average
Minimum	8
Maximum	29
Midpoint	18

To demonstrate a net benefit for this option, the midpoint cost estimate of \$18 million per year needs to be balanced with \$18 million per year in benefits. This equates to avoiding approximately 18 cases of bladder cancer (which could be attributed solely to exposure to hazardous dyes in direct and prolonged contact articles), each year.

As stated throughout this draft RIS, the importation and supply of direct and prolonged contact articles is already governed by the general provisions of the ACL and the defective goods regime, a series of industry standards and various contractual arrangements. The ACCC argues that suppliers should already be ensuring their products meet the general provisions of the ACL, including that they are of acceptable quality and safe. Under this option many suppliers will need to conduct additional testing to verify and be sure that their

⁵⁴ Department of Prime Minister and Cabinet, Office of Best Practice Regulation, Regulatory Burden Measurement Framework Guidance Note, July 2014, p. 5, available: https://www.dpmc.gov.au/deregulation/obpr/reporting-publications/publications/guidance/docs/005_Regulatory_Burden_Measurement_Framework.pdf

products meet the general provisions of the ACL and regulation. The number of tests a supplier conducts is not set by regulation but will depend on the type of article supplied and the supplier's confidence in their quality control processes. It is anticipated that as business gains confidence in these processes (which may include testing of raw materials prior to manufacturing), the need for testing finished product will fall. This assumption is reflected in the calculation of additional costs.

Gaining a better understanding of these costs via stakeholder consultation will assist in understanding the overall cost burden for Australian business in an environment where it appears the majority of international suppliers are already meeting international regulatory requirements for direct and prolonged contact articles.

No responses to the request for information were received from suppliers that identified as 'bargain' outlets. These suppliers are typically small, purchase products from manufacturers or sourcing intermediaries with whom they do not have an ongoing relationship and who are likely to source their products through low-cost 'off-shore' avenues. Relative to their product volume, this type of supplier is likely to experience a higher financial burden from the expectation of supply chain management and testing. This burden may result in these suppliers either leaving the market for these types of products, increasing product prices to recover costs (resulting in a higher price increase for low cost goods compared to the price increase for high cost goods) or choosing to supply the products without regard to the possible use of hazardous azo dyes. If hazardous azo dyes are used in these products and they are supplied, this will result in unnecessary exposure of consumers to these chemicals.

Some suppliers expressed concern about penalties that could apply for breach of a mandatory standard. It is unclear whether this concern was driven by the financial cost of such penalties or the cost associated with reputation or brand damage. Because of the significant penalties that would apply under a regulatory option, suppliers that detect aromatic amines in their products may be less likely to inform the ACCC of the breach (compared to their approach to engagement with the ACCC under a non-regulatory option), for fear of facing penalties for breaching regulations. Any reluctance to notify the regulator of problems and detections could even be counter-productive by failing to protect consumers from hazardous azo dyes.

Penalties for breach of a regulation made under the ACL, such as a mandatory standard, are determined by the Court. Maximum penalties, set out in section 224 of the ACL are \$1.1 million for a corporation and \$220 000 for an individual.

In determining the appropriate penalty, the Court is required to have regard to the following matters:

- the nature and extent of the breach (how serious the breach was) and any loss or damage suffered as a result of the breach (such as whether the breach caused a serious injury)
- the circumstances in which the breach took place
- whether the supplier has previously been found by a court to have engaged in similar conduct (a court will view repeated breaches more seriously than a first breach).

The Court may also have regard to factors such as:

- the size of the supplier

- the deliberateness of the breach and the period over which it extended
- whether senior management was involved
- whether the supplier had a culture of compliance
- whether the supplier cooperated with the regulator once the breach was identified
- whether the conduct was systematic, deliberate or covert.

As noted earlier, the ACCC exercises its discretion to direct resources to the investigation and resolution of matters that provide the greatest overall benefit for competition and consumers. Where companies have strong compliance cultures and good supporting systems in place, and/or strong stewardship processes exist, the ACCC is unlikely to pursue matters that are isolated events.

Where a specific regulation is introduced, suppliers are expected to manage the supply of direct and prolonged contact articles so that they meet that regulation. A minority of suppliers may be unwilling to change/improve practices to ensure unsafe articles are not supplied to Australian consumers. In these circumstances, where suppliers are aware of and wish to avoid penalties for non-compliance, they may choose to exit the industry.

Costs to consumers

As noted above, it is unclear from industry submissions, to what extent the costs associated with this option exceed the implicit costs of maintaining appropriate product stewardship under existing legislative and contractual obligations.

Any increased costs to suppliers would be either absorbed by suppliers or wholly or partially passed on to consumers. Submissions from business were divided on whether additional costs would be passed on to consumers. A number of suppliers indicated that they would pass on these costs with one large supplier stating that the impact could result in an increase of 10 cents per individual garment. While this may appear to have a minimal impact on consumers, it may have greater impact on consumers with low incomes and large families. Other suppliers stated that they would absorb any additional costs, which would in turn impact retailer margin but not result in increased consumer costs.

The ACCC's estimate of the increase in the price of direct and prolonged contact articles will be 6 cents per article in the first year of regulation and 2 cents per article in the last year of the 10 year period (see Attachment 8 for further information). This assumes all additional costs incurred by business, as estimated by the ACCC, are passed on to consumers via higher prices.

Ultimately it may be that any increase in costs attributable to this option would be very small at a 'per unit' level and cumulatively may be a reasonable price for consumers to pay to reduce their exposure to hazardous chemicals. More and better attributed costing information from industry would further inform this analysis.

Costs to government

The ACCC would absorb the costs of development and maintenance of regulation. The ongoing costs of administering regulation for hazardous aromatic amines would be similar to the costs in option 2. The ACCC would devote a proportion of its compliance budget to administering the mandatory standard and conducting testing of items in the market. This cost for staff and testing is expected to be about \$50 000 per year. Any costs of maintaining the ACCC (Product Safety Australia) website are likely to be modest and would be absorbed by the ACCC.

Regulatory burden and cost offset estimate table

Table 5.3 sets out the regulatory burden and cost offset estimate for option 3.⁵⁵

Table 5.3: Regulatory burden and cost offset estimate table for option 3

Average annual regulatory costs (from business as usual)				
Change in costs (\$million)	Business	Community Organisations	Individuals	Total change in cost
Total, by sector	\$18	\$0	\$0	\$18
Cost offset (\$ million)				
Cost offset (\$ million)	Business	Community organisations	Individuals	Total, by source
Agency	\$0	\$0	\$0	\$0
Within portfolio	\$18	\$0	\$0	\$18
Outside portfolio	\$0	\$0	\$0	\$0
Total by Sector	\$18	\$0	\$0	\$18
Are all new costs offset?				
<input checked="" type="checkbox"/> Yes, costs are offset <input type="checkbox"/> No, costs are not offset <input type="checkbox"/> Deregulatory—no offsets required				
Total (Change in costs – Cost offset) (\$million) = \$0				

Note: A regulatory offset has been identified from within the Treasury portfolio, relating to the MyTax reforms.

6. The preferred option

There is currently no preferred option. The ACCC will consider submissions on this draft RIS before it settles on a preferred option to recommend to the Minister, who is the decision maker. It is expected the RIS consultation phase will further inform cost and benefit

⁵⁵ Department of Prime Minister and Cabinet, Office of Best Practice Regulation, Guidance Note, *Regulatory Burden Measurement Framework*, July 2014, p. 5. Available: <https://www.dpmc.gov.au/deregulation/obpr/reporting-publications/publications.cfm>.

considerations. In accordance with government policy, the preferred option will have the highest net benefit.⁵⁶

7. Implementation and evaluation

Planning for implementation and evaluation of the preferred option will be discussed in the final RIS. The ACCC will continue to actively engage with suppliers of direct and prolonged contact articles and collect information that will support the effective reduction of exposure of consumers to hazardous azo dyes.

If regulation is ultimately implemented, suppliers may need time to ensure compliant stock is available for supply. Suppliers are invited to comment on a suitable timeframe for implementation of the option involving regulation.

8. Form of possible regulation

The wording for any possible future regulation has not yet been finalised, however it is likely to be similar to the key elements of the EU requirements set out in Regulation (EC) No 1907/2006.⁵⁷

Under the EU Regulation, azo dyes which, by reductive cleavage of one or more azo groups, may release one or more of 22 aromatic amines in detectable concentrations, i.e. above 30 mg/kg, in the finished articles or in the dyed parts thereof, must not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity.

Attachment 9 of this paper includes a list of the 22 aromatic amines likely to be included in any regulation and provides for a total limit of 30 mg/kg. It is proposed that the 30 mg/kg total limit apply to the finished article or in the finished articles dyed parts.

9. Submissions

All stakeholders – including consumers, medical professionals, advocates, industry associations, importers, wholesalers, manufacturers and suppliers are invited to make submissions on any issue canvassed in this draft RIS.

Where stakeholders prefer one option over others, they are requested to explain why, and where relevant provide supporting evidence or documentation.

Industry stakeholders are also requested to provide further specific information on *additional costs*. Additional costs are those new costs to meet either the *non-regulatory option* (Option 4.2) or the *regulatory option* (Option 4.3). *Additional costs* do not include:

- any cost now being incurred from improved practices to meet current expectations following the ACCC survey
- the baseline costs consistent with the appropriate stewardship expected from general provisions of the ACL.

⁵⁶ *The Australian Government Guide to Regulation*, p. 48.

⁵⁷ Regulation (EC) 1907/2006 is available online: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907&from=en>.

1. What additional costs, if any, will you incur if the non-regulatory option, which includes the status quo combined with education and ACCC surveys (Option 4.2) is adopted?
2. What are the additional costs you will incur if the regulatory option (Option 4.3) is adopted?
3. Please comment on the cost estimates and assumptions used to derive the cost estimates for the regulatory option, as set out in Attachment 8. To what extent do the estimates and assumptions reflect the likely impact of regulation on your business?
4. The ACCC is seeking information on the downstream implications of any additional costs on business. For example, will business fully or partially pass costs on or absorb them, or cut costs elsewhere?
5. What is the average price increase that would result from the regulatory option (Option 4.3) if it were adopted?
6. If the regulatory option (Option 4.3) were adopted, how long would you need to ensure you only supply compliant stock?

Consultation commences on Tuesday 24 February 2015 and closes on Friday 10 April 2015.

Our preferred method of receiving submissions is via the ACCC Consultation Hub at: <https://consultation.accc.gov.au/>.

However, electronic submissions (MS Word preferred) and can be sent to the ACCC via productsafety.regulation@acc.gov.au or hard copy material mailed to:

Director
Policy and Engagement Section
Product Safety Branch
Australian Competition and Consumer Commission
GPO Box 3131
CANBERRA ACT 2601

If the information provided is of a confidential nature, you can be assured that the details provided by you will be treated confidentially. That is, the ACCC will not disclose the confidential information to third parties, other than advisors or consultants engaged directly by the ACCC, without first providing you with notice of its intention to do so, such as where it is compelled to do so by law. Please note that any information which you believe to be of a confidential nature should be clearly marked or identified as confidential.

The ACCC may be compelled by law to disclose submissions (for example under subpoena or following a request under the *Freedom of Information Act 1982*). For more information see the ACCC-AER Information Policy available via www.accc.gov.au

Attachment 1: Summary of comments from June 2014 call for information

In June 2014 the ACCC requested Australian suppliers provide general information about their business and provide data on the anticipated additional costs they may incur due to regulation or publishing non-regulatory safety reference limits. Nineteen submissions were received and the following points are drawn from submissions. A number of suppliers requested that their submissions be treated as confidential, so individual suppliers have not been identified.

- Nearly all of the retailers sourced products through multiple channels including directly from overseas manufacturers, from importers/wholesalers and/or through international sourcing agents.
- The range of countries where goods are sourced include China, Bangladesh, India, Vietnam, Thailand, Cambodia, Taiwan, Pakistan, Indonesia and Malaysia.
- All responses indicated a high level of awareness of the safety issues associated with certain azo dyes that reduce to hazardous aromatic amines. Most stated that their awareness spans many years.
- While there was divergence on total costs, there was a level of consistency in some elements of the cost estimates, including actual product testing and administration costs associated with managing testing programs and test results.
- Most retailers indicated they already work to the same limits as the EU and had in place quality assurance measures that specified against the use of hazardous azo dyes.
- Suppliers indicated that additional costs would be greater under a regulatory option than a non-regulatory option. A number of stakeholders stated that there would be minimal change to their practices under the non-regulatory option.
- There was concern that regulation may impose significant additional costs on suppliers and those costs may make it too expensive to stay in business. Generally there was a view that the compliance costs for the regulatory option would be the highest.
- One stakeholder stated that medium to large businesses may incur additional costs of between \$100 000 and \$300 000 in the first year, but industry asserts these costs are a conservative estimate and at least one major supplier estimates costs significantly higher.
- A number of responses indicated that they had recently increased their controls for hazardous azo dyes such as introducing random end product testing or surveying all suppliers to determine how they manage the issue.
- There are currently insufficient testing laboratories available to conduct testing on all products under the regulatory option.
- The scope of the products captured would be an important determinant in the compliance costs associated with any regulation. For example there was uncertainty whether products like headwear, scarves, bath towels and handbags would be included.
- For Australian retailers the quality assurance or compliance costs are the same for their online and 'bricks and mortar' businesses.
- Testing finished product is inefficient but may be necessary in the short term if regulation is imposed. In the longer term Australian suppliers will need to better manage their relationships with overseas suppliers and be more involved in product manufacture earlier than they are now.

Attachment 2: Development of the existing product safety system in Australia

The government has a longstanding role in consumer safety. From its inception the *Trade Practices Act 1974* (TPA) had provisions for product standards and bans to be made. In 1992 the government established a broad general product safety framework when a regime of strict liability was introduced. This regime gave consumers who were injured or suffered property damage as a result of a defective product a right to compensation without the need to prove negligence on the part of the manufacturer.⁵⁸ The regime provided that goods were 'defective' if they did not have the degree of safety which persons generally are entitled to expect in all circumstances.⁵⁹ It was asserted that these provisions becoming law would be beneficial for the whole community and expectations were for any increased business cost to be almost imperceptible in the initial years and then very gradual after that.⁶⁰ These provisions became known as the defective goods regime.

Governments in Australia continue to play an important role in consumer safety. Consumer Affairs Australia New Zealand (formerly the Standing Committee of Officials of Consumer Affairs) has previously considered what improvements were needed for product safety. It was noted at the time that Australia's product safety system reacted to injury rather than anticipating it, and for this reason various approaches to improving the 'proactive' nature of the system were examined.⁶¹ It was considered that a proactive system involves regulators being able to identify safety hazards before consumers suffer harm, with responsible businesses thinking sufficiently about safety issues in product design and consumers better understanding the risks involved before using a product.⁶² A range of enhancements were contemplated; including revising the definition of unsafe goods, introducing mandatory reporting obligations upon businesses, broadening the scope of regulation to cover foreseeable misuse of consumer goods and ensuring regulators have better data.⁶³

Some of these issues were further considered by the Productivity Commission, including the case for a *general safety provision*.⁶⁴ Such provisions exist in some other jurisdictions and they can include an offence provision. In discussion the Productivity Commission considered that while such a provision is intended to make producers more proactive, strict product liability rules should already have this effect.⁶⁵ In December 2009 the COAG Legislative and Governance Forum on Consumer Affairs (formerly the Ministerial Council on Consumer Affairs) agreed to further specific product safety measures to be incorporated into the ACL, to enable governments to act more proactively on consumer safety.⁶⁶

As a result, the Building a Better Product Safety System project was developed by the ACCC in 2009. The project resulted in many changes to the way product safety was

⁵⁸ The Parliament of the Commonwealth of Australia, Senate, *Trade Practices Act Amendment Bill 1992, Explanatory Memorandum*, p. 2.

⁵⁹ *ibid.*

⁶⁰ *ibid.*, p. 3.

⁶¹ The Ministerial Council on Consumer Affairs, *Review of the Australian Consumer Product Safety System*, August 2005, p. 5.

⁶² *ibid.*, p. 17.

⁶³ *ibid.*, pp. 17-35.

⁶⁴ Productivity Commission, *Review of the Australian Consumer Product Safety System, Productivity Commission Research Report, Forward*, January 2006, p. xxvii.

⁶⁵ *ibid.*, p. xxviii.

⁶⁶ The Parliament of the Commonwealth of Australia, Senate, *Trade Practices Act Amendment Bill 1992, Explanatory Memorandum*, p. 242.

managed in Australia and prepared the way for changes to the TPA and the introduction of the ACL. The project resulted in the harmonisation of existing state/territory and Commonwealth mandatory standards and bans, a national compliance approach with a single law and multiple regulators (both state/territory and Commonwealth) and an increased awareness and focus on chemicals in consumer products.

The ACL took effect on 1 January 2011. As well as including the *defective goods regime* there was a deliberate strengthening of the product safety provisions. The ACL also introduced a number of general provisions intended to ensure businesses supply safe consumer goods. These include statutory guarantees to consumers that goods are of *acceptable quality* as defined in the ACL, a notable shift from the former law⁶⁷. The guarantees extend to all products being safe, durable, free from defects, fit for purpose, acceptable in appearance, match their description and match any sample or demonstration model.⁶⁸ A failure to comply with a guarantee is a major failure when goods are unsafe. While consumer guarantees provide rights that accompany the purchase of goods or services, any failure to comply with a guarantee generally gives rise to specific remedies provided for in the ACL and it is generally not treated as a contravention of the ACL.⁶⁹

Even before specific controls were introduced, the legal system has a long history in guiding acceptable conduct by businesses. The body of decisions developed over hundreds of years by different judges is called the common law. It is basically the collected principles of law extracted from all the decisions handed down in the senior courts of England, Australia and other countries that share our type of legal system. There are a number of precedents entrenched in common law relevant to the supply of safe direct and prolonged contact articles.

In 1932 the *Donoghue v Stevenson* case created the modern concept of negligence when the House of Lords found that the manufacturer of a bottle of ginger beer breached its duty of care to a consumer who became sick after finding a decomposed snail in the bottle. An Australian case in 1936, *Grant v Australian Knitting Mills Ltd*, related to a defective undergarment purchased from a retailer. The undergarment contained excess sulphite and the consumer contracted dermatitis which resulted in hospitalisation. The manufacturer was found to be negligent in leaving excess sulphites in the garment. Even in the absence of product specific mandatory standards, the supply of unsafe goods in Australia is unacceptable, and has been since early last century.

The recent survey suggests underinvestment in product stewardship has occurred. This draft RIS therefore considers options to better ensure that this existing obligation is met and additional controls that can be considered. The RIS also seeks to clarify how much additional controls may add to existing compliance costs.

⁶⁷ *ibid.*, p. 181.

⁶⁸ The Australian Consumer Law and Your Safety, viewed 8 July 2014, http://www.consumerlaw.gov.au/content/Content.aspx?doc=fact_sheets/safety.htm.

⁶⁹ The Parliament of the Commonwealth of Australia, House of Representatives, Trade Practice Act Amendment (Australian Consumer Law) Bill (No 2) of 2010, Explanatory Memorandum, p. 337.

Attachment 3: The cost of benzidine-based dye exposure

Three benzidine-based dyes (Direct Black 38, Direct Blue 6 and Direct Brown 95) have been tested for carcinogenicity in animals. The IARC concluded that there was sufficient evidence that dyes metabolised to benzidine and were carcinogenic based on these studies.⁷⁰ The observed effects included increased incidence of hepatocellular carcinomas (a common type of liver cancer) and liver neoplastic nodules (abnormal growth in the liver) with all three dyes and mammary gland cancers with one dye. A slight increase in transitional cell carcinoma of the urinary bladder was observed with one dye.⁷¹

While some studies have reported an association between benzidine exposure and cancer in other parts of the body (i.e. liver, kidney, central nervous system, oral cavity, larynx, oesophagus, bile duct, gallbladder, stomach, and pancreas); the evidence for an association with benzidine is more limited for cancer in these parts of the body than for urinary bladder cancer.⁷²

Smoking is by far the strongest risk factor for bladder cancer with a clear dose-response relationship.⁷³ In Australia, tobacco use is considered the most significant contributor to the risk of bladder cancer. It is estimated that 2 400 Australians are diagnosed with bladder cancer each year.⁷⁴

Numerous epidemiological studies (case reports and cohort studies) of workers in various geographical locations have reported a strong association between significant long term occupational exposure to benzidine and urinary bladder cancer. Exposure from inhalation as well as dermal contact often features in occupational cases. Epidemiological data suggests that urinary bladder cancer incidence has decreased since measures to limit benzidine exposure were instituted in the workplace. A few studies have evaluated exposure to benzidine alone; however, in many studies, workers were co-exposed to other chemicals including tobacco.⁷⁵ The risk of bladder cancer is greatly increased for those who both smoke and experience chemical exposure in the workplace.⁷⁶ Caution should be exercised when extrapolating from occupational data as exposure to workers in the chemicals or dyeing industries would be orders of magnitude higher than that of consumers in contact with dyed articles.

Evidence from the United States indicates that bladder cancer is considered a 'survivable cancer' which requires lifelong monitoring and treatment due to its high rate of recurrence.⁷⁷

⁷⁰ National Industrial Chemical Notification and Assessment Scheme, 6 June 2013, *Inventory Multi-Tiered Assessment and Prioritisation Human Health Tier II Assessment for Benzidine-Based Dyes*, available: http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=513.

⁷¹ *ibid.*

⁷² *ibid.*

⁷³ K Golka, Goebell, P.J., Rettenmeier, A.W., *Bladder Cancer: Etiology and Prevention Part 1 of a series on urothelial carcinoma*, Dtsch Arztebl, 104(11), A719-23, 2007.

⁷⁴ Cancer Council NSW, Bladder cancer statistics, viewed 4 March 2014, <http://www.cancercouncil.com.au/73739/b1000/bladder-cancer-10/bladder-cancer-statistics/>.

⁷⁵ United States Department of Health and Human Services, Report on Carcinogens, 12th Edition, 2011, p. 62, viewed 4 April 2014, <http://ntp.niehs.nih.gov/ntp/roc/twelfth/roc12.pdf>.

⁷⁶ G Steinberg., *Bladder Cancer*, The University of Chicago Medical Centre, Centre of Urology, viewed 30 June 2014, <http://www.ucurology.org/areas-of-specialization/bladder-cancer>.

⁷⁷ D.A Barocas, Globe, D.R., Colayco, D.C., Onyenwenyi, A., Bruno, A.S., Bramley, T.J., and Spear, R.J. "Surveillance and Treatment of Non-Muscle-Invasive Bladder Cancer in the USA", *Advances in Urology*, 2012, pp. 1-8.

The Cancer Council of NSW commissioned Access Economics to compile an independent report to determine the true cost of cancer to affected individuals, their families and society.⁷⁸ The report found that the most costly cancers in terms of economic burden were lung, colorectal, breast, stomach, liver and pancreatic cancer while the least costly were bladder, kidney and brain cancer. The total cost of bladder cancer and an average of the total cost of all cancers are provided in Table A6.1.

Table A6.1: Lifetime economic cost of cancer, NSW, \$(2005) per case⁷⁹

Cancer	Value of Burden of Disease	Total financial cost	Total cost
Bladder	734 700	78 800	813 500
All cancers	851 600	114 500	966 000

The lifetime *household* financial costs for bladder cancer are provided in Table A6.2. In 2005 dollars they were estimated to be \$27 200 per household. Household costs comprise costs to individuals and families only. When these costs are escalated to 2014 dollars using CPI data, the total cost to households of bladder cancer is close to \$35 000 per household. This figure represents the financial cost only and does not include the value of the burden of the disease on households.

Table A6.2: Lifetime financial cost faced by households, by age/sex, \$(2005) per person⁸⁰

Cancer	Average financial cost	Males						Females		
		Males			Females					
		0-14	15-64	64+	0-14	15-64	65+			
Bladder	27 200	273 200	99 400	10 800	-	43 400	11 500			
All cancers	47 200	308 500	137 400	13 400	154 000	51 500	10 600			

⁷⁸ Access Economics, , *Cost of Cancer in NSW – A report by Access Economics Pty Limited for the Cancer Council NSW*, 2007, Executive Summary, pp. v-vi, viewed 4 August 2014, http://www.cancercouncil.com.au/wp-content/uploads/2010/11/costofcancer_summary.pdf.

⁷⁹ Access Economics, *Cost of Cancer in NSW – A report by Access Economics Pty Limited for the Cancer Council NSW*, 2007 Sections 3 - 10, Table 9-5, p. 127, viewed, 4 August 2014, http://cancercouncil.com.au/wp-content/uploads/2010/11/costofcancer_costs.pdf.

⁸⁰ Access Economics, *Cost of Cancer in NSW – A report by Access Economics Pty Limited for the Cancer Council NSW*, 2007 Executive Summary, p. xi, viewed 4 August 2014, http://www.cancercouncil.com.au/wp-content/uploads/2010/11/costofcancer_summary.pdf.

Attachment 4: Chemicals and textiles

Industrial chemicals⁸¹ are important in our modern economy, but at the same time they can present risks for public health, workplace safety, the environment, and national security. To manage these risks regulation is an important tool,⁸² and there are several grounds for government policy intervention. Significant negative externalities⁸³ and information asymmetries exist concerning the risks associated with the hazardous nature of some chemicals or products which may contain them. Also, if there are chemical hazards in consumer goods, it is often difficult for consumers to detect them. If consumers are being exposed to risks they are ill-equipped to deal with, this is relevant for considering the need for government intervention.⁸⁴ There is also a public good argument that protection of public health is underprovided by the private sector.⁸⁵ Public health has been identified as one of four significant areas of public policy concern that relate to the hazardous nature of some chemicals.⁸⁶

The textiles sector produces clothing and other textiles that everyone comes into contact with. The sector is important for the global economy and is also one of the most globalised.⁸⁷ In recent years attention has increased on chemicals in textiles products. Chemicals are used both for fibre production and during the manufacturing process and it is suggested that:

- there is growing awareness and concern of real or potential safety issues related to chemicals in consumer products generally including those in textiles
- the general community is more aware of the hazards associated with chemicals used in the sector, particularly in countries which have established chemical disclosure requirements when placing goods into markets.⁸⁸

Europe has regulated hazardous azo dyes since 2003 and consumer attitudes to incidental contact with chemicals are routinely surveyed by the European Commission (EU). In 2012 one survey revealed that three out of 10 respondents thought that it was possible to completely eliminate chemical substances from their daily life while seven in 10 said that it was not possible.⁸⁹ Other European studies identify that consumers consider exposure to even a small amount of a hazardous chemical to be potentially harmful.⁹⁰

In Australia there has been a general trend to manufacture and source finished goods from countries with lower production costs, commonly known as 'off-shoring'. While there may be cost benefits associated with this trend there are also additional hidden costs in moving production a long way from the intended market for supply.⁹¹ Quality risk, where the quality of product declines, can increase costs for suppliers particularly where it means products

⁸¹ NICNAS, Defining an industrial chemical, viewed 11 July 2014, <http://www.nicnas.gov.au/regulation-and-compliance/nicnas-handbook/handbook-main-content/do-i-need-to-register-with-nicnas/what-is-an-industrial-chemical>.

⁸² Productivity Commission, *Chemicals and Plastics Regulation, Productivity Commission Inquiry Report, Forward*, July 2008, p. iii.

⁸³ Common negative externalities include pollution and exposure to hazardous chemicals.

⁸⁴ *The Australian Government Guide to Regulation*, p. 18.

⁸⁵ Productivity Commission, *Chemicals and Plastics Regulation, Productivity Commission Inquiry Report, Overview*, July 2008, p. xxvi.

⁸⁶ *ibid.*, p. xxv.

⁸⁷ United Nations Environment Program DTIE / Chemicals Branch, *The Chemicals in Products Project: Case Study of the Textiles Sector*, 2001, p. v.

⁸⁸ *ibid.*

⁸⁹ European Commission, Flash Eurobarometer 361, *Chemicals Report*, 2013, p. 8.

⁹⁰ United Nations Environment Program DTIE / Chemicals Branch, *The Chemicals in Products Project: Case Study of the Textiles Sector*, 2001, p. v.

⁹¹ The Economist, *Reshoring manufacturing, Coming Home*, 19 January 2013. viewed 17 September 2014, <http://www.economist.com/node/21569570/print>.

become unsafe for consumers. There are a number of ways Australian suppliers can manage quality risk including ensuring that manufacturers understand the threshold for a quality product and monitoring output.⁹² This output management may be achieved via testing of finished goods or, preferably via supply chain monitoring (which would be expected to contain some level of auditing and testing). Regardless of the mechanism, consumers are entitled to expect that every manufacturer, importer and retailer in Australia adheres to appropriate levels of product stewardship and complies with relevant laws.

⁹²

How to manage and mitigate offshore risks, viewed 17 September 2014, <http://outsourcing-center.com/2009-06-how-to-manage-and-mitigate-offshore-risks-article-37409.html>.

Attachment 5: Identifying hazardous aromatic amines in goods

Detection of aromatic amines in clothing, textiles and leather articles can only be achieved via chemical testing in a laboratory. It is not possible to detect their presence via visual inspection. This complicates any compliance assessment process and ultimately increases costs.

Testing for aromatic amines by accredited test laboratories costs approximately \$US60 per test. Garments made from one piece of material require one test only, however garments like jeans with pockets made from separate material require two or more tests. A number of the recalls following ACCC commissioned testing were due to high levels of aromatic amines in pocket material.

The accredited test methods extensively used by industry to detect aromatic amines are set out below:

- EN 14362-1:2012 for textile material
- EN 14362.3:2012 & EN ISO 17234.2:2011 for p-Aminoazobenzene
- EN ISO 17234.1:2010 for leather material.

Where p-Aminoazobenzene is detected using the test method in EN 14362-1:2012, an additional two tests (using EN 14362.3:2012 & EN ISO 17234.2:2011) need to be completed to accurately determine the level. This additional testing increases compliance costs.

Further, where test results indicate aromatic amines at levels close to the limit of 30 mg/kg, further testing needs to be conducted. The detection limit is 5 mg/kg, so detection between 25 mg/kg and 35 mg/kg would need further investigation and testing.

Attachment 6: Constraints and barriers

Some of the constraints to consider include the cost, efficiency and veracity of various activities that might be undertaken. Testing of all final products is inefficient. Waiting until product is completed before testing is conducted can result in unnecessary losses for manufacturers, wholesalers and potentially retailers. It also creates delays in moving stock until test results are confirmed and increases warehousing costs.

Arguably a better approach would be to ensure the fabric is free of hazardous azo dyes prior to any manufacturing. This may require Australian suppliers to have a greater presence and involvement during product manufacture and conduct some product testing on finished goods to be satisfied that product substitution has not taken place. However, both greater presence by staff (or company agents) or third party certification schemes are not infallible and can be susceptible to fraud or other corruption.

Another constraint is the large and diversified nature of suppliers and their varying supply chains. There are a large number of Australian wholesalers and retailers. The statistics listed in Table A6.1 provide an indication of the number of businesses likely to be affected.

Table A6.1 Statistics for clothing and textiles suppliers in Australia

Stakeholder group	Number of businesses ⁹³	Total annual revenue (\$bn)	Total annual profit (\$m)
Clothing retailers	11 320	13.1 ⁹⁴	629.5 ⁹⁵
Manchester and other textile goods retailing	1 585	2.1 ⁹⁶	102.7 ⁹⁷
Clothing and footwear wholesaling	4 131	8.3 ⁹⁸	478.5 ⁹⁹
Textile product wholesaling	1 261	2.4 ¹⁰⁰	86.0 ⁹⁸¹⁰¹

The problem relates only to articles likely to be in direct and prolonged contact with the skin. However the likely list of products affected will be extensive and includes (but is not necessarily limited to) dyed underwear, socks, leggings, jeans, pants, shirts and tops, nightwear, dresses, inner articles of sports and work wear, school and work uniforms, baby clothes, cloth nappies, sheets and pillow cases.

⁹³ Australian Bureau of Statistics, *8165.0 Counts of Australian Businesses, including Entries and Exits, June 2009 to June 2013*, Release date 31 May 2014. Available: <http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/8165.0Jun%202009%20to%20Jun%202013?OpenDocument>

⁹⁴ IBISWorld, *Clothing Retailing in Australia*, Industry Report G4251, November 2014.

⁹⁵ Ibid.

⁹⁶ IBISWorld, *Fabric Retailing in Australia*, Industry Report G4214, January 2014.

⁹⁷ Ibid.

⁹⁸ IBISWorld, *Clothing Wholesaling in Australia*, Industry Report F3713, July 2014.

⁹⁹ Ibid.

¹⁰⁰ IBISWorld, *Textile Product Wholesaling in Australia*, Industry Report F3711, September 2014.

¹⁰¹ Ibid.

It appears that clothing retailers are tending to bypass wholesalers as retailers source more products directly from low cost manufacturers. So some products will be sourced direct from factories and others will be supplied via wholesalers.¹⁰²

The online supply of clothing is also growing. Consumers are increasingly purchasing online and as the individual operators of online sales platforms can be hard to identify and engage with, it may be difficult to obtain robust assurance that the manufacturer or wholesaler has supplied safe goods.

Ideally, suppliers will be aware of the broad safety framework under the general provisions of the ACL and should be supplying safe goods to consumers. Where this approach does not result in safe products, other interventions including non-regulatory and regulatory measures can be considered to improve consumer protection.

¹⁰² IBISWorld, *Clothing Wholesaling in Australia*, Industry Report F3713, March 2014.

Attachment 7: International controls

There are a number of international controls on both articles dyed with hazardous azo dyes and the hazardous azo dyes themselves. These controls are described below.

Controls on articles dyed with hazardous azo dyes

In the EU, 22 hazardous aromatic amines derived from certain azo dyes are restricted in articles which may come into direct and prolonged contact with the human skin or oral cavity. The maximum total concentration for all of the hazardous aromatic amines is 30 mg/kg (or 30 parts per million).¹⁰³ The full list of 22 hazardous aromatic amines is provided in Attachment 9.

In China, the limit for hazardous aromatic amines in leather and fur products is 30 mg/kg (the Chinese standard is *GB 20400-2006, Leather and Fur - Limit of Harmful Matter*).¹⁰⁴ Carcinogenic aromatic amines are banned in any apparel, decoration textiles and household textiles placed on the Chinese market. The Chinese standard for textiles is *GB 18401-2010 National General Safety Technical Code for Textile Products*.¹⁰⁵

In Japan, the 22 hazardous aromatic amines restricted in Europe are listed in a voluntary standard. The voluntary standard was developed by the Japan Textile Federation (JTF) and the Japan Leather Industry Association (JLIA). Compliance with the Standard may be demonstrated by providing a certificate of analysis or self-declaration.¹⁰⁶ Importation of textiles into Japan must be accompanied by test reports, certification documentation (that certain azo dyes have not been used) and information on the manufacturing facility.¹⁰⁷

In New Zealand, there are no regulations restricting the presence of hazardous aromatic amines in clothing or textile articles. After the recent ACCC survey, companies that recalled articles recently in Australia also undertook recalls in New Zealand where they had also supplied the affected articles.

Controls on hazardous azo dyes

In the United States, benzidine-based dyes are covered by a significant new use rule (SNUR) under the *Toxic Substances Control Act*. The United States Environmental Protection Agency (US EPA) must be notified at least 90 days before a person starts to manufacture, import or process these dyes for any significant new use. Notification would enable the US EPA to evaluate the significant new use of these chemical substances and, if necessary, appropriately address risks to human health or the environment by limiting or prohibiting those uses before they occur.¹⁰⁸ There are currently exemptions to notify a significant new use for benzidine-based dyes in certain articles, however a proposal to

¹⁰³ See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:en:PDF>.

¹⁰⁴ See https://www.iaaqaservices.bureauveritas.com/reach-ccr/regulation_updates/59737.html.

¹⁰⁵ See <http://www.intertek.com/textiles/gb-18401/>.

¹⁰⁶ See http://www.gmn.hkpc.org/en_newsletter_details.asp?id=62.

¹⁰⁷ See http://www.cti-cert.com/en/news/news_de.aspx?id=3707.

¹⁰⁸ National Industrial Chemical Notification and Assessment Scheme, *Inventory Multi-Tiered Assessment and Prioritisation Human Health Tier II Assessment for Benzidine-Based Dyes*, 6 June 2013, available: http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=513 and;

Federal Register, *Significant New Use Rule (SNUR); Benzidine-Based Dyes; Di-n-pentyl phthalate (DnPP); and Alkanes, C12-13, Chloro*, viewed 27 June 2014, <https://www.federalregister.gov/regulations/2010-AJ73/significant-new-use-rule-snur-benzidine-based-dyes-di-n-pentyl-phthalate-dnpp-and-alkanes-c12-13-chl>.

remove this exemption is currently being considered. Access to benzidine-based dyes for home use is not permitted.¹⁰⁹

Canada has undertaken a human health and environmental risk assessment of a number of benzidine-based dyes. However regulations restricting supply of textile articles dyed with benzidine-based dyes have not been introduced on the basis that risk to the general population of Canada from exposure to these substances is not expected.¹¹⁰

In a number of international jurisdictions benzidine-based dyes are banned for use in cosmetics.

¹⁰⁹ National Industrial Chemical Notification and Assessment Scheme, *Inventory Multi-Tiered Assessment and Prioritisation Human Health Tier II Assessment for Benzidine-Based Dyes*, viewed 6 June 2013, http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=513.

¹¹⁰ *Draft Screening Assessment Aromatic Azo and Benzidine-based Substance Grouping Certain Azo Solvent Dyes*, Environment Canada/Health Canada, November 2013, viewed 1 September 2014, <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=AB88B1AB-1#toc31>.

Attachment 8: Determination of the estimated additional costs to business of option 3

The purpose of this attachment is to estimate the cost to business of conducting testing for carcinogenic aromatic amines in direct and prolonged contact articles. Costs are comprised of substantive compliance costs (product testing), administrative costs ('back office' administration to ensure compliance with regulation) and the cost to business of delay in supplying product for sale due to product testing). The default duration for cost estimation is 10 years.

Summary of estimated additional costs under the regulatory option

Table A8.1 sets out a summary of the estimated cost of regulation averaged over the default 10 year period. This summary has been calculated based on the substantive compliance costs, administration costs and delay costs described later in this attachment.

Costs have been determined under both a 'minimum' and 'maximum' cost scenario which reflects an estimation of the minimum and maximum number of tests that businesses may need to conduct to determine if their articles meet regulation. Because the minimum and maximum costs are considered cost boundaries, the midpoint between these two values has been calculated and used to estimate costs. The average annual compliance cost under the regulatory option has been estimated to be \$18 million per annum (i.e. the 'midpoint' figure in Table A8.1).

It is assumed that additional costs will decline over the 10 year period in response to the assumption that business will develop greater confidence in quality control processes over time. Accordingly, costs in the second and third years of regulation are expected to fall by 20 per cent each year and costs in the following seven years will fall by 10 per cent each year.

In submissions to the 'Call for Information' paper, a number of businesses stated that if regulation proceeded product testing costs and administration costs would increase significantly while other businesses indicated these costs would not increase. The survey results seem to indicate that the problem is not widespread (though the survey sample size was not large). On one hand it seems reasonable to believe that increased costs under the regulatory option will be high and on the other, taking into account the current apparent high level of safe articles being supplied in Australia, costs may not be as high as expected. Therefore a scaling factor of 50 per cent has been applied to the calculated costs. There is some uncertainty around this estimate and stakeholders are again invited to provide submissions on the estimates.

Table A8.1 sets out the estimated cost of regulation after the scaling process described above has been applied.

Table A8.1: Summary of estimated additional costs due to regulation averaged over the 10-year period from 2015-16 to 2024-25, \$m

Range of estimated costs	Average
Minimum	8
Maximum	29
Midpoint	18

The average additional cost per business over the 10 year period is set out in Table A8.2. Estimates are calculated based on the total additional costs set out in Table A8.1 and the total number of affected businesses (details of which are provided below).

Table A8.2: Additional cost per business (regardless of size) averaged over the 10-year period from 2015-16 to 2024-25, \$

Cost per business	Average
Minimum	628
Maximum	2 228
Midpoint	1 428

The percentage of average additional cost (in 2015-16) to estimated industry revenue for 2015-16 is set out in Table A8.3. Estimates are based on the figures used to derive Table A8.1 and estimated industry revenue figures for the 2015-16 year provided by IBISWorld.¹¹¹

Table A8.3: Percentage of additional cost (2015-16) to estimated industry revenue (2015-16), %

Percentage of additional cost to revenue	Average (%)
Minimum	0.1
Maximum	0.3
Midpoint	0.2

The estimated additional cost for each direct and prolonged contact article due to the additional costs arising from regulation (assuming suppliers pass on all additional costs) is estimated to be 6 cents per article in the first year of regulation (i.e. 2015-16). This estimate is based on:

¹¹¹ IBISWorld, *Clothing Retailing in Australia*, Industry Report G4251, November 2014 and IBISWorld, *Fabric Retailing in Australia*, Industry Report G4214, January 2014.

- a population of 24.3 million people at June 2016, increasing at a rate of 1.7 per cent each year¹¹²
- regulation is estimated to impact articles used by all Australians, from birth to death and each person would purchase (or have purchased for them), 25 new direct and prolonged contact articles each year¹¹³
- the estimated additional cost to business in the first year of regulation (i.e. 2015-16).

Derivation of costs

Substantive compliance costs

Substantive compliance costs are costs incurred to deliver the regulated outcomes being sought. The cost of testing direct and prolonged contact articles to establish that they meet regulation make up substantive costs.

Substantive costs depend on the number of tests businesses conduct and the cost of testing.

Table A8.7 sets out the number of businesses likely to be affected by regulation. They have been divided into self-employed, small, medium and large businesses based on data from the Australian Bureau of Statistics.

Table A8.8 sets out an estimation of the number of tests each size of business is likely to need to conduct. A number of large businesses provided information on the number of additional tests they would need to undertake under the regulatory option. The estimate for large businesses is based on that advice and the estimates for other businesses have been pared back based size (i.e. medium size businesses conducting fewer tests than large businesses etc.). As noted above, estimates are stated in both minimum and maximum number of tests per size of business.

Table A8.9 sets out the cost of testing in Australian dollars.

Substantive costs are estimated by multiplying the number of businesses, the number of tests and the cost of testing. The midpoint (between minimum and maximum) is then determined.

A summary of substantive costs in the first year of regulation is set out in Table A8.4.

¹¹² Based on estimates of current population (on 14 December 2014) and the current rate of increase in population provided by Australian Bureau of Statistics, <http://www.abs.gov.au/ausstats/abs@.nsf/mf/3101.0>

¹¹³ It is anticipated that regulation would apply to direct and prolonged contact articles for all Australians (i.e. cradle to grave). It is estimated that on average, consumers would purchase, or have purchased for them, approximately 30 articles each year. Given the range of articles regulation is likely to apply to, an estimate of 25 articles per person seems reasonable. If the actual number were to be 15 articles per person the additional cost per article would be around 9 cents per article, and if the number of articles is 35 per person, the additional cost per article would be 4 cents in the first year. These costs per article will decline each year as the additional cost to business falls (as explained in the RIS).

Table A8.4: Summary of substantive compliance costs in the first year of regulation (2015-16), \$m

Stakeholder (includes costs of both clothing and Manchester and other textile goods suppliers)	Non-employing	Small 1-19 employees	Medium 20-199 employees	Large 200+ employees	Total
Testing costs					
Minimum estimated additional cost	2.0	7.3	1.1	1.3	11.7
Maximum estimated additional cost	6.1	24.5	6.4	4.7	41.6
Midpoint estimated additional costs	4.0	15.9	3.8	3.0	26.7

Administration costs

It is anticipated that business compliance staff will need to perform a number of additional tasks. Costs depend on the estimated:

- number of businesses affected (Table A8.7)
- number of tests conducted (Table A8.8)
- hourly rate for compliance staff (Table A8.10)
- time spent on each task.

The tasks which create additional administrative costs are:

- Managing compliance testing – negotiating contracts for testing with an accredited test laboratory, organising batch samples for testing, reviewing test results. Estimated time per test – 30 minutes.
- Record keeping – Maintaining internal records of compliance with regulation. Estimated time per test – 15 minutes.
- Internal reporting – Reporting to management on levels of compliance. Estimated time per test – 5 minutes.

The time estimates for administrative tasks take into account efficiencies by managing a number of compliance tests at one time. It is assumed that the more testing a business conducts, more efficient it will be in its 'back office' processes.

Table A8.5 sets out a summary of estimated administrative costs in the first year based on the estimated number of additional tests likely to be conducted.

Table A8.5: Estimated additional administrative costs in the first year of regulation (2015-16), \$m

Stakeholder (includes costs of both clothing and Manchester and other textile goods suppliers)	Non-employing	Small 1-19 employees	Medium 20-199 employees	Large 200+ employees	Total
Managing compliance testing					
Minimum estimated additional cost	0.8	3.1	0.5	0.5	4.9
Maximum estimated additional costs	2.5	10.2	2.7	2.0	17.4
Record keeping					
Minimum estimated additional cost	0.4	1.5	0.2	0.3	2.5
Maximum estimated additional cost	1.3	5.1	1.3	1.0	8.7
Internal reporting					
Minimum estimated additional cost	0.1	0.5	0.1	0.1	0.8
Maximum estimated additional cost	0.4	1.7	0.4	0.3	2.9
Total minimum estimated additional administrative costs	1.4	5.1	0.8	0.9	8.2
Total maximum estimated additional administrative cost	4.2	17.0	4.5	3.3	29.0
Midpoint for total estimated additional administrative cost	2.8	11.1	2.6	2.1	18.6

Delay costs

Delay costs reflect the cost to businesses due to the delay in offering product for sale because of testing for compliance with regulation.

Some direct and prolonged contact articles are seasonal and delays delivering product for supply mean the period where full prices can be charged (prior to end of season discounting) is reduced.

As not all direct and prolonged contact articles are seasonal (e.g. underwear and socks) and therefore not subject to seasonal discounting and not all articles subject to seasonal discounting will be subject to delay costs because business are expected factor testing into delivery timelines, it is anticipated that only 3 per cent of articles tested will create delay costs. Based on discussion with business, it has been assumed that each delay due to testing will cost a business \$2000. This estimate will vary depending on the price of each article and the size of the consignment, therefore delay costs may vary significantly from business to business.

Table A8.6: Estimated additional delay costs in the first year of regulation (2015-16), \$m

Stakeholder (includes costs of both clothing and Manchester and other textile goods suppliers)	Non-employing	Small 1-19 employees	Medium 20-199 employees	Large 200+ employees	Total
Cost of delay					
Minimum estimated additional cost (\$m)	1.7	6.2	0.9	1.1	9.9
Maximum estimated additional cost (\$m)	5.1	20.6	5.4	3.9	35.0
Midpoint estimated additional costs (\$m)	3.4	13.4	3.2	2.5	22.5

Data and assumptions supporting substantive compliance, administrative and delay costs

Number of businesses affected

The Australian Bureau of Statistics (ABS) provides data on the number of retailers in the clothing and textile industries. Table A8.7 provides retailer data. Basing calculations on retailers is considered appropriate. Many retailers bypass wholesalers and source goods direct from the manufacturer. Basing cost estimates on wholesalers alone may underestimate costs.

Table A8.7: Clothing and Manchester and other textile goods retailers at 30 June 2013¹¹⁴

Stakeholder	Non- employing ¹¹⁵	Small	Medium	Large	Total
		1-19 employees	20-199 employees	200+ employees	
Clothing retailers	4901	6067	294	58	11320
Manchester and other textile goods retailers	767	798	16	4	1585

Estimated number of tests required to gauge compliance with regulation

The number of tests that business may need to conduct has been estimated based on industry submissions to the call for information paper and ACCC discussion with stakeholders. Table A8.8 sets out the estimated minimum and maximum tests based on the size of businesses.

¹¹⁴ Australian Bureau of Statistics, *8165.0 Counts of Australian Businesses, including Entries and Exits, June 2009 to June 2013*, Release date 31 May 2014. Available: <http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/8165.0Jun%202009%20to%20Jun%202013?OpenDocument>

¹¹⁵ A 'non-employing' business is defined by the ABS as: a business without an active Income Tax Withholding (ITW) role or which has not remitted ITW for five consecutive quarters. A business which employs and pays a salary to (or plans to employ and pay a salary to) one or more persons, is required to register as such with the Australian Tax Office and have an ITW role.

Table A8.8: Estimated number of compliance tests for each size of business¹¹⁶

Stakeholder	Non- employing	Small 1-19 employees	Medium 20-199 employees	Large 200+ employees
Clothing retailers				
Minimum number of tests per business	1	10	50	300
Maximum number of tests per business	10	50	300	1100
Manchester and other textile goods retailers				
Minimum number of tests per business	1	10	50	200
Maximum number of tests per business	10	50	200	1000

The cost of testing

The cost of testing is set out in Table A8.9. Some garments require more than one test per garment. For example, a pair of jeans may require a test on the garment shell and another test on the pocket lining which will be in direct contact with the skin. The costs are based on the price per test offered to the ACCC and information provided to the ACCC from stakeholders. Some businesses conducting large numbers of testing may be able to negotiate volume discounts with test laboratories.

Table A8.9: Cost of testing

Price and exchange rate	Amount per test
Cost per test (USD) ¹¹⁷	\$62
USD:AUD exchange rate	1.15
Cost per test (AUD)	\$71.30

¹¹⁶ Estimated number of additional tests by size of business is based on advice provided by business to the ACCC.

¹¹⁷ Estimated based on prices quoted by business and the price paid by the ACCC for testing.

Business compliance staff hourly rate

Table A8.10 sets out the estimated hourly rate for compliance staff. The rate and scaling factor of 1.75 takes account of wages, non-wage labour costs and overheads. It is based on figures provided by OBPR.¹¹⁸

Table A8.10: Compliance officer hourly rate

Labour cost	Rate
Labour hourly rate	\$34.02
Hourly rate multiplier to account for non-wage labour and overheads	1.75
Gross labour hourly rate	\$59.54

Stakeholder feedback on estimation of additional costs

Stakeholders are encouraged to make submissions and comment on the estimations and assumptions used to derive the additional costs set out above.

The estimation of additional costs set out in this draft RIS may change once submissions are received. Changes will be reflected in the final RIS.

¹¹⁸ Department of Prime Minister and Cabinet, Office of Best Practice Regulation, *Regulatory Burden Measurement Framework Guidance Note*, July 2014, p.15, available: https://www.dpmc.gov.au/deregulation/obpr/reporting-publications/publications/guidance/docs/005_Regulatory_Burden_Measurement_Framework.pdf

Attachment 9: List of 22 aromatic amines and their safe limits

Particulars of Goods					
Type of consumer good	Concentration of hazardous chemical	Chemical name and Chemicals Abstract Service (CAS) number of aromatic amines.	Health effects	Reference	Examples of types of consumer goods
Clothing, textiles and leather articles in direct and prolonged contact with the human skin or oral cavity.	Total concentrations of aromatic amines over 30 mg/kg (or 0.003% by weight) shall not be present in the described type of consumer good	<ol style="list-style-type: none"> 1. 4-Aminodipheny (CAS 92-67-1) 2. Benzidine (CAS 92-87-5) 3. 4-Chloro-o-Toluidine (CAS 95-69-2) 4. 2-Naphthylamine (CAS 91-59-8) 5. o-Aminoazotoluene (CAS 97-56-3) 6. 2-Amino-4-Nitrotoluene (CAS 99-55-8) 7. p-Chloroaniline (CAS 106-47-8) 8. 2,4-Diaminoanisole (CAS 615-05-4) 9. 4,4'-Diaminodiphenylmethane (CAS 101-77-9) 10. 3,3'-Dichlorobenzidine (CAS 91-94-1) 11. 3,3'-Dimethoxybenzidine (CAS 119-90-4) 12. 3,3'-Dimethylbenzidine (CAS 119-93-7) 13. 3,3'-Dimethyl-4,4'diaminodiphenylmethane (CAS 838-88-0) 14. p-Cresidine (CAS 120-71-8) 15. 4,4'-Methylene-Bis(2-Chloroaniline) (CAS 101-14-4) 16. 4,4'-Oxydianiline (CAS 101-80-4) 17. 4,4'-Thiodianiline (CAS 139-65-1) 18. o-Toluidine (CAS 95-53-4) 19. 2,4-Toluylenediamine (CAS 95-80-7) 20. 2,4,5-Trimethylaniline (CAS 137-17-7) 21. o-Anisidine (CAS 90-04-0) 22. p-Aminoazobenzene (CAS 60-09-3) 	<p>All the aromatic amines listed are either known or suspected human carcinogens.</p> <p>The critical health effects for risk characterisation include systemic long-term effects including carcinogenicity, reproductive toxicity and developmental toxicity.</p>	<p>The NICNAS IMAP Human Health Tier II Assessment for benzidine-based dyes recommended that the supply of textiles and leather goods likely to come into direct and prolonged contact with the human skin that may plausibly result in exposure to benzidine-based dyes at unacceptable concentrations be restricted:</p> <p>http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=513</p> <p>Identifying benzidine-based dyes in these consumer goods means testing for certain aromatic amines.</p>	<p>The consumer goods captured by this regulation include but are not limited to:</p> <ul style="list-style-type: none"> • clothing such as shirts, singlets, pants, jeans, shorts underwear, socks, gloves and footwear such as sandals; • bedding, such as sheets, pillow cases doona covers sleeping bags; and • yarn and fabrics supplied to consumers where the finished article is likely to be in direct and prolonged contact with the skin.