**ATTACHMENT 1**

# Productivity Commission Study of the Regulatory Burden on the Chemicals Industry

# Report of ACCORD Industry Survey on the impacts and costs of regulation

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# 1 The ACCORD Survey: purpose and background

This Survey was initiated to collect impact and cost data related to the regulatory burden on the formulated chemicals industry along with illustrative case studies based on company experiences.

This Survey Report has been prepared by ACCORD as an important supplementary report to the Productivity Commission study of chemicals and plastics regulation.

Its genesis goes back to early 2007, when ACCORD members started to consistently flag specific concerns relating to the performance of our sector's key regulatory agency, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

It is for this reason that the Survey focuses primarily on issues relating specifically to NICNAS matters.

However, ACCORD feels that these are indicative and illustrative of many of the problems and issues encountered throughout Australia's complex and confusing system of chemicals and plastics regulation. As such the Survey findings highlight a range of key issues that could in essence be considered the tip of the iceberg.

Prior to deciding to initiate a Survey, ACCORD scoped the major concerns regarding aspects of NICNAS operations via discussions with the company specialists in our Regulatory Affairs Committee.

This culminated in a joint workshop with PACIA and ACCORD members on 4 October 2007 to further scope out the main problems being experienced by companies with NICNAS operations.

As an outcome of this workshop, ACCORD decided to develop and issue a detailed Survey to member companies to formally collect information. This was to be used both in direct discussions with NICNAS and also to provide additional data in support of the industry's submissions to the Productivity Commission study.

The survey consisted of two parts, the first collecting data broadly, in areas relevant to all industry members.

The second part asked targeted questions of key members in a range of supply chains to identify the:

- lost opportunities - the impact of the current regulatory system on the realisation of commercial opportunities;
- effectiveness or otherwise of the Low Regulatory Concern Chemicals Regulatory Reforms (LRCC), and;
- operational performance of the Regulator.

# 2 Key findings of the Survey

- Eighty-nine percent (89%) of ACCORD industry and regulatory consultant members responded to the ACCORD Industry Survey.
- Ninety-two percent (92%) of survey participants having experience with NICNAS reported negative impacts from this association.
- Ninety-three percent (93%) of respondents who have experienced difficulties with NICNAS reported that products/formulations from their worldwide portfolio are unavailable in Australia due to Australian regulatory factors.
- Products are formulated/reformulated to avoid dealing with NICNAS.
- The current regulatory system is a barrier to innovation.
- The consequences of regulatory burden reported by members show that Australia is placed at a disadvantage with regard to commercial opportunity, compared to the major EU and US markets.

- Costs, data and time factors are individually cited in over fifty percent (50%) of cases as causes of regulatory burden.

- Based on financial estimates provided by a reasonably representative sample of ACCORD member companies, it is estimated that the **lost opportunity cost to the industry** represented by ACCORD (in terms of products being unavailable on the Australian market) is **$400 million**.

- The current regulatory system is biased towards larger companies (companies with a turnover of greater than $10 million).

- Thirty-six percent (36%) of larger companies were still prepared to pursue Australian market entry for a chemical/product despite saying that the data requests in Australia were too great, compared to five percent (5%) of smaller companies (turnover less than $10 million).

- Sixteen percent (16%) of larger companies were still prepared to pursue Australian market entry despite saying that regulatory costs in Australia were too high, compared to nil for smaller companies.

- In around fifty percent (50%) of cases where a company has the opportunity to self assess through the LRCC initiative, they choose not to do so, for reasons such as onerous auditing requirements.

- In general, with the various LRCC reforms, at the time of introduction of the chemical the regulatory burden is reduced, but annual reporting has significantly increased the ongoing regulatory compliance and red-tape burden for industry.

- Irrelevant data is often requested and it is frequently considered that the level of assessment is greater than the level of risk.

- An average of thirty-eight percent (38%) of assessments required unique Australian data.

- There would be advantage in streamlining and co-ordinating the activities of the different regulatory agencies, especially in terms of determining which agency is actually responsible for any given product or situation.

# 3 Overview

The Productivity Commission (PC) has indicated that particular value would be placed on industry-wide impact and cost data related to the regulatory burden on the chemicals industry. As a representative of a significant sector of the chemicals industry, ACCORD developed a survey to collect data and costs from its members.

ACCORD Australasia is the peak national industry association that represents the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers.

With an estimated $10 billion plus in annual product sales, the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy. It is a dynamic and growing industry, employing Australians and - through our industrial and institutional sector - supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions, farmers and consumers. Our industry has more than 50 manufacturing operations throughout Australia and member companies include large global consumer product manufacturers to small dynamic Australian-owned businesses.

ACCORD, on behalf of its member companies, has a specific and direct interest in the Productivity Commission's (PC) study. In particular it looks forward to recommendations for reform for the establishment of an effective and efficient governance framework for the chemicals sector.

ACCORD has been promoting the need for a fully integrated national framework for chemical policy and management for a considerable period and regards this as a high priority.

This Survey indicated that regulatory impacts were related in large part to Australia's unique regulatory system and that inefficiencies delivered cost burdens resulting in a business operating environment which stifled competitiveness and innovation.

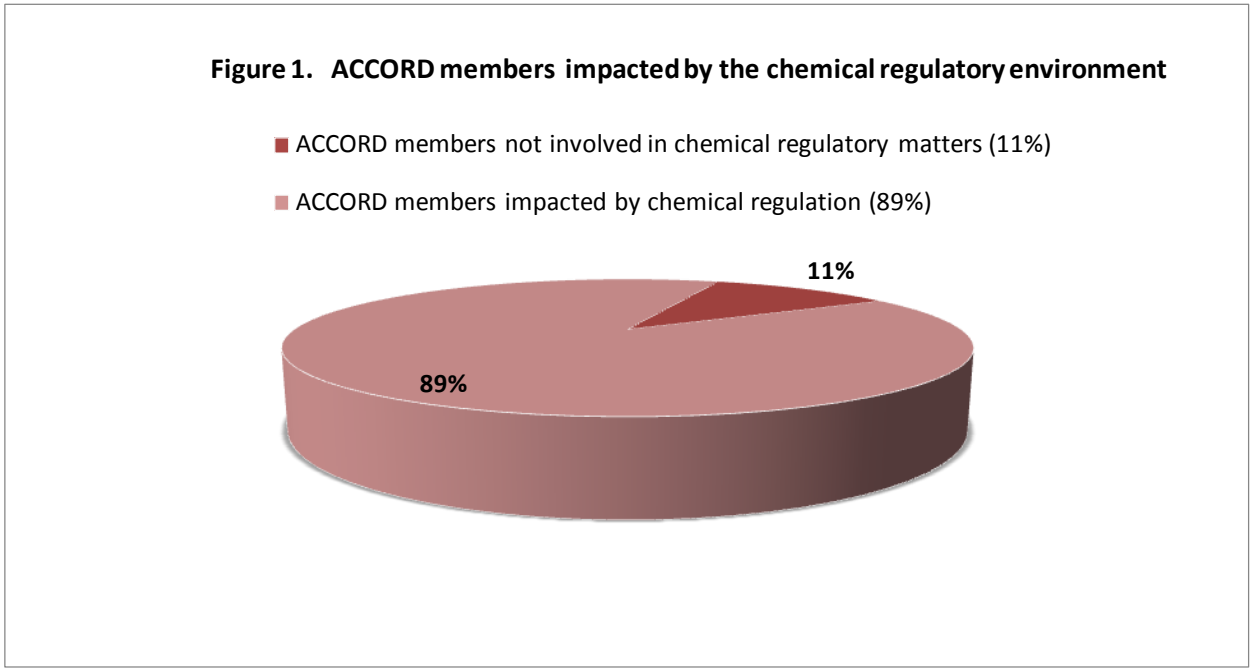
The ACCORD Industry Survey had two parts.

In the first part a general, broad ranging survey was made of the membership body to ascertain NICNAS regulatory burdens and consequences.

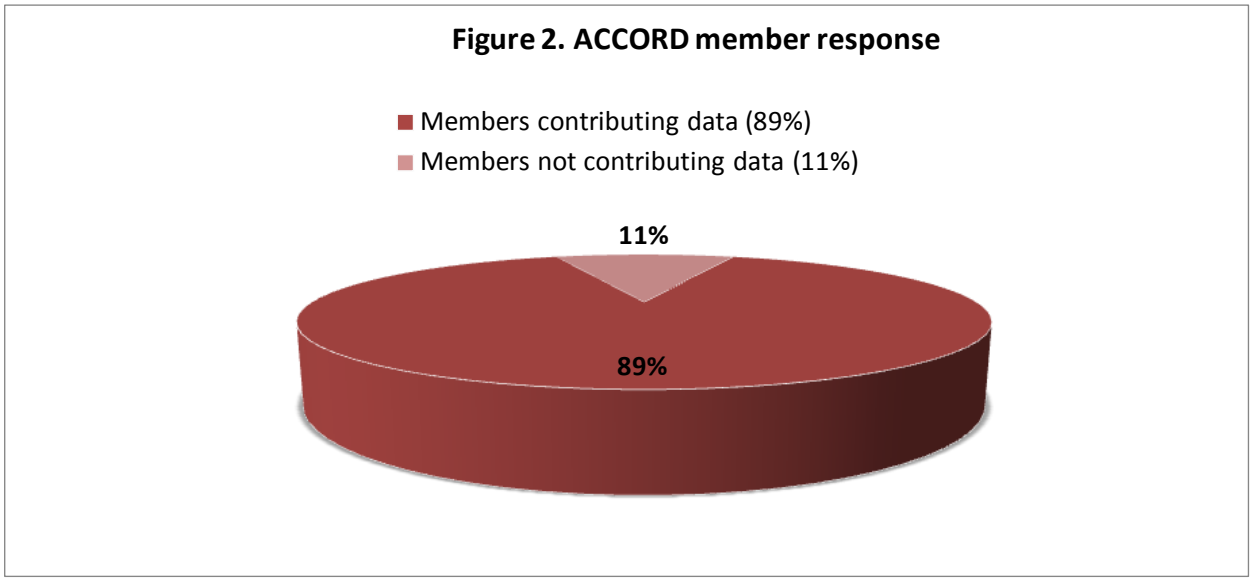
In the second part of the survey more detailed questions were put forward. A smaller number of targeted member companies participated in this part and considered issues of lost opportunities, the effectiveness or otherwise of LRCC Regulatory Reforms and the operational performance of the regulator.

# 4 Survey participation

At the time of this survey (November 2007) ACCORD had 99 members. Of these, 11 are not involved in chemical regulatory matters and therefore were not invited to participate in data collection. These are associate members operating in the areas of: specialist laboratories and testing; equipment and packaging supply; logistics and; legal and business management. The 88 members asked to contribute to the survey are from: the Consumer, Cosmetic and Personal Care industries (50 members); the Hygiene and Specialty Products industries (32 members) and; the Regulatory and Technical Consultant sector (six associate members). Figure 1 represents the proportion of members impacted / not impacted by chemical regulatory matters.




Of the members asked to contribute to Part 1 of the industry survey, 78 of the 88 responded (see Figure 2). The findings are therefore considered to be highly representative of the complete ACCORD membership.

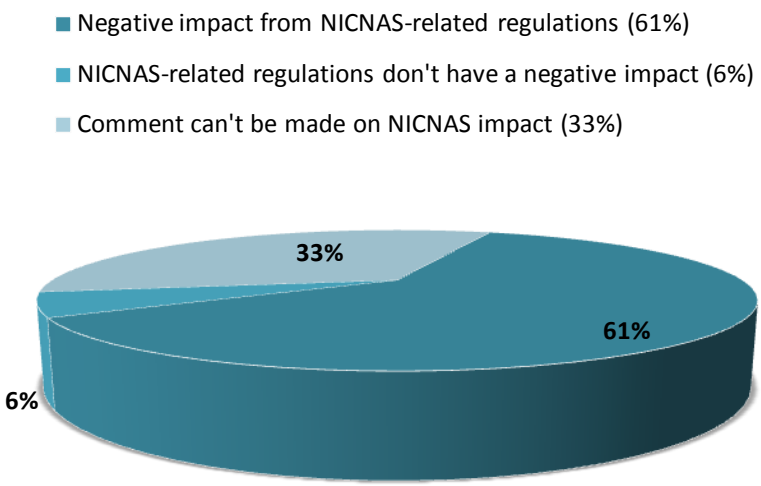



Part 2 of the survey was targeted to a smaller subset of companies and represented a good cross section of the ACCORD membership base.

# 5 Part 1: Survey of broad ACCORD membership on regulatory burden

Of the 72 chemical industry members contributing data, 44 reported a negative impact from NICNAS-related regulation, four reported no negative impact and 24 reported that they couldn't comment on NICNAS current activities (see Figure 3).

**Figure 3. NICNAS regulatory impact**




The main reasons members gave for being unable to comment on NICNAS were that their company formulates and/or distributes products with materials already listed on the Australian Inventory of Chemical Substances (AICS) and/or that they consider raw material suppliers responsible for listings.

It is considered very likely that some of these companies only market products with ingredients currently listed in the Australian Inventory of Chemical Substances as a way of avoiding the regulatory burden associated with listing and that therefore the negative findings expressed in this Survey underestimate the overall level of negative impact across the industry.

Four charts follow, showing the consequences of the regulatory burden, and the causes and factors involved, as given by respondents. Respondents may have reported multiple causes and consequences. The data is reported in the charts as a proportion of the overall 44 negative findings.

Three members reported that their company policy not to get involved with NICNAS applications was due to a perception that the process was too difficult and expensive. These companies had not completed any NICNAS applications but made their decision following attendance at NICNAS seminars and from discussions they had with other industry people. This indicates a need for greater and clearer guidance from NICNAS, a factor mentioned in 14 percent of cases.

ACCORD has continually argued that the Australian and New Zealand markets are too small to create and sustain a unique regulatory regime which is out of step with our major trading partners.

An overwhelming 93% of respondents who have experienced difficulties with NICNAS reported that products/formulations from their worldwide portfolio are unavailable in Australia due to Australian regulatory factors.

The regulatory system was also seen as a barrier to innovation by 59%.

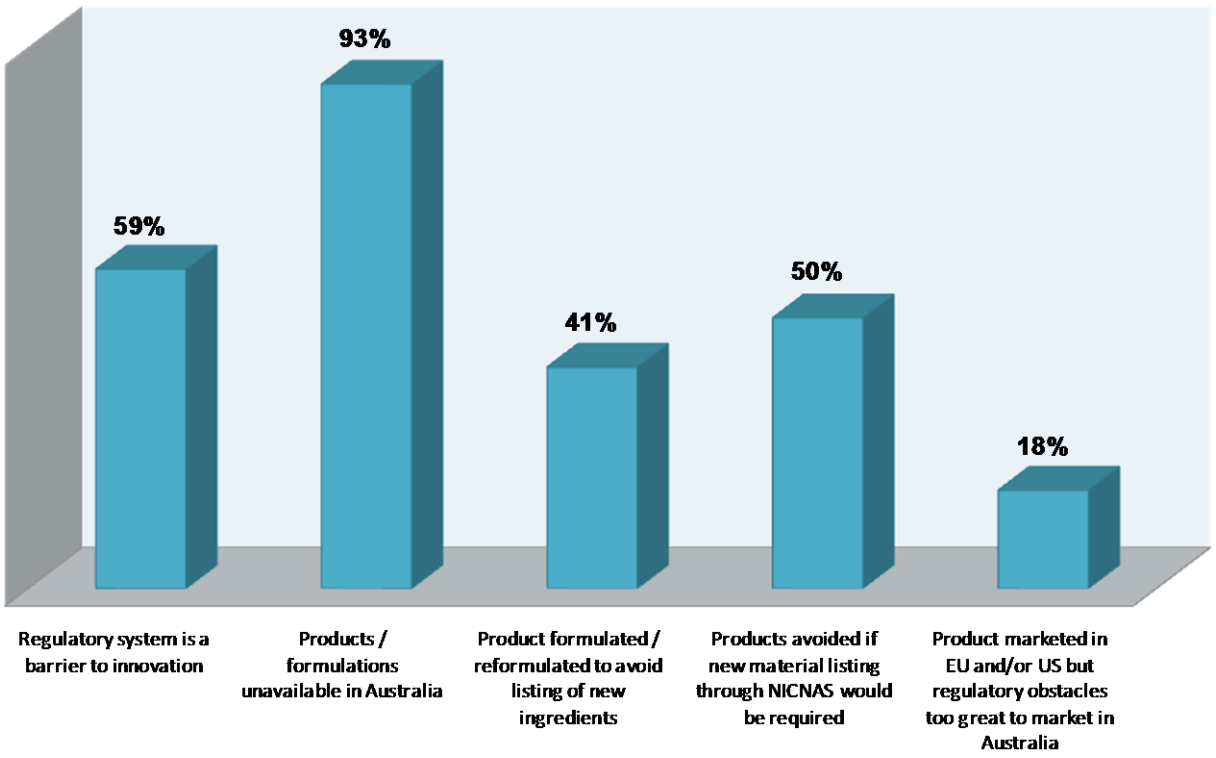
Additonally, 41% reported that products were formulated/re-formulated to avoid listing material on the Australian Inventory of Chemical Substances through NICNAS and 50 percent avoided products that would require listing through NICNAS.

Further to this, 18 percent reported that their companies marketed products in the EU and/or US but that the regulatory obstacles were too great to market these same products in Australia.

All consequences of regulatory burden reported by members (see Figure 4) show that Australia is placed at a disadvantage with regard to commercial opportunities and, more importantly, innovation.

It is also apparent that Australian industry faces an additional resource burden - when companies persist with introductions, they are often incurring additional costs associated with formulating or re-formulating to avoid the difficulties of dealing with the regulatory system.

**Figure 4. Consequences of regulatory burden**



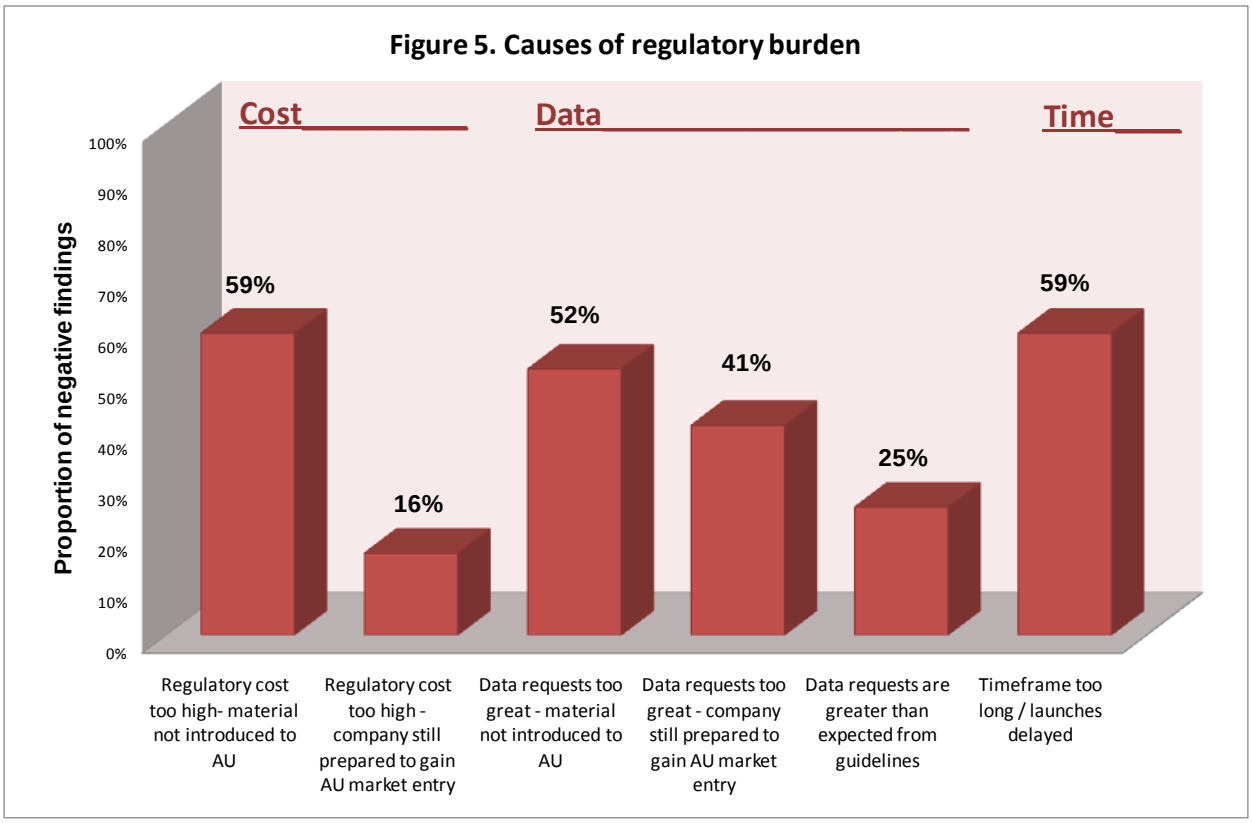

Costs, data and time factors are individually cited in over 50 percent of cases as causes of regulatory burden.

For businesses introducing new innovations and products, launch delays are of great commercial significance. To miss a launch date can mean missing an entire year of sales and ultimately compromise the commercial return associated with undertaking development work for innovation. A problem with the existing regulatory system relates to uncertainty in achieving 'approval' within the published statutory timeframes. While it is not incumbent on regulators to work to a company's desired launch date, it is essential that the process for consideration of applications is efficient and provides certainty in terms of meeting agreed timeframes.

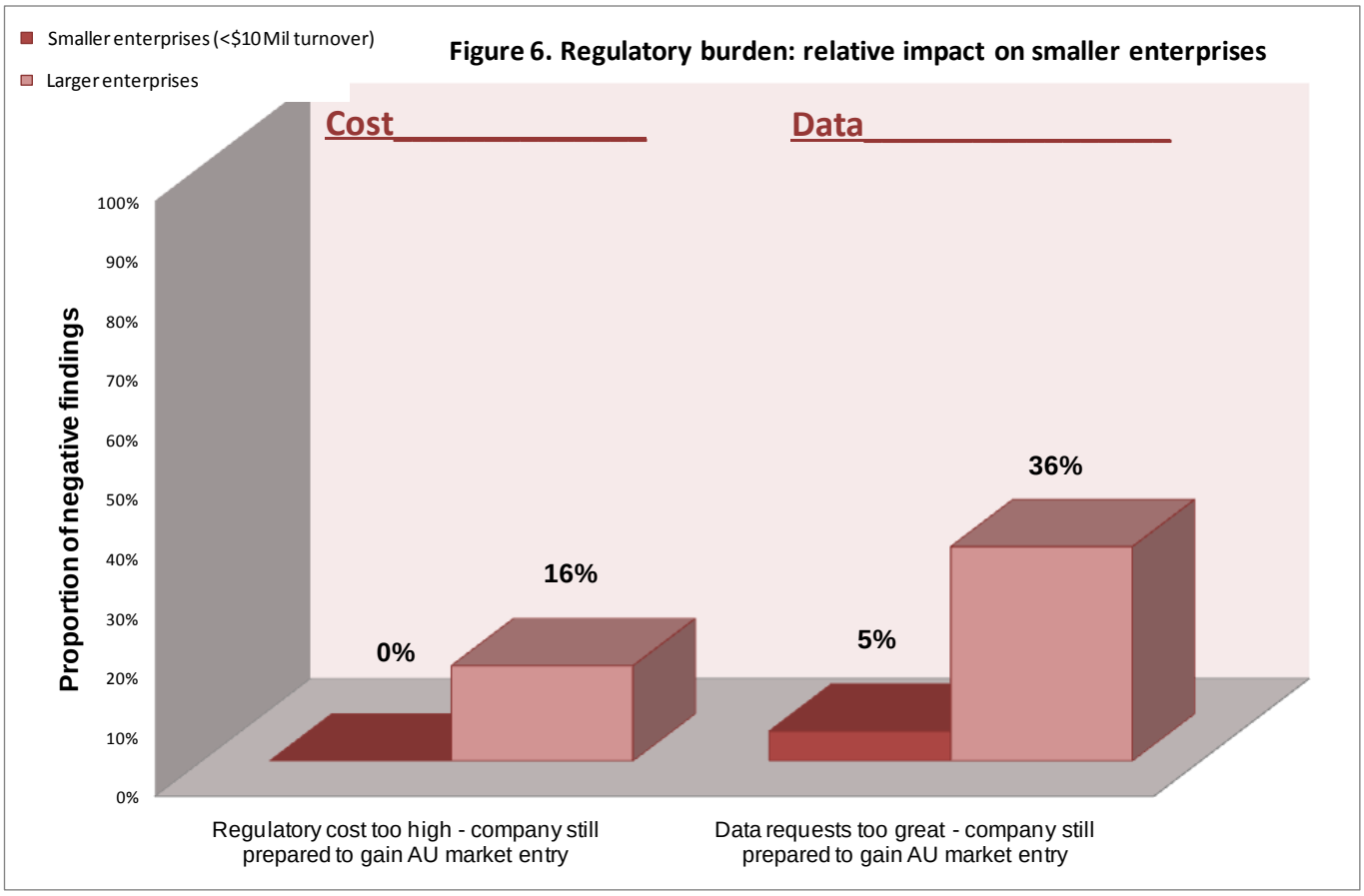
The impact of cost and time on introduction of a product to Australia should also be noted.

For example, in 59 percent of cases the high regulatory cost[1] results in non-introduction to Australia and in only 16 percent of cases the company was still prepared to do the work to gain entry to the Australian market. Cost and time impacts are shown in Figure 5.

[1] *Table 2 – Worldwide Registration Costs Comparisons* on page 49 of ACCORD's 24-10-07 submission to the Productivity Commission showed that Australia has the costliest system in terms of government application fees ($14,418). This compares to $2,797 for the USA and $122 for Korea. The cost differential also needs to be put into perspective in comparison to the major market size difference between, say, Australia and the USA. This factor acts as a barrier to the introduction of chemicals/products.

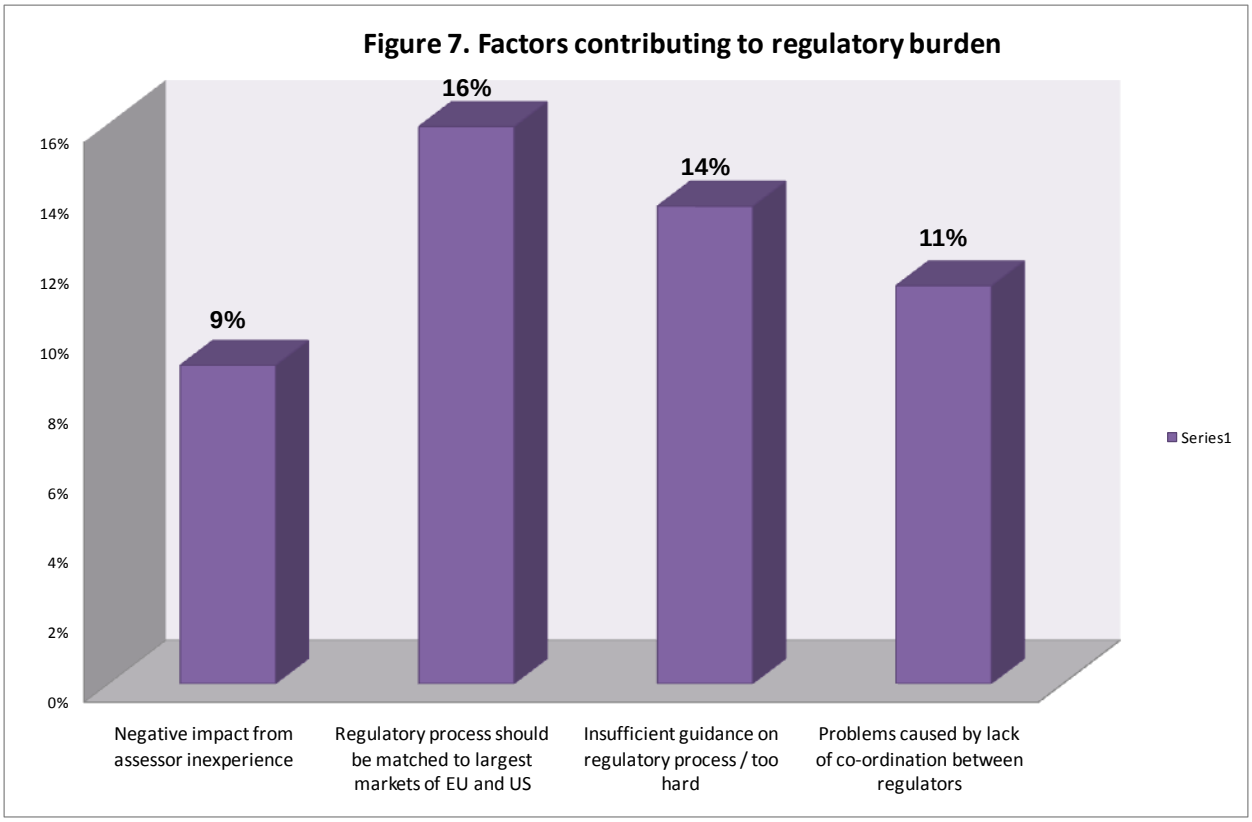



The impact of cost and data requirements on the ability of smaller enterprises[2] to introduce new chemistry to Australia can be seen in Figure 6. This compares the number of smaller versus larger companies prepared to gain Australian market entry under cost and data conditions they consider onerous.




[2] $10 Mil turnover

A number of other factors (see Figure 7) indicate that there would be great advantage in streamlining and co-ordinating the activities of the different regulatory agencies. The resource savings in such an approach could be channelled into training of assessors and applicants. In addition, harmonisation and mutual recognition of Australian regulatory processes with those of the larger EU and US markets could reduce the regulatory workload for industry.




ACCORD Members made a number of comments in responding to the Survey, describing, for example, their experiences or company policy surrounding regulatory burden. Examples of those of importance to Productivity Commission deliberations are listed below. Case studies submitted by members are in a latter part of this report.

- "We try and do the right thing but the regulations are too complicated".
- "We believe there should be guidelines and lists that everyone can follow, and that are updated regularly."
- "We avoid choosing products that would require listing of new ingredients on the Australian Inventory of Chemical Substances (AICS)."
- "The only interaction that we have had with NICNAS over the last two years is with low volume/percentage ingredients for cosmetics. The changes in this area have been very beneficial to our business because the new regulations mean that there are no regulatory delays in getting our products to market."
- "We develop new products but restrict ourselves to materials already listed on the Australian Inventory of Chemical Substances (AICS). We have the perception from seminars with NICNAS and from what we have heard that it would be too hard and expensive."
- "Our policy is to not go ahead with any products that would require notification through NICNAS - the cost wouldn't be justified and it is too hard to get data on innovative chemistry."
- "Bringing materials in through NICNAS is an onerous task and introducing something new is always questioned because of the burden. On rare occasions we have gone through the process ourselves but it is very hard to get all the data."
- "It is straight-forward preparing the data for EU but there are constant issues with NICNAS."

- “Our company automatically doubles the indicated time to allow for a slow process at NICNAS.”
- “Products are re-formulated if the ingredients aren't on the Australian Inventory of Chemical Substances (AICS).”
- “Suppliers used to promote innovate materials but then would get into difficulty when they had orders and couldn't get through NICNAS. Now suppliers are much more cautious and only promote materials already listed on the Australian Inventory of Chemical Substances (AICS).”
- “Inexperienced assessors ask for more data than the experienced assessors because they don't have the experience with risk assessment to know what is reasonable.”
- “The process is too expensive, especially when some data is Australia-specific.”
- “We have given up on trying to introduce new materials because the data requirements, cost and time are too great. This is not good for innovation.”
- “We would like to use innovative materials from overseas but see NICNAS as obstructive.”
- “If a raw material in a formulation proposed for Australia is not on the Australian Inventory of Chemical Substances (AICS) we either reformulate or drop the product. This is because we do not see a good payoff equation for a market that has such short product life cycles.”
- “We are prepared to spend money to get accreditation marks for the UK and US because the process is defined. We are not prepared to go through NICNAS because the time and cost is open-ended.”
- “The material was commercial in the US, without the same requirements as in Australia. This stifled commercial opportunity.”
- “We make no Standard Notifications (STD) because of the prohibitive cost of doing so. Hence we get away with a Limited Notification (LTD) and let them run out in five years (i.e. become standard by default).”
- “The burden is not in cost of making applications because many, if not most applications don’t get made because of the time and cost. So the cost is in not making applications.”
- “One of the strongest marketing cases for new chemicals is that they are safer to humans and the environment. Why would a company use a harmful chemical when it can be substituted by a safer one? Only one reason in Australia, you can’t get access to new chemicals without a lot of cost, time and effort.”

# 6 Part 2: Targeted, in-depth survey on regulatory burden

ACCORD prepared a more detailed survey to identify failures of the regulatory system, with particular reference to barriers to trade and innovation for consumer, cosmetic, hygiene and specialty products. Questions focused on NICNAS but responses on TGA and the APVMA were invited to be submitted separately, along with instances where conflicting Federal, State and Local requirements have caused problems.

The survey was divided into three sections:

SECTION 1: Lost opportunities - the impact of the current regulatory system on the realization of commercial opportunities.

SECTION 2: Rating of the success of the, already implemented, LRCC Regulatory Reforms

SECTION 3: Operational performance of the Regulator

Eleven members participated in this section of the study. Two of the participants were regulatory consultants. The consultants’ experience is drawn from representation of a range of large and small companies, both within and outside the ACCORD membership.

### *6.1 Failure of the regulatory system: lost opportunity*

All industry participants reported that some of their company's worldwide product portfolio is unavailable in Australia due to Australian regulatory factors.

On average, 14 percent of a portfolio was not introduced to Australia in the last two years, for regulatory reasons. Smaller companies are likely to be at a disadvantage in this area.

As can be seen in Table 1, costs, specifically: the regulatory cost compared to expected revenue; the fees for an application; the cost of application preparation, and; the cost and difficulty in obtaining Australia-specific data requirements, were the largest regulatory contributors to product unavailability in Australia.

This section of the survey sought to give more detailed information on the elements of cost, data and time than was collected in the general survey.

In particular, data was sought for cases of lost opportunity (as opposed to the experience reported in the first section for all cases, whether the product came to market or not). It is important to see that the results highlight data and cost, already identified by the wider body of members, as regulatory burdens.

The two most common cost contributors to non-introduction can be linked directly to Australia's unique regulatory system.

These factors are the regulatory cost compared to expected revenue and the cost of obtaining Australia-specific data. It is then not surprising that the difficulty and time involved in obtaining Australia-specific data were frequently cited.

The identification of Australia-specific data requirements as a contributor to lost opportunity indicates the need for an internationally harmonised system here.

The results support ACCORD's argument that for fast moving consumer goods Australia should not impose any additional market entry barriers such as unique notification and assessment requirements[3], if these products already comply with the regulatory requirements of our comparable trading partners such as the European Union (EU), the United States of America (USA), Japan, Canada or New Zealand.

Annual reporting requirements were not a large cause of non-introduction of products to the Australian market, although members do see this as a considerable contributor to regulatory burden (as discussed in the following section of this report).

Specific data on the $AUD cost of lost opportunities in terms of products not made available in Australia because of regulatory barriers was provided by six companies.

On the basis of the known share of the Australian market of these six companies (which are collectively broadly representative of the overall market), ACCORD is able to estimate that the total lost opportunity cost for the sector we represent is in the vicinity of $400 million.

In terms of the overall chemicals industry, including other key sectors in plastics, polymers and paints, this figure would be anticipated to be much higher.

[3] This also applies to trade measurement and ingredient labelling

**Table 1. Identification of cost, data and time elements acting as barriers to introduction of products to the Australian market**

| Factor acting as a barrier to availability on the Australian market | Average occurrence, percent (there may be more than one causal factor reported) |
|---|---|
| **Costs** | |
| Regulatory cost compared to expected revenue | **45** |
| Obtaining Australia-specific data | **43** |
| Application preparation | **17** |
| Application fees | **19** |
| **Data** | |
| Difficulty in obtaining Australia-specific data | **41** |
| **Time** | |
| Obtaining Australia-specific data | **12** |
| Assessment timeframe | **5** |
| Unpredictability of assessment timeframes | **2** |
| Application preparation | **1** |
| **Reporting** | |
| Annual reporting requirements | **1** |

### *6.2 Success of regulatory reforms*

This section of the survey sought to rate the success of the, already implemented, LRCC Regulatory Reforms.

Participants were asked to report on the proportion of cases where self assessment has been an option for their company, but that the decision was to not to self assess. (See Table 2).

**Table 2. Proportion of cases where self assessment has been an option but the decision was to not to self assess.**

| Category | Proportion, Average, % |
|---|---|
| Non hazardous chemicals | 46 |
| Non hazardous polymers | 57 |
| Polymers of low concern | 43 |

Reasons given for the decision not to self assess were:

Auditing requirements: Complicated protocol: Joint company applications

Participants were asked to assess whether the range of LRCC reforms implemented to date had been beneficial in reducing the regulatory burden. Respondents indicated that at the time of introduction of the chemical the regulatory burden is reduced, but that annual reporting has significantly increased the ongoing regulatory burden.

### *6.3 Operational performance*

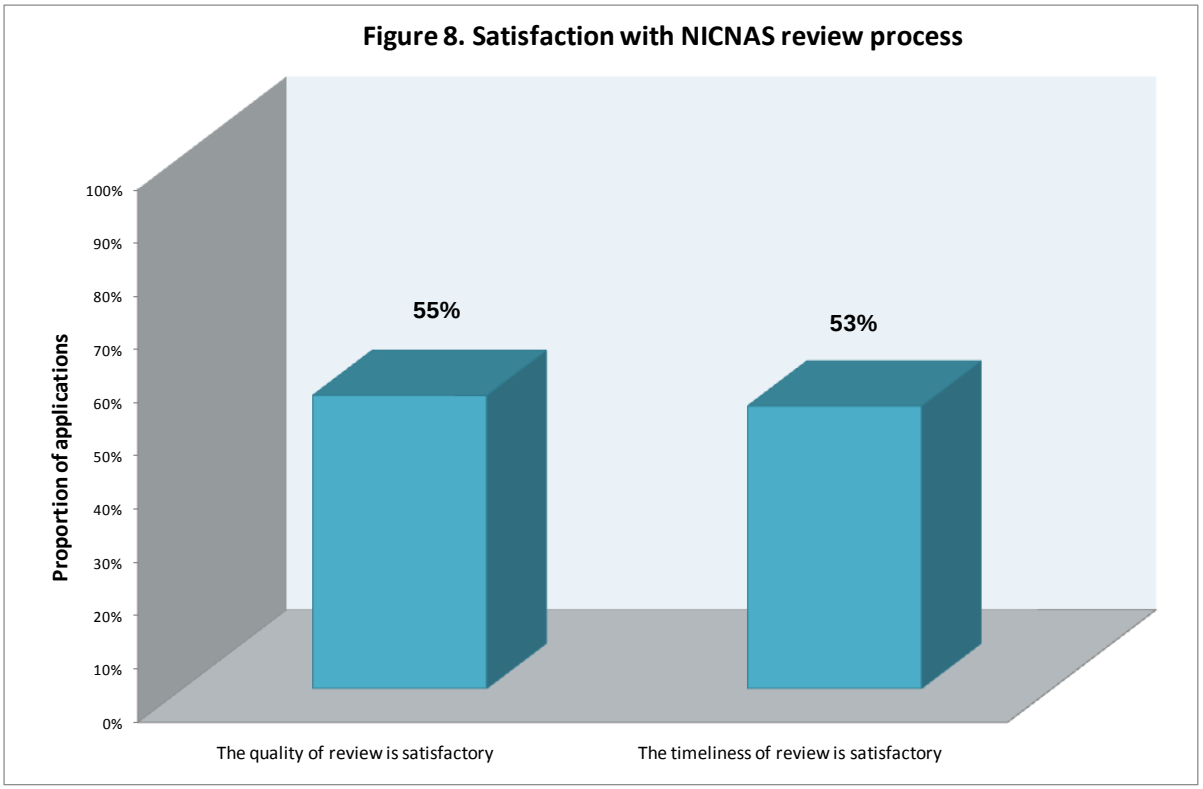
A number of survey questions were designed to elicit member opinion on NICNAS operational performance. Responses ranged from approval to disapproval of operational performance. This variation is not surprising when the response to questions on assessment consistency is considered.

Respondents rated consistency from one application to another with regard to assessment process and assessor performance. The responses varied considerably. On average, respondents did not agree that there was consistency. Some comments follow:

- "The amount of information required depends significantly on the assessor."
- "I can model an application on a previous assessment report and still get a different range of questions and amendments even for similar substances."
- "Inexperience generally causes conservative assessments."

A number of questions were put to participants to assess areas of concern within the review process. The quality and timeliness of the review was considered satisfactory in only about 55 percent of cases (see Figure 8). Whether the responses were due to actuality or perception is not known. However, it is clear that there is considerable room for improvement in the assessments themselves and / or the communication with applicants on the process and requirements.

**Figure 8. Satisfaction with NICNAS review process**

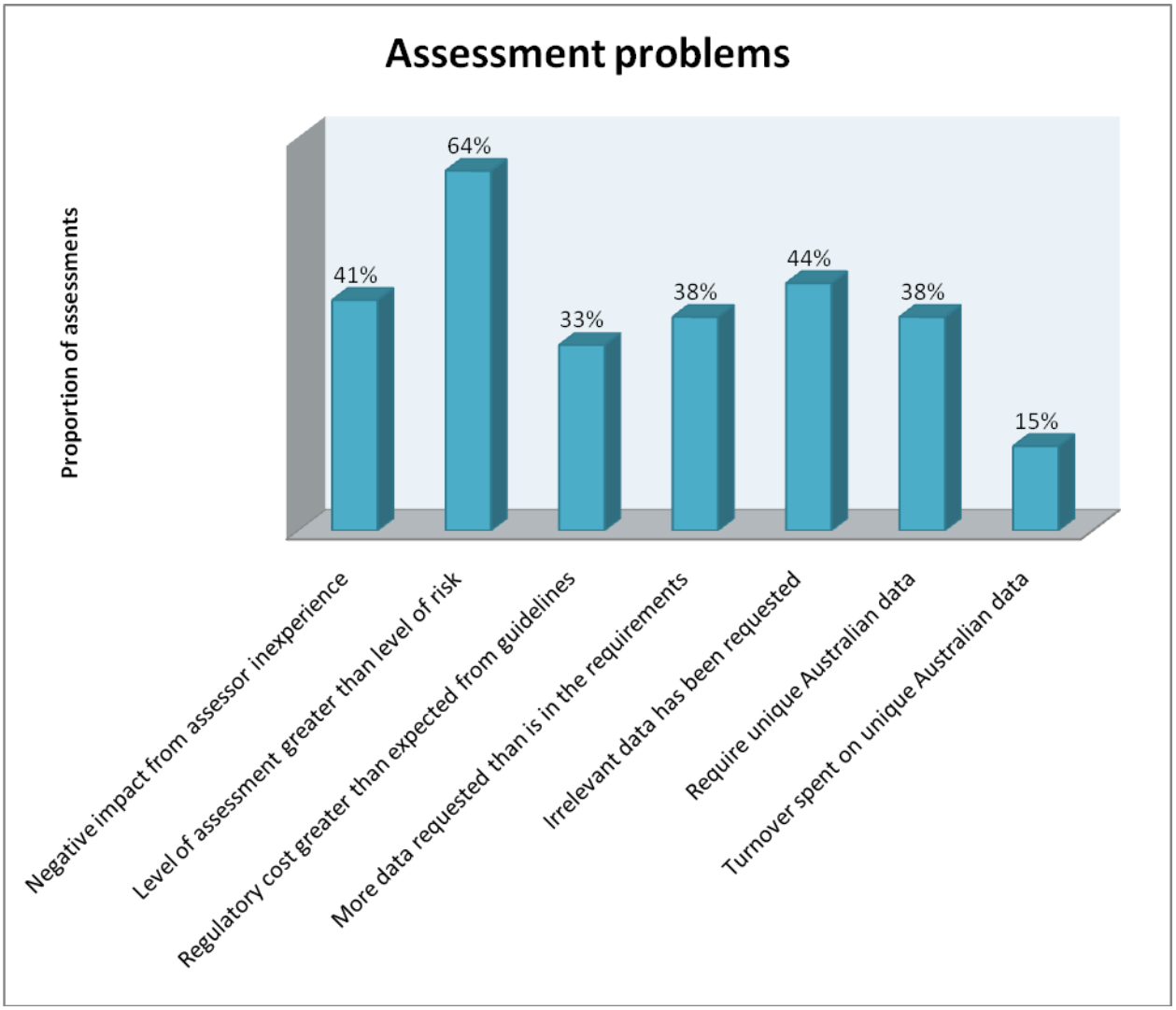



Survey participants were asked to report on the proportion of assessments for which a range of problems occurred (see Figure 9). The results, averaged across responses, are reported in the following chart. A negative impact from assessor inexperience was reported in 41 percent of cases. Comments were made that:

- "Assessors have become more pedantic and less helpful in assisting to overcome issues in each assessment."

- “There has been an increase in assessors using their discretion in asking for additional data that are outside the data requirements in the criteria”.

Respondents felt that irrelevant data was requested for nearly half the assessments and, it is significant that in 64 percent of cases, it was considered that the level of assessment was greater than warranted for the level of risk. It was commented that the excessive amount of information required is not related to the nature of the potential hazards a chemical may pose to the Australian environment or to the public. Data requirements are not commensurate with notification category and do not relate to the level of risk a chemical poses. Thirty eight percent of assessments required Australian data.




Data requests during screening have a particular impact on assessment timeframes as the regulator is not subject to statutory time constraints in this period. The following comments were made on screening data requests:

- “Environmental data can be the most problematic in screening.”
- “Inexperience of assessors contributes to the screening period being extended significantly. Sometimes this is a case of not reading the data properly, other times it is a lack of understanding of basic chemistry, for example in asking for the solubility of insoluble materials.”

# 7 Regulatory agency coordination

Industry has for a number of years raised its concerns about the need for the APVMA, TGA, NICNAS and the Australian Government Department of the Environment, Water, Heritage and the Arts (DEWHA) to streamline their assessment processes and data requirements so that relevant information can be more freely exchanged between regulatory agencies, hence reducing the reporting and cost burden on industry seeking approval for the same chemical for different purposes from different regulatory agencies.

As mentioned in a preceding section, members reported problems from a lack of co-ordination between regulators. An example is that a chemical can be imported for use in a therapeutic product, having gone through the TGA process, but cannot then be used in a cosmetic or household product without re-review by NICNAS.

# 8 Case studies

A number of case studies were put forward by members to highlight their survey responses:

Case study 1

This company deals with an agency where the overseas Principal has developed some new chemicals particularly geared towards use in personal care products. The chemicals are covered by patents, and use renewable resources. Simple skin irritancy trials show that they are significantly milder on the skin than some of the products they are designed to replace. Other tests carried out include the Het-Cam test which is a replacement test for the Draize test to determine eye irritancy, mutagenicity testing and LD50 test (which shows the product is completely harmless).

In one case the product is apparently now listed on the US Toxic Substances Control Act (TSCA) Inventory (which cost the company $100), without a lot of extra testing. NICNAS will require significantly more testing, such as biodegradability, to be carried out for a Standard Notification. The cost estimate for NICNAS approval would be in excess of $100,000 and the company is still to decide whether to proceed with the product.

Case study 2

When this company wants to introduce a new formulation to Australia they first check if all ingredients have been notified with NICNAS. If new non-polymer materials haven't been notified the company will usually re-formulate because of the expense, time delay and uncertain outcome of going through the NICNAS process. The cost to the company in reformulation is additional development and research expense and lost time. Major retailers, Woolworths and Coles only allow introduction of new laundry products once a year. If there is delay of even one month, the product is then pushed back a year, which means one year of lost sales.

In early 2007 the company asked its supplier to notify a fabric softening ingredient. NICNAS informed them that the toxicology data that had sufficed in the US for approval in that market wouldn't be sufficient for Australia. The testing required to generate the additional data would have cost $418,084). The company wasn't sufficiently large in Australia to justify this cost. The formulants not listed on the Australian Inventory of Chemical Substances (AICS) were replaced. The delay was four months, which converts to a year's delay to market

Case study 3

This company reports that the consumer care market is asking for additional benefits in its products. As listing of ingredients on the Australian Inventory of Chemical Substances (AICS) is too difficult commercial opportunities are lost to the company and innovative or beneficial products are not available to consumers. Various marketing ingredients, such as green tea extracts are left out of personal care products and fabric softeners, fungicides, bactericides and optical brighteners are left out of laundry products.

In a recent case there was a new chemical to add in a liquid detergent to condition fabric. After discussion with the supplier, it appeared that they did not have the data package required for Australia. Some of the data gaps relate to unique Australian requirements for human and environmental toxicity.

The supplier investigated alternate data availability but some testing would still be required. The 1000 kg "low volume" approval was not an option. A standard application was required which meant EU 125K + (about $210k AUD) to generate the required data. It was not considered commercially viable for the supplier to support the generation of the data. In addition, it was not certain that, once generated, the data would be sufficient for certification.

The company decision was to abandon the idea to list the material on the Australian Inventory of Chemical Substances (AICS) and instead to investigate an alternate technology.

Costs:

| | |
|---|---|
| Six months development lost + lengthy discussion with suppliers | $35K |
| Six month development of an alternate technology | $25K |
| Investment to handle the alternate technology in plant (now a powder) | $250K |
| Estimated lost business opportunity (one year delay on market) | $300K |

Case study 4

This company finds the cost of maintaining their product portfolio a huge regulatory burden. The main burden is the continuing monitoring and evaluation of the volume introduced. For each ingredient it is necessary to establish proportion of the product, then continually monitor that the volume imported does not breach the level applied for. Data requirements from one volume threshold to the next are greatly increased and the company can see no benefit to the consumers or the environment or their staff.

The company considers the information required to introduce a polymer of low concern (PLC) excessive, in particular when the material is already on the Australian Register of Therapeutic Goods (ARTG) for use in therapeutics. The lack of cooperation between the agencies confounds the situation.

This company spends about $100 000 a year in staff and consultancy costs, over and above fees to NICNAS, on gathering data and reporting requirements for its portfolio of approximately 7,500 formulas, made up of 3,000 different ingredients.

Case study 5

A recent issue for this company was their warehouses' ability to handle a cleansing agent used at less than 10 percent of a facial cleaner. As part of an LTD (limited notification category) application they had to provide details on handling, storage, and environmental protection within the warehouse for the ingredient in its raw form. As it is in a compound the information was totally inappropriate and superfluous, however the company had to put resources into gathering the data and proving the capacity for safe handling in the event of a spill. The company reports that, at the end of the day, if there was a spill, they would have a very clean floor and hands.

Case study 6

This company would not consider the introduction of new chemicals due to the excessive cost. They recently took on an agency for a US manufacturer who was very keen to market their many novel chemicals in Australia. Their first attempt has cost $100,000 to date (still incomplete) and as a result they have lost interest in listing further chemicals on the Australian Inventory of Chemical Substances.

Case study 7

This company is a contract manufacturer. While much production has been lost to Asia over the last 10 years the economics of local manufacture have significantly improved and as a result they have just won back a significant amount of business from China. Looking forward the opportunities to supply regionally are very real. However, there are considerable concerns as problems with certification of new chemicals will seriously impact on these opportunities. If a potential tender uses chemicals not registered in Australia, then any economic advantage of local production will be lost.

Case study 8

This company develops new products and formulates. They believe the guidelines are too tough but will usually go through the NICNAS process because, being fairly large, have the money to generate the

data. However they do a cost benefit analysis and, in three years, with three potential notifications, one had added cost and delay with data requests and one didn't go ahead: the company considered that the cost and time of up to 12 months wasn't justified when the product may be re-formulated in eight months for market reasons anyway.

Case study 9

This company has about 55 employees. They have submitted eight to ten notifications in the last two years. This company finds there are problems when the assessors are inexperienced and have little commercial knowledge or experience. These assessors ask for more data than experienced assessors because they don't have the experience with risk assessment to know what is reasonable. The process is too expensive, especially when some data is Australia-specific. Two submissions didn't go ahead in the last two years because of cost. Two didn't go ahead because of difficulty - fluoro-polymer submissions have got harder to do with the data requirements. Sometimes alternate materials are substitutes in formulations but are not as good technically.

Case study 10

This company is a Specialty Chemical manufacturer. It is a small company with approximately 20 employees. They no longer go through the NICNAS process because of the cost and resources required. They had gone through the process of listing a material on the Australian Inventory of Chemical Substances (AICS): it cost $30,000 and took 18 months. It was a long and tedious process because data was not available. The material was commercial in the US, without the same requirements as in Australia. This stifled commercial opportunity as by the time it was cleared for use the company had missed the timing for a commercial advantage. Now, applications to NICNAS are outside the company's budget and it will usually be put back on suppliers.

On one occasion the company was purchasing a material through an agent. A review showed that it wasn't listed on the Australian Inventory of Chemical Substances (AICS) so they reformulated while waiting for the supplier to go through the listing process. The supplier has spent the last two years dealing with NICNAS on this material, and it is still not finalised.

Case study 11

A company was recently pulled up by the TGA - $500 000 of product was seized by customs for having an unapproved ingredient and having claims that hadn't been approved. They had been using the ingredient for years. On two occasions they went through NICNAS and had approval but then the TGA confiscated the product. They asked the TGA why this could happen and the TGA said NICNAS had nothing to do with them.

Case study 12

This company formulates and develops formulations. They had a situation where there were two suppliers and difficulties with making an application. So the company decided to do the work themselves. The material was a sanitising active and they approached NICNAS. NICNAS said they would only look at it after the TGA and APVMA but there was no progress. The company eventually got the TGA and the APVMA to put it in writing that they had no interest in the active, for reasons of concentration and use situation. Only then was the company able to get NICNAS to look at their application. This process took three years!

## APPENDIX 1

# *Members*

## Consumer, Cosmetic and Personal Care:

Advanced Skin Technology Pty Ltd
Alberto Culver Australia
Amway of Australia Pty Ltd
Apisant Pty Ltd
Aroma Science
AVON Products Pty Limited
Baylor Limited
Beiersdorf Australia Ltd
Chanel Australia
Clorox Australia Pty Ltd
Colgate-Palmolive Pty Ltd
Combe International Ltd
Cosmax Prestige Brands Australia Pty Ltd
Coty Australia Pty Limited
Creative Brands Pty Ltd
Dermalogica Pty Ltd
Elizabeth Arden Australia
Emeis Cosmetics Pty Ltd
Estée Lauder Australia
Frostbland Pty Ltd
GlaxoSmithKline Consumer Healthcare
Helios Health & Beauty Pty Ltd
Innoxa Pty Ltd
Johnson & Johnson Pacific
Kao (Australia) Marketing Pty Ltd
Keune Australia
Kimberly Clark Australia
La Biosthetique Australia
La Prairie Group
L'Oreal Australia Pty Ltd
LVMH Perfumes and Cosmetics
Mary Kay Australia Pty Ltd
Nutrimetics Australia
NYX Pty Ltd
Procter & Gamble Australia Pty Ltd
PZ Cussons Pty Ltd
Reckitt Benckiser
Revlon Australia
Scental Pacific Pty Ltd
Schwarzkopf
Shiseido (Australia) Pty Ltd
Thalgo Australia
The Heat Group Pty Ltd
The Purist Company Pty Ltd
Tigi Australia Pty Ltd
Trilogy Products
Trimex Pty Ltd
Ultraceuticals
Unilever Australasia
YSL Beaute

## Hygiene and Specialty Products

Albright & Wilson (Aust) Ltd
Applied Australia Pty Ltd
BP Castrol Australia Pty Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
Castle Chemicals Pty Ltd
Chemetall (Australasia) Pty Ltd
Chemform
Ciba Specialty Chemicals
Clariant (Australia) Pty Ltd
Cleveland Chemical Co Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
E Sime & Company Australia Pty Ltd
Ecolab Pty Limited
Henkel Australia Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Lab 6 Pty Ltd
Milestone Chemicals Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL
Recochem Inc
Rohm and Haas Australia Pty Ltd
Solvay Interox Pty Ltd
Sonitron Australasia Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited

## Associate Members

**Specialist Laboratories and Testing**

ams Laboratories

Dermatest Pty Ltd

Silliker Microtech Laboratories Pty Ltd

**Equipment and Packaging Suppliers**

EquipNet Inc.

HydroNova Australia NZ Pty Ltd

SCHÜTZ DSL Group Pty Ltd

**Logistics**

Star Track Express Pty Ltd

**Legal and Business Management**

Fisher Cartwright Berriman

Middletons Lawyers

PricewaterhouseCoopers

TressCox Lawyers

**Regulatory and Technical Consultants**

Archer Emery & Associates

Cintox Australia Pty Ltd

Competitive Advantage

Engel Hellyer & Partners Pty Ltd

Robert Forbes & Associates

Sue Akeroyd & Associates

November 2007

# APPENDIX 2



ACCORD
Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

## Productivity Commission Study of the Regulatory Burden on the Chemicals and Plastics Industry

## ACCORD Industry Survey (Part 1)

This survey to identify in broad terms, the impacts and costs related to the regulatory burden on the chemicals industry, with particular reference to barriers to trade and innovation for consumer, cosmetic, hygiene and specialty products.

Questions focus on NICNAS but responses on the TGA and the APVMA will also be collated.

Responses are sought on NICNAS activities over the last **2 years**.

Responses will be collated without identification of company, product or chemical.

---

The survey is divided into two sections:

SECTION 1: Identification of the company size, type of organization and overall interaction with the regulator.

SECTION 2: Identification of causes and consequences of regulatory burden

---

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## SECTION 1: Identification of survey participant

### 1.1) Company name and size

| | |
|---|---|
| Company Name | |
| Size of organization (≤20 / 20-100 / ≥100 employees)* | |
| Date | |

* Size of organization in terms of turnover will be identified separately from ACCORD records and not recorded with the rest of the survey responses.

### 1.2) Member business category

| Tick the member business category | | |
|---|---|---|
| Industry members | 1: Consumer, cosmetic and personal care products | |
| | 2: Hygiene and specialty products | |
| Associate members | 3: Specialist laboratories and testing | |
| | 4: Equipment and packaging suppliers | |
| | 5: Logistics | |
| | 6: Legal and business management | |
| | 7: Regulatory and technical consultants | |

## SECTION 2: Identification of regulatory burden

### 2.1) Impact of NICNAS-related regulations

| | |
|---|---|
| What impact do NICNAS-related regulations have on your business? (positive / negative / neutral / can't comment) | |
| Please note the reasons, if you are unable to comment on NICNAS | |

The remainder of the survey is to be completed where participants reported a negative impact from NICNAS-related regulations

## 2.2) Consequences and causes of regulatory burden

| Please tick any of the following consequences of regulatory burden which apply to your product portfolio: | |
|---|---|
| There is a barrier to innovation | |
| Product / formulations are unavailable in the Australian market | |
| Product marketed in EU and/or US but regulatory obstacles too great to market in Australia | |
| Product formulated / reformulated to avoid AICS listing of new ingredients | |
| Products avoided if new material listing through NICNAS would be required | |
| Regulatory cost too high - material not introduced to Australia | |
| Regulatory cost too high - company prepared to bear the cost to gain Australia market entry | |
| Data requests too great - material not introduced to Australia | |
| Data requests too great but company in position to obtain data to gain Australia market entry | |
| Timeframe too long / launches delayed | |
| What aspects of the regulations or process cause the regulatory burden? | |
| Data requests are greater than expected from guidelines | |
| Assessor inexperience | |
| Lack of harmonization with major trading partners (EU / US) | |
| Lack of coordination between regulators | |
| Other (please comment) | |
| Comments | |
| Case studies | |

# APPENDIX 3



ACCORD
Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

## Productivity Commission Study of the Regulatory Burden on the Chemicals and Plastics Industry

## ACCORD Industry Survey

This survey is to identify failures of the regulatory system, with particular reference to barriers to trade and innovation, for consumer, cosmetic, hygiene and specialty products.

Questions focus on NICNAS but responses on TGA and the APVMA would be welcome *separately*, along with instances where conflicting Federal, State and Local requirements have caused problems.

---

The survey is divided into three sections:

SECTION 1: Lost opportunities - the impact of the current regulatory system on the realization of commercial opportunities.

SECTION 2: Rating of the success of the, already implemented, LRCC Regulatory Reforms

SECTION 3: Operational Performance of the Regulator

---

Responses will be collated without identification of company, product or chemical.

Instructions for completing the form:

Type your answers in the blank fields in the tables

or

Print the form and handwrite your responses.

---

Please answer the questions for your experience with NICNAS over the last **2 years.**

If you don't have experience in any of the areas under investigation, please make a note to that effect in the response field.

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| | |
|---|---|
| Company Name | |
| Size of organization<br>( ≤20 / 20-100 / ≥100 employees) | |
| Date | |

## SECTION 1: LOST OPPORTUNITY

### 1.1) Product availability in the Australian market

| | |
|---|---|
| Of your company's worldwide product/substance portfolio, what **percentage** is **unavailable** in Australia due to **Australian regulatory factors**? | |

### 1.2) Causes of unavailability of products to the Australian market

| For the products/substances unavailable due to regulatory factors, in what proportion of cases were the following contributing factors?<br>( there may be more than one causal factor for a product) | % |
|---|---|
| Regulatory cost compared to expected revenue | |
| Regulatory data requirements (difficulty in obtaining Australia-specific data) | |
| Regulatory data requirements (cost of obtaining Australia-specific data) | |
| Regulatory data requirements (timeframe for obtaining Australia-specific data) | |
| Regulatory assessment timeframe | |
| Unpredictability of regulatory assessment timeframes | |
| Time required for application preparation | |
| Cost of application preparation | |
| Regulatory application fees | |
| Annual reporting requirements | |
| Comments | |

### 1.3) Value of lost opportunity

| | |
|---|---|
| For the products/substances not introduced to Australia in the last 2 years, for regulatory reasons, what was the expected turnover ex manufacture? | |

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## SECTION 2: SUCCESS OF REGULATORY REFORMS

### 2.1) How many notifications has your company made to NICNAS?

| | | |
|---|---|---|
| Exemption low volume (<100kg) | Letter of Consent | |
| Commercial Evaluation Chemical (CEC) | Permit | |
| Low Volume Chemical (LVC) | Permit | |
| Polymers of Low Concern (PLC) | Certificate | |
| Limited notification (LTD) | Certificate | |
| Standard Notification (STD) | Certificate | |
| Extension of Original Assessment Certificate | Certificate | |

### 2.2) Uptake of the LRCC reforms

| For the following questions, please give your answer as a percentage | % |
|---|---|
| Where you have had the option of self assessment, in what proportion of cases have you **chosen not to self assess?** | |
| Non hazardous chemicals | |
| Non hazardous polymers | |
| Polymers of low concern | |
| Where you have had the option of self assessment, in what proportion of cases have you **chosen not to self assess because of the level of auditing required?** | |
| Non hazardous chemicals | |
| Non hazardous polymers | |
| Polymers of low concern | |

| | |
|---|---|
| Comment on reasons for not taking up self assessment | |

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## 2.3) Rate the success of the LRCC reforms

| Assign the following statements a rating from 1 to 5<br>1=Strongly agree 2=Agree 3=Neutral 4 =Disagree 5=Strongly Disagree N/A= Not Applicable | | | | | | |
|---|---|---|---|---|---|---|
| Overall, the LRCC reforms implemented to date have been beneficial in reducing the regulatory burden | | | | | | |
| The speed of introduction of LRCC **reforms that didn't take immediate effect in 2004** is satisfactory | | | | | | |
| **The following reforms, introduced in 2004, have been successful in reducing the regulatory burden** associated with assessment timeframe, fees, data requirements, resourcing of application preparation, post notification requirements (auditing etc):<br>**(1-5 rating)** | Overall reduction in regulatory burden | Timeframe | Fees | Data requirements | Application preparation | Post-notification regulatory requirements |
| Exemption category changes and additions: | | | | | | |
| Transhipment exemption (new) | | | | | | |
| Increase in the volume restriction for the exemption for chemicals introduced solely for the purpose of research, development and analysis from 50 to 100kg/annum | | | | | | |
| Increase in the volume restriction for the exemption of low-risk non-cosmetic chemicals from 10 to 100kg/annum | | | | | | |
| Introducers of low risk cosmetic chemicals, in quantities of less than 10kg/annum, are no longer required to notify NICNAS prior to introduction | | | | | | |
| Increase in the volume restriction for the exemption of low risk non-cosmetic chemicals from 10 to 100kg/annum | | | | | | |
| Non-hazardous chemicals introduced in cosmetics at a concentration at 1% or less do not need to be notified to NICNAS prior to introduction | | | | | | |
| New range of permits | | | | | | |
| Renewal of CEC and LVC Permits | | | | | | |
| Removal of national volume restriction for LVC Permits | | | | | | |
| Self assessment | | | | | | |
| Non hazardous chemicals | | | | | | |
| Non hazardous polymers | | | | | | |
| Polymers of low concern | | | | | | |

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## SECTION 3: OPERATIONAL PERFORMANCE OF THE REGULATOR

### 3.1) Director's power of discretion

| For secondary notifications the Director may put forward that assessment is only required for matters of particular significance , i.e. not all matters<br><br>Assign the following statements a rating from 1 to 5<br>1=Strongly agree 2=Agree 3=Neutral 4 =Disagree 5=Strongly Disagree N/A= Not Applicable | |
|---|---|
| The Director's use of her powers of discretion in relation to secondary notifications has **remained constant** over the last 2 years | |
| The Director's use of her powers of discretion in relation to secondary notifications has **increased** over the last 2 years | |
| The Director's use of her powers of discretion in relation to secondary notifications has **decreased** over the last 2 years | |
| Comment | |

### 3.2) Consistency

| Assign the following statements a rating from 1 to 5<br>1=Strongly agree 2=Agree 3=Neutral 4 =Disagree 5=Strongly Disagree N/A= Not Applicable | |
|---|---|
| There is consistency from one application to another with regard to assessment process | |
| There is consistency from one application to another with regard to assessor performance | |
| Comment | |

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### 3.3) Impact of operational performance

| For the following questions, please give your answer as a percentage | % |
|---|---|
| In what proportion of applications are you satisfied with the **quality of review?** | |
| What proportion of assessments have been negatively impacted by **assessor inexperience?** | |
| In what proportion of applications is the **regulatory cost** greater than expected from guidelines? | |
| In what proportion of applications are you satisfied with the **timeliness** of review? | |
| In what proportion of assessments is the **level of assessment greater than the level of risk**? | |
| Polymers of Low Concern (PLC) notification | |
| Limited notification (LTD) | |
| Standard Notification (STD) | |
| In what proportion of your applications have you been asked to provide **more data than is in the requirements**? | |
| Polymers of Low Concern (PLC) notification | |
| Limited notification (LTD) | |
| Standard Notification (STD) | |
| What proportion of products/substances require **unique Australian data?** | |
| What proportion of a product/substances's turnover is spent on **unique Australian data?** | |
| In what proportion of your applications have you been asked to provide **irrelevant data** (eg solubility data for an insoluble substance? | |
| Polymers of Low Concern (PLC) notification | |
| Limited notification (LTD) | |
| Standard Notification (STD) | |

| | |
|---|---|
| Details of irrelevant data required (see also section 3.7 following) | |
| Additional comments | |

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### 3.4) Additional data requirement details

If you have been asked to provide more data than is set out in the guidelines complete the following for as many of these applications as you can:

| Category | Example | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Data was already available to your company (Y/N) | | | | | | | |
| Data generation required (Y/N) | | | | | | | |
| Type of data (eg Chem, Env) | | | | | | | |
| Time to collect, compile and submit additional data (check corresponding box) | | | | | | | |
| 1-2 weeks | | | | | | | |
| 2-4 weeks | | | | | | | |
| 1-3 months | | | | | | | |
| 3-6 months | | | | | | | |
| >6 months | | | | | | | |
| Comment on NICNAS justification for the additional requirements (for the examples above) | | | | | | | |
| Example 1 | | | | | | | |
| Example 2 | | | | | | | |
| Example 3 | | | | | | | |
| Example 4 | | | | | | | |
| Example 5 | | | | | | | |
| Example 6 | | | | | | | |
| Example 7 | | | | | | | |

### 3.5) Time in screening

Please identify the time in screening for all applications and for low and non-hazardous materials

| Category | Time (days) in screening (**total** number of products) | | | | | | |
|---|---|---|---|---|---|---|---|
| | 0 | 0-7 | 8-14 | 15-21 | 22-28 | 29-90 | >90 |
| STD | | | | | | | |
| LTD | | | | | | | |

| Category | Time (days) in screening (number of **low-hazard** products) | | | | | | |
|---|---|---|---|---|---|---|---|
| | 0 | 0-7 | 8-14 | 15-21 | 22-28 | 29-90 | >90 |
| STD | | | | | | | |
| LTD | | | | | | | |

| Category | Time (days) in screening (number of **non-hazardous** products) | | | | | | |
|---|---|---|---|---|---|---|---|
| | 0 | 0-7 | 8-14 | 15-21 | 22-28 | 29-90 | >90 |
| STD | | | | | | | |
| LTD | | | | | | | |

LTD= Limited Notification

STD= Standard Notification

| Comment | |
|---|---|

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### 3.8) Change of category requirement

| | |
|---|---|
| If you have you experienced a shift in category requirement overtime<br>(eg a material type previously notified as a PLC now must be assessed as a STD or LTD Notification)<br><br>complete the following | |
| **Example 1** | |
| Describe the change | |
| What justification was given by NICNAS? | |
| **Example 2** | |
| Describe the change | |
| What justification was given by NICNAS? | |
| **Example 3** | |
| Describe the change | |
| What justification was given by NICNAS? | |

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### 3.9) Annotation of AICS

| Is AICS annotation being used beyond the scope of the original intent? (Yes / No) | |
|---|---|

| | Describe the annotation | Why do you think this annotation is inappropriate? |
|---|---|---|
| Example 1 | | |
| Example 2 | | |
| Example 3 | | |
| Example 4 | | |
| Example 5 | | |
| Example 6 | | |
| Example 7 | | |

### 3.10) Cost of delays

| Delayed assessments impose a cost burden.<br>Please show worked examples of the cost of delay in getting to the market |
|---|

| **EXAMPLE 1** | |
|---|---|
| Type of material | |
| Time delay (eg 3 months) | |
| Cause of delay | |
| Cost element and value (eg x hours on additional negotiations and data provision at cost of $y) | |
| Data generation costs | |
| Loss in turnover | |
| Other costs, eg storage | |
| Comments | |

| EXAMPLE 2 | |
|---|---|
| Type of material | |
| Time delay (eg 3 months) | |
| Cause of delay | |
| Cost element and value (eg x hours on additional negotiations and data provision at cost of $y) | |
| Data generation costs | |
| Loss in turnover | |
| Other costs, eg storage | |
| Comments | |

| EXAMPLE 3 | |
|---|---|
| Type of material | |
| Time delay (eg 3 months) | |
| Cause of delay | |
| Cost element and value (eg x hours on additional negotiations and data provision at cost of $y) | |
| Data generation costs | |
| Loss in turnover | |
| Other costs, eg storage | |
| Comments | |

# APPENDIX 4

*Table 2 – Worldwide Registration Costs Comparisons* from page 49 of ACCORD's 24-10-07 submission to the Productivity Commission showed that Australia has the costliest system in terms of government application fees ($14,418). This compares to $2,797 for the USA and $122 for Korea. The cost differential also needs to be put into perspective in comparison to the major market size difference between, say, Australia and the USA. This factor acts as a barrier to the introduction of chemicals/products.

**Table 2. Worldwide Registration Cost Comparisons**

| Data item | Australia | Korea | USA | Japan | | EU | Canada | Philippines | China |
|---|---|---|---|---|---|---|---|---|---|
| **National Inventory** | AICS | KECI/ TCCL | TSCA | (Controlled under ISHL) | ENCS (Controlled under CSCL) | ELINICS (moving to REACH) | DSL | PICCS | IECSC |
| **Volume (per year)** | >1 tonne | <1 t/>1t | Unlimited | <100 kg/100 kg | <1 t / >1t | 1-10 tonne | Unlimited | <1 t/>1t | <10 tonne |
| **Government Application Fee** | 14418 AUD | KRW 50,000/100, 000 | 2,500 USD | No | No | 5,165 EURO (ELINCS) (REACH fees not set) | 3,500 $Cdn | P 3750 | Notification registration fee |
| **Government Application Fee** $AU | $14,418 | $61/122 | $2,797 | | | $8,227 | $4,025 | $95 | $? |
| **Exempt Information Fee** $AU | 633 AUD | None | None | None | None | None | None | None | None |
| **Variation of Data Requirements** (if needed) | 1140 AUD | None | None | None | None | None | None | None | None |
| **Timing (mth)** Consolidate / submit Government Screening, Assessment, Review | 3 | 6 | 4 | 3 / 7 | 1/18 ENCS listing 18-36 | 10-12 | 2.5 | 3-6 | 4 |
| **Polymer exemptions** | Not exempt | Not exempt. Reduced requirements | Exemptions | Exemption under certain conditions if covered by CSCL | No exemption. Reduced requirements | Registration not required | RRR (Recuced Regulatory Requirement) | Exempt | Reduced requirements, 1 mth review |

- The timeframes indicated are based on no clock stops or concerns raised by competent authorities, i.e., EPA in US
- The EU timing and costs covers all member states incl. UK. However Switzerland is not covered and a separate notification is necessary. EU tests are sufficient. We suggest to submit after the EU approval is available, because then both fee and review in Switzerland are reduced (CHF 6'500, 30 days).