Business Risk in the Age of AICIS

(Complying with the Australian Industrial Chemicals Introduction Scheme (AICIS)

Requirements, Categorisation & Reporting)

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to

Surface Coatings Association Australia

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Slide 1:

Welcome to this presentation by Adrian Thomas of Chemicalia Pty Ltd to the Surface Coatings Association Australia.

The title of this talk is “Business risk in the age of AICIS” where we discuss complying with the Australian Industrial Chemicals Introduction Scheme (which I will refer to as AICIS) and comments regarding the requirements, categorisation and reporting.

This presentation will focus on business risk.

Business Risk in the Age of AICIS

There are two risks to worry about:

- Human error in categorising introductions;
- Timely supporting information for categorising introductions.

Why?

- Because the introducer is responsible under the legislation for being correct. That means no errors and being able to prove correctness with tests and study reports.
- AICIS is potentially policeman, judge, jury and executioner.
- AICIS WILL REVOKE AUTHORISATION AND MAY ISSUE FINES IF THE LEGISLATION IS BREACHED.
- Fines are the least of the worries if the supply-chain is interrupted.

Slide 2:

In the July 2020 presentation to the Surface Coatings Association Australia or SCAA we covered, exempted, reported and assessed introductions in detail.

We have now had over a year of AICIS operations.

This presentation will try to reveal what we have learnt during that time.

We will summarise our previous presentation and highlight the business risk to introducers that we predicted last year, we will also review what AICIS covers by way of listing and briefly describe the different introductions, but in view of the time involved we will not be covering all aspects, such as legislative exclusions etc.

The descriptions will be brief and are intended really to prompt questions which whilst dealt with at the end of this presentation, will not be recorded in this presentation for brevity.

There are two main risks to worry about.

We have the human error in categorising introductions and the timely support of information required for categorising introductions.

This is because the introducer is responsible under the legislation to ensure that the information is correct, which reminds me somewhat of the self-assessment with respect to the Australian Taxation Office and this means no errors are permitted with the requirement to prove correctness with appropriate data and study test reports.

Whether we like it or not, AICIS is potentially policeman, judge, jury and executioner and AICIS will revoke authorisation to introduce the chemical and may issue fines if the legislation is breached.

AICIS fines may be the least of the worries if the supply chain to customers is interrupted.

Chemicalia Pty Ltd

Involved in four areas of activity relating to industrial chemicals:

- Trading in specialty raw materials;
- Marketing Consulting (including supply of raw materials and finished products);
- Technical Consulting (including expert witness);
- Regulatory Affairs.

Regulatory Affairs includes:

- Complying with regulations in Australia with emphasis on:
  - Australian Industrial Chemical Introduction Scheme (AICIS):
    - Complying with AICIS requirements for introduction (importation and manufacture) of chemicals into Australia.
    - Preparation of AICIS documentation for Australia.
  - Labelling of chemicals (consumer and industrial).
  - Preparation of Safety Data Sheets (SDS) to comply with Australian requirements.
- Complying with the Hazardous Substances And New Organisms Act (HSNO) for importation of chemicals into New Zealand.

Slide 3:

Let me introduce myself to some of you who may not be aware and may not know me from before.

I qualified at university in Chemistry in England and migrated in 1969 immediately after graduation to Australia.

I worked for a number of chemical companies including Shell Chemical Australia, focusing particularly on marketing and technical support, technically supporting raw materials for a variety of industries including surface coatings and construction chemicals and at the time of this presentation have been a member of SCAA for 49 years.

In 2000, I started up Chemicalia which, as we can see from the slide is involved in a variety of areas predominately trading in specialised materials and consulting in regulatory affairs, focusing especially on areas such as the Hazardous Substances And New Organisms Act (HSNO) for importation of chemicals into New Zealand and what was then the Australian National Industrial Chemical Notification Assessment Scheme or NICNAS.

Because of pressure from a variety of stakeholders including especially industry personnel and industry associations, the Australian government announced a reform initiative to NICNAS in 2015, which was finally fully implemented on 1 July 2020 with the evolution to The Australian Industrial Chemicals Introduction Scheme or AICIS.

The aim was to reduce the regulatory burden on the industrial chemicals sector by streamlining assessment processes and refocusing assessment effort on high-risk industrial chemicals while also ensuring that Australia's robust safety standards are maintained.

Whilst it's only been just over a year since the changes have occurred, I've been involved in over 10 introductions of industrial chemicals under the AICIS scheme and at the same time have also tested out quite a number of others in various concepts.

Regulation of chemicals in Australia 1

Four chemical regulatory bodies exist in Australia:

- APVMA
  - Pesticides
  - Veterinary medicines
- FSANZ
  - Food additives and residues
- TGA
  - Medicines
  - Medical devices
- AICIS (formerly NICNAS)
  - Industrial chemicals, including cosmetics

Slide 4:

If we firstly try to examine the regulation of chemicals in Australia, we can see there are four chemical regulatory bodies which exist in Australia, and their jurisdiction essentially depends upon the use of the chemical rather than innate properties of the chemicals such as the physicochemical, toxicological or eco-toxicological properties.

These bodies are:

- The Australian Pesticides and Veterinary Medicines Authority (APVMA);
- Food Standards Australia New Zealand (FSANZ);
- The Therapeutic Goods Administration (TGA)
- Australian Industrial Chemicals Introduction Scheme (AICIS).

Effectively, AICIS defines industrial use by exclusion where the use is not covered by the other three chemical regulatory bodies.

As a general rule of thumb, if it's not covered by APVMA, TGA or FSANZ then it falls under the AICIS jurisdiction for industrial uses.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an Australian Government statutory authority established to centralise the registration of all agricultural and veterinary (agvet) chemical products into the Australian marketplace.

The APVMA is the independent statutory authority responsible for assessing and registering pesticides and veterinary medicines proposed for supply in Australia.

The APVMA is responsible for protecting people, animals, crops, the environment, and trade.

Food Standards Australia New Zealand (FSANZ) is an Australian government agency that develops and manages standards for food – known as the Australia New Zealand Food Standards Code.

It regulates the use of ingredients, processing aids, colourings, additives, vitamins and minerals.

It also covers the composition of some foods and includes standards for genetically modified foods.

FSANZ is also responsible for labelling of both packaged and unpackaged food, including mandatory warnings or advisory labels.

In Australia, FSANZ also sets primary production and processing standards, and maximum residue limits for agricultural and veterinary chemicals.

In New Zealand, these activities are undertaken by the New Zealand Ministry for Primary Industries.

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

Almost any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia.

Regulation of chemicals in Australia 2

Effectively, AICIS define industrial use by exclusion:

- This means that an industrial use is any use that is not:
  - an agricultural chemical product – as defined by the AgVet Code;
  - a veterinary chemical product - as defined by the AgVet Code;
  - use as a substance or mixture of substances prepared by a pharmacist or veterinary surgeon, or in the preparation of these – as defined by paragraph 5(4)(a) of the AgVet Code;
  - a therapeutic good – as defined by the Therapeutic Goods Act 1989; or
  - use as food for humans or animals, or in the preparation of it.
- An important note about use is that a chemical can have multiple types of uses.
  - For each use a chemical has, the regulations for each responsible regulator need to be followed.

Slide 5:

As previously noted, if an industrial chemical is not regulated by APVMA, TGA or FSANZ then it is effectively covered by AICIS for industrial uses.

It is also appropriate to bear in mind that a chemical can have multiple types of uses and may therefore be regulated by one or more of the other agencies under a particular use scenario but also by AICIS for other uses.

Regulation of chemicals in Australia 3
Business or hobby

Registration depends on whether the introducer is importing or manufacturing industrial chemicals (and products that release industrial chemicals) for personal, hobby or commercial use.

- Hobby and personal use
  - An introducer does not need to register with AICIS if introducer:
    - Makes products at home or buy products from overseas for the introducer's personal use;
    - Gifts the introducer's work to friends or family;
    - Sells the introducer's work for the cost of the materials.

- However, an introducer must register with AICIS if the introducer sells products for a profit or uses them to market the introducer's business - even if the introducer is a small or start-up business.
- Further guidance is available from the Australian Government Department of Industry, Innovation and Science on the difference between a hobby and a business.

Slide 6:

In a more general sense, registration by an introducer with AICIS really depends upon whether the introducer is importing or manufacturing industrial chemicals for hobby and personal use or commercial use.

We can see from the slide that for hobby and personal use an introducer is not required to register with AICIS.

However, an introducer must register with AICIS if the introducer sells products for a profit or uses them to market the introducer's business - even if the introducer is a small or start-up business.

Further guidance is available from the Australian Government Department of Industry, Innovation and Science on the difference between a hobby and a business.

Regulation of chemicals in Australia 4

Which chemicals are not affected by the AICIS scheme?

- If the following chemicals which are discussed below are introduced (imported or manufactured) into Australia for **commercial purposes** then there is no requirement for:
  - the introducer to register their business with AICIS;
  - the chemical to be listed on the Inventory;
  - the chemical to be categorized for introduction, even if the chemical is not on the Inventory;
  - the introducer to comply with the terms of listing for the chemical even if the chemical is on the Inventory.

- The various chemicals are:
  - naturally-occurring chemicals;
  - non-isolated intermediates;
  - incidentally introduced chemicals;
  - chemicals unintentionally released from an article;
  - trans-shipment chemicals;
  - chemicals introduced incidentally on an aircraft or ship;
  - articles.

Slide 7:

As noted in the previous slide, where an industrial chemical is introduced for commercial use then the introducer must be registered with AICIS.

However, if the following chemicals which are discussed below are introduced (imported or manufactured) into Australia for commercial purposes then they are not affected by the scheme, the various chemicals are:

- naturally-occurring chemicals;
- non-isolated intermediates (these might be chemical intermediates which are produced in a chemical process but are not isolated);
- incidentally introduced chemicals;
- chemicals unintentionally released from an article;
- trans-shipment chemicals (these might be chemicals which just come in and out of a port but are not landed in Australia);
- chemicals introduced incidentally on an aircraft or ship (these might be small quantity chemicals that are brought in as duty-free items etc.);
- articles.

Naturally-occurring Chemicals

Examples	Naturally-occurring	Not naturally-occurring
Essential oils: Aroma compounds extracted from plant materials are commonly used in cleaning compounds, cosmetics etc.	If essential oils are produced using maceration, cold-press extraction or water distillation of plants, then they are defined as naturally occurring chemicals.	If essential oils are produced using steam distillation or solvent extraction of plants - including the stems, leaves, roots, flowers or fruit, then they are not defined as naturally-occurring chemicals. These processes change the chemical composition of the source product.
Chemicals used in construction:	These chemicals and products containing these ingredients are defined as naturally-occurring if they are obtained from the earth without chemical or heat processing: non-bleached clays; silica; mined gypsum.	These chemicals and products containing these ingredients are not defined as naturally-occurring: lime; soda; cement; mortar; grout; epoxies.
Mineral ores:	These mineral ores are defined as naturally-occurring if they are obtained from the earth without chemical or heat processing: hematite; magnetite; bauxite; chalcopyrite.	Extractive and secondary manufacturing methods, such as refining, roasting, smelting, steel making and leaching, result in chemicals that are not defined as naturally-occurring.

Slide 8:

We referred earlier on to naturally-occurring chemicals and in a sense, the simple method of differentiating between what AICIS consider as naturally-occurring chemicals and those which are not naturally-occurring chemicals is that it's a chemical which occurs in nature and if the chemical has not encountered chemical or heat processing, then AICIS regard the chemical as naturally-occurring.

However, if we consider the example of a seed oil which has been steam distilled or solvent extracted and even though seed oil was naturally-occurring in nature, it is still regarded as not non-naturally occurring by AICIS because its composition has changed from the naturally-occurring substance because of the extraction process which it has undergone.

Articles

Examples in the following table may clarify the definition of an article:

Item	Shaped for purpose	Shaped during manufacture	No chemical change (1)	Not a particle or fluid	Is it an article? (2)
Cosmetics (e.g. shampoo, condition, lotions, foundation, skin care products)	✗	✗	✓	✗	No
Furniture, e.g. chairs, desks	✓	✓	✓	✓	Yes
Plastic bottle	✓	✓	✓	✓	Yes
Contents of plastic bottle	✗	✗	✓	✗	No
Empty ink cartridge	✓	✓	✓	✓	Yes
Ink cartridge filled with ink	✓	✓	✓	✗	No
Adhesives e.g. liquid glue	✓	✓	✓	✗	No
Plastic pellets - as part of a children's toy	✓	✓	✓	✓	Yes
Plastic pellets - for use in manufacture by melting or pulverising	✓	✗	✓	✓	No
Steel ball bearings	✓	✓	✓	✓	Yes
Compounded plastic pipe	✓	✓	✓	✓	Yes

Notes:
(1) Except as an intrinsic aspect of its intended use.
(2) No means the introducer is not introducing an article and must register with AICIS.

Slide 9:

We will now consider the exclusion of articles from consideration under the AICIS jurisdiction.

On the face of it, this might appear to be a relatively straightforward area for exclusion.

Probably a good example would be that if a thermoplastic polymer was being introduced as plastic pellets then they are not regarded as an article because they will be subsequently processed by moulding and are therefore subject to regulation by AICIS.

However, a preformed article which for example has been made from a thermoplastic polymer would be regarded an article and would therefore not be subject to AICIS regulation.

I had a particularly interesting interaction with NICNAS a few years ago on this topic and it is still relevant now with AICIS.

My client was wishing to introduce a dishwashing tablet which the client had encased in a water-soluble plastic film, which although not being listed on the NICNAS inventory at that time had been imported into Australia for well over 30 years as a plastic film (and in fact, I had previously imported it when working in that industry), I was able to persuade NICNAS that the plastic film was not subject to NICNAS regulation and this avoided having to go through an assessment which at that time would have attracted a NICNAS fee of at least $14,000.

However, I incurred some time and expense to collect the appropriate chemical information and persuade NICNAS with my argument.

Effectively, I was able to persuade NICNAS at that time that the plastic film dissolved in water, but didn't change its composition in its use and so its introduction could be permitted in the form of a packaged article into Australia without any required assessment.

AICIS Emphasis

What is risk?

- Risk is a measure of the likelihood of harm to human health or the environment from exposure to an industrial chemical.
- Risk is a function of both a chemical's innate hazards and the level of human or environmental exposure to that chemical.
- A chemical may be very hazardous but, if nothing is exposed to it, then the risk is low.

i.e. Risk = Hazard x Exposure

Slide 10:

If we then look how the emphasis of AICIS has especially differed from that of NICNAS.

AICIS are now focusing much more forensically on risk as a function of hazard and exposure.

Risk is a measure of the likelihood of harm to human health or the environment from exposure to an industrial chemical.

As we state in the slide, risk is a function of both a chemical's innate hazards and the level of human or environmental exposure to that chemical.

So, you could have the situation where a chemical may be very hazardous but, if nothing is exposed to it, then the risk is low.

This combination of hazard and exposure has an impact on the categorisation of the industrial chemical for both human health and the environment and consequently how AICIS categorise its introduction, whether imported into or manufactured in Australia.

AICIS Categories of Industrial Chemicals

Categories of industrial chemicals:

- If listed on the AICIS inventory (the Inventory):
  - Listed Category
    - The industrial chemical is listed on the AICIS inventory (the Inventory). .
- If not listed on the AICIS inventory (the Inventory) they may be categorised as one of the following 6 categories:
  - Exempted Introduction:
    - New category which refers to industrial chemicals which have been classified as Very Low Risk;
  - Reported Introduction:
    - New category which refers to industrial chemicals which have been classified as Low Risk;
  - Assessed Introduction:
    - Similar to the old assessment certificate and refers to industrial chemicals which have been classified as Medium to High Risk;
  - Commercial Evaluation Authorisation (CEA) Introduction:
    - New category which replaces the former NICNAS commercial evaluation permit (CEC).
  - Exceptional circumstances introduction:
    - Category for introductions required under exceptional circumstances, authorised by the Minister or AICIS Executive Director;
  - Restricted introduction:
    - Examples include chemicals listed in the Rotterdam Prior Informed Consent (PIC) Convention and the Stockholm persistent organic pollutants (POPs) Convention.

Slide 11:

As stated in the previous slide, the move from NICNAS to AICIS manifested itself as a particularly heightened emphasis on the combination of hazard and exposure with the risk level assessed separately for human health and the environment, resulting in the risk level for the introduction of the industrial chemical.

In a presentation to SCAA in July 2020, we explained in great detail the process of introduction of chemicals into Australia.

Part of this involved a step-by-step process for the categorisation of the new industrial chemicals, which if not already listed on the AICIS inventory and within the scope of any conditions on the inventory could only be introduced within the six listed categories.

So, we can see that a chemical is either listed on the inventory or if it is not listed on the inventory, then the only means of introduction are either as an exempted introduction, a reported introduction, an assessed introduction, a commercial evaluation authorisation introduction, an exceptional circumstances introduction or a restricted introduction.

I suppose a good example of an exceptional circumstances introduction might be where let's say an emergency occurs and the AICIS Executive Director authorises the introduction of chemicals to deal with that urgency.

An example might be the importation of specialised oil spill chemicals to deal with an oil spill causing an environmental hazard.

The last example is a restricted introduction such as the introduction of certain chemicals listed in the Rotterdam Prior Informed Consent (PIC) Convention or in the Stockholm persistent organic pollutants (POPs) Convention.

Determining the introduction category of the introduced industrial chemical

		Your indicative human health risk		
		Very low risk	Low risk	Medium to high risk
Your indicative environment risk	Medium to high risk	Assessed (AICIS Fee = $23,375)	Assessed (AICIS Fee = $23,375)	Assessed (AICIS Fee = $34,965)
	Low risk	Reported (AICIS Fee = $0)	Reported (AICIS Fee = $0)	Assessed (AICIS Fee = $23,375)
	Very low risk	Exempted (AICIS Fee = $0)	Reported (AICIS Fee = $0)	Assessed (AICIS Fee = $23,375)

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Slide 12:

Following on from the previous slide and putting aside the three specific introductions of commercial evaluation authorisations, exceptional circumstances and restricted ones, listed in the Rotterdam Prior Informed Consent (PIC) Convention or in the Stockholm persistent organic pollutants (POPs) Convention, we end up with the three categories of exempted, reported, and assessed introductions.

The July 2020 SCAA presentation revealed what I had learned, and the salient points were:

- The risk-based approach considers hazard and exposure in context;
- The risk level is assessed separately for human health and the environment;
- The highest risk level determines introduction type - Exempted, Reported or Assessed.

We can see the various AICIS costs involved with the three types of introduction.

An exempted introduction relates to chemicals which are very low risk for both human health and environment.

It is permitted to be introduced with a post-introduction declaration providing appropriate study reports and data confirm the chemical does not fall into a higher risk category, such as a low risk or a medium to high-risk category.

The appropriate box is coloured green in the displayed figure and an exempted introduction does not attract an AICIS fee.

A reported introduction relates to chemicals which are low risk for both human health and environment or very low risk or low risk, but not medium to high risk, for either human health or environment.

It is permitted to be introduced with a pre-introduction report providing appropriate study reports and data confirm the chemical does not fall into a higher risk category, such as a medium to high-risk category.

The appropriate boxes are coloured yellow in the displayed figure and a reported introduction does not attract an AICIS fee.

An assessed introduction relates to chemicals which are medium to high risk for either or both human health and environment and is permitted only after full assessment by AICIS.

Where the chemical is medium to high risk for human health or environment the appropriate boxes are coloured red in the displayed figure and attracts an AICIS fee of at least $23,375, at time of presentation.

Where the chemical is medium to high risk for both human health and environment the appropriate box is coloured purple in the displayed figure and attracts an AICIS fee of at least $34,965, at time of presentation.

To all of these costs needs to be added the cost of preparation of the application for assessment (which may be carried out by a consultant acting as an agent) and the cost of sourcing the data (which may require expenditure on study reports).

Business Risk

Slide 13:

Effectively, our presentation relates to business risk. As well as what was discussed in the previous slide, introducers are responsible for categorising the introduction type.

AICIS requires proof on demand of any claims leading to categorisation.

Such proof may include disproving an alleged hazard which was not otherwise considered.

At the same time AICIS only allow for 20 business days for the introducer to produce studies supporting categorisation.

I turned my study of the new AICIS system into a template to follow in introducing industrial chemicals for my clients.

I found that even with sufficient knowledge and experience to assemble my 2020 presentation it was taking me several days before I even knew what type of introduction the legislation demanded.

This was obviously unlikely to be commercially viable in the longer term. I then assembled a Microsoft Excel workbook to guide me logically through the process to consider all the factors required by the AICIS legislation.

Over a period of time, this workbook quickly grew to more than 30 worksheets.

I found that after I had gathered the necessary data, this templated process was taking me, even with my knowledge and experience no less than a whole day to determine whether the introduction of one industrial chemical would be exempted, reported or required to be assessed.

The cost to my clients was significant because I have to charge my time, but again it is obviously still not commercially viable in the longer term.

With familiarity with the process, I could see the time required would reduce, but unfortunately there was no guarantee that the propensity for human error would also decrease.

Let me digress.

Error is unacceptable in a consulting situation because my whole business could be seriously harmed with a single mistake which could certainly significantly harm my reputation with my client base.

Essentially, with the new AICIS system, introducers are given the responsibility to categorise their own introductions.

AICIS have the enforcement role.

They also have the technical expertise to audit introductions.

We can talk about their budget and staffing levels and cost recovery a little later if anyone is interested to ask for my opinion.

Anyway, getting back to my digression, if I wrongly categorised an introduction as Assessed instead of say Exempted the worst case is that my client might be out of pocket as much as about $35,000 plus my costs.

On the other hand, if my mistake resulted in an Exempted or Reported introduction instead of Assessed and AICIS decided to audit that introduction, then my client would have serious problems.

AICIS would be derelict in their legislated duty if they ignored the matter, and they would be highly likely to withdraw authorisation for that introduction.

Consequently, supply of the industrial chemical to the market would cease.

All the just-in-time supply lines would be disrupted for my client's customers.

I could go on and really paint the picture darkly, but you get the meaning.

The same problem can be caused by any AICIS audit, if they ask an introducer for information which the introducer doesn't have.

Remember, you only have 20 business days to find this information and sometimes it can be particularly difficult to get support from overseas, especially with issues such as absence of key personnel on holidays etc.

Now, let me return to last year.

A colleague with whom I have been working with on another information management project saw my July presentation and afterwards we discussed a solution for regulatory complexity and problems arising from short deadlines.

I mentioned that my Excel solution takes a day after data entry to categorise an exempted, reported or assessed introduction.

Our new solution called Chemintro produces an immediate result after data entry.

More importantly, it eliminates human error, equally importantly, it solves the 20-day problem.

I'll come back to Chemintro and show you in detail what it does and answer any questions.

Meanwhile, let's consider the monitoring activities of AICIS.

Business Risk
AICIS Monitoring 1

AICIS goals

- The objectives of AICIS monitoring activities are to:
  - promote awareness of obligations under Australian laws;
  - check that record-keeping obligations are being met;
  - identify and manage cases of non-compliance.

  - AICIS use a **risk-based approach** and focus on introducers at higher risk of non-compliance as well as introductions that pose a higher risk to human health and the environment. AICIS also modify their monitoring activities to accommodate emerging risks.

Slide 14:

As we can see from this slide on AICIS's goals, their objectives are:

- To promote awareness of obligations under Australian laws.
- To check that record-keeping obligations are being met.
- To identify and manage cases of non-compliance.

AICIS use a risk-based approach which as we can see focuses on introducers at higher risk of non-compliance as well as introductions that pose a higher-risk to human health and the environment.

They will modify their monitoring activities to accommodate any emerging risks, of which they are aware.

So even if you have, say an introduction of an industrial chemical that represents a relatively low hazard, if the volumes are quite significant then its quite likely that AICIS may at some stage carry out some type of audit on the introduction of that chemical.

Business Risk
AICIS Monitoring 2

AICIS monitoring activities

- Check that an introducer is registered with AICIS at the correct level.
- Check that an introducer has correctly categorised their introductions and has the required information to justify their introduction category.
- Identify non-compliance and manage it.
- Check that an introducer has met their reporting obligations.

Slide 15:

AICIS's monitoring activities include:

- Whether the introducer has registered their organisation at the correct level (based on annual dollar value of introductions).
- Checking whether the introducer has correctly categorised their introductions and has the required information to justify the introduction category (this might include physicochemical data, toxicological data and eco-toxicological data including test study reports).
    - I have seen this occur a matter of months after an introduction has commenced, where AICIS communicate with an introducer, generally by email, requesting information regarding why an introducer has chosen a particular introduction category and request access to appropriate data such as test study reports.
- Identify non-compliance by introducers and manage it.
    - This might be where an introducer is introducing a chemical (which AICIS might detect from their data interface with the Australian Border Force section responsible for Customs control of imports) and after some investigations, including literature searches, AICIS determines that the introducer has not registered an ingredient in the chemical with AICIS.
    - I was involved in such a situation once where a client came to me in a panic and we ended up having to prepare an application for assessment of the chemical, for which a certificate was ultimately granted.
    - In the meantime, business regarding this chemical was halted until receipt of the certificate, some months later.
- Check that the introducer has met the reporting obligations.

We'll come back a little later with further comments on reporting obligations.

Business Risk
AICIS Monitoring 3

The types of non-compliance AICIS monitor

AICIS continually evaluate compliance risks when planning and carrying out compliance monitoring activities. AICIS monitor these compliance risks associated with Australian laws about introducers of industrial chemicals:

- failure to register their business, or register at the correct level;
- failure to identify industrial chemicals that they are manufacturing or importing;
- failure to categorise introductions;
- incorrect categorisation of introductions, including:
    - use of new animal test data in contravention of the ban or restrictions;
- provide false or misleading information to AICIS;
- failure to report new hazard information;
- failure to provide information on request;
- failure to keep records of chemical introductions.

Slide 16:

Other types of non-compliance which AICIS monitor, and this is all available on their website are:

They continually evaluate compliance risks associated with Australian laws.

These include:

- Failing to register a register a business with AICIS, or registering at the wrong level (remember ignorance of the law is no excuse);
- Failure to identify industrial chemicals which are being manufactured in or imported into Australia (again ignorance is no excuse);
- Failure to categorise introductions;
- Incorrect categorisation of introductions, including especially use of new animal test data in contravention of the ban;
- Providing false or misleading information to AICIS;
- Failure to report new hazard information;
- Failure to provide information when requested, (remember, sometimes it's a maximum of 20 business days to respond in);
- Failure to keep records of chemical introductions (sometimes these can be quite complicated and voluminous, and this is an area where Chemintro can assist with secure data maintenance).

War stories on some chemical introductions

Acetone	Already listed on the AICIS inventory and within scope
Benzyl Acetate Test Solvent 1	Already listed on the AICIS inventory and within scope
Cosmetic GC	Exempted - very low risk
Hydrocarbon X	Exempted - very low risk
Polymer in resin solution 51/70 BAc	Exempted - very low risk
Amyl ethyl ether	Reported - low risk
Organoplatinum	Reported - low risk
Silica gel, reaction products with bis(triphenylsilyl) ester and ethoxydiethylaluminum	Reported - low risk
2,3-dihydroxy-[2-(2-hydroxy)ethyl]-[3-(2-hydroxy)propyl]-[(9Z,12Z)-octadeca-9,12-dienyl]azanium; chloride	Reported - low risk
Heavy metal paint	Assessed - medium to high risk
Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoroethyl)-	Assessed - medium to high risk

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Slide 17:

Let me give you a few war stories on some chemical introductions in which I have been involved.

Some are from my previous experience with NICNAS, but they will illustrate some points.

I should also point out that to respect client confidentiality I have sanitised the names of these chemicals.

So, if we look if we look at Acetone this is very much just a reference point to show a chemical which is already listed on the AICIS inventory (which they call the inventory) and is within scope, so no further action occurs with that chemical, except that it is referred to as listed when submitting an annual declaration to AICIS.

The next example of Benzyl Acetate is also just a test case, so we do not need to discuss this any further.

The next one is Polymer in resin solution 51/70 BAC.

This was effectively a solution of an acrylic copolymer resin in normal Butyl Acetate.

This was a relatively simple chemical introduction, because we determined that it was a Polymer of Low Concern, which became an exempted introduction.

Once we had the appropriate data on the introduced polymer from the manufacturer, such as Number Average Molecular Weight (Mn), Weight Average Molecular Weight (Mw) as well as percentage of Number Average Molecular Weight < 500 and < 1000 g/mol, and its starting point monomers, we were able to determine that the Introduced Polymer was a Polymer of Low Concern under AICIS.

Cosmetic GC was an example of an industrial chemical raw material, which was proposed to be used in cosmetic formulations.

This was an interesting example because this raw material contained an ingredient chemical which was required to be introduced.

It was classified as a very low risk chemical which was an exempted introduction, so there was no AICIS fee for its introduction.

However, at the same time I did flag to the introducer that he needed to have technical data support from his supplier of this particular raw material to ensure that it met the appropriate test for biodegradability.

Providing he had confirmation from his supplier that the supplier would supply the appropriate data reports on biodegradability to AICIS, I suggested to him that it was appropriate to go ahead and introduce this raw material.

We come to the industrial chemical raw material Hydrocarbon X.

This was a chemical which is composed of a range of hydrocarbons, and like many hydrocarbons exhibits an aspiration hazard.

It was categorised as a very low risk chemical which was an exempted introduction, so there is no AICIS fee for its introduction.

Interestingly, AICIS focus on protection of health and environment but in their introduction categorisation they do not appear to be concerned about issues such as the Australian Dangerous Goods Code classification, where the classification does not impinge upon health or environment.

In this particular case, Hydrocarbon X has a flashpoint which is > 140°C, which means that it is not classified as Dangerous Goods according to the Australian Dangerous Goods Code, although it is classified as a class C2 combustible liquid under Australian Standard AS 1940 “The storage and handling of flammable and combustible liquids”.

However, even if a chemical were to have a flashpoint resulting in the chemical being classified as flammable liquid under GHS, AICIS do not appear to regard this as critical in their assessment of human health or environment, and we will see an example of this later when we look at the example of tertiary-Amyl Ethyl Ether.

Anyway, back to Hydrocarbon X, when considering the human health hazard band categorisation there are 20 items to be considered, and a further 14 items under the environmental hazard band categorisation.

So, we can see that there is a total of 34 items, and I advised the introducer that supporting data needed to be prepared to ensure that all 34 items were considered to support its categorisation as a very low risk chemical which becomes an exempted introduction.

Frankly, the communications with the overseas supplier of Hydrocarbon X took an extended period of time to obtain sufficient study report data to support this conclusion.

Because of the high volume of this particular industrial chemical, there is a good argument to be made for making application for an assessment certificate on the basis that even though the chemical is regarded as a very low risk chemical and does not require an assessment certificate, the advantage of having an AICIS assessment certificate is that AICIS have already examined the technical data supporting this and are not expected to need to come back for a subsequent audit at a later stage, with all the potential disruption to business that an audit might incur.

We now come to the organo-platinum, where by examining the hazard characteristics of the particular raw material chemical as well as its level of exposure to both human health and environment we were able to advise the introducer that it could be introduced as a low risk chemical under a reported introduction, providing that the introducer had sufficient information (in relation to the 34 items previously discussed) to demonstrate that it should not be a higher category, such as a medium to high risk which would then require assessment.

The same situation occurred with the next example of the silica gel reaction products with bis(triphenyl silyl) ester and ethoxydiethylaluminium where we were able to advise the introducer that it could be introduced as a low-risk chemical under a reported introduction, providing that the introducer had sufficient information (in relation to the 34 items) to demonstrate that it should not be a higher category.

A parallel situation occurs with the next example of the azanium chloride salt where we were able to advise the introducer that it could be introduced as a low-risk chemical under a reported introduction, providing that the introducer had sufficient appropriate information.

The next example of the heavy metal paint was just a test of the Chemintro program where a paint which contains a heavy metal paint automatically falls into the medium to high-risk category which would then require AICIS assessment.

The last example is that of a fluorinated industrial chemical which was being used as a surfactant. I advised the introducer that because of its particular properties it was categorised as a medium to high-risk introduction which would require assessment, unless he was able to obtain appropriate environmental hazard data from the supplier.

He realised that he would not be able to obtain this from the supplier and chose to not proceed any further with the introduction of this chemical.

Hopefully, these examples have provided some insight into the new AICIS scheme.

Record keeping & Reporting 1 - AICIS Annual Declaration

The introducer is required to complete an Annual Declaration about introduced chemicals (imported into or manufactured in Australia) during the previous registration year to confirm that the introductions were authorised under AICIS laws.

The period that the annual declaration covers: 1st September – 31st August (AICIS reporting year).

The period that the first annual declaration covers: 1st July 2020 – 31st August 2021.

The annual declaration is to be submitted during the period: 1st August 2021 – 30th November 2021

The annual declaration will include:

- The Introducer's AICIS Business Registration number (starting with 'NIC');
- The introduction categories for the chemicals which were imported or manufactured during the AICIS registration year:
  - Listed Category;
  - Exempted Introduction;
  - Reported Introduction;
  - Assessed Introduction;
  - Commercial Evaluation Authorisation Introduction;
  - Exceptional circumstances introduction.
- A declaration that all of the introductions were authorised under sections 25 to 30 of the Industrial Chemicals Act (2019)

Slide 18:

Now in this slide we move to the area of record keeping and reporting. An annual declaration is required to be submitted by the introducer to AICIS.

This refers to all introduced chemicals.

On this occasion, the first annual declaration covers will be from the 1st July 2020 to 31st August 2021 and is to be submitted any time from the beginning of August until the end of November 2021.

Subsequent declarations will cover the reporting period from 1st September to 31st August, which was the reporting period under NICNAS.

The reason for the different reporting period in 2021 is because NICNAS ceased operation on 30th June 2020 when it was replaced on the next day, 1st July by AICIS, and introductions during the intervening period of 1st July 2020 to 31st August 2020 would otherwise have been excluded.

As we can see from the slide it needs to contain the following information:

The introducer needs to provide the AICIS Business Registration Number (which is generally a six-digit number starting with NIC50….).

What is curious about this declaration is that it also refers to defining whether there are any of the following categories which have been introduced, and these are listed, exempted, reported, assessed, commercial evaluation authorisation or exceptional circumstances.

In previous years under NICNAS, when a chemical was already on the Australian Inventory of Chemical Substances (AICS), which was the previous inventory name, NICNAS did not ask for any information about whether any chemicals which were on the inventory were being introduced.

They just took it on face value that if it was listed on the inventory (and complied with any conditions of that listing), then it could be freely imported.

What is unusual now is that this annual declaration requires all categories for chemicals introduced during that previous AICIS registration year to be defined as whether they are listed, exempted etc.

At the same time, the declaration requires that all of the introductions were authorised under sections 25 to 30 of the Industrial Chemicals Act, and this refers to aspects such as if any of the chemicals are high-risk such as high hazard chemicals and whether they are covered by the Rotterdam and Stockholm Conventions etc.

Whilst the annual declaration does not require information on which specific industrial chemicals were introduced under each category, certainly the declaration does provide an opportunity for AICIS to contact the introducer at a later stage if apparent discrepancies exist between the AICIS records and what the introducer has stated on the annual declaration.

Like all submissions to any authorities, we would suggest that the prudent introducer would ensure that they held supporting records for which introduced chemicals were in each specific category.

So, as we can see there is a far greater emphasis on all record keeping than there may appear to have been in the past.

Record keeping & Reporting 2 – Post-introduction Declaration (PID)

The introducer is required to complete a Post-Introduction Declaration (PID) about the following exempted introductions:

- polymers of low concern;
- low-concern biopolymers;
- Industrial chemicals which the introducer has categorised as **very low risk** for human health and the environment.

- The first post-introduction declaration is due by **30th November 2021** and covers the period 1st July 2020 - 31st August 2021.
- From 2022, introducers must submit a post-introduction declaration (PID) by 30th November each year following the end of the previous AICIS registration year: 1st September - 31st August.
- Subsequently, introducers will no longer need to submit another PID for the same chemical introductions.

Slide 19:

If we're talking about an Exempted Introduction then AICIS require an introducer to complete a post-introduction declaration or PID.

As we saw occurred with the AICIS annual declaration, the first annual declaration covers from the 1st July 2020 to 31st August 2021 and is to be submitted by 30th November 2021.

Subsequent post-introduction declarations will cover the reporting period from 1st September to 31st August.

This refers to:

- Polymers of low concern;
- Low concern biopolymers;
- Industrial chemicals which the introducer has categorised as very low-risk for human health and the environment.

As we said earlier, the introducer needs to ensure they have the appropriate data (such as study reports) to support that categorisation and that it does not fall into a higher categorisation.

This is a once-off declaration that is to be submitted after these exempted introductions have been made for the first time.

So, once the introducer has submitted the post introduction declaration, there will no longer be required to submit another PID for the same chemical introductions in the future.

Record keeping & Reporting 3 – Pre-introduction Report (PIR)

- The introducer is required to complete a Pre-Introduction Report (PIR) about the following reported introductions:
  - Highest indicative risk of your introduction is low risk (this is the most common type)
  - Low-risk flavour or fragrance blend reported introduction
  - Research and development reported introduction
  - Chemicals that are internationally assessed for human health and the environment
  - Chemicals that are internationally assessed for human health and are low or very low risk for the environment
  - Chemicals that are internationally assessed for the environment and are low or very low risk for human health
- The pre-introduction report (PIR) is submitted online through the AICIS portal prior to introduction of the industrial chemical.
- On receipt of the PIR AICIS will send a confirmation email to the introducer prior to introduction advising that introduction may commence.

Slide 20:

Finally, we come to the area of pre-introduction reports (PIR) and these refer to:

- Where the highest indicative risk of the introduction is low-risk (that is expected to be the most common type);
- Low-risk flavours or fragrances reported introductions;
- Research and development reported introductions;
- Chemicals that are internationally assessed for human health and the environment, etc. as we can see in the slide.

The pre-introduction report is submitted online through the AICIS portal prior to introduction of the industrial chemical.

On receipt of the pre-introduction report, AICIS will send a confirmation email to the introducer advising that introduction may commence.

This can occur in as short a period as 10 minutes after submission to AICIS.

In essence, we can really say that the confirmation email is basically notifying the introducer that AICIS have received the pre-introduction report.

Whilst it states that introduction may commence, it doesn't mean that AICIS have necessarily examined the information which has been supplied to possibly any greater extent than that there are no apparent inconsistencies or errors in the submission.

I really regard the AICIS response as somewhat like a robo-response which has been automatically generated to demonstrate receipt by AICIS of the pre-introduction report (PIR).

AICIS introduction categories categorised by Chemintro

The AICIS introduction categories which Chemintro categorises for industrial chemicals/polymers are:

- Exempted Introductions;
- Reported Introductions;
- Assessed Introductions.

Slide 21:

As discussed earlier, just to reinforce the point, Chemintro categorises the following AICIS introduction categories for industrial chemicals or polymers:

- Exempted Introduction;
- Reported Introduction;
- Assessed Introduction.

Record keeping & Reporting 4 - Keeping good records of formulations

1. On occasions, (which presumably relate to audits) AICIS have asked for information such as:
    1) Name of introduced product.
        a) This might refer to a raw material or a finished product formulation, such as a paint, ink, adhesive etc.
    2) % composition of raw material ingredients in introduced product.
        a) It appears that AICIS will require information on all raw material ingredients in an introduced product, such that this totals to 100%.
    3) CAS name for raw material ingredient.
    4) Chemical Abstract Services (CAS) number.
    5) A written undertaking from the chemical information holder regarding ability to supply appropriate information to support the categorisation of the introduction.
    6) Whether the raw material ingredient is listed on the Australian Inventory of Industrial Chemicals (Inventory).
    7) The terms of the Inventory listing.
    8) The Introduction Category (out of 6 categories as stated in the Annual Declaration).
    9) A copy of the Inventory web link (https://www.industrialchemicals.gov.au/search-inventory).
2. We would recommend that any introducer of industrial chemicals (whether as raw materials or as finished products) would need to:
    1) Determine what industrial chemicals they are introducing.
    2) Determine whether the introduced industrial chemicals are imported and/or manufactured.

Slide 22:

I should also point out that AICIS have in the past and will presumably in the future, when carrying out an audit or investigation, ask for information such as:

- The name of an introduced product, so this might even be a raw material, or a finished product formulation such as a paint ink adhesive etc., it really doesn't matter;
- The % composition of the raw material ingredients in the introduced product, requiring a complete breakdown, sufficient to add up to 100%;
- The Chemical Abstract Services (CAS) name for the raw material ingredient;
- The Chemical Abstract Services (CAS) number;
- A written undertaking from the chemical information holder regarding the ability to supply the appropriate information to support the categorisation of the introduction for each industrial chemical ingredient;
- Whether the raw material ingredients are listed on the AICIS inventory, and if there are any terms of the inventory listing;
- At the same time to list the introduction category, out of the six categories that we saw stated in the annual declaration;
- Finally. to provide a copy of the web link to the AICIS inventory search.

My recommendation is that you never know when you're going to be asked to provide such information and so I would recommend that for anybody who is introducing raw materials or finished product formulations, they would need to:

- Determine what industrial chemicals they are introducing;
- Determine whether the introduced industrial chemicals are imported and/or manufactured.

So, if we have let’s say a local paint manufacturer who is purchasing industrial chemical raw materials locally then it's not their concern because they are not introducing (i.e. importing or manufacturing) the chemical into Australia.

So, they are not responsible to AICIS to provide such a listing.

It's the people who are introducing the industrial chemicals, whether manufacturing locally or importing into Australia who are responsible for the determination of the categorisation of that industrial chemical.

So, we can see that this very much focuses on the importance of keeping appropriate records.

This is an area where a lot of problems can arise and Chemintro provides a solution to these issues.

Introducing Chemintro

Visit https://chemintro.com

Chemintro was established in 2021
CEO and founder is Adrian Thomas (Director of Chemicalia Pty Ltd)
CTO and cofounder is Mike Dewhirst (Director of Climate Pty Ltd)

Chemintro automates your AICIS industrial chemical categorisations.

- Why automate your AICIS categorisations?
  - Not getting it right *first time* might result in enormous time and expense including:
    - Consulting costs;
    - Chemical testing costs;
    - AICIS charges.
  - Other issues could include:
    - Halted introductions;
    - Marketing delays;
    - Lost business;
    - General opportunity costs.

Slide 23:

As you can see, Chemintro has only recently been established, I am the CEO and Founder, and Mike Dewhirst is the Chief Technical Officer and Co-Founder, and is responsible for IT.

Mike is a Director of Climate Pty Ltd (which incidentally stands for Client's Mate) and has been very heavily involved in the support of Dangerous Goods for the Fire Services, so he is no stranger to hazardous chemicals.

With the background of being quite an IT guru with exposure to industrial chemicals he has devised the structure of Chemintro so that it automates your AICIS industrial chemical categorisations straightaway.

As we show on the slide, if you don't get it right first time, you may end up with enormous time and expense, including consulting costs, chemical testing costs and unnecessary AICIS charges.

You may also face the risk of halted introductions, marketing delays, lost business and general opportunity costs (which whilst sometimes unrecognised can also be significant).

That's why it's so important to have this information at your fingertips.

In particular, the advantage with Chemintro is that the result (and the ability to reach the marketing conclusion) is generated once you have input the data (which would typically take say 20 or 30 minutes for the first time).

This is a significant reduction when compared with the number of hours required for me to be able to achieve the same result using my Excel workbook (which you may remember was no less than a whole day).

Also, the introducer does not have to wait in a queue for a chemical consultant to have the opportunity to deal with the introducer's project.

Finally, and by no means least, Chemintro as an automated computer-based system carries out the tedious categorisation process speedily but avoids the potential errors which can frequently occur where humans carry out multiple routine tasks.

Chemintro Benefits

Chemintro:

- Manages the risks:
  - human error from complexity and need for speed/profit contributing to errors can all be solved by computerising the drudgery leaving judgement to humans including an ability for an expert user to defeat the computer.
  - audit response must be timely, so information management is critical. Nominating the Chemical Information Holder (CIH) and preparation with links to studies address the issue.
  - annual declarations need to include ALL introductions.
    - Getting the reporting wrong may attract AICIS attention!!!!
    - So, Chemintro doesn't charge for the non-calculated introductions.

Slide 24:

As we discussed in the previous slide Chemintro manages the risks because human errors from complexity and the need for speed and profit contributing to errors can all be solved by computerising the drudgery, hence leaving judgement to humans, including an ability for an expert user to defeat the computer, because sometimes you may need to override that information, providing you have the appropriate supporting test data.

Also, an audit response needs to be timely, so information management is critical.

Chemintro can also nominate the chemical information holder, sometimes referred to with the acronym of CIH (who may be somebody overseas who holds all the study reports etc.) and its links to the retained studies addresses this issue.

As we said before, annual decorations need to include all introductions, and getting the reporting wrong may attract AICIS (unwanted) attention.

If AICIS, when they look at the annual declaration, see one of the introduction boxes ticked, but they haven't seen such introductions previously, they may then be motivated to carry out an audit on the introducer because of inconsistency between the annual declaration and AICIS's records.

Chemintro can retain the details of all an introducer's introductions over the various introduction categories in readiness for such an audit.

Also, Chemintro does not charge for any introductions which are not calculated.

Such AICIS introductions not categorised by Chemintro include:

- The listed category, which is listed on the Inventory with no regulatory obligations or restrictions;
- The listed category, which is listed on the Inventory with a defined scope of assessment and is within scope;
- The listed category, which is listed on the Inventory with conditions of introduction or use on the Inventory and complies with these conditions;
- The listed category, which is listed on the Inventory with specific information requirements;
- The listed category, which is listed on the Inventory and is not within any defined scope or conditions of introduction;
- Commercial Evaluation Authorisation Introductions;
- Exceptional circumstances introductions;
- Restricted introductions (which may include industrial chemicals such as those under the Rotterdam Convention and Stockholm Convention).

AICIS introduction categories not categorised by Chemintro

The AICIS introduction categories for industrial chemicals/polymers:

- Listed Category:
  - Listed on inventory and no regulatory obligations or restrictions;
  - Listed on inventory and within a defined scope of assessment;
  - Listed on inventory and within conditions of introduction or use;
  - Listed on inventory with specific information requirements;
  - Listed and not within any defined scope or conditions of introduction.
- Commercial Evaluation Authorisation Introduction;
- Exceptional circumstances introduction;
- Restricted introduction.

Slide 25:

1. Putting aside the Exempted, Reported or Assessed introductions which are categorised by Chemintro let us elaborate on the remaining groups.
2. We can see in this slide the AICIS introduction categories which are not categorised by Chemintro for industrial chemicals/polymers, and these fall within the following four groups:
    a. Listed category:
        i. We can define 5 categories under Listed category:
            1. Listed on the Inventory and no regulatory obligations or restrictions;
            2. Listed on the Inventory and within a defined scope of assessment;
            3. Listed on the Inventory and within conditions of introduction or use;
            4. Listed on the Inventory with specific information requirements;
            5. Listed on the Inventory and not within any defined scope or conditions of introduction.
        ii. The 1st category of "Listed on the Inventory and no regulatory obligations or restrictions" has no conditions applied to it and consequently the industrial chemical may be introduced but like all introductions, an introducer must submit an annual declaration after the end of an AICIS registration year which demonstrates that an introduction has occurred.
            1. Also, an introducer must keep certain records about the chemical introductions to confirm they are authorised as listed introductions. These records must be kept for 5 years, even after introduction of the industrial chemical has ceased.
        iii. For the 2nd category of "Listed on the Inventory and within a defined scope of assessment", 2 conditions exist:
            1. Where the industrial chemical is within the defined scope of assessment (which typically cover use, volume or concentration), then the industrial chemical may be introduced but as before, an introducer must submit an annual declaration as well as keep certain records about the chemical introductions.
            2. Where the industrial chemical is not within the defined scope of assessment (e.g. a different use, higher volume or higher concentration) then AICIS will not authorise the introduction.
                a. If the introduction is not authorised then an introducer can:
                    i. Explore other introduction options which are:
                        1. An exempted introduction.
                        2. A reported introduction.
                    ii. Ask AICIS to vary the defined scope of assessment through an assessment.
        iv. For the 3rd category of "Listed on the Inventory and within the conditions of introduction or use", again 2 conditions exist:
            1. Where the industrial chemical is within the conditions of introduction or use (such as what quantity can be introduced and for which application the chemical is permitted to be used) then the industrial chemical may be introduced but as before, an introducer must submit an annual declaration as well as keep certain records about the chemical introduction.

2. Where the industrial chemical is not within the conditions of introduction or use then the introducer will need to apply to vary the terms of an Inventory listing to cover the use. A fee applies and if AICIS approve the application, AICS will vary the condition of introduction or use on the chemical's Inventory listing so the introducer can introduce it. As before, once AICS has varied the condition of introduction or use on the chemical's Inventory listing an introducer must submit an annual declaration as well as keep certain records about the chemical introduction.

v. For the 4th category of "Listed on the Inventory with specific information requirements", an example of this may be the statement that "You must tell us within 28 days if the circumstances of your importation or manufacture (introduction) are different to those in our assessment". An introducer can then search for the AICIS assessment report on that chemical. If the introducer finds the assessment, the introducer should look for the heading "Secondary notification" to see the circumstances under which an introducer must submit information to AICIS.

    1. If the introducer cannot find the assessment, the introducer should submit the fee-free online form to AICIS to provide information about the introduction if:

        a. The introducer cannot find the AICIS assessment;

        b. The introducer is unsure whether these information obligations apply to the introducer;

        c. The introducer has found the AICIS assessment and the secondary notification obligations require the introducer to inform AICIS about the introduction.

    2. An introducer must also inform AICIS about any new hazard information if the introducer is introducing a chemical which AICIS has already assessed or evaluated which includes:

        a. Any new hazards that AICIS has not identified from the introduction or use of the chemical in their most recent assessment or evaluation statement.

        b. If there is an increase in the severity of a hazard which AICIS has already identified their most recent assessment or evaluation statement.

    3. Based on this information AICIS will determine if they need to reassess a chemical. AICIS refer to such reassessments as an "evaluation", and it is fee-free.

vi. For the 5th category of "Listed on the Inventory and not within any defined scope or conditions of introduction":

    1. This covers the two situations described above where:

        a. The industrial chemical is listed on the Inventory and not within a defined scope of assessment.

        b. The industrial chemical is listed on the Inventory and not within the conditions of introduction or use.

    2. These situations have been discussed above as well as the appropriate required actions.

3. Commercial Evaluation Authorisation (CEA) introduction:
    a. This is a new category which replaces the former NICNAS commercial evaluation permit (CEC).
    b. The Commercial Evaluation Authorisation (CEA) pathway encourages innovation by providing a faster, cost-effective way to introduce (import or manufacture) a chemical to evaluate its commercial potential.
    c. A CEA is valid for up to 4 years and authorises a maximum volume of 10 tonnes over 4 years.
    d. A CEA cannot be renewed or extended beyond the 4-year validity period.
    e. An introducer can apply for a new CEA for the chemical if the end use is different.
4. Exceptional circumstances introduction:
    a. This is where the AICIS Executive Director or Federal Minister of Health authorises a chemical's introduction because it's in the public interest and is needed to manage significant human health or environmental risks.
    b. It might be required for the introduction of a new chemical in response to an emergency situation, e.g. an oil spill where an urgent introduction was warranted.
5. Restricted introduction:
    a. A restricted introduction could include such chemicals as:
        i. Chemicals listed in the Rotterdam Prior Informed Consent (PIC) Convention:
            1. The Annex III to the Rotterdam Convention is a list of pesticides and industrial chemicals that have been severely restricted for health or environmental reasons.
            2. An example of this is tetraethyl lead for aviation fuel.
        ii. Chemicals listed in the Stockholm persistent organic pollutants (POPs) Convention
            1. The Stockholm Convention is a global treaty that aims to protect human health and the environment from the effects of persistent organic pollutants (POPs).
            2. Australia does not automatically adopt controls for these chemicals but must take measures to eliminate or reduce their release into the environment.

AICIS introduction categories not categorised by Chemintro

The AICIS excluded introduction categories for industrial chemicals/polymers:

- naturally occurring chemicals;
- non-isolated intermediates;
- incidentally introduced chemicals;
- chemicals unintentionally released from an article;
- trans-shipment chemicals;
- chemicals introduced incidentally on an aircraft or ship;
- articles.

Slide 26:

Also, at the same time Chemintro does not charge for the AICIS excluded categories such as naturally occurring chemicals, which we discussed earlier, non-isolated intermediates etc., all the way down to articles, as we see on this slide.

Because these introductions are excluded and Chemintro did not categorise them, then no charge is incurred.

Chemintro provides a solution to the issues in this paper

- Chemintro also provides:
  - A secure information management system (only an introducer and their authorised users have access) for:
    - Input data for chemical categorisation;
    - Supporting data e.g. testing study reports, TDS, SDS.
    - Automatic generation of a pre-introduction report (for reported introductions);
    - Automatic generation of a post-introduction declaration (for exempted introductions);
    - Automatic generation of an annual declaration for all introductions (linking to product formulations, raw materials, and introduced chemicals in raw materials);
    - Retention of data on formulations, raw materials, and introduced chemicals in preparation for an AICIS audit.

Slide 27:

As we said before, Chemintro focuses on the three introduction categories of exempted, reported or assessed, and if we look at these, Chemintro also provides a secure information management system so that only an introducer and their authorised users have access to be able to input data for the chemical categorisations together with supporting data testing study reports, TDS, SDS, etc.

Chemintro provides automatic generation of a pre-introduction report (for reported introductions) and we will see an example of that later.

It also provides automatic generation of a post-introduction declaration (for exempted introductions) as well as automatic generation of an annual declaration for all introductions.

This can also link to product formulations, raw materials and introduced industrial chemicals in raw materials.

Chemintro can also enable retention of data on formulations, raw materials and introduced industrial chemicals in preparation for an AICIS audit.

So, all of the data can be put into the Chemintro system, (remember only the introducer and the authorised users have access).

They control the password and consequently they control the access.

As I said, I've spent the last two years or so focussing on AICIS and nearly the last year in the development of Chemintro with Mike Dewhirst.

As a secure information management system, it may be used by anybody (whether in Australia or overseas), including industrial chemical raw material manufacturers' representatives & producers, fully formulated finished product manufacturers (including surface coatings, cosmetics etc.), industrial chemical raw material importers as well as finished product importers.

Now, let's work with the example of tertiary-Amyl Ethyl Ether on the next few pages just to demonstrate the capabilities of Chemintro.

Chemintro - Chemical Pre-introduction report for tertiary-Amyl Ethyl Ether 1

Chemical: **Amyl ethyl ether**

Category: Reported - low risk

Focus: Very low to low risk

AICIS fee: Optional $7,435 application fee for assessment certificate

A pre-introduction report will be required. Annual declarations will be required.

Business name:	ABC Australia Pty Ltd
Business contact:	Adrian Thomas
Agent:	Not appointed
Report contact:	Adrian Thomas
AICIS registration number:	NIC515242
Portfolio ID:	NIC1005242
PIR ID:	Not entered
Type of report:	Highest indicative risk is low
Name of industrial chemical:	Amyl ethyl ether
Do you know the proper name:	Yes
Proper name:	tert-Amyl ethyl ether

Slide 28:

So, we show here our work on the example of tertiary-Amyl Ethyl Ether on the next 10 slides, just to demonstrate the capabilities of Chemintro.

As an aside, I should point out that this is based on a real introduction, but some of the data has been sanitised sufficiently to protect the identity of the introducer, without taking away from its value as a worked example.

So, on this slide we have here the first page of a pre-introduction report (PIR).

This was a reported, low risk chemical introduction where the focus ranges from very low risk for the Environmental risk and low risk for the Human Health risk.

As a consequence, a pre-introduction report is required to be submitted to AICIS.

An introducer could also make an application for an assessment certificate.

Sometimes, this may be considered to be appropriate, and we can see the AICIS optional application for an assessment fee of $7435, at time of presentation.

This can have two advantages:

- Firstly, if such an assessment were to be carried out then automatically AICIS have in effect, put their stamp of approval on the categorisation of the particular chemical when carrying out the assessment. Even though this chemical could be introduced at no charge, by going through the process of an assessment certificate then there should be no need for AICIS to come back later on and carry out an audit.
- Secondly, as a consequence of such an assessment, it provides the opportunity for listing on the AICIS inventory, 5 years after assessment. Also, for an additional fee of $1490, at time of presentation, an application can be made for early listing of the industrial chemical on the Inventory, thus enabling the industrial chemical and formulations containing the industrial chemical to be introduced by other introducers, where desired, after the listing.

We can see here the typical type of information that is generated for a pre-introduction report automatically using the Chemintro system and the reader can see that this represents quite a bit of information not only on this slide but on the next slide.

Chemintro - Chemical Pre-introduction report for tertiary-Amyl Ethyl Ether 2

CAS number:	919-94-8
Primary name:	Amyl ethyl ether
Is it a UVCB:	No
Is it a high molecular weight polymer:	Not a polymer
Will it be imported or manufactured in Australia:	Imported
What is the maximum total volume of the chemical introduced in Australia during a registration year	> 10,000 kg
What is the end use of the chemical	Fuel, oil and related products
Specify the end use of the chemical	Gasoline or petrol
Does the introduction belong to a specified class	None
Does the introduction involve "a designated kind of release to the environment"	No
Will the industrial chemical have an end use in cosmetics	No
What is the maximum concentration at end use	10%
Does the chemical have a human health hazard characteristic	Yes
Does the chemical have an environment hazard characteristic	No
What is the human health exposure band for the chemical	Band 4
What criteria was used to determine the human health exposure band	Item no. 6
What is the environment exposure band for the chemical	Band 3
What criteria was used to determine the environment exposure band	Item no. 3

Slide 29:

On this slide we have here the second page of a pre-introduction report (PIR), which we have split up into 2 slides, purely for ease of presentation purposes.

This particular industrial chemical which we are considering is contained in a racing fuel formulation, which is imported at a level of 560 tonnes per annum, and the racing fuel contains about 10% of this particular tertiary-Amyl Ethyl Ether and contains 90% of other ingredients.

We can see that the whole process requires categorisation. In other words, data on the hazard characteristics and exposure bands both for human health and environment needs to be reported to AICIS in the pre-introduction report.

Frankly, completing a report like this requires a particularly good understanding of the Industrial Chemicals (General) Rules as well as the Industrial Chemicals Categorisation Guidelines.

This is exhibited in one of the questions "What criteria was used to determine the human health exposure band" to which the answer was "Item number 6", which requires more than a passing appreciation of the Rules and Guidelines.

Also, it should be appreciated that one of the questions is "What is the maximum total volume of the chemical introduced in Australia during a registration year", where the response should be reported in one of the following volume ranges:

- ≤ 25 kg
- > 25 kg to ≤ 100 kg
- > 100 kg to ≤ 1,000 kg
- > 1,000 kg to ≤ 10,000 kg
- > 10,000 kg

In this example, the racing fuel formulation is being imported at 560 TPA or 560,000 kg PA.

The racing fuel contains about 10% of tertiary-Amyl Ethyl Ether which then computes to 56,000 kg PA and so the answer to the question "What is the maximum total volume of the chemical introduced in Australia during a registration year" becomes 56,000 kg PA which requires reporting in the volume range of > 10,000 kg PA.

Please note that this does not refer to the total volume of the racing fuel formulation product being introduced into Australia.

As mentioned before, this report is submitted to AICIS prior to introduction of the chemical.

A Post-introduction declaration (PID) is required to be submitted to AICIS where a very low risk industrial chemical is introduced.

As previously stated, the first PID is due by 30th November 2021 and covers the period 1st July 2020 – 31st August 2021.

From 2022, introducers must submit a PID by 30th November each year following the end of the previous AICIS registration year: 1st September – 31st August.

Chemintro can also produce a PID but for the sake of brevity in this presentation we are purely focusing on the more complicated pre-introduction report (PIR) as our example of a reported, low risk chemical introduction.

Chemintro – Data Entry report (audit) for tertiary-Amyl Ethyl Ether 1

This report shows data used as input for categorisation plus other information (including “Useful Links”) of possible interest to AICIS in the event of an audit.

Industrial chemical data

Trade or chemical name:	**Amyl ethyl ether**
CAS name:	**tert-Amyl ethyl ether**
Portfolio ID:	NIC1005242
Division	ABC Australia Pty Ltd - Operations
Access status	Default - all identifying information (name, CAS etc) visible
Physical state	Liquid
Origin	Imported
Information availability	Introducer does know the CAS number and CAS name for the introduced chemical
CAS number	919-94-8
AICIS listing	Not entered
CAS name	tert-Amyl ethyl ether
IUPAC name	Not entered
INCI name	Not entered
Nano-material	No
Incidental nano-material	No
UVCB substance	Not applicable
UVCB substance description	Not applicable
GM product	No
Name of GM organism	Not applicable

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Slide 30:

Here we show the full information, that was used to prepare this pre-introduction report.

We describe it as a data entry report (audit) on the basis that if an audit were to occur then all the information is available in one report.

As we can see here it is quite lengthy and is presented on the next 8 slides, i.e. from slide 30 to slide 37, which we have again split up purely for ease of presentation purposes.

So, on this slide show the 1st section of a data entry report (which may be used for a subsequent audit) which contains the data used to prepare the previous chemical pre-introduction report for tertiary-Amyl Ethyl Ether.

As we state at the top of this slide, this report shows data used as input for categorisation plus other information (including “Useful Links”) of possible interest to AICIS in the event of an audit.

As we can see, information on the industrial chemical data was input by the introducer in response to various categories.

Chemintro – Data Entry report (audit) for tertiary-Amyl Ethyl Ether 2

Biological chemical	No
Biochemical	No
Biocidal active	No
Organotin	No
UV filter	No
Polyhalogenated organic	No
Fully fluorinated carbons	No
Highly branched organic	Not applicable
Persistent	No
Readily biodegradable	No
Bioconcentration factor	Not entered
Bioaccumulation factor	Not entered
Octanol/Water partition ratio	Not entered
Aqueous solubility	Not entered

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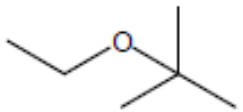
Slide 31:

Here we show the 2nd section of a data entry report (which may be used for a subsequent audit) which contains the data used to prepare the previous chemical pre-introduction report for tertiary-Amyl Ethyl Ether.

This continues to present further information which was input by the introducer under various categories.

Chemintro – Data Entry report (audit) for tertiary-Amyl Ethyl Ether 3

CIH company	Not entered
Information holder	Adrian Thomas adrian@chemicalia.com ABC Australia Pty Ltd 1234567 Elsewhere Qld 4444 Australia
International assessment	Not entered
International health assessment	No
International environment assessment	No
Stockholm/Rotterdam	Not detected
Formula	$C_7H_{16}O$
2D structure	
Chemical structure	Not entered
Molecular weight	116.2 g/mol

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Slide 32:

Here we show the 3rd section of a data entry report (which may be used for a subsequent audit) which contains the data used to prepare the previous chemical pre-introduction report for tertiary-Amyl Ethyl Ether.

At the top of the slide, we see reference to CIH or the Chemical Information Holder.

This is especially used where for example an overseas company may hold technical information (essentially relating to physicochemical, toxicological and eco-toxicological data and study reports) and may be prepared to supply to AICIS but not to the Australian introducer.

On this occasion no CIH company was entered, because I am the information holder, showing my email address and the fictitious address and details for ABC Australia Pty Ltd.

We can also see that no data was entered for international assessment, international health assessment or international environment assessment.

We can also see on this slide that when the chemical was compared against chemicals listed on the Stockholm Convention on Persistent Organic Pollutants and the Rotterdam Convention, it was not detected on either of the two lists.

The software automatically generated the chemical formula and the two-dimensional molecular structure and the molecular weight for the introduced chemical.

This together with all other supporting information was produced in literally less than a minute of supply by the introducer of all the required input data.

Chemintro – Data Entry report (audit) for tertiary-Amyl Ethyl Ether 4

EC No	Not entered
ChemSpider ID	12939
Standard InChIKey	KFRVYYGHSPLXSZ-UHFFFAOYSA-N (commonchemistry.cas.org) KFRVYYGHSPLXSZ-UHFFFAOYSA-N (ChemSpider)
Standard InChI	InChI=1S/C7H16O/c1-5-7(3,4)8-6-2/h5-6H2,1-4H3 (commonchemistry.cas.org) InChI=1S/C7H16O/c1-5-7(3,4)8-6-2/h5-6H2,1-4H3 (ChemSpider)
SMILES structure	CCC(C)(C)OCC (commonchemistry.cas.org) CCC(C)(C)OCC (ChemSpider)

Chemical volume

Product name	Racing fuel
End use scenario	Fuel, oil and related products
End use	Gasoline or petrol
Maximum end use concentration	10 %
Aerosolised during end use	No
Any consumer end use	No
No of items	Not entered
Item unit weight	Not entered
Product volume	560 t
Precise proportion	10% m/m Amyl ethyl ether
Chemical volume	56 t

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Slide 33:

Here we show the 4th section of a data entry report (which may be used for a subsequent audit) which contains the data used to prepare the previous chemical pre-introduction report for tertiary-Amyl Ethyl Ether.

As we saw previously, the software automatically generated technical information on the introduced chemical.

On this page we see some further information including the ChemSpider ID from the ChemSpider database, as well as the Standard InChiKey which is from two sources, on this occasion.

The condensed, 27 character standard InChIKey is a hashed version of the full InChI and is designed to allow for easy web searches of chemical compounds.

In this context, a hash function is any function that can be used to map data of arbitrary size to fixed-size values.

There is a very small, but non-zero chance of two different molecules having the same InChIKey, but the probability for duplication of only the first 14 characters has been estimated as only one duplication in 75 databases each containing one billion unique structures.

The standard InChi turned out to be too lengthy for easy searching, and therefore the InChIKey was developed, and we can see the Standard InChi which is from two sources, on this occasion.

Finally in this area of data for the industrial chemical we show the SMILES (simplified molecular-input line-entry system) line notation for describing the structure of chemical species using short ASCII strings.

As we stated earlier, this together with all other supporting information was automatically produced once the introducer had provided all the required input data.

At the same time, when looking at the introduction of an industrial chemical the introducer needs to provide information regarding the volume and end use scenario.

As we stated on an earlier slide the AICIS emphasis is on risk which is a combination of hazard and exposure.

So, in this chemical volume area, we need to provide information regarding the end use scenario, the maximum concentration in % at end use, the product volume, and the proportion of the active ingredient in the introduced formulation since this then determines the volume of the introduced industrial chemical.

Here we are essentially focusing on the exposure of the industrial chemical to both human health and the environment.

As we previously discussed in slide 29 relating to the pre-introduction report of this industrial chemical, this industrial chemical is contained in a racing fuel formulation, imported at 560 tonnes per annum, and the racing fuel contains about 10% or 56 tonnes per annum of this particular chemical which is tertiary-Amyl Ethyl Ether.

We also report the maximum end use concentration of the industrial chemical, which is 10%, since under certain circumstances sometimes the end use concentration may have an impact on the exposure band relating to the chemical.

As stated before, the maximum total volume of this chemical introduced in Australia during a registration year becomes 56 tonnes per annum or 56,000 kg per annum and this does not refer to the total volume of the racing fuel formulation product being introduced into Australia.

Chemintro – Data Entry report (audit) for tertiary-Amyl Ethyl Ether 5

Introduction

Report ID	Not entered
Exclusion	Not applicable
Specified class	Not applicable
Categorisation	Not applicable
Introduction	Reported - low risk
Total introduced	56,000.0 kg
Maximum concentration	10 %
Software revision	0.9.26

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Slide 34:

Here we show the 5th section of a data entry report (which may be used for a subsequent audit) which contains the data used to prepare the previous chemical pre-introduction report (PIR) for tertiary-Amyl Ethyl Ether.

On this slide we see the result of the risk determination with the result that the introduction is a reported introduction based on a low-risk categorisation for the industrial chemical.

It also shows the total volume of the chemical introduced and its maximum concentration at end use.

The report also shows the Chemintro software revision used to prepare this report.

On the next slide we will move to the Globally Harmonized System of Classification and Labelling of Chemicals or GHS hazard classification.

Chemintro – Data Entry report (audit) for tertiary-Amyl Ethyl Ether 6

Hazard

H371	Specific target organ toxicity - single exposure: Category 2

Synonyms

.. aka ..	2-Ethoxy-2-methylbutane
.. aka ..	Butane, 2-ethoxy-2-methyl-
.. aka ..	Ether, ethyl tert-pentyl
.. aka ..	Ethyl 1,1-dimethylpropyl ether
.. aka ..	Ethyl tert-amyl ether
.. aka ..	Ethyl tert-pentyl ether
.. aka ..	tert-Amyl ethyl ether

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Slide 35:

Here we show the 6th section of a data entry report (which may be used for a subsequent audit) which contains the data used to prepare the previous chemical pre-introduction report for tertiary-Amyl Ethyl Ether.

On this slide we show the hazard, under GHS for the introduced chemical.

We also show the synonyms for this industrial chemical which yet again were automatically produced once the introducer had provided all the required input data.

Chemintro – Data Entry report (audit) for tertiary-Amyl Ethyl Ether 7

Useful links

AICIS assessment	https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=919-94-8
AICIS obligations	https://www.industrialchemicals.gov.au/chemicals/Alkane%20Ethoxy%20Methyl-
Attachment 1 - SciFinder Alkane, ethoxy-methyl-	https://www.dropbox.com/s/ihjme92wi0ma4ft/Item%204%20-%20Attachment%201%20-%20SciFinder%20Alkane%2C%20ethoxy-methyl-%20%20highlighted.pdf?dl=0
Attachment 10 - SDS Racing Fuel (NICNAS Use)	https://www.dropbox.com/s/c0mvhdfgxswz8rg/Item%2022%20-%20Attachment%2010%20-%20SDS%20Racing%20Fuel%20%28NICNAS%20Use%29.pdf?dl=0
Attachment 11 - SDS Racing Fuel (Public Use)	https://www.dropbox.com/s/pkd4q7pyi2u46nx/Item%2024%20-%20Attachment%2011%20-%20SDS%20Racing%20Fuel%20%28Public%20Use%29.pdf?dl=0
Attachment 12 - Racing Fuel 200 L Label Front Panel	https://www.dropbox.com/s/tdz4h4j5s6jdnem/Item%2026%20-%20Attachment%2012%20-%20Racing%20Fuel%20200%20L%20Label%20Front%20Panel.pdf?dl=0
Attachment 13 - Racing Fuel 200 L Label Rear Panel	https://www.dropbox.com/s/vpabb599cz5w67o/Item%2028%20-%20Attachment%2013%20-%20Racing%20Fuel%20200%20L%20Label%20Rear%20Panel.pdf?dl=0
Attachment 14 - Racing Fuel 20 L Label Front Panel	https://www.dropbox.com/s/8vux19bey5o8da9/Item%2030%20-%20Attachment%2014%20-%20Racing%20Fuel%2020%20L%20Label%20Front%20Panel.pdf?dl=0
Attachment 15 - Racing Fuel 50 L Label Rear Panel	https://www.dropbox.com/s/wtnvkut04pj05kn/Item%2032%20-%20Attachment%2015%20-%20Racing%20Fuel%2050%20L%20Label%20Rear%20Panel.pdf?dl=0
Attachment 16 - Racing Fuel 20 L Label Front Panel	https://www.dropbox.com/s/c3yc5d94zf3o401/Item%2034%20-%20Attachment%2016%20-%20Racing%20Fuel%2020%20L%20Label%20Front%20Panel.pdf?dl=0
Attachment 17 - Racing Fuel 20 L Label Rear Panel	https://www.dropbox.com/s/ejz0xrwa58irksb/Item%2036%20-%20Attachment%2017%20-%20Racing%20Fuel%2020%20L%20Label%20Rear%20Panel.pdf?dl=0
Attachment 2 - Alkane, ethoxy-methyl-, Explosive	https://www.dropbox.com/s/0j9krl1igjc9mo9/Item%206%20-%20Attachment%202%20-%20Alkane%2C%20ethoxy-methyl-%2C%20Explosive%20Properties%20and%20Oxidising%20Properties%20%28Liquids%29.pdf?dl=0

Slide 36:

Here we show the 7th section of a data entry report (which may be used for a subsequent audit) which contains the data used to prepare the previous chemical pre-introduction report for tertiary-Amyl Ethyl Ether.

As we referred to on an earlier slide, Chemintro has a section referred to as “Useful Links” which may be of value when dealing with AICIS in the event of an audit.

The program also automatically generates a link to the AICIS Inventory noting that this chemical is not on the AICIS inventory.

If the industrial chemical were on the AICIS inventory, then the Chemintro program also advises whether there are any obligations in relation to the industrial chemical.

This “Useful Links” area provides an opportunity to store as much information as the introducer wishes regarding study reports on test data, etc. in the introducer’s own Dropbox account which is automatically linked to Chemintro.

This area contains 19 files, 12 are shown on this slide and 7 on the next slide.

Chemintro – Data Entry report (audit) for tertiary-Amyl Ethyl Ether 8

Properties and Oxidising Properties (Liquids)	
Attachment 3 - Merck Alkane, ethoxy-methyl-SDS_AU_EN	https://www.dropbox.com/s/r8ue3rs2se851l7/Item%208%20-%20Attachment%203%20-%20Merck%20Alkane%2C%20ethoxy-methyl-SDS_AU_EN%20highlighted.PDF?dl=0
Attachment 4 - EFOA Alkane, ethoxy-methyl- Product-Bulletin	https://www.dropbox.com/s/0pl5mbjuljfhjng/Item%2010%20-%20Attachment%204%20-%20EFOA%20Alkane%2C%20ethoxy-methyl-%20Product-Bulletin-%20highlighted.pdf?dl=0
Attachment 5 - EpiWin Alkane, ethoxy-methyl-	https://www.dropbox.com/s/w042m4qy8ayzgvr/Item%2012%20-%20Attachment%205%20-%20EpiWin%20Alkane%2C%20ethoxy-methyl-%20highlighted.pdf?dl=0
Attachment 6 - Alkane, ethoxy-methyl- - A Toxicological Review	https://www.dropbox.com/s/tg40px27w6xva1b/Item%2014%20-%20Attachment%206%20-%20Alkane%2C%20ethoxy-methyl-%20-%20A%20Toxicological%20Review%20highlighted.pdf?dl=0
Attachment 7 - Stability of Methyl tert-Butyl Ether, tert-Amyl Methyl Ether, and Alkane, ethoxy-methyl- in Acidic Media	https://www.dropbox.com/s/a1k8thx43ny497g/Item%2016%20-%20Attachment%207%20-%20Stability%20of%20Methyl%20tert-Butyl%20Ether%2C%20tert-Amyl%20Methyl%20Ether%2C%20and%20Alkane%2C%20ethoxy-methyl-%20in%20Acidic%20Media%20highlighted.pdf?dl=0
Attachment 8 - NICNAS Full Public Report on t-Amyl methyl ether (TAME) NA_878	https://www.dropbox.com/s/p4x3drp51w75pef/Item%2018%20-%20Attachment%208%20-%20NICNAS%20Full%20Public%20Report%20on%20t-Amyl%20methyl%20ether%20%28TAME%29%20NA_878%20highlighted.pdf?dl=0
Attachment 9 - European Union Risk Assessment Report, Tert-Butyl Methyl Ether, 2002	https://www.dropbox.com/s/k3l5s1xe7lrfwz4/Item%2020%20-%20Attachment%209%20-%20European%20Union%20Risk%20Assessment%20Report%2C%20Tert-Butyl%20Methyl%20Ether%2C%202002%20highlighted.pdf?dl=0
Note	
Author details	04 May 2021 Please note your details here so people with access to this page can get in touch if necessary. Name: Phone: Email: Date: Please also remember that the terms of the license to use this site requires notification of any defects or shortcomings in the software or data being shared. Your collaboration is appreciated

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Slide 37:

Here we show the 8th and final section of a data entry report (which may be used for a subsequent audit) which contains the data used to prepare the previous chemical pre-introduction report for tertiary-Amyl Ethyl Ether.

As we stated on the previous slide, we are still looking at the section referred to as “Useful Links” which may be of interest to AICIS in the event of an audit.

This slide shows the final 7 files held in the Dropbox repository.

The advantage of this and the previous slide is that, if an audit were to occur, then the industrial chemical introducer can just access any of those files, have a look at them and submit them to AICIS when requested and are hopefully well within the 20 working days that are required to meet an AICIS audit deadline.

This is, if you like a data entry report, which may be invaluable if a subsequent AICIS audit were to occur.

I should point out that an audit can occur at any time.

Let me tell you a real-life experience of such a situation.

One of my clients submitted a pre-introduction report for a reported introduction at the end of September 2020.

At the time they had been assured by the overseas industrial chemical raw material supplier that all required technical data and study reports would be made available to support this introduction, if AICIS were to request such data.

In late March 2021, nearly literally 6 months to the day AICIS carried out an audit and sent a request to the introducer asking the introducer to provide information to demonstrate the basis on which the introducer had determined the category of the introduction with a response required within 20 working days.

On behalf of my client, I sent a response within the deadline providing 13 supporting files justifying the category of the introduction.

In early July 2021 AICIS advised by email that detailed information, including full study reports, was required to be provided to AICIS, and that the introducer must hold a written undertaking that it holds the information.

After correspondence with the overseas raw material supplier, we were finally able to determine that the supplier had only literature data to support their product, but held no adequate specific study reports.

AICIS had requested the information within 14 days of their email, but due to delays with the overseas supplier, with AICIS’s agreement for our lateness, we responded 21 days after receiving the AICIS email, and told them we could not provide any new, additional data more than we had already submitted.

In early August 2021, about a week after we sent this email, AICIS sent a further letter on the basis that the reported introduction was not authorised and requesting information within 2 weeks on which steps will be taken to ensure that introductions of the Chemical will be authorised, and what volume of the chemical had been imported since the pre-introduction report was lodged at the end of September 2020.

After I consulted with my client on how to respond, he rang the contact at AICIS explaining the situation with the overseas supplier not having sufficient information and sent a brief email through to AICIS advising that there were no stocks of the industrial chemical in Australia and that they would not proceed with any further importation.

AICIS were quite surprised that this situation had ended up this way, because they had presumed that their new system would be easier for the introduction of new low-hazard chemicals.

AICIS sent a final letter in mid-September 2021 advising that they would be taking no further action in relation to this matter.

This whole process which I just described demonstrates how long the AICIS process can take and also how much lost opportunity time can be spent having to deal with AICIS communications.

In some ways, this example demonstrates a lack of appreciation by AICIS of real-world situations where overseas suppliers do not automatically hold all the data that AICIS may presume they would.

Chemintro – Annual Declaration summary for ABC Australia Pty Ltd 1

[Save and continue editing] to refresh the counts.

The six types of introductions of interest to AICIS in the annual declaration are Listed, Exempted, Reported, Assessed, Commercial Evaluation and Exceptional Circumstances.

Other types mentioned below do not need to be declared. If there are any it is because the data exists in those categories.

Company:

ABC Australia Pty Ltd

Declaration year:

2021

There can be only one summary per year. The value in this field names this annual summary.

Declaration submitted:

No

While this field is set to 'No', saving will automatically refresh the numbers of introductions AND will also blank out *Date submitted*

When set to 'Yes' and saved, *Date submitted* will be set to today and no further changes will be made to this record by the software.

Date submitted:

Date: Today |

Time: Now |

Note: You are 10 hours ahead of server time.

Date cannot be saved unless *Declaration submitted* is 'Yes'

This UTC date/time represents when you submitted your actual annual declaration on the AICIS website

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Slide 38:

Back on slide 18 we also talked about the AICIS annual declaration, which as its name implies is submitted once a year.

On this slide 38 and the next one, slide 39 we provide information which is useful in preparation of an annual declaration.

Chemintro – Annual Declaration summary for ABC Australia Pty Ltd 2

Listed Introductions:

2

Means AICIS listed and within scope or no regulatory obligations.

Industrial chemicals which are listed but out-of-scope are shown under *Prohibited introductions*.

Exempted Introductions:

3

Reported Introductions:

4

Assessed Introductions:

2

Commercial Evaluation Introductions:

0

Exceptional Circumstances Introductions:

0

This applies to introductions resulting from acceptance of an application for special consideration by the AICIS Executive Director or the Minister.

Prohibited Introductions:

0

This applies where a chemical is not or will not be introduced due to being listed in the AICIS inventory but not within scope or due to rejection of an application to the AICIS Executive Director or the Minister.

Excluded Introductions:

0

Should always be zero because the Act does not apply and AICIS is therefore not interested. The field is here purely for completeness in case such chemicals are entered for unspecified reasons.

Person responsible:

Mike Dewhirst

Job title:

Director

Modified:

July 3, 2021, 6:25 a.m.

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Slide 39:

As previously discussed on slide 18, the AICIS annual declaration needs to contain the following information, the AICIS Business Registration Number and whether any introductions have occurred which are listed, exempted, reported, assessed, commercial evaluation authorisation or exceptional circumstances introductions.

Chemintro provides this summary which includes all of the above introductions together with:

- Prohibited introductions, this applies where a chemical is not or will not be introduced due to being listed in the AICIS Inventory but not being within scope or due to rejection of an application to the AICIS Executive Director or the Minister.
- Excluded introductions, this should always be zero because the Industrial Chemicals Act (2019) does not apply and AICIS is therefore not interested in collecting such data; the field is here purely for completeness in case such chemicals are entered for unspecified reasons.

This one is a work in progress.

In other words, the Annual Declaration has not yet been submitted to AICIS.

If the declaration had been submitted to AICIS then automatically on the previou slide we would have seen the date and time when it was submitted, with the date and time recorded in this annual declaration summary.

So, if we look at what is shown in this summary, we can see that for all of the industrial chemicals or formulations that ABC Australia Pty Ltd have introduced during the year, they have:

- 2 listed introductions, which are within scope and have no regulatory obligations;
- 3 exempted introductions;
- 4 reported introductions;
- 2 assessed introductions;
- No commercial evaluation authorisation introductions;
- No exceptional circumstances introductions;
- No prohibited introductions;
- No excluded introductions.

Chemintro – Chemical introductions Report for ABC Australia Pty Ltd 1

Chemical introductions report

Logged in as: Adrian Thomas, ABC Australia Pty Ltd

Always refresh your browser to see any changes: 2021-07-19 01:10:55 UTC

Software has calculated results you see here based on data you entered. Please be aware that AICIS may demand evidence in study reports to prove the validity of your data and possibly to prove that undeclared hazards do not exist. Should this occur you are advised to engage a competent consultant.

Please be advised that this report will change whenever underlying data is adjusted. It always represents the current snapshot of the data. If this report is used for a significant purpose such as a reference for data entry on the AICIS website you should print it and retain it safely for your records.

Slide 40:

So, on the previous two slides we covered the issue of completion of the annual declaration prior to submission to AICIS.

On the face of it, the situation appears to be relatively straightforward from the point of view of submitting a relatively simple form to AICIS.

The difficulty is that if AICIS were then at some later stage to contact the introducer and ask questions such as what are the 2 listed introductions, what are the 3 exempted introductions, what are the 4 reported introductions and what are the 2 assessed introductions.

This is entirely possible, especially where discrepancies exist between the AICIS data on their files and the data contained in the annual declaration.

This is where Chemintro is particularly useful because it automatically retains such categorisation data on all industrial chemicals retained on the database for ABC Australia Pty Ltd.

Chemintro – Chemical introductions Report for ABC Australia Pty Ltd 2

Acetone	Already listed on the AICIS inventory and within scope
Benzyl Acetate Test Solvent 1	Already listed on the AICIS inventory and within scope
Cosmetic GC	Exempted - very low risk
Hydrocarbon X	Exempted - very low risk
Polymer in resin solution 51/70 BAc	Exempted - very low risk
Amyl ethyl ether	Reported - low risk
Organoplatinum	Reported - low risk
Silica gel, reaction products with bis(triphenylsilyl) ester and ethoxydiethylaluminum	Reported - low risk
2,3-dihydroxy-[2-(2-hydroxy)ethyl]-[3-(2-hydroxy)propyl]-[(9Z,12Z)-octadeca-9,12-dienyl]azanium; chloride	Reported - low risk
Heavy metal paint	Assessed - medium to high risk
Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoroethyl)-	Assessed - medium to high risk

Slide 41:

So, in this slide we can see the background to the annual declaration summary.

We can see that here are the names of the industrial chemicals or formulations that ABC Australia Pty Ltd have introduced during the year, namely:

- 2 listed introductions, which are within scope and have no regulatory obligations:
    - Acetone, and Benzyl Acetate Test Solvent 1;
- 3 exempted introductions:
    - Cosmetic GC, Hydrocarbon X, and Polymer in resin solution 51/70 BAc;
- 4 reported introductions;
    - tertiary-Amyl Ethyl Ether, Organoplatinum, Silica gel, reaction products with bis(triphenylsilyl) ester and ethoxydiethylaluminum, and 2,3-dihydroxy-[2-(2-hydroxy)ethyl]-[3-(2-hydroxy)propyl]-[(9Z,12Z)-octadeca-9,12-dienyl]azanium; chloride;
- 2 assessed introductions:
    - Heavy metal paint, and Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoroethyl)-.

In this chemical introductions report ABC Australia Pty Ltd did not make any:

- commercial evaluation authorisation introductions;
- exceptional circumstances introductions;
- prohibited introductions;
- excluded introductions.

Consequently, they were not reported in the annual declaration.

There is the possibility that any introducer may introduce many industrial chemical raw materials, containing correspondingly many industrial chemicals, and they may also introduce many finished product formulations containing industrial chemical raw materials which in turn contain correspondingly many industrial chemicals, a lesser number of which industrial chemicals may be common across a number of raw materials and/or formulations.

This process can be quite onerous for an introducer to measure and consequently report on to AICIS.

This is where Chemintro simplifies the onerous task and provides all the detail that AICIS require.

Contact details

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Slide 42:

On this slide I’m providing my contact details.

Thank you for your attention

Any questions?

Visit https://chemintro.com

Slide 43:

Finally, I would like to thank you very much for your time and provide you a link to the Chemintro website where there is further information.

Thank you for your attention to the presentation and I welcome questions.