

EXPLANATORY STATEMENT

INDUSTRIAL CHEMICALS (GENERAL) RULES

Authority

The *Industrial Chemicals Act 2019* (the Act) establishes the legislative framework for a new risk-based scheme for the Commonwealth regulation of the introduction of industrial chemicals in Australia.

Section 180 of the Act provides that the Minister may make rules, providing for matters required or permitted by the Act, or necessary or convenient in order to carry out or give effect to the Act.

Purpose

The Industrial Chemicals (General) Rules 2019 (these rules) form part of the legislative framework to establish a new risk-based regulatory scheme for the introduction of industrial chemicals in Australia.

The new framework delivers major reforms following a Government decision in May 2015. As part of these reforms, the Australian Industrial Chemicals Introduction Scheme (AICIS) will replace the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

NICNAS is a statutory scheme administered by the Office of Chemical Safety (OCS), within the Department of Health. NICNAS helps protect the Australian people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use.

To ensure the continued Commonwealth regulation of the introduction of industrial chemicals, these rules establish the technical and operational details of AICIS including:

- preliminary matters such as definitions and detail regarding terms defined in the Act, the prescribed bodies that the Executive Director will consult with, and criteria for commercial evaluation authorisations
- categorisation of industrial chemical introductions, including what is exempted and what is reported
- requirements for reporting information about introductions
- requirements for record keeping
- confidentiality and disclosure
- international agreements and arrangements, and
- additional functions for the Executive Director.

Prescribing the kinds of matters in these rules (which are described at Attachment A) provides flexibility in an area where there are frequent scientific developments and advancements in relation to chemical identification, the hazards associated with

chemicals, and their risks to human health or the environment. It also enables adjustments to be more readily made to technical details and data requirements as, over time, new information comes to light about the evaluation of risks of chemicals.

Background

The Act establishes the legislative framework for a new risk-based regulatory scheme. These rules prescribe details to support the framework. This legislative package implements arrangements that will see regulatory effort more proportionate to the level of risk to human health and safety and the environment from the introduction and use of industrial chemicals, while maintaining Australia's robust health, safety and environmental standards.

The Act rebalances pre- and post-introduction regulatory controls for industrial chemical introductions so that there will be less emphasis on pre-introduction assessment of lower risk chemicals and a greater focus on post-introduction evaluation and monitoring.

This approach responds to the concerns of stakeholders by balancing the desire of industry for decreased regulation for lower risk chemicals (and certain protections for commercial business information) with the desire of community stakeholders for increased transparency of information, particularly for higher risk chemicals, and increased post-introduction monitoring and compliance capability. Improved post-introduction monitoring and compliance powers will provide the safeguards necessary to ensure that protections of health and safety of consumers, workers and the environment are maintained.

To allow flexibility to adapt to scientific and regulatory developments, much of the technical detail supporting the new regulatory framework was designed to be included in delegated legislation. The Act therefore establishes a principles-based framework with these rules establishing the technical and operational details of AICIS.

The existence of these rules relies on authority set out in the *Industrial Chemicals Act 2019*, which commences on 1 July 2020. These rules are being made in advance of this commencement date. This is possible in accordance with section 4 of the *Acts Interpretation Act 1901*, which allows for the exercise of powers between enactment and commencement of an Act including, for example, the power to make Rules.

Documents incorporated by reference

These rules incorporate the Industrial Chemicals Categorisation Guidelines (the Guidelines), as existing from time to time. The Guidelines are a non-legislative instrument issued by the Executive Director. The authority for this manner of incorporation is subsection 180(3) of the Act.

The Guidelines are non-legislative because they include technical detail to support introducers to categorise introductions of industrial chemicals, including, for example, information about:

- how to calculate the environment categorisation volume when determining the environment exposure band
- how to calculate the human health categorisation volume when determining the human health exposure band
- how to determine the hazard characteristics of chemicals for the purposes of determining indicative risk
- the types of technical records that must be kept in relation to the hazard characteristics (for exempted and reported introductions), and
- certain terms used in the rules (that require further technical explanation).

The Guidelines will be updated as required, including to keep in line with technical progress internationally, such as the development of non-animal tests for identifying hazards. Registered introducers will be notified of any changes to the Guidelines in advance of changes being made.

The draft Guidelines may be accessed at www.nicnas.gov.au before 1 July 2020. The Guidelines issued by the Executive Director will be able to be accessed at www.industrialchemicals.gov.au after 1 July 2020.

These rules incorporate the International Fragrance Association (IFRA) Transparency List as existing from time to time. This is publicly available (accessed at <https://ifrafragrance.org>) and lists the chemicals known to be used as fragrance ingredients based on a survey conducted by IFRA. It is used within the rules as an alternative option to providing chemical identity information, for specific low risk introductions. The inclusion of this option was in response to stakeholder feedback on the exposure draft of the rules.

Consultation

These rules were the subject of extensive consultation. Public consultation on the proposed technical details of the reform commenced in October 2015, with the major consultation on the technical details to be included in these rules and Guidelines occurring in June 2017.

Following this consultation, changes were made to details about the categorisation of industrial chemicals, reflected in these rules and the Guidelines.

On 9 March 2018, OCS published an exposure draft of the rules together with a draft of the Guidelines on the NICNAS website inviting public comment. OCS also met with both industry and community stakeholders to advise them of the proposed changes to the scheme and to invite comment.

Consultation on the exposure draft of the rules and the draft Guidelines closed on 4 May 2018 and OCS received 29 submissions.

Following passage of the Act a further consultation was undertaken between 4 April 2019 and 17 May 2019, which proposed changes to the draft version of the rules to take account of amendments to the Act that were made during its passage, as well as stakeholder feedback on criteria for the exempted and reported introduction categories. OCS received 26 submissions.

The submissions received on both the exposure draft of the rules and the further consultation on changes to the rules, informed further changes that were made to the technical details of AICIS, as now set out in these rules.

Regulatory impact assessment

The Government decision for the NICNAS reforms is covered by Regulatory Impact Statement (RIS) OBPR ID 17496. This RIS can be accessed at:

<https://ris.pmc.gov.au/2015/06/05/industrial-chemicals-assessment-reforms-%E2%80%93-regulation-impact-statement> .

Following the Government decision, a preliminary assessment was undertaken specific to the regulatory treatment of chemicals to be used for commercial evaluation. In relation to this assessment, the Office of Best Practice Regulation (OBPR) advised that the preliminary assessment was sufficient and a RIS was not required (OBPR ID 21108).

The OBPR was further consulted in relation to the making of these rules. The OBPR advised that RIS OBPR ID 17496 covers the package of NICNAS reforms and no further RIS is needed.

Commencement

These rules commence immediately after commencement of section 3 of the Act.

Details on these rules can be found at Attachment A.

These rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Industrial Chemicals (General) Rules 2019

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The Industrial Chemicals (General) Rules 2019 form part of the legislative framework for a new scheme to be known as the Australian Industrial Chemicals Introduction Scheme (AICIS). This scheme replaces the existing National Industrial Chemicals Notification and Assessment Scheme (NICNAS), established in 1989, and enables the Commonwealth to continue to regulate the introduction of industrial chemicals in Australia.

The scheme rebalances the current regulatory approach to be more proportionate to risk, and to promote safer innovation by encouraging the introduction of lower risk chemicals. This new approach encourages greater harmonisation with international approaches to the regulation of industrial chemicals and provides for the use of assessments of comparable international regulators.

The scheme also improves transparency, striking an appropriate balance between confidentiality and publicly available information, as the Executive Director will publish information that is more meaningful for industry and the public about chemical assessments, while allowing for appropriate confidentiality for business information through partially masked names and/or end use when in the public interest.

Human rights implications

This instrument engages the following rights:

- Right to health – Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), and
- Right to privacy and reputation – Article 17 of the *International Covenant on Civil and Political Rights* (ICCPR).

Right to health

This instrument engages the right to health as set out in Article 12 of the International Covenant on Economic, Social and Cultural Rights by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The requirements in this instrument to categorise industrial chemical introductions according to indicative human health risk and indicative environment risk promotes

protection of public health, and improvement of environmental and industrial hygiene. Having criteria for streamlined introduction pathways (reported and exempted introductions) will also encourage the introduction of newer and safer chemical products for consumers.

Right to privacy and reputation

Lawful interference with the right to privacy is permitted under Article 17 of the ICCPR, provided it is not arbitrary. In order for an interference with the right to privacy to be permissible, the interference must be authorised by law, be for a reason consistent with the ICCPR and be reasonable in the particular circumstances. The United Nations Human Rights Committee has interpreted the requirement of ‘reasonableness’ to imply that any interference with privacy must be proportional to the end sought and be necessary in the circumstances.

Chapter 5 of the instrument provides for the publication of certain information relating to reported introductions and prescribes the entities to whom disclosure of protected information in certain circumstances is legal. These provisions build on Part 6, Division 4, Subdivision C of the *Industrial Chemicals Act 2019* (the Act), which establishes a scheme for the protection of certain information and for the disclosure of such information in limited circumstances.

The scheme engages the right to protection against arbitrary and unlawful interferences with privacy by describing an approach that assumes protection of protected information (with penalties for inappropriate disclosure by entrusted persons) while also enabling disclosure in limited circumstances where this is reasonable and warranted. Chapter 5 of these rules sets out the details for how certain information (such as proper chemical name and end use) will be protected, and the people to whom notice is given when this protection is reviewed.

These provisions of the Act will predominantly apply to business entities, while a small proportion of chemical introducers will conduct business as individuals. This instrument will operate to ensure that, for such individuals, privacy is only interfered with to the extent necessary to protect occupational health and safety, public health and the environment by the publication of information about risks associated with introduction and use of industrial chemicals, i.e. consistent with the right to health of all Australians.

Conclusion

The legislative instrument is compatible with human rights because to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate for the protection of human health and the environment.

Mark Coulton
Minister for Regional Services, Decentralisation and Local Government

Details of the Industrial Chemicals (General) Rules 2019

Chapter 1 – Preliminary

Part 1 – Preliminary

Section 1 Name

This section provides for these rules to be cited as the Industrial Chemicals (General) Rules 2019.

Section 2 Commencement

These rules commence immediately after the commencement of section 3 of the *Industrial Chemicals Act 2019*.

The Federal Register of Legislation may be accessed at www.legislation.gov.au.

Section 3 Authority

These rules are made under the *Industrial Chemicals Act 2019*.

Section 4 Simplified outline of this instrument

Section 4 gives an overview of the content of these rules by reference to each of the six chapters. It summarises the content of each chapter:

- Chapter 1 – includes preliminary provisions and definitions. It also sets out certain circumstances in which a ban on the use of animal test data for applications under the Act apply.
- Chapter 2 – deals with the categorisation of industrial chemical introductions across the six categories of introduction established in the Act.
- Chapter 3 – sets out reporting obligations, including for pre-introduction reports and annual declarations.
- Chapter 4 – specifies the record keeping obligations in relation to all introduction categories.
- Chapter 5 – deals with confidentiality and disclosure of information.
- Chapter 6 – deals with the movement of industrial chemicals into and out of Australia and approvals to move certain chemicals on application.
- Chapter 7 – addresses miscellaneous matters, including additional functions for the Executive Director and reviewable decisions.

Section 5 Definitions

Section 5 includes definitions for terms used in these rules.

Some of these definitions refer to other laws for their meaning. For example the definitions of *fuel* and *supply* have the same meaning as in the *Fuel Quality Standards Act 2000*.

Some of these definitions refer to the meaning given by the Industrial Chemicals Categorisation Guidelines issued by the Executive Director (the Guidelines). These are for terms used in the categorisation, reporting or record keeping parts that require more complex technical detail. For example:

- The definition of *environment categorisation volume* refers to the Guidelines so that the detailed method for calculating this volume (including the formula and the default factors to be used in the calculation) can be specified.
- The definition of *persistent* refers to the Guidelines so that the acceptable test guidelines to measure this property, along with the relevant degradation thresholds, can be specified.

As far as possible, definitions have been aligned with comparable international regulatory schemes for chemicals. For example:

- The definition of *biocidal active* and *harmful organism* have taken into account the equivalent definitions in the European Biocidal Products Regulation, while also recognising that in Australia certain end uses as biocidal actives are regulated under the Agvet Code.
- The definition of *research and development* has taken into account an agreed definition resulting from activities of the Organisation for Economic Co-operation and Development (OECD).
- The definitions of *polymer* and its related terms (such as *monomer*, *reactant*, *reactive functional group*, and *low cationic density*) have taken into account the equivalent definitions in the industrial chemical regulatory schemes in the United States and Canada.

Section 6 Internationally-assessed industrial chemicals

Section 6 describes the circumstances in which, for the purposes of the scheme, an industrial chemical will be internationally-assessed for human health, internationally-assessed for the environment, or internationally-assessed for both.

For an industrial chemical to be internationally-assessed for human health (or the environment) it must have been assessed or evaluated by a trusted international assessment body, the names of which are given in subsection 6(3) of these rules, together with the corresponding kinds of assessment or evaluation.

The assessment or evaluation must relate to the risks to human health (or the environment, as relevant) and be detailed in a report. A single assessment or evaluation by an international assessment body may be used as the basis for an industrial chemical to be internationally-assessed for both human health and the environment, as long as the international assessment body has considered the risks to both human health and the environment. The use of a single assessment or evaluation is not possible for those conducted by the following international assessment bodies: the European Commission Scientific Committee on Consumer Products, the European Commission Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, the European Scientific Committee on Consumer Safety, and the European Food Safety Authority (refer to subsection 6(4))

Two different international assessment bodies (and their corresponding assessments or evaluations) may also be used as the basis for an industrial chemical to be internationally-assessed for human health and internationally-assessed for the environment.

Section 7 Specified classes of introductions

Section 7 describes the introductions that will be a specified class of introduction. Additional, or different, requirements relating to hazard information, reporting or record keeping apply to specified classes of introductions. This is due to an increased level of concern for these introductions because of greater potential for particular hazards or high levels of human or environmental exposure.

This section lists which types of chemicals and chemical end uses are ‘specified classes of introductions’. In this section, the specified classes of introduction are grouped according to the main basis for their increased level of concern, as follows:

- Subsection 7(2) lists the classes that are mainly related to increased levels of environmental concern,
- Subsection 7(4) lists the classes that are mainly related to increased levels of human health concern, and
- Subsection 7(3) lists the classes that are related to increased levels of both environmental and human health concern.

Part 2 – Provisions relating to defined terms in the Act

Section 8 Kinds of data or information that relate to tests conducted on animals

Section 9 of the Act provides that animal test data means data or information prescribed by the rules. Section 8 of these rules sets out the kinds of data or information that are considered to be animal test data. There are two kinds of data or information prescribed:

- Data or information that results from tests involving the industrial chemical, either on its own or in a mixture with other chemicals, being applied to an animal (live vertebrate animal, or animals prescribed in section 9 of these rules), and
- Data or information from experiments to test any effects of the industrial chemical, either on its own or in a mixture with other chemicals, on an animal (live vertebrate animal, or animals prescribed in section 9 of these rules).

Section 9 Additional kind of animal for the purposes of the definition of *animal test data*

The definition of animal test data in the Act refers to tests conducted on particular types of animals. It sets out any live vertebrate animal (other than a human being) and allows for further kinds of animals to be prescribed in these rules. Section 9 of these rules prescribes cephalopods (such as squid, octopus, or nautilus), so that tests conducted on this type of animal will also be considered animal test data. This aligns

with the definition of animal in the National Health and Medical Research Council's *Australian code for the care and use of animals for scientific purposes*.

Section 10 Kinds of objects that are not articles

Section 9 of the Act provides that the rules may prescribe an object that is not an article. Section 10 of these rules sets out two kinds of objects, which despite meeting the elements of the definition of "article" set out in the Act, are not articles for the purposes of the Act. These are:

- objects that are a piece of matter (i.e. particulate objects) that have a purpose which is determined more by the chemical composition than by the object's shape, surface or design. An example of such an object is blasting grit. Despite being formed to a particular shape, its purpose is dependent on the hardness and cleavage properties, which depends more on the chemical composition of the material, and
- objects that are wholly fluid. This means that objects which contain a fluid (but are not wholly fluid) may still be articles (if they meet all the elements of the definition in the Act).

Section 11 Prescribed international agreements

Part 9 of the Act deals with the obligations Australia has under international agreements that provide for countries to ban, restrict or otherwise regulate the introduction, use or export of an industrial chemical for the purposes of protecting the environment, public health or occupational health and safety. Section 11 of these rules is made for the purposes of paragraph (b) of prescribed international agreement in section 9 of the Act and prescribes the international agreements that are relevant for these obligations – the Rotterdam Convention and the Stockholm Convention.

Section 12 Days that are not working days

Section 12 is made for the purposes of the definition of "working day" in the Act, and sets out particular days of the year that are not considered working days under the Act. This means that the days prescribed in this section are not included in the calculation of the various consideration periods in the Act.

Section 13 Chemicals or substances that are not industrial chemicals

Section 10 of the Act defines industrial chemical, and subsection 10(2) of the Act allows the rules to prescribe chemicals or substances that will not be industrial chemicals for the purpose of the Act. Section 13 of these rules provides that radioactive chemicals are not industrial chemicals, despite meeting the definition in section 10(1) of the Act. Radioactive chemicals are defined in section 5 of these rules, by reference to the chemicals regulated under the *Australian Radiation Protection and Nuclear Safety Act 1998* and the Australian Radiation Protection and Nuclear Safety Regulations 2018.

Section 14 Circumstances in which introductions are excluded introductions

Under subsection 11(4) of the Act, excluded introductions are not subject to the requirement to be categorised, and introducers are not required to be registered in relation to excluded introductions. Section 14 of these rules sets out an additional type of introduction that is an excluded introduction, namely, where the industrial chemical:

- comes into Australia on an aircraft or ship which is primarily carrying passengers or other products
- leaves Australia within 25 working days
- is used to support the operation of the aircraft or ship (e.g. lubricating fluids, engine oil); and
- is not freight.

Section 15 Introductions that are taken not to be for personal use

Section 15 is made for the purposes of subsection 11(6) of the Act, and clarifies that if an introduction of an industrial chemical is for the purposes of carrying on an enterprise (within the meaning of the *A New Tax System (Goods and Services Tax) Act 1999*) then it is not for the individual's personal use.

Part 3 – Prescribed bodies

Part 3 of Chapter 1 sets out the authorities in the Australian Government or a State/Territory Government that the Executive Director must, or may, seek advice from under certain circumstances.

Section 16 Bodies from which the Executive Director must seek advice

The Act provides that before taking certain regulatory action relating to assessment certificates, the Executive Director must consult with a body prescribed in the rules. Section 16 sets out the bodies, based on the risk mentioned in the specified item in the table, that the Executive Director must seek advice from when considering or deciding on taking the following actions (in accordance with the Act) because risks cannot otherwise be managed:

- not issuing an assessment certificate (refer to paragraph 37(1)(b) of the Act)
- including certain conditions on an assessment certificate (refer to paragraph 34(1)(b) of the Act)
- including, removing, or varying certain conditions on an assessment certificate (refer to paragraph 49(1)(a) or 71(1)(a) of the Act)
- not varying the terms of an assessment certificate, when requested by the applicant (refer to paragraph 49(1)(b) of the Act)
- cancelling an assessment certificate following the outcomes of an evaluation of an introduction authorised by the assessment certificate (refer to paragraph 71(1)(b) of the Act)
- including, removing, or varying a condition on the Inventory (refer to paragraph 93(1)(a) of the Act), or

- not varying the terms of an Inventory listing as requested by the applicant (refer to paragraph 93(1)(b) of the Act).

The table in this section specifies the relevant body that the advice must be sought from when the risks are in relation to certain areas. For example, the Environment Department must be consulted if the risks relate to the environment; the Health Department must be consulted if the risks relate to public health.

Section 17 Bodies from which the Executive Director may seek advice

Section 17 sets out the bodies that the Executive Director may seek advice from, as provided for by the Act, when:

- conducting an evaluation (refer to subsection 71(2) and paragraph 75(a) of the Act), or
- when considering any of the following types of applications:
 - an assessment certificate application (refer to subsection 34(2) of the Act)
 - an application to vary the terms of an assessment certificate (refer to subsection 46(2) of the Act)
 - a commercial evaluation authorisation application (refer to subsection 56(1) of the Act)
 - an application to vary the terms of an Inventory listing (refer to subsection 91(2) of the Act)
 - an application for the proper name or end use to be treated as confidential business information (CBI) (refer to subsection 107(1) of the Act), or
 - an application for continued protection of CBI (refer to subsection 111(5) of the Act).

Part 4 – Commercial evaluation authorisations

Section 18 Circumstances in which an application cannot be made

Section 18 is made for the purposes of subparagraph 53(1)(b)(i) of the Act. It sets out the circumstances in which a person cannot apply for a commercial evaluation authorisation. These circumstances are:

- making the industrial chemical available to the general public
- the total introduction volume over the period of the authorisation exceeding 10 tonnes
- the industrial chemical being made available to the general public as part of an article that is designed to release the industrial chemical
- the industrial chemical being made available to the general public as part of an article with a food contact end use, or
- the industrial chemical being made available to the general public as part of an article that is a children’s toy or children’s care product.

Part 5 – Restrictions on animal test data for applications relating to end use in cosmetics

Section 19 Restriction on animal test data for applications for industrial chemicals with multiple end uses including an end use in cosmetics

Section 19 sets out the information that an application under the Act must not contain if the introduction is of an industrial chemical that has multiple end uses, with one of those end uses being in cosmetics, and one or more end uses being non-cosmetic. For example, the industrial chemical may be introduced for end uses in both surface coatings (e.g. paints) and cosmetics (e.g. body lotion).

Subsection 19(2) provides that the information that such an application must not contain is animal test data obtained from tests conducted on or after 1 July 2020, other than particular types of animal test data set out in this provision (refer to paragraphs (2)(a) to (c)), which are necessary to continue to protect human health and the environment, and to align as far as possible with comparable international restrictions on animal test data.

The first type is animal test data that both demonstrates that the industrial chemical has a hazard characteristic (e.g. that demonstrates that the chemical has the potential to cause skin sensitisation (allergies)) and which conflicts with the other information in the application for this hazard characteristic. This means that an applicant will need to have non-animal test data in their application to fulfil the information requirements as set out in the approved form, and can only include the animal test data if it is showing an adverse result that the non-animal test data does not (e.g. the non-animal test data indicates that the chemical does not cause skin sensitisation, but the animal test data demonstrates that it does).

Allowing the use of this type of animal test data provides continued protection of human health and the environment by not allowing an applicant to ignore adverse data on human health or environmental effects, whilst also creating no incentive for an introducer to generate new animal test data to fulfil regulatory requirements for AICIS.

The second type is animal test data that is the only information that can demonstrate whether or not the industrial chemical has a particular environment hazard characteristic (such as acute toxicity to fish). That is, there are no validated alternative tests to determine this characteristic other than animal tests. For example, while computer modelling is a validated alternative for many chemicals to predict aquatic toxicity, for some chemicals the modelling is not accurate. This includes surfactant chemicals and UVCBs. Allowing the use of this type of animal test data provides continued environmental protection and aligns with the EU REACH regulation restrictions on animal test data.

The third type is where the animal test data results from tests conducted with an industrial chemical that is not the industrial chemical for which the application has been submitted, and which is not being introduced by the person for an end use in cosmetics. This allows the use of read-across information, such as animal test data on an analogue chemical (which is similar enough in structure and properties to the industrial chemical to be able to predict the health or environmental effects of the

industrial chemical). For some hazard characteristics, read-across information is the only non-animal option currently available.

Section 20 Applications for industrial chemicals with multiple end uses including an end use in cosmetics

Section 20 is made for the purposes of subsection 167(1B) of the Act. It sets out a process by which an applicant may apply to the Executive Director to include animal test data obtained from tests conducted on or after 1 July 2020 (that is not one of the three types specified in subsection 19(2)), in an application for an industrial chemical with multiple end uses including an end use in cosmetics. The provision also gives the Executive Director the authority to request further information in respect of the application and sets out when that information must be provided.

Section 21 Decision on application

Section 21 sets out the factors that the Executive Director must consider when deciding on an application made under section 20, and requires the Executive Director to make a decision on the application within 10 working days after the day the application is made (subject to subsection 5).

The Executive Director must have regard to whether the non-cosmetic end use involves exposure of humans or the environment to the industrial chemical, where the animal test data is for the purpose of identifying a human health or environment hazard characteristic, respectively. This provides continued human health and environmental protection.

Section 22 Ban on animal test data for applications for industrial chemicals with end use solely in cosmetics

Section 22 is made for the purposes of subsection 168(2) of the Act. It sets out the circumstances in which the ban on including animal test data in applications will apply for applications for industrial chemicals to be introduced for an end use solely in cosmetics.

The circumstances in which the ban will apply, are all circumstances except for three limited exceptions. These exceptions are required to continue to protect human health and the environment, and to align as far as possible with comparable international bans on animal test data.

The first circumstance is where the animal test data both demonstrates that the industrial chemical has a hazard characteristic (e.g. that demonstrates that the chemical has the potential to cause skin sensitisation (allergies)) and conflicts with the other information in the application for this hazard characteristic. This means that an applicant will need to have non-animal test data in their application to fulfil the information requirements as set out in the approved form, and can only include the animal test data if it is showing an adverse result that the non-animal test data does not (e.g. the non-animal test data indicates that the chemical does not cause skin sensitisation, but the animal test data demonstrates that it does).

Allowing the use of this animal test data in this circumstance provides continued protection of human health and the environment by not allowing an applicant to ignore adverse data on human health or environmental effects, whilst also creating no incentive for an introducer to generate new animal test data to fulfil regulatory requirements for AICIS.

The second circumstance is where the animal test data is the only information that can demonstrate whether or not the industrial chemical has a particular environment hazard characteristic (such as acute toxicity to fish). That is, there are no validated alternative tests to determine this characteristic other than animal tests. For example, while computer modelling is a validated alternative for many chemicals to predict aquatic toxicity, for some chemicals the modelling is not accurate. This includes surfactant chemicals and UVCBs. Allowing the use of this animal test data in this circumstance provides continued environmental protection and aligns with the EU REACH regulation restrictions on animal test data.

The third circumstance is where the animal test data results from tests conducted with an industrial chemical that is not the industrial chemical for which the application has been submitted, and that other chemical is not being introduced by the person for an end use solely in cosmetics. This allows the use of read-across information, such as data on an analogue chemical (which is similar enough in structure and properties to the industrial chemical to be able to predict the health or environmental effects of the industrial chemical). For some hazard characteristics read-across information is the only non-animal option currently available.

Chapter 2 – Categorisation of industrial chemicals

Part 1 – Simplified outline of this Chapter

Section 23 Simplified outline of this Chapter

Section 23 summarises the content of Chapter 2 of these rules, which sets out the circumstances in which an introduction can be categorised as an exempted introduction or as a reported introduction. Chapter 2 describes circumstances in which introductions are, or are not, exempted or reported. Chapter 2 then goes on to describe steps for determining the level of risk to human health and the environment of an introduction, which can be used to determine the highest indicative risk for the introduction, and thus to determine whether the introduction may be categorised as exempted or reported.

Part 2 – Determining if an introduction is exempted or reported

Section 24 Determining if an introduction is exempted or reported

Section 24 describes the method for working out if an introduction of an industrial chemical can be categorised as exempted or reported. The steps of the method statement are:

- Step 1 – Is the introduction a type that cannot be exempted or reported? (see section 25 of these rules)
- Step 2 – Is the introduction an exempted introduction? (see section 26 of these rules)
- Step 3 – Is the introduction a reported introduction? (see section 27 of these rules)
- Step 4 – What is the indicative human health risk for the introduction? (see section 28 of these rules)
- Step 5 – What is the indicative environment risk for the introduction? (see section 29 of these rules)
- Step 6 – What is the introduction category based on the highest indicative risk from steps 4 and 5?

The method statement is a step-wise process that is worked through until an outcome is reached. For example, if an introduction is determined to be an exempted introduction at step 2, then categorisation is complete and there is no need to proceed to step 3.

For step 6 of the method statement the following table summarises the introduction category outcomes based on comparison of the indicative risks determined in steps 4 and 5.

		Indicative human health risk		
		Very low	Low	Medium to high
Indicative environment risk	Very low	Exempted	Reported	Assessed*
	Low	Reported	Reported	Assessed*
	Medium to high	Assessed*	Assessed*	Assessed*

* If the outcome of this method statement is that the introduction is **not** categorised as exempted or reported and it is not listed on the Inventory, it will likely be an assessed introduction, unless the introduction is eligible for a commercial evaluation authorisation (CEA).

If the outcome of this method statement is that the introduction is **not** categorised as exempted or reported and it is listed on the Inventory (for example the categorisation may have been conducted because the introduction was to be outside of the defined scope of assessment listed on the Inventory) it will require an application to vary the Inventory listing (under section 88 of the Act).

Section 25 Circumstances in which introductions are not exempted or reported

Section 25 sets out the criteria for step 1 of the method statement in section 24. The introductions described in this section are considered to be medium to high risk and therefore cannot be exempted or reported introductions. They will generally require assessment under the scheme, or an application to vary the Inventory, before introduction can commence.

The introduction covered by subsection 25(2) is of chemicals that have been listed in the Rotterdam or Stockholm Conventions and action has not yet been taken to restrict the chemicals in Australia. Once a decision has been made to restrict these chemicals (for example through a ratification process) these chemicals will be listed in section 71, 72 or 73 of these rules, and be subject to the requirements set out in Part 9 of the Act.

The introduction covered by subsection 25(3) is considered to be medium to high risk because the introduction is outside of the conditions of introduction or use listed on the Inventory. These conditions can only be placed on an Inventory listing when they are needed to manage risks to human health or the environment. If an introducer is wanting to introduce outside of those conditions, an application to vary the terms of the Inventory (under section 88 of the Act) is required.

The introduction covered by subsection 25(4) cannot be exempted or reported as a request to provide information relating to the introduction (for example as part of an audit) has not been provided. For example, if an introducer has a written undertaking in place with the chemical identity holder (because they do not know the proper name of the chemical) and the chemical identity holder does not provide the proper name (either through the introducer or directly to the Executive Director), then the introduction is no longer authorised as an exempted or reported introduction. It is possible for the introduction to again be authorised as an exempted or reported introduction if either:

- the information that was requested was provided to the Executive Director; or
- the Executive Director agrees that the information is no longer needed. This may happen if the introducer re-categorises such that the information is no longer needed to support the categorisation. For example, if the introducer could not provide information to demonstrate very low risk (such as information to demonstrate the absence of certain hazard characteristics), then it may be possible to demonstrate that the chemical is low risk without that information and re-categorise as a reported introduction (followed by the submission of a pre-introduction report).

Section 26 Circumstances in which introductions are exempted introductions

Section 26 sets out the criteria for step 2 of the method statement. The introductions described in this section are considered to be very low risk to human health and the environment and therefore can be categorised as exempted introductions.

The introduction covered by subsection 26(2) is of an industrial chemical that is imported and subsequently exported, and while in Australia:

- the packaging is never opened
- the chemical remains under the control of the introducer or customs (if the introduction does not meet the requirements for being an excluded introduction (section 11 of the Act)).

The introduction covered by subsection 26(3) is of an industrial chemical that is solely for use in research and development (as defined in section 5 of these rules), either for use by the introducer or for supply to another person who will only use it in research and development. In addition, the industrial chemical is not available to the general public, control measures must be in place to eliminate or minimise risks, and certain thresholds for the total volume introduced in a registration year must be met:

- no more than 10 kg, if the chemical is introduced as a solid or dispersion and meets the nanoscale particle size criteria, or
- otherwise - no more than 250 kg.

The introduction covered by subsection 26(4) is of a polymer that is comparable to a polymer that is listed on the Inventory because it meets the '2% rule'. This means that any additional reactant (that the listed polymer does not contain) does not make up more than 2% by weight of the polymer.

The introduction covered by subsection 26(5) is of an industrial chemical that is considered to be comparable to a listed chemical, such that its introduction is of no greater risk than that of the listed chemical. The table sets out the chemicals that are considered to be comparable to particular chemicals listed on the Inventory.

The introduction covered by subsection 26(6) is of a polymer that meets the polymer of low concern (PLC) criteria (which are set out in Schedule 2 to these rules) and that is not a high molecular weight polymer that has lung overloading potential (within the meaning of the Guidelines).

The introduction covered by subsection 26(7) is of a low concern biological polymer, which is a biological polymer that would otherwise be a PLC, except that it fails the stability requirement to be a PLC.

The introduction covered by subsection 26(8) is of a surface treated chemical, for which all chemicals involved in the surface treatment reaction are listed on the Inventory, and the reaction does not result in any new reactive functional groups on the substrate chemical. It does not apply to a chemical that is introduced as a solid or dispersion and meets the nanoscale particle size criteria.

Section 27 Circumstances in which introductions are reported introductions

Section 27 sets out the criteria for step 3 of the method statement. The introductions described in this section are considered to be low risk to human health and the environment and therefore can be categorised as reported introductions.

The introduction covered by subsection 27(2) is of an industrial chemical introduced as a solid or dispersion that meets the nanoscale particle size criteria and is solely for

use in research and development (as defined in section 5 of these rules), either for use by the introducer or for supply to another person who will only use it in research and development. In addition, the industrial chemical cannot be made available to the general public, control measures must be in place to eliminate or minimise risks, and no more than 100 kg can be introduced in a registration year by the introducer.

The introduction covered by subsection 27(3) is of an industrial chemical that is solely for use in research and development where that use is subject to the control of the introducer. In addition, the industrial chemical is not available to the general public, and control measures must be in place to eliminate or minimise risks. The total volume of the industrial chemical introduced in a registration year by the introducer is greater than 250 kg. This introduction sub-category cannot be used for a chemical that is introduced as a solid or dispersion and meets the nanoscale particle size criteria.

The introduction covered by subsection 27(4) is for chemicals introduced in fragrance blends or flavour blends that also meet other criteria to be considered low risk, including concentration, end use and hazard criteria. This introduction type accommodates the relatively common situation in which an introducer does not know all the ingredients in the fragrance or flavour blend they are introducing. It does this by allowing for the chemicals to either be on the publicly accessible International Fragrance Association (IFRA) Transparency List when the pre-introduction report is submitted, or for the detailed information to be provided to the Executive Director (e.g. by the fragrance supplier) prior to introduction occurring.

Part 3 – Determining indicative risk

If an introduction does not fit within the circumstances set out in sections 26 and 27 of these rules, the introduction may still be exempted or reported depending on the level of indicative risk to human health (section 28) and the environment (section 29) from the introduction.

Section 28 Indicative human health risk for introduction of an industrial chemical

The table in subsection 28(1) sets out the indicative human health risk, for the purposes of step 4 in the method statement in section 24 of these rules. The table is divided into introductions that are medium to high risk, low risk and very low risk to human health. These indicative risk determinations are based on:

- properties of the industrial chemical related to the human health hazard, including structural features (such as the fluorinated features in table item 1) or the physical-chemical properties (such as chemicals at the nanoscale in table item 3)
- factors related to exposure, such as the UV filter criterion in table item 8, and
- both exposure and hazard, such as for table items 4, 5, 9, 10, 11, 12, 13 and 14.

To work through the table to determine the indicative human health risk, the following needs to be considered:

1. Is the introduction that of an industrial chemical described in table items 1, 2 or 3? If so, the indicative human health risk is medium to high risk.

2. Is the introduction that of an industrial chemical that is internationally-assessed for human health (as defined in section 6 of these rules) and meets the other criteria set out in table item 6? If so, the indicative human health risk is low risk (unless the introduction can be further demonstrated to be very low risk based on consideration of the exposure and hazard band criteria).
3. If neither 1 or 2 results in a determination of the indicative human health risk then it will be determined based on consideration of the human health exposure band (as defined in clause 1 of Schedule 1 of these rules) and the hazard characteristics in human health hazard bands (as defined in clause 2 of Schedule 1 of these rules). The way to consider human health characteristics is that either it is known that the industrial chemical has them (for medium to high risk) or it can be demonstrated that the industrial chemical does not have them (for low and very low risk). The relevant table items are 4, 5, 9, 10, 11, 12, 13 and 14. These table items are summarised in the risk matrix diagram below, which illustrates the way exposure and hazard bands interact to determine the indicative human health risk.
4. For some introduction types the indicative human health risk will be at least low risk (i.e. it may be medium to high risk or low risk, but not very low risk). These are described in table items 7 and 8.

		Human health exposure band			
		1	2	3	4
Human health hazard band	C	Low risk	Medium to high risk	Medium to high risk	Medium to high risk
	B	Very low risk	Very low risk	Low risk	Medium to high risk
	A	Very low risk	Very low risk	Low risk	Low risk
	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk

Subsection 28(2) provides the detail relevant to table item 3, for when the introduction of the nanoscale portion of the industrial chemical is not incidental to the introduction of the non-nanoscale portion of the industrial chemical. For example, the changes that are intended to be captured by subsection 28(2)(c) are aspects of the manufacturing process that impact on the particle size of the resulting chemical and properties at the nanoscale. These could include: mechanical action such as milling, grinding, shearing, sieving or sonication, chemical reactions such as electrochemical exfoliation and catalysts, changes in temperature, pressure, pH, or solvent.

Section 29 Indicative environment risk for introduction of an industrial chemical

The table in subsection 29(1) sets out the indicative environment risk, for the purposes of step 5 in the method statement in section 24 of these rules. The table is divided into introductions that are medium to high risk, low risk and very low risk to the environment. These indicative risk determinations are based on:

- properties of the industrial chemical related to the environment hazard, including structural features (such as the fluorinated features in table item 1) or the physical-chemical properties (such as chemicals at the nanoscale in table item 3)
- factors related to exposure, such as end use as a biocidal active in table item 11, and
- both exposure and hazard, such as for table items 6, 7, 8, 12, 13, 14, 15, 16 and 17.

To work through the table to determine the indicative environment risk, the following need to be considered:

1. Is the introduction that of an industrial chemical described in table items 1, 2, 3, 4 or 5? If so, the indicative environment risk is medium to high risk.
2. Is the introduction that of an industrial chemical that is internationally-assessed for the environment (as defined in section 6 of these rules) and meets the other criteria set out in table item 9? If so, the indicative environment risk is low risk (unless the introduction can be further demonstrated to be very low risk based on consideration of the exposure and hazard band criteria).
3. If neither 1 or 2 results in a determination of the indicative environment risk, then it will be determined based on consideration of the environment exposure band (as defined in clause 3 of Schedule 1 of these rules) and the hazard characteristics in environment hazard bands (as defined in clause 4 of Schedule 1 of these rules). The way to consider environment hazard characteristics is that either it is known that the industrial chemical has them (for medium to high risk) or it can be demonstrated that the industrial chemical does not have them (for low and very low risk). The relevant table items are 6, 7, 8, 12, 13, 14, 15, 16 and 17. These table items are summarised in the risk matrix diagram below, which illustrates the way exposure and hazard bands interact to determine the indicative environment risk.
4. For some introduction types the indicative environment risk will be at least low risk (i.e. it may be medium to high risk or low risk, but not very low risk). These are described in table items 10 and 11.

		Environment exposure band			
		1	2	3	4
Environment hazard band	D	Medium to high risk	Medium to high risk	Medium to high risk	Medium to high risk
	C	Low risk	Low risk	Medium to high risk	Medium to high risk
	B	Very low risk	Low risk	Low risk	Medium to high risk
	A	Very low risk	Very low risk	Very low risk	Low risk
	Not A, B, C or D	Very low risk	Very low risk	Very low risk	Very low risk

Subsection 29(2) provides the detail relevant to table item 3, for when the introduction of the nanoscale portion of the industrial chemical is not incidental to the introduction of the non-nanoscale portion of the industrial chemical. For example, the changes that are intended to be captured by subsection 29(2)(c) are aspects of the manufacturing

process that impact on the particle size of the resulting chemical and properties at the nanoscale. These could include: mechanical action such as milling, grinding, shearing, sieving or sonication, chemical reactions such as electrochemical exfoliation and catalysts, changes in temperature, pressure, pH, or solvent.

Part 4 – Information required to demonstrate categorisation

Section 30 Information required to demonstrate categorisation

Section 30 sets out the information required to demonstrate categorisation if the introduction is to be authorised as an exempted or reported introduction. That is, an introduction that is not covered by section 25 of these rules (which specifies introductions that cannot be exempted or reported) and is **not** authorised as:

- a listed introduction (section 25 of the Act)
- an assessed introduction (section 28 of the Act)
- a commercial evaluation introduction (section 29 of the Act), or
- an exceptional circumstances introduction (section 30 if the Act)

Subsection 30(2) details the type of information a person must have regard to (i.e. must consider) in order to determine the introduction category. This information must be able to be provided to the Executive Director of AICIS if requested (see subsection 102(2) of the Act).

This information relates to:

- how the industrial chemical will be introduced
- how the industrial chemical will be used, and
- the characteristics of the industrial chemical.

In relation to the hazard characteristics of the industrial chemical, when determining the highest indicative risk the information required is:

- information that demonstrates that the chemical has a hazard characteristic, within the meaning given in the Guidelines (if that hazard characteristic is relevant for determining the highest indicative risk), and
- information detailed in the Guidelines to demonstrate that the industrial chemical does not have a particular hazard characteristic, if the highest indicative risk determination relies on the absence of that hazard characteristic.

If existing information available to an introducer is not sufficient to demonstrate the absence of a hazard characteristic (in accordance with the Guidelines), and thus for determination of the highest indicative risk of the introduction, new information may need to be generated. The Guidelines will advise that generation of new animal test data should be considered as a last resort, and the options for non-animal test data should be considered first.

Section 31 Restriction on using animal test data for determining category of introduction for industrial chemicals with multiple end uses including an end use in cosmetics

Section 31 sets out the information that a person must not have regard to when determining the category of an introduction if it is for an industrial chemical that has multiple end uses, with one of those end uses being in cosmetics, and one or more end uses being non-cosmetic. For example, the industrial chemical may be introduced for end uses in both surface coatings (e.g. paints) and cosmetics (e.g. body lotion).

The information that a person must not have regard to is animal test data obtained from tests conducted on or after 1 July 2020, other than particular animal test data set out in this provision, which is necessary to continue to protect human health and the environment, and to align as far as possible with comparable international restrictions on animal test data.

The first type is animal test data that demonstrates that the industrial chemical has a hazard characteristic (e.g. that demonstrates that the chemical has the potential to cause skin sensitisation (allergies)) and which, if the person did not have regard to that data, would result in the determination of the category of introduction in a lower risk category. For example, without the animal test data being considered, the category of introduction would be exempted, but when the animal test data is regarded, the category of introduction would instead be reported.

This means that an applicant can only have regard to that animal test data if it changes the outcome of the introduction category determination in a way that improves human health or environment protection.

If an introducer has both animal and non-animal test data for a particular hazard characteristic they will not be able to have regard to the animal test data unless that data conflicts with the non-animal test data and having regard to the animal test data would result in a different (higher risk) introduction category being determined.

If an introducer only has animal test data, and that animal test data demonstrates that the chemical has a particular hazard characteristic (i.e. the animal test data is 'adverse' for the hazard characteristic), whether or not the introducer can have regard to that data is dependent on the information requirements set out in the Guidelines for the hazard characteristic. For most hazard characteristics, an introducer will not be able to have regard to the 'adverse' animal test data as the outcome will not differ between having regard and not having regard to the data. This is because, for categorisation purposes, if the introducer does not have the information to demonstrate the absence of a hazard characteristic, then they assume the chemical does have the hazard characteristic. The exception to this is when the Guidelines allow an information waiver at particular volumes (such as for specific target organ toxicity – repeated exposure). In this case, not having regard to the 'adverse' animal test data could result in a different (lower risk) introduction category being determined, if the human health exposure band for the introduction is 4. This means that the introducer must have regard to the animal test data in such circumstances.

Allowing the use of this type of animal test data provides continued protection of human health and the environment by not allowing an introducer to ignore adverse data on human health or environmental effects, where it would change the categorisation outcome to a higher risk category.

The second type is animal test data that is the only information that can demonstrate whether or not the industrial chemical has a particular environment hazard characteristic (such as acute toxicity to fish). That is, there are no validated alternative tests to determine this characteristic other than animal tests. For example, while computer modelling is a validated alternative for many chemicals to predict aquatic toxicity, for some chemicals the modelling is not accurate. This includes surfactant chemicals and UVCBs. Allowing the use of this type of animal test data provides continued environmental protection and aligns with the EU REACH regulation restrictions on animal test data.

The third type is where the animal test data results from tests conducted with an industrial chemical that is not the industrial chemical for which the introduction category is being determined, and which is not being introduced by the person for an end use in cosmetics. This allows the use of read-across information, such as data on an analogue chemical (which is similar enough in structure and properties to the industrial chemical to be able to predict the health or environmental effects of the industrial chemical). For some hazard characteristics read-across information is the only non-animal option currently available.

The fourth type is animal test data that has been approved by the Executive Director under section 33 of these rules to be used in determining the category of introduction.

Section 32 Applying for approval to use animal test data for determining category of introduction for industrial chemicals with multiple end uses including an end use in cosmetics

Section 32 sets out a process by which a person may apply to the Executive Director to have regard to animal test data obtained from tests conducted on or after 1 July 2020 (that isn't one of the three types specified in paragraphs 31(2)(a), (b) or (c)), in determining the category of introduction for an industrial chemical.

Section 33 Decision on application

Section 33 requires the Executive Director to make a decision in respect of an application made under section 32. The section also sets out what the Executive Director must consider when deciding on an application made under section 32, and provides that the decision must be made within 10 working days after the day the application is made.

The Executive Director must have regard to whether the non-cosmetic end use involves exposure of humans or the environment to the industrial chemical, where the animal test data is for the purpose of identifying a human health or environment hazard characteristic, respectively. This provides continued human health and environmental protection.

Section 34 Ban on using animal test data for determining category of introduction for industrial chemical with end use solely in cosmetics

Section 34 is made for the purposes of subsection 103(2) of the Act. It sets out the circumstances in which the ban on using animal test data when determining the category of introduction will apply for an industrial chemical to be introduced for an end use solely in cosmetics.

The circumstances in which the ban will apply, are all circumstances except for three limited exceptions. These exceptions are required to continue to protect human health and the environment, and to align as far as possible with comparable international bans on animal test data.

The first circumstance is where the animal test data both demonstrates that the industrial chemical has a hazard characteristic (e.g. that demonstrates that the chemical has the potential to cause skin sensitisation (allergies)) and if the person did not have regard to that data, would result in the determination of the category of introduction in a lower risk category. This is provided for by paragraph 34(a) of these rules. For example, without the animal test data being regarded, the category of introduction would be exempted, but when the animal test data is considered, the category of introduction would instead be reported.

This means that an applicant can only have regard to that animal test data if it changes the outcome of the introduction category determination in a way that improves human health or environment protection.

If an introducer has both animal and non-animal test data for a particular hazard characteristic they will not be able to have regard to the animal test data unless that data conflicts with the non-animal test data and having regard to the animal test data would result in a different (higher risk) introduction category being determined.

If an introducer only has animal test data, and that animal test data demonstrates that the chemical has a particular hazard characteristic (i.e. the animal test data is 'adverse' for the hazard characteristic), whether or not the introducer can have regard to that data is dependent on the information requirements set out in the Guidelines for the hazard characteristic. For most hazard characteristics an introducer will not be able to have regard to the 'adverse' animal test data as the outcome will not differ between having regard and not having regard to the data. This is because for categorisation purposes if the introducer does not have the information to demonstrate the absence of a hazard characteristic, then they assume the chemical does have the hazard characteristic. The exception to this is when the Guidelines allow an information waiver at particular volumes (such as for specific target organ toxicity – repeated exposure). In this case, not having regard to the 'adverse' animal test data could result in a different (lower risk) introduction category being determined, if the human health exposure band for the introduction is 4. This means that the introducer must have regard to the animal test data in such circumstances.

Allowing the use of this animal test data in this circumstance provides continued protection of human health and the environment by not allowing an introducer to

ignore adverse data on human health or environmental effects, where it would change the categorisation outcome to a higher risk category.

The second circumstance is where the animal test data is the only information that can demonstrate whether or not the industrial chemical has a particular environment hazard characteristic (such as acute toxicity to fish). This is provided for by paragraph 34(b) of these rules. That is, there are no validated alternative tests to determine this characteristic other than animal tests. For example, while computer modelling is a validated alternative for many chemicals to predict aquatic toxicity, for some chemicals the modelling is not accurate. This includes surfactant chemicals and UVCBs. Allowing the use of this animal test data in this circumstance provides continued environmental protection and aligns with the EU REACH regulation restrictions on animal test data.

The third circumstance is where the animal test data results from tests conducted with an industrial chemical that is not the industrial chemical for which the application has been submitted, and that other chemical is not being introduced by the person for an end use solely in cosmetics. This is provided for by paragraph 34(c) of these rules. This allows the use of read-across information, such as data on an analogue chemical (which is similar enough in structure and properties to the industrial chemical to be able to predict the health or environmental effects of the industrial chemical). For some hazard characteristics read-across information is the only non-animal option currently available.

Chapter 3 – Reporting

Part 1 – Simplified outline of this Chapter

Section 35 Simplified outline of this Chapter

Part 2 of this Chapter sets out the information that must be included in the post-introduction declaration about an exempted introduction. It also outlines the circumstances when a post-introduction declaration about an exempted introduction will not be needed.

Part 3 of this Chapter sets out the information that must be included in a pre-introduction report for a reported introduction. The exact information required for this purpose varies depending on the type of reported introduction. For example, the information required in a pre-introduction report for a reported introduction that is a low-risk flavour or fragrance blend is different from what is needed in a pre-introduction report for a reported introduction that is internationally-assessed for human health and the environment. These differences are to ensure that requirements are proportionate and that the information needed in a pre-introduction report are appropriate to the particular type of introduction.

Part 4 of this Chapter sets out the information required for annual declarations, where a person must indicate the categories of introduction that they utilised during the registration year, and that all of their introductions were authorised under the Act.

Part 2 – Post-introduction declarations for exempted introductions

Section 36 Post-introduction declarations for exempted introductions

Subsection 96A(2) of the Act provides that the post-introduction declaration about an exempted introduction must be in an approved form and contain the information prescribed in the rules for the type of exempted introduction. Section 36 sets out the information that must be included in a post-introduction declaration about an exempted introduction.

Subsection 36(2) specifies the information needed in a post-introduction declaration for an introduction that is exempted due to its highest indicative risk being very low (that is, the outcome of considering step 6 of the method statement in section 24 is that the highest indicative risk for the introduction is very low risk). The table in subsection 36(2) specifies:

- the chemical identity of the industrial chemical. The nature of the chemical identity information needed is dependent upon whether the proper name for the industrial chemical is known to the introducer, and the total volume of the industrial chemical introduced by the introducer during the registration year. If the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the introducer, it must be provided in the declaration, together with the CAS number for the industrial chemical, if one has been assigned. If the introducer does **not** know the proper name of the industrial chemical and the total volume introduced during the registration year does not exceed 10 kg, the introducer must provide information that they do know about the identity of the chemical (their name(s) for the industrial chemical, and the name of the chemical identity holder). If the introducer does **not** know the proper name of the industrial chemical and the total volume introduced during the registration year exceeds 10 kg, they must still provide the name(s) by which they know the industrial chemical. In addition, the chemical identity holder must have provided the Executive Director with the proper name of the industrial chemical (including the CAS name or the IUPAC name) and its CAS number, if one has been assigned. This must have been provided prior to a valid post-introduction declaration being submitted
- the total volume of the industrial chemical introduced by the introducer during the registration year
- the end uses for the industrial chemical
- the maximum end use concentration of the industrial chemical, and
- additional information needed if the introduction of the industrial chemical includes one or more end uses that are in cosmetics.

If the introduction is of an industrial chemical that has an end use in cosmetics, the declaration must include a statement about the use of animal test data, by specifying which of the circumstances specified in subsection 36(3) of these rules apply to the introduction.

Subsection 36(4) specifies the information needed for a post-introduction declaration of industrial chemicals that are polymers of low concern and low concern biological polymers. For these introductions, the post-introduction declaration must include the number of different individual polymers of these types that have been introduced.

Section 37 Circumstances in which a post-introduction declaration for exempted introductions is not required

Section 37 sets out the types of exempted introductions that do not need a post-introduction declaration. These are introductions of industrial chemicals that are:

- imported and subsequently exported
- solely for use in research and development
- polymers that are comparable to listed polymers
- comparable to listed industrial chemicals, and
- chemicals that result from non-functionalised surface treatment of listed industrial chemicals.

Part 3 – Pre-introduction reports for reported introductions

Section 38 Introductions of industrial chemicals that are internationally-assessed for human health and the environment

Section 38 sets out the information that must be included in a pre-introduction report for a reported introduction that is internationally-assessed for both human health and the environment. The table in subsection 38(2) specifies:

- the chemical identity of the industrial chemical. The nature of the chemical identity information needed is dependent upon whether the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the introducer. If the proper name for the industrial chemical is known to the introducer, it must be provided in the report, together with the CAS number for the industrial chemical, if one has been assigned, and any other name(s) by which the chemical is known to the introducer. If the introducer does **not** know the proper name of the industrial chemical they must provide the name(s) by which they know the industrial chemical. In addition, the chemical identity holder must have provided the Executive Director with the proper name of the industrial chemical (including the CAS name or the IUPAC name) and its CAS number, if one has been assigned. This must have been provided prior to a valid pre-introduction report being submitted.
- how the chemical is introduced into Australia (import or manufacture)
- the maximum total volume of the industrial chemical intended to be introduced in a registration year by the introducer
- the end uses for the industrial chemical
- the maximum concentration of the industrial chemical at each end use
- any known hazard classification for the industrial chemical
- information relating to the international assessment or evaluation of the industrial chemical and how these relate to the introduction of the chemical in Australia, and
- declarations to confirm that some of the requirements in section 28, table item 6 and in section 29, table item 9 are complied with.

Section 39 Introductions of industrial chemicals that are internationally-assessed for human health but not internationally-assessed for the environment

Section 39 sets out the information that must be included in a pre-introduction report for a reported introduction that is internationally-assessed for human health but not internationally-assessed for the environment (this means that the indicative environment risk must be low risk or very low risk). The table in subsection 39(2) specifies:

- the chemical identity of the industrial chemical. The nature of the chemical identity information needed is dependent upon whether the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the introducer. If the proper name for the industrial chemical is known to the introducer, it must be provided in the report, together with the CAS number for the industrial chemical, if one has been assigned, and any other name(s) by which the chemical is known to the introducer. If the introducer does **not** know the proper name of the industrial chemical they must provide the name(s) by which they know the industrial chemical. In addition, the chemical identity holder must have provided the Executive Director with the proper name of the industrial chemical (including the CAS name or the IUPAC name) and its CAS number, if one has been assigned. This must have been provided prior to a valid pre-introduction report being submitted.
- how the chemical is introduced into Australia (import or manufacture)
- the maximum total volume of the industrial chemical intended to be introduced in a registration year by the introducer
- the end uses for the industrial chemical
- the maximum concentration of the industrial chemical at each end use
- any known hazard classification for the industrial chemical
- environment hazard characteristics of the industrial chemical that are known to the introducer
- information relating to the international assessment or evaluation of the industrial chemical and how these relate to the introduction of the chemical in Australia
- declarations to confirm that some of the requirements in section 28, table item 6 are complied with
- information relating to the categorisation of the environment aspects of industrial chemical introduction (such as the environment exposure band for the introduction). The corresponding information for the human health aspects is not required because these are covered by the international assessment or evaluation of the industrial chemical that is being relied upon
- a declaration that information about the hazard characteristics of the industrial chemical have been considered appropriately
- a statement about the use of animal test data for the categorisation of the industrial chemical introduction (if the end uses for the industrial chemical include one or more end uses in cosmetics), and
- identifying whether the introduction is a specified class of introduction and, if so, which one it is (in accordance with section 7 of these rules).

Subsection 39(3) specifies the circumstances for the purposes of item 12 of the table in subsection (2). Item 12 requires that if the industrial chemical is to be introduced for an end use in cosmetics, a statement as to which of the circumstances specified in subsection (3) in relation to animal test data applies to the introduction.

Section 40 Introductions of industrial chemicals that are internationally-assessed for the environment but not internationally-assessed for human health

Section 40 sets out the information that must be included in the pre-introduction report for a reported introduction that is internationally-assessed for the environment but not internationally-assessed for human health (this means that the indicative risk for human health must be low risk or very low risk). The table in subsection 40(2) specifies:

- the chemical identity of the industrial chemical. The nature of the chemical identity information needed is dependent upon whether the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the introducer. If the proper name for the industrial chemical is known to the introducer, it must be provided in the report, together with the CAS number for the industrial chemical, if one has been assigned, and any other names by which the chemical is known to the person. If the introducer does **not** know the proper name of the industrial chemical they must provide the name(s) by which they know the industrial chemical. In addition, the chemical identity holder must have provided the Executive Director with the proper name of the industrial chemical (including the CAS name or the IUPAC name) and its CAS number, if one has been assigned. This must have been provided prior to a valid pre-introduction report being submitted.
- how the chemical is introduced into Australia (import or manufacture)
- the maximum total volume of the industrial chemical intended to be introduced in a registration year by the introducer
- the end uses for the industrial chemical
- the maximum concentration of the industrial chemical at each end use
- any known hazard classification for the industrial chemical
- human health hazard characteristics of the industrial chemical that are known to the introducer.
- information relating to the international assessment or evaluation of the industrial chemical and how these relate to the introduction of the chemical in Australia
- declarations to confirm that some of the requirements in section 29, table item 9 are complied with
- information relating to the categorisation of the human health aspects of industrial chemical introduction (such as the human health exposure band for the introduction). The corresponding information for the environment aspects is not required because these are covered by the international assessment or evaluation of the industrial chemical that is being relied upon
- a declaration that information about the hazard characteristics of the industrial chemical have been considered appropriately
- a statement about the use of animal test data for the categorisation of the industrial chemical introduction (if the end uses for the industrial chemical include one or more end uses in cosmetics), and
- identifying whether the introduction is a specified class of introduction and, if so, which one it is (specified in section 7 of these rules).

Subsection 40(3) specifies the circumstances for the purposes of Item 11 of the table in subsection (2). Item 11 requires that if the industrial chemical is to be introduced

for an end use in cosmetics, a statement as to which of the circumstances specified in subsection (3) in relation to animal test data applies to the introduction.

Section 41 Introductions of industrial chemicals that are solely for use in research and development

Section 41 sets out the information that must be included in the pre-introduction report for a reported introduction that is solely for use in research and development. This information is required for industrial chemicals at the nanoscale (under subsection 27(2) of these rules) and also industrial chemicals that are not at the nanoscale (under subsection 27(3) of these rules). The table in subsection 41(2) specifies:

- the chemical identity of the industrial chemical. The nature of the chemical identity information needed is dependent upon whether the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the introducer. If the proper name for the industrial chemical is known to the introducer, it must be provided in the report, together with the CAS number for the industrial chemical, if one has been assigned, and any other name(s) by which the chemical is known to the introducer. If the introducer does **not** know the proper name of the industrial chemical they must provide the name(s) by which they know the industrial chemical. In addition, the chemical identity holder must have provided the Executive Director with the proper name of the industrial chemical (including the CAS name or the IUPAC name) and its CAS number, if one has been assigned. This must have been provided prior to a valid pre-introduction report being submitted
- how the chemical is introduced into Australia (import or manufacture)
- the maximum total volume of the industrial chemical intended to be introduced in a registration year by the introducer
- whether the industrial chemical will be introduced in a solid or in a dispersion, and
- a declaration that the requirements of subsection 27(2) or 27(3) of these rules, for industrial chemicals at the nanoscale or industrial chemicals other than at the nanoscale, respectively, have been met.

Section 42 Low-risk flavour or fragrance blend introductions

Section 42 sets out the information that must be included in the pre-introduction report for a reported introduction where it is a low-risk flavour or fragrance blend introduction (under subsection 27(4) of these rules). A single pre-introduction report can be submitted for all of the industrial chemicals in a flavour or fragrance blend introduced by an introducer. The table in subsection 42(2) specifies:

- the name of the flavour or fragrance blend that the industrial chemical is to be introduced as a part of
- the chemical identity of the industrial chemical. The nature of the chemical identity information needed is dependent upon whether the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the introducer. If the proper name for the industrial chemical is known to the introducer, it must be provided in the report, together with the CAS number for the industrial chemical, if one has been assigned, and any other name(s) by which

the chemical is known to the introducer. If the proper name for the industrial chemical is **not** known to the introducer, the name of the chemical identity holder for the flavour or fragrance blend that the industrial chemical is to be introduced as a part of should be provided instead

- the number of industrial chemicals in the flavour or fragrance blend that the introducer is introducing, and
- a statement about the use of animal test data for the categorisation of the industrial chemical introduction (if the end uses for the industrial chemical include one or more end uses in cosmetics).

Subsection 42(3) specifies the circumstances for the purposes of item 5 of the table in subsection (2). Item 5 requires that if the industrial chemical is to be introduced for an end use in cosmetics, a statement as to which of the circumstances specified in subsection (3) in relation to animal test data applies to the introduction.

Subsection 42(4) allows a person to prepare a single-introduction report for all the industrial chemicals in a flavour blend or a fragrance blend that are to be introduced in accordance with subsection 27(4) of these rules.

Section 43 Other introductions where the highest indicative risk is low risk

Section 43 sets out the information that must be included in the pre-introduction report for an introduction that is reported due to its highest indicative risk being low risk (that is, the outcome of considering step 6 of the method statement in section 24 is that the highest indicative risk for the introduction is low risk). The table in subsection 43(2) specifies:

- the chemical identity of the industrial chemical. The nature of the chemical identity information needed is dependent upon whether the proper name for the industrial chemical (including the CAS name or the IUPAC name) is known to the introducer. If the proper name for the industrial chemical is known to the introducer, it must be provided in the report, together with the CAS number for the industrial chemical, if one has been assigned, and any other name(s) by which the chemical is known to the introducer. If the introducer does **not** know the proper name of the industrial chemical they must provide the name(s) by which they know the industrial chemical. In addition, the chemical identity holder must have provided the Executive Director with the proper name of the industrial chemical (including the CAS name or the IUPAC name) and its CAS number, if one has been assigned. This must have been provided prior to a valid pre-introduction report being submitted
- how the chemical is introduced into Australia (import or manufacture)
- the maximum total volume of the industrial chemical intended to be introduced in a registration year by the introducer
- the end uses for the industrial chemical
- information relating to the categorisation of the industrial chemical introduction (such as the human health exposure band and the environment exposure band for the introduction)
- hazard characteristics of the industrial chemical that are known to the introducer
- a declaration that information about the hazard characteristics of the industrial chemical have been considered appropriately

- a statement about the use of animal test data for the categorisation of the industrial chemical introduction (if the end uses for the industrial chemical include one or more end uses in cosmetics)
- identifying whether the introduction is a specified class of introduction and, if so, which one it is (in accordance with section 7 of these rules).

Subsection 43(3) specifies the circumstances for the purposes of Item 15 of the table in subsection (2). Item 15 requires that if the industrial chemical is to be introduced for an end use in cosmetics, a statement as to which of the circumstances specified in subsection (3) in relation to animal test data applies to the introduction.

Part 4 – Annual declaration for all introduction categories

Section 44 Annual declaration for all introduction categories

Section 44 describes what must be included in a declaration under paragraph 99(2)(b) of the Act in relation to introductions for a registration year:

- the introducer’s registration number
- which categories of introduction were used by the introducer during a registration year. This does **not** require information on which specific industrial chemicals were introduced under each category, and
- that all introductions made by the introducer during the registration year were authorised by the Act.

This requirement applies to all introduction categories – listed introductions, exempted introductions, reported introductions, assessed introductions, commercial evaluation introductions and exceptional circumstances introductions. This requirement is in addition to any requirements that are specific to a particular introduction category, such as a post-introduction declaration for exempted introductions, or a pre-introduction report for a reported introduction.

Chapter 4 – Record keeping

Part 1 – Simplified outline of this Chapter

Section 45 Simplified outline of this Chapter

This Chapter sets out the information or records that must be kept about an introduction by a person who introduces an industrial chemical (other than an excluded introduction, which is not required to be categorised) during a registration year. This is a requirement for all categories of introduction (listed introductions, exempted introductions, reported introductions, assessed introductions, commercial evaluation introductions and exceptional circumstances introductions), with the kinds of records required for this purpose varying depending upon the introduction category. The kinds of records also vary depending on the type of introduction within a category. For example, the records required for the exempted introduction of a polymer of low concern are different from the records required for the exempted introduction of an industrial chemical that is solely for use in research and

development. These differences are to ensure that requirements are proportionate and that the records are appropriate to the particular type of introduction.

This Chapter also sets out the kind of information that must be kept for introductions authorised under section 163 of the Act (chemicals subject to international agreements or arrangements such as the Rotterdam Convention).

Part 2 – Record keeping for listed introductions

Section 46 Listed introductions

Section 46 sets out the kinds of records that must be kept in specified circumstances for a listed introduction:

- the chemical identity of the industrial chemical. If the CAS number for the industrial chemical is known to the introducer, this must be kept as a record, together with its CAS name or INCI name. If the CAS number is not known to the introducer, or is not assigned, the introducer can keep the CAS name as a record. Alternatively, if the CAS number is not known to the introducer, or not assigned, the introducer can instead keep a record of the name(s) by which the industrial chemical is known to the introducer and a written undertaking from the chemical identity holder that the CAS name and CAS number (if assigned) will be provided to the Executive Director upon request, and
- records to demonstrate that any terms of the Inventory listing are being complied with.

Part 3 – Record keeping for exempted introductions

Section 47 Certain introductions of industrial chemicals under section 26

Section 47 sets out the kinds of records that must be kept in relation to certain exempted introductions of industrial chemicals, including those that are:

- imported and subsequently exported
- comparable to listed industrial chemicals
- polymers of low concern, and
- low concern biological polymers.

The requirements for records include:

- chemical identity information for the industrial chemical
- records to demonstrate that the introduction is not a type that is not exempted or reported under section 25 of these rules, and
- records to demonstrate which type of exempted introduction it is (from the list above), together with records to demonstrate that the requirements for that type of introduction are being met.

The nature of the record keeping requirements differs depending on whether the introducer knows the proper name for the industrial chemical. Where the introducer knows this information, they are required to keep the above records in relation to the

exempted introduction. Where the introducer does not know the proper name for the industrial chemical, for most of these records they are instead required to keep written undertakings from the chemical identity holder that the necessary records will be provided to the Executive Director upon request.

Section 48 Introductions of industrial chemicals that are solely for use in research and development

Section 48 sets out the records that must be kept in relation to exempted introductions of industrial chemicals that are solely for use in research and development:

- where the total volume of the industrial chemical introduced by the introducer in a registration year is low (10 kg or less), the records are to include the number of individual industrial chemicals that are introduced solely for use in research and development at total volumes of 10 kg or less in a registration year. That is, the chemical identity information for each individual industrial chemical is not required
- where the total volume of the industrial chemical introduced by the introducer in a registration year is higher (greater than 10 kg), the records are to include chemical identity information for the industrial chemical
- records to demonstrate that the introduction is not a type that is not exempted or reported under section 25 of these rules, and
- records to demonstrate that the requirements for introductions of industrial chemicals that are solely for use in research and development (in accordance with section 26(3) of these rules) are being met.

The exact nature of the record keeping requirements differs depending on whether the introducer knows the proper name for the industrial chemical. Where the introducer knows this information, they are required to keep the above records in relation to the exempted introduction. Where the introducer does not know the proper name for the industrial chemical, for most of these records they are instead required to keep written undertakings from the chemical identity holder that the necessary records will be provided to the Executive Director upon request.

Section 49 Introductions of polymers that are comparable to listed polymers

Section 49 sets out the records that must be kept in relation to exempted introductions of industrial chemicals that are comparable to polymers listed on the Inventory.

There are different record keeping requirements for a person who first introduces the industrial chemical before 1 July 2020 and a person who first introduces the industrial chemical on or after 1 July 2020.

If the first introduction is before 1 July 2020, the records relate to the chemical identity of the industrial chemical that is listed on the Inventory that the industrial chemical is comparable to, that is, the listed polymer (rather than the industrial chemical that the person is introducing). If the introducer does **not** know the proper name for the listed polymer they can instead keep a record of the name(s) by which the listed polymer is known to the person, together with a written undertaking from

the chemical identity holder to provide the chemical identity of the listed polymer to the Executive Director upon request.

If the first introduction is on or after 1 July 2020, the requirements for records are:

- chemical identity information for the industrial chemical itself (the unlisted polymer)
- records to demonstrate that the introduction is not a type that is not exempted or reported under section 25 of these rules, and
- records to demonstrate that the requirements for introductions of polymers that are comparable to listed polymers (in accordance with section 26(4) of these rules) are being met.

The exact nature of the record keeping requirements (where the first introduction is on or after 1 July 2020) differs depending on whether the introducer knows the proper name for the unlisted polymer. Where the introducer knows this information, they are required to keep the above records in relation to the exempted introduction. Where the introducer does not know the proper name for the unlisted polymer, for most of these records they are instead required to keep written undertakings from the chemical identity holder that the necessary records will be provided to the Executive Director upon request.

Section 50 Introductions of industrial chemicals resulting from non-functionalised surface treatment of listed industrial chemicals

Section 50 sets out the records that must be kept in relation to exempted introductions of industrial chemicals that result from non-functionalised surface treatment of listed industrial chemicals:

- chemical identity information for the industrial chemical, for the substrate chemical, and for all other industrial chemicals involved in the reaction at the surface of the substrate chemical
- records to demonstrate that the introduction is not a type that is not exempted or reported under section 25 of these rules, and
- records to demonstrate that the requirements for introductions of industrial chemicals resulting from non-functionalised surface treatment of listed industrial chemicals (in accordance with section 26(8)(c) and (d) of these rules) are being met.

The exact nature of the record keeping requirements differs depending on whether the introducer knows the proper name for the industrial chemical. Where the introducer knows the proper name, they are required to keep the above records in relation to the exempted introduction. Where the introducer does not know the proper name for the industrial chemical, for most of these records they are instead required to keep written undertakings from the chemical identity holder that the necessary records will be provided to the Executive Director upon request.

Section 51 Other introductions where the highest indicative risk is very low risk

Section 51 sets out the records that must be kept in relation to exempted introductions of industrial chemicals where the highest indicative risk is very low risk, including:

- chemical identity information for the industrial chemical
- the indicative human health risk and the indicative environment risk for the introduction
- the names of any products containing the industrial chemical that are imported into Australia by the introducer
- records to demonstrate that the introduction is not a type that is not exempted or reported, under section 25 of these rules
- records to demonstrate that the introduction is not any of the types that are specified in certain table items of subsection 28(1) and 29(1) of these rules because they cannot be very low indicative human health risk or very low indicative environment risk. For example, introductions of industrial chemicals that are organotin chemicals at certain volumes (for indicative environment risk), or industrial chemicals that are UV filters (for indicative human health risk)
- records to demonstrate the polymer molecular weight details of the industrial chemical if it is a high molecular weight polymer and the human health exposure band for its introduction is 4
- how the chemical is introduced into Australia (import or manufacture)
- records to demonstrate the end uses for the industrial chemical
- the maximum total volume of the industrial chemical intended to be introduced in a registration year by the introducer
- the human health exposure band and the environment exposure band for the introduction and the exposure band criteria on which these were based
- in circumstances where the exposure band criteria are dependent upon the human health categorisation volume or the environment categorisation volume, what the relevant categorisation volume is, together with records to demonstrate that these volumes have not been exceeded
- records to demonstrate any known hazard classification for the industrial chemical
- hazard characteristics of the industrial chemical that are known to the introducer
- detailed information relating to how the absence of certain hazard characteristics was determined (where relevant). This detailed information should include the types of full study reports specified in the Guidelines. If the introducer does not have the required detailed information, they can instead keep records of the outcomes of the information specified in the Guidelines, together with a written undertaking from the person who has the detailed information that the detailed information meets the requirements of the Guidelines and will be provided upon request, and
- additional record keeping requirements for certain specified classes of introduction, specifically:
 - introductions that involve a designated kind of release into the environment
 - introductions of biochemicals
 - introductions of GM products
 - introductions where the end use is in an article with food contact, and

- introductions where the end use is in an article that is a children's toy or a children's care product.

The exact nature of some of the record keeping requirements differs depending on whether the introducer knows the proper name for the industrial chemical. If the introducer knows the proper name for the industrial chemical, they are required to have records of this, and any other records that rely upon the specific chemical identity being known (such as the records to demonstrate that the introduction is not one that cannot be very low indicative human health risk or very low indicative environment risk, and polymer molecular weight details, if relevant). If the introducer does not know the proper name for the industrial chemical, they can instead keep records of the name(s) by which the industrial chemical is known to the introducer, together with written undertakings from the chemical identity holder that the specific chemical identity information and any other information that relies on the specific chemical identity being known, will be provided to the Executive Director upon request.

Subsection 51(4) provides details of requirements for the purposes of item 22 of the table in subsections (2) and (3). Item 22 relates to specified classes of introductions and the table in subsection 51(4) specifies those classes and the kinds of records that must be kept in relation to those classes.

Part 4 – Record keeping for reported introductions

Section 52 Introductions of industrial chemicals that are internationally-assessed for human health and the environment

Section 52 sets out the records that must be kept in relation to reported introductions of industrial chemicals that are internationally-assessed for human health and the environment:

- chemical identity information for the industrial chemical
- the names of any products containing the industrial chemical that are imported into Australia by the introducer
- records to demonstrate that the introduction is not a type that is not exempted or reported under section 25 of these rules
- records to demonstrate that the introduction is not any of the types that are specified in certain table items of subsection 28(1) and 29(1) of these rules (certain introductions of medium to high risk for human health or for the environment). For example, introductions of industrial chemicals that contain fully fluorinated carbon atoms with certain chain lengths (for indicative human health risk and indicative environment risk), persistent gases at certain volumes (for indicative environment risk), organotin chemicals at certain volumes (for indicative environment risk), or certain industrial chemicals at the nanoscale (for indicative human health risk and indicative environment risk)
- records to demonstrate any known hazard classification for the industrial chemical

- records to demonstrate that the maximum total volume introduced by the person in a registration year does not exceed the information that they provided in their pre-introduction report relating to this introduction, and
- records to demonstrate that the requirements relating to the reliance upon the international assessment or evaluation for categorisation purposes are being met by the introducer.

The exact nature of some of the record keeping requirements differs depending on whether the introducer knows the proper name for the industrial chemical. If the introducer knows the proper name for the industrial chemical, they are required to have records of this, and any other records that rely upon the specific chemical identity being known (such as records to demonstrate that the introduction is not one of the certain introductions that are medium to high indicative risk for human health or the environment). If the introducer does not know the proper name for the industrial chemical, they can instead keep records of the name(s) by which the industrial chemical is known to the introducer. These name(s) must include the name given in the pre-introduction report for the industrial chemical. Written undertakings from the chemical identity holder that any information that relies on the specific chemical identity being known will be provided to the Executive Director upon request are also required.

Section 53 Introductions of industrial chemicals that are internationally-assessed for human health but not internationally-assessed for the environment

Section 53 sets out the records that must be kept in relation to reported introductions of industrial chemicals that are internationally-assessed for human health but not internationally-assessed for the environment:

- chemical identity information for the industrial chemical
- the names of any products containing the industrial chemical that are imported into Australia by the introducer
- records to demonstrate that the introduction is not a type that is not exempted or reported under section 25 of these rules
- records to demonstrate that the introduction is not any of the types that are specified in certain table items of subsection 28(1) and 29(1) of these rules (certain introductions of medium to high risk for human health or for the environment). For example, introductions of industrial chemicals that contain fully fluorinated carbon atoms with certain chain lengths (for indicative human health risk and indicative environment risk), persistent gases at certain volumes (for indicative environment risk), organotin chemicals at certain volumes (for indicative environment risk), or certain industrial chemicals at the nanoscale (for indicative human health risk and indicative environment risk)
- in circumstances where the exposure band criteria are dependent upon the environment categorisation volume, what the environment categorisation volume is, together with records to demonstrate that these volumes have not been exceeded. The corresponding information for the human health aspects is

- not required because these are covered by the international assessment or evaluation of the industrial chemical that is being relied upon
- which designated kind of release into the environment occurs (if any)
- records to demonstrate any known hazard classification for the industrial chemical
- detailed information relating to how the absence of certain environment hazard characteristics was determined (where relevant). This detailed information should include the types of full study reports specified in the Guidelines. If the introducer does not have the required detailed information, they can instead keep records of the outcomes of the information specified in the Guidelines, together with a written undertaking from the person who has the detailed information that the detailed information meets the requirements of the Guidelines and will be provided upon request. The corresponding information for the human health aspects is not required because these are covered by the international assessment or evaluation of the industrial chemical that is being relied upon
- records to demonstrate that the requirements relating to the reliance upon the international assessment or evaluation for categorisation purposes are being met by the introducer, and
- additional record keeping requirements for certain specified classes of introduction that are relevant for environment considerations, specifically:
 - introductions that involve a designated kind of release into the environment
 - introductions of biochemicals, and
 - introductions of GM products.

The exact nature of some of the above record keeping requirements differs depending on whether the introducer knows the proper name for the industrial chemical. If the introducer knows the proper name for the industrial chemical, they are required to have records of this, and any other records that rely upon the specific chemical identity being known (such as the records to demonstrate that the introduction is not one of the certain introductions that are medium to high indicative risk for human health or the environment). If the introducer does not know the proper name for the industrial chemical, they can instead keep records of the name(s) by which the industrial chemical is known to the introducer. These name(s) must include the name given in the pre-introduction report for the industrial chemical. Written undertakings from the chemical identity holder that any information that relies on the specific chemical identity being known will be provided to the Executive Director upon request are also required.

Section 54 Introductions of industrial chemicals that are internationally-assessed for the environment but not internationally-assessed for human health

Section 54 sets out the records that must be kept in relation to reported introductions of industrial chemicals that are internationally-assessed for environment but not internationally-assessed for human health:

- chemical identity information for the industrial chemical

- the names of any products containing the industrial chemical that are imported into Australia by the introducer
- records to demonstrate that the introduction is not a type that is not exempted or reported under section 25 of these rules
- records to demonstrate that the introduction is not any of the types that are specified in certain table items of subsection 28(1) and 29(1) of these rules (certain introductions of medium to high risk for human health or for the environment). For example, introductions of industrial chemicals that contain fully fluorinated carbon atoms with certain chain lengths (for indicative human health risk and indicative environment risk), persistent gases at certain volumes (for indicative environment risk), organotin chemicals at certain volumes (for indicative environment risk), or certain industrial chemicals at the nanoscale (for indicative human health risk and indicative environment risk)
- records to demonstrate the polymer molecular weight details of the industrial chemical if it is a high molecular weight polymer and the human health exposure band for its introduction is 4
- records to demonstrate that the maximum total volume introduced by the person in a registration year does not exceed the information that they provided in their pre-introduction report relating to this introduction
- in circumstances where the exposure band criteria are dependent upon the human health categorisation volume, what the relevant categorisation volume is, together with records to demonstrate that these volumes have not been exceeded. The corresponding information for the environment aspects is not required because these are covered by the international assessment or evaluation of the industrial chemical that is being relied upon
- records to demonstrate any known hazard classification for the industrial chemical
- detailed information relating to how the absence of certain human hazard characteristics was determined (where relevant). This detailed information should include the types of full study reports specified in the Guidelines. If the introducer does not have the required detailed information, they can instead keep records of the outcomes of the information specified in the Guidelines, together with a written undertaking from the person who has the detailed information that the detailed information meets the requirements of the Guidelines and will be provided upon request. The corresponding information for the environment aspects is not required because these are covered by the international assessment or evaluation of the industrial chemical that is being relied upon
- records to demonstrate that the requirements relating to the reliance upon the international assessment or evaluation for categorisation purposes are being met by the person, and
- additional record keeping requirements for certain specified classes of introduction that are relevant for human health considerations, specifically:
 - introductions of biochemicals
 - introductions of GM products
 - introductions of UV filters in human health exposure band 4
 - introductions where the end use is in an article with food contact, and

- introductions where the end use is in an article that is a children's toy or a children's care product.

The exact nature of some of the above record keeping requirements differs depending on whether the introducer knows the proper name for the industrial chemical. If the introducer knows the proper name for the industrial chemical, they are required to have records of this, and any other records that rely upon the specific chemical identity being known (such as the records to demonstrate that the introduction is not one of the certain introductions that are medium to high indicative risk for human health or the environment). If the introducer does **not** know the proper name for the industrial chemical, they can instead keep records of the name(s) by which the industrial chemical is known to the introducer. These name(s) must include the name given in the pre-introduction report for the industrial chemical. Written undertakings from the chemical identity holder that any information that relies on the specific chemical identity being known will be provided to the Executive Director upon request are also required.

Section 55 Introduction of industrial chemicals that are solely for use in research and development

Section 55 of these rules sets out the records that must be kept in relation to reported introductions of industrial chemicals that are solely for use in research and development:

- chemical identity information for the industrial chemical
- records to demonstrate that the introduction is not a type that is not exempted or reported under section 25 of these rules
- certain records relating to demonstrating the industrial chemical does not consist of particles in the nanoscale for introductions above certain introduction volumes by an introducer in a registration year, and
- records to demonstrate the relevant requirements relating to research and development are being met.

The exact nature of some of the record keeping requirements differs depending on whether the introducer knows the proper name for the industrial chemical. If the introducer knows the proper name for the industrial chemical, they are required to have records of this, and any other records that rely upon the specific chemical identity being known (such as the records to demonstrate that the introduction is not one of the certain introductions that are medium to high indicative risk for human health or the environment). If the introducer does **not** know the proper name for the industrial chemical, they can instead keep records of the name(s) by which the industrial chemical is known to the introducer. These name(s) must include the name given in the pre-introduction report for the industrial chemical. Written undertakings from the chemical identity holder that any information that relies on the specific chemical identity being known will be provided to the Executive Director upon request are also required.

Section 56 Low-risk flavour or fragrance blend introductions

Section 56 sets out the records that must be kept in relation to reported introductions of industrial chemicals that are low-risk flavour or fragrance blend introductions:

- the name of the flavour or fragrance blend that the industrial chemical is to be introduced as a part of
- names of any products containing the flavour or fragrance blend imported into Australia by the introducer.
- records to demonstrate that the introduction is not a type that cannot be exempted or reported under section 25 of these rules
- records to demonstrate that the introduction meets the requirements of the low-risk flavour or fragrance blend introduction under subsection 27(4) of these rules
- total volume information relating to the introduction of the flavour or fragrance blend by the introducer, and
- records to demonstrate the types of products introduced by the introducer that contain the flavour or fragrance blend, such as shampoo or body cream, and the maximum concentrations of the flavour or fragrance blend that each type of product contains.

The exact nature of some of the above record keeping requirements differs depending on whether the introducer knows the proper name for the industrial chemical. If the introducer knows the proper name for the industrial chemical, they are required to have records of information that relies upon the chemical identity being known. These include the records to demonstrate that the introduction is not one of the certain introductions that cannot be exempted or reported; and records to demonstrate that the industrial chemical does not have certain hazard characteristics. If the introducer does **not** know the proper name for the industrial chemical, they can instead keep written undertakings from the chemical identity holder that these requirements have been met and that the records to demonstrate this will be provided to the Executive Director upon request.

Section 57 Other introductions where the highest indicative risk is low risk

Section 57 sets out the records that must be kept in relation to reported introductions where the outcome of considering step 6 of the method statement in section 24 is that the highest indicative risk for the introduction is low risk:

- chemical identity information for the industrial chemical
- the names of any products containing the industrial chemical that are imported into Australia by the introducer
- records to demonstrate that the introduction is not a type that is not exempted or reported under section 25 of these rules
- records to demonstrate that the introduction is not any of the types that are specified in certain table items of subsection 28(1) and 29(1) of these rules (certain introductions that are medium to high risk for human health or medium to high risk for the environment). For example, introductions of industrial chemicals that contain fully fluorinated carbon atoms with certain chain lengths (for indicative human health risk and indicative environment risk), persistent gases at certain volumes (for indicative environment risk), organotin chemicals at certain volumes (for indicative environment risk), or certain industrial chemicals at the nanoscale (for indicative human health risk and indicative environment risk)

- records to demonstrate the polymer molecular weight details of the industrial chemical if it is a high molecular weight polymer and the human health exposure band for its introduction is 4
- records to demonstrate the end uses for the industrial chemical
- in circumstances where the human health exposure band criteria used for the introduction are dependent upon concentration, the maximum concentration of the industrial chemical at introduction and at end use
- in circumstances where the exposure band criteria are dependent upon the human health categorisation volume or the environment categorisation volume, what the relevant categorisation volume is, together with records to demonstrate that these volumes have not been exceeded
- which designated kind of release into the environment occurs (if any)
- records to demonstrate any known hazard classification for the industrial chemical
- detailed information relating to how the absence of certain hazard characteristics was determined (where relevant). This detailed information should include the types of full study reports specified in the Guidelines. If the introducer does not have the required detailed information, they can instead keep records of the outcomes of the information specified in the Guidelines, together with a written undertaking from the person who has the detailed information that the detailed information meets the requirements of the Guidelines and will be provided upon request, and
- additional record keeping requirements for certain specified classes of introduction, specifically:
 - introductions that involve a designated kind of release into the environment
 - introductions of biochemicals
 - introductions of GM products
 - introductions of UV filters in human health exposure band 4
 - introductions where the end use is in an article with food contact, and
 - introductions where the end use is in an article that is a children's toy or a children's care product.

The exact nature of some of the above record keeping requirements differs depending on whether the introducer knows the CAS number for the industrial chemical, or whether a CAS number has been assigned for the industrial chemical. If the introducer knows the CAS number for the industrial chemical, they are required to have records of the CAS number and proper name, as well as any other records that rely upon the specific chemical identity being known (such as the records to demonstrate that the introduction is not one of the certain introductions that are medium to high indicative risk for human health or the environment, and the polymer molecular weight details, if relevant). If the CAS number for the industrial chemical has not been assigned, or is not known to the introducer, they can keep either a record of the proper name for the chemical, or the name(s) by which the industrial chemical is known to the introducer. These name(s) must include the name given in the pre-introduction report for the industrial chemical. Written undertakings from the chemical identity holder that any information that relies on the specific chemical identity being known will be provided to the Executive Director upon request are also required.

Part 5 – Record keeping for assessed introductions

Section 58 Assessed introductions

Section 58 sets out the records that must be kept in relation to assessed introductions:

- the chemical identity of the industrial chemical (either the proper name, or the AICIS Approved Chemical name (AACN) if the proper name is not known to the introducer), and
- records to demonstrate that the terms of the assessment certificate are being complied with.

Part 6 – Record keeping for commercial evaluation introductions

Section 59 Commercial evaluation introductions

Section 59 sets out the records that must be kept in relation to commercial evaluation introductions:

- the chemical identity of the industrial chemical (either the proper name, or the AICIS Approved Chemical name (AACN) if the proper name is not known to the introducer), and
- records to demonstrate that the terms of the commercial evaluation authorisation are being complied with.

Part 7 – Record keeping for exceptional circumstances introductions

Section 60 Record keeping for exceptional circumstances introductions

Section 60 sets out the records that must be kept in relation to exceptional circumstances introductions:

- the proper name of the industrial chemical, if the proper name is a term of the authorisation, and
- records to demonstrate that any conditions, requirements or scope of the authorisation are being complied with.

Part 8 – Record keeping for introductions under section 163 of the Act

Section 61 Introductions under section 163 of the Act

Section 61 sets out the records that must be kept in relation to introductions which have been approved under section 163 of the Act:

- the name of the industrial chemical, and
- records to demonstrate that any conditions of the approval are being complied with.

Chapter 5 – Confidentiality and disclosure

Part 1 – Simplified outline of this Chapter

Section 62 Simplified outline of this Chapter

Part 2 of this Chapter specifies the kinds of information that will be published about reported introductions that are internationally-assessed for human health or the environment.

Part 3 of this Chapter deals with protected Confidential Business Information (CBI), particularly the use of an AICIS Approved Chemical Name (AACN) or Generalised End Use (GEU) to protect the disclosure of full chemical identity (proper name) or detailed end use, respectively. Rules in this Chapter specify when an AACN or a GEU must be published instead of the proper name or end use, and provide details about who must be notified when an approval for CBI is due to be reviewed.

This Chapter also lists the State, Territory and international entities to whom the Executive Director of AICIS may disclose CBI.

Part 2 – Publication of certain information

Section 63 Publication of information relating to reported introductions

Under section 97 of the Act, the Executive Director of AICIS may publish information on reported introductions. Section 63 of these rules describes information that must be published, in relation to reported introductions that have been internationally-assessed. The information is the proper name and end use of the industrial chemical, and the name of the international body that assessed the industrial chemical.

Part 3 – Confidentiality and disclosure

Part 6 of the Act provides for the protection of the proper name (full chemical identity) and end use of an industrial chemical in certain circumstances. Protection may also be available under the Act for other kinds of information. Such information is known as “Confidential Business Information” (CBI). Part 3 of these rules deals with the publication and disclosure of such information.

Section 64 Notice of proposed variations to Inventory listings

“Subsequent assessment certificate” means a certificate where an earlier assessment certificate has already been issued for the same industrial chemical. The industrial chemical will be listed on the Inventory 5 years after issue of the earlier assessment certificate (or earlier if an earlier certificate holder applies for early listing under section 83 of the Act, and all holders of certificates for that industrial chemical consent), while the subsequent assessment certificate is still in force.

If the terms of the subsequent assessment certificate include a different end use than the earlier assessment certificate, under section 87 of the Act the Executive Director

may vary the Inventory listing for the chemical to incorporate the terms of the subsequent certificate, i.e. to add the different end use.

This variation of the Inventory can occur 5 years after the subsequent assessment certificate was issued, or a holder of a subsequent assessment certificate can apply for the variation before 5 years have passed.

Section 64 of these rules prescribes additional people who must be notified when an industrial chemical is listed on the Inventory, and a subsequent holder of an assessment certificate has applied (under section 87 of the Act) to have the Inventory listing varied to incorporate terms of the subsequent assessment certificate. The additional people are:

- a confidence holder for a CBI approval for end use of the industrial chemical (not necessarily the same end use), and
- a person nominated to the Executive Director as someone who should receive any notices regarding the CBI approval for end use of the industrial chemical (this nomination can be done by a confidence holder under subsection 68(2) of these rules).

Section 65 Protection of proper name or end use

Section 65 of these rules prescribes additional circumstances in which a person can apply under section 105 of the Act for the proper name or end use to be protected as CBI, where the person has:

- provided to the Executive Director the proper name or end use of an industrial chemical, for example as part of a pre-introduction report or response to a call for information
- given notice under section 112 of the Act of an intention to have that information (proper name or end use) protected from publication, and then
- received a notice (under section 113 of the Act) that the Executive Director proposes to publish the information.

An application under subsections 105(1) and (2) of the Act must be given to the Executive Director either at the same time as the related application or pre-introduction report mentioned in those provisions is given, or the other time set out in subsection 65(3) of these rules.

Section 66 When an AACN or generalised end use must be used

When CBI protection of chemical identity or end use has been approved by the Executive Director, section 109 of the Act provides that an AACN or generalised end use must be published in lieu of the proper name or end use if circumstances prescribed by the rules apply. Section 66 of these rules prescribes the following circumstances:

- when the Executive Director issues an assessment statement and certificate
- when the Executive Director issues a commercial evaluation authorisation
- when the Executive Director provides a draft evaluation statement

- when the Executive Director publishes an evaluation statement
- when the Executive Director publishes a notice in relation to an evaluation
- when the Executive Director conducts a public consultation
- when the Executive Director lists the chemical on the Inventory
- when the Executive Director varies the Inventory in relation to subsequent assessment certificates, and
- when the Executive Director publishes certain information related to reported introductions (the information detailed under section 63 of these rules).

Section 67 Circumstances in which notice of review of protection of proper name or end use must be given

Under section 110 of the Act, the Executive Director must, in certain circumstances, give notice to holders of an approval for CBI protection of proper name or end use, telling them that the approval will be revoked unless an application for continued protection is made and approved under section 111 of the Act. This process is called 'review of protection'.

Section 110 of the Act provides that these notices must be sent, 5 years after the approval was given, to each holder of a CBI approval in relation to an industrial chemical that either is due to be listed on the Inventory 5 years after an assessment certificate has been issued for the chemical (under section 82 of the Act), or has been listed on the Inventory earlier than 5 years since the issue of an assessment certificate (under section 83 of the Act).

Section 67 of these rules prescribes additional circumstances in which the Executive Director must give notice of a review of CBI protection of proper name or end use.

The additional circumstances in which a review of CBI protection of proper name or end use will occur are:

- When the Executive Director has concluded, as part of an evaluation under Part 4 of the Act, that a review of CBI protection of proper name or end use is in the public interest (refer to subsection 67(2))
- When an approval for CBI protection of proper name or end use has been given in circumstances other than in relation to an assessment certificate application (for example, if CBI protection of proper name was approved for a commercial evaluation authorisation or pre-introduction report), and subsequently an application for an assessment certificate for introduction of the same chemical is made (refer to subsections 67(3) and (4)). If the CBI protection is for end use, the assessment certificate application must be for the same end use as the existing CBI approval
- When the Executive Director is proposing to vary an Inventory listing to add the terms of a subsequent assessment certificate, 5 years after the subsequent assessment certificate was issued (under paragraph 87(1)(c)(i) of the Act). This applies to CBI protection of end use only, and
- 5 years after the issue of a subsequent assessment certificate where the Executive Director has previously varied the Inventory to include the terms of the subsequent certificate upon application by a holder of the subsequent

certificate (under paragraph 87(1)(c)(ii) of the Act). This applies to CBI protection of end use only.

Section 68 Persons to whom notice regarding protection of proper name or end use is to be given

Subsection 110(1) of the Act provides for review of CBI protection 5 years after approval (or re-approval) has been given, of an AACN or generalised end use for industrial chemicals listed (or proposed to be listed) on the Inventory.

Subsection 110(2) of the Act defines the term “confidence holder”, which then applies to provide the people who must be given notice of a review under subsection 110(1) of the Act. Under paragraph 110(2)(a), “confidence holder” includes each holder of the approval for CBI protection.

Section 68 of these rules prescribes additional people who are included in the definition of “confidence holder” under subsection 110(2), based on certain prescribed circumstances occurring.

If a review of CBI protection is happening because of a conclusion in an evaluation (under Part 4 of the Act), the additional people are:

- ‘bona fide introducers’ to whom, under section 120 of the IC Act, an ‘entrusted person’ from AICIS has disclosed the connection between protected information and the proper name or end use (because the ED is satisfied that the bona fide introducer intends to introduce the chemical and this disclosure is necessary for its safe introduction and use);
- holders of other approvals for CBI protection of the same proper name or end use of the same industrial chemical, and anyone nominated for this purpose by such a holder; and
- recipients of assessment certificates, assessment statements, commercial evaluation authorisations or evaluation statements that included the same AACN or a generalised end use (not necessarily the same generalised end use) for the same industrial chemical.

If a review of CBI protection is happening because 5 years have passed since approval of CBI protection was given, and the industrial chemical is proposed to be listed on the Inventory, or is already (early-)listed on the Inventory, the additional people are:

- ‘bona fide introducers’ to whom, under section 120 of the IC Act, an ‘entrusted person’ from AICIS has disclosed the connection between protected information and the proper name or end use (because the ED is satisfied that the bona fide introducer intends to introduce the chemical and this disclosure is necessary for its safe introduction and use);
- holders of other approvals for CBI protection of the same proper name or end use of the same industrial chemical, and anyone nominated for this purpose by such a holder; and
- recipients of assessment certificates, assessment statements, commercial evaluation authorisations or evaluation statements that included the same

AACN or a generalised end use (not necessarily the same generalised end use) for the same industrial chemical.

If a review of CBI protection is happening because of an assessment certificate application for introduction of an industrial chemical that has previously had CBI protection of proper name or end use approved in other circumstances, the additional people are:

- the assessment certificate applicant
- holders of other approvals for CBI protection of the same proper name or end use of the same industrial chemical, and anyone nominated for this purpose by such a holder; and
- recipients of commercial evaluation authorisations or evaluation statements that included the same AACN or a generalised end use (not necessarily the same generalised end use) for the same industrial chemical.

If a review of CBI protection is happening because of a variation to an Inventory listing to incorporate the terms of a subsequent assessment certificate, the additional people are:

- ‘bona fide introducers’ to whom, under section 120 of the IC Act, an ‘entrusted person’ from AICIS has disclosed the connection between protected information and the proper name or end use (because the ED is satisfied that the bona fide introducer intends to introduce the chemical and this disclosure is necessary for its safe introduction and use);
- holders of other approvals for CBI protection of the same proper name or end use of the same industrial chemical, and anyone nominated for this purpose by such a holder; and
- recipients of assessment certificates, assessment statements, commercial evaluation authorisations or evaluation statements that included a generalised end use (not necessarily the same generalised end use) for the same industrial chemical.

If the holder of an assessment certificate applies under section 83 of the Act to list the industrial chemical before 5 years have passed since the certificate was issued, section 83 provides that the Executive Director must give written notice of this application to any other “confidence holders” for an approval for CBI protection of proper name or end use of the industrial chemical. Under section 68 of these rules, additional people defined as “confidence holders” under subsection 110(2) of the Act are:

- holders of other approvals for CBI protection of the same proper name or end use of the same industrial chemical, and anyone nominated for this purpose by such a holder; and
- recipients of assessment certificates, assessment statements, commercial evaluation authorisations or evaluation statements that included the same AACN or a generalised end use (not necessarily the same generalised end use) for the same industrial chemical.

Section 69 Disclosure to certain entities

The Executive Director may disclose protected information to Australian state, territory and international entities prescribed in section 69 of these rules. The prescribed international entities are those for which Australia has a co-operative arrangement in place relating to the assessment or regulation of industrial chemicals, which includes handling of CBI.

Chapter 6 – International agreements and arrangements

Part 1 – Simplified outline of this Chapter

Section 70 Simplified outline of this Chapter

Section 163 of the Act provides that the rules may prohibit or restrict the introduction or export of industrial chemicals that are included in certain international agreements that are prescribed by these rules. Section 11 of these rules prescribes the Rotterdam Convention and the Stockholm Convention for this purpose. Chapter 6 of these rules prescribes:

- industrial chemicals restricted from introduction or export, and
- how to apply to introduce or export a restricted industrial chemical.

Part 2 – Movement of industrial chemicals into or out of Australia

Section 71 Introduction of certain industrial chemicals subject to conditions

Section 71 lists the industrial chemicals which are the subject of an international agreement (the Rotterdam Convention) and for which the introduction must be approved by the Executive Director, prior to introduction. Subsection 71(1) provides that the introduction of an industrial chemical specified in subsection (2) by a person is subject to the conditions specified in paragraphs (1)(a) and (b).

Section 72 Introduction of tetraethyl lead subject to conditions

Section 72 sets out the conditions for the introduction of tetraethyl lead, including the need for an approval by the Executive Director prior to introduction in Australia. Subsection 72(2) provides for the circumstances and other requirements that need to be met for a person to be able to introduce tetraethyl lead, such as the tetraethyl lead is in leaded fuel.

Section 73 Export of certain industrial chemicals subject to conditions

Section 73 sets out the industrial chemicals which are the subject of an international agreement (the Rotterdam Convention) and for which the export must be approved by the Executive Director, prior to export. The person exporting an industrial chemical specified in subsection 73(2) are subject to the conditions set out in paragraphs (1)(a) and (b).

Section 74 Applying for approval to introduce or export restricted industrial chemicals

Section 74 sets out the process for a person to apply to the Executive Director for approval to introduce the chemicals listed in sections 71 or 72 or to export the chemicals listed in section 73. The application must be in writing, the Executive Director may request further information, and if such information is not provided within the period specified in the notice, the application may be treated as withdrawn.

Section 75 Decision on application

Section 75 describes the matters that the Executive Director must have regard to (in relation to an application made under section 74) and also describes the process relating to decision making. A decision not to approve the introduction or export is a reviewable decision.

Chapter 7 – Miscellaneous

Part 1 – Simplified outline of this Chapter

Section 76 Simplified outline of this Chapter

This Chapter contains provisions about additional functions for the Executive Director, and about reconsideration and review of decisions made under these rules.

Part 2 – Miscellaneous

Section 77 Additional function of Executive Director

Section 77 prescribes an additional function for the Executive Director to provide advice about how to manage risks that arise from the introduction or use of industrial chemicals. For example, the Executive Director may make recommendations to Commonwealth standard setting bodies relating to particular risks covered by their risk management framework. The function to provide advice is on the Executive Director's initiative and the advice can be provided to the bodies prescribed in section 16 of these rules (where specific bodies are prescribed in relation to specific types of risks) or to any other person.

Section 78 Reconsideration and review of decisions

Section 78 sets out the decisions under these rules that are subject to reconsideration and review under section 166 of the Act:

- a decision under section 21 of these rules to not approve the inclusion of animal test data in an application
- a decision under section 33 of these rules to not approve a person having regard to animal test data when categorising an introduction, and

- a decision under section 75 of these rules to not approve introduction or export of a chemical that is included in an international agreement or arrangement prescribed by these rules.

Section 79 Calculating the consideration period for an application

Section 79 prescribes additional circumstances that must be taken into account when calculating consideration periods under the Act. These are in relation to when advice is being sought from prescribed bodies or the Gene Technology Regulator during consideration of an application to vary the Inventory.

Schedule 1 – Exposure bands and hazard bands

Schedule 1 is divided into two parts, one for human health and one for environment. Part 1 – Human health, describes the human health exposure bands (clause 1) and the human health hazard bands (clause 2). Part 2 – Environment, describes the environment exposure bands (clause 3) and the environment hazard bands (clause 4).

Part 1 – Human health

Clause 1 Human health exposure band

Clause 1 contains the criteria for each of the four human health exposure bands (exposure bands 1 – 4). The potential level of exposure to humans is lowest in exposure band 1 and increases such that it is highest in exposure band 4. The exposure band criteria are dependent upon several parameters:

- the human health categorisation volume for the industrial chemical
- the concentration of the industrial chemical at introduction
- the concentration of the industrial chemical at end use
- whether the introduction involves a designated kind of human exposure, that is, exposure arising from end use in a tattoo ink or a personal vaporiser, and
- whether there are any consumer end uses for the introduction of the industrial chemical.

Clause 2 Human health hazard band

Clause 2 specifies the human health hazard bands that apply to certain hazard characteristics that an industrial chemical may have. The level of hazard to humans is lowest in hazard band A and increases such that it is highest in hazard band C.

The meaning of each hazard characteristic is described in the Guidelines. This is because it requires complex technical detail, including specification of the appropriate test guidelines and the relevant results from certain toxicological study reports.

The hazard characteristics within each hazard band are ordered to match the sequence in which they appear in the Guidelines, with human health hazard characteristics in

hazard band C appearing first. This ordering is intended to match the order in which an introducer of an industrial chemical would need to consider each hazard characteristic, i.e. they will need to demonstrate the absence of hazard characteristics (in accordance with subparagraph 30(2)(c)(iv) of these rules) in the highest hazard bands first. The ordering of hazard characteristics within each human health hazard band is based on the ease with which the absence of each hazard characteristic can be demonstrated, with the easiest appearing first.

Part 2 – Environment

Clause 3 Environment exposure band

Clause 3 contains the criteria for each of the four environment exposure bands (exposure bands 1 – 4). The potential level of exposure to the environment is lowest in exposure band 1 and increases such that it is highest in exposure band 4. The exposure band criteria are dependent upon:

- the environment categorisation volume for the industrial chemical, and
- whether the introduction involves a designated kind of release into the environment.

The definition of *environment categorisation volume* is given in section 5 of these rules, and the kinds of releases that are a *designated kind of release into the environment* are given in subclause 3(2).

Clause 4 Environment hazard band

Clause 4 specifies the environment hazard bands that apply to certain hazard characteristics that an industrial chemical may have. The level of hazards to the environment is lowest in hazard band A and increases such that it is highest in hazard band D.

The meaning of many of the hazard characteristics is described in the Guidelines. This is because it requires complex technical detail, including specification of the appropriate test guidelines and the relevant results from certain toxicological or fate study reports.

The hazard characteristics within each hazard band are ordered to match the sequence in which they appear in the Guidelines, with environment hazard characteristics in hazard band D appearing first. This ordering is intended to match the order in which an introducer of an industrial chemical would need to consider each hazard characteristic. They will need to demonstrate the absence of hazard characteristics (in accordance with subparagraph 30(2)(c)(iv) of these rules) in the highest hazard bands first. The ordering of hazard characteristics within each environment hazard band is based on the ease with which the absence of each hazard characteristic can be demonstrated, with the easiest appearing first.

Schedule 2 – Polymers of low concern

Part 1 – Polymers of low concern

Schedule 2 contains the criteria for an industrial chemical to be a polymer of low concern (PLC). The introduction of an industrial chemical that meets the PLC criteria can be an exempted introduction.

As far as possible, the PLC criteria have been aligned with the equivalent criteria from the international chemical regulatory schemes of the US and Canada.

The PLC criteria cover:

- molecular weight of the polymer
- low molecular weight species
- reactive functional groups
- cationic density
- stability
- elemental composition, and
- water absorbing potential

Clause 1 Polymers of low concern

Clause 1 contains the PLC criteria, with subsequent clauses giving further details for certain of the criteria. For a polymer to be a PLC it must meet all of the criteria listed in paragraphs (a) to (i) of clause 1.

Paragraph 1(a) provides two options ((i) and (ii)) for the number average molecular weight ranges of a PLC, and a third option ((iii)), for certain polyesters, that is independent of the number average molecular weight. Clauses 2 and 3 then detail the other criteria that a PLC with a number average molecular weight within the specified ranges must meet (for subparagraphs 1(a)(i) and (ii), respectively). Clause 4 contains the prescribed reactants, for the purposes of subparagraph 1(a)(iii), that a polyester that is a PLC can be made from.

Paragraph 1(b) states that a PLC must have a low cationic density. The definition of *low cationic density* is in section 5 of these rules.

Paragraph 1(c) states that a PLC must not have any known hazard classification. The definition of *known hazard classification* is in section 5 of these rules.

Paragraph 1(d) states that a PLC must be stable. The meaning of *the polymer is stable* is specified in the Guidelines.

Paragraph 1(e) states that a PLC must contain 2 or more of the chemical elements listed in clause 5 as an integral part of its composition.

Paragraph 1(f) states that there are certain chemical elements that a PLC cannot contain as an integral part of its composition. However, these certain chemical elements can be present in a PLC as impurities. The chemical elements that this

applies to are any that are not listed in clause 6. This means that the chemical elements listed in clause 6 are chemical elements that a PLC may contain.

Paragraph 1(g) states that there are certain chemical elements that a PLC cannot contain as an integral part of its composition (unless they are present as impurities) above certain levels. The relevant chemical elements are listed in subclauses 6(s) to (zc). The combined levels of these chemical elements in a PLC must not be 0.2% or more by weight.

Paragraph 1(h) states that a PLC cannot contain any difluoromethylene or trifluoromethyl groups.

Paragraph 1(i) states that if a PLC is capable of absorbing its own weight in water, it must have a number average molecular weight that is less than 10,000 g/mol.

Clause 2 Number average molecular weight greater than or equal to 1,000 g/mol and less than 10,000 g/mol

Clause 2 contains the criteria that a PLC must meet if it has a number average molecular weight that is greater than or equal to 1,000 g/mol but less than 10,000 g/mol. Subclause 2(2) specifies the levels of low molecular species that such a PLC can contain. Subclauses 2(5), (6) and (7) specify the reactive functional groups that are considered to be of low, moderate and high concern. Subclauses 2(3) and (4) give the values for the combined functional group equivalent weights that a PLC can have depending on the level of concern of any reactive functional groups that are present in the polymer.

Note that polymers may contain functional groups that are not considered to be *reactive* functional groups.

Clause 3 Number average molecular weight that is greater than or equal to 10,000 g/mol

Clause 3 specifies the levels of low molecular weight species that a PLC can contain if it has a number average molecular weight that is greater than or equal to 10,000 g/mol.

Clause 4 Prescribed reactants

Clause 4 provides the further details required for subparagraph 1(a)(iii). It lists the chemicals that are prescribed reactants for the purposes of that subparagraph. These are certain:

- dibasic acids that are in the table in clause 7
- tribasic acids that are in the table in clause 7
- modifiers that are in the table in clause 8
- monobasic acids that are in the table in clause 9
- natural oils that are in the table in clause 9
- polyols that are in the table in clause 10, and

- derivative substances that are in the table in clause 11.

The PLCs described by subparagraph 1(a)(iii) are polyesters that are made only from prescribed reactants. These have no restrictions on number average molecular weight.

Clause 5 Chemical elements the polymer must contain as an integral part of composition

Clause 5 lists the chemical elements that a PLC must contain 2 or more of. These chemical elements must form an integral part of the composition of any polymer that is a PLC. This clause provides the further detail required for paragraph 1(e).

Clause 6 Chemical elements the polymer may contain as an integral part of composition

Clause 6 lists the chemical elements that a PLC may contain as an integral part of its composition. Any element not listed cannot be present in a PLC. Paragraphs 6(s) to (zc) list chemical elements that can only be present in a PLC if the combined levels of any of them are not 0.2% or more by weight. This clause provides the further details required for paragraphs 1(f) and (g).

Part 2 – Prescribed reactants

Clause 7 Dibasic and tribasic acids

Clause 7 lists prescribed reactants that are dibasic and tribasic acids (referred to in paragraph 4(a) of Part 1 of Schedule 2).

Clause 8 Modifiers

Clause 8 of Part 2 lists prescribed reactants that are modifiers (referred to in paragraph 4(b) of Part 1 of Schedule 2).

Clause 9 Monobasic acids and natural oils

Clause 9 lists prescribed reactants that are modifiers (referred to in paragraph 4(c) of Part 1 of Schedule 2).

Clause 10 Polyols

Clause 10 lists prescribed reactants that are polyols (referred to in paragraph 4(d) of Part 1 of Schedule 2).

Clause 11 Derivatives

Clause 11 lists prescribed reactants that are derivatives (referred to in paragraph 4(e) of Part 1 of Schedule 2).