

EXPLANATORY STATEMENT

INDUSTRIAL CHEMICALS (CONSEQUENTIAL AMENDMENTS AND TRANSITIONAL PROVISIONS) RULES 2019

Authority

The Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 (the Transitional Rules) are part of a legislative package that establishes a new risk-based regulatory scheme for the Commonwealth to continue to regulate the introduction of industrial chemicals in Australia.

Section 50 of the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) provides that the Minister may make rules providing for matters required or permitted by the Transitional Act, or necessary or convenient in order to carry out or give effect to the Transitional Act. The rules may also prescribe matters of a transitional nature (including savings and application provisions).

Purpose

The Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 (the Transitional 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.

The main purpose of the Transitional Rules is to ensure the effective transition of the Commonwealth regulation of industrial chemicals, from the old scheme (NICNAS) to the new scheme (AICIS), including in relation to the recognition and transition of:

- assessment certificates under the old scheme,
- commercial evaluation permits under the old scheme,
- low volume permits under the old scheme,
- controlled use permits under the old scheme,
- early introduction permits under the old scheme,
- introductions under section 21 of the old scheme,
- assessment of priority existing chemicals under the old scheme,
- secondary notification under the old scheme,
- application fees, information, reporting and confidentiality, and
- matters relating to Inventory listings.

Background

The *Industrial Chemicals Act 2019* (IC Act) (the new law) establishes the legislative framework for a new risk-based regulatory scheme, and the Industrial Chemicals (General) Rules 2019 (IC Rules) prescribe details to support this framework. In addition, the Transitional Act and the Transitional Rules provide the legislative framework to transition the old arrangements to the new, and to deal with other transitional matters that arise from the enactment of the new framework as it replaces the *Industrial Chemicals (Notification and Assessment) Act 1989* (the old law).

The new legislative framework maintains Australia's robust health, safety and environmental standards. The new framework 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.

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

This approach responds to the concerns of stakeholders in a balanced and considered way, through deregulation for industry for lower risk chemicals and increased transparency for the community through better availability of information about higher risk chemicals. These are balanced against increased post-introduction monitoring and compliance capability for the regulator and certain confidentiality protections for business information for industry. 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.

Having established the new scheme for the introduction of industrial chemicals in Australia, the Transitional Act and the Transitional Rules provide for certain matters under the old law to transition to be managed under the new law.

Consultation

The new legislative framework was the subject of extensive consultation. Public consultation on the proposed technical details of the reform commenced in October 2015, and the major consultation on the technical details to be included in the IC Rules and the Industrial Chemicals Categorisation Guidelines (the Guidelines) occurred in June 2017.

On 9 March 2018, OCS published an exposure draft of the IC 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 IC Rules and the draft guidelines closed on 4 May 2018 and OCS received 29 submissions.

Following the passage of the IC Act, a further consultation was undertaken between 4 April 2019 and 17 May 2019. As a consequence of these consultations, changes were made to the draft IC Rules to take account of amendments made during passage of the IC Act, as well as stakeholder feedback on the criteria for the exempted and reported introduction categories. OCS received 26 submissions.

The submissions received on both the exposure draft of the IC 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 the IC Rules and in these Transitional 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 this legislative instrument. The OBPR advised that RIS OBPR ID 17496 covers the package of NICNAS reforms and no further RIS is needed.

Commencement

This instrument commences immediately after the commencement of Schedule 1 to the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019*.

Details on these rules are at Attachment A.

This instrument is 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 (Consequential Amendments and Transitional Provisions) 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 (Consequential Amendments and Transitional Provisions) 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 measures in this instrument to transition industrial chemical introductions into the new regulatory framework promotes continued protection of public health, environmental and industrial hygiene. The measures in this instrument increase transparency and protection for workers through publication of the Executive Director's assessment reports. This will facilitate access to health and environmental information, including risk management measures and conditions (where applicable).

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.

Section 174 of the *Industrial Chemicals Act 2019* (the IC Act) describes the requirements the Executive Director needs to adhere to when retaining and copying documents provided to the Executive Director under the IC Act. Part 12 of this instrument ensures that the same protection is afforded to information and documents that were obtained under the old law as is afforded to information obtained under the IC Act (i.e. section 80 of this instrument extends the protection in section 174 of the IC Act).

Division 4 of Part 6 of the IC Act provides a framework for protection of confidential business information in the context of the requirements under the new law for publication of certain information relating to the risks associated with the introduction and use of industrial chemicals. Part 11 of this instrument provides additional avenues for protection of such information (i.e. section 74 of this instrument extends the right to apply for confidential Inventory listing to additional persons).

These provisions of the IC 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 it supports the right to health. 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 (Consequential Amendments and Transitional Provisions) Rules 2019

Part 1 – Preliminary

Section 1 Name

This section provides for the instrument to be cited as the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019.

Section 2 Commencement

This section provides for the whole of this instrument to commence immediately after the commencement of Schedule 1 to the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019*. This Act commences 1 July 2020.

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

Section 3 Authority

This section provides that the instrument is made under the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act).

Section 4 Definitions

Section 4 includes definitions for terms used in this instrument. Some of these definitions have the same meaning as in the old law (such as *chemical name*); others have been defined for the purpose of this instrument. For example, the term *old regulations* is defined to mean the Industrial Chemicals (Notification and Assessment) Regulations 1990, as in force immediately before 1 July 2020.

The terms *assessment report* and *evaluation report* have also been defined for the purposes of this instrument.

Part 2 – Assessment certificates under new law

Division 1 – Pending applications for assessment certificates

Division 1 of Part 2 of the Transitional Rules contains details on pending applications for assessment certificates. Pending applications are applications submitted and paid for under the old law for which a decision has not been reached before the commencement of the new law (i.e. before 1 July 2020). The intent is that these applications will transition to the new law at no further cost to the applicant.

Section 5 Application of Division

Subject to any modifications made by the Transitional Rules, item 13 of Schedule 2 to the Transitional Act provides for an application for an assessment certificate that is pending on 1 July 2020 to be treated as though it was an application for an assessment certificate made under section 31 of the new law.

Section 5 of the Transitional Rules specifies that Division 1 of Part 2 of the Rules modifies the operation of the IC Act in relation to:

- an application for an assessment certificate that is made under the old law (i.e. made before 1 July 2020 under section 23 of the old law), and
- an assessment certificate that is issued under the new law as a result of an application made under the old law that is transitioned such that the new law applies.

Section 6 Pending applications for variation of requirements of section 23 of old law

Under section 24 of the old law, an application can be made to waive or substitute a requirement to include certain matters in an assessment certificate application (for example to use data from a similar ‘analogue’ chemical instead of the chemical that is the subject of the application). This is called a “variation application”.

Section 6 of the Transitional Rules provides that, if the decision on the variation application is pending immediately before 1 July 2020 (i.e. on 30 June 2020), the certificate application will still transition to the new law under item 13 of Schedule 2 to the Transitional Act (despite not meeting the complete set of data requirements).

Section 7 Period within which decision must be made on application for assessment certificate

Section 7 of the Transitional Rules states that the decision on a transitioned assessment certificate application must be made within 80 working days after the application was made.

Section 7 further provides that this period does not include any time taken to receive further information that the Executive Director requested under section 30A of the old law, which deals with applications for an “early introduction permit” (a permit that allows introduction of the chemical before the final decision on the assessment certificate application has been made) for a non-hazardous industrial chemical.

Section 8 Matters Executive Director must have regard to in considering application

Section 8 of the Transitional Rules provides that, when considering a transitioned assessment certificate application, the Executive Director must have regard to any application made in accordance with section 11 of the Transitional Rules, which stipulates that AICIS must prepare a draft assessment report (not assessment statement) and provide it to the applicant, who may apply to vary the report.

Section 9 Requests for further information under old law

Section 9 of the Transitional Rules provides that any request made by the Director of NICNAS under section 27 of the old law for further information relating to an assessment certificate application, is treated as a request made by the Executive Director of AICIS under section 33 of the new law for further information relating to an assessment certificate application.

Section 10 Draft assessment statement not to be provided

Under the new law, when an assessment certificate is granted, an assessment statement is published, which is eventually linked to the subsequent Inventory listing for the industrial chemical. Assessment statements under the new law will contain pertinent information concerning any risks to human health or the environment arising from introduction of the industrial chemical, and will not contain identifying details of the applicant. Assessment statements will also protect confidential business information (CBI) with the use of an AICIS approved chemical name (AACN) or generalised end use (GEU) if the relevant application for such protection has been approved.

Section 10 of the Transitional Rules provides that the Executive Director is not to prepare a draft assessment statement for a transitioned assessment certificate application (as is required for certificate applications made after 1 July 2020), as a draft assessment report under section 11 of the Transitional Rules will be prepared instead.

Section 11 Executive Director must prepare draft assessment report and public report

Section 11 of the Transitional Rules provides that the Executive Director, who under section 10 of the Transitional Rules is not to prepare a draft assessment statement, must instead provide each transitioned certificate applicant with a draft assessment report and a draft public report. Certificate applicants may then make an application to vary the draft assessment report. The Executive Director must consider any such application and decide, within 10 working days, whether to vary the draft assessment report (and, correspondingly, the draft public report) based on whether the variation would be correct. This is consistent with assessment certificate applications under the old law.

Section 12 Issue of assessment certificate and assessment report

Under the old law, the Director of NICNAS did not have the power to decide not to issue an assessment certificate. The Director was limited to making recommendations that could be acted upon by risk management bodies. This was to maintain the distinction between NICNAS, a risk assessment scheme, and other government bodies responsible for risk management. However, this can lead to a regulatory 'gap' if the actions available to the relevant risk management body cannot accommodate a risk associated with an industrial chemical once it has been introduced to Australia. The IC Act provides 'last resort' powers of risk management that can only occur if risk associated with introduction of an industrial chemical cannot be managed by existing

risk management frameworks. These ‘last resort’ powers include to decide not to issue an assessment certificate.

To preserve the rights of assessment certificate applicants under the old law, section 12 of the Transitional Rules provides that the Executive Director does not have the power under subsection 37(1) and subsection 37(3) of the IC Act to decide not to issue an assessment certificate that was applied for before 1 July 2020. Section 12 also removes the requirement under subsection 37(2) of the IC Act that the Executive Director be satisfied that any risks to human health of the environment can be managed before deciding to issue an assessment certificate.

Section 12 removes the requirement in subsection 37(7) of the IC Act that the Executive Director publish an assessment statement, as an assessment report under section 13 of the Transitional Rules will be published instead.

Section 13 Publication of public report

For transitioned certificate applications, section 13 of the Transitional Rules provides that the Executive Director must publish the “public report” (assessment report) for the industrial chemical. However, the public report must not be published if:

- the applicant withdraws the application before the report is published;
- an application for protection of confidential information in the report has been made – until a decision has been made and all reconsideration and review rights have been exhausted or have expired; or
- an application for variation of the assessment report has been made - until a decision has been made and all reconsideration and review rights have been exhausted or have expired.

Section 14 Content of assessment certificate

Under section 25 of the old law, an applicant for an assessment certificate can apply to have certain information treated as “exempt information”. If such an application is made for the name of the industrial chemical, the application must include a “trade name” to be used in the assessment report and public report in lieu of the proper name of the chemical.

For transitioned certificate applications, section 14 of the Transitional Rules provides that an assessment certificate issued after a transitioned certificate application will include the name for the industrial chemical that was published in the public report. This would be either the proper name, or a trade name if the proper name is approved as “exempt information” under the old law, or as protected confidential business information (CBI) under the new law.

Section 14 of the Transitional Rules also states that an assessment certificate issued after a transitioned certificate application will not include a “defined scope of assessment”, which is a feature of assessment statements in the new law that does not exist under the old law.

Section 15 General requirements for applications

Section 167 of the IC Act stipulates general requirements for applications. Section 15 of the Transitional Rules states that section 167 of the IC Act applies to transitioned assessment certificate applications, with a modification to subsection 167(5) to provide that an applicant for a transitioned assessment certificate application may withdraw the application at any time before publication of the public report under section 13 of the Transitional Rules.

Division 2 – Pending applications for variation of assessment report

Section 16 Pending applications for variation of assessment report

Under section 37 of the old law, a certificate applicant may apply to vary an assessment report given to the applicant under section 36 (before publication). Section 16 of the Transitional Rules provides that any application under section 37 of the old law to vary an assessment report provided to the applicant under section 36 of the old law that has not been decided on 30 June 2020, is to be treated as though it were an application to vary a draft assessment report under section 11 of the Transitional Rules.

Section 17 Reconsideration and review of decision

Section 166 of the IC Act lists reviewable decisions under the new law. Section 17 of the Transitional Rules adds to this list a decision not to vary a draft assessment report under section 11 of the Transitional Rules, i.e. this decision may be reviewed under the new law.

Division 3 – Pending applications for extension of assessment certificate

Under section 40A of the old law, a person may apply for an extension of an assessment certificate to cover that person as an additional introducer of the industrial chemical. Such an application may include significant variation in matters affecting occupational, environmental or public exposure compared to the original certificate, and must include any new information available to the applicant about the health and environmental effects of the chemical (hazards). The original certificate holder's consent is required.

If all application requirements are met, the original assessment report is modified, and the extension applicant is given an assessment certificate, referred to as an “extension certificate”.

Pending applications are applications submitted and paid for under the old law for which a decision has not been reached before the start of the new law (i.e. before 1 July 2020). The intent is that these applications will transition to the new law at no further cost to the applicant.

Section 18 Pending applications under section 40A of old law—no significant variations

Section 18 of the Transitional Rules provides that an application under the old law for an extension certificate that does not include any significant variation in matters affecting occupational, environmental or public exposure, that is pending immediately before 1 July 2020, will be treated as an application to add a person covered by a certificate under section 40 of the IC Act. This means that the Executive Director must add the person covered if satisfied that each holder of the certificate consents to the application.

Section 19 Pending applications under section 40A of old law—significant variations

Section 19 of the Transitional Rules provides that an application under the old law for an extension certificate that includes significant variation in matters affecting occupational, environmental or public exposure, that is pending immediately before 1 July 2020, will be treated as an application to vary a term of the original assessment certificate under subsection 43(1) of the IC Act, as if who the assessment certificate covers were a term of the assessment certificate. This means that a risk assessment process must occur before the Executive Director can make a decision whether to vary the original certificate.

Division 4 – Transitioned assessment certificates

Section 20 Varying or cancelling an assessment certificate

Under section 20 of the Transitional Rules, transitioned assessment certificates are:

- certificates that were issued under the old law, and are taken to be certificates issued under the new law under item 11 of Schedule 2 to the Transitional Act; and
- certificates that were issued after an assessment certificate application was made under the old law and then a decision was made under the new law in accordance with item 13 of Schedule 2 to the Transitional Act.

Under the IC Act, assessment certificates can be varied following an application by a certificate holder, or following an evaluation by the Executive Director. The Executive Director may also cancel an assessment certificate following an evaluation. A varied assessment statement is published after each of these actions.

Item 12 of Schedule 2 to the Transitional Act removes the requirement to publish assessment statements for variations of transitioned assessment certificates commenced under the IC Act.

Section 20 of the Transitional Rules provides that, in assessment statements prepared in relation to variations of transitioned assessment certificates commenced under the IC Act, the name used for the industrial chemical is the same as the name published in the public report for the original certificate assessment. This would be either the proper name, or a trade name if the proper name is approved as “exempt information” under the old law, or as protected confidential business information (CBI) under the new law.

Part 3 – Commercial evaluation permits under new law

Division 1 – Pending applications for commercial evaluation permits

Division 1 of Part 3 of the Transitional Rules contains details on pending applications for commercial evaluation permits. Pending applications are applications submitted and paid for under the old law for which a decision has not been reached before the commencement of the new law (i.e. before 1 July 2020). The intent is that these applications will transition to the new law at no further cost to the applicant.

Section 21 Application of Division

Subject to any modifications made by the Transitional Rules, item 18 of Schedule 2 to the Transitional Act provides for an application for a commercial evaluation permit that is pending immediate before 1 July 2020 to be treated as though it was an application for a commercial evaluation authorisation made under section 53 of the new law.

Section 21 of the Transitional Rules specifies that Division 1 of Part 3 of the Rules modifies the operation of the IC Act in relation to:

- an application for a commercial evaluation permit that is made under the old law (i.e. made before 1 July 2020 under subsection 21B(1) of the old law), and
- a commercial evaluation authorisation that is issued under the IC Act as a result of an application made under the old law that is transitioned such that the new law applies.

Section 22 Consideration of application

Subsection 54(2) of the IC Act stipulates the time period for consideration of a commercial evaluation authorisation application, which is 20 working days, or a period specified by the General Rules for a type of application, or a period agreed between the applicant and the Executive Director.

Section 22 of the Transitional Rules provides that, for a transitioned application for a commercial evaluation permit, the consideration period for a commercial authorisation application commences on 1 July 2020.

Subsection 54(3) of the IC Act specifies the matters that the Executive Director must have regard to when considering an application for a commercial evaluation authorisation. Section 22 of the Transitional Rules removes the requirement to consider whether the application meets certain restrictions for commercial evaluation authorisations under paragraph 53(1)(b) of the IC Act, which do not apply to applications for commercial evaluation permits under the old law.

Section 23 Requests for further information under old law

Section 23 of the Transitional Rules provides that any request made by the Director of NICNAS under section 21F of the old law for further information relating to a commercial evaluation permit application, is treated as a request made by the

Executive Director of AICIS under section 55 of the IC Act for further information relating to a commercial evaluation authorisation application.

Section 24 Content of authorisation

Under section 21P of the old law, an applicant for a commercial evaluation permit can apply to have certain information treated as “exempt information”. If such an application is made for the name of the industrial chemical, under section 75 of the old law the application must include a “trade name” to be used in lieu of the proper name of the chemical when publishing a notice of the permit under section 21J of the old law.

Section 24 of the Transitional Rules provides that a commercial evaluation authorisation issued after a transitioned commercial evaluation permit application, and the corresponding information published on the AICIS website, will include the name for the industrial chemical that was published in the public report. This would be either the chemical name or a trade name (as defined under the old law).

Section 25 Applying for protection of end use

A person can apply for CBI (confidential business information) protection of the end use of an industrial chemical that is the subject of a commercial evaluation authorisation under the IC Act, as long as the CBI application is made at the same time as the application for the authorisation.

Under section 25 of the Transitional Rules, a CBI application can be made for protection of end use in relation to a transitioned application for a commercial evaluation permit, and the requirement that the CBI application for end use be made at the same time as the authorisation application does not apply. Instead, the application must be made within 10 working days after 1 July 2020.

Division 2 – Pending applications for renewal of commercial evaluation permits

Section 26 Pending applications for renewal to be treated as variation applications under new law

A holder of a commercial evaluation permit can apply under the old law for the permit to be renewed for a further period (but once only). Section 26 of the Transitional Rules applies to an application for renewal of a commercial evaluation permit that is pending immediately before 1 July 2020.

Under section 26 of the Transitional Rules, a pending application for renewal of a commercial evaluation permit will be treated as an application to vary a term of a commercial evaluation authorisation under section 62 of the IC Act. Section 26 of the Transitional Rules provides that the transitioned authorisation remains in force until a decision is made on the transitioned renewal application.

Section 27 Requests for further information under old law

Section 27 of the Transitional Rules provides that any request made by the Director of NICNAS under section 21F of the old law for further information relating to a commercial evaluation permit renewal application, is treated as a request made by the Executive Director of AICIS under the IC Act, and that the Executive Director must consider any information provided when deciding on the renewal application.

Section 28 Consideration of application

Subsection 63(2) of the IC Act stipulates the time period for consideration of an application to vary a commercial evaluation authorisation, which is 20 working days, or a period specified by the General Rules for a type of application, or a period agreed between the applicant and the Executive Director.

Section 28 of the Transitional Rules provides that, for a transitioned application for a commercial evaluation permit renewal, the consideration period under subsection 63(2) of the IC Act commences on 1 July 2020.

Division 3 – Transitioned commercial evaluation permits

Item 17 of Schedule 2 to the Transitional Act provides that a commercial evaluation permit in force under the old law at 1 July 2020 is taken to be a commercial evaluation authorisation under the IC Act.

Section 29 Transitioned permits subject to 4-year limit

Paragraph 17(2)(e) of Schedule 2 to the Transitional Act provides that the period of the transitioned commercial evaluation authorisation will be the remaining period for which the commercial evaluation permit would have been in force under the old law.

Section 29 of the Transitional Rules provides that the maximum period of 4 years for a commercial evaluation authorisation under the IC Act will, for a transitioned commercial evaluation permit, be counted from the day the permit was issued under the old law. This will apply if a holder of a commercial evaluation permit that is transitioned to a commercial evaluation authorisation applies for a variation to extend the time period of the transitioned authorisation.

Section 30 Application to vary term of transitioned permit—further information

Section 30 of the Transitional Rules provides that an application can be made to vary a term of a commercial evaluation authorisation that was transitioned from a commercial evaluation permit in force under the old law. The Executive Director may request further information in relation to such an application, by written notice giving a deadline of at least 10 working days, after which if the information has not been provided, the variation application may be taken to be withdrawn.

Part 4 – Low volume permits under new law

Division 1 – Pending applications for low volume permits

Division 1 of Part 4 of the Transitional Rules contains details on pending applications for low volume permits. Pending applications are applications submitted and paid for under the old law for which a decision has not been reached before the commencement of the new law (i.e. before 1 July 2020). The intent is that these applications will transition to the new law at no further cost to the applicant.

Section 31 Application of Division

Subject to any modifications made by the Transitional Rules, item 21 of Schedule 2 to the Transitional Act provides for an application for a low volume permit that is pending immediately before 1 July 2020 to be treated as though it was an application for an assessment certificate made under section 31 of the new law.

Section 31 of the Transitional Rules specifies that Division 1 of Part 4 of the Rules modifies the operation of the IC Act in relation to:

- an application for a low volume permit that is made under the old law (i.e. made before 1 July 2020 under subsection 21R of the old law), and
- an assessment certificate that is issued under the IC Act as a result of an application made under the old law that is transitioned such that the new law applies.

Section 32 Period within which decision must be made on application

Subsection 32(2) of the IC Act stipulates the time period for consideration of an assessment certificate application, which is 70 working days, or a period specified by the General Rules for a type of application, or a period agreed between the applicant and the Executive Director.

Section 32 of the Transitional Rules states that the reference in subsection 32(2) of the IC Act to 70 working days is to be taken as a reference to 20 working days.

Section 33 Draft assessment statements not required

Low volume permits issued under the old law do not require issue or publication of an assessment report. Section 33 of the Transitional Rules provides that no draft assessment statement is required in relation to a transitioned low volume permit application.

Section 34 Requests for further information under old law

Section 34 of the Transitional Rules provides that any request made by the Director of NICNAS under section 21SA of the old law for further information relating to a transitioned low volume permit application, is treated as a request made by the Executive Director of AICIS under section 33 of the IC Act (that is, a request for further information in relation to an application for an assessment certificate).

Section 35 Issue of assessment certificate

Section 35 of the Transitional Rules modifies the requirements (under section 37 of the IC Act) for issuing an assessment certificate for a transitioned application for a low volume permit. Section 35 of the Transitional Rules provides that, prior to issuing the assessment certificate, the Executive Director must be satisfied that:

- the end use for the industrial chemical does not pose an unreasonable risk to human health or the environment, having regard to Schedule 1AA to the old regulations (the Industrial Chemicals (Notification and Assessment) Regulations 1990), and any other matter the Executive Director considers relevant, and
- the total volume of the industrial chemical that will be introduced will be no more than:
 - 100 kg per year, or
 - 1000 kg per year if the industrial chemical meets the criteria in clauses 2 and 3 of Schedule 1AA to the old regulations.

Under the old law, risks to human health or the environment are mitigated by the low volume restriction, and the requirement that the end use pose ‘no unreasonable risk’. The Director of NICNAS must, under the old law, refuse an application for a low volume permit that does not meet those requirements.

Noting that the requirements regarding low volume and ‘no unreasonable risk’ from the old law have been preserved in relation to transitioned low volume permit applications, section 35 of the Transitional Rules provides that the Executive Director does not have regard to whether any risks to human health or the environment can be managed, and the Executive Director is not required to refuse issue of the assessment certificate if any risks to human health or the environment cannot be managed.

Section 35 of the Transitional Rules provides that no assessment statement need be provided to the applicant under section 37 of the IC Act (Item 24 of Schedule 2 to the Transitional Act provides that no assessment statement is to be published in relation to transitioned applications for low volume permits.) Section 35 of the Transitional Rules provides that, instead of publishing an assessment statement, the Executive Director must give written notice of the decision and publish a notice setting out the trade name or chemical name, the end use, and the period the assessment certificate is to be in force.

Section 36 Content of assessment certificate

Under section 21ZB of the old law, an applicant for a low volume permit can apply to have certain information treated as “exempt information”. If such an application is made for the name of the industrial chemical, under section 75 of the old law the application must include a “trade name” to be used in lieu of the proper name of the chemical when publishing a notice of the permit under section 21Y of the old law.

Section 36 of the Transitional Rules provides that an assessment certificate issued after a transitioned low volume permit application will include the chemical name or trade name. It also provides that such an assessment certificate will not have a ‘defined scope of assessment’.

Section 37 Applying for protection of end use

A person can apply for CBI protection of the end use of an industrial chemical that is the subject of an assessment certificate under the IC Act, as long as the CBI application is made at the same time as the application for the assessment certificate.

Under section 37 of the Transitional Rules, a CBI application can be made for protection of end use in relation to a transitioned application for a low volume permit, and the requirement that the CBI application for end use be made at the same time as the assessment certificate application does not apply. Instead, the application must be made within 10 working days after 1 July 2020.

Division 2 – Pending applications for renewal of low volume permits

Section 38 Pending applications for renewal to be treated as variation applications under new law

A holder of a low volume permit can apply under the old law for the permit to be renewed for a further period. Section 38 of the Transitional Rules applies to an application for renewal of a low volume permit that is pending immediately before 1 July 2020.

Under section 38 of the Transitional Rules, a pending application for renewal of a low volume permit is treated as an application to vary a term of an assessment certificate under section 43 of the IC Act (that term being the period that the assessment certificate is in force). Section 38 of the Transitional Rules provides that the transitioned assessment certificate for the low volume permit remains in force until a decision is made on the transitioned renewal application.

Section 38 of the Transitional Rules provides that, for a transitioned application for a low volume permit renewal, the consideration period under paragraph 44(2)(a) of the IC Act is 20 working days from the day the application was made.

Section 38 of the Transitional Rules removes the requirement that the Executive Director consult with prescribed bodies or the Gene Technology Regulator in relation to the industrial chemical.

Section 38 of the Transitional Rules stipulates that an assessment certificate arising from a transitioned application to vary a low volume permit must not be in force for more than 3 years from the date of notice of the Executive Director's decision. No assessment statement need be sent to the applicant along with the assessment certificate. (Item 20 of Schedule 2 to the Transitional Act provides that no assessment statement is to be published in relation to a transitioned low volume permit renewal application.)

Section 38 of the Transitional Rules provides matters of which the Executive Director must be satisfied when considering a transitioned low volume permit renewal application:

- that the function or use of the industrial chemical has not and is not likely to change significantly;

- that the method of manufacture (if relevant) has not changed in a way that may result in increased risk to occupational health and safety, public health or the environment, and is not likely to change;
- that the volume introduced has not and is not likely to increase significantly;
- that no additional information has become available to the applicant as to any adverse effects of the industrial chemical.

Division 3 – Transitioned low volume permits

Subject to any modifications made by the Transitional Rules, item 19 of Schedule 2 to the Transitional Act provides for a low volume permit issued under the old law to be treated as though it was an assessment certificate made under the IC Act.

Section 39 Application of Division

Section 39 of the Transitional Rules provides that Division 3 of Part 4 of the Transitional Rules prescribes modifications of the new law in relation to assessment certificates that have been issued:

- for transitioned low volume permits (under item 19 of the Transitional Act), or
- for transitioned low volume permit applications (under item 21 of the Transitional Act).

Section 40 Modification of period for which transitioned low volume permits are taken to be in force

Item 19 of Schedule 2 to the Transitional Act provides that an assessment certificate arising from a transitioned low volume permit will be in force for the remaining period for which the permit would have been in force under section 21V of the old law.

Section 40 of the Transitional Rules modifies this item so that an assessment certificate arising from a transitioned low volume permit will be in force either until 30 June 2022, or for the remaining period for which the permit would have been in force under the old law, whichever comes later. Additionally, the period that the transitioned low volume permit remains in force will end if any of the circumstances listed in paragraphs 39(a) to (c) of the IC Act occurs. This includes cancellation of the certificate (by application or following an evaluation) or in accordance with a condition of the assessment certificate.

Section 41 Varying the assessment certificate

Section 41 of the Transitional Rules provides that the period for consideration of an application to vary an assessment certificate that arises from a transitioned low volume permit or transitioned low volume permit application, is 20 working days after the day the application is made. Section 41 of the Transitional Rules removes the requirement that the Executive Director consult with prescribed bodies or the Gene Technology Regulator in relation to such a variation application, and no assessment statement (draft or final) need be provided to the applicant nor published.

Section 42 Variations on Executive Director's initiative

Under section 50 of the IC Act, the Executive Director may vary a term of an assessment certificate following an evaluation that concludes such a variation may be necessary to manage risks to human health and the environment.

Section 42 of the Transitional Rules provides that the Executive Director may vary an assessment certificate arising from a transitioned low volume permit or transitioned low volume permit application, under section 50 of the IC Act, without the requirement to have completed an evaluation, or to have concluded variation is necessary to manage risks to human health or the environment. The Executive Director is still required to give written notice with reasons for the proposed variation, and consider any submissions made in response to that notice. Section 42 of the Transitional Rules provides that no assessment statement in relation to the variation need be sent to the certificate holder, or published.

Section 43 Cancellation on Executive Director's initiative

Under section 52 of the IC Act, the Executive Director may cancel an assessment certificate following an evaluation that concludes risks to human health and the environment cannot be managed.

Section 43 of the Transitional Rules provides that the Executive Director may cancel an assessment certificate arising from a transitioned low volume permit or transitioned low volume permit application, under section 52 of the IC Act, without the requirement to have completed an evaluation, if the Executive Director is not satisfied that risks to human health or the environment can be managed. The Executive Director is still required to give written notice with reasons for the proposed variation, and consider any submissions made in response to that notice. Section 43 of the Transitional Rules provides that no assessment statement in relation to the variation need be published.

Part 5 – Controlled use permits under new law

Division 1 – Pending applications for controlled use permits

Subject to any modifications made by the Transitional Rules, item 28 of Schedule 2 to the Transitional Act provides for an application for a controlled use permit that is pending on 1 July 2020 to be treated as though it was an application for an assessment certificate made under section 31 of the IC Act.

Section 44 – Application of Division

Section 44 of the Transitional Rules provides that Division 1 of Part 5 of the Transitional Rules prescribes modifications of the law in relation to:

- a pending application for a controlled use permit, and
- an assessment certificate issued under the new law following a pending application for a controlled use permit (under item 28 of Schedule 2 to the Transitional Act).

Section 45 Period within which decision must be made on application

Section 45 of the Transitional Rules states that the decision on a transitioned controlled use permit application must be made within 20 working days after the application was made.

Section 46 Requests for further information under old law

Section 46 of the Transitional Rules provides that any request made by the Director of NICNAS under section 22D of the old law for further information relating to a transitioned controlled use permit application, is treated as a request made by the Executive Director of AICIS under section 33 of the IC Act (that is, a request for further information in relation to an application for an assessment certificate).

Section 47 Issue of assessment certificate

Section 47 of the Transitional Rules modifies the requirements (under section 37 of the IC Act) for issuing an assessment certificate for a transitioned application for a controlled use permit. Section 47 of the Transitional Rules provides that the Executive Director must be satisfied that:

- the end use for the industrial chemical does not pose an unreasonable risk to human health or the environment, having regard to Schedule 1AB to the old regulations (the Industrial Chemicals (Notification and Assessment) Regulations 1990), and any other matter the Executive Director considers relevant.

Under the old law, risks to human health or the environment are mitigated by the requirement that use, handling and disposal of the industrial chemical are highly controlled, and the requirement that the end use pose ‘no unreasonable risk’. The Director of NICNAS must, under the old law, refuse an application for a controlled use permit that does not meet application requirements.

Noting that the relevant definition of ‘no unreasonable risk’ from the old law has been preserved in relation to transitioned controlled use permit applications, section 47 of the Transitional Rules provides that the Executive Director does not have regard to whether any risks to human health or the environment can be managed, and the Executive Director is not required to refuse issue of the assessment certificate if any risks to human health or the environment cannot be managed.

Section 47 of the Transitional Rules provides that no assessment statement need be provided to the applicant under section 37 of the IC Act. (Item 31 of Schedule 2 to the Transitional Act provides that no assessment statement is to be published in relation to transitioned applications for controlled use permits.) Section 47 of the Transitional Rules provides that, instead of publishing an assessment statement, the Executive Director must give written notice of the decision and publish a notice setting out the trade name or chemical name, the end use, and the period the assessment certificate is to be in force.

Section 48 Content of assessment certificate

Under section 22O of the old law, an applicant for a controlled use permit can apply to have certain information treated as “exempt information”. If such an application is made for the name of the industrial chemical, under section 75 of the old law the application must include a “trade name” to be used in lieu of the proper name of the chemical when publishing a notice of the permit under section 22L of the old law.

Section 48 of the Transitional Rules provides that an assessment certificate issued after a transitioned controlled use permit application will include the chemical name or a trade name. It also provides that such an assessment certificate will not have a ‘defined scope of assessment’.

Section 49 Applying for protection of end use

A person can apply for CBI protection of the end use of an industrial chemical that is the subject of an assessment certificate under the IC Act, as long as the CBI application is made at the same time as the application for the assessment certificate.

Under section 49 of the Transitional Rules, a CBI application can be made for protection of end use in relation to a transitioned application for a controlled use permit, and the requirement that the CBI application for end use be made at the same time as the assessment certificate application does not apply. Instead, the application must be made within 10 working days after 1 July 2020.

Division 2 – Pending applications for renewal of controlled use permits

Section 50 Pending applications for renewal to be treated as variation applications under the new law

A holder of a controlled use permit can apply under the old law for the permit to be renewed for a further period. Section 50 of the Transitional Rules applies to an application for renewal of a controlled use permit that is pending immediately before 1 July 2020.

Under section 50 of the Transitional Rules, a pending application for renewal of a controlled use permit will be treated as an application to vary a term of an assessment certificate under section 43 of the IC Act (that term being the period that the assessment certificate is in force). Section 50 of the Transitional Rules provides that the transitioned assessment certificate for the controlled use permit remains in force until a decision is made on the transitioned renewal application.

Section 50 of the Transitional Rules provides that, for a transitioned application for a controlled use permit renewal, the consideration period under paragraph 44(2)(a) of the IC Act is 20 working days from the day the application was made.

Section 50 of the Transitional Rules removes the requirement that the Executive Director consult with prescribed bodies or the Gene Technology Regulator in relation to the industrial chemical.

Section 50 of the Transitional Rules stipulates that an assessment certificate arising from a transitioned application to vary a controlled use permit must not be in force for more than 3 years from the date of notice of the Executive Director's decision. No assessment statement need be sent to the applicant along with the assessment certificate. (Item 31 of Schedule 2 to the Transitional Act provides that no assessment statement is to be published in relation to a transitioned controlled use permit renewal application.)

Section 50 of the Transitional Rules provides matters of which the Executive Director must be satisfied when considering a transitioned low volume permit renewal application:

- that the function or use of the industrial chemical has not and is not likely to change significantly;
- that, if manufactured in Australia, the method of manufacture has not changed in a way that may increase risk to occupational health and safety, public health or the environment;
- that, if the controlled use permit is for an industrial chemical that was not intended by the applicant to be manufactured in Australia when the permit was granted, that it has not in fact been manufactured in Australia by the applicant since the permit was granted;
- that the volume introduced has not and is not likely to increase significantly; and
- that no additional information has become available to the applicant as to any adverse effects of the industrial chemical.

Division 3 – Transitioned controlled use permits

Subject to any modifications made by the Transitional Rules, item 26 of Schedule 2 to the Transitional Act provides for a controlled use permit issued under the old law to be treated as though it was an assessment certificate made under the IC Act.

Section 51 Application of Division

Section 51 of the Transitional Rules provides that Division 3 of Part 5 of the Transitional Rules prescribes modifications of the new law in relation to:

- an assessment certificate issued under the new law for a transitioned controlled use permit (under Item 26 of Schedule 2 to the Transitional Act), or
- an assessment certificate issued under the new law following a pending application for a controlled use permit (under Item 28 of Schedule 2 to the Transitional Act).

Section 52 Modification of period for which transitioned controlled use permits are taken to be in force

Item 26 of Schedule 2 to the Transitional Act provides that an assessment certificate arising from a transitioned controlled use permit will be in force for the remaining period for which the permit would have been in force under section 22G of the old law.

Section 52 of the Transitional Rules modifies this item so that an assessment certificate arising from a transitioned controlled use permit will be in force either until 30 June 2022, or for the remaining period for which the permit would have been in force under the old law, whichever comes later. Additionally, the period that the transitioned low volume permit remains in force will end if any of the circumstances listed in paragraphs 39(a) to (c) of the IC Act occurs. This includes cancellation of the certificate (by application or following an evaluation) or in accordance with a condition of the assessment certificate.

Section 53 Varying the assessment certificate

Section 53 of the Transitional Rules provides that the period for consideration of an application to vary an assessment certificate that arises from a transitioned controlled use permit or transitioned controlled use permit application is 20 working days from the date the application is made. Section 53 of the Transitional Rules removes the requirement that the Executive Director consult with prescribed bodies or the Gene Technology Regulator in relation to such a variation application, and no assessment statement (draft or final) need be provided to the applicant nor published.

Section 54 Variations on Executive Director's initiative

Under section 50 of the IC Act, the Executive Director may vary a term of an assessment certificate following an evaluation that concludes such a variation may be necessary to manage risks to human health and the environment.

Section 54 of the Transitional Rules provides that the Executive Director may vary an assessment certificate arising from a transitioned controlled use permit or transitioned controlled use permit application, under section 50 of the IC Act, without the requirement to have completed an evaluation, or to have concluded variation is necessary to manage risks to human health or the environment. The Executive Director is still required to give written notice with reasons for the proposed variation, and consider any submissions made in response to that notice. Section 54 of the Transitional Rules provides that no assessment statement in relation to the variation need be sent to the certificate holder, or published.

Section 55 Cancellation on Executive Director's initiative

Under section 52 of the IC Act, the Executive Director may cancel an assessment certificate following an evaluation that concludes risks to human health and the environment cannot be managed.

Section 55 of the Transitional Rules provides that the Executive Director may cancel an assessment certificate arising from a transitioned controlled use permit or transitioned controlled use permit application, under section 52 of the IC Act, without the requirement to have completed an evaluation, if the Executive Director is not satisfied that risks to human health or the environment can be managed. The Executive Director is still required to give written notice with reasons for the proposed variation, and consider any submissions made in response to that notice. Section 55 of the Transitional Rules provides that no assessment statement in relation to the variation need be published.

Part 6 – Early introduction permits

Under section 30 of the old law, a person who has applied for an assessment certificate may apply to the Minister for a permit authorising introduction of the chemical before an assessment certificate is used, if it is in the public interest, and consistent with the reasonable protection of occupational health and safety, public health and the environment.

Under section 30A of the old law, a person who has applied for an assessment certificate may apply to the Director of NICNAS for an early introduction permit to introduce the chemical before the assessment report is completed, if the chemical is a polymer of low concern or a non-hazardous chemical, or is otherwise prescribed by the old regulations.

Item 4 of Schedule 2 to the Transitional Act provides for section 30A of the old law to continue to apply, i.e. to continue to authorise introduction under an early introduction permit, until a decision is made on the related assessment certification application.

Section 56 Permits allowing introduction before assessment in the public interest

Under section 56 of the Transitional Rules, section 30 of the old law continues to provide the basis for deciding an application to the Minister for a permit for early introduction of an industrial chemical (before an assessment certificate application has been decided) in the public interest. If the permit is granted by the Minister under section 30 of the old law, it is treated as an exceptional circumstances permit under section 30 of the IC Act; and the requirement to publish a notice relating to the early introduction permit refers to the AICIS website rather than to the Chemical Gazette (which will cease to exist under the IC Act, with relevant publication instead being made on the AICIS website).

Section 57 Pending applications for permits allowing introduction before assessment of non-hazardous chemicals

Section 57 of the Transitional Rules applies to a pending application for an early introduction permit under section 30A of the old law, or an early introduction permit continued under the new law by item 4 of Schedule 2 to the Transitional Act; it provides that the requirement to publish a notice relating to the early introduction permit refers to the AICIS website rather than to the Chemical Gazette (which will cease to exist under the IC Act, with relevant publication instead being made on the AICIS website).

Part 7 – Introductions under section 21 of the old law

Section 21 of the old law prohibits introduction of a new industrial chemical (i.e. an industrial chemical not listed on the Australian Inventory of Chemical Substances (the old Inventory)). Section 21 provides exceptions to this prohibition, for new industrial chemicals introduced in accordance with certificates or permits, and for new industrial

chemicals that meet certain criteria (often referred to as “exemptions” from the general prohibition).

Section 27 of the IC Act authorises introduction of an industrial chemical that is a reported introduction in accordance with the General Rules, with a requirement that a pre-introduction report be given to the Executive Director.

Section 58 Introductions under section 21 of the old law

Sections 33 and 34 of the Transitional Act authorise under section 27 of the IC Act (subject to any modifications prescribed by the Transitional Rules) the continued introduction of an industrial chemical that complies with the requirements of paragraph 21(3)(b), subsection 21(4), or paragraphs 21(6)(a) or 21(6)(c) of the old law (which provide exemptions from the general prohibition on introduction of new chemicals without an authorising permit or certificate), until 30 June 2021.

Section 58 of the Transitional Rules replaces sections 33 and 34 of the Transitional Act with a new provision (new section 33) that authorises under section 27 of the IC Act the continued introduction of an industrial chemical that complies with the requirements of paragraph 21(3)(b), subsection 21(4), or paragraphs 21(6)(a) or 21(6)(c) of the old law (including any regulations made in relation to the authorising provisions), until 31 August 2022. The terms of the pre-introduction report required by section 27 of the IC Act are stipulated by section 58 of the Transitional Rules to be the terms of the old law authorising provision, and any regulation made in relation to the authorising provision (set out in new paragraph 33(2)(b)).

Part 8 – Assessment of priority existing chemicals

Section 59 Publication of final assessment reports where a variation request has been made

Section 60F of the old law requires publication of a final assessment report for a priority existing chemical assessed under Division 5 of Part 3 of the old law.

Section 59 of the Transitional Rules provides that section 60F of the old law continues to operate if a draft assessment report for a priority existing chemical is prepared before 1 July 2020, and the final assessment report is not prepared before 1 July 2020, if the reason it has not been published is because of the requirement under the old law to delay preparation of the final report for 28 days after publishing a notice of a decision regarding a request to vary the draft assessment report, or because an application to the Administrative Appeals Tribunal for review of such a decision is pending.

Part 9 – Secondary notifications under old law

Division 1 – Incomplete assessments under old law following secondary notification

Subdivision A – Incomplete assessments under old law following secondary notification

Section 60 Incomplete assessments under old law following secondary notification

Under section 65 of the old law, the Director of NICNAS may require secondary notification and assessment of an industrial chemical because of information given by a person, or information of which the Director otherwise becomes aware. This information may relate to, for example, changes in the function or use of the chemical, or a significant increase in introduction volume, or information about an adverse effect of the chemical. Secondary notification under the old law results in publication of an assessment report.

Under section 60 of the Transitional Rules, if a secondary notification assessment has been commenced under the old law, but a final assessment report has not been published before 1 July 2020, then the assessment is taken to be an evaluation under Part 4 of the IC Act. The Executive Director must, within 20 working days of 1 July 2020, give written notice specifying the period of the evaluation. Written notice would be sent directly to the certificate holder(s) for secondary notification of a chemical under certificate, or be published on the AICIS website for a chemical not under certificate. The Executive Director does not need to provide a draft evaluation statement or publish a final evaluation statement.

Subdivision B – Evaluations of introductions of industrial chemicals that are authorised by an assessment certificate

Section 61 Application of Subdivision

Section 61 of the Transitional Rules provides that Subdivision B of Division 1 of Part 9 of the Transitional Rules applies to a transitioned secondary notification assessment of introduction of an industrial chemical that is authorised by an assessment certificate.

Section 62 Executive Director must prepare draft assessment report and public report

Section 62 of the Transitional Rules provides that after assessing a transitioned secondary notification of an industrial chemical introduced under an assessment certificate, the Executive Director must provide each person who gave secondary notification under the old law with a draft assessment report and a draft public report. A person given these reports may apply within 10 working days to vary the draft assessment report, and the Executive Director must consider any such application before deciding whether to so vary the draft assessment report within 10 working days after the variation application. The variation must be made if the Executive Director is satisfied that the draft assessment report as varied would be correct.

Section 63 Issue of assessment report and public report

Under section 63 of the Transitional Rules, each person who gave secondary notification of an industrial chemical introduced under an assessment certificate must

be given an assessment report and public report, within the period specified in the notice published in accordance with section 60 of the Transitional Rules.

Section 64 Publication of public report

Under section 64 of the Transitional Rules, the Executive Director must publish the public report for an industrial chemical introduced under an assessment certificate that has been assessed after transitioned secondary notification, at least 20 working days after the assessment report has been given, or earlier by consent of all persons who received the report. The report must not be published until any application for variation of the assessment report has been decided and all reconsideration and review rights under section 102 of the old law have been exhausted or expired. The report must also not be published until any application for exempt information or CBI (confidential business information) protection has been decided and all reconsideration and review rights have been exhausted or expired.

Subdivision C – Evaluations of introductions of industrial chemicals other than introductions that are authorised by an assessment certificate

Section 65 Application of Subdivision

Section 65 of the Transitional Rules provides that Subdivision C of Division 1 of Part 9 of the Transitional Rules applies to a transitioned secondary notification assessment of introduction of an industrial chemical other than an introduction that is authorised by an assessment certificate.

Section 66 Executive Director must prepare draft evaluation report

Section 66 of the Transitional Rules provides that after assessing a transitioned secondary notification of an industrial chemical other than one introduced under an assessment certificate, the Executive Director must publish a draft evaluation report. A person may apply within 20 working days after publication to vary the draft assessment report, and the Executive Director must, within 20 working days, consider any such application before deciding whether to vary the draft evaluation report. The variation must be made if the Executive Director is satisfied that the draft evaluation report as varied would be correct. The decision whether to vary the evaluation report must be published.

Section 67 Publication of evaluation report

Under section 67 of the Transitional Rules, the Executive Director must publish the evaluation report for an industrial chemical introduced other than under an assessment certificate that has been assessed after transitioned secondary notification, within the period specified in the notice published at the commencement of the evaluation under section 60 of the Transitional Rules. This must be at least 20 working days after either the draft evaluation report has been published or the decision to vary the draft evaluation report has been published. The report must not be published until any application for variation of the draft evaluation report has been decided and all reconsideration and review rights under section 102 of the old law have been exhausted or expired. The report must also not be published until any application for

exempt information or CBI protection of information that the Executive Director wishes to publish in the evaluation report has been decided and all reconsideration and review rights have been exhausted or expired.

Subdivision D – Reconsideration and review of decisions to not vary reports

Section 68 Reconsideration and review of decision to not vary a draft assessment report or a draft evaluation report

Section 68 of the Transitional Rules adds a decision by the Executive Director to not vary a draft assessment report or a draft evaluation report for a transitioned secondary notification, of either an introduction authorised by assessment certificate or otherwise, to section 166 of the IC Act, making these decisions subject to reconsideration and review under the IC Act.

Division 2 – Variations following secondary notification assessment under old law

Section 69 Assessment certificate variations following secondary notification assessment under old law

Section 69 of the Transitional Rules applies when the Director of NICNAS concludes as part of an assessment following secondary notification under the old law of an industrial chemical introduced under an assessment certificate, that the certificate requires variation, and the proposed variation has not been made before 1 July 2020. The assessment is taken to be an evaluation completed by the Executive Director under Part 4 of the IC Act, and section 50 of the IC Act applies to vary the certificate.

Section 69 of the Transitional Rules removes the requirement (for evaluations under the IC Act) for the Executive Director to conclude that the variation is necessary to manage risks to human health or the environment, and removes the requirements (for evaluations under the IC Act) to give to the certificate holder, and publish, an evaluation statement. Instead, the certificate holders will be given written notice of the decision.

Section 70 Inventory listing variations following secondary notification assessment under old law

Section 70 of the Transitional Rules applies when the Director of NICNAS concludes as part of an assessment following secondary notification under the old law of an industrial chemical other than one introduced under an assessment certificate, that the Inventory listing for the chemical requires variation, and the proposed Inventory variation has not been made before 1 July 2020. The assessment is taken to be an evaluation completed by the Executive Director under Part 4 of the IC Act, and section 86 of the IC Act applies to vary the Inventory listing. Section 70 of the Transitional Rules removes the requirement (for evaluations under the IC Act) for the Executive Director to conclude that the variation is necessary to manage risks to human health or the environment, and removes the requirement (for evaluations under the IC Act) to conduct public consultation as part of the evaluation.

Division 3 – Requirement to provide information for the purposes of an assessment under old law

Section 71 Requirement to provide information for the purposes of an assessment under old law

Section 71 of the Transitional Rules provides that any request made by the Director of NICNAS under section 69 of the old law for further information relating to an assessment following secondary notification, is treated as a request made by the Executive Director of AICIS under section 70 or section 76 of the IC Act for further information relating to an evaluation of a chemical introduced under an assessment certificate, or otherwise, respectively.

Part 10 – Application fees payable under old law

Section 72 Application fees payable under old law

Section 72 of the Transitional Rules provides that if a fee was payable under a provision of the old law in relation to an application, section 170 of the IC Act applies in relation to that fee as though it were payable under a provision of the new law.

Section 170 of the IC Act enables the Executive Director to wholly or partly waive fees that would otherwise be payable under a provision of that Act.

Part 11 – Inventory

The Australian Inventory of Chemical Substances (AICS) is the “old Inventory”, established under the old law, which comprises listings of chemical substances that may be introduced into Australia (imported or manufactured) subject to any terms of the listing (which may include conditions of introduction or use). Under the IC Act the Australian Inventory of Industrial Chemicals (AIIC) is “the Inventory”, which comprises listings of industrial chemicals that may be introduced into Australia subject to any terms of the listing, which may include a ‘defined scope of assessment’ or conditions of introduction or use. The Transitional Act provides that industrial chemicals listed on the old Inventory become chemicals listed on the Inventory under the IC Act. The intent of the law is that the terms of the old Inventory listings of industrial chemicals will transition to the new law with minimal disruption to introducers of chemicals on the old Inventory.

Section 73 Application for confidential listing

Item 43 of Schedule 2 to the Transitional Act provides that, when the Executive Director gives notice to a holder of an assessment certificate that was in force under the old law, that the chemical is due to be listed on the Inventory, the holder of the assessment certificate may apply to have the word “confidential” published in lieu of each term of the Inventory listing for the chemical.

Section 73 of the Transitional Rules provides that a notice under item 43 must also be given to, and an application for the word “confidential” to be published in lieu of each

term of an Inventory listing may also be made by, the holder of a certificate that was issued following transition of a pending assessment certificate application under item 13 of Schedule 2 to the Transitional Act.

An application for “confidential” listing must be made within 20 working days of the day the notice is given by the Executive Director. Such an application may also be made by a person given a notice under section 74 of the Transitional Rules, and if an application is made by such a person, the chemical may not be listed on the Inventory until a decision has been made on the application and all reconsideration and review rights are exhausted or expired.

Section 73 of the Transitional Rules provides that, if notice was given under the old law of proposed Inventory listing 5 years after an assessment certificate was issued, then an equivalent notice need not be given under the IC Act.

Section 74 Confidence holders and holders of old law assessment certificates may also apply for confidential listing

Section 74 of the Transitional Rules applies to an industrial chemical for which:

- a transitioned assessment certificate, or an assessment certificate arising from a transitioned assessment certificate application, has been issued (under item 11 or item 13 of Schedule 2 to the Transitional Act, respectively), and
- the Executive Director has given notice to such a certificate holder that the chemical is to be listed on the Inventory, and
- another, later, certificate has been issued under item 11 or item 13 of Schedule 2 to the Transitional Act for the same chemical, **or** there are one or more confidence holders for an approval for the proper name or end use of the chemical to be protected as CBI.

Section 74 of the Transitional Rules provides that the Executive Director must give written notice of proposed listing of the industrial chemical on the Inventory under item 43 of Schedule 2 to the Transitional Act (i.e. providing that the person given the notice may make an application for the word “confidential” to be used in lieu of each term of the listing) to:

- each holder of the later certificate, and
- any person covered by an extension to the certificate under the old law, and
- each confidence holder.

Section 75 Particulars of listing under old law

Item 39 of Schedule 2 to the Transitional Act provides that an industrial chemical on the non-confidential section of the old Inventory is taken to have been listed on the Inventory under the IC Act. Approved particulars of the listing under the old law that are taken to be terms of the Inventory listing under the IC Act are:

- any particulars in relation to a previously regulated chemical (under paragraph 12(3)(db) by reference to subsection 15AB(1) of the old law), and

- any condition to which introduction of the chemical is subject (under paragraphs 12(3)(f) and (g) of the old law).

Item 40 of Schedule 2 to the Transitional Act provides that an industrial chemical on the confidential section of the old Inventory is taken to be listed on the Inventory under the IC Act, and a reference in the IC Act to a requirement to publish an AICIS approved chemical name (AACN) or generalised end use (GEU) to protect the proper name or end use as confidential business information (CBI), is taken to be a requirement to publish the word “confidential” in lieu of each term of the Inventory listing. Approved particulars of the listing under the old law that are taken to be terms of the Inventory listing under the IC Act are:

- of a chemical transferred from the non-confidential Inventory: any approved particulars of the non-confidential listing (under paragraph 12(4)(a) of the old law), and
- any condition of use to which introduction of the chemical is subject (under subsection 12(4A) of the old law).

Paragraph 75(2)(a) of the Transitional Rules provides that if the approved particulars under subsections 12(3), (4) or (4A) of the old law included a condition of use, the condition is taken to be:

- the defined scope of assessment – if the chemical is listed in clause 1 of Schedule 1 to the Transitional Rules, or
- a condition of introduction or use of the industrial chemical under the IC Act – if the chemical is listed in clause 2 of Schedule 1 to the Transitional Rules.

Paragraph 75(2)(b) of the Transitional Rules provides that for a transitioned Inventory listing of a polymer of low concern under the old law, the secondary notification obligation under section 64(1) of the old law is taken to be a specific requirement to provide information to the Executive Director under the IC Act.

Paragraph 75(2)(c) of the Transitional Rules provides that for a transitioned Inventory listing for an industrial chemical that was not a polymer of low concern under the old law, the secondary notification obligations under subsections 64(1) and 64(2) of the old law are taken to be specific requirements to provide information to the Executive Director under the IC Act.

Paragraph 75(2)(d)(i) of the Transitional Rules provides that for a transitioned Inventory listing of an industrial chemical that was the subject of an assessment certificate issued under the old law, the term of the listing providing any specific requirements to provide information to the Executive Director under section 81(1)(e) of the IC Act is taken to be a requirement to publish “obligations to provide information apply”.

Paragraph 75(2)(d)(ii) of the Transitional Rules provides that for a transitioned Inventory listing of an industrial chemical that was a priority existing chemical (PEC) under the old law, the term of the listing providing any specific requirements to provide information to the Executive Director under section 81(1)(e) of the IC Act is

taken to be a requirement to publish the secondary notification obligations under sections 64(1) and (2) of the old law.

Paragraph 75(2)(e) of the Transitional Rules removes the restrictions on the kinds of conditions that may be listed on the Inventory under subsection 81(2) of the IC Act.

Section 76 Removing chemicals that have been wrongly listed on the Inventory

Section 76 of the Transitional Rules provides that a chemical listed in the non-confidential section of the old Inventory that is not an industrial chemical, under the old law or the new law, is taken to have never been listed in the old Inventory (and therefore does not transition to being listed on the new Inventory). The Executive Director must publish a list of these chemicals.

Section 77 Exempt information ceases to be taken to be protected information in certain circumstances

Item 37 of Schedule 2 to the Transitional Act provides that a pending application for information to be treated as exempt information under the old law is treated as if it were an application for CBI protection of “other” information (i.e. other than proper name or end use under section 105 of the IC Act).

Item 38 of Schedule 2 to the Transitional Act provides that exempt information under the old law, and information that has been approved for CBI protection under item 37 of Schedule 2 to the Transitional Act, is taken to be protected information under the IC Act.

Section 77 of the Transitional Rules provides that, if notice of a proposed Inventory listing is made under the old or new law, and the proper name of the chemical is taken to be protected information under item 38 of Schedule 2 to the Transitional Act, and no application has been made within 20 working days for the word “confidential” to be published in lieu of each term of the Inventory listing, then the proper name of the chemical ceases to be protected information (i.e. the proper name of the chemical is to be listed on the Inventory).

Part 12 – Information, reporting and confidentiality

Section 78 Post-introduction declarations for exempted introductions

Section 96A of the IC Act requires introducers of industrial chemicals categorised as exempted introductions to make a declaration up to one month before or up to 3 months after the end of the registration year containing information prescribed by the General Rules.

Section 78 of the Transitional Rules specifies that the post-introduction declaration under section 96A of the IC Act for the registration year beginning 1 September 2020 includes the period 1 July 2020 to 31 August 2020 inclusive. This removes the need for introducers to make a separate post-introduction declaration for exempted introductions made in the first 2 months of the new scheme.

Section 79 Annual declaration for all introduction categories

Section 99 of the IC Act requires all introducers to make an annual declaration up to one month before or up to 3 months after the end of the registration year containing information prescribed by the General Rules.

Section 79 of the Transitional Rules specifies that the annual declaration under section 99 of the IC Act for the registration year beginning 1 September 2020 includes the period 1 July 2020 to 31 August 2020 inclusive. This removes the need for introducers to make a separate annual declaration for introductions made in the first 2 months of the new scheme.

Section 80 Information and documents obtained under section 100G of old law

Under section 100G of the old law, the Director of NICNAS may request a person give information necessary to allow Australia to comply with the Rotterdam Convention, and it is an offence not to comply with this request.

Section 174 of the IC Act describes the requirements imposed on the Executive Director when retaining and copying documents provided under that Act. Under this provision, there is no limit to the amount of time the Executive Director may possess a document produced under a provision of the IC Act. However, the person who provided the Executive Director with the document is entitled to be supplied with a certified copy of the document by the Executive Director as soon as practicable. In the interim, the person can inspect and make copies of the document retained by the Executive Director.

Under section 80 of the Transitional Rules, the Executive Director of AICIS will keep documents obtained under section 100G of the old law for Rotterdam Convention purposes. Section 80 ensures that the same protection is afforded to information and documents that were obtained under the old law as is afforded to information obtained under the IC Act.

Part 13 – Movements authorised under section 106 of old law

Section 106 of the old law provides authority for regulations to prohibit or restrict introduction or export of chemicals subject to prescribed international agreements. The Rotterdam Convention is prescribed for this purpose under the old regulations, which also set out provisions for authorising introduction and export of certain chemicals subject to the Rotterdam Convention. Part 13 of the Transitional Rules sets out arrangements to transition authorisations issued under section 106 of the old law.

Section 81 Introduction of industrial chemicals authorised under section 106 of old law

Section 81 of the Transitional Rules provides that a written approval, still in force on 30 June 2020, given by the Director of NICNAS under the old regulations for introduction of a chemical subject to the Rotterdam Convention under section 106 of

the old law, is treated as an approval given under the new General Rules for the purposes of section 163 of the IC Act.

Section 82 Export of industrial chemicals authorised under section 106 of the old law

Section 82 of the Transitional Rules provides that a written approval, still in force on 30 June 2020, given by the Director of NICNAS under the old regulations for export of a chemical subject to the Rotterdam Convention under section 106 of the old law, is treated as an approval given under the new General Rules for the purposes of section 163 of the IC Act.

Part 14 – Consideration period

Section 83 Calculating the consideration period for an application

Section 169 of the IC Act provides a list of circumstances that are excluded when calculating the relevant consideration period for certain applications, requests and decisions. Paragraph 83(1)(b) of the Transitional Rules lists additional circumstances to exclude from consideration periods:

- New table item 13: When information is requested from an assessment certificate applicant under section 27 of the old law – until a complete response is given to the Executive Director or the period specified in the request expires (whichever occurs earlier).
- New table item 14: When information is requested under section 21F of the old law, i.e. in relation to an application for a commercial evaluation permit (or renewal of a commercial evaluation permit), and the request is pending immediately before 1 July 2020 – until a complete response is given to the Executive Director or the period specified in the request expires (whichever occurs earlier).
- New table item 15: When information is requested under section 21SA of the old law, i.e. in relation to an application for a low volume permit (or renewal of a low volume permit) – until a complete response is given to the Executive Director or the period specified in the request expires (whichever occurs earlier).
- New table item 16: When an applicant amends an application for a low volume permit under section 21T of the old law – the period from the day the original application was made until the day the application was amended.
- New table item 17: When information is requested under section 22D of the old law, i.e. in relation to an application for a controlled use permit (or renewal of a controlled use permit) – until a complete response is given to the Executive Director or the period specified in the request expires (whichever occurs earlier).
- New table item 18: When an applicant amends an application for a controlled use permit under section 22E of the old law – the period from the day the original application was made until the day the application was amended.
- New table item 19: When a copy of the assessment report and public report is given to the assessment certificate applicant under section 36 of the old law – until the day an application is made to vary the assessment report, or the day the applicant consents to publication of the assessment report, or the end of 14 days after the notice was given (whichever occurs earlier).

- New table item 20: When a draft assessment report is given to the applicant for a transitioned assessment certificate application under section 11 of the Transitional Rules - until the day an application is made to vary the assessment report, or the day the applicant consents to publication of the assessment report, or the end of the period given in the notice providing the report (whichever occurs earlier)..
- New table item 21: When a person requests a variation of a draft assessment report for a transitioned assessment certificate application provided under section 11 of the Transitional Rules – until the day a decision is made on the variation application, or the end of the period given in the notice providing the report (whichever occurs earlier).
- New table item 22: When information is requested from an applicant to vary a transitioned commercial evaluation authorisation under section 30 of the Transitional Rules – until a complete response is given, or at the end of the period given in the notice requesting the information (whichever occurs earlier).

The definition of “consideration period” in section 9 of the IC Act lists certain applications and refers to specific subsections of the IC Act to define the consideration period for each application.

Paragraph 83(1)(a) of the Transitional Rules includes in the definition of “consideration period” in section 9 of the IC Act, reference to the period defined for consideration of an application to vary a draft assessment report in subsections 11(4), 62(4) and 66(4) of the Transitional Rules (in relation to transitioned assessment certificate applications, transitioned secondary notification assessments for chemicals under assessment certificate, or transitioned secondary notification assessments for chemicals not under assessment certificate, respectively). The period specified in each of these sections is 10 working days.

Subsection 83(2) of the Transitional Rules clarifies that, if both item 1 of the table in subsection 169(1) of the IC Act and item 13, 15 or 17 of the table in this section applies to a request for information under sections 9, 33 or 45 of the Transitional Rules (in relation to a transitioned request for information relating to an assessment certificate application, to a low volume permit application or to a controlled use application, respectively), then item 13, 15 or 17 of the table in this provision applies, and the exclusion period is only counted once.

Subsection 83(3) of the Transitional Rules clarifies that, if both item 5 of the table in subsection 169(1) of the IC Act and item 14 of the table in this provision apply to a request for information under section 23 of the Transitional Rules (in relation to a transitioned request for information relating to a commercial evaluation permit), then item 14 of the table in this provision applies, and the exclusion period is only counted once.

Schedule 1 – Particulars of old Inventory listings

Section 75 of the Transitional Rules provides that if the approved particulars for an Inventory listing under the old law included a condition of use, then on the transitioned listing on the new Inventory that condition is taken to be:

- the defined scope of assessment – if the chemical is listed in clause 1 of Schedule 1 to the Transitional Rules, or
- a condition of introduction or use of the industrial chemical under the IC Act – if the chemical is listed in clause 2 of Schedule 1 to the Transitional Rules.

Clause 1 Conditions of use that are taken to be the defined scope of assessment

Section 1 of Schedule 1 to the Transitional Rules lists industrial chemicals listed on the old Inventory with conditions of use; each condition is taken to be the defined scope of assessment for the transitioned listing on the new Inventory.

Clause 2 Conditions of use that are taken to be conditions relating to introduction or use

Section 2 of Schedule 1 to the Transitional Rules lists industrial chemicals listed on the old Inventory with conditions of use; each condition is taken to be a condition of introduction or use for the transitioned listing on the new Inventory.