Outcomes of the review of Appendix J of the Standard for the Uniform Scheduling of Medicines and Poisons 2017

INTER-JURISDICTIONAL WORKING GROUP POISONS CONTROL

Outcomes of the review of Appendix J

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Summary

The review of Appendix J completes the actions that were agreed to by the Australian Health Ministers Advisory Council (AHMAC) to achieve national consistency of controls on poisons in response to the 2008 Productivity Commission Research Report on Chemicals and Plastics Regulation.

The Inter-Jurisdictional Working Group – Poisons Control (IJWGPC) was established under the auspices of AHMAC to progress the options identified in the *Decision Regulation Impact Statement: Strategies to implement a national approach to poisonous chemical controls*[1] (Decision RIS). The Decision RIS supported the retention of Appendix J, provided that a review of the chemicals was undertaken and the appendix updated.

An internal review of Appendix J (the Review) was undertaken by the IJWGPC to examine the contemporary use patterns and availability of Appendix J poisons and to develop criteria to use for inclusion of Schedule 7 poisons (S7s) in Appendix J. Consideration was also given to how the controls could be administered.

Once the review was completed, a formal consultation process with stakeholders was undertaken. A total of 15 responses were received from industry bodies, companies involved in the manufacture and supply of chemicals, and government agencies. While the responses received indicated general support for proposals, a number of issues were highlighted and considered further by the IJWGPC before final recommendations were made to AHMAC.

All proposals were endorsed by AHMAC at the 8 December 2017 meeting, including that:

- Appendix J poisons be available only to authorised or licensed persons.
- the use of Appendix J poisons that are banned, obsolete or subject to international conventions be restricted to analytical and research purposes only.
- additional controls be reinstated on the possession and use of certain Appendix J poisons that present an unacceptable level of public health risk as a result of their use pattern.
- the title of Appendix J be amended to "*Schedule 7 poisons requiring additional controls on availability and use*".

AHMAC also endorsed the scheduling factors for the inclusion of S7s in Appendix J, and their incorporation into the revised Scheduling Policy Framework. In addition, AHMAC noted that two substances, trichloroisocyanuric acid and 4-dimethylaminobenzene, be considered for rescheduling.

The IJWGPC has now completed its role in progressing national consistency of controls on poisons as directed by AHMAC. It is anticipated that the monitoring and updating of Appendix J in the future will be carried out by the Chemicals and Medicines Scheduling Secretariat, Therapeutic Goods Administration.

[1] A copy of the Decision RIS can be found at https://www.health.qld.gov.au/__data/assets/pdf_file/0020/444251/national-approach-poisonous-chem.pdf

Introduction

The review of Appendix J completes the actions that were agreed to by the Australian Health Ministers Advisory Council (AHMAC) to achieve national consistency of controls on poisons. The Inter-Jurisdictional Working Group Poisons Control (IJWGPC), established under the auspices of AHMAC, undertook a review of Appendix J and drafted a number of proposals to address issues identified. Consultation with stakeholders was undertaken in 2017, after which the proposals were finalised and recommendations presented to AHMAC for endorsement in December 2017. This paper provides a summary of the outcomes of the consultation and of the recommendations endorsed by AHMAC.

Background

In July 2008, the Productivity Commission Research Report on Chemicals and Plastics Regulation (the Report) was released. Recommendation 5.2 of the Report stated that State and Territory Governments should:

- adopt poisons scheduling decisions made by the Department of Health and Ageing directly by reference, as published in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
- uniformly adopt regulatory controls for poisons through either a template or model approach, as published in the SUSMP.

The *Decision Regulation Impact Statement: Strategies to implement a national approach to poisonous chemical controls*[2] (Decision RIS), commissioned to identify the approach to meet recommendation 5.2 of the Productivity Report, proposed 12 options to address the regulatory control issues identified for Schedule 5, 6 and 7 poisons. The IJWGPC was established under the auspices of AHMAC to progress the Decision RIS options.

The Decision RIS supported the retention of Appendix J, provided that a review of the chemicals was undertaken and the appendix updated. In response to the Decision RIS recommendation to review Appendix J, the IJWGPC undertook an internal review of Appendix J (the Review) to examine the contemporary use patterns and availability of Appendix J poisons and to develop criteria to use for inclusion of Schedule 7 poisons (S7s) in Appendix J. Consideration was also given to how the controls could be administered.

Consultation

Once the review of Appendix J was completed, a formal consultation process with stakeholders was undertaken. A consultation paper, *Review of Appendix J, Standard for the Uniform Scheduling of Medicines and Poisons*, provided an overview of the key issues associated with the existing Appendix J and put forward proposals to facilitate consistency in the implementing of controls for chemicals included in Appendix J into the future. Feedback via a consultation response form or written submission was invited. The paper and the consultation response form

[2] A copy of the Decision RIS can be found at https://www.health.qld.gov.au/__data/assets/pdf_file/0020/444251/national-approach-poisonous-chem.pdf

could be accessed via the Queensland Health website. A letter was sent to relevant stakeholders advising them of the consultation and inviting them to participate in the process. An email about the consultation was also sent by the Therapeutic Goods Administration to the contacts on their distribution list.

The consultation response form asked stakeholders to indicate their level of agreement with statements regarding the proposed approach to managing and updating Appendix J, and the proposals outlined in the consultation paper. The form also asked whether stakeholders thought that there may be unintended consequences or impacts of the proposals, and whether there were any other factors that should be considered by the IJWGPC.

The consultation period was open for six weeks, from 5 June 2017 until 19 July 2017. Responses submitted on printed forms were entered into the online survey until the closing date. Data from the online survey was downloaded into an Excel spreadsheet format. Responses received after the closing date were manually added to the Excel spreadsheet. Comments added to the form or provided by written submissions were summarised and collated. All responses were considered by the IJWGPC.

Responses

A total of 15 responses were received from industry bodies, companies involved in the manufacture and supply of chemicals, and government agencies. Seven respondents completed the consultation response form, with six of them providing additional comments. Eight respondents provided comments via a written submission. While the responses received indicate general support for proposals, a number of concerns were raised. Details of the responses to the proposals and questions are attached in Attachment 1.

Respondents' comments can be summarised into the following themes:

- Unintended consequences / impacts due to:
    - the proposed restrictions on possession and use to analytical and research purposes affecting current and potentially future business activities.
    - no cut-off limits for very low concentrations/impurities of S7s - if the requirements of the Poisons Standard were applied literally, end-products containing impurities could only be used by authorised or licensed persons.
- Other factors for consideration:
    - overlap with other legislation such as workplace health and safety and labelling requirements under the Globally Harmonized System for Classifying and Labelling of Chemicals (GHS).
    - interaction with proposed national harmonised model for licensing and training for users of agricultural and veterinary (agvet) chemicals.
- Requests for clarification:
    - whether substances with a separate listing in Schedule 7 are impacted if an ingredient or parent chemical is included in Appendix J.
- Other comments relating to the:
    - process used in the Review to identify which chemicals should be listed for analytical or research purposes only.
    - Australian scheduling policy – hazard-based rather than risk-based.
    - incorrect spelling of bromadiolone.
    - chemical nomenclature used in SUSMP versus that used by the Australian Pesticides and Veterinary Medicine Authority (APVMA).

- usability of SUSMP – the inclusion of Chemical Abstracts Service (CAS) numbers, chemical and common names, and links from the Index to entries in the Schedules would be beneficial.

Outcomes

All stakeholder feedback was considered by the IJWGPC before the proposals were finalised and recommendations prepared for AHMAC. The working group noted that there was support for proposals outlined to amend Appendix J. It was also noted that some comments received or issues raised were determined to be outside of the scope of the Review or of the IJWGPC, and would need to be referred to the appropriate body for consideration.

Amended proposal

The IJWGPC agreed that five poisons (carbadox, carbon tetrachloride, epidermal growth factor, folpet, and halofuginone) not be restricted to analytical and research purposes only because they do not meet the agreed criteria for this restriction.

One stakeholder commented that ethylene dibromide is listed in Schedule 10 of the model Work Health and Safety regulations with restricted use as a fumigant, and therefore, limiting its use to analytical or research may not be appropriate. However, there are no products containing ethylene dibromide registered by the APVMA for use in Australia. Ethylene dibromide is also listed as a chemical subject to the Rotterdam Convention. Therefore, it was decided that the 'a' annotation against ethylene dibromide should remain.

Clarification

Clarification was provided to the stakeholder concerned that, while a chemical substance contains an Appendix J poison, the substance is not captured under Appendix J if it is listed separately in Schedule 7. For example, while arsenic is listed in Appendix J, two preparations containing arsenic (MSMA & DSMA) are listed separately in Schedule 7. Therefore, the Appendix J conditions do not apply to them.

Issues referred to Secretary of the Australian Department of Health

A number of matters were referred to the Secretary, Australian Department of Health for consideration.

- The request for cross-referencing of 4-aminopropiophenone and para-aminopropiophenone (PAPP) in the SUSMP has been actioned.
- The issue of impurities in final products and no cut-off levels in the Poisons Standard has been noted.

Recommendations endorsed by AHMAC

The IJWGPC recommended a number of proposals to AHMAC with respect to updating Appendix J and facilitating consistent controls over the availability and use of the high-risk poisons listed in Appendix J. The proposals were considered and endorsed at the AHMAC meeting held on 8 December 2017.

AHMAC endorsed that:

- Appendix J poisons should be available only to authorised or licensed persons.
- The use of Appendix J poisons that are banned, obsolete or subject to international conventions must be restricted to analytical and research purposes only.
- Additional controls should be reinstated on the possession and use of certain Appendix J poisons that present an unacceptable level of public health risk as a result of their use pattern.
- The title of Appendix J should be amended to "*Schedule 7 poisons requiring additional controls on availability and use*".

AHMAC also endorsed three scheduling factors for the inclusion of S7s in Appendix J, and their incorporation into the revised Scheduling Policy Framework. The factors are:

1. Significant, severe and possible irreversible injury may occur without the individual being aware of exposure – whether that is a single or repeated exposure or a low or high dose exposure.
2. Specialised skills and/or equipment are required to mitigate the risks of using the poison.
3. The patterns of use of the poison pose an unacceptable risk resulting from direct or indirect exposure to the public.

AHMAC noted that two substances, trichloroisocyanuric acid and 4-dimethylaminobenzene, be referred for consideration for rescheduling.

An updated Appendix J, reflecting the amendments endorsed by AHMAC, is attached in Appendix 2.

A letter advising of AHMAC's decisions has been sent to the Secretary, Australian Department of Health.

Conclusion

The review of Appendix J completes the actions that were agreed to by the Australian Health Ministers Advisory Council (AHMAC) to achieve national consistency of controls on poisons.

The review undertaken by the IJWGPC examined the contemporary use patterns and availability of Appendix J poisons and developed criteria to use for inclusion of S7s in Appendix J. Consideration was given to how controls on the use of the poisons could be administered.

In response to the findings of the review, the IJWGPC drafted a number of proposals to address the issues identified and to update the appendix. Following consultation with stakeholders, the proposals were finalised and recommendations presented to AHMAC in December 2017. AHMAC endorsed all recommendations.

The IJWGPC has now completed its role in progressing national consistency of controls on poisons as directed by AHMAC. It is anticipated that monitoring and updating of Appendix J in the future will be carried out by the Chemicals and Medicines Scheduling Secretariat, Therapeutic Goods Administration.

Attachment 1: Consultation responses

Respondents who completed the form were asked to indicate their level of agreement with 10 statements regarding the proposed approach to managing and updating Appendix J, and the proposals outlined in the consultation paper. The form also asked two questions regarding unintended consequences or impacts of these proposals, and any other factors that the IJWGPC should consider. Seven respondents completed the consultation response form, with six of them providing additional comments. Eight respondents provided comments via a written submission. Table 1 shows the number of responses and level of agreement with each statement, while Table 2 presents the respondents' comments, collated and grouped according to theme.

Table 1: Level of agreement with each statement

Statement		Agree	Neutral	Disagree
1	The proposed approach to managing dangerous poisons listed in Appendix J and updating and improving the uniformity of application of Appendix J controls is reasonable.	7	0	0
2	Trichloroisocyanuric acid should be removed from Appendix J as it is not an S7.	4	3	0
3	Inclusion of 4-dimethylaminobenzene in Appendix J should be reviewed by the Advisory Committee on Chemicals Scheduling (ACCS).	5	2	0
4	Obsolete conditions 2 and 4 in Appendix J 'Part 1 Conditions for availability and use', should be removed.	6	1	0
5	The condition for fluoroacetic acid, fluoroacetamide, 4-aminopropiophenone and thallium should be amended from condition 3 to condition 1 to reflect the need for authorisation.	5	2	0
6	Poisons with uses limited to analytical and research purposes should be identified in Appendix J.	6	1	0
7	The seven poisons previously identified in the former Part 3 s41(3) of the SUSMP as being of extreme risk due to use patterns should be once again specifically identified in Appendix J as requiring authorisation by the appropriate authority to possess or use.	6	0	1
8	The title of Appendix J should be amended to "Schedule 7 Poisons Requiring Additional Controls on Availability and Use".	4	3	0
9	A guideline to support jurisdictional interpretation and implementation of Appendix J controls should be developed.	5	2	0
10	The proposed scheduling factors are appropriate for consideration during assessment of a poison for inclusion in Appendix J.	4	3	0

Table 2: Collated comments

Unintended consequences / impacts
The proposal to limit use of carbadox to analytical or research purposes would have significant commercial impact on a manufacturer of a veterinary medicine containing carbadox.
Two chemicals, Epidermal Growth Factor and Halofuginone, are currently used in registered agvet chemicals, and should not be restricted to analytical and research purposes only.
Ethylene dibromide and carbon tetrachloride are listed in Schedule 10 of the model Work Health and Safety regulations, with restricted uses. Therefore, condition 'a' may not be appropriate.
There is no exemption for products containing very low concentrations of Appendix J S7s present as impurities in the final product. This is a significant problem where these substances can be present as a manufacturing by-product or residual raw material. If the requirements of the Poisons Standard were applied literally, these products could only be used by authorised or licensed persons.
Other factors for consideration
Controls on the agvet chemicals [in Appendix J] need to fit within the broader system for managing agvet chemicals, and align with the regulatory model for harmonised control of use for agvet chemicals. The proposed model includes training requirements for users of Restricted Chemical Products (RCPs) and S7s, and licensing of fee-for-service users.
Under workplace health and safety legislation, workplaces are required to comply with the Globally Harmonized System for Classifying and Labelling of Chemicals (GHS). Issues arise when manufacturers have to label products to comply with both sets of requirements [WHS and Poisons Standard]. Signal words used in the GHS and the SUSMP are different, leading to confusion for end users. Guidance on how to prepare labels should be provided in a guideline.
The regulatory framework for poisons, especially S7s in workplaces, overlaps with other legislation and duplicates workplace health and safety laws, resulting in costs and burdens without any benefit.
The Poisons Standard adopts an archaic approach to S7s with controls that are hazard-based rather than risk-based. A review of the cut-off levels for all products is required to ensure a proportionately balanced system for very low concentrations.
Requests for clarification
The SUSMP states that a schedule entry includes preparations containing the poison in any concentration and all salts and derivatives unless stated otherwise. For example, it is possible that the arsenic entry in Appendix J may cover common agricultural chemicals (e.g. MSMA, DSMA). MSMA & DSMA have separate entries in Schedule 7 but are not in Appendix J. Clarification is sought that MSMA & DSMA are not intended to be covered by Appendix J.

Other
A number of respondents questioned the process that was undertaken to identify which chemicals should be listed for analytical or research purposes only.
Bromadiolone is incorrectly spelt in the poison use table.
Common names used for agvet chemicals in the SUSMP should be aligned with those used by APVMA, e.g. SUSMP '4-aminopropiophenone' vs APVMA 'para-aminopropiophenone'. When referring to common names, the name should be referenced from *AS1719 Recommended common names for pesticides* and draft amendments or *ISO1750 Pesticides and other agrochemicals – Common names*.
The SUSMP needs to include CAS numbers, chemical and common names, & have links from the Index to entries in the Schedules.
The proposals appear to be maintenance activities to ensure that Appendix J remains relevant. Will a mechanism be put in place to ensure discrepancies/divergences do not occur again or can be quickly identified and addressed?
The opportunity to develop better reform/greater efficiencies has been missed.

Attachment 2: Amended Appendix J

APPENDIX J: SCHEDULE 7 POISONS REQUIRING ADDITIONAL CONTROLS ON AVAILABILITY AND USE

Controls are recommended for the S7s listed in the table below and may be implemented through poisons controls or other State or Territory legislation.

- All poisons included in this Appendix are not to be available except to authorised or licensed persons.
- The use of a poison may be restricted for a particular purpose.

Authorisation considerations

- Poisons marked with 'p' have been identified as representing a significant risk to public health. Additional restrictions on their possession and use must be applied through an authorisation or licensing process which includes a case by case assessment of risks to public health.
- Poisons marked with 'a' are restricted to analytical or research purposes only.

Poison	Authorisation considerations
Abamectin	
Acibenzolar-s-methyl	
Acrolein	
Acrylonitrile	
Alachlor	**a**
Allyl Alcohol	
4-aminopropiophenone	
4-aminopyridine	
Arprinocid	**a**
Arsenic	**p**
Azocyclotin	**a**
Benzene	
Bifluoride	
Boron Trifluoride	
Brodifacoum	
Bromadiolene	
Bromine	
Brucine	
Calciferol	
Captafol	**a**
Carbadox	
Carbon Tetrachloride	

Poison	Authorisation considerations
Carbonyl sulfide	
Chlordecone	**a**
Chlordimeform	**a**
Chlorine	
Chloromethiuron	**a**
Chloropicrin	
4-Chloro-o-toluidine	**a**
Colecalciferol	
Coumatetralyl	
Cyanogen	
Cyhexatin	**a**
4,4'-Diaminodiphenylmethane	
1,2-Dibromo-3-chloropropane	**a**
1,3-Dichloropropene	
Difenacoum	
Dinitrocresols	**a**
Dinitrophenols	**a**
Dinoseb	**a**
Epichlorhydrin	
Epidermal Growth Factor	
Etaconazole	**a**
Ethylene Dibromide	**a**
Ethylene Oxide	
Fluoroacetamide	**p**
Fluoroacetic acid	**p**
Folpet	
Halofuginone	
Halogenated Dibenzodioxins and Dibenzofurans	**a**
HCB	**a**
Hydrocyanic acid and cyanides	**p**
Hydrofluoric acid	
Hydrosilicofluoric acid	
Iodomethane	
Maduramicin	
Mercury	
Methacrifos	

Poison	Authorisation considerations
Methoxyethylmercuric acetate	**a**
Methoxyethylmercuric chloride	
Methyl Bromide	
4,4'-Methylenebis[2-chloroaniline]	
Mirex	**a**
Molinate	
Nicotine	
Nitrofen	**a**
Phenylmercuric acetate	
Phosphide, metallic	
Phosphine	
Propylene oxide	
Pyrinuron	**a**
Strychnine	**p**
Sulcofuron	**a**
Tetrachloroethane	
2,2'6,6'-Tetraisopropyl-diphenyl-carbodiimide	
Thallium	**p**
Ortho-tolidine	
Vinyl chloride	