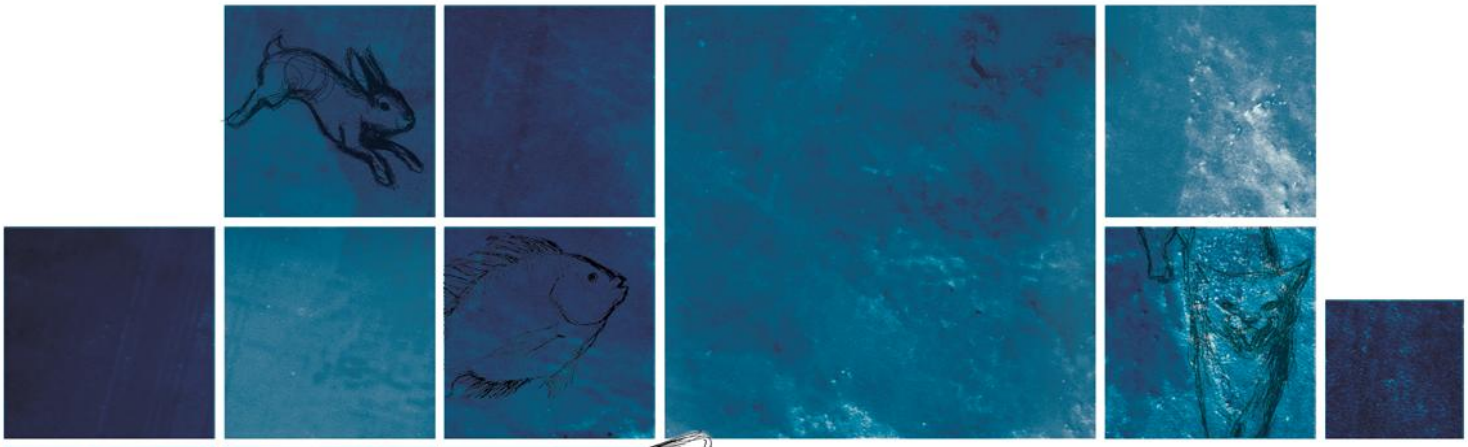

PESTSMART

Pathways to adoption of Cyprinid herpesvirus 3 as a biological control agent for carp in Australia

October 2013

Wayne Fulton

Invasive Animals CRC

An Australian Government Initiative

CRC AUSTRALIA

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MURRAY–DARLING BASIN AUTHORITY

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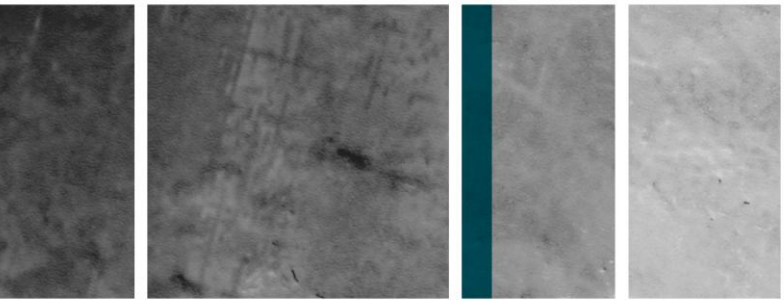

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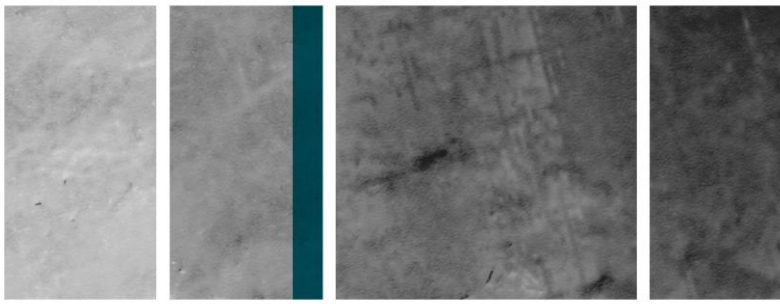
Front cover image: Murray River near Hattah. Image by Martin Asmus, NSW Department of Primary Industries.



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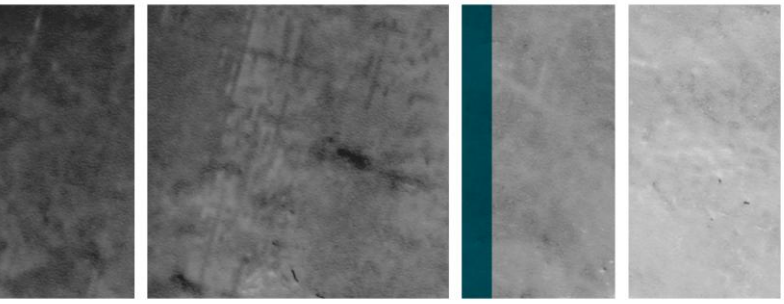
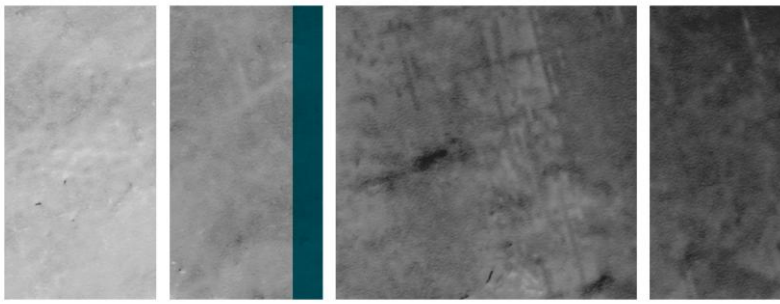




Summary

The approval process for Cyprinid herpesvirus 3 (CyHV-3)

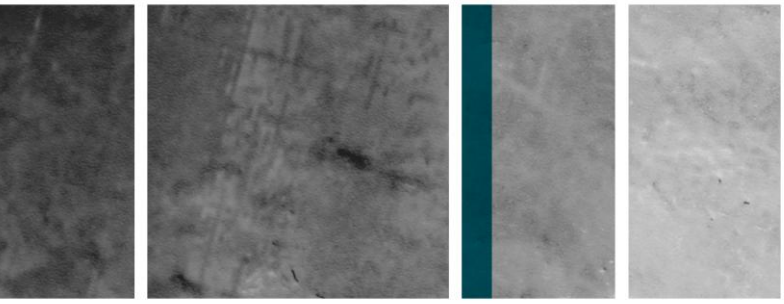
There are a number of statutory processes that need to be satisfied to obtain approval for the release of a biological control agent in Australia. The course to be followed also depends to some degree on the nature of the control agent and also the target organism. The use of a virus as the control agent will require approvals under the Quarantine Act 1908 (for importation and release of the virus) and the Environment Protection and Biodiversity Conservation Act 1999 (EPBC) (for release of the virus into the environment). It would also be appropriate to seek approvals under the Biological Control Act 1984 (BA) because of the structured public consultation and indemnity provisions that this legislation contains. The latter legislation has not always been used for biological control agents, particularly for plants. However in cases where it is likely that there will be conflicts of interest it would appear most appropriate to use this legislation. For example, it was used for assessment of Rabbit Haemorrhagic Disease (RHD) in the 1990's and was particularly valuable in terms of the structured public consultation process.

In relation to critical evaluation of the safety and efficacy of the control agent for carp (ie CyHV-3), the virus should also be assessed under the *Agricultural and Veterinary Chemicals Code Act 1994* (APVMA Code) administered by the Australian Pesticides and Veterinary Medicines Authority. Under this legislation the control agent is considered as either an agricultural or a veterinary chemical and specific data are required for detailed assessment by the APVMA. This process is essentially a detailed environmental impact assessment of the use of the virus. The data are also referred to other agencies such as the Department of Sustainability, Environment, Water, Population and Communities (SEWPaC) for compliance with the EPBC Act and the Office of Chemical Safety for compliance with human health and occupational health and safety issues.

As the combination of the Biological Control Act and APVMA review has rarely been used to the full extent, it is unclear as to exactly how the two processes link as there does not appear to be any formal arrangement or requirement for this to happen. However, the information that needs to be prepared for the APVMA is very extensive and would most likely be adaptable to cover the requirements of the Authority and the public under the Biological Control Act. The timing of the two processes therefore needs to be coordinated to avoid unnecessary duplication of effort.

In the past, the release of RHD to control rabbits was assessed by the APVMA, but there is little detail of this process. The APVMA legislation was updated extensively in 1994 and the RHD assessment process was already in progress at this time. However, it was determined that neither an Environmental Impact Statement nor a Public Environment Report were required at least in part due to the concurrent assessments under the *Biological Control Act 1984* and the *Agricultural and Veterinary Chemicals Code Act 1994*.

The information that is prepared for the APVMA would also most likely be sufficient for



assessments under the Quarantine Act. This Act is currently (June 2012) under revision so it is not possible at this stage to be prescriptive in relation to the process, although advice from Department of Agriculture Fisheries and Forestry (DAFF) indicates that this revision should not change the approval requirements for CyHV-3.

If approval is granted for the use of CyHV-3 as a biological control agent for carp there will still be other primarily state based legislation to consider. For example, the APVMA conducts the registration process for a pesticide to ensure that it is safe to use, but from the point of sale onwards, its use is subject to State legislation.

The Commonwealth Biological Control Act is mirrored in State legislation and parallel declarations will need to be made in the states. These declarations would extend the BCA and APVMA approvals to the release phase Australia wide. In addition, State fisheries legislation contains a number of provisions relating to fish and fisheries and there will be other environmental and health issues associated with fish kills to be considered.

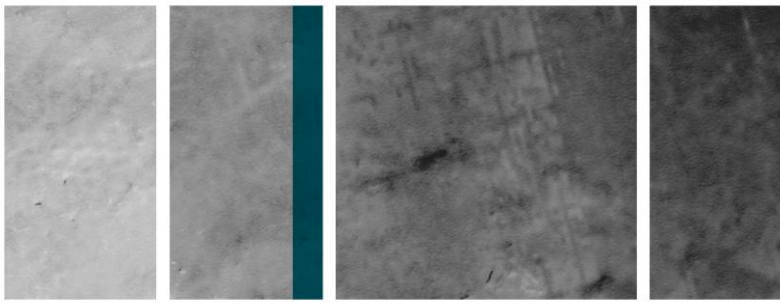
The major legislation is considered in separate sections under the following headings.

- Quarantine Act 1908 and Environment Protection and Biodiversity Conservation Act 1999
- Biological Control Act 1984
- Australian Pesticides and Veterinary Medicines Authority
- Agricultural and Veterinary Chemicals Code Act 1994
- Other (State) legislation relating to fish and fisheries

As the use of a biological control agent of this nature and extent is not a routine process, it will be essential to establish consultative links with the agencies responsible for the assessment and review processes. Data requirements and timelines can then be worked out for each process where these are not defined by statute. The emphasis should be on parallel processes with close cooperation to ensure timelines match and information preparation efforts are not duplicated.

It is strongly recommended that some form of group or committee be formed under the auspices of VPC to work through the various regulatory processes that need to be considered and to develop an action plan and timelines for addressing these. If this is not done then there is no doubt that processes will not match in terms of timing and information and resources may well be wasted.

To assist this process, a draft plan of action is proposed in Section 5. This firstly needs to be discussed and expanded on between the IA CRC and the release proponent. The next major step in this process should be to consult with the head of DAFF to set up an initial meeting to map out a process. At present the process for taking CyHV-3 through the Quarantine Act and the Biological Control Act are not clearly defined and staff within DAFF have advised that they do not presently know what the process would be or specifically who would deal with it. This discussion should lead to the identification of information requirements for each major piece of legislation and timelines for submissions. It is not possible to be more specific than this at the moment.



1. Quarantine Act 1908 and Environment Protection and Biodiversity Conservation Act 1999

The Quarantine Act is primarily designed to protect Australia from the introduction of pests and diseases of plants and animals (including humans) whilst the *Environment Protection and Biodiversity Conservation Act* (EPBC Act) adds compliance with obligations under the Convention of International Trade in Invasive Species (CITES) as well as further protection for Australia's native flora and fauna. (The EPBC Act also provides for the importation of all aquarium fish species.) The EPBC Act is relevant in later consideration of the possible impacts of use of any imported virus as a biological control agent.

Importation of a virus as a biological control agent can be a two part process as the release of the virus into the Australian environment does not always follow its importation. For example it may be deemed unsuitable after evaluation or it may have been imported only for disease preparedness or diagnostics purposes.

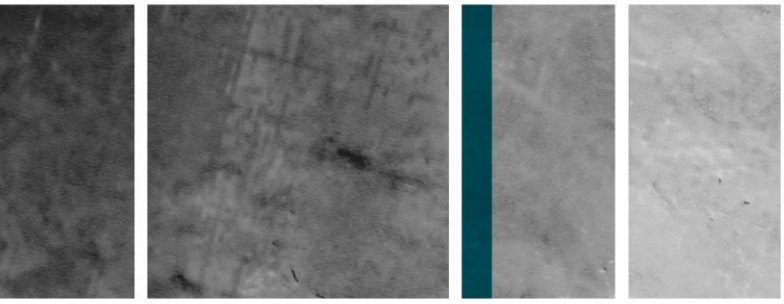
Application can be made to import the intended agent into Australia where it must be held in quarantine in secure facilities such as the Australian Animal Health Laboratories (AAHL) at Geelong. Currently, an application to import a virus for biological control would be first subject to Import Risk Assessment protocols as determined by DAFF Biosecurity Australia. (see www.daff.gov.au/ba/ira).

In the case of CyHV-3, a permit was obtained by CSIRO to import the virus from Indonesia. This was done under a general permit issued by AQIS on 8 August 2006 to CSIRO Livestock Industries (AAHL Geelong) under Section 13(2AA) of the *Quarantine Act 1908*.

This permit is for research purposes only and the information and process required for its issue is relatively simple. It does not allow for the virus to be released from the secure facilities at AAHL and to change the status of this permit is akin to an application for release of the virus albeit that we are in a much better position to provide information in support of that application.

To import a virus into Australia (or to move the virus presently held at AAHL outside of the secure facilities) for use as a biological control agent and to release it from quarantine will require further approval under the *Quarantine Act 1908*. Approval under the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act) is not required for importation of a virus (at least for research purposes) as a virus is not included under the scope of that Act. However, the release of a virus such as CyHV-3 from quarantine will require an assessment under the EPBC Act for any possible impact on natural resources and for this reason a release application will certainly need to be considered under the EPBC Act.

The Australian Quarantine and Inspection Service (AQIS) of the Department of Agriculture Fisheries and Forestry (DAFF) administers the *Quarantine Act*. AQIS has the responsibility for compliance with regulations under this Act. In 1987, AQIS published a set of procedures for the importation and release of biological control agents in Australia that were agreed upon by State agricultural and conservation authorities and CSIRO. The passage of time and many



changes to government structures as well as infrequent use means that these are no longer applicable and a new process needs to be developed. Advice from DAFF indicates that the process should be approached on individual merit and the Biological Imports Program (BIP) within DAFF should be consulted for this purpose. BIP is likely to refer the application to Animal Biosecurity and may also need to consult with the Chief Veterinary Officer and other agencies in the relevant states and territories.

The process used for the release of RHD from quarantine is summarised below. This would appear to be a suitable starting point for CyHV-3.

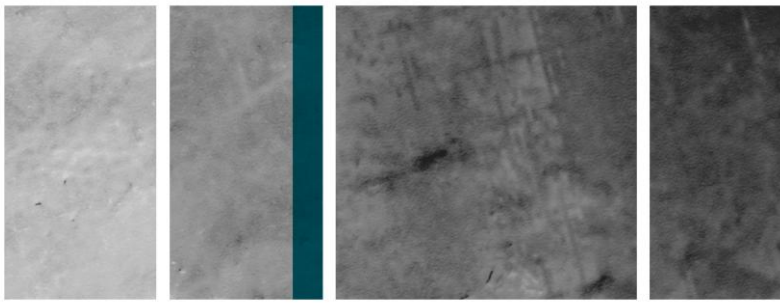
1. Applicant prepares an application with detailed* information under three headings:
    - The target species
    - The biological control agent
    - Release and monitoring protocols

    (*More detailed information on what is required in this application process is included at the end of this section at Appendix 1a)
2. Application submitted to AQIS
3. Notification of other agencies. Application is referred to SEWPAC and State/Territory Departments of Primary Industries, conservation authorities and CSIRO.
4. Agencies assess the application by assessment of risk** against certain criteria and respond to AQIS. AQIS forwards responses to SEWPaC.

    (**More detailed information on what is required for a risk assessment is included at the end of this section at Appendix 1b)
5. AQIS assess responses in consultation with applicant and referees. (Host specificity of the control agent is a critical issue in this determination)
6. If successful both AQIS and SEWPaC draw up permits to release the control agent.

The links between AQIS and SEWPaC processes should be noted here. Separate referral to SEWPaC does not appear to be required at this point. Whilst SEWPaC does have its own protocols for importation of biological control agents (see www.daff.gov.au/biodiversity), viruses are excluded from the EPBC Act but are covered under the Quarantine Act for import purposes. However, they need to be considered under the EPBC Act in relation to possible impact of their release. This is where the APVMA assessment is critical.

Before any application processes are undertaken under the Quarantine Act, the requirements under the Biological Control Act and for APVMA approval (following chapters) should also be considered as the various processes are closely related and overlapping at some points. It is likely that there could be some coordination of processes to avoid duplication of resources and to streamline approvals.



Appendix 1a: Guidelines on information to be provided with an application to import or release Biological Control Agents

These follow the details set out for RHD by Bureau of Rural Sciences (1994)

Targets

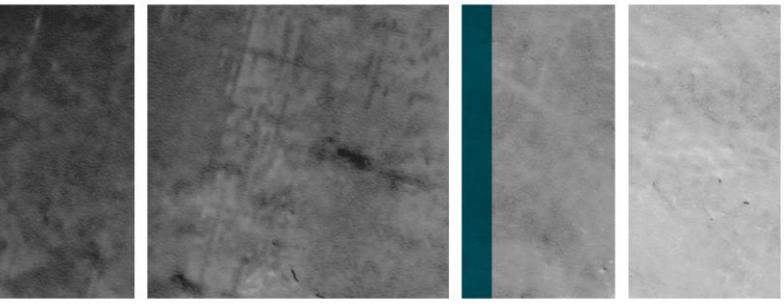
- Scientific name (order, family, genus, species and author) common name.
- Native range and likely centre of origin.
- Distribution in Australia, including a map, and in any other country where it is a pest or a normal part of the fauna.
- Related Australian native fauna
- Pest status
    - Host organism(s) attacked by it
    - Nature of damage caused
    - Extent of losses caused, average and extremes
    - Estimated value of production loss
- Other control methods available (if any)
    - Type of control (chemical, physical, management)
    - Effectiveness
    - Costs
    - Any undesirable side effects

Agent

- Scientific name (order, family, genus, species and author) common name.
- Brief biology of the agent.
- Native range and, if known, probable centre of origin.
- Related species and a summary of their host range.
- Proposed sources of agent.
- Mode of action against target organism and extent of action.
- Potential for control of target.
- Non-target organisms at risk from agent (include those closely related biologically and those ecologically similar)
- Possible interactions with existing biological control programs (of same or related targets and other targets).
- Host specificity testing program to be proposed to, or which has been accepted by, quarantine and conservation authorities (include list of host/test organisms, methods of testing).
- Progress of testing program and results of testing program and conclusions.

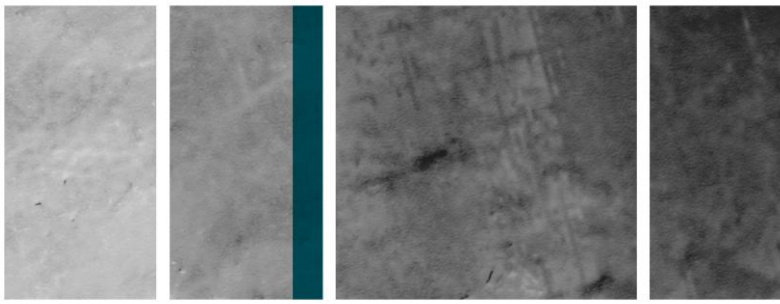
Release and monitoring

- When and where initial releases are proposed.



- Methods to be used for evaluating establishment, dispersal and effect on target and for what period of time.
- Methods to be used for evaluating establishment, dispersal and effect on other species in the vicinity of the target and for what period of time.
- Collaborative research with other departments
- Assistance to be sought from other agencies eg in making releases, mass rearing, secondary distribution, monitoring of spread and effectiveness.
- Assistance to be offered to other agencies eg in making releases in their areas, provision of stocks for release, provision of starter cultures etc.

These requirements are to be considered as a guide only. In some cases more information may be required, in other instances not all of these points will need to be addressed. Where references are cited, a full copy should be included.



Appendix 1b: Guidelines for the risk assessment process required under the Quarantine Act

The requirement for preparation of a risk assessment comes from the provisions of the *Quarantine Act 1908*. It is likely to be required for assessment of impacts under the EPBC Act. The relevant sections from the Quarantine Act are reproduced below;

Part IIA—Proposed decisions affecting the Environment

11C Requirement to seek from Environment Minister advice about proposed decision involving significant risk of environmental harm

1) Before making a decision under this Act, the implementation of which is likely to result in a significant risk of harm to the environment, a Director of Quarantine must comply with the requirements of this section.

2) The Director of Quarantine must give written notice to the Environment Minister:

    a. stating that consideration is to be given to the making of such a decision; and

    b. requesting the Environment Minister to give advice to the Director as to the adequacy of the risk assessment process that is proposed to be followed in assessing the risk of harm to the environment.

3) After preliminary findings have been made as a result of the risk assessment process, the Director of Quarantine must give written notice to the Environment Minister requesting the Environment Minister to give advice to the Director as to the adequacy of the preliminary findings in relation to the protection of the environment.

There are no formal guidelines describing what format or process the risk assessment should follow so a protocol needs to be established for this particular case. The RHD evaluation process does not give any clear direction in relation to this.

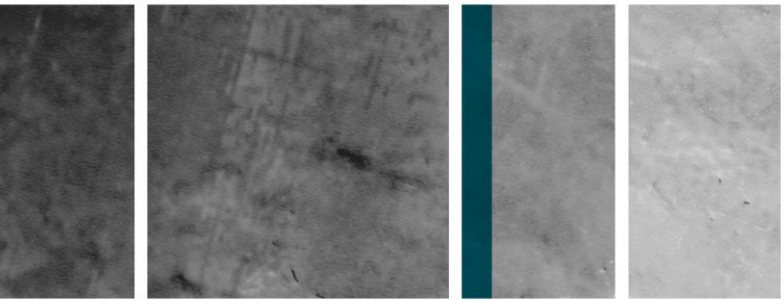
A more recent process that did undertake a detailed risk assessment for the purposes of the release of a biological control agent was for the release of the yellow fever mosquito *Aedes aegypti* containing a naturally occurring strain of *Wolbachia pipientis* for dengue fever control. Whilst the organism is not a GM, it was decided to use the framework for risk assessment as described under the Gene Technology Act 2000 as this provided a suitable framework for a similar purpose. The outcomes of this particular risk assessment have been published (Murphy et al 2010).

The risk assessment framework from the Gene Technology Act is included in Part 5 of Division 4 of the Act. The sections that relate to what needs to be covered in the risk assessment are included below:

Under Part 5 Division 4 of the Gene Technology Act 2000

50 Regulator must prepare risk assessment and risk management plan

1) Before issuing the licence, the Regulator must prepare a risk assessment and a risk management plan in relation to the dealings proposed to be authorised by the licence.



51 Matters Regulator must take into account in preparing risk assessment and risk management plan

1) In preparing the risk assessment in relation to the dealings proposed to be authorised by the licence, the Regulator must take into account the following:

    a. the risks posed by those dealings, including any risks to the health and safety of people or risks to the environment, having regard to the matters prescribed by the regulations;

    b. any advice in relation to the risk assessment provided by a State or a local council in response to a request under subsection 50(3);

    c. any advice in relation to the risk assessment provided by the Gene Technology Technical Advisory Committee in response to a request under subsection 50(3);

    d. any advice in relation to the risk assessment provided by a Commonwealth authority or agency in response to a request under subsection 50(3);

    e. any advice in relation to the risk assessment provided by the Environment Minister in response to a request under subsection 50(3);

    f. any other matter prescribed by the regulations for the purposes of this paragraph.

2) In preparing the risk management plan, the Regulator must take into account the following:

    a. the means of managing any risks posed by those dealings in such a way as to protect:

        i. the health and safety of people; and
        ii. the environment;

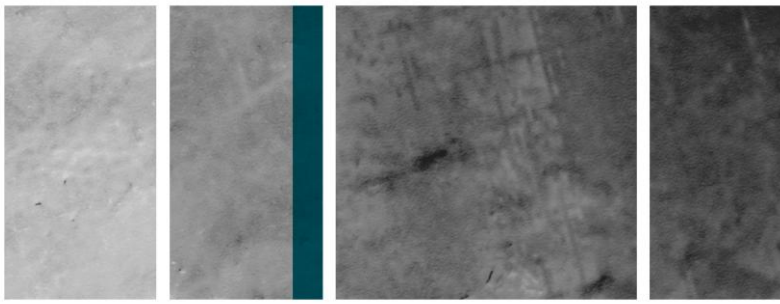
    b. any advice in relation to the risk management plan provided by a State or a local council in response to a request under subsection 50(3);

    c. any advice in relation to the risk management plan provided by the Gene Technology Technical Advisory Committee in response to a request under subsection 50(3);

    d. any advice in relation to the risk management plan provided by a Commonwealth authority or agency in response to a request under subsection 50(3);

    e. any advice in relation to the risk management plan provided by the Environment Minister in response to a request under subsection 50(3);

    f. any other matter prescribed by the regulations for the purposes of this paragraph.

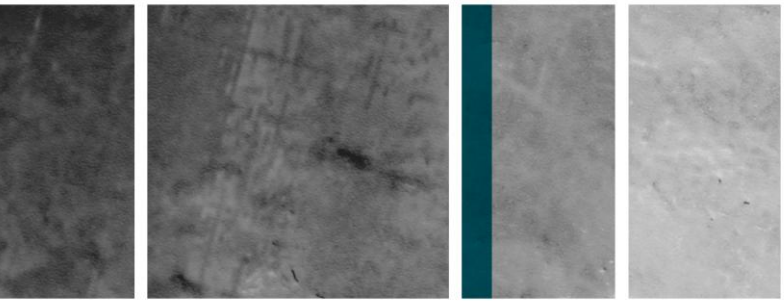


3) For the avoidance of doubt, in taking into account the means of managing risks as mentioned in paragraph (2)(a), the Regulator:

    a. is not limited to considering submissions or advice mentioned in paragraphs (2)(b), (c), (d), (e) and (f); and

    b. subject to section 45, may take into account other information, including, but not limited to, relevant independent research.

These guidelines are still not particularly specific so it would be up to the proponents to design a process that would identify and evaluate the risks specific to this proposal. If a risk assessment is actually considered to be necessary, a dedicated expert workshop would most likely be required to do this.



2. Biological Control Act 1984

This legislation came about when the Australian Agricultural Council decided that it needed uniform national legislation to control the release of biological control agents in Australia. The *Biological Control Act 1984* resulted from this. The *Biological Control Act* is subservient to the *Quarantine Act 1908* so it does not constitute an alternative mechanism for approval of the release of a biological control agent.

The Commonwealth *Biological Control Act 1984* established procedures for assessing the impact of biological control agents and authorising biological control programs in the Australian Capital Territory. The Act establishes an 'Authority' (the Commonwealth Biological Control Authority) to administer the Act. The Authority is the Minister who currently sits on 'Council' (currently the Minister who represents the Commonwealth on Standing Council on Primary Industries (SCoPI). The Authority may declare a target and/or agent species under the Act following unanimous agreement and nomination by SCoPI.

Under an agreement on biological control between the Commonwealth, States and Territories, complementary legislation has been passed by State and Territory Governments. Once a declaration is made under the Commonwealth Act, then declarations also need to be made under related State and Territory legislation to gain the full benefits of the legislation.

The main purposes of the Biological Control Act are to provide a structured mechanism for review processes, particularly in relation to public consultation, when the biological control proposal raises conflicting interests or is of high public interest or concern. The other main purpose is that approval under this Act and the complementary State legislation provides both legal indemnity from actions taken as well as protection from injunctions.

As there is likely to be some public opposition to the release of CyHV-3 it is likely that a public consultation process will be required. If this is the case then the best process to follow would be that set out within the *Biological Control Act 1984*.

The Bureau of Resource Sciences (1996) provided a summary of the steps needed for lawful declaration of RHD as a biocontrol agent and rabbits as a target organism in the Australian Capital Territory, the States and the Northern Territory. This is included as Appendix 2a to this Section.

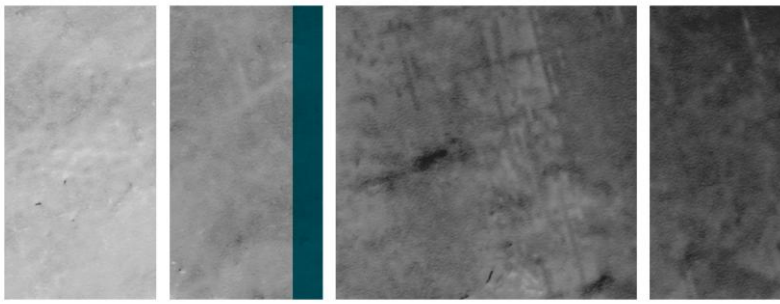
Provisions of the Act

The *Biological Control Act* provides for the declaration of an organism (living or dead, but not human) as a 'target organism'; that is, an organism that is to be the target of biological control. It also provides for the declaration of an organism as an 'agent organism' which is the organism used as the biological control agent. 'Control' has a relatively lenient definition;

Control, in relation to target organisms, includes:

a) reduce the number of those organisms;

b) prevent an increase in the number of those organisms;



c) reduce the activity or appetite of some or all of those organisms; and

d) modify the behaviour or characteristics of some or all of those organisms.

The Act is divided into eight parts as follows;

Part I – Preliminary

Part II – Target organisms

Part III – Agent organisms

Part IV – Special declarations of target organisms and agent organisms

Part V – Release of agent organisms

Part VI – Biological control under State laws

Part VII -- Inquiries

Part VIII – Miscellaneous

Part I contains the definitions and scope of the Act as well as establishing the Commonwealth Biological Control Authority. The Act applies to control in the Australian Capital Territory. Mirror Acts have been enacted in each of the States.

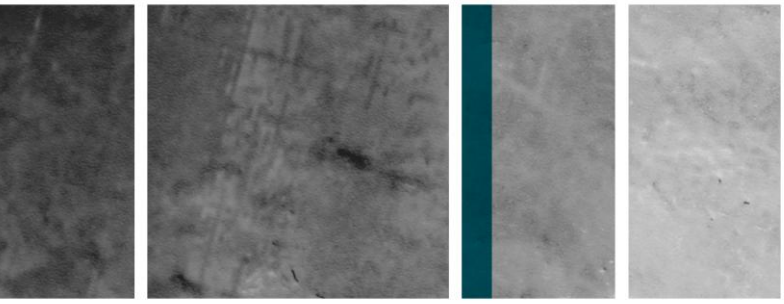
Part II provides for the declaration of target organisms

It gives details of the Application process and what information should be submitted to the Authority. The application is then referred to the Council for consideration. If the application is accepted by the Council a process for public consultation and, if necessary an enquiry is put in place before the application is accepted or rejected

Part III provides for the declaration of agent organisms under essentially parallel provisions to that for target organisms in Part II.

The relevant provisions of the Biological Control Act as it relates to CyHV-3 are included at Appendix 2b below.

The Act is administered by an 'Authority' (the Commonwealth Biological Control Authority) established under Section 8 of the Act. The Authority is the Minister who currently sits on 'Council' with Council under the Act being the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ), or whoever currently has that role. At present that would be the Minister who represents the Commonwealth on Standing Council on Primary Industries (SCoPI).



A summary of the current 'Council' structure as it relates to pest fish control is included below.

Structure of Councils

Background

Through 1999-2000 a new Natural Resources Management Ministerial Council (NRMMC) was formed to take on the natural resources management issues previously dealt with by three organisations: the Australian and New Zealand Environment and Conservation Council (ANZECC), the Ministerial Council on Forestry, Fisheries and Aquaculture (MCFFA) and ARMCANZ. The remaining industry related functions of the latter two councils were placed under a new Primary Industries Ministerial Council (PIMC).

In February 2011 the Council of Australian Governments (COAG) reformed the Ministerial Council system and replaced NRMMC and PIMC with standing councils on Primary Industries and one on environment and water.

Standing Council on Primary Industries (SCoPI)

The Terms of Reference for the Council are at the level of national significance. It is chaired by the member representing the Commonwealth Government and membership includes Commonwealth, State, Territory and New Zealand Ministers with responsibility for primary industries matters.

The Council is the peak forum to:

- pursue and monitor priority issues of national significance affecting Australia's primary production sectors which require a sustained and collaborative effort across jurisdictions; and
- address key areas of shared Commonwealth, state and territory responsibility and funding for Australia's primary production sectors.

Primary Industries Standing Committee (PISC)

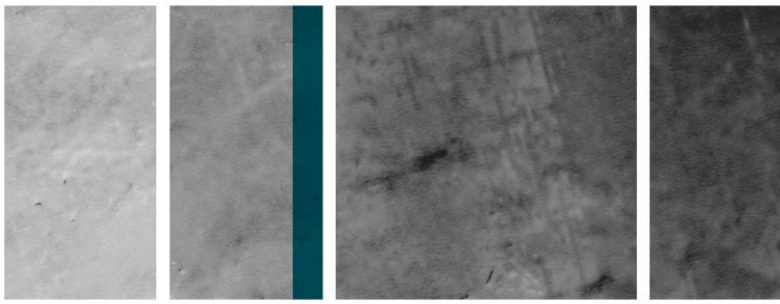
The Primary Industries Standing Committee (PISC) supports the SCoPI in the achievement of its objectives. It develops cooperative and coordinated approaches to matters of concern to SCoPI.

Having regard to SCoPI's terms of reference, PISC:

- directs the work of its subordinate committees
- secures cooperation between its members
- advises SCoPI on the initiation, review and development of PISC activities.

Membership

All department heads/CEOs of Australian/state/territory and New Zealand government agencies responsible for primary industries policy issues are members of PISC. The chair of



PISC is the Secretary of the Australian Government Department of Agriculture, Fisheries and Forestry. The secretariat is provided by the Australian Government Department of Agriculture, Fisheries and Forestry.

Subordinate committees

Advice to PISC and SCoPI on a wide range of issues is developed by expert subordinate committees which currently include:

- National Biosecurity Committee (NBC)
- Industries Development Committee
- Animal Welfare and Product Integrity Taskforce
- Forestry and Forest Products Committee

The supporting committee structure is under review following the establishment of SCoPI. For pest fish issues the NBC is the relevant group.

National Biosecurity Committee

According to the DAFF website, "the NBC was established to provide strategic leadership in managing national approaches to emerging and ongoing biosecurity policy issues across jurisdictions and sectors. NBC will take an overarching, cross-sectoral approach to national biosecurity policy, and will work collaboratively to achieve national policy objectives for biosecurity in Australia."

Environmental, animal and plant biosecurity issues are considered by the NBC, with a view to resolution or for the development of advice to PISC.

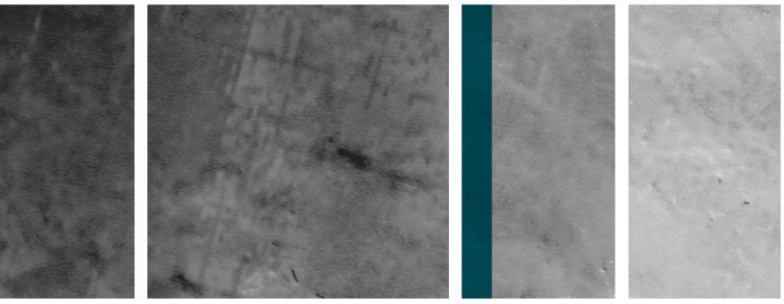
There are also a number of sectoral committees and working groups that report to NBC with the relevant one for pest fish issues being the Vertebrate Pests Committee (VPC).

Vertebrate Pests Committee

The Vertebrate Pests Committee is an Australian sectoral committee that provides coordinated policy and planning solutions for pest animal issues. Membership includes representatives from the Australian Governments and all Australian state and territory governments. New Zealand and agencies such as the CSIRO, Invasive Animals Cooperative Research Centre and Bureau of Rural Science provide Observers to the Committee; other experts may also be accorded Observer status.

The VPC is primarily responsible for overseeing the implementation of the Australian Pest Animal Strategy. This Strategy provides a framework for all governments to work together to address the management of established pest animal species and prevent the introduction and spread of new pest animals into Australia. A national coordinator has been engaged to assist in the implementation of the Australian Pest Animal Strategy and attends VPC meetings in an ex officio capacity.

Under current national biosecurity policy and institutional arrangements, the VPC reports to



the National Biosecurity Committee which reports to both the Natural Resource Management and the Primary Industries Standing Committees. The VPC convenes a number of Working Groups to advise on technical matters. It maintains links with other national sectoral committees such as the Animal Health Committee, Animal Welfare Committee and Australian Weeds Committee to address areas of overlap and common interest.

The VPC has responsibility for coordinated management of pest fish issues and in 2007 the VPC created the Vertebrate Pests Committee, Freshwater Fish Working Group (VPC FFWG) to facilitate effective and coordinated management of freshwater pest fish. Its key role was to provide advice to the

- freshwater pest fish, in particular, prioritising species and assets for research and management action
- international best practice for freshwater pest fish management
- identifying new freshwater fish with pest potential.

Membership of the VPC FFWG includes the federal government, each state and territory government and the Murray–Darling Basin Authority

In parallel with the VPC, the Australian Fisheries Management Forum established the Ornamental Fish Management Implementation Group (OFMIG) in 2007. OFMIG's role was to implement a national strategy for the management of the aquarium trade. This strategy focused on managing Biosecurity risks associated with the ornamental trade.

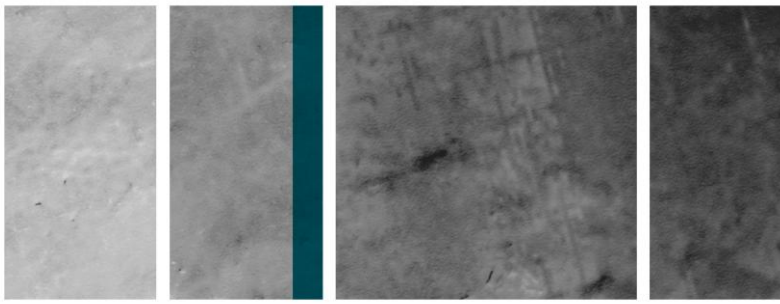
In 2011 OFMIG merged with the VPC FFWG. The merger of these two groups provides for a coordinated and comprehensive management approach to all freshwater pest fish issues in Australia. The new FFWG, through the VPC, has been tasked with the development of a comprehensive freshwater pest fish strategy that is consistent with the Australian Pest Animal Strategy.

Advice to Committees re CyHV-3

The process for approval of CyHV-3 will need to be supported by good science but it will also require considerable effort to brief, inform and consult the various committees as well as to prepare information for the various consultative processes that will arise.

An initial information brief should be provided to VPC as soon as possible and this should probably also go to the Australian Fisheries Managers Forum (AFMF) for information.

In relation to the Biological Control Act, the 'Authority' requires the unanimous agreement of the 'Council' before CyHV-3 can be approved as a biological control agent. In practice this should be taken to mean that unanimous approval will be required at all stages through the committee chain from VPC through NBC to PISC and SCoPI. It will be essential to undertake briefings of various committee members prior to meetings so that they are aware of issues in advance. In practice it will require one of the committees under NBC to drive the process and this logically should be VPC. It is also likely that the Biological Control Authority would delegate responsibility to an agency.



Appendix 2a: Steps for declaration of RHD in States and Territories

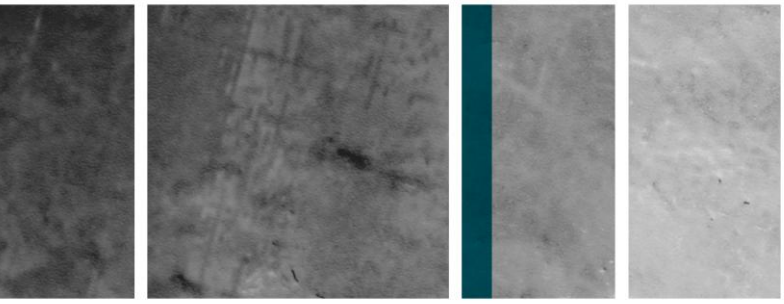
The Bureau of Resource Sciences produced a report under the Biological Control Act (Bureau of Resource Sciences 1996) which summarised the processes and information for the assessment of RHD as a biological control agent for rabbits under the BCA. An attachment to that report summarised 'the steps needed for lawful declaration of agent and target organisms in the Australian Capital Territory, the States and the Northern Territory'.

The steps are reproduced below:

1) Nomination of target and agent organisms by ARMCANZ (March 1995).
2) Submissions requested from the public (25 November 1995).
3) Public consultation period closed (10 January 1996).
4) Consideration of submissions received and report to the Biological Control Authority covering that consideration.
5) Consultation by the Commonwealth Biological Control Authority with ARMCANZ as to whether or not to:
    a) declare target and agent organisms; or
    b) undertake further investigation including initiating a formal inquiry under the Biological Control Act, Environmental Protection (Impact of Proposals) Act and or Industry Commission.
6) Unanimous ARMCANZ agreement for declarations.
7) Gazettal of declarations of agent and target organisms by the Commonwealth Biological Control Authority.
8) Gazettal of declarations by State and Territory Biological Control Authorities. This requires amendments to legislation in some jurisdictions.

Where ARMCANZ is referred to this would currently be SCoPI. The Environmental Protection (Impact of Proposals) Act is now covered by the EPBC Act.

These types of changes need to be considered in relation to declarations under the State jurisdictions to check that the relevant committees etc. (eg ARMCANZ to SCoPI) have automatically transitioned within the State legislation. If not, then legislative amendments will be required prior to or along with the declarations.



Appendix 2b: Relevant provisions of the *Biological Control Act 1984*

Part II—Target organisms

12 Target organisms

1) Subject to and in accordance with this Part, organisms of a particular kind may be declared to be target organisms for the purposes of this Act.

2) Action for the declaration of target organisms in accordance with this Part may be commenced by:

    a. a unanimous recommendation to the Authority by the Council; or

    b. an application under section 13.

13 Target application

1) Where a person considers that organisms of a particular kind are causing harm in the Australian Capital Territory and are, or are likely to be, controllable by biological means, the person may make an application to the Authority for a declaration that organisms of that kind are target organisms for the purposes of this Act.

2) A target application shall be in writing signed:

    a. in the case of an application by a natural person—by the applicant; or

    b. in any other case—by a natural person authorized by the applicant to do so.

3) A target application in relation to organisms of a particular kind shall set out:

    a. particulars identifying the organisms;

    b. particulars of the reasons why the organisms are considered to be causing harm in the Australian Capital Territory;

    c. reasons why the applicant considers that the organisms are, or are likely to be, controllable by biological means; and

    d. such other particulars (if any) as are prescribed.

15 Referral of target application to Council

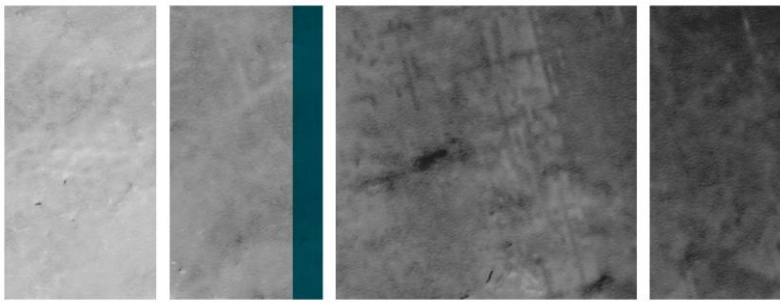
1) Subject to subsection (2), where a target application is received by the Authority, the Authority shall refer the application to the Council for its consideration.

2) The Authority is not required to refer to the Council a target application in respect of organisms of a particular kind if:

    a. other action to have them declared to be target organisms is being, or has been, taken under this Act; or

    b. action to have them declared to be organisms that may be controlled by biological means is being, or has been, taken under a relevant State law.

16 Notice of rejection of target application



17 Notice of proposed target organisms

1) Where the Council has unanimously recommended to the Authority that organisms of a particular kind should be target organisms, the Authority shall publish in the *Gazette* and in such newspapers or journals as the Authority considers appropriate a notice that the Authority is contemplating declaring those organisms to be target organisms.

2) Without limiting the generality of subsection (1), a notice under that subsection shall be published in each State and the Australian Capital Territory by being published in at least one newspaper circulating generally in that State or Territory.

3) A notice under subsection (1) in relation to organisms of a particular kind shall:

    a. set out particulars identifying the organisms;

    b. set out brief particulars of the reasons why the organisms are believed to be causing harm in the Australian Capital Territory;

    c. set out brief particulars of the benefits (if any) resulting from the absence of biological control of the population of the organisms;

    d. state that the Council has unanimously recommended that the organisms should be declared to be target organisms;

    e. where the recommendation of the Council followed a target application in relation to the organisms—inform the public that copies of the target application can be perused at a place specified in the notice; and

    f. invite any persons who object to, or support, the organisms being declared to be target organisms to submit written particulars of the grounds for that objection or support, as the case may be, to the Authority within the period of 6 weeks after the date of the publication of the notice in the *Gazette*, or within such further period as the Authority (either before or after the expiration of that period) allows.

4) Where the Authority publishes a notice under subsection (1) in relation to a target application, the Authority shall cause copies of the application to be available for perusal at the place specified in the notice in accordance with paragraph (3)(e).

18 Consideration of submissions relating to target organisms

The Authority shall consider any submissions in response to an invitation referred to in paragraph 17(3)(f).

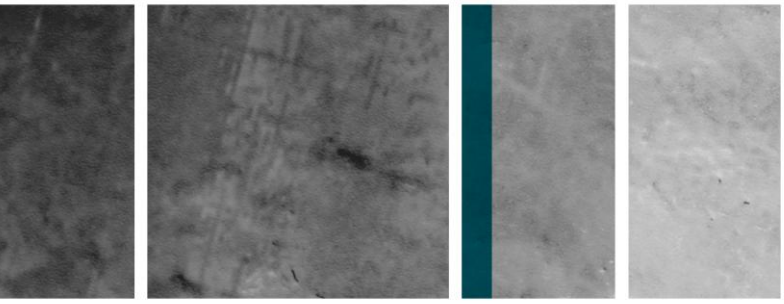
19 Inquiries relating to target organisms

1) Where the Authority, after:

    a. complying with sections 17 and 18 in respect of a target recommendation;

    b. consulting the Council regarding the appropriateness of action under this section in respect of that recommendation;

    c. considering the nature of, the proceedings in, and the findings of, any inquiry that the Authority considers relevant to the recommendation (which may be an inquiry conducted on behalf of a State); and



d. considering any reports relating to the recommendation made by any person or authority competent to do so that the Authority considers relevant;

considers that there is evidence that a person or the environment would be adversely affected by the control of organisms of the kind to which the recommendation relates but an adequate investigation or inquiry into the effect of such control has not been held, the Authority may:

e. direct that an inquiry under Part VII be conducted in respect of the recommendation; or

f. arrange for the Minister who administers the *Productivity Commission Act 1998* to refer the recommendation to the Productivity Commission for inquiry and report.

(1A) Action shall not be taken under paragraph (1)(e) or (f) in respect of a target recommendation unless the Council, upon being consulted in accordance with paragraph (1)(b), has unanimously recommended that the action be taken.

2) Where the Authority takes action under paragraph (1)(e) or (f) for an inquiry in relation to a target recommendation, the Authority shall not take any further action under this Act in relation to that recommendation unless and until the Authority has considered the report made as the result of that inquiry.

20 Declaration of target organisms

1) Where the Authority, after:

a. complying with the preceding provisions of this Part in relation to a target recommendation;

b. considering all reports and other matters relating to that recommendation that the Authority considers it appropriate to consider; and

ba. consulting the Council regarding the appropriateness of action under this section in respect of that recommendation;

is satisfied:

c. that organisms of the kind to which the recommendation relates are causing harm in the Australian Capital Territory;

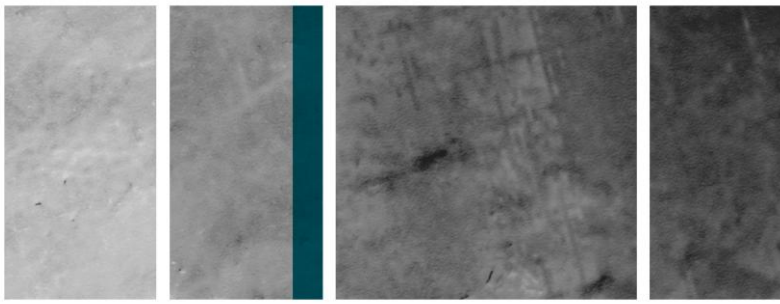
d. that organisms of that kind are, or that there is a probability that organisms of that kind are likely to be, controllable by biological means; and

e. that:

i. the control throughout Australia of organisms of that kind would not cause any significant harm to any person or to the environment; or

ii. any harm caused to persons or to the environment by the control throughout Australia of organisms of that kind would be significantly less than the harm caused, or likely to be caused, by failure to control organisms of that kind throughout Australia;

the Authority, subject to subsection (2), shall, by notice published in the *Gazette*, declare organisms of that kind to be target organisms for the purposes of this Act.



2) The Authority shall not make a declaration under subsection (1) in respect of a target recommendation unless the Council, upon being consulted in accordance with paragraph (1)(ba), has unanimously recommended that the declaration be made.

Part III—Agent organisms

21 Agent organisms

1) Subject to and in accordance with this Part, prescribed live organisms of a particular kind may be declared to be agent organisms for the purposes of this Act.

2) Action for the declaration of agent organisms in accordance with this Part may be commenced by:

    a. a unanimous recommendation made to the Authority by the Council; or

    b. an application under section 22.

22 Agent application

1) Where a person considers that the release of prescribed live organisms of a particular kind would result in the control of:

    a. target organisms of a particular kind or kinds; or

    b. organisms to which a target recommendation applies or target recommendations apply;

    (whether or not the organisms referred to in paragraph (a) or (b) can be controlled by existing agent organisms) the person may make an application to the Authority for a declaration that the first-mentioned organisms are agent organisms for the purposes of this Act.

2) An agent application in relation to organisms of a particular kind shall set out:

    a. particulars identifying the organisms;

    b. particulars of the possible ways in which the applicant considers that the release of the organisms could control the relevant population of target organisms; and

    c. such other particulars (if any) as are prescribed.

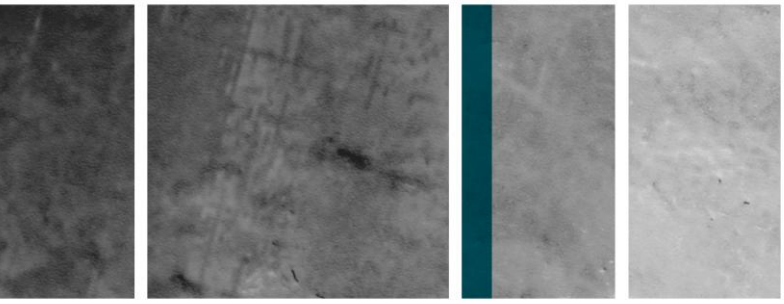
23 Withdrawal of agent application

1) A person who has made an agent application may withdraw that application at any time before the application is referred to the Council under subsection 24(1).

2) The withdrawal of an agent application is to be effected by the making of a request for withdrawal to the Authority in writing signed:

    a. in the case of an application by a natural person—by the person who signed the application or by the legal personal representative of that person; or

    b. in any other case—by the person who signed the application or by a person authorized by the applicant to sign the request.



24 Referral of agent application to Council

1) Subject to subsection (2), where an agent application is received by the Authority, the Authority shall refer the application to the Council for its consideration.

2) The Authority is not required to refer to the Council an agent application in respect of organisms of a particular kind if:

    a. other action to have them declared to be agent organisms is being, or has been, taken under this Act; or

    b. action to have them declared to be organisms that may be released to control the population of other organisms is being, or has been, taken under a relevant State law.

25 Notice of rejection of agent application

1) If the Council, after considering an agent application referred to it by the Authority, informs the Authority that it does not recommend that the organisms to which the application relates should be agent organisms, the Authority shall cause to be given, in such manner as the Authority considers appropriate, to the person who made the agent application and to the persons (if any) who made a later agent application in respect of those organisms notice in writing that the Council does not recommend that those organisms should be agent organisms.

2) A notice under subsection (1) shall:

    a. if reasons have been given by the Council for not recommending that organisms to which the notice relates should be agent organisms—set out those reasons; and

    b. if there are circumstances in which, in the opinion of the Authority, an agent application in relation to those organisms might result in a recommendation by the Council that those organisms should be agent organisms—specify those circumstances.

26 Notice of proposed agent organisms

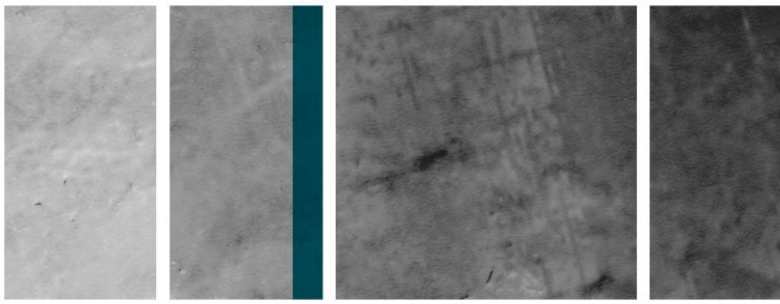
1) Where the Council has unanimously recommended to the Authority that prescribed live organisms of a particular kind should be agent organisms, the Authority shall publish in the *Gazette*, and may publish in such newspapers or journals as the Authority thinks appropriate, a notice that the Authority is contemplating declaring those organisms to be agent organisms.

2) A notice under subsection (1) in relation to organisms of a particular kind (in this subsection referred to as the ***relevant organisms***) shall:

    a. set out particulars identifying the relevant organisms;

    b. specify the organisms which it is intended to control by the release of the relevant organisms;

    c. set out brief particulars of the manner in which the relevant organisms would control the organisms specified in the notice in accordance with paragraph (b);



d. state that the Council has unanimously recommended that the relevant organisms should be declared to be agent organisms;

e. where the recommendation of the Council followed an agent application in relation to the organisms—inform the public that copies of the agent application can be perused at a place specified in the notice; and

f. invite any persons who object to, or support, the relevant organisms being declared to be agent organisms to submit written particulars of the grounds for that objection or support, as the case may be, to the Authority within the period of 6 weeks after the date of the publication of the notice in the Gazette, or within such further period as the Authority (either before or after the expiration of that period) allows.

3) Where the Authority publishes a notice under subsection (1) in relation to an agent application, the Authority shall cause copies of the application to be available for perusal at the place specified in the notice in accordance with paragraph (2)(e).

4) Where the Council has recommended to the Authority that 2 or more kinds of organisms should be agent organisms for the purpose of the control of the same population of particular organisms, a notice under subsection (1) relating to one of those kinds may be combined with a notice under that subsection relating to the other kind or kinds.

27 Consideration of submissions relating to agent organisms

The Authority shall consider any submissions in response to an invitation referred to in paragraph 26(2)(f).

28 Inquiries relating to agent organisms

1) Where the Authority, after:

a. complying with sections 26 and 27 in respect of an agent recommendation;

b. consulting the Council regarding the appropriateness of action under this section in respect of that recommendation;

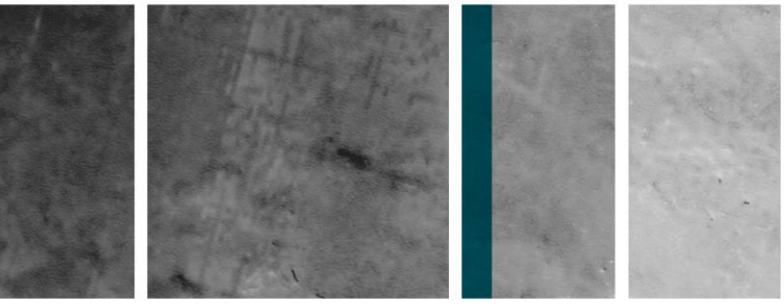
c. considering the nature of, the proceedings in, and the findings of, any inquiry that the Authority considers relevant to the recommendation (which may be an inquiry under Part VII in respect of a target recommendation or an inquiry conducted on behalf of a State); and

d. considering any reports relating to the recommendation made by any person or authority competent to do so that the Authority considers relevant;

considers that there is evidence that a person or the environment would be adversely affected by the release of organisms of the kind to which the recommendation relates but an adequate investigation or inquiry into the effect of such a release has not been held, the Authority may:

e. direct that an inquiry under Part VII be conducted in respect of the recommendation; or

f. arrange for the Minister who administers the *Industries Assistance Commission*



Act 1973 to refer the recommendation to the Industries Assistance Commission for inquiry and report.

(1A) Action shall not be taken under paragraph (1)(e) or (f) in respect of an agent recommendation unless the Council, upon being consulted in accordance with paragraph (1)(b), has unanimously recommended that the action be taken.

2) An inquiry by virtue of paragraph (1)(e) or (f) in respect of an agent recommendation that recommends that organisms of a particular kind should be declared to be agent organisms if organisms to which a target recommendation applies are declared to be target organisms and an inquiry by virtue of paragraph 19(1)(e) or (f), as the case may be, in respect of that target recommendation may be conducted as if they were one inquiry.

3) Where the Authority takes action under paragraph (1)(e) or (f) for an inquiry in relation to an agent recommendation, the Authority shall not take any further action under this Act in relation to that recommendation unless and until the Authority has considered the report made as the result of that inquiry.

29 Declaration of agent organisms

1) Where the Authority, after:

a. complying with the preceding provisions of this Part in relation to an agent recommendation;

b. considering all reports and other matters relating to that recommendation that the Authority considers it appropriate to consider; and

ba. consulting the Council regarding the appropriateness of action under this section in respect of that recommendation;

is satisfied:

c. that the release of organisms of the kind to which the recommendation relates (in this subsection referred to as the ***relevant organisms***) could result in the control of target organisms of a particular kind or kinds in the Australian Capital Territory; and

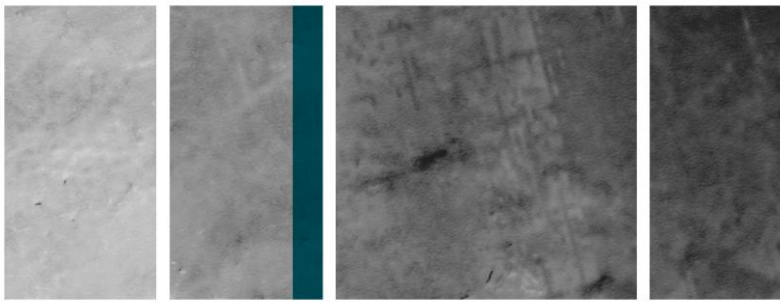
d. that:

i. the release of the relevant organisms would not cause any significant harm to any person or to the environment, other than the harm (if any) resulting from the control throughout Australia of target organisms of that kind or those kinds; or

ii. any harm caused to persons or to the environment by the release of the relevant organisms, other than the harm (if any) resulting from the control throughout Australia of target organisms of that kind or those kinds, would be significantly less than:

a) the harm caused, or likely to be caused, by failure to control target organisms of that kind or those kinds throughout Australia; and

b) where target organisms of that kind or those kinds can be controlled by the release of other organisms or otherwise than by biological means—the harm (if any) caused, or likely to be caused, by controlling target organisms of that kind or those kinds throughout



Australia by the release of those other organisms or by those other means;

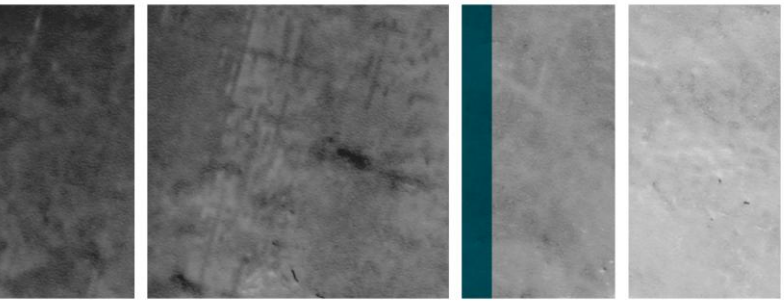
the Authority, subject to subsection (1A), shall, by notice published in the *Gazette*, declare the relevant organisms to be agent organisms for the purposes of this Act.

1A) The Authority shall not make a declaration under subsection (1) in respect of an agent recommendation unless the Council, upon being consulted in accordance with paragraph (1)(ba), has unanimously recommended that the declaration be made.

2) A notice under subsection (1) declaring organisms of a particular kind to be agent organisms may set out conditions under which those organisms may be released, which conditions may be or include:

a. conditions specifying the persons who may release those organisms; or

b. conditions specifying the circumstances in which those organisms may be released.



3. Australian Pesticides and Veterinary Medicines Authority (APVMA)

This summary comes primarily from the APVMA website (www.apvma.gov.au) which contains an extensive amount of information relevant to its product registration processes.

Background

In 1991, the Commonwealth, States and Territories agreed to establish a new National Registration Scheme (NRS) for agricultural and veterinary chemicals to replace a previously fragmented regulatory structure. The APVMA was established in 1993 as an independent statutory authority of the Australian Government to undertake the commonwealth's regulatory roles under the NRS.

The governing legislation for the APVMA is contained within the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the Agricultural and Veterinary Chemicals Code (the Agvet Code) which is a schedule of the *Agricultural and Veterinary Chemicals Code Act 1994*.

Role of APVMA

The APVMA is responsible for the regulation of the manufacture of agricultural and veterinary chemicals throughout Australia and for their control up to and including the point of retail sale. This includes responsibility for their registration and quality assurance and compliance during manufacture and sale.

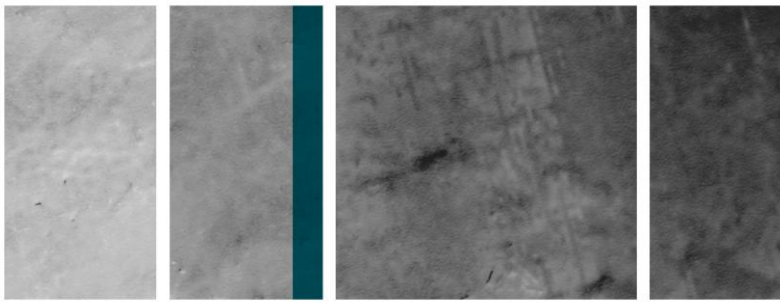
Before an agricultural or veterinary chemical product can be legally supplied, sold, or used in Australia it must be registered by the APVMA. The APVMA has the responsibility to ensure that all agricultural and veterinary chemicals registered for use in Australia are suitably formulated and properly labelled and when used according to instructions are:

- Safe to the host, the user, consumers and the environment.
- The product does the job that it claims it shall do.
- It is not unduly prejudicial to trade.

For farmers, food producers, the chemical industry and the general public, registration means that the product is safe and will work when used according to the label.

Biological or natural products are sometimes used for the treatment of, or protection from pests and diseases. In cases where a biological product claims to control a particular condition or have beneficial effects, registration is required.

The States and Territories maintain responsibility for control over use of the chemicals after retail sale. In relation to fish control products this means that the approval of an 'agent' must go through the APVMA process. Once this is completed its use may be regulated further under State and Territory legislation. In the case of a 'normal' agricultural or veterinary chemical this would be under 'use guidelines'. These provisions are unlikely to apply to the



use of CyHV-3 but some provisions of State and Territory Fisheries legislation may apply (See Chapter 5 below)

Why does CyHV-3 need to be considered under the Agvet code at all? There are probably a number of reasons for this. The most important being that it falls within the definitions under the Code while another good reason is that it provides for a structured process to evaluate the environmental and public health safety as well as the efficacy of the product in the same way that the public expects agricultural and veterinary chemicals to be evaluated prior to their approval for use.

In summary the APVMA process is effectively a very detailed environmental impact assessment process for the use of CyHV-3 as a biological control agent for carp.

APVMA evaluation of RHD

Munro and Williams (1994) produced a detailed coverage of the issues related to the assessment of RHD for use as a biological control agent for rabbits. They included coverage of the legislation that needed to be considered. This did not include any mention of the APVMA legislation. This is not surprising considering the *Agricultural and Veterinary Chemicals Code Act* only received assent in 1994, by which time their publication was probably in press.

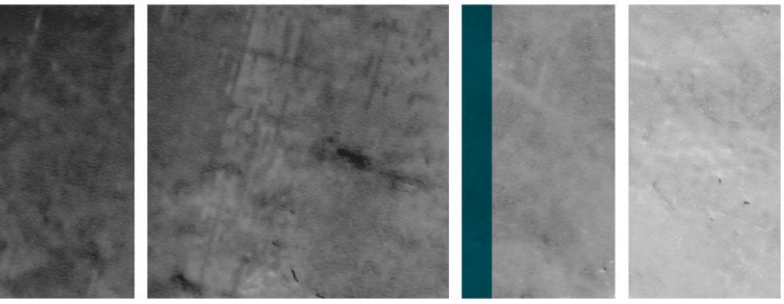
Some two years later, Bureau of Resource Sciences (1996) in reporting on the requirements of the Biological Control Act states as follows;

> *"The Minister for Primary Industries and Energy referred the deliberate release of RCD to the Minister for the Environment under the* Environment Protection (Impact of Proposals) Act 1974 *as an action which may have significant environmental impact…*
>
> *The Minister for Environment considered advice from the Environment Protection Agency, a notice of intention provided by the designated proponents, concurrent assessments under the* Biological Control Act 1984 *and the* Agricultural and Veterinary Chemicals Code Act 1994 *and determined that neither an Environmental Impact Statement nor a Public Environment Report was required."*

In other words there was already enough suitable information being collected to satisfy the environmental requirements under the environmental legislation. The APVMA assessment framework provides for a very thorough consideration of likely environmental impacts of the use of an agricultural or veterinary chemical and should serve the requirements of SEWPaC under the EPBC Act. However, this will need to be determined in the early stages of discussions.

APVMA process including data requirements.

The first decision within the APVMA process determines whether the product is an agricultural chemical or a veterinary chemical for the purposes of the Code. These two basic groups of products are evaluated in the same generally structured way but against slightly differing criteria. The definition has a number of aspects and is described in detail in the Agvet Code



Act. In relation to CyHV-3 the relevant clause is contained in Section 4.

Section 4 Definition of agricultural chemical product

1) This section defines what is meant by an agricultural chemical product for the purposes of this Code.

2) Subject to subsections (3) and (4), an agricultural chemical product is a substance or mixture of substances that is represented, imported, manufactured, supplied or used as a means of directly or indirectly:

    a. destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, a place or a thing; or

    b. destroying a plant; or

    c. modifying the physiology of a plant or pest so as to alter its natural development, productivity, quality or reproductive capacity; or

    d. modifying an effect of another agricultural chemical product; or

    e. attracting a pest for the purpose of destroying it.

3) An agricultural chemical product includes a substance or mixture of substances declared by the regulations to be an agricultural chemical product.

4) An agricultural chemical product does not include:

    a. a veterinary chemical product; or

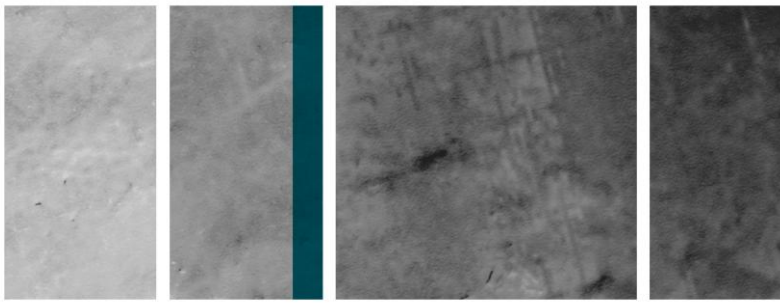
    b. a substance or mixture of substances declared by the regulations not to be an agricultural chemical product.

There are other specific inclusions and some specific exclusions which are in some cases relevant to fish control products. For example section (e) above would have the effect of declaring pheromones used as carp attractants as an agricultural chemical. However, there are some further sections to specifically include chemicals not clearly picked up under the definitions and also some specific exclusions of substances that would have been covered. One of the specific exclusions (Schedule 3 subreg 7(2) of Agvet Code Regulations 1994) states;

> *Any invertebrate pest management lure based on food and not containing any active constituent, and any vertebrate pest management lure*

The latter part of this would now specifically exclude the pheromone carp attractants developed by the IA CRC. However they would still need to comply with other criteria under State or Territory fisheries legislation.

As CyHV-3 would be considered an agricultural chemical the Agricultural Manual of Requirements and Guidelines (agMORAG) should be followed for the application process. The agMORAG consists of 5 Volumes as follows;



Volume 1: sets out the legal background to the National Registration Scheme. It also gives information on how to make an application to the APVMA and then how the APVMA manages the registration process.

Volume 2: describes the 25 different application categories so that applicants can select the correct category for their application.

The aim of Volume 2 is to enable applicants for approval of a new active constituent, or registration of a new agricultural or veterinary (agvet) chemical product, or approval of a label, or variations to a product, active constituent or label, to easily determine:

- the correct application category
- the fee and timeframe applicable to the application
- data requirements for the application.

Volume 3: gives details of the requirements and guidelines for each of the 10 data parts which might apply to different types of applications.

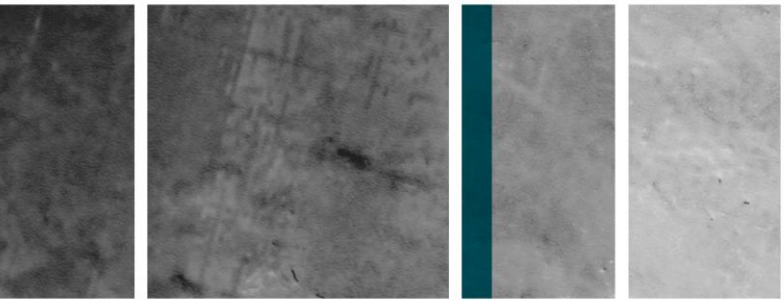
Volume 4: sets out guidelines for applications to register specific types of products.

Volume 5: contains the Ag Labelling Code which sets out requirements and best practice for product labels. Volume 5 also describes how the APVMA approves labels which will be attached to registered products.

Application category

As found in Volume 2, there are a number of different categories for applications under MORAG. These are as listed below;

Category	Type of application
1	Application for approval of a new active constituent and registration of a product and approval of the label (agricultural products only)
2	Application for approval of a new active constituent and registration of a product and approval of the label: modular
3–10	Application for registration of a product containing an approved active constituent and approval of the label (Categories 3 & 4 apply only to agricultural products)
11–14	Application to vary a product or label (Category 11 applies only to agricultural products)
15–17	Application for approval of an active constituent
18	Application for variation to approval of an active constituent
19–23	Application for a permit
24–25	Other applications



A decision tree is provided to determine the specific application category that should be used. The use of a virus to control pest fish falls into Category 2.

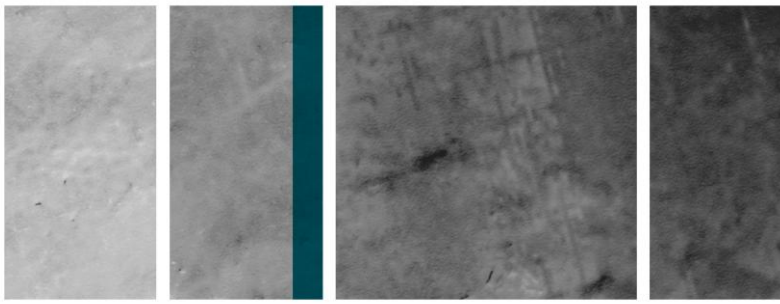
Also of relevance here is the Category 25 application category that can be used for pre-approval of a trial protocol. Certain components of the work on CyHV-3 require the use of specific procedures that need to be consistent and need to be appropriate for approval. In addition the effects of the virus on non-target species of native fish will be critical to gaining approval for release. Consequently a Category 25 application for pre-approval of some methods and of the protocol for choosing non-target species for testing will be submitted to APVMA for approval of the methods. Note that this is an approval of the methods not the results.

In considering whether to grant an application for registration of any product, the APVMA must be satisfied that the product will be safe and effective and that its label is suitable. As part of making this broad assessment, the APVMA conducts a number of separate evaluations. The data required to assess a product application are divided into 10 parts as follows:

1) Application Overview
2) Chemistry and Manufacture
3) Toxicology
4) Metabolism and kinetics
5) Residues and Trade considerations
6) Occupational health and safety
7) Environment
8) Efficacy and crop safety
9) Non-food trade assessment
10) Special data

The APVMA uses the services of a number of Australian and State government agencies as advisers to help with some of these evaluations. These include:

- the Office of Chemical Safety (OCS) of the Commonwealth Department of Health and Ageing which evaluates and reports on toxicology and metabolism studies and the occupational health and safety aspects of an application and recommends safety directions and occupational controls on use and advises on a Material Safety Data Sheet (MSDS).
- the Commonwealth Department of Sustainability, Environment, Water, Population and Communities (SEWPaC) which evaluates environmental data and recommends appropriate use controls and instructions for the product that will protect the environment, (eg for compliance with the EPBC Act)
- State and Territory departments responsible for agricultural and primary industries which evaluate and report on efficacy and target crop or animal safety data for new agricultural chemicals and new uses of registered products.
- In some cases the APVMA contracts this work out to other agencies such as universities, the CSIRO or to other experts



Data to be submitted for CyHV-3

In general terms the level of data required for a Category 2 application such as for CyHV-3 is the most extensive of any application. However, not all of the 10 Parts listed above will require data for CyHV-3 as they are not all relevant. If Parts or sub-parts are to be excluded, reasons will need to be given as to why they are not included. The standard data requirements for each of the Parts that are relevant are included below. These should be evaluated in more detail initially by the proponent but then probably also in consultation with the APVMA and/or the other relevant agencies as soon as possible so that any gaps in present data are identified. The data requirements are presented in modular form in the agMORAG. There is a very large amount of information on each section so it is best to follow the agMORAG numbering and terminology (not always the same as the part numbers given above) to avoid confusion.

Part 2. Chemistry and Manufacture

It could probably be argued that Module 2.2, which includes new biological products, could be used rather than Module 2.1 which is supposed to cover Category 2 applications. However there is very little difference between the data requirements for the 2 modules in practice so the slightly more comprehensive Module 2.1 is included.

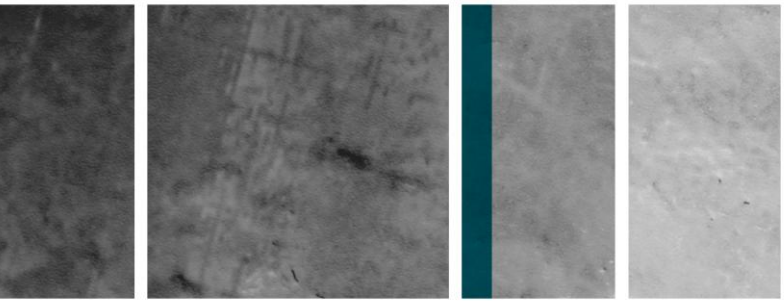
A Chemistry data package for comprehensive assessment requires submission of all of the following data, or submission of valid scientific argument not to submit certain data:

Active constituent

- identification (common name, chemical name, molecular and structural formula, spectral data, physical and chemical properties);
- stability data;
- manufacturer and site of manufacture;
- manufacturing process (including quality control, impurities);
- declaration of composition (specifications);
- batch analysis data;
- analytical methods;
- validation data;
- analytical reference standards;
- packaging

Product

- active constituent standard;
- product details:
    - distinguishing name;
    - formulation type;



- formulator and site of formulation;
- formulation composition;
    - non-active constituent specifications;
- manufacturing process (including quality control);
- physical and chemical properties;
- product specifications;
- batch analysis data;
- stability data;
- in-use stability data (where relevant);
- analytical methods;
- validation data;
- packaging;
- draft label

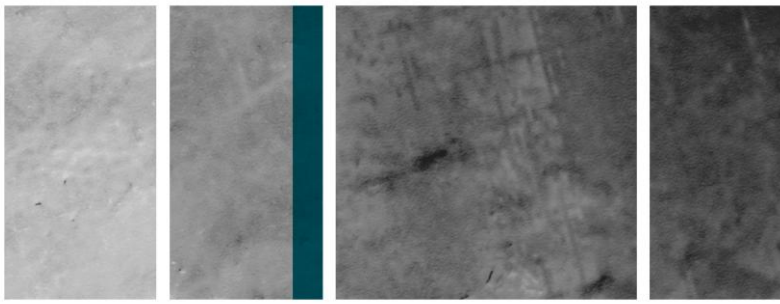
The data requirements for each of these components are explained in even more detail in Part 2 of the agMORAG.

Part 3. Toxicology

Included below is the information that would normally be required under this section. It relies firstly on information submitted in relation to Chemistry and Manufacture and also on the following section on Metabolism and Kinetics. Large parts of this section are not likely to be required but this will warrant detailed discussions with APVMA and their advisors.

A Toxicology data package for comprehensive assessment requires submission of all of the following studies, or submission of valid scientific argument not to submit certain studies:

- chemistry and manufacture (data Part 2);
- toxicokinetics and metabolism (data Part 4);
- acute toxicity studies:
    - studies on the active constituent;
    - studies on the product;
- short-term toxicity studies (repeat-dose studies of less than 90 days duration);
- sub-chronic toxicity studies (90 days to less than 12 months);
- long-term (chronic) toxicity studies (12 months or longer):
    - carcinogenicity studies;
    - chronic toxicity and/or carcinogenicity studies;
- reproduction studies;
- developmental (teratology) studies;
- genotoxicity studies



- additional studies
    - toxicity of metabolites and impurities;
    - other adverse effects;
    - toxicity of mixtures;
- human toxicological data;
- no-observed-effect level (NOEL);
- acceptable daily intake (ADI);
- acute reference dose (ARfD);
- first aid instructions and safety directions;
- toxicological database

The data requirements for each of these components are explained in more detail in Part 3 of the agMORAG.

Part 4. Metabolism and kinetics

As a virus, CyHV-3 will not produce chemical resides or metabolites and therefore data are probably not required in relation to this section, although this requires confirmation with APVMA.

Part 5. Residues and trade

Data are probably not required for CyHV-3 in relation to these sections although this requires confirmation with APVMA. An issue may arise with trade in that CyHV-3 is a notifiable disease and there may be some associated issue for trade in carp to any destinations where the disease is not already present.

Part 6. Occupational health and safety

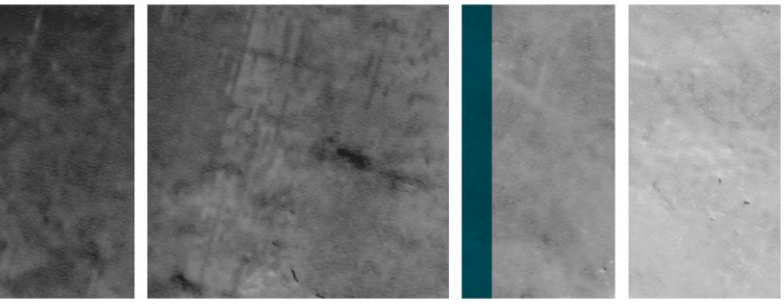
An OH&S data package for comprehensive assessment requires submission of all of the following data, or submission of valid scientific argument not to submit certain information:

Hazard:

- physical and chemical properties:
    - active constituent
    - product;
    - individual constituents;
- toxicology;

Occupational exposure:

- mixing and loading;
- product application;
- re-entry and re-handling;



- dermal absorption;

Risk management and workplace information:

- measures to control occupational exposure:
    - before and during end-use;
    - re-entry or re-handling
- product label;
- Material Safety Data Sheet (MSDS);
- training requirements;
- occupational exposure monitoring:
    - atmospheric monitoring;
    - health surveillance;
- tank mixing;
- contraindications

Risk assessment:

- margin of exposure (MOE);
- further requirements where the MOE is inadequate;
- risk assessment proposed by the applicant (acute and repeat dose)

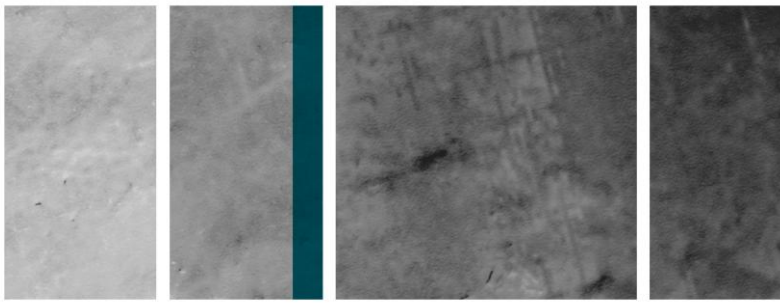
The data requirements for each of these components are explained in more detail in Part 6 of the agMORAG.

Part 7. Environment

An Environment data package for comprehensive, reduced or limited assessment requires submission of all of the following studies, or submission of valid scientific argument not to submit certain studies:

Environmental chemistry and fate

- assessment of the extent of, and potential for, environmental exposure:
    - amount of chemical to be used;
    - manufacturing plant of the active constituent;
    - formulating plant of the product;
    - use and application;
    - product disposal;
    - accidental release;
- physicochemical degradation:
    - hydrolysis;
    - photodegradation (aqueous, soil, degradation in air);
- biodegradation:



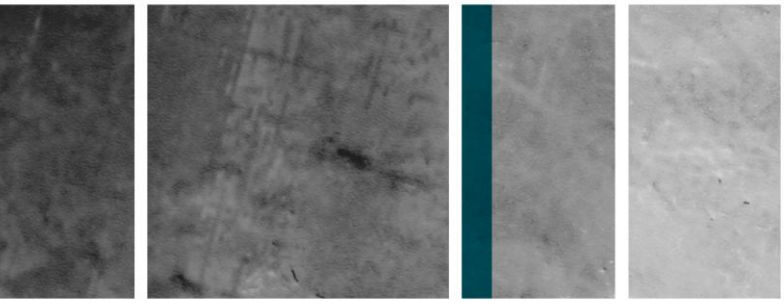
- soils (aerobic, anaerobic);
- water;

- mobility:
  - volatility;
  - adsorption/desorption;
  - leaching potential;
- field dissipation:
  - soils;
  - water;
  - air;
  - plants;
- accumulation/metabolism:
  - bioaccumulation in fish and aquatic organisms;
  - accumulation potential in soils;
  - metabolism in target animals;
  - other species e.g. birds, earthworms;
- modelling studies

Environmental toxicology

- wild birds, mammals and other vertebrates:
  - acute;
  - short-term;
  - special studies – chronic, reproduction, simulated or actual field testing;
- aquatic organisms (freshwater and marine):
  - acute (fish, microcrustacea, algae);
  - short-term (sub-chronic);
  - special studies — chronic, sediment, simulated or actual field testing
- non-target terrestrial invertebrates:
  - predators;
  - parasites;
  - bees;
  - earthworms and soil invertebrates;
  - soil micro-organisms;
  - other;
- non-target vegetation:
  - results from laboratory tests;
  - observations from field trials or efficacy tests;
- assessment of environmental hazard

The data requirements for each of these components are explained in even more detail in Part 7 of the agMORAG.



Part 8. Efficacy and crop safety

An Efficacy and Host Crop Safety data package for comprehensive assessment requires submission of all of the following Australian studies, or submission of valid scientific argument not to submit certain studies: It is expected that most of the crop safety issues would not be required in this section whilst some of the other parts such as safety for non-target species will be covered elsewhere.

Efficacy studies

- efficacy studies for every host and pest claimed on the label;
- studies to demonstrate the optimum application rate for each host / pest combination

Host crop safety studies

- safety to host crop including yield data;
- safety to following crops;
- safety to non-target crops;
- effects on taste of produce (organoleptic effects)

Other related studies

- compatibility / tank mix tests;
- studies conducted overseas;
- effects of residues on subsequent processing;
- animal welfare;
- safety to non-target animals;
- implications for resistance management;
- effects on other industries

The data requirements for each of these components are explained in more detail in Part 8 of the agMORAG.

Part 9. Non-Food Trade

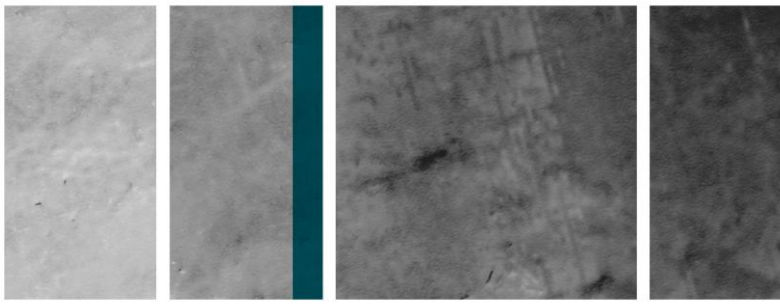
If data are required under this part they will relate to the risks to trade from transmission of the disease to other international jurisdictions through trade in carp.

Data specific to the relevant trade risk will be required if deemed necessary.

Further detailed information is contained in Part 9 of the agMORAG.

Part 10. Special Data

This section usually relates to new anti-biotic of GMO's and is unlikely to be required for CyHV-3 unless something is missed in the sections above.



Conditions of approval and registration

In approving an active constituent for a chemical product, or in registering a chemical product, or in approving a label for containers for a chemical product the APVMA may impose conditions as it thinks are appropriate: section 23 of the Agvet Code.

One condition of registration that the APVMA may impose on an agricultural or veterinary chemical product is that the chemical product is supplied only in a container of a kind prescribed in the Agvet Regulations. For this purpose, regulation 18 of the Agvet Regulations provides that a container for a chemical product must

a. be impervious to, and incapable of chemical reaction with, its contents when under conditions of temperature and pressure that are likely to be encountered in normal service;

b. have sufficient strength and impermeability to prevent leakage of its contents during handling, transport and storage under normal handling conditions;

c. if it is intended to be opened more than once - be able to be securely and readily closed and reclosed;

d. have sufficient excess capacity to prevent it from breaking if its contents expand during handling, transport or storage; and

e. enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot

    i. harm any person; or
    ii. have an unintended effect that is harmful to the environment

It is now usual for the APVMA to impose a condition of registration on an agricultural or veterinary chemical product to the effect that the chemical product can be supplied only in a container of a kind prescribed in regulation 18 of the Agvet Regulations.

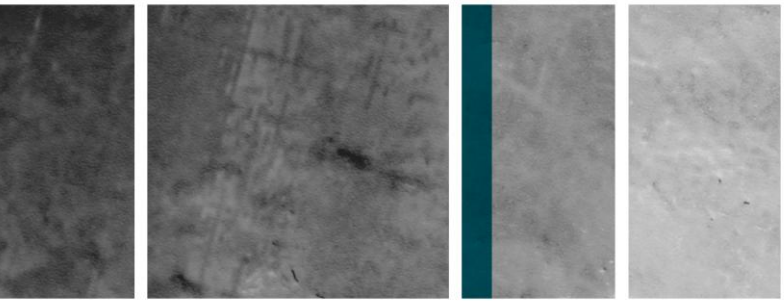
Section 36 of the Agvet Code further provides that a breach of a condition is grounds upon which the APVMA may suspend or cancel the approval or registration.

The APVMA will also have specific requirements regarding labelling of the product containers which must include certain details regarding the contents of the containers and the prescribed conditions of use. This label is subject to approval during the registration process.

Public consultation

The Agvet Code (sections 12 and 13) requires the APVMA to publish a general notice in the APVMA Gazette about new active constituents being considered for approval and chemical products containing new active constituents being considered for registration. In the notice the APVMA is to invite written comment from the public on specific grounds on whether the application for approval of the active constituent or registration of the chemical product should be granted.

Additionally, if the product is to be used on a food-producing species, a Public Release



Summary (PRS) of the information provided in the application for registration is prepared and the public and relevant industry bodies are notified that the PRS is available on request.

Where trade issues have to be assessed in the registration of a new chemical product the APVMA publishes a Trade Advice Notice (TAN) in the Gazette seeking public comment, on trade grounds only, as to whether the application for registration of the product should be granted.

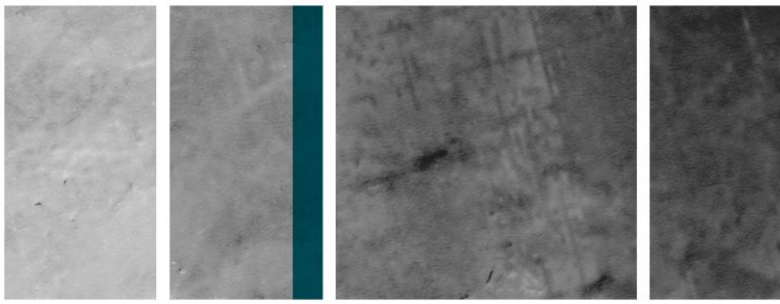
This public consultation process allows members of the public and relevant industry bodies to have an opportunity to raise matters of concern about human and environmental safety and, where relevant, trade. The APVMA must take into account any submissions received in response to public consultation notices before it makes a decision as to whether or not to grant an application for approval of an active constituent or an application for registration of a chemical product.

The potential for overlap of this process with the public consultation processes specified under the Biological Control Act will need to be considered to avoid duplication.

Time Frames

The Agvet Code regulations include timeframes for assessment of applications which give a general guide to the minimum time likely to be taken. Each of the Modules can be submitted separately so there is no need to wait until all information has been compiled. There is an initial screening process with no set timeframe which is designed to determine basic suitability of data. Then each Module has its own assessment time. Most of the major modules for CyHV-3 have a 12 month assessment time. There is then a 3 month finalisation period meaning that the minimum time for overall assessment would be 15 months, assuming the unlikely event that all Modules could be submitted at the same time.

However there is no reason why preparation of the data and submission of some sections could not proceed immediately at the same time as compliance with other legislative requirements is being undertaken.



4. Other Legislation

The legislative arrangements referred to in previous sections relate to specific processes that will need to be complied with if CyHV-3 is to be used as a biological control agent for carp in Australia. They are not only for fish related purposes but may apply more generally.

In Australia, the legislation relating specifically to fish and fisheries resources is contained in a number of different statutes under many different jurisdictions. Generally the legislation relating to international movement of fish, either into or out of Australia is contained in Federal legislation whilst administration of imported fish once inside the country is the responsibility of the states. Laws related specifically to pest, noxious or regulated fish species are covered under relevant Federal, State or Territory legislation. Management of freshwater resources as well as recreational and commercial fisheries (including aquaculture) of introduced and native species is primarily controlled by individual state or territory law usually also within specific fisheries legislation.

There are many other laws and rules that can impact on the management of fish and fisheries such as environmental, health and planning legislation.

The following summaries are intended for general information only and for more detailed explanations the appropriate acts, regulations etc should be consulted directly or expert legal advice sort.

Commonwealth

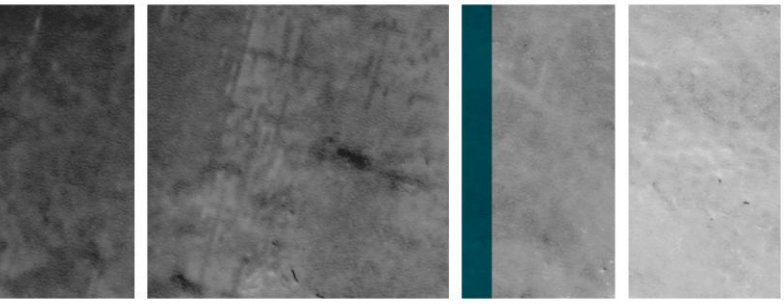
Under the Environmental Protection and Biodiversity Conservation Act *1999* (Commonwealth) Division 6A, Section 301A 'Regulations for control of non-native species' the regulations may provide for the establishment and maintenance of a list of species, other than native species, whose members do or may threaten biodiversity in the Australian jurisdiction; or would be likely to threaten biodiversity in the Australian jurisdiction if they were brought into the Australian jurisdiction.

They may also make provision to:

- regulate or prohibit the bringing into the Australian jurisdiction of members of a species included in the abovementioned list and
- regulation or prohibition of trade in members of these species between States and Territories and
- the making and implementation of plans to reduce, eliminate or prevent the impacts of members of species included in the list on biodiversity in the Australian jurisdiction.

This legislation is administered by the Department of Sustainability, Environment, Water, Population and Communities (SEWPaC).

Further sections under the Act provide for the listing of species (including fish) that may be imported and under what conditions they may be imported. It also establishes processes for review of, and additions to this list.



Fish imports, primarily for the aquarium trade, may come directly into any port in Australia although this is primarily done through Sydney, Melbourne and Brisbane. On arrival they are subject to inspection by AQIS on behalf of SEWPaC.

Commonwealth fisheries are managed by AFMA under the Fisheries Management Act 1991 with some aspects also coming under the Torres Strait Fisheries Act 1984. Commonwealth managed fisheries are all marine although some marine fisheries and all freshwater fisheries are under state control.

State legislation

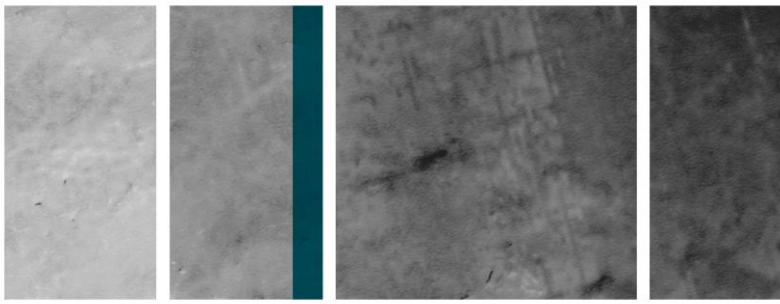
Once imported fish have been released from quarantine they come under State control. Fish that are already established in inland waters are also subject to State legislation. The State legislation usually applies to all 'fish'. The definition of fish is usually much wider than the strict taxonomic classification of fish, eg it may include crustaceans such as yabbies as well as other invertebrates that spend most of their life in water and also usually the eggs of these animals. The definitions section of each Act will define what is meant by 'fish' in each State.

There will also be different categories of fish with all fish subject to the general legislation and a specific group usually classified under 'noxious' or a category with similar intent. The general provisions of the legislation in each State as they relate to noxious fish are covered briefly below.

Queensland

Matters related to noxious fish are mostly covered under the *Fisheries Act 1994* (Qld), and the *Fisheries Regulations 2008*. Noxious fish are listed in Schedule 6 of the *Fisheries Regulation 2008*. Hybrids of fish identified in Schedule 6 are also included in the definition of a noxious fisheries resource. Relevant sections of the Act are as follows:

- Unless an appropriate permit is held, noxious fish cannot be bought into the State, can't be possessed, reared, sold or bought and can't be released or caused to be released into Queensland waters without an authority (Section 89). Similar restrictions apply to non-indigenous fisheries resources.
- The chief inspector may order an inspector to remove or destroy noxious, non-indigenous or aquaculture fisheries resources if they are a significant threat to other fisheries resources or fish habitats (Section 108). This order can be made even though other fisheries resources, plants or other property may be destroyed. The costs incurred by a fisheries agency in taking these actions may be payable by the person who committed the offence, additional to any penalty incurred.
- Alternatively, if the chief executive considers that there is no practicable way to remove or destroy such resources, he or she may order an inspector to take all action necessary to stop these resources from escaping.
- Compensation is payable only if the chief executive considers it appropriate in the circumstances.
- A person who unlawfully takes or possesses non-indigenous fish is required to immediately destroy the fish and notify an inspector of the destruction within two business days of taking or first possessing them; or immediately give the fisheries



resources to an inspector; or immediately notify an inspector of taking or possessing non-indigenous fish

New South Wales

Division 6 of Part 7 of the *Fisheries Management Act 1994* provides for fish to be declared as noxious fish by regulation.

Under the Act;

- A person may not possess noxious fish unless they have a permit
- This does not apply if they can prove that they did not introduce nor maintain the noxious fish in the water concerned
- A fisheries officer may seize and destroy any noxious fish
- If noxious fish are found on a property the owner or occupier may be required to take specific measures to remove the fish. If they do not comply a fisheries officer may take such measure as required to destroy the fish.
- No compensation is payable for seizure or destruction of noxious fish.

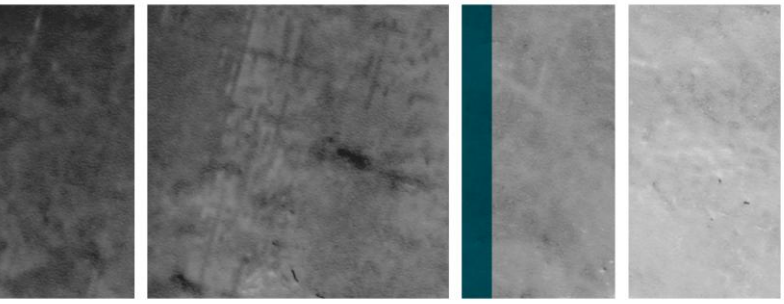
Fisheries Management (General) Regulations 2002 and amendments contain the fish that have been declared as noxious.

Victoria

Under the *Fisheries Act 1995* Section 75 provides for any aquatic species (other than protected aquatic species, mammals, reptiles, amphibians or birds) to be declared as noxious by an Order in Council.

- The declaration may apply to all or a specified part of Victoria
- A person may not bring any noxious species into Victoria or take, possess, sell or release them into any container or protected water.
- A permit may be issued to do anything with noxious fish that is prohibited under the Act.
- If a person knows of the existence of a noxious fish they must notify the Secretary
- An authorised officer may seize and destroy any noxious fish
- If noxious fish are found on a property the owner or occupier may be required to take specific measures to remove the fish. If they do not comply an authorised officer may take such measures as required to destroy the fish.
- The Secretary may order the destruction of noxious fish in any protected waters and specify the means and the persons who may do this.
- There is no penalty if a person kills a noxious fish immediately after it is taken.

The Fisheries Act also provides for the preparation of a Management Plan for a noxious aquatic species consistent with the provisions of the Act.



Tasmania

In Tasmania noxious fish are covered under the *Inland Fisheries Act 1995* and in Schedule 1 of the *Inland Fisheries (Controlled Fish) Order 2007* (S.R. 2007, No. 120).

- It is an offence to possess or sell noxious fish without an authority.
- A fisheries officer may seize and destroy any live noxious fish, or take possession of any fish the officer reasonably suspects are noxious.
- The Minister may, by notice in writing, require any person in possession of noxious fish to take specified measures to destroy the fish.
- If that person does not comply with the order, a fisheries officer may take appropriate measures to destroy any live noxious fish.
- In either case, compensation is not payable for the seizure or destruction of noxious fish.

South Australia

In South Australia, it is an offence to bring aquatic resources of a noxious species that have been kept apart from their natural habitat into the State, or to purchase, sell, deliver, possess or be in control of such species, except as authorised by a permit issued under the (SA) Fisheries Management Act 2007 Also, it is an offence to release into any waters exotic fish that have been kept outside their natural habitat except for fish of a prescribed class which are released under the authority of a permit

Western Australia

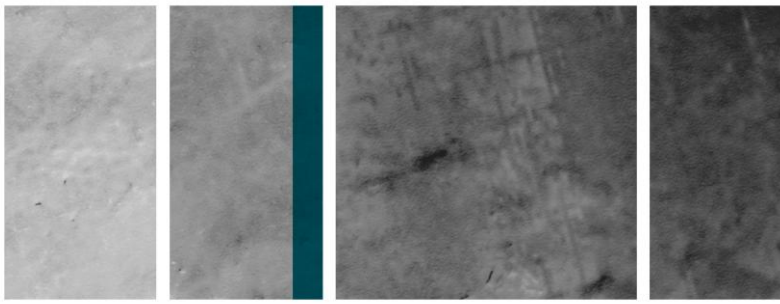
Noxious fish are covered under the Fish Resources Management Act 1994 and the Fish Resources Management Regulations 1995 - Schedule 5.

It is an offence in any area where fish are prescribed as noxious to:

- keep, breed, hatch or culture any noxious fish;
- possess noxious fish;
- consign or convey noxious fish;
- release noxious fish into any waters; or
- put any noxious fish into a container or receptacle in which it might remain alive.
- In addition, it is an offence to bring any noxious fish into the State, or move noxious fish from one area of the State to another. A fisheries officer may, by notice in writing, require a person to deliver or destroy all noxious fish in their possession, or to produce evidence that the fish have been destroyed. Where a person fails to comply with the notice, a fisheries officer may seize and destroy the fish. Compensation is not payable for either the loss or damage to the fish or for damage to other property arising from the destruction of the fish.

Northern Territory

Matters related to noxious fish are covered under the Northern Territory of Australia Fisheries Act and the Fisheries Amendment (noxious fish and aquatic pests) regulations 2009



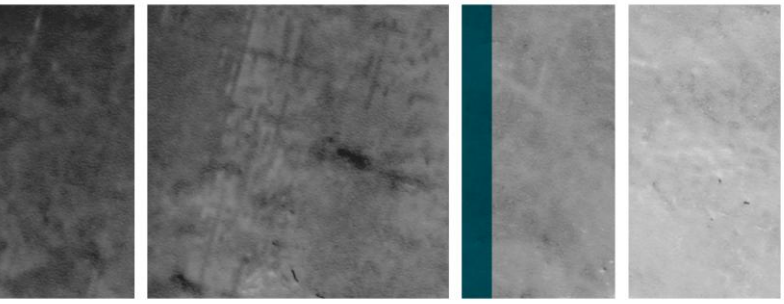
In the Northern Territory, it is an offence to import or be in possession of a noxious fish. It is also not permitted to bring in, or release in, the Territory any live aquatic life or possess or sell noxious fish. There is also provision for Fisheries Officers to search for and destroy noxious fish. A person who sees a noxious fish or aquatic pest must as soon as possible report and provide information about the sighting to the Director.

Other Provisions

This summary relates primarily to noxious species provisions as they are usually contained within discreet sections of State legislation (noxious fish). However there are a number of other provisions that will be relevant such as the taking or killing of fish by means other than those provided for by general licences. Introduction of a virus and its potential to pollute inland waterways for example by causing large scale fish mortalities and possible increases in biological oxygen demand would also be illegal under fisheries legislation as well as under state environment protection legislation and probably also human health provisions. These cannot be covered in full here but state agencies will need to consider these during the course of approvals for CyHV-3 release.

State Biological Control acts

As mentioned above the State Biological Control Acts are complementary to the Commonwealth *Biological Control Act 1984*. Once a declaration of a target species or agent is made under the Commonwealth legislation a similar declaration under the State Act is required but the referral and consultation processes do not have to be duplicated.



5. Approval Processes and Time Frames

It is very difficult to be specific about timeframes and information requirements when there is no directly applicable precedent for the processes. The case for release of rabbit haemorrhagic disease (RHD) for control of rabbits in Australia is often quoted as a comparable precedent. This is certainly true in some aspects particularly in relation to the use of the *Biological Control Act*, but due to the passage of time and changes to departmental structures and personnel, probably little else is comparable. For example, in considering the issues for the release of RHD almost 20 years ago, Munro and Williams (1994) put forward possible timelines for approval under the Biological Control Act suggesting that the process would take about 36 months. Almost 18 months of this was to be taken up by an EIS process which was not subsequently required during the approval process.

There have also been significant changes to agency structures as well as to referral requirements and council/committee structures since the RHD example. There is now most likely little corporate memory of the RHD process as well. In other words, we are starting with a blank slate, and staff within DAFF and APVMA are regarding this proposal as unique. Consequently, to propose a timeline without knowing the exact information requirements or the actual review and referral processes would not be particularly helpful. The best way to address this would be to initiate a process as follows;

A 'team' needs to be established under the auspices of the VPC and it first needs to familiarise itself with the processes in general terms. This team will require support and information from the IA CRC and related projects. As it is going to be responsible for the 'bigger picture' this team first needs to have a general understanding of the processes involved, ie;

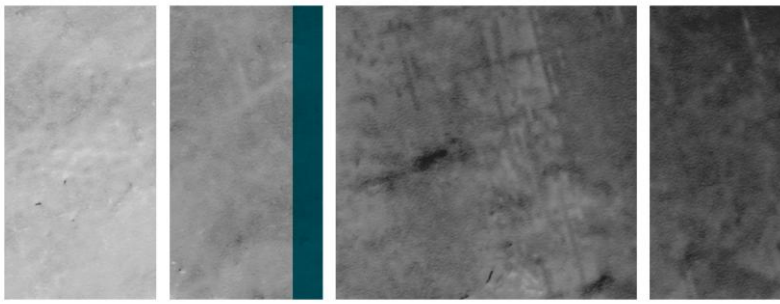
- What legislation is involved and who is responsible for it
- The general process for the proposal under each major piece of legislation
- An understanding of how the processes are related
- An understanding of the timelines involved
- An understanding of the roles of the agencies and committees
- An understanding of the information requirements of the processes

This should be done by convening one or more meetings and briefings. Once the team has this background it should then engage more widely.

Staff within DAFF are now aware that this process is in progress and they have already undertaken to commence their own process to determine who should be involved and what needs to be done.

Quarantine Act and Biological Control Act

The responsibility for both these Acts rests somewhere within DAFF and/or its Minister, although there are no clearly defined paths for assessment. The Quarantine Act takes



precedence and therefore it is probably best to determine the processes and information requirements for this first and then follow on to the Biological Control Act. The logical starting point would be to request a meeting via the Head of DAFF to determine the processes and map out a program, timelines and responsibilities under the Quarantine Act. The Biological Imports Program and Animal Biosecurity Branch within DAFF would certainly be involved in relation to the Quarantine Act approvals but the responsibility for the Biological Control Act requires clarification. The same Minister responsible for DAFF is also the Biological Control Authority under the Biological Control Act. He is likely to delegate his role but he should be formally contacted in the first instance. It would probably be feasible (and preferable) for one meeting to be convened to look at both Acts although different sections of DAFF would probably be involved. As the requirements of the EPBC Act are also central to both processes, representatives from SEWPaC should also be involved and so should APVMA as their process is essentially an EIS on CyHV-3.

A suggested process would therefore be to firstly request a meeting (workshop really) ensuring that attendees have knowledge of processes under both Acts.

An agenda for this meeting would include;

- Establish a referral group for the project
- Determine processes and detailed information requirements for Quarantine Act and Biological Control Act
- Determine requirements under EPBC Act
- Determine overlapping areas for these and other processes such as APVMA approvals
- Map possible timelines for various components
- Determine other interested parties who need to be involved
- Determine relevant committees (eg VPC, NBC) councils (eg Ministerial Councils) and authorities (eg Biological Control Authority or delegate) that must be involved.
- Refer back to all parties for confirmation of outputs and sign-up to the process and assess timelines

Convene a second meeting to confirm processes, stakeholders and timelines.

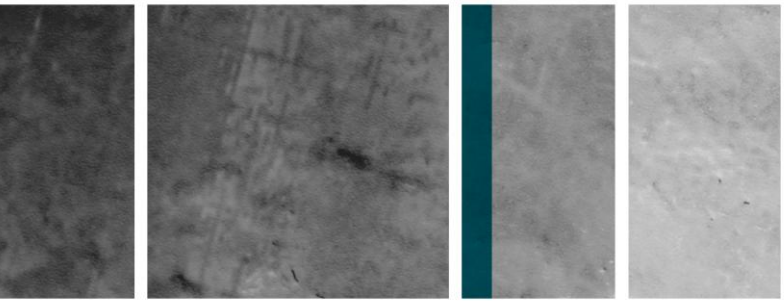
- Agree to processes
- Confirm timelines for each part and party

There will no doubt be a number of additional requirements that come out of these meetings that will need to be addresses, for example state processes. It is suggested that standard briefings be prepared for roll-out as required.

APVMA requirements

The process described above should ensure that APVMA assessment meshes with the other information requirements.

The APVMA process itself is more clearly established than the others. Whilst consideration of



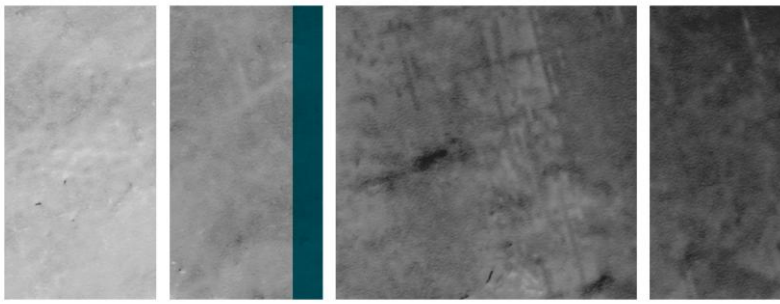
a virus under this legislation may be a little out of the ordinary, the processes are clearly established and regularly used. There are detailed published guidelines for data requirements and also some timelines for assessment, so that provides a good starting point. It is likely to be by far the most extensive in terms of data collection.

However, it is still unclear as to exactly what will be required in some sections. A response to the Category 25 application for approval of a trial protocol will help with this but several additional meetings to finalise and clarify these requirements are required.

- An initial meeting should be convened with the APVMA to discuss the data requirements in general.
- A meeting (or meetings) then needs to be held with APVMA and its various assessors to discuss each of the modules to finalise data requirements.

Australian Fisheries Managers Forum (AFMF)

The approvals processes are essentially run through federal agencies and national legislation. However there are state functions and state legislation that are also relevant. The Biological Control Act for example has parallel state legislation; APVMA approval goes up to point of sale and then state legislation is relevant. In the case of CyHV-3, point of sale is probably point of release of the virus. The state agencies will no doubt be picked up during various referrals and public consultations, but having the intentions and agreed processes placed clearly on the agenda of the AFMF is another necessary part of the approval plan.



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