Chemical Marker Registration

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Objectives

To clarify what regulatory requirements, if any, need to be met to allow for extension of the experimental fish marking techniques to broad scale use by hatcheries throughout the Murray-Darling Basin. Specifically, the project deliverables for this project are:

- Registration of calcein for marking fish in hatcheries
- Either registration or a detailed scoping study of further requirements for registration of alizarin red S, enriched barium isotope 137 and enriched strontium isotope 86.

Legislative framework

- Commonwealth Legislation establishes national codes and standards
- State's Legislation designed to implement regulatory controls in accordance with these codes and achieve consistency between States.
- Three types of legislation and regulation important for this research – Animal research, Veterinary chemicals, and Food Safety.

Australian Pesticides and Veterinary Medicines Authority (APVMA)

- National Authority constituted to maintain an up to date register of chemicals used for agricultural and veterinary purposes.
- AgVet code
- Minor use permits
- Reviews
- Approvals
- www.apvma.gov.au

Food Standards Australia New Zealand (FSANZ)

- Australasian authority constituted to maintain an up to date set of food standards for the two countries
- Assessments of applications for new food standards or variations to existing standards
- Reviews of existing standards
- Intergovernmental agreements on responsibilities.
- www.fsanz.gov.au

Relevant State Agencies and Legislation

State	Regulation of Chemical Use	Regulation of Food Safety
NSW	NSW DPI, Stock Medicines Act 1989	NSW Food Authority, Food Act 2003
Vic	Vic DPI, Agricultural And Veterinary Chemicals (Control Of Use) Act 1992	Dept Human Services - Food Act 1984
SA	PIRSA - Agricultural And Veterinary Products (Control Of Use) Act 2002	Dept of Health - Food Act 2001
Qld	QDPIF, Chemical Usage (Agricultural And Veterinary) Control Act 1988	Qld Health - Food Act 2006

Progress to date

- Relevant definitions – AgVet Code (Commonwealth)
- veterinary chemical product is a substance or mixture of substances that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly:

  (a) preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest; or

  (b) curing or alleviating an injury suffered by the animal; or

  (c) modifying the physiology of the animal:

  (i) so as to alter its natural development, productivity, quality or reproductive capacity; or

  (ii) so as to make it more manageable; or

  (d) modifying the effect of another veterinary chemical product.

Progress to date (continued)

- Rulings from APVMA, On 25 September 2006 the APVMA responded to the consultant. The APVMA ruling states in part (copy attached):
- Calcein ……; and Alizarin Red S…….; do not require registration under *the Agriculture and Veterinary Chemical Code Act 1994 legislation* as a Veterinary Chemical Product provided they are only supplied, used and represented as being suitable for use as part of a fish marking technique using a facilitated cutaneous absorption method called “osmotic induction”.
- NSW DPI and Vic DPI have advised that use is not captured by either the Stock Medicines Act or the Agricultural And Veterinary Chemicals (Control Of Use) Act 1992

Progress to date (continued)

- APVMA advised us to discuss the use of these chemicals with FSANZ
- FSANZ advised that:
- Fish may be considered as food
- Registration of calcein and alizarin red S as food additives may be required if there are quantifiable residues of these chemicals in the fish
- Residue data and toxicological data will be necessary for consideration of registration

What next?

- Clarify the FSANZ requirements.
- Go back to State agencies responsible for food safety to clarify whether any offence is committed if fish are marked and released into the wild (i.e. whether the Food Act in each State will be breached).
- If required to meet FSANZ and State Food Regulatory requirements then conduct further research on:
  - Quantifiable residues – develop techniques and conduct analyses (Est. cost $28K)
  - Toxicological data – conduct experiments to determine the effect of consumption of fish marked with calcein and alizarin Red S (Cost unknown)

Case study: US approval process for calcein

- INAD process: Calcein (SE-Mark)
- Compassionate Investigational New Animal Drug (INAD) Exemption #10-987
- Allows for research to gather efficacy data to support a new animal drug approval.
- Limited approval to use SE-Mark in experimental projects on fish less than 2 g in weight.
- 39 trials reported in 2005, 12 species of fish. Further trials conducted in 2006, and 2007 – One looking at inclusion of calcein into feed to induce marks on young hatchery fish.

Case study: US approval process for calcein

- INAD process for calcein has been running for three years with many technical studies (mostly govt. /industry partnerships) to back up the eventual application by the manufacturers for full registration as an aquaculture. Despite all this work over a number of years, SE-Mark is not yet registered for unlimited use in the US

- This sounds a note of caution for the Australian situation, where the amount of investigative work is much less, and the regulatory framework is different.

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