Question: 14

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: OH&S Investigations
Proof Hansard page: 6 (28/05/2013)

Senator BACK asked:

Dr Bryce: As part of the registration of the product an assessment was carried out by the Office of Chemical Safety in the department of health. They assess occupational health and safety risks and their recommendation was that the product was safe to use from an occupational health and safety perspective. There have been some reports of operators suffering from headaches, but when they have been investigated by us we have not been able to establish that there has been any causal connection between the use of the product and the symptoms that were shown. Very few cases have been reported.

Senator BACK: On notice, would you be able to give us more details of those that you might have had a look at or investigated. So it would fall to your agency to undertake those investigations, would it, rather than Health or—

Answer:

Tri-solfen was available for use on lambs to provide pain relief following mulesing, under Australian Pesticides and Veterinary Medicines Authority (APVMA) permit, from September 2005 until its registration in December 2011. During this period, over 500 000 sheep were treated with this product, and reporting of adverse experiences was mandatory. In the APVMA’s Public Release Summary published in October 2011, the APVMA noted five reports of possible adverse reactions in humans. Following investigation, one of the reports, a case of skin irritation reported in 2010, was classified as possibly related to the use of the product. None of the other adverse experiences were attributed to the use of the product.

Since Tri-Solfen was registered in December 2011, there have been no further adverse experience reports involving the product submitted to the APVMA’s Adverse Experience Reporting Program.
Question: 15

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Tri-Solfen
Proof Hansard page: 6-7 (28/05/13)

Senator BACK asked:

Dr Bryce: Some of the allegations that trisulfyn is causing health problems.
Senator BACK: So they have not made them directly to you?
Dr Bryce: Yes.
Senator BACK: They have?
Dr Bryce: No, I am saying that it is correct that they have not.
Senator BACK: Okay. But actual cases of people themselves believing themselves to be affected adversely as you say, with headaches or whatever the symptoms are, you have had none or very few?
Dr Bryce: Very few. If you like, we can take it on notice and give you the exact information on that.

Answer:

Since Tri-Solfen was registered in December 2011, there have been no adverse experience reports involving the product submitted to the Australian Pesticides and Veterinary Medicines Authority’s Adverse Experience Reporting Program.
Question: 16

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Diuron
Proof Hansard page: 11-12 (28/05/13)

Senator MACDONALD asked:

Senator IAN MACDONALD: I understand that in particular Ingham canegrowers and certainly the Canegrowers organisation generally is making further submissions in relation to the use of diuron because of the reason I mentioned before—the cost of alternatives is just prohibitive and it will be another nail in the coffin of one of Australia's rural industries. There have been complaints to me that the research done by GBRMPA and others was done at times of flooding and at peak tides that create a sort of a false high reading.

Dr Bhula: I would have to take that on notice. I could not comment on that. But we have said that, when we completed the review, based on any monitoring information that would come through in the next three to five years under any work that is done under the Reef Rescue plan or through the Great Barrier Reef Marine Park Authority, we would reconsider again. We have completed this part of the review. However, we would rely on future monitoring information and data to look at the chemical again if that were the situation.

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) did not receive any research results from Great Barrier Reef Marine Park Authority (GBRMPA) for the review of diuron. The assessment of diuron did consider a large amount of monitoring data from both agricultural and marine areas in Queensland, NSW and Victoria, much of which was generated post the Reef Rescue initiative. The data were generated from both normal flow conditions as well as those at times of flooding.

The diuron review conclusions were based on the assumption of normal flow conditions. If the conclusions had been based on the modelled values from peak flood conditions, many of the uses that are no longer permitted could have been retained. The Department of Sustainability, Environment, Water, Population and Communities’ (SEWPaC) assessment noted that flood conditions will not always result in the highest in-stream concentration due to dilution and therefore the more conservative and realistic normal flow conditions were used.

Note: Canegrowers was a key participant in the review of diuron through the submission of information as well as direct liaison with the APVMA. Since the completion of the diuron review in November 2012, the APVMA has not received any submissions from either Ingham canegrowers or Canegrowers in relation to the outcomes of the diuron review.
Question: 17

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: FSANZ Carbendazim Risk Assessment
Proof Hansard page: 14 (28/05/13)

Senator XENOPHON asked:

Ms Arthy: The only role we played is that we had a proposal in place at the time that was going through the WTO through an SPS notification. Based on the presentations we had from Food Standards, we chose not to act to remove that standard at that time, to allow Food Standards time to do their own risk assessment and put a limit in place.

Senator XENOPHON: And what has happened to that risk assessment? While you say it is a matter for Food Standards Australia New Zealand there is obviously an exchange of information between the two entities.

Ms Arthy: It is very informal because it does not relate to the approved use of carbendazim in Australia. What happened was that Food Standards did their own risk assessment. There was a public notification of the new limit that they would set, and I understand—but we would have to take this on notice or talk to Food Standards—there is a new limit in place now.

Senator XENOPHON: If you could take it on notice, because I am aware that I only have another minute or so.
Ms Arthy: Okay.

Answer:

Question: 18

**Division/Agency:** Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

**Topic:** Chemical Use for Goats

**Proof Hansard page:** Written

**Senator WILLIAMS asked:**

There appears to be a considerable difference of opinion between APVMA and the companies that produce anthelmintics on the potential market for chemical use on goats. The size of the goat industry does not reflect the potential market for chemicals. In NSW the majority of goats are in the dryer western areas and do not contribute to the market for chemicals. Is APVMA aware that less than 10% of goats in Australia are regularly treated with anthelmintics?

**Answer:**

The Australian Pesticides and Veterinary Medicines Authority does not have data on the proportion of goats in Australia that are regularly treated with anthelmintics.
Question: 19

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Chemical Use for Goats
Proof Hansard page: Written

Senator WILLIAMS asked:

Would recognition of the low percentage of goats actually available to the drench market change APVMA’s attitude to the classification of goats as a minor species?

Answer:

No.
Senator HEFFERNAN asked:

With regards to Answer 1 (Feb Estimates), does the APVMA believe that “Gloricide” satisfies the definition of an Agricultural Chemical Product? If no, please explain why. If yes, please explain why the APVMA has allowed this Agricultural Chemical Product to continue without a valid Permission under Permit 11463 or Registration.

Answer:

No.

The name ‘Gloricide’ has been used to describe a tank mix of two registered agricultural products containing metsulfuron-methyl and 2,4-D. The Australian Pesticides and Veterinary Medicines Authority has issued a permit to Biosecurity Queensland that allows the use of a range of herbicides for the control of environmental weeds in non-agricultural areas in Queensland (Permit 11463) that includes products containing these active constituents.
Question: 21

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Should “Gloricide” require APVMA Approval or Registration as it appears to satisfy your definition and the Products MSDS claims to approve mixing up different chemical formulas together without Label Approvals or Permit approvals or a Product Registration or pH or volatility or synergistic compounds risks or information, not a research or trial basis but as a Region Wide Program? Is this correct?

Answer:

No.

As previously stated in the answer to part 2 of question 46 from Additional Budget Estimates February 2013:

“A tank mix of registered chemical products is not itself another chemical product. The making of a tank mix is not an offence under state control of use legislation, unless product labels specifically prohibit mixing of one product with another.”
Senator HEFFERNAN asked:

The MSDS for the Agricultural Chemical Product commercially named “Gloricide” by the SCRC, identifies Sunshine Coast Regional Council as the Official Supplier of the 'Product'. The MSDS fails to disclose any relevant Health or Environmental Information and declares and Labels the product 'Non Dangerous and Non Hazardous'. SCRC are the Designers, Manufactures, Suppliers, Principal Contractors and Regulators of 'Gloricide'. Is SCRC in a conflict of interest in all of the above when Contractors who refuse to use Councils latest great new product are dismissed for not using the product due to WH&S and Environmental Law.

Answer:

This is a question for the Sunshine Coast Regional Council.

Note that the answer to Part 6 of Question 46 from Additional Estimates February 2013 stated:

“‘Gloricide’ is not a registered chemical product. The department understands that it is a name used by some people to refer to a tank mix of registered chemical products approved for certain uses in Queensland under a permit. The MSDS in question was prepared to satisfy the relevant state WorkSafe authority. As such, it is inappropriate for the APVMA to provide specific comment.”
Senator HEFFERNAN asked:

Did APVMA issue a Permit to SCRC to manufacture and use Gloricide by SCRC where the product is reasonably likely to enter waterways and aquatic areas? If so, who and where? The APVMA has documented how approval to mix chemicals is permitted such as Permit 10540. Permit 11463 does not provide instructions/permission on mixing chemicals, thus does not permit mixing. Is this correct?

Answer:

No. A permit was issued to Biosecurity Queensland that allows the use of a range of herbicides for the control of environmental weeds in non-agricultural areas in Queensland (Permit 11463).

The name ‘Gloricide’ has been used to describe a tank mix of two registered products containing metsulfuron-methyl and 2,4-D. These products are listed in Permit 11463.

No. Permit 11463 does not prohibit mixing of products.
Question: 24

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

What is the difference between a 'mixture of chemicals' and 'tank mixture' as per your answer to Question 2 (Feb Estimates)? Is there any difference? Is there a significantly different Risk Profile to be considered?

Answer:

There is a difference between a 'tank mixture' and a 'mixture of chemicals'. A ‘tank mixture’ is the colloquial term for the simultaneous application of a number of different registered chemical products, by combination/mixing in a tank by an operator, as permitted by the label instructions of the relevant registered products or by Australian Pesticides and Veterinary Medicines Authority permit, and the laws of the State or territory in which is it applied.

A ‘mixture of chemicals’, otherwise referred to as ‘a mixture of [chemical] substances’, is the result of combining two or more chemicals in their concentrated form and is an agricultural chemical product when it is represented, imported, manufactured, supplied or used as a means of directly or indirectly:

- 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
- destroying a plant; or
- modifying the physiology of a plant or pest so as to alter its natural development, productivity, quality or reproductive capacity; or
- modifying an effect of another agricultural chemical product; or
- attracting a pest for the purpose of destroying it.

The risk profile of a 'tank mixture' is generally considered to be lower than the formulated products as it is diluted for use. Where tank mixing may pose an unacceptable risk, the label instructions will preclude mixing of specific chemicals.
Question: 25

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Question 3 (Feb Estimates) APVMA claim that using 2,4-D or Metsulfuron methyl or any product on Permit 11463 may breach State Laws in relation to WH&S, Environment etc. and thus the need for the Federal Permit. Is the use of Gloricide, 2,4-D or Metsulfuron methyl in and around Aquatic Areas a breach of the respective Product Labels and MSDS's and thus a breach of perhaps every possible Federal and International Law on Herbicide Use, Administration and WH&S?

Answer:

Please note that the answer to part 3 of Question 46 from Additional Budget Estimates February 2013 states:

“Permit PER 11463 was issued to allow a range of registered products to be used to control environmental weeds in a range of situations, such as bushland, forests, wetlands, coastal areas and non-agricultural areas not currently on the product labels. Without this permit the use would otherwise be an offence under the control-of-use legislation in the jurisdiction for which the permit is issued, i.e. Queensland.”

Whether PER 11463 prohibits use in and around aquatic areas is dependent upon the individual product labels.
Question: 26

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Does SCRC or any other Council/company need a Federal APVMA Permit to use Gloricide, Amicide, Brushoff etc. where it would contravene explicit label conditions on the products such as Use in and around Aquatic Areas? If so, how does APVMA monitor this?

Answer:

Yes.

The Australian Pesticides and Veterinary Medicines Authority does not monitor the use of products in accordance with labels and permits. The control of use of products is a State and Territory responsibility.
Question: 27

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority  
Topic: Agricultural Chemicals  
Proof Hansard page: Written

Senator HEFFERNAN asked:

Does Permit 11463 allow 2,4-D formulas to be use in and around Aquatic Areas? Yes or No?

Answer:

Permit 11463 includes the instruction:

“Only those specific products which have label approvals currently in place for aquatic use, may be used in or near aquatic areas.”

The 2,4-D products specified in the permit do not have label instructions for aquatic use.
Question: 28

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Does Permit 11463 allow Metsulfuron methyl formulas to be use in and around Aquatic Areas? Yes or No?

Answer:

Permit 11463 includes the instruction:

“Only those specific products which have label approvals currently in place for aquatic use, may be used in or near aquatic areas.”

The metsulfuron-methyl products specified in the permit do not have label instructions for aquatic use.
Senator HEFFERNAN asked:

Does Permit 11463 allow Gloricide to be used in and around Aquatic Areas? Yes or No?

Answer:

The permit does not include the term 'Gloricide' as there is no commercial product of this name. The most restrictive conditions on the labels of the products used would apply.
Senator HEFFERNAN asked:

Is 2,4-D, Metsulfuron and/or Gloricide being used in and around aquatic areas or where they will reasonably enter Aquatic Areas?

Answer:

There are registered 2,4-D and metsulfuron-methyl products with label instructions that allow use in or around aquatic areas such as drains or for aquatic weeds, that may be used in Australia. Use in combination as a tank mix is not prohibited.
Senator HEFFERNAN asked:

Is the APVMA aware that WH&SQ revealed on the 17/12/2012 to the OQO and ATP Environmental P/L that 2,4-D methyl ester and 2(2-(2-oxo-3-oxazolidinyl)ethyl-1,2-benzisothiazolin-3-one were created in the lab by mixing up Gloricide as per Council’s instructions? If so what date did you become aware of this and how did APVMA monitor this?

Answer:

No.
Senator HEFFERNAN asked:

Was chlorinated water or distilled water used in the above experiment? If chlorinated water was used in such an experiment, would you expect 2,4,5-T and dioxin contamination as well?

Answer:

This is a question for the authors of the report.

No. The Australian Pesticides and Veterinary Medicines Authority has not received a copy of this report, but as stated in the answer to part 10 of Question 46 from Additional Budget Estimates February 2013 “to form 2,4,5-T from 2,4-D the conditions would have to achieve addition of a chlorine atom to the 2,4-D molecule, which is highly unlikely except under specialised laboratory conditions.”
Senator HEFFERNAN asked:

Were specific active ingredients mixed together or whole commercial formulas used in the above experiment, as per the Councils Instructions? If whole commercial formulas were used would you expect further synergistic reactions as well, beyond those created by just mixing 2 active ingredients? You claim to have done an assessment, please document what happens in this worst case scenario.

Answer:

This is a question for the authors of the report (WH&SQ).

It is unclear as to which assessment the question is referring.
Question: 34

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

If whole formulas were used in the experiments and the products were destabilised and used in combination with Chlorinated water in a pressurised spray pressure vessel in the sun, the results would be far worse for Human Safety and the Environment, is this correct?

Answer:

Australian Pesticides and Veterinary Medicines Authority has not received the report and cannot comment on the contents of the report.
Question: 35

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

The documented synergistic compounds were only created when tank mixing/ a mixture of chemicals were added together. They were not created when tested using CG-MS analysis on individual formulas, only with Gloricide. Is this a health risk for Product Users? Has the APVMA informed consumers on the health effects and legality of Gloricide and risks to people who have been contaminated.

Answer:

Australian Pesticides and Veterinary Medicines Authority has not received the report and cannot comment on the contents of the report.

Registered product labels contain appropriate first aid instructions and safety directions to protect human health and safety.

Note that there is no commercial product with the name of ‘Gloricide’.
Question: 36

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Is APVMA aware of the dangers of mixing 2,4-D with town water or other formulas, what are the protocols?

Answer:

The Australian Pesticides and Veterinary Medicines Authority is not aware of any dangers of mixing 2,4-D with town water. Where there is a known risk arising from mixing with other chemical products, there will be restrictions on product labels or permits.
Question: 37

**Division/Agency:** Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority  
**Topic:** Agricultural Chemicals  
**Proof Hansard page:** Written

Senator HEFFERNAN asked:

Mr Adam Presnell was informed by WH&SQ on the 17/12/2012 that prior to January 2012, SCRC and the Queensland Government/SCRC did not have a WH&S Duty of Care to him or his staff as Designers, Manufacturers, Official Suppliers and Principal Contractors? What is APVMA’s policy in relation to the use of gloricide?

Answer:

The Australian Pesticides and Veterinary Medicines Authority policy is that all registered products, including any products used as a tank mix, should be used according to label instructions, any permit instructions and relevant State or Territory legislation.
Question: 38

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

ATP Environmental P/L approached the APVMA Chief Science Officer to complete his WH&S and Environmental and UN Due Diligence and demanded to know if any Chlorine was present in Brushoff or Pulse and was denied access to this necessary scientific and WH&S information. This was asked because it was discovered in research (not on APVMA or Manufacturers info) the risks of chlorinating 2,4-D. If the label does not say what is in the product, how does APVMA address this issue?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) considers a wide range of safety data for each product it registers, including chemical stability. The APVMA also ensures that First Aid Instructions and Safety Directions are included on approved labels to inform users of the correct procedure to mitigate any risks associated with using the product. Chemical users should consider this label information when making their due diligence assessments, as unlike Material Safety Data Sheets, which indicate hazards and require users to undertake their own risk assessments, an APVMA label or permit is based on a risk assessment.
Question: 39

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Is it the APVMA's duty to inform the States and Product Users of known and potential WH&S risks to their Contractors, Rotterdam Convention, Convention on Biological Diversity, Federal Environmental Laws etc. and to investigate refer breaches to prosecution?

Answer:

No. The Australian Pesticides and Veterinary Medicines Authority's (APVMA) duty is to ensure that approved labels for registered products must contain adequate instructions for use as described in Section 14 of the Agvet Code, which is a Schedule to the Agricultural and Veterinary Chemicals Act 1994. These include Safety Directions for use. Additionally all active constituents and any other ingredients or solvents that are scheduled poisons must be listed on product labels.

If product labels do not include the required information it is the APVMA’s responsibility to investigate and take appropriate action. This may include providing the Commonwealth Director of Public Prosecutions with a brief of evidence.
Question: 40

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority

Topic: Agricultural Chemicals

Proof Hansard page: Written

Senator HEFFERNAN asked:

If the APVMA and manufacturers do not advise what specific chemicals they are mixing when mixing commercial chemical formulas, not even SCRC, the Product Designers and Suppliers, how is anyone meant to know if they are jeopardising not just their own lives but all of their future generations by manufacturing and using Gloricide under APVMA False Approvals. Is it not the APVMA duty to inform users of the risks of using AgChem Products?

Answer:

The Australian Pesticides and Veterinary Medicines Authority's duty is to ensure that approved labels for registered products must contain adequate instructions for use as described in Section 14 of the Agvet Code, which is a Schedule to the Agricultural and Veterinary Chemicals Act 1994. These include First Aid and Safety Instructions listed on the label of registered products to inform users of the correct procedure to mitigate the risks associated with using any product. Additionally all active constituents and any other ingredients or solvents that are scheduled poisons must be listed on product labels.
Question: 41

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Q3 (Feb Estimates) you mention the APVMA undertook an assessment of the Proposed use of herbicides by SCRC i.e. in and around aquatic areas in the Coastal Zone and in protected Habitat for EVR species, by the Principal Contractors and Manufactures of Gloricide SCRC. Please provide an outline of that assessment?

Answer:

Please note that in the answer to part 3 of Question 46 from Additional Budget Estimates February 2013 the Australian Pesticides and Veterinary Medicines Authority (APVMA) did not claim to have assessed the proposed use of herbicides by the SCRC. Therefore, there is no assessment to be provided.

The APVMA response was:

“Permit PER 11463 was issued to allow a range of registered products to be used to control environmental weeds in a range of situations, such as bushland, forests, wetlands, coastal areas and non-agricultural areas not currently on the product labels. Without this permit the use would otherwise be an offence under the control-of-use legislation in the jurisdiction for which the permit is issued, i.e. Queensland.”

For those products that specify uses in and around aquatic areas, these uses have been assessed as part of product registration, either by the APVMA or by the States and territories prior to the formation of the APVMA.
Question: 42

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Q6 (Feb Estimates) APVMA acknowledged Gloricide as a “Product” with a MSDS and again refer to it as something other than a Chemical Product and as just a name used to refer to a tank mixture that you advised SCRC have a permit for. Again I ask people working under your Permits/Approval Notices are risking their lives, based on your advice, what is AVPMA’s policy in respect to this issue?

Answer:

The first statement is incorrect. Question part 6 of Question 46 from Additional Budget Estimates February 2013 was

"Is the APVMA aware of the WH&S Rating of Gloricide established in the MSDS for the product and do you agree that workers are fully informed of the dangers to themselves, the Community and the Environment?"

This question was answered:

"‘Gloricide’ is not a registered chemical product. The department understands that it is a name used by some people to refer to a tank mix of registered chemical products approved for certain uses in Queensland under a permit. The MSDS in question was prepared to satisfy the relevant state WorkSafe authority. As such, it is inappropriate for the Australian Pesticides and Veterinary Medicines Authority (APVMA) to provide specific comment.”

The APVMA regulates the label approvals and the safety directions for the registered products that may have been used. Users should adhere to label instructions, permit instructions and any relevant State or Territory legislation.
Question: 43

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

The Manufactures of 2,4-D and Metsulfuron methyl have not provided consent to authorise the use of Gloricide (especially in and around aquatic areas) and the States need a valid APVMA permit to override the Manufactures which they do not have. Does the APVMA have jurisdiction and a responsibility to workers operating under an APVMA Permit and/or under an APVMA Approval Notice to allow the continued use of “Gloricide” without a Product Registration or valid Permit?

Answer:

The first statement is not correct. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has issued two permits that allow the use of these products in specific circumstances.

The APVMA does not have jurisdiction over workers using a product, regardless of whether it is under an APVMA permit or label. This is the responsibility of the relevant State authorities such as Biosecurity Queensland and Work Health and Safety, Queensland.

As stated in the answer to part 6 of Question 46 from the Additional Budget Estimates February 2013:

‘Gloricide is not a registered chemical product. The department understands that it is a name used by some people to refer to a tank mix of registered chemical products approved for certain uses in Queensland under a permit. …”
Question: 44

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Q7 last sitting you were asked if it appropriate that certain products are reregistered with you without empirical information. You answered that the products must contain adequate instructions under the Agvet Code. If the instructions say not to use the product in and around aquatic areas, why did you approve the use of 2,4-D, Metsulfuron methyl and Gloricide to be used under Permit 11463 by SCRC where they will knowingly cause damage to aquatic areas by using them in Wetlands and Coastal Areas with sandy soils an against the Label Instructions and MSDS.

Answer:

The Australian Pesticides and Veterinary Medicines Authority did not approve use against the label instructions regarding aquatic areas in Permit 11463.

Permit 11463 includes the instruction:

“Only those specific products which have label approvals currently in place for aquatic use, may be used in or near aquatic areas.”
Question: 45

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

In Q8 (Feb Estimates) Permit 10540 carries instructions not to use Glyphosate within 20m of a waterway? What distance can 2,4-D and Metsulfuron methyl be used from waterways under the permit? Can 2,4-D and/or Metsulfuron methyl be used within 20m of a waterway under the Permit?

Answer:

Permit 10540 is issued for control of the weed Lippia in pastoral land and fallow situations only.

Permit 10540 does not introduce any additional restrictions on use of 2,4-D and metsulfuron methyl in and around sensitive areas such as waterways. Therefore, those restrictions currently on product labels apply.
Question: 46

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

It is true that 2,4-D and/or Metsulfuron methyl are much more toxic to aquatic ecosystems than Glyphosate 450! With regards to Permit 10540, why has no distance been set for either 2,4-D and/or Metsulfuron methyl on the Permit or on the Labels, when one has been set for only the least toxic of the components? Do Glyphosate 450 Products disclose a 20m setback distance as standard on the Product Label, MSDS or on other APVMA Permits, please specify? If not, why?

Answer:

The permit sets a buffer zone for the glyphosate 450 product as it may contain surfactants that are not suitable for aquatic use. The glyphosate product formulations were all reviewed in 1996 based on concerns that particular surfactants in some formulations were potentially harmful to aquatic environments. Glyphosate itself is not regarded as being of high toxicity to aquatic environments. The permit therefore recommends that a glyphosate formulation that is approved for aquatic use be used instead.

Buffer zones are included on labels when required to manage an identified risk. They are not required in all situations of use or for all products. As yet there have been no concerns raised that have led to the inclusion of aquatic buffer zones for products containing metsulfuron-methyl or 2,4-D.

Some glyphosate products carry label warnings precluding use in aquatic areas depending on the potential aquatic toxicity of the surfactants.
Question: 47

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Have users of Permit 10540 or the Permit Holder BQ, been informed of WH&SQ findings regarding the synthesis of 2,4-D Esters are 2(2-(2-oxo-3-oxazolidinyl)ethyl)-1,2-benzisothiazolin-3-one? Will the APVMA continue issuing permits knowing the risks have been publicly disclosed?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has not received the report and cannot comment at this stage. The APVMA has written to the Permit Holder seeking information about the contents of the report. Permit holders are obliged to submit ‘relevant information’ to the APVMA under Section 161 of the Agricultural and Veterinary Chemicals Code Act 1994. On receipt of such information, the APVMA will determine whether further regulatory action is needed.
Question: 48

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

How does APVMA monitor this? In the case of Sunshine Coast Beaches and wetlands, how far can these products be used from the water or from ephemeral waterways full of EVR species, 1cm, 1m, 10m, 20m, 100m, 5km?

Answer:

It is not clear what monitoring is referred to in this question. The Australian Pesticides and Veterinary Medicines Authority does not monitor the use of chemical products; the control of use of products is a State and Territory responsibility.

Setbacks from sensitive areas are specified, when required, on product labels. The 2,4-D and metsulfuron-methyl products listed in permit 11463 do not specify buffer zones on the labels. There are some other registered 2,4-D and metsulfuron-methyl products with product labels that include instructions for use in or around aquatic areas such as drains or for aquatic weeds.
Question: 49

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Has the APVMA approved SCRC to use and mix 2,4-D and/or Metsulfuron methyl where it has a reasonable chance of entering aquatic areas or in aquatic areas when the manufactures have warned the APVMA and users not to apply them in certain situations by disclosing a warning on the Label/s?

Answer:

No.

Permit 11463 was issued to Biosecurity Queensland to allow the use of a range of herbicides for the control of environmental weeds in non-agricultural areas in Queensland. This permit includes the instruction:

“Only those specific products which have label approvals currently in place for aquatic use, may be used in or near aquatic areas.”
Senator HEFFERNAN asked:

What are the consequences for the Queensland Government and SCRC approving the continued use of Gloricide without a valid permit or Product Registration?

Answer:

This is a question for the Queensland government, as it is responsible for control of use in Queensland. If the Queensland government concluded there was a breach of its control of use legislation, the Sunshine Coast Regional Council would be able to advise any additional consequence over and above those applied by the Queensland government.

As stated in the answer to part 6 of Question 46 from the Additional Budget Estimates February 2013:

'Gloricide is not a registered chemical product. The department understands that it is a name used by some people to refer to a tank mix of registered chemical products approved for certain uses in Queensland under a permit. ..."
Question: 51

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Q9 (Feb Estimates) APVMA quoted “The UNEP is not responsible for investigating the use of chemicals listed in Annex 111 of the Rotterdam Convention”. This is proof that the UN has no enforcement mechanism under the Convention and all responsibility relies on the DSEWPaC, APVMA, DAFF, is this correct and does AVPMA have a policy in relation to this Convention?

Answer:

The lead government agency responsible for the Rotterdam Convention is the Australian Government Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC); the Australian Pesticides and Veterinary Medicines Authority (APVMA) assists DSEWPaC to meet the government’s obligations under the convention in regards to pesticides. The Agricultural and Veterinary Chemicals (Administration) Regulations 1995 prescribes the APVMA’s policy on the Rotterdam Convention in relation to pesticides.
Question: 52

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Q 10 (Feb Estimates) APVMA claim that 2, 4-D can be converted into Agent Orange simply in the presence of a chlorine molecule. Can you clarify this statement?

Answer:

The Australian Pesticides and Veterinary Medicines Authority has made no such claim, the answer to part 10 of Question 46 from Additional Budget Estimates February 2013 stated:

“Yes. However, to form 2,4,5-T from 2,4-D the conditions would have to achieve addition of a chlorine atom to the 2,4-D molecule, which is highly unlikely except under specialised laboratory conditions.”
Senator HEFFERNAN asked:

APVMA understands the risks of mixing 2,4-D with town water as it has been investigating the product since its inception and laymen can work it out for themselves through Google, that 2,4-D will create Agent Orange if mixed with chlorine. Why haven’t the manufacturers disclosed this to users and the community? What is APVMA’s policy in regard to this issue?

Answer:

Specialised knowledge is required to properly assess the risks from chemical products. The Australian Pesticides and Veterinary Medicines Authority (APVMA), supported by experts in the Department of Health and Ageing and the Department of Sustainability, Environment, Water, Population and Communities, carry out various risk assessments.

Section 161 of the Agricultural and Veterinary Chemicals Code Act 1994 (the AgVet Code) requires that ‘interested persons’ (e.g. registrants) and holders of permits submit ‘relevant information’ to the APVMA as soon as possible.

Under the law, interested persons and permit holders need to provide information to the APVMA if information becomes available that alters or might alter the conclusions that the APVMA would have made about the product had the information been available at the time of registration or issue of permit.

Such information can become available as a result of:
- new studies being conducted that show different information to that previously available
- experiences obtained as a result of manufacture, supply or use of the product, eg. adverse experience reports, residues monitoring, epidemiological studies.

The APVMA has not received any information under s161 or from any other sources that suggest that this is a significant risk. The advice provided by the APVMA in answer to part 10 of Question 46 from Additional Budget Estimates February 2013 stated:

“Yes. However, to form 2,4,5-T from 2,4-D the conditions would have to achieve addition of a chlorine atom to the 2,4-D molecule, which is highly unlikely except under specialised laboratory conditions.”
Question: 54

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Q 11 (Feb Estimates) APVMA was asked if registered and unregistered Agvet Chemicals used under the Federal Jurisdiction of Permit 11463, were being used in and around Aquatic Areas by SCRC. You claim to have done an assessment of SCRC's use of Chemicals, what was the outcome?

Answer:

Please refer to the answer to Question on Notice 41 (Australian Pesticides and Veterinary Medicines Authority) from the 2013 May Budget Estimates hearing.
Question: 55

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Q 12 (Feb Estimates) APVMA was asked if registered and unregistered Agvet Chemicals used under the Federal Jurisdiction of Permit 11463, were being used in and around Critical Habitat for International, Federally, State, Local listed EVR species. You claim to have done an assessment of SCRC use of Chemicals, where are they using this product specifically and can you list the International and Federally Listed EVR Species which have been potentially contaminated?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) did not claim to have assessed the proposed use of herbicides by the SCRC.
Question: 56

**Division/Agency:** Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority  
**Topic:** Agricultural Chemicals  
**Proof Hansard page:** Written

**Senator HEFFERNAN asked:**

Which agency in Federal Government is responsible for issuing an approval notice for the continued use of Gloricide, 2,4-D formulas and Metsulfuron methyl formulas use in and around Aquatic Areas and in critical habitat for International and Federally listed EVR species by SCRC, BQ etc.?

**Answer:**

There is no commercial product of the name 'Gloricide' therefore no approval notice would be issued.

The Australian Pesticides and Veterinary Medicines Authority has issued a permit 11463.

PER 11463 allows use in non-agricultural areas, bushland, forests, wetlands, coastal and adjacent areas. It restricts use in and around aquatic areas to only those products with label approvals for use in aquatic situations. The Queensland government is responsible for determining if there has been an offence under state and territory control of use law. However, it is the responsibility of the user to determine compliance with the *Environment Protection and Biodiversity Conservation Act 1999* and state and territory environment laws.
Question: 57

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Permit 10540 claims that a Gloricide type concoction can be used twice per year and yet under Permit 11463 apparently every herbicide listed on the schedule can be mixed and applied right up to the edge of the ocean, why has no frequency of use been documented on Permit 11463 or any mention of mixing only strict accordance with the Attachment?

Answer:

Specific instructions on frequency of use and mixing of products were not required for Permit 11463 noting that the labels of the products to be used give adequate instructions regarding the frequency of use and compatibility of products when required.

As previously stated in the answer to part 2 of question 46 from Additional Budget Estimates February 2013:

“A tank mix of registered chemical products is not itself another chemical product. The making of a tank mix is not an offence under state control of use legislation, unless product labels specifically prohibit mixing of one product with another.”
Question: 58

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Q16 (Feb Estimates), is it legal for SCRC and BQ to use Gloricide in and around Aquatic Areas?

Answer:

Any questions regarding compliance with instructions for use of either permits or approved labels for 2,4-D and metsulfuron-methyl used as a tank mix should be referred to the relevant State authority with responsibility for control of use.
Question: 59

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

In Q24 (Feb Estimates) 2,4-D Esters were banned in 2006. Were you aware that WH&SQ revealed last year that 2,4-D methyl esters were created by mixing up Gloricide? Why did APVMA allow Gloricide to continue if there are risks of destabilising synthetic oestrogen (2,4-D) by mixing it with Metsulfuron methyl?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) suspended the high volatile esters of 2,4-D in 2006. This suspension was based on potential environmental risks due to off-target vegetation damage if these high volatile ester (ethyl ester, butyl ester and isobutyl ester) forms of 2,4-D were used on broadacre crops in summer.

The APVMA is not aware of the WH&SQ report and has written to the permit Holder seeking information about the contents of the report.
Question: 60

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals

Senator HEFFERNAN asked:

Q 25 (Feb Estimates) what are the Standards on the Label and does that differ from the APVMA previous responses on Gloricide.

Answer:

Gloricide is not a registered product and therefore, it does not have a label.

It is not clear which standards are referred to in this question. Approved labels for registered products must contain adequate instructions for use as described in Section 14 of the Agvet Code.
Question: 61

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

In Question 8 (October 2012) APVMA said that Labels for products containing metsulfuron methyl and products containing 2,4-D do not specify buffer zones. Does this mean that manufacturers have been allowed by the APVMA to sell their products for years without standards on the Label. The APVMA has allowed individual interpretation of the Label without one standard. Why is this?

Answer:

As stated in the answer to Part 8 of Question 231 from the Supplementary Budget Estimates October 2012:

“Labels for products containing metsulfuron-methyl and products containing 2,4-D do not specify any buffer zone to be observed when using near aquatic areas. Product labels, however, contain a warning “DO NOT contaminate streams, rivers or waterways with the chemical or containers”. Responsibility for control-of-use rests with the relevant state authority, QDAFF”.

In accordance with the Agricultural and Veterinary Chemicals Code Act 1994, the Australian Pesticides and Veterinary Medicines Authority is satisfied that the labels for these products contain adequate instructions to ensure safe use.
Senator HEFFERNAN asked:

You claim in Answer 26 February 2013, that if products are used contrary to APVMA Permits, that responsibility to investigate and prosecute rests with the States. Is this true?

Answer:

Yes.
Question: 63

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Is there any mechanism in Commonwealth Law whereby the Commonwealth has Jurisdiction to investigate crimes/breaches made under its Permits.

Answer:

Yes.
Question: 64

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Has the Commonwealth or Queensland potentially jeopardised International Trade by allowing Gloricide to be used without a Permit or Registration by using products that will manufacture Agent Orange, 2,4-D Esters and other deadly products seemingly unknown to you?

Answer:

There is no registered product of the name ‘Gloricide’. The Australian Pesticides and Veterinary Medicines Authority understands that it is a name used by some people to refer to a tank mix of registered chemical products approved for certain uses in Queensland under a permit.

Any disruption to international trade, by allowing the use of registered products as a tank mix under permit, is highly unlikely.

The making of a tank mix is not an offence under state control of use legislation, unless product labels specifically prohibit mixing of one product with another.

The formation of 2,4,5-T or high volatile esters of 2,4-D, from registered chemical products is highly unlikely except under specialised laboratory conditions. Further, formation of “Agent Orange” in a tank mix is virtually impossible.
Senator HEFFERNAN asked:

APVMA has advised the Queensland Government, the SCRC, Contractors etc. that Gloricide is legally authorised by APVMA Permits. Is this correct? If the control of use of chemicals under Federal Permits is a State Issue, how can the States administer Control of Use of Chemicals, if there is no control of use or regulation of Federal Permits by the Commonwealth and we have not enforced any standards on the Labels or have independent and accountable regulators when the States get it wrong?

Answer:

No. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has not referred to “Gloricide” as there is no commercial product of that name. The APVMA has advised that a tank mix of 2,4-D and metsulfur on methyl is not prohibited by labels on products it registers and is therefore possible unless prohibited under State legislation.

The States and Territories regulate control of use of agricultural chemical products, including the use of products under permits.
Question: 66

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

In AVPMA’s opinion, what experience/qualifications should a designer and principal contractor experimenting with synthetic hormonal chemicals have under the directions of a MSDS? What is APVMA’s policy on regard to this issue?

Answer:

Further clarification of this question is required for the Australian Pesticides and Veterinary Medicines Authority to be able to answer.
Question: 67

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

In the last 5 years, how many Local Councils in Australia have developed new agricultural chemical products by way of developing and registering an agricultural chemical product with the APVMA?

Answer:

None.

A search of PUBCRIS (17/06/13) does not show any registrant names including the word Council, Shire or City.
Question: 68

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority  
Topic: Agricultural Chemicals  
Proof Hansard page: Written

Senator HEFFERNAN asked:

Is the SCRC the first Council that has gone to these lengths of a Trail Project, Region Wide Program Delivery and producing a MSDS to use their own Unregistered Agricultural Chemical Products?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) cannot comment on matters referring the use of agricultural chemical products as this is the responsibility of relevant State and Territory governments.

The APVMA has responsibility to investigate the matters relating to the supply of unregistered agricultural chemical products. The APVMA is not aware of the supply of unregistered agricultural chemical by any councils.

As stated in the answer to part 6 of Question 46 from the Additional Budget Estimates February 2013:

'Gloricide is not a registered chemical product. The department understands that it is a name used by some people to refer to a tank mix of registered chemical products approved for certain uses in Queensland under a permit. The MSDS in question was prepared to satisfy the relevant state WorkSafe authority. ..."
Question: 69

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural Chemicals
Proof Hansard page: Written

Senator HEFFERNAN asked:

Has the Minister been briefed by APVMA on the use of Gloricide by the SCRC?

Answer:

No.
Question: 70

Division/Agency: Agricultural Productivity Division
Topic: Farmer Fury of passing of Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (the Bill)
Proof Hansard page: Written

Senator COLBECK asked:

How is the new system of reregistration not going to add significant additional cost to the reregistration process and leave Australian farmers without access to necessary agvet chemicals? We now know the environment assessment costs are going up by up to 67% - with the largest increase in cost for tier 2 assessments. How does this sit with the Government’s own commitment to cut onerous regulation and costs for primary producers?

Answer:

The re-approval and re-registration scheme design imposes minimal requirements on industry, delivering a systematic means of considering all products registered for use in Australia. The scheme ensures chemicals continue to meet appropriate contemporary health and safety standards. The scheme imposes the least burden necessary on chemicals companies, making sure that safe and useful chemicals are not lost to users.

The cost of a re-registration application is to be set at $700. Given the minimum re-registration period is to be seven years, this equates to a maximum per-year cost of $100 for each re-registration application.

The scheme does not require approval or registration holders to generate new data about their chemicals for the Australian Pesticides and Veterinary Medicines Authority (APVMA). Holders of approvals or registrations would only need to provide information they could be reasonably expected to have or to have access to. It is only circumstances where the APVMA has concerns about the safety of a chemical that it may request further information and data from the holder.

Fees and charges applied by the APVMA are imposed in accordance with the government’s cost recovery guidelines. The fee increases due from 1 July 2013 are in large part driven by a rebalancing of the APVMA’s levy income, which will be reduced by up to 12.5 per cent. This will mean a return to the long standing policy of 60 per cent cost recovery from levies.