Senate Rural Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2011

Agriculture, Fisheries and Forestry

Question: 56

Division/Agency: APD/APVMA – Australian Pesticides and Veterinary Medicines Authority
Topic: Pesticide Usage
Proof Hansard Page: Written

Senator Colbeck asked:

1. What action has the APVMA taken in relation to concerning recent reports of stunted piglets, deformed chicks, deformed frogs, stunted chicks, dead fish larvae, honey bees dropping dead and wild birds dropping dead that could be linked to pesticide use in the Sunland area?
2. What is the role of APVMA in these type of matters?
3. Has the APVMA satisfied itself that pesticides were not the cause of these adverse events?
4. What action remains to be taken by the APVMA in relation to the Sunland incidents?
5. What regulatory action has been considered by the APVMA in relation to the Sunland incidents?
6. What further information has APVMA sought in relation to these incidents at Sunland?
7. What are the responsibilities of APVMA to protect public health?
8. In general, does the APVMA have any potential liability for failure to properly investigate reports that result in future damage to human or animal health?
9. Can you explain APVMA's general duty of care to act in the interests of human and animal health?

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) received six adverse experience reports related to the Sunland area on 27 January 2011. These reports identified headaches in humans, two dead bees, two dead birds, tadpoles with delayed development, chickens with stunted growth and piglets with poor growth rates. The APVMA conducted a preliminary assessment of the information in the reports and is liaising with Queensland state authorities to gather any other information that would assist its assessment.

2. The APVMA's primary role is to assess and register pesticides and veterinary medicines proposed for use on the Australian market to see if they work and can be used safely subject to conditions the APVMA may impose. The APVMA also monitors the ongoing quality and safety of registered products and can impose regulatory action if new information raises concerns about the use or safety of a particular chemical or product.

   The APVMA's Adverse Experience Reporting Program (AERP) provides feedback on the performance of registered pesticides and veterinary medicines in the field to ensure that registration decisions made by the APVMA are appropriate and effective. The AERP does not replace the primary role of state governments in regulating control of use; including investigating any suspected inappropriate use of registered agricultural and veterinary chemical products.

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Adverse experience reports received by the APVMA are assessed to determine their seriousness, if the problem was created by the permitted use of a product and whether any regulatory action is justified. In assessing these reports, the APVMA may seek advice from the states and territories and/or other government agencies and independent experts, where appropriate. It then evaluates any advice it receives and decides whether the causal relationship between the use of the product(s) and the reported adverse experience is probable, possible, unlikely or unknown.

3. The most recent reports are still being assessed. The APVMA has not yet made any determination whether pesticides were involved.

4. The APVMA is continuing to liaise with Queensland Government authorities to seek further information to assess the six most recent reports and is also seeking advice from the Australian Government Department of Health and Ageing and the Department of Sustainability, Environment, Water, Population and Communities.

5. The reports assessed to date have not triggered consideration of regulatory action.

6. In cases where the reports did not supply important details such as dates of events, relevant post-mortem examinations and results of the indicative laboratory tests, the APVMA is seeking this information from the Queensland state authorities.

7. The responsibilities of the APVMA to protect public health are set out in the APVMA's governing legislation and indicate the matters of which the APVMA must be satisfied before granting a registration and before taking regulatory action.

8. The exercise of statutory powers does not automatically create a duty of care. It is possible for a duty to arise but each case will depend on its particular facts. Even if a duty does arise and the APVMA has breached that duty, section 69H of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* provides an exemption from liability.

9. Please see answer to Question 8 above.

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Question: 57

Division/Agency: APD/APVMA – Australian Pesticides and Veterinary Medicines Authority
Topic: Use of Lemongrass and Bugbam
Proof Hansard Page: Written

Senator Heffernan asked:

1. There are currently no approvals in Australia for lemon grass extract as an insect repellent for humans, what is APVMA's current policy on lemongrass?
2. I understand APVMA has said lemongrass causes cancer in mice, yet the Therapeutic Goods Administration (TGA) has approved lemongrass in teas, body lotion oils, etc and is a well known cooking ingredient in Thai food. The TGA has an approval for lemon grass oil in a Listed Medicine. Do APVMA and TGA consult with each other? If not, why not. (please do not answer stating each agency is an independent authority)
3. In light of the recent flooding in QLD and Victoria, why won't APVMA approve a product called Bugbam? (bugbam is a wristband and grids made with all natural ingredients and food-grade materials that deters mosquitoes and other flying, biting insects from biting. Bug Bam products were used by cleanup crews after the earthquake in Haiti and in Louisiana for Hurricane Katrina.
4. The Bugbam product has the following endorsements yet APVMA continues to refuse approval, please explain in detail your reasons and when will it be approved?
    - 100% natural, FDA food-grade, EPA exempt ingredients (citronella, geranium, lemongrass).
    - US FDA approved/EPA exempt food-grade materials (synthetic latex).
    - Waterproof, sweat-proof, recyclable and eco-friendly.
    - Safe for Kids (of all ages).
    - Scientifically tested for efficacy (successfully) against mosquitoes capable of carrying yellow fever, dengue fever, west nile virus & malaria at leading entomology labs in the USA.
    - Scientifically tested for skin and eye irritation (non-irritant).
    - Endorsed by the PGA Tour Partners (Golf).
    - Endorsed by the National Home Gardening Club.
    - Endorsed by the National Camp Association.
    - Awarded BEST PRODUCT and HOT PRODUCT by iParenting Media
    - Official repellent of the Boy Scouts of America.
    - Currently in Phase-2 of testing with the United Nations to be adopted by their Rollback Malaria program.
5. Surely in light of the recent QLD and Victorian floods, the Bugbam product would qualify for emergency registration, APVMA's guidelines state "The APVMA may also issue a permit to individuals, organisations or corporations allowing them (or others) to use a particular agricultural or veterinary chemical product in a limited way (such as for minor uses, emergency uses and experimental purposes) when that product is either not registered or the proposed use of a registered product is contrary to the use instructions and directions on the approved label of the product." On what grounds did APVMA refuse Bugbam's application for an emergency registration?

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) does not have a policy specifically on lemongrass.

   Lemongrass or lemongrass extract is currently not an approved active constituent under the agricultural or veterinary chemicals legislation. Lemongrass or lemongrass extract when contained in insect repellent products for humans must be assessed and approved by the APVMA. The legislation sets out the criteria that must be satisfied and the matters that the APVMA must have regard to, in order to approve an active constituent and register a product.

2. The APVMA seeks expert advice on public and occupational health matters from the Office of Chemical Safety and Environmental Health (OCSEH) within the Department of Health and Ageing. The OCSEH advised the APVMA that a number of published studies showed that topical application of citral (of which lemongrass oil contains high concentrations) suggest a serious toxicological effect (i.e. induced benign or atypical hyperplasia in ventral prostate of rats after 10 to 30 days dermal exposure).

   There are differences in the regulatory frameworks for therapeutic goods and pesticides, which determine what type and level of information is required for approval. On matters of public health and pesticides, the APVMA relies on the toxicology expertise of the OCSEH, which assesses the data submitted by the applicant or any publicly available information.

   Oil extracts, such as lemongrass oil containing citral, are generally in a more concentrated form than in the plant that is used for cooking and the potential health effects must be based on the evidence or body of knowledge that currently exists.

   The APVMA and TGA consult each other on a case by case basis on regulatory matters common to both agencies.

3. The APVMA received two applications for Bug Bam (a mosquito repelling wrist band and a mosquito repelling grid) on 21 September 2009. The APVMA did not approve these applications. The applicant did not provide the efficacy data required by the APVMA or address other concerns raised as part of the preliminary assessment process. Because the applicant did not provide the required efficacy data required for the assessment, the APVMA treated the applications as having been withdrawn in accordance with the *Agricultural and Veterinary Chemicals Code Act 1994*.

4. The APVMA must make decisions based on scientific, evidence-based information. While endorsements can have some use in supporting scientific data, they cannot be used as the sole supporting information on which to base a regulation approval.

   The APVMA has not received a formal application for an emergency permit for Bug Bam.

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The agricultural and veterinary chemical framework allows for the APVMA to assess and issue emergency permits. A situation may be treated as an emergency if there are no currently registered products for that purpose or if the currently registered products are either ineffective or unavailable. In these situations, the APVMA must be equally satisfied that the proposed product complies with all relevant statutory matters regarding safety, quality and efficacy.

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Agriculture, Fisheries and Forestry

Question: 58

Division/Agency: APD/APVMA – Australian Pesticides and Veterinary Medicines Authority
Topic: Pesticide Reviews
Proof Hansard Page: Written

Senator Siewert asked:

1. Please provide an update on the APVMA review of diuron. Since the preliminary review findings were released in 2005, please indicate what if anything has been done to implement any changes to the use of diuron?
2. Given paraquat has been under review by APVMA since 1997 and is now banned in Europe, please provide an update on the APVMA review of paraquat? When will APVMA's preliminary findings be released?
3. The Australian Government made a commitment before the election to reform Australia's pesticide laws to better protect human health and the environment. Will the new regime lead to the de-registration of pesticides that have been banned overseas on human health or environmental grounds? For example, the 80+ pesticides identified as prohibited in the European Union in the WWF/National Toxics Network report "A list Australia's most dangerous pesticides".
4. How will the Government treat carcinogenic pesticides under the new regime?
5. How will the new regime treat endocrine (hormone) disrupting pesticides?

Answer:

1. In response to the release of the preliminary review findings (PRF), registrants and industry representatives provided a significant amount of new data and information. As a result, the environmental assessment has been revised.

   The new assessment utilised revised ecotoxicity endpoints, improved modelling, made greater use of monitoring data, and adopted a different approach to risks associated with broadacre agriculture. The Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) is providing additional information associated with spray drift risk. Once this has been finalised, the Australian Pesticides and Veterinary Medicines Authority (APVMA) will consider whether it is required to publish a second PRF (because of the changes since the first PRF was published) or whether to conduct a more targeted consultation with user industries and registrants.

   No interim actions have been taken but the key data provider has been conducting extensive monitoring and modelling of specific Queensland sugarcane catchments, and conveying these results to the APVMA and DSEWPaC.

2. Paraquat is still being reviewed by the APVMA.

   The APVMA and **Office of Chemical Safety and Environmental Health (**OCSEH) are aware of emerging concerns about possible links between long-term (i.e. chronic) exposure to low doses of paraquat and the risk of Parkinson's Disease. In 2010, the

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APVMA commissioned the OCSEH to prepare a detailed targeted report on the current experimental and epidemiological evidence for the neurotoxicity concern. The draft OCSEH report is undergoing external expert peer review.

The APVMA is aware of ongoing research using animal models, to better understand whether the possible increase in Parkinson's disease risk in users of agricultural chemicals is specifically associated with paraquat, or with some other agricultural chemicals. The results of this research will be an important component of the APVMA's review.

3. The Australian Government is finalising the policy details of proposed reforms of Australia's pesticide laws to better protect human health and the environment.

An issues paper (http://www.daff.gov.au/agriculture-food/food/regulation-safety/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals) was recently released for public comment until 4 February 2011. It included consideration of a re-registration scheme for agriculture and veterinary (agvet) chemicals which would include the need for an assessment review if relevant chemicals had been banned overseas on human health and environment grounds since registration. Ninety two submissions were received in response to the discussion paper.

4. & 5. The government intends to retain a risk based approach to the registration of all agvet chemicals.