Animal Medicines Australia

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RRAT Committee Secretary
Senate Standing Committees on Rural and Regional Affairs and Transport
Parliament House
Canberra ACT 2600

By email only: rrat.sen@aph.gov.au

Re: Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019

Thank you for the opportunity to comment on the Agricultural and Veterinary Chemicals Legislation Amendment Bill (the Bill). Animal Medicines Australia (AMA) is the peak industry association representing Australia's animal health sector, supporting both Australia's $28 billion livestock industry and $13 billion pet industry. AMA and our members maintain a strong interest in maintaining an effective, efficient, independent and rigorous process for the scientific assessment and registration of veterinary medicines.

AMA notes that the measures contained within this bill were also introduced into the previous parliament. Our submissions to the *Operational Efficiency Bill* and the *Streamlining Regulation Bill* are available at:

- Operational Efficiency Bill 2017: http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/streamlining/operational-efficiency-bill-2017
- Streamlining Regulation Bill 2018: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Rural_and_Regional_Affairs_and_Transport/APVMABill/Submissions

In summary, we support, or do not oppose, all key measures contained within the Bill. We expect that their implementation will provide minor improvements in operational efficiencies for both registrants and the regulator.

However, AMA **does not support** a governance Board for APVMA, as proposed in the Bill at this stage. AMA has consistently not supported the establishment of a Board for the following reasons:

- A clear case for establishing a Board has not been established. AMA encourages the government to consider the problems and challenges facing the APVMA and conduct an independent and transparent process to consider which solutions are likely to achieve the greatest benefits at lowest cost. This may or may not include establishing a Board, but it should also include meaningful consultation with industry and analysis of other options;
- It remains unclear whether any benefits that accrue from establishing a Board will exceed the costs imposed. As a cost-recovered agency, the APVMA is funded by a mix of fees and levies imposed on the regulated industry. This includes AMA members; and
- Government has recently announced a 'first principles' review of the Agvet Code and the inter-governmental agreement that established the national registration system for agricultural chemicals. This includes reviewing the APVMA's governance arrangements as outlined in the 2013 inter-governmental agreement between all States, Territories and the Commonwealth (attached). Implementing a governance board at this time pre-empts the findings of that review.

AMA recognises and supports the need for a globally respected, rigorous and transparent regulatory scheme for veterinary medicines. We look forward to continuing to work closely with Government to deliver targeted reforms that improve regulatory efficiency and predictability. We similarly look forward to working with government to review all governance options to consider the relative merits and costs for communities, governments and the regulated industry.

If you have any questions, please feel free to contact me.

Sincerely

Ben Stapley

Executive Director

An AGREEMENT made the day of 2013

Between:

The COMMONWEALTH OF AUSTRALIA ("the Commonwealth")

and

The States of: NEW SOUTH WALES
VICTORIA
QUEENSLAND
SOUTH AUSTRALIA
WESTERN AUSTRALIA
TASMANIA (collectively called "the States") the
NORTHERN TERRITORY OF AUSTRALIA ("the Northern Territory") and the
AUSTRALIAN CAPITAL TERRITORY

WHEREAS:

A. The Commonwealth, each of the States, and the Northern Territory have enacted legislation that provides for the evaluation, registration and control of agricultural and veterinary chemical products, and for related matters, and established an Agvet Code which among other things prohibits supply, or possession for supply, of unregistered agricultural or veterinary chemical products.

B. The Commonwealth has enacted the *Agricultural and Veterinary Chemicals (Administration) Act 1992* which established the Australian Pesticides and Veterinary Medicines Authority ('APVMA').

C. The Commonwealth, each of the States, and the Northern Territory agreed at a meeting of the Australian Agricultural Council (AAC, now called the Standing Council on Primary Industries) ('SCoPI') held on 2 August 1991 to establish a National Registration Scheme to provide for the registration of agricultural and veterinary chemicals under which the Commonwealth will be responsible for the registration of agricultural and veterinary chemicals with each State and Territory remaining responsible for the control of use of such chemicals.

NOW IT IS HEREBY AGREED AS FOLLOWS:

1. This Agreement is an agreement for the purposes of section 9A of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. This agreement is constituted in its own right under s9A and replaces the previous agreement. The ACT was not party to the 1995 agreement which has been significantly changed in this agreement.

Interpretation

2. In this Agreement, unless the contrary intention appears:
   (a) words importing a gender include every other gender; and
   (b) words in the singular number include the plural number and words in the plural number include the singular number.

Objectives

3. In undertaking their regulatory duties, the Parties will be guided by the policy principles and policy outcomes provided in the National Policy Framework for the Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals, agreed by the Council of Australian Governments in August 2010 (at Annex 1).

Implementation

4. In this Agreement, each Party shall take such steps as are appropriate to provide for consistent regulation on the following:
   (a) minimum licensing requirements for chemical users;
   (b) minimum competency requirements for chemical users;
   (c) monitoring of chemical residues in produce and resulting traceback violations;
   (d) minimum controls on access to chemicals at and after the point of retail sale, including restrictions on usage; and
   (e) recordkeeping requirements for chemical sale and use and associated user audits.

5. The Commonwealth has enacted Commonwealth legislation which makes provision for the following:
   (a) the establishment of the Agvet Code;
   (b) the implementation of the Agvet Code in the Australian Capital Territory and in any other Territory that is declared by regulations to be a participating Territory;
   (c) any necessary consequential amendments to legislation that are necessary because of the enactment of such legislation.

6. The Commonwealth, the States and Territories agree that there is a need to maintain consistent regulation within the areas listed in clauses 4 and 5.

7. Subject to Budget approval and SCoPI agreement, the Commonwealth will provide funding to the States and Territories to undertake some specific activities, as agreed by the Parties.

8. The Commonwealth agrees to fund a project comprising national produce monitoring and traceback activities required by the project. The project will be funded for five years.

9. The harmonised regulations will be reviewed by SCoPI within 5 years of the making of this agreement. The manner and form of the review to be determined by SCoPI within 4 years of the making of this agreement. The review will consider, amongst other things, the need and format of an ongoing review cycle.

Legislation

10. Each State and the Northern Territory has included in the legislation enacted by their Parliaments a provision empowering the APVMA to approve active constituents for proposed or existing chemical products and to register agricultural chemical products and veterinary chemical products, and any consequential amendments that are necessary because of the enactment or consequential amendments of the Commonwealth legislation.

11. Each State and the Northern Territory has secured the passage of legislation which has provided for the Agvet Code to be in force in the State or the Northern Territory as the case may be which legislation is in accordance with the general Model State Bill which was prepared following the meeting of AAC (now SCoPI) held 2 August 1991.

12.

(a) The relevant Ministers will not submit to their respective Parliaments any Bill to amend or repeal legislation, or enact legislation which modifies or otherwise affects the Agvet Code, which is enacted without first giving at least 3 months notice, or such other agreed period, to the other parties of its intention to do so accompanied by a draft of the proposed amending, modifying or repealing legislation and consulting with the other parties concerning terms of the proposed amendment.

(b) Each party to this Agreement shall give at least 3 months notice, or such other agreed period, to each of the other parties of its intention to make regulations pursuant to the Agvet Code enacted by the Parliament of the Commonwealth, the States, or the Northern Territory, and provide particulars of the proposed registrants.

(c) Concerning legislation in addition to that covered by clauses 12(a) and (b) which may affect the application of the Agvet Code, each party to this Agreement shall notify the other parties of any legislation which has been made or which are intended to be made to the legislation of that party as soon as practicable and provide particulars of the regulations or proposed regulations.

13. The State or Territory Minister responsible for the administration of matters relevant to this Agreement shall be the Minister who administers the legislation enacted pursuant to clause 10 or any other Minister acting on behalf of, or for the time being acting for, that Minister.

14. The Commonwealth Minister responsible for the administration of matters relevant to this Agreement shall be the Minister who administers the Commonwealth legislation enacted pursuant to clause 9 or any other Minister acting on behalf of, or for the time being acting for, that Minister.

Policy

15.

(a) The parties agree to give effect to the policies as determined by SCoPI or such other body as may be established as a successor to SCoPI performing substantially the same functions as those which are now performed by SCoPI.

(b) The parties further acknowledge that decisions which have been taken by SCoPI and its predecessor since June 1991 in respect of matters of the type mentioned in this Agreement will be given effect by the APVMA pursuant to section 9A of the Agricultural and Veterinary Chemicals (Administration) Act 1992.

(c) In regards to the APVMA, the Minister must, where appropriate and practicable to do so, consult with the States and Territories as partners to the establishment of the APVMA.

(d) The States and Territories, as partners, will have input into the development of and endorse the APVMA strategic goals through SCoPI, or a delegated sub-committee.

(e) The Chief Executive Officer of the APVMA is to be appointed by the Commonwealth Minister for Agriculture, Fisheries and Forestry, following agreement on the selection criteria and appointment process by SCoPI or a delegated sub-committee.

(f) The APVMA Corporate Plan is to be submitted to the Commonwealth Minister for approval, following consultation with SCoPI or a delegated sub-committee.

(g) The Australian Government Minister for Agriculture will prepare a Statement of Expectations for inclusion in the APVMA Corporate Plan, for discussion by SCoPI. The APVMA will provide a report to SCoPI of its activities against the Statement of Expectations annually.

Roles and Responsibilities

16. The legislation enacted by the States and the Northern Territory (and enacted by the Commonwealth as a law in the ACT) has empowered the APVMA:

(a) to register agricultural and veterinary chemical products;

(b) to approve active constituents for chemical products, and to approve labels for chemical products;

(c) in accordance with Sections 101 to 103 inclusive of the Agvet Code;

(d) to issue licences to persons to carry out steps in the manufacture of agricultural and veterinary chemical products;

(e) to issue permits in respect of active constituents for proposed chemical products, or in respect of chemical products;

(f) to ensure compliance with the Commonwealth legislation.

17. The States and Territories are responsible, within their respective jurisdictions, for the control of use of chemical products.

18. The APVMA have:

(a) authorised as inspectors, under subsection 69F(1) of the Agricultural and Veterinary Chemicals (Administration) Act for the purposes of that Act and the Agvet Code of their respective States or Territories employees of the APVMA and may authorise other persons, including employees of the States or Territories, for the purposes of undertaking surveillance, investigation and sampling to monitor compliance with that Act and the Agvet Code of the respective State or Territory; and

(b) appointed as analysts, under subsection 69G(1) of the Agricultural and Veterinary Chemicals (Administration) Act 1992 for the purposes of that Act and the Agvet Code of their respective States or Territories employees of the States or Territories and may authorise other persons for the purposes of undertaking testing and analysis to monitor compliance with that Act and the Agvet Code of the respective State or Territory.

(c) The APVMA, the Commonwealth, States and Territories may enter into agreements for the delivery of agreed services related to the control of use of agricultural and veterinary chemicals, including agreements as to the funding of those services.

19. The Commonwealth, each State and each Territory will ensure that the respective prosecuting authorities will confer as necessary for determining what prosecutions should be commenced against persons who may have committed offences against both the Agvet Code and other legislation of a State or Territory controlling the use of agricultural and veterinary chemical products.

Dispute Resolution

20. Any Party may give notice to other Parties of a dispute under this Agreement. Officials of relevant Parties will attempt to resolve any dispute in the first instance.

21. If a dispute cannot be resolved by officials, it may be escalated to the relevant Ministers and if necessary, SCoPI.

22. If a dispute cannot be resolved by the relevant Ministers, it may be referred by a Party to the Council of Australian Governments for consideration.

Variation of the Agreement

23. The agreement may be amended at any time by agreement in writing by all the Parties.

24. Any party can propose an amendment to the Agreement for consideration at the next available meeting of the parties.

25. The Commonwealth will maintain the Agreement and provide an updated Agreement to the States and Territories if it changes.

Withdrawing from the Agreement

26. If any party to this Agreement intends to withdraw from this Agreement it shall give not less than 12 months notice in writing to each of the other parties of its intention to withdraw.

27. Notwithstanding clause 26, if any party to this Agreement withdraws from this Agreement without having given 12 months notice in writing to each of the parties of its intention to withdraw or if any party has failed to give the period of notice required by clause 12(a) or 12(b) any other party to this Agreement will be at liberty to withdraw from this Agreement in respect of the first mentioned party on giving the same period of notice as was given by the first mentioned party.

28. The Commonwealth may withdraw from this Agreement in accordance with clause 26 or clause 27 in respect of one or more parties without withdrawing from this Agreement in respect of the other parties.

The parties have confirmed their commitment to this agreement as follows:

Signed for and on behalf of the
Commonwealth of Australia by

Senator the Hon. Joe Ludwig
Minister for Agriculture, Fisheries and Forestry
3 / 5 / 2013

Signed for and on behalf of the
State of New South Wales by

The Hon. Katrina Hodgkinson MP
Minister for Primary Industries
3 / 5 / 2013

Signed for and on behalf of the
State of Victoria by

The Hon. Peter Walsh MP
Minister for Agriculture and Food Security
3 / 5 / 2013

Signed for and on behalf of the
State of Queensland by

The Hon. Dr John McVeigh MP
Minister for Agriculture, Fisheries and Forestry
6 / 7 / 2013

Signed for and on behalf of the
State of Western Australia by

The Hon. Ken Baston MLC
Minister for Agriculture and Food
3 / 5 / 2013

Signed for and on behalf of the
State of South Australia by

The Hon. Gail Gago MLC
Minister for Agriculture, Food and Fisheries
3 / 5 / 2013

Signed for and on behalf of the
State of Tasmania by

The Hon. Bryan Green MP
Minister for Primary Industries and Water
3 / 5 / 2013

Signed for and on behalf of the
Australian Capital Territory by

Mr Shane Rattenbury MLA
Minister for Territory and Municipal Services
27 / 6 / 2013

Signed for and on behalf of the
Northern Territory of Australia by

The Hon. Willem Westra van Holthe MLA
Minister for Primary Industry and Fisheries
3 / 5 / 2013

Annex 1

GOVERNANCE AND POLICY DEVELOPMENT

National Policy

Policy Principles

1. National framework policy is developed, reviewed and adopted in partnership between the states, territories and the Commonwealth.
2. National operational policy is developed and managed in close and ongoing consultation with stakeholders and as a partnership between states, territories and the Commonwealth.
3. The national framework is efficient and flexible enough to respond to state and regional issues and encourage industry co-regulation.
4. The national framework contains clear policy direction and areas of defined responsibility for agvet regulators and recognition of other regulatory frameworks.

Policy Outcomes

1. States, territories and the Commonwealth are equal partners in policy development, adoption and implementation.
2. Stakeholders have a clear pathway to provide input into the national framework.
3. Policy on access to, and use of, agvet chemicals is clear and applied nationally and ensures that the level of risk is held within acceptable limits.
4. Agvet regulatory policy is developed in a manner which recognises other regulatory frameworks, with input from relevant ministerial councils.
5. The regulator only has responsibility for assessing products that are clearly agvet chemicals.
6. The assessment agency can receive and request broad policy direction from governments.
7. The national framework is underpinned by best practice legislation that
   - accurately reflects nationally agreed government policy
   - allows flexible and adaptive regulatory responses
   - provides for intervention at the most effective point of the supply/use chain
   - provides for regional or local risk management solutions to deal with the impacts of chemicals that are consistent with nationally agreed principles
   - provides a system that is integrated between policy makers and regulators.

Legislative Instruments

Policy Principles

1. The national framework recognises industry co-regulation efforts where it is effective and efficient to do so.
2. Legislation provides agvet regulators with the flexibility to choose the most effective and efficient instruments.
3. Immediate and significant human health and environmental risks override right of administrative review so that agvet regulators are able to take action, particularly when there is a safety risk involved.

Policy Outcomes

1. Legislation has a range of legislative instruments, providing a full range of assessment, authorisation, monitoring, investigative and enforcement options.
2. Legislation facilitates development of codes of practice for manufacture, supply and use and recognises those codes where appropriate.
3. Legislation allows for industry co-regulation, where appropriate.
4. The manufacture, sale and use of agvet chemicals, and the risks to human health, trade and the environment, are managed.

Accountability for Performance

Policy Principles

1. Roles and responsibilities of the agvet regulators and the regulated community are clear.
2. Monitoring is sufficient to effectively inform the management of risks to human health, environment and trade and to demonstrate the performance of the scheme.
3. Systems are in place to obtain and make effective use of feedback from industry and the broader community.

Policy Outcomes

1. A performance monitoring structure in which there are clearly articulated roles and responsibilities for both the agvet regulators and the regulated parties.
2. A national framework that is responsive and transparent to stakeholders and which monitors and reports on its performance in meeting stakeholder expectations.
3. A national framework where feedback is provided and utilised to inform policy and improve operations.
4. A monitoring scheme that provides the necessary assurances that chemicals are being used safely.
5. Continuous improvement in the responsible use of agvet chemicals.

ACCESS TO CHEMICALS

The Operating Environment

Policy Principles

1. Regulation is efficient and ensures that all domestic or imported agvet chemicals are supplied and used safely and responsibly.
2. Jurisdictional boundaries do not unnecessarily restrict access to agvet chemicals or increase the costs to business of using those chemicals.
3. The national framework is such that participants in the chemical manufacturing industry and users have incentives to develop and operate efficiently.
4. Regulation does not constrain development of particular activities or industries unless that constraint is a necessary part of risk management.

Policy Outcomes

1. Effective regulation manages the risks to human health, environment and trade while minimising costs for businesses.
2. Users in all jurisdictions have the same right of access to agvet chemicals.
3. An internationally competitive scheme that facilitates access to new and existing agvet chemicals.
4. Regulation of agvet chemicals facilitates, rather than unduly constrains, industry development particularly for
   - industries with minor use demands for agvet chemicals
   - developing chemical industries.

Assessment and Registration

Policy Principles

1. Registration of agvet chemicals is based on a scientifically sound assessment of the risks to human health, environment and trade underpinned by data.
2. An appropriately conservative approach is taken where the science is uncertain or incomplete.
3. Efficiency in assessment is assured by

(a) alignment of assessment effort and data requirements with the level of risk
(b) transparency and predictability of process
(c) appropriate use of overseas data, methodologies and assessments.

4. The system facilitates registration of products to be used on as wide a range of pests/ host crops/animals as possible.
5. The standard setting roles and responsibilities of the national assessment agency, and other agvet chemical standard setting bodies, are clear.

Policy Outcomes

1. The system of assessment, registration and management of the portfolio of registered chemicals (including standard setting) is transparent, clearly articulated and easily understood.
2. The acceptable levels of risk and assessment methodologies are transparent and current.
3. Assessment processes are commensurate with the level of risk.
4. Assessment and review processes and risk communication are transparent so that all stakeholders can be confident that the risks associated with the use of agvet chemicals are being managed.
5. Assessment requirements and timeframes are appropriate to efficiently assess risks.
6. Provision of scientific advice to the agvet chemical regulator to inform its risk assessment is open to contestable processes where possible.
7. The national framework clearly articulates roles and responsibilities and the assessment methodologies of other agvet chemical standard setting bodies.
8. Agvet chemicals are available for use on as wide a range of host/pest combinations as possible.

Management of Chemical Portfolio and Chemical Review

Policy Principles

1. The regulatory effort in the management of the chemical portfolio is directed toward management of the aggregate risk.
2. Processes are responsive to new information, efficient in assessing against current standards and completed in a timely manner.
3. The registrant (or holder of approval) is responsible for ensuring that a registered product continues to meet current standards.

Policy Outcomes

1. Chemical reviews are carried out according to clearly defined priorities and timelines.
2. Priorities in chemical review are set on the basis of minimising the aggregate risk from the whole portfolio of registered chemicals.
3. Transparent and open consultation with stakeholders on chemical reviews.
4. Efficient processes ensure that agvet chemicals meet current standards.
5. The responsibility lies with the registrant (or holder of approval) to demonstrate that a registered product meets current standards.

Assessment and Use Information

Policy Principles

1. The national agvet assessment agency determines the instructions for use of a registered chemical and the standards for dissemination of those instructions.
2. The national agvet assessment agency is not required to determine those instructions for which it does not have direct responsibility.
3. The provision of product use information is up to date and accessible through the most efficient media.

4. The review, redesign and renewal of information is directed at efficient management of aggregate risk.

Policy Outcomes

1. Users have access to full information on how agvet chemicals should be used.
2. Instructions on labels and in other media are clear, easily understood, up to date and enforceable.
3. Information can be delivered by the most appropriate technology – eg electronically.
4. The registrant is responsible for meeting the regulatory requirements, for labelling and other information, of all relevant agencies.

Permits and Permissible Uses

Policy Principles

1. The scheme allows uses outside the approved uses in certain circumstances or with specific approvals.
2. The scheme contains a mechanism to restrict approved uses.
3. Development of particular activities or industries is not constrained by the scheme unless that constraint is a necessary part of risk management.
4. The scheme achieves a balance between the community's right to know and commercial interests.

Policy Outcomes

1. A process exists for arranging appropriate authorisation to ensure timely access to agvet chemicals for
   (a) emergency responses
   (b) research and development.
2. Access to chemicals for minor industries and minor uses in larger industries.
3. Permissible uses do not carry unacceptable risk.
4. Community awareness of information provided as part of a research and development permit is balanced against commercial interests to achieve the greatest net public benefit.

Supplier (importers, manufacturers and retailers/distributors) Compliance and Enforcement – Registration and Post Registration

Policy Principles

1. In the management of the risks of agvet chemical use the regulatory system recognises the contribution and responsibilities of other parties that deliver industry stewardship and quality assurance programs.
2. Regulatory powers, monitoring and enforcement effort are sufficient to ensure that the chemicals supplied are in accord with those that were assessed.
3. Suppliers form part of any mechanism that regulates access to agvet chemicals.

Policy Outcomes

1. Suppliers facilitate effective and appropriate supply and use of agvet chemicals.
2. The product supplied accords with the product assessed and registered and the approved instructions accord with those registered for the product.
3. A range of options is available to ensure compliance and encourage behavioural change.
4. Industry expertise and co-regulation, compliance, training, quality assurance programs, codes of practice and best management practice in compliance and enforcement arrangements are used by agvet regulators where appropriate to achieve continuous improvement in chemical use practice.

Veterinarians' prescribing rights

Policy Principles

1. 'Prescribing rights' are defined so that their exercise provides for the protection of animal health and welfare without creating unacceptable risks to human health, trade or the environment.
2. Prescribing rights (including compounding rights) do not substitute for the registration of veterinary chemical products or the use of existing registered veterinary chemicals.

Policy Outcomes

1. The exercise of prescribing rights is limited to those with agreed registration to practise and does not create unacceptable risks associated with use of chemical products.
2. Veterinarians may use unregistered veterinary chemicals or registered veterinary chemicals off-label by right in certain circumstances where risks can be managed.
3. Veterinarians do not compound chemicals and supply them except for the treatment of animals which are directly under their care.

USE OF CHEMICALS

User Competence and Training

Policy Principles

1. Link access to chemicals to user competency.
2. The level of competence required is commensurate with the identified risk.
3. Where appropriate, consideration is given to industry initiatives as the instrument to ensure compliance.
4. A consistent set of competency requirements is set within the national framework which applies across jurisdictional boundaries.

Policy Outcomes

1. Users
   - are aware that they need to use chemicals safely and responsibly
   - are competent in the use of agvet chemicals
   - can demonstrate competence, through training or other appropriate means.
2. The national training competencies reflect the required management of agvet chemical risk.
3. Only authorised users are able to purchase and use certain categories of chemicals and the level of competency required is commensurate with the risk.

Use risk management, emergency response, monitoring and traceback

Policy Principles

1. Monitoring is undertaken to allow early identification of issues/problems and to assess the appropriateness of the current risk management arrangements.
2. Regulators are adequately resourced with competent staff.
3. Supporting regulation is sufficient to allow effective traceback and emergency response.
4. Regulators coordinate with user industry co-regulatory approaches where it can be shown that
   (a) coordination avoids duplication of monitoring and enforcement effort
   (b) the co-regulatory regimes provide effective risk management.

Annex 1

Policy Outcomes

1. Effective and efficient monitoring of agvet chemical use and practices and any negative effects.
2. Capacity to identify and respond to emergency and emerging issues.
3. Recognition of industry expertise through co-regulatory approaches to compliance and enforcement
   - encouragement/empowerment of industry programs to support/expand government regulation (eg industry managed training programs, quality assurance programs, codes of practice, compliance arrangements and best management practice)