s. 22(1)(a)(ii)

From: s. 47F(1) <s. 47F(1)@yahoo.com>
Sent: Thursday, 13 August 2020 1:28 PM
To: 's. 47F(1) '; 'Gaglia, Julie'
Cc: 's. 47F(1) '; 's. 47F(1) '; Agvetreview
Subject: RE: s. 11C(1)(b) minutes and web summaries [SEC=UNOFFICIAL]
Attachments: s. 11C(1)(b) meeting 1_ALS s. 47F edits s. 47F(1 edits 130820(002).docx; s. 11C(1)(b) meeting 1_web summary s. 47F edit s. 47F(1 edits130820.docx; s. 11C(1)(b) meeting 2 s. 47F edits s. 47F(1 edits 130820.docx; s. 11C(1)(b) meeting 2_web summary s. 47F edits s. 47F(1 edits 130820.docx; reflections s. 47F edits s. 47F(1 edits 130820.docx

Follow Up Flag: Follow up
Flag Status: Completed

Categories: s. 22(1)(a)(ii)

Dear Julie

Please find the documents with my edits from the s. 11C(1)(b) meetings attached.

Thank you

s. 47F(1)

From: s. 47F(1)
Sent: Wednesday, 12 August 2020 11:27 AM
To: 'Gaglia, Julie' ; 's. 47F(1) '
Cc: 's. 47F(1) ' ; 's. 47F(1) ' ; 'Agvetreview'
Subject: RE: s. 11C(1)(b) minutes and web summaries [SEC=UNOFFICIAL]

Dear Julie,

Please find attached reviewed documents.

Best regards

s. 47F(1)

From: Gaglia, Julie <Julie.Gaglia@awe.gov.au>
Sent: Tuesday, 11 August 2020 8:34 PM
To: s. 47F(1) <s. 47F(1) @yahoo.com>; s. 47F(1) <s. 47F(1)@bigpond.net.au>
Cc: 's. 47F(1) ' <s. 47F(1) 100@gmail.com>; 's. 47F(1) ' <s. 47F(1)@abclass.com.au>; Agvetreview <agvetreview@agriculture.gov.au>
Subject: s. 11C(1)(b) minutes and web summaries [SEC=UNOFFICIAL]

Hi s. 47F(1) and s. 47F(1),

Please find attached the minutes and web summaries from the s. 11C(1)(b) meetings and the reflection minutes for your consideration.

Also just a gentle reminder if you have any changes to the minutes from the 29 July panel meeting if you could send these through so we can finalise and send out with the panel papers for next weeks meeting.

Cheers,
Julie

Julie Gaglia
Assistant Secretary
Agvet Chemicals & Forestry Branch | Agvet Chemicals, Fisheries, Forestry and Engagement

Phone 02 6272 4298 | Mobile s. 47F(1)
julie.gaglia@agriculture.gov.au
Department of Agriculture. Water and the Environment
18 Marcus Clarke Street, Canberra ACT 2601 Australia
GPO Box 858 Canberra ACT 2601 Australia

The department acknowledges the traditional owners of country throughout Australia and their continuing connection to land, sea and community. We pay our respects to traditional owners, their cultures and elders past and present.

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AGVET REVIEW PANEL USE ONLY

INDEPENDENT REVIEW OF THE AUSTRALIAN AGRICULTURAL AND VETERINARY CHEMICALS REGULATORY FRAMEWORK (AGVET REVIEW)

MINUTES – MEETING WITH s. 11C(1)(b) MEMBERS (GROUP 1)

22 July 2020 ⇔ 10:01am ~~pm~~ – 12:05pm

Attendees

Panel: Ken Matthews (Chair), Dr Craig Suann, Dr Anne Astin (joined meeting at 11am)

Department: Julie Gaglia, s. 22(1)(a)(ii) , s. 22(1)(a)(ii)

Stakeholders: s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b) s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) and s. 11C(1)(a) (s. 11C(1)(b) s. 11C(1)(b)), s. 11C(1)(a) and s. 11C(1)(a) (s. 11C(1)(b)).

Secretariat: s. 22(1)(a)(ii), s. 22(1)(a)(ii)

Apologies: Dr Mary Corbett

1. Welcome

The Chair commenced the meeting at 10:01 am and introduced each of the panel members.

The Chair outlined eight key areas that are shaping the panel's consideration following consultations to date; the value of the APVMA, the breadth of the review, a coherent package of reforms, two equal objectives for the future system, importance of social licence, the effect of COVID-19, the vulnerability of the system through current~~from~~ control of use arrangements, and delivering on the government's deregulation agenda.

The Chair stated the following in relation to these areas:

- The panel respects the APVMA and the need to allow its continued independence and risk-and science-based decision making and to enhance this where possible in the future.
- The review is not a review of just the APVMA. The panel's remit is a 'whole of system' regulatory review, covering agvet chemicals design, manufacture, supply, use and disposal.
- The panel intends to develop a coherent package of reform, rather than a collection of disconnected improvements. The package should be understood by members of the public, and all those that use it. The Chair clarified the panel was not afraid to make unpopular recommendations if they would deliver sound and sensible improvements to the system.
- The panel has identified two equal outcomes for reform – improved access to chemicals for users, and ensuring the safety and protection of human health, animal welfare and the environment. Neither is more important than the other.
- Australia's social licence for using agvet chemicals is under growing threat and any future regulatory system needs to continue to build society's confidence in its effectiveness and objectives. There are many current threats to social licence for agvet chemical use, such as societal attitudes in Europe and the western states of the USA to glyphosate and GMO, community concerns for animal welfare in live animal export discussions, anti-vaccine movements as well as a preference for biological controls.
- While COVID-19 and the issues it has highlighted in terms of supply chains was not part of the panel's terms of reference, the panel would be remiss not to consider the implications and include these in its report to government. The panel sees the response to COVID-19 as bringing to the fore the need for supply chain assurance and flexibility to respond better to such disasters in the future.
- The panel acknowledges the regulatory system is only as strong as its weakest link and has heard repeatedly from stakeholders that control of use is a fundamental flaw in the current

system. The panel will be making recommendations to improve national consistency of control of use.

- The current government has a focused deregulation agenda~~;~~, however the panel believes that it is important to balance streamlining processes with protecting the health of humans, animals and the environment and maintaining public confidence. Where deregulation makes sense, the panel will be actively pursuing such options, but not simply for the sake of deregulation.

The Chair summarised the goals of the panel as building a regulatory system for the next 20 to 30 years that continues to build~~s~~ public confidence in the system and retains public licence for chemical use.

2. Stakeholder feedback
Benefits test

Stakeholders voiced concern around the use of a benefits test, advising that global experience is that such a test does ~~they~~ do not achieve the~~ir~~ policy intent and does not result in new science in the assessment process. It also requires evidence and assessment of aspects that are hard to predict at registration, as the value of the product will change with other changes in the landscape e.g. when resistance develops.

Stakeholders were opposed to having to prove a benefit to society as a condition of registration. Any benefits test would have to be coupled with efficacy to confirm the stated claims.

The Chair responded that as a principle, benefits ought to always be brought into any regulatory decision making. Rather than being a test, the intent was to allow the decision maker to consider reasonable national or regional benefits as an offset for downsides of certain chemicals. The panel will need to think carefully about how closely the legislation should prescribe any benefits to be considered or leave discretion to the regulator. Specifying what benefits should be considered in legislation would lose the desired room for flexibility and common sense. Stakeholders stated that the APVMA already considers benefits when assessing applications~~;~~ it is just not stipulated in the legislation.

Stakeholders discussed whether there was a way to prioritise the regulator's process in some situations, such as applications for new, more innovative, or more environmentally benign products.

s. 11C(1)(b) noted it ~~they~~ had originally suggested the concept to manage the reduced throughput and enable applications to be prioritised during the APVMA's relocation. Prioritisation towards higher value applications remains a key issue but s. 11C(1)(b) was no longer convinced that a benefits test was the best way to achieve this. The APVMA's inability to prioritise does make it difficult to participate in some global activities like joint reviews. If a prioritisation system was implemented, careful consideration would be needed to determine how to weigh negative and positive impacts to decide which applications get priority. The Chair responded that prioritisation means there would be winners and losers, but it would be a sensible thing to have a rational way of assigning priority.

The Chair asked stakeholders whether the regulator fully used discretion currently available to it under the legislation. One stakeholder stated that this was the case and they use their discretion to shift resources around to meet their quarterly timeframes for completing assessments.

Overlap of regulators

Stakeholders described the considerable delays that occur when regulators' responsibilities overlap. They asked the panel to look at whether such interactions are administered efficiently and if not, how they could be streamlined.

Stakeholders advised that poisons scheduling is subject to the biggest potential delays due to its reliance on a small number of meetings fixed throughout the year; missing a meeting can result in a delay of 8 months in getting an application approved. Stakeholders informed the panel that whilst the TGA process was reformed to allow applicants to go directly to the TGA, in practice this has not worked, as the TGA are not resourced to assess applications and refer them to the APVMA for assessment. Stakeholders suggested that allowing the APVMA to be a delegate for poisons scheduling would be an ideal way of improving this process.

Stakeholders also raised concerns over between the overlaps between the OGTR and the APVMA and see this as duplicative and inefficient. There should be clear responsibilitiesy and accountabilities for each of the two regulators. that do not cross over. The panel responded that this is a prime n area ripe for reform and streamlining, and they are looking at whether there is scope for the APVMA to take on board the OGTR's current responsibilities role in relation to agvet chemical products.

Stakeholders advised that the timeframes for gaining biosecurity import permits (for biologicals) often created delays in bringing product to Australia and they cannot be renewed or extended so there is a continuously need to reapply. It was suggested that it appears to depend on which officer is doing the assessment so there is a lack of consistency by the APVMA.

The Chair stated that as they were looking at the entire agvet chemicals regulatory system, that this also included where the scheme interacts with other systems, so they could make recommendations about other agencies if this would bring efficiencies and reduce unnecessary regulation for agvet chemicals.

Registration by reference

Stakeholders supported the regulator's existing discretion to consider international data to expedite appropriate applications while but retaining the requirement for relevant local assessments. The Chair queried whether the APVMA re – examines does the international assessment provided with applications. There were mixed views from stakeholders on this, with some suggesting that in their experience the APVMA will reassess the information.

Stakeholders suggested that the appropriateness of registration by reference would need to be considered on a case by case basis, dependent on the product and the need for specific local data. Stakeholders stated that the proposal has merit where there is strong alignment of the comparable international regulatory systems, but this would not always be the case. For example, the treatment of residues in the US is very different to how they are considered in Australia. In addition, stakeholders considered that this model would result in Australia having to ban or remove chemicals that were removed in the reference country. The Chair clarified that the panel did not consider that there would be an automatic requirement for the removal of chemicals removed in reference countries as it would depend on the reasons for removal and thosee reasons may not be relevant to Australia.

Stakeholders queried whether a registration by reference approach was needed given their assertion that many chemicals are registered in Australia prior to registration in other countries. The panel inquired as to what makes Australia an attractive place for first registrations. Stakeholders advised that it was due to several reasons, being counter-seasonal to the northern hemisphere, the

credibility and reputation of the APVMA, and the ability to get easier registration in Asia if registered in Australia.

Global recognition of regulatory system quality

Stakeholders emphasised the importance of Australia having a world class regulator in the APVMA and how other regulators refer to Australia's credible science-based decision-making process. Some stakeholders indicated that this was evidence that the APVMA does not require significant changes to its operations and only minor tweaks to improving ~~approve~~ its processes should be considered.

Community consultative committee/national leadership/governance

Stakeholders stated that whilst having a community consultative committee was good in theory, in reality it was costly and difficult to sustain. An alternative option may be to hold an annual public consultation meeting that allows for public comment and APVMA interaction with the public. The Chair responded that if a consultative committee was to be considered, it would need to be well designed with meaningful reporting requirements and responsibilities.

The stakeholders suggested there is considerable scope for the APVMA to improve its public communication. The APVMA's current communication strategy is focused on information for applicants rather than engagement with the wider community (e.g., its website is not at all consumer focused), unlike FSANZ that has a very effective consumer portal.

Stakeholders stated that the APVMA's media engagement could also be more proactive, especially when it commences ~~engaging on~~ products ~~under~~ reviews, or where there is media focus ~~coverage~~ (e.g., on products banned in EU or elsewhere). They further suggested that the APVMA could be more proactive about its ~~their~~ science and risk-based decisions, so the community was aware of what is being ~~they~~ considered.

Stakeholders suggested that in terms of communicating on the broader regulatory system, that the department was the most appropriate body to undertake this role. They further proposed that the department should also provide overall governance for the system. The panel advised that they are considering governance of the whole system and exploring options for providing national leadership.

Harmonisation of Control of Use regulation

Stakeholders stated that having control of use within a national compliance system is very important. They receive constant feedback that while the states and territories are responsible for control of use, they are not adequately resourced and undertake little to no compliance which risks the community's ~~ies~~ trust in the regulatory system. There was general agreement that the current control of use system is not working, and a national system would be preferable to current arrangements.

It was suggested by one stakeholder that the Victorian system of control of use was the ultimate in a co-regulatory system and consideration is needed on whether this provides an ideal model that should be implemented in other jurisdictions.

Co-regulation

Stakeholders agreed that there is merit in using industry quality assurance schemes and co – regulation models. However, their primary role is as marketing tools, so there would be concern if there was a loss of accountability that would impact public confidence in the system.

There was discussion about ~~round~~ the ability of industry schemes to be used to aid in compliance activities within the scheme and whether this would be an effective way of redistributing the responsibility for ensuring those within the regulatory system were compliant. This would be most

effective where data required under industry schemes could be linked into the regulatory system. An example discussed was the ability for smart labelling to link data on labels with real time information from farmers on use and to provide alerts and access to the most up- to- date information.

Monitoring

Stakeholders stated that environmental monitoring was important to maintain public confidence and it is not currently done very well. Monitoring is done differently in each state and it would be more desirable to have a nationally consistent monitoring methodology that was published and transparent and aligned with international standards. Stakeholders suggested their preference would be to have an independent body undertake the monitoring to further build public trust in the regulatory system.

Stakeholders further indicated that the current model for monitoring in the Great Barrier Reef (GBR) was something they would not want to see replicated anywhere else. The methodology used in the GBR is not published and this makes it difficult to be able to defend registrations approved by the APVMA that indicate the risks of use can be adequately managed. Stakeholders further stated that current publishing of residue monitoring is counter-productive because it is published in isolation without context, and residues in themselves do not necessarily indicate there is a problem – but this is not well communicated to the public.

National Capability, new technologies and innovation

The Chair asked stakeholders if an external party could encourage or incentivise the uptake of registrations by smaller SMEs. Stakeholders acknowledged the regulator's efforts to support smaller start-up companies ~~new SMEs~~, however they felt more support was needed, especially regarding complex novel biological product assessments.

Stakeholders supported the possibility of Universities and innovative firms assisting the regulator with research for new technologies and noted there would be benefits if this option was legislated. However, some stakeholders said that the current legislation was already technology neutral and able to adequately assess new technologies as they came to market.

Stakeholders supported the proposal to have third-party accredited assessors. They advised that the APVMA, after running a pilot suggested that there are not enough assessors available to support the provision of external assessment. It was suggested that if there was a market for this service then assessors would be available. Stakeholders indicated that it would be important to ensure that if such a system was implemented that the APVMA wasere not re-doing assessments provided by third parties as this would defeat the purpose.

3. Meeting wrap-up

The Chair thanked the stakeholders for their valuable feedback.

The Chair closed the meeting at 12:05 pm.

Australian Government
Department of Agriculture, Water and the Environment

Review of agvet chemicals regulatory framework

Issues arising from stakeholder consultation with crop protection companies

Meeting held on 22 July 2020

- Stakeholders were not convinced that a specified benefit~~'~~s test was desirable and were concerned that it would bring complexity into the registration process and would not add any improvements given that they consider the APVMA can already, and does, consider benefits.
- Stakeholders raised concerns over the overlap and potential duplication and inefficiencies between the APVMA and other regulators such as the Therapeutic Goods Authority and the Office of the Gene Technology Regulator and requested the panel consider how to improve these interactions
- Stakeholders suggested that the appropriateness of the registration by reference proposal would depend on the product and the need for specific local data. They were also concerned about whether this would lead to automatic withdrawal of products in Australia when they are removed in the reference country.
- In addition, stakeholders indicated that Australia is already a first-choice market for chemical registrations.
- Stakeholders emphasised the importance of maintaining a world-class regulator (the APVMA) and that any reform changes should not diminish the APVMA's standing.
- Stakeholders supported the need for more ~~better~~ proactive communication by the APVMA with the community but were not convinced that a community consultative committee would achieve this effectively. It was suggested that the APVMA could improve its website to be more consumer friendly and informative and they should actively explain their decisions to build greater trust in how they reach conclusions.

Commented [s. 47F(1): "decisions" rather than "conclusions"?

- Stakeholders supported the need for a national control of use system as the current arrangements with state and territories having responsibility was clearly not working.
- Stakeholders generally supported the notion of co-regulation as long as this didn't reduce accountability. Being able to link data from industry schemes with the regulatory system was supported. Smart labelling was cited as a good example if it could link label information with real time use to improve chemical application.
- Stakeholders suggested that environmental monitoring of chemical residues needs improving as it was a critical mechanism to ensure the community that regulatory controls were effective. It was stated that monitoring should be based on a nationally consistent methodology that was transparent and should be published with appropriate context to enable the community to understand the implications of the results.

- Stakeholders saw merit in having better relationships between the regulator and research institutions, especially in allowing external experts to be able to produce guidance material for new technologies rather than it solely being the responsibility of the regulator.
- Stakeholders supported the proposal for third party accredited assessors and stated that the APVMA should not be able to re-examine ~~do~~ such assessments as this would defeat the purpose of having an external assessment service.

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AGVET REVIEW PANEL USE ONLY

INDEPENDENT REVIEW OF THE AUSTRALIAN AGRICULTURAL AND VETERINARY CHEMICALS REGULATORY FRAMEWORK (AGVET REVIEW)

MINUTES – MEETING WITH CHEMICAL COMPANY STAKEHOLDERS

22 July 2020 ⇔ 1:05pm – 2:48pm

Attendees

Panel: Ken Matthews (Chair), Dr Craig Suann, Dr Anne Astin

Department: Julie Gaglia, s. 22(1)(a)(ii) , s. 22(1)(a)(ii)

Stakeholders: s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) and s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b)), s. 11C(1)(a) (s. 11C(1)(b))

Secretariat: s. 22(1)(a)(ii), s. 22(1)(a)(ii)

Apologies: Dr Mary Corbett

Welcome

The Chair commenced the meeting at 1.05pm and introduced each of the panel members.

The Chair outlined eight key areas that are shaping the panel's consideration following consultations to date; the value of the APVMA, the breadth of the review, a coherent package of reforms, two equal objectives for the future system, importance of social licence, the effect of COVID-19, the vulnerability of the system through current~~from~~ control of use arrangements, and delivering on the government's deregulation agenda.

The Chair stated the following in relation to these areas:

- The panel respects the APVMA and the need to allow its continued independence and risk- and science-based decision making and to enhance this where possible in the future.
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- The panel intends to develop a coherent package of reform, rather than a collection of disconnected improvements. The package should be understood by members of the public, and all those that use it. The Chair clarified the panel was not afraid to make unpopular recommendations if they would deliver sound and sensible improvements to the system.
- The panel has identified two equal outcomes for reform – improved access to chemicals for users, and ensuring the safety and protection of human health, animal welfare and the environment. Neither is more important than the other.
- Australia's social licence for using agvet chemicals is under growing threat and any future regulatory system needs to build society's confidence in its effectiveness and objectives. There are many current threats to social licence for agvet chemical use, such as societal attitudes in Europe and the western states of the USA to glyphosate and GMO, community concerns for animal welfare in live animal export discussions, anti-vaccine movements as well as a preference for biological controls.
- While COVID-19 and the issues it has highlighted in terms of supply chains was not part of the panels' terms of reference, the panel would be remiss not to consider the implications and include these in its report to government. The panel sees the response to COVID-19 as bringing to the fore the need for supply chain assurance and flexibility to respond better to such disasters in the future.
- The panel acknowledges the regulatory system is only as strong as its weakest link and has heard repeatedly from stakeholders that control of use is a fundamental flaw in the current

system. The panel will be making recommendations to improve national consistency of control of use.

- The current government has a focused deregulation agenda~~,~~ however the panel believes that it is important to balance streamlining processes with protecting the health of humans, animals and the environment and maintaining public confidence. Where deregulation makes sense, the panel will be actively pursuing such options, but not simply for the sake of deregulation.

The Chair summarised the goals of the panel as building a regulatory system for the next 20 to 30 years that continues to build~~s~~ public confidence in the system and retains public licence for chemical use.

Trade information (MRLs)

Stakeholders queried whether the review's scope included marketers for the trade of commodities and the need to meet importing country requirements such as MRLs. For instance, the wine industry is very good at keeping informed on ~~on top of~~ relevant MRLs, but in other industries this is not done as well and it takes ~~up~~ considerable resources for individual commodities to keep track of ever-changing MRLs in export markets. Often growers do not know where to source ~~get~~ relevant information on MRL~~s~~S and therefore do not know if they will be able to meet importing country requirements. The panel advised that this issue had been raised consistently throughout the consultations and they would be considering options to improve MRL information dissemination.

Harmonisation of Control of Use regulation

Stakeholders argued that having state-based control of use results in each jurisdiction operating to ~~pushing~~ their own agenda's rather than acting ~~operating~~ in the national interest. Consensus is difficult and almost impossible to achieve because of state-based interests. In addition, the relevant state compliance officers (eg Environmental Health Officers) often have little awareness of the system as their primary role is on ~~in~~ other areas. They act only in response to ~~with only responsibility for~~ 'nuisance complaints' in this area. ~~(e.g. Environment, health inspectors).~~

Stakeholders were of the view that control of use needs to be national and that this could only be successfully achieved if the Commonwealth were to take over responsibility for delivery. This would deliver a consistent~~ly~~ national system for both supply and control of use. Stakeholders stated that if this was achieved, industry would have greater confidence in bringing products to market knowing the same requirements on use applied in every jurisdiction. Stakeholders also considered that the APVMA 'having boots on the ground' would provide them with better feedback relating to ~~on~~ their regulatory decisions on registrations.

It was suggested that the Australian Dangerous Goods Code implementation provided an effective model of how a national agvet chemical control of use system could operate.

Smart labelling

Stakeholders considered that smart labelling could deliver significant improvements in user friendliness and chemical application.

There was strong support to maximise the smart labelling concept by allowing for local assessments based on the specific circumstances of use. Currently label use pattern instructions are based on the worst-case scenario for a product with respect to withholding period, etc. However, if users were able to access software allowing them to type in different application rates and get an automatic MRL, this would ensure that residue limits are met. Thus, a complete and ~~full~~ dynamic smart label could allow for the real-time entry of ~~the~~ actual use details to provide ~~get~~ a more relevant withholding period, etc.

This could be cutting edge risk management that would ~~and~~ allow Australia to lead the world, as smart labels in other countries are just glorified QR codes to access the standard label.

The panel advised that they are keen to use the full capability and flexibility that smart labelling can offer and to look at how this could also link in with users' spray diaries etc.

Listing and low risk products

Stakeholders generally agreed that there needed to be more use of appropriate pathways for low risk products. The APVMA currently has the option of listed products, however stakeholders stated that this has only been used for pool and spa chemicals. Stakeholders suggested that it would probably be easier to simply take those types of low regulatory risk products, such as pool and spa chemicals, out of the agvet chemicals regulatory system.

Commented [s. 47F1]: This was strongly put by stakeholders

It was suggested that guidance on how the regulator should address low risk products would be of benefit. Currently, this has only been addressed in part (e.g., the guidelines for biologicals). In overseas regulatory authorities there is clear guidance on when a product is low risk and does not need to provide data for every part of an assessment.

Overlap of regulators

Stakeholders raised concerns about the regulatory overlap and apparent contradictions between the multiple regulators that agvet chemicals interact with (APVMA, TGA, OGTR, WHS, ACCC and dangerous goods). They were keen to have the review examine ~~look at~~ opportunities for improved efficiencies and the removal of duplication and overlap between these multiple regulators. Finding improvements to the TGA poisons scheduling process was specifically identified as an area that could be streamlined.

Stakeholders stated that ~~s~~as frequent importers, they also encounter issues with overlap of international and domestic regulation of the same matters. This is not a space that is commonly looked at from a compliance and regulatory burden point of view. For instance, a dangerous good shipment by sea must bear the relevant international dangerous goods label. However, these same containers then need to be re-labelled to comply with the Australian Dangerous Goods Codes before they can be distributed across ~~round~~ the country.

Biosecurity permits

Stakeholders raised concerns with the lack of renewal available under the Biosecurity Import Conditions (BICON) permit system. The permits are only issued for two years with no differentiation based on whether the product remains under active research and is therefore changing or whether it has become ~~is~~ a settled formulation. It takes 3-4 months to obtain ~~get~~ a renewal for ~~of~~ a product, even when it has been previously assessed and is identical (no change).

Stakeholders suggested that this could be simplified and improved by making changes to the permit, with a notification or declaration from the manufacturer stating that nothing has changed. This would remove the potential for discontinuity in supply associated with delays in reassessing the permit.

Building capacity

Stakeholders saw merit in having better relationships between the regulator and research institutions, especially in allowing external experts to be able to produce guidance material for new technologies rather than it falling solely on the regulator. This has been achieved successfully in the US through the IR-4 minor use program.

Stakeholders stated that there are, however, big differences between Australia and the US in employment opportunities and our greater reliance on distributed agronomists for this work versus a consolidated government-led resource like IR-4 could make this more difficult.

The panel advised that building national capacity was an area they were very focused on and they were considering options on how best to achieve this.

Social licence

Stakeholders discussed how the maintenance or improvement of social licence and public acceptance for agvet chemicals could be measured and benchmarked. It was stated that FSANZ and the NSW Food ~~a~~Authority were recognised as having been successful at working to engage with the public and building reputational trust and confidence. Stakeholders noted that while they have a high level of public acceptance, their work is not as controversial as the use of agvet chemicals.

Stakeholders suggested that if the agvet chemicals regulators were more transparent and engaged more with the community, this would continue to enhance public ~~it could build~~ confidence in our system, especially if the~~y~~ regulator, or other parties in the agvet regulatory system, explained the important role these chemicals play in food production. The panel agreed that more transparency and engagement was needed to build community trust in the regulatory system.

Stakeholders considered that having a clear spokesperson to address issues and explain the regulatory system's importance is critical and currently lacking. It was agreed that communication cannot be based solely on the science, as most people do not understand or even want to know about the science. The Chair stated that people's views will be influenced by who is presenting and using the science and whether they are a trusted source~~, so it was important to find a respected science communicator~~.

From s. 11C(1)(b) perspective governance of the whole system and therefore a communication/spokesperson role would sit appropriately within the Department of Agriculture, Water and the Environment (department) rather than the APVMA. The APVMA does have a role in being more transparent about its ~~their~~ processes, which are currently not well understood or communicated ~~very difficult to find out about~~ and the department could assist in this communication. A harmonised governance structure would allow for the department to be the go-to point on how the regulatory system works and for working through peoples' concerns.

Efficacy

Stakeholders considered the proposed removal of efficacy assessments to be a concern. They suggested that ~~the~~ efficacy testing will still be undertaken for company liability and insurance purposes so there is no real savings to be made. Stakeholders considered that there is a risk that removing efficacy could undermine community confidence in the system.

Registration by reference

Stakeholders were concerned about there being any mandatory obligation for ~~impetus that the~~ APVMA to ~~must~~ accept overseas registrations and the likelihood that this would mean that they must ~~had to~~ also accept overseas decisions to remove chemicals. They considered that the discretionary ability of the APVMA to consider overseas assessments currently works well ~~fine~~. Industry has had a lot of success with getting the APVMA to recognise overseas assessments, particularly in the area of using overseas toxicology assessments for poisons scheduling.

Funding

s. 11C(1)(b) stated that their views on funding and cost recovery arrangements can be found in their submission to the recent CRIS process.

Stakeholders reiterated the need for a complete, first principles review as first promised in 2014. Companies would be ~~happy~~ willing to pay for getting work done quicker. FSANZ uses a model where the applicant receives ~~gets~~ a refund if the agency can process the application quicker and at less cost than anticipated.

There was also concern about the likely cross-subsidisation in the system, with big agricultural products subsidising other products, especially veterinary medicines such as many exogenous vaccines that are dealt with as unregistered (by permit) and so incur no sales levy.

Commented [s. 47F]: autogenous?

Stakeholders raised the issue about the perception that some sectors of the community have on the reliance of the APVMA on cost recovery from industry compromising ~~presenting issues for~~ their independence, and that there was the need to change the narrative around this perception. The Chair raised the notion of maybe having a third party collect the fees and charges on behalf of the APVMA and whether that would ~~allay~~ reduce community concerns. There was concern that this may increase costs for industry.

It was suggested that there should be more government funding of activities undertaken by the APVMA that were seen to be in the public interest and that this may assist in alleviating the argument the agency is 'bought and paid for by the agricultural chemicals industry'.

Meeting wrap-up

The Chair thanked the stakeholders for their valuable feedback and closed the meeting at 2:48pm.

Australian Government
Department of Agriculture, Water and the Environment

Review of agvet chemicals regulatory framework

Issues arising from stakeholder consultation with crop protection companies

Meeting held on 22 July 2020

- Stakeholders were supportive of improvements to monitoring international Maximum Residue Limits. The ever-changing standards in export markets are difficult for industry and users to track and it would be beneficial ~~good~~ if this was centralised in some form.
- Stakeholders were supportive of a national control of use system that operated in the national interest rather than the current system that focuses on state/territory arrangements and interests.
- Stakeholders were supportive of the potential for smart labelling to deliver significant improvements for ~~in~~ end users ~~friendliness~~. There was strong support to use smart labelling to allow for local assessments based on real-time entry of the specific circumstances of use, to produce improvements in chemical application with more relevant withholding periods.
- Stakeholders were supportive of the need for more use of appropriate pathways for low risk products with more guidance on how the regulator will address low risk products. Stakeholders suggested it may be easier to simply take low regulatory risk products such as pool and spa chemicals out of the agvet chemicals regulatory system.
- Stakeholders expressed the ~~a~~ need to improve efficiencies and reduce duplication~~s~~ and overlap between the multiple regulators of agvet chemicals (APVMA, TGA, OGTR, ACCC, dangerous goods and WHS regulators).
- Stakeholders were supportive of any reform changes that would improve the renewal timeframes for the Biosecurity Import Conditions (BICON) permit system. Stakeholders suggested that a manufacturer be able to make a declaration stating no change in formulation to allow for expedited renewal of their BICON permit.
- Stakeholders saw merit in having better relationships between the regulator and research institutions, especially in allowing external experts to be able to produce guidance material for new technologies rather than it falling solely on the regulator.
- Stakeholders agreed that building public trust and confidence in the system is important, but communication cannot be based solely on the science.
- Stakeholders raised concerns related to ~~around~~ the removal of the requirement to assess efficacy, noting companies will still undertake ~~do~~ efficacy work for the purpose of company liability and insurance. There is a risk that removing the need for efficacy data as part of the registration process could undermine community confidence in the system.

- Stakeholders discussed registration by reference and considered that the discretionary ability of the APVMA to consider overseas assessment currently works well ~~fine~~. Industry has had a lot of success with getting the APVMA to recognise overseas assessments, particularly in using overseas toxicology assessments for poisons scheduling.
- Stakeholders were concerned about the likely cost-recovery cross-subsidisation in the system, with major agricultural products subsidising other products.
- Stakeholders suggested there should be more government funding of activities undertaken by the APVMA, that in their view, are in the public interest. Reducing the reliance of the APVMA on cost recovery from industry may reduce any public perception of industry capture.

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AGVET REVIEW PANEL USE ONLY

INDEPENDENT REVIEW OF THE AUSTRALIAN AGRICULTURAL AND VETERINARY CHEMICALS REGULATORY FRAMEWORK (AGVET REVIEW)

MINUTES – REFLECTIONS (s. 11C(1)(b) and s. 11C(1)(b))

22 July 2020 ⇔ 5:03pm – 5:23pm

Attendees

Panel: Ken Matthews (Chair), Dr Craig Suann, Dr Anne Astin

Department: Julie Gaglia, s. 22(1)(a)(ii) , s. 22(1)(a)(ii)

Secretariat: s. 22(1)(a)(ii), s. 22(1)(a)(ii)

Apologies: Dr Mary Corbett

Reflection of s. 11C(1)(b) and s. 11C(1)(b) meetings

The Chair commenced the meeting at 5.03pm.

The panel reflected that there had been a lot of declaratory statements throughout the day but little in the way of solutions orf options ofor reform stakeholders were interested in pursuing. The panel expressed that they were expecting more sophisticated feedback from these meetings given these are the stakeholders with the most intimate experience with the regulatory system. The secretariat suggested that greater detail may come from these groups through their written submissions.

The Chair reflected that throughout all the consultations no-one had raised any fatal flaws with the proposals outlined in the issues paper. Some stakeholders appeared reluctant rather than resistant to change or wanted change but did not want to invest in it.

The panel discussed the need for companies to engage with the regulator earlier in their development process, especially new start-up companies who are not as experienced with the regulatory system. It was suggested that companies could build that into their applications when applying for development grants or alternatively there could be public funds set aside to enable the regulator to provide free advice to start-up companies.

Stakeholders had indicated strong support for a national control of use system – this was clear from both s. 11C(1)(b) and s. 11C(1)(b) members.

However, there appeared to be more caution in response to the concept of co-regulation. Stakeholders appeared to be only seeing this from a liability perspective, ie. providing them with the ability to have more control or responsibility in the system was viewed as creating ~~they had would result in more~~ greater liability. The panel discussed the need for further consideration on how best to ~~incorporate~~ utilise QA schemes ~~into~~ for~~the~~ control of use purposes without disturbing the primary purposes of the schemes, and without requiring changes to those schemes (unless their sponsors saw sufficient value to volunteer to do so)~~arrangements~~.

The Chair sought clarification about the issue of export slaughter intervals (ESI) that was raised by s. 11C(1)(b) members. The secretariat mentioned the report they had commissioned from EY and how this found that the red meat sector supported the ESI system and wanted ~~to~~ no changes. The secretariat offered to provide the report to the Chair.

The panel thought that it would be useful to start thinking about measures of success and what performance indicators would be~~like –~~ needed to clearly articulate what the regulatory system will achieve ~~is trying to be achieved~~, and to ~~which~~ provide~~s~~ context for the review's conclusions and recommendations ~~proposals being recommended~~.

The Chair closed the meeting at 5.23pm.