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Archived: Friday, 29 July 2022 1:35:56 PM From: S. 22(1)(a)(ii)
S. 22(1)(a)(ii)

From: Gaglia, Julie

Sent: Saturday, 2 May 2020 9:54 PM **To:** s. 22(1)(a)(ii); s. 22(1)(a)(ii)

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

Subject: RE: Wednesday arvo workshop [SEC=OFFICIAL]

 $\operatorname{Hi}^{s.22(1)(}$ and $^{s.22(1)(a)(ii)}$

I'm happy for you to provide a rundown on authorisations and the attached paper is a good discussion starter that should be circulated prior to the meeting.

Also happy for you to share the two pager on registration by reference prior to the workshop.

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

Happy to discuss – but thank you so much s. 22(1)(a)(a) for all the work you are putting in to this, I really appreciate it.

Cheers,

Julie

From: S. 22(1)(a)(ii) < S. 22(1)(a)(ii) @agriculture.gov.au>

Sent: Saturday, 2 May 2020 6:06 PM

To: Gaglia, Julie < Julie. Gaglia@agriculture.gov.au>; s. 22(1)(a)(ii) < s. 22(1)(a)(ii)@agriculture.gov.au>

Subject: Wednesday arvo workshop [SEC=OFFICIAL]

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

I was thinking about how to deal with registration by reference at Wednesday arvo's workshop.

What I would like to do is:

- 1. Provide a little bit of a rundown about 'authorisations' (registration, licences, permits and exemptions) at Wednesday arvo's workshop and how they work with the general product obligations. I think this because it is a bit difficult to talk about 'registration by reference' without this background. Is that OK?
- 2. I prepared a two pager about authorisations (attached). Do you think I should circulate it as a background document for the workshop?
- 3. I also prepared a two pager (attached) about 'registration by reference' that could help people get across some of the issues. I got some feedback that s. 22(1)(a)(ii) efficacy discussion was a little easier (with a two page intro) than my discussion about general product obligations (that did not have an intro). Is the attached two pager suitable as a 'thought-starter' for registration by reference (that I would provide in advance of the workshop)?

s. 22(1)(a)(ii

Assistant Director | Agvet Chemicals Review and Projects | S. 22(1)(a)(ii)

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Archived: Friday, 29 July 2022 1:36:07 PM

Document 2

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

Sent: Mon, 4 May 2020 10:46:18

To: Gagia, Julie s. 22(1)(a)(ii) s. 22(1)(a

Subject: Wednesday Workshop 6 May 2020 [SEC=OFFICIAL]

Sensitivity: Normal **Attachments:**

Attachment AAAA Authorisations workshop.docx; Attachment EEE Reg by ref Workshop Summary.docx;

All

At the workshop on Wednesday, I would like to discuss the topic of 'registration by reference' for overseas registered products. To assist with our discussion, I prepared a background document about authorisations (things like registration, licensing etc) and a specific background document about issues with and options for 'registration by reference'. They are both attached. These build on previous documents about the topic of registration by reference.

If I missed anyone, I am sorry and please feel free to forward the documents to them.

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

Assistant Director | Agvet Chemicals Review and Projects | S. 22(1)(a)(ii)

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Attachment AAAA

Authorisations for a Revised Agvet Chemical Regulatory Scheme

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

Licence

Currently, agvet legislation uses licences only in the context of authorising the manufacture of chemical products (specifically certain veterinary chemical products). This is similar to the approach in therapeutic goods legislation. In addition, the Agvet Code provides for conditions for licences to apply. Licences are usually used to regulate an activity (e.g. licence to drive a motor vehicle) and therefore are issued to a person.

Licensing certain dealings with agvet chemicals (other than manufacture) could provide for more streamlined and fit for purpose regulatory pathways to be implemented. Licensing could include a fit and proper person test that would apply for the issue of a licence (like GMP licences do now). Licences may have more 'status' than exemptions or permits.

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