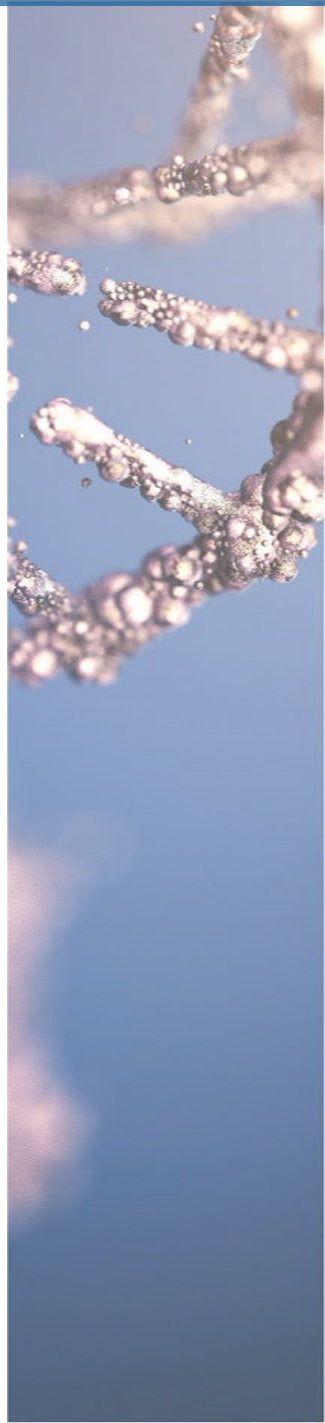
Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

Review of the PC2 facility certification guidelines

Geraldine Lester

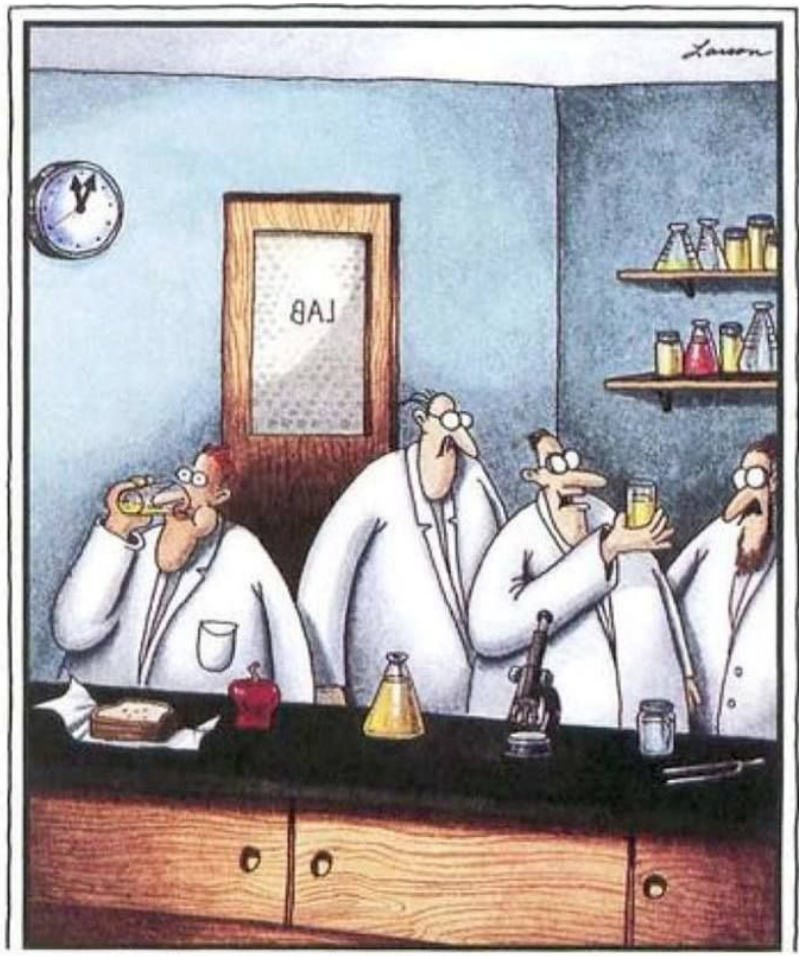
IBC Forum

October 2026



PC2 Guidelines review

- PC2 Guidelines were updated in 2013 and 2014
- Trend in requests for the certification of multipurpose facilities
- Clarify behavioural requirements
- Amend condition to align with the new version of the PC3 Guidelines



"What the? … This is lemonade! Where's my culture of amoebic dysentery?"

Current PC2 Guidelines

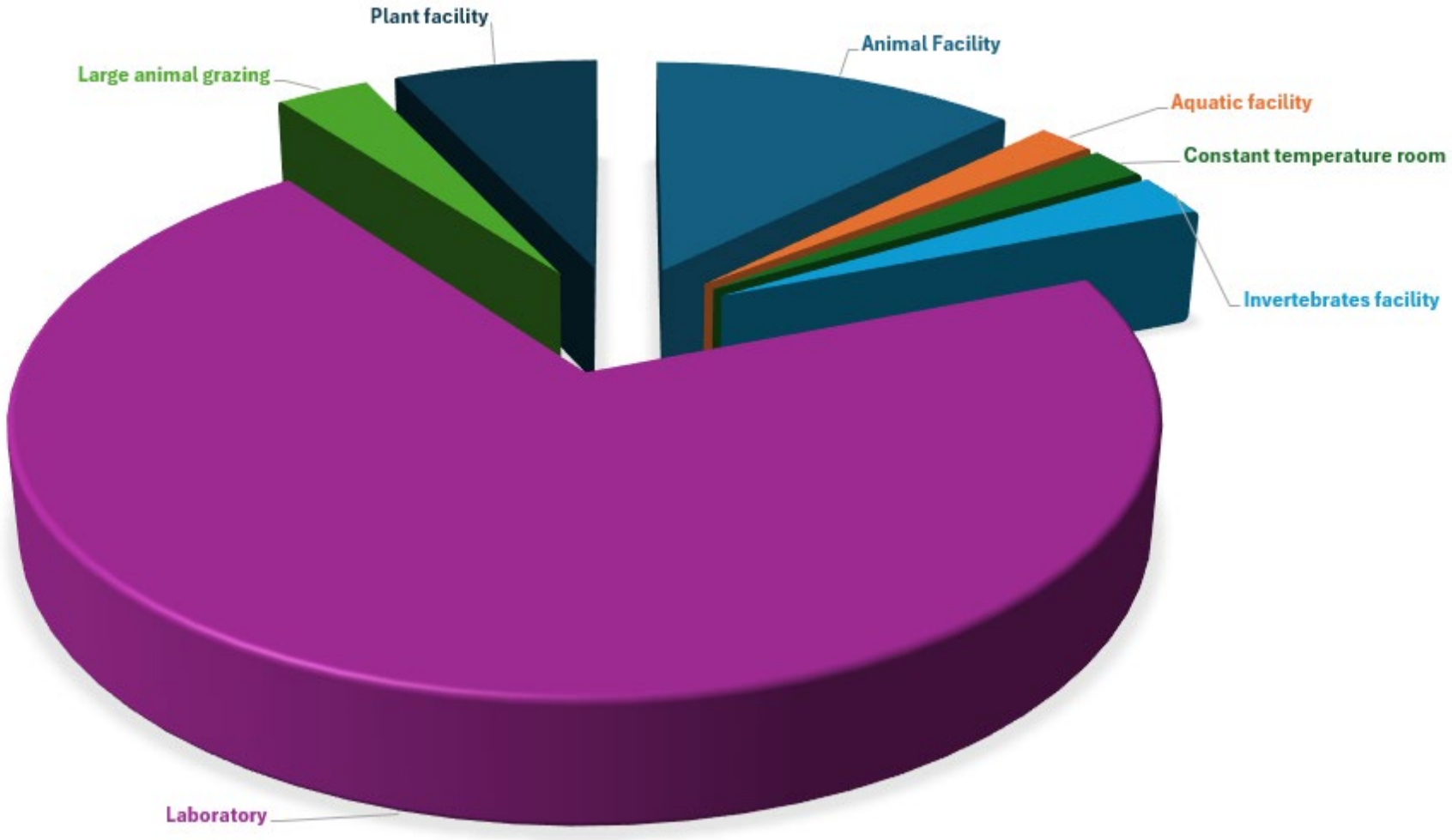
- PC2 Laboratory
- PC2 Animal Facility
- PC2 Plant Facility
- PC2 Invertebrate Facility
- PC2 Aquatic Facility
- PC2 Constant Temperature Room
- PC2 Large Grazing facility







Types of low-level certified facilities



New Guidelines - the proposed approach

Updated Guidelines

Guidelines for Certification of a physical containment Level 2 Facility- Dealings Not Involving GM Micro-Organisms

- Annexe 1- Animal specific Conditions
- Annexe 2- Aquatic specific Conditions
- Annexe 3- Invertebrates specific Conditions
- Annexe 4- Plant specific Conditions

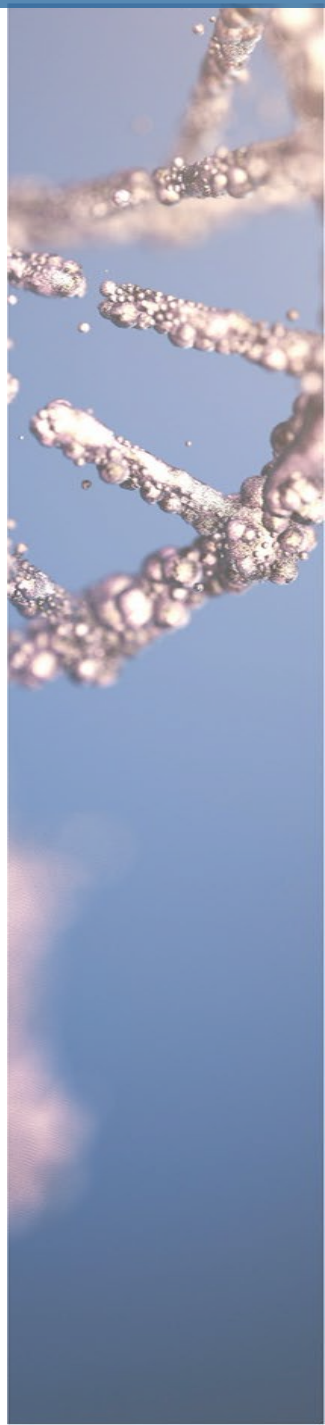
Guidelines for Certification of a physical containment Level 2 Facility- Dealings Involving GM Micro-Organisms

- Annexe 1- Animal specific Conditions
- Annexe 2- Aquatic specific Conditions
- Annexe 3- Invertebrates specific Conditions
- Annexe 4- Plant specific Conditions

Retained Guidelines

Guidelines for Certification of a physical containment Level 2 Constant Temperature Room

Guidelines for Certification of a physical containment Level 2 Large Grazing Animal Facility



Macro Guidelines

Guidelines for Certification of a physical containment Level 2 Facility- Dealings Not Involving GM Micro-Organisms

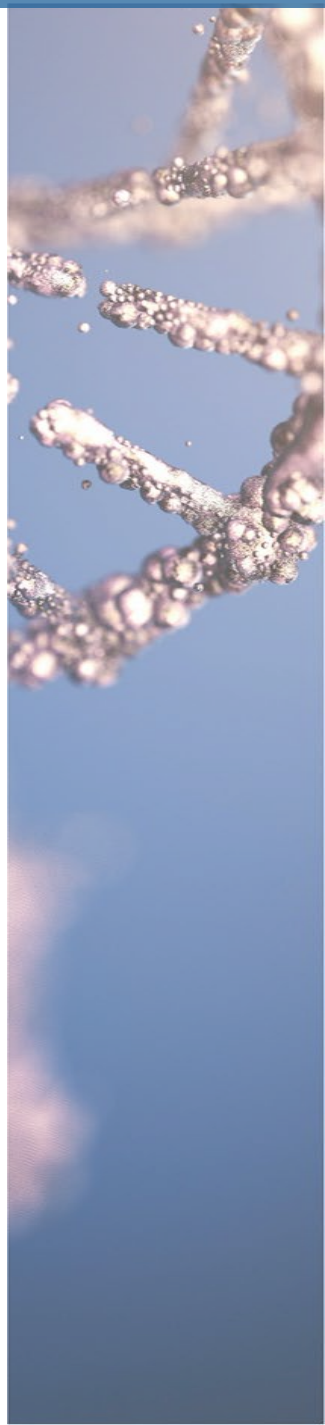
Annexe 1- Animal specific Conditions

Annexe 2- Aquatic specific Conditions

Annexe 3- Invertebrates specific Conditions

Annexe 4- Plant specific Conditions

- No work with GM micro-organisms is authorised within a facility certified under these Guidelines
- Reduced requirements and conditions to reflect reduced risk of harm as a result of exposure from GMOs
- Decontamination and PPE only required when dealing with GM reproductive material likely to persist such as GM sperm, eggs, pollen or seeds
- Capture:
    - Breeding facilities (GM animal, aquatic, invertebrate)
    - Most plant facilities



Micro Guidelines

Guidelines for Certification of a physical containment Level 2 Facility- Dealings Involving GM Micro-Organisms

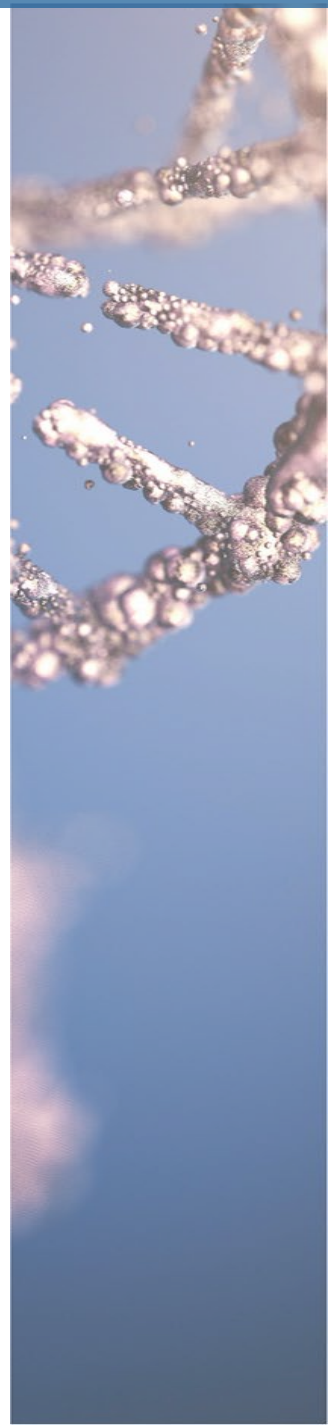
Annexe 1- Animal specific Conditions

Annexe 2- Aquatic specific Conditions

Annexe 3- Invertebrates specific Conditions

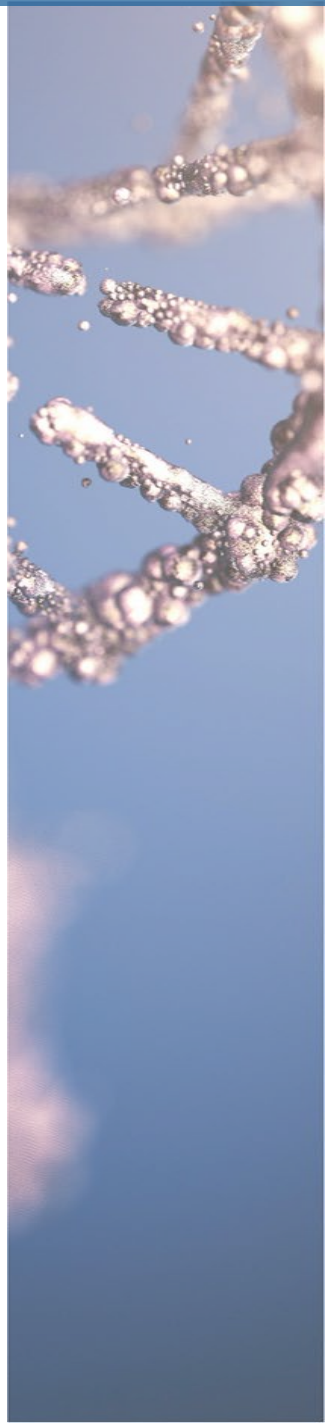
Annexe 4- Plant specific Conditions

- Work with GM micro-organisms authorised within a facility certified under these Guidelines
- Requirements and conditions focused on aerosol containment as well as the physical containment of the organisms used in the facility
- PPE always required regardless to the type of activities conducted within the facility
- Capture:
    - Any dealings involving GM micro-organisms



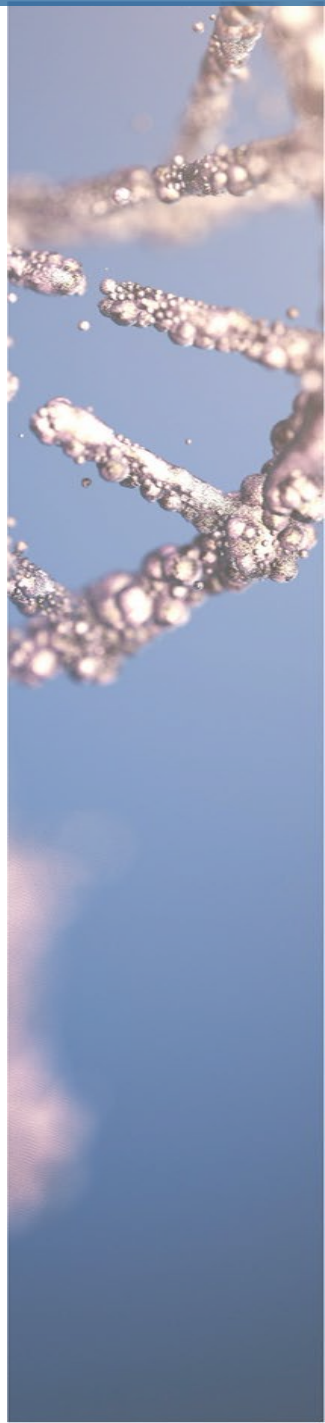
Consultation of the Micro and Macro Guidelines

- Extensive consultation internally and externally
- Quite a few meetings through out January-March 2025 with
  - group of Stakeholders
  - individual organisations
- Received over 30 submissions in addition to feedback and questions during those meetings.



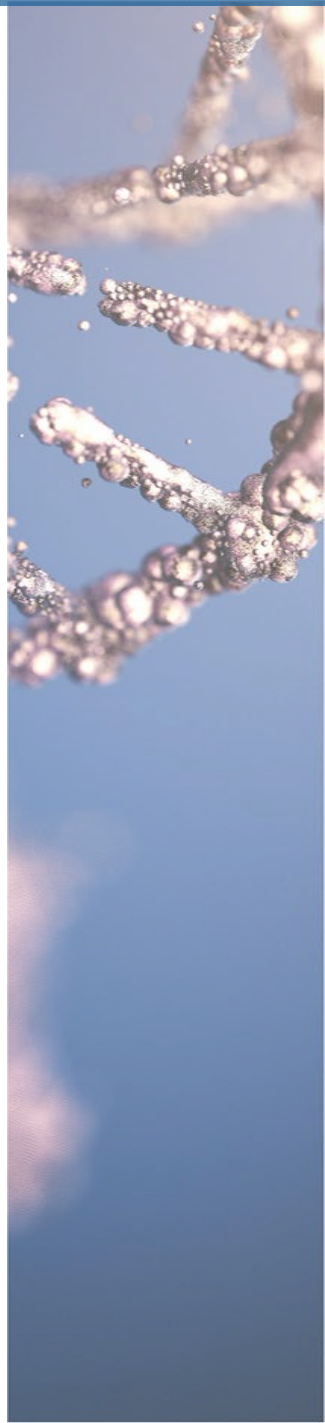
What you said

- Overwhelmingly- Lack of clarity for some conditions
- Conditions have become much broader and outcome focused
- A need for a comprehensive Guidance document
- Some inaccuracy/contradictions



New Guidelines – changes

- Change in structure and adoption of a modular approach- micro versus macro
- Obligation of the Certification holder
- Access to the facility
- Autoclaves – Clarification of what is expected



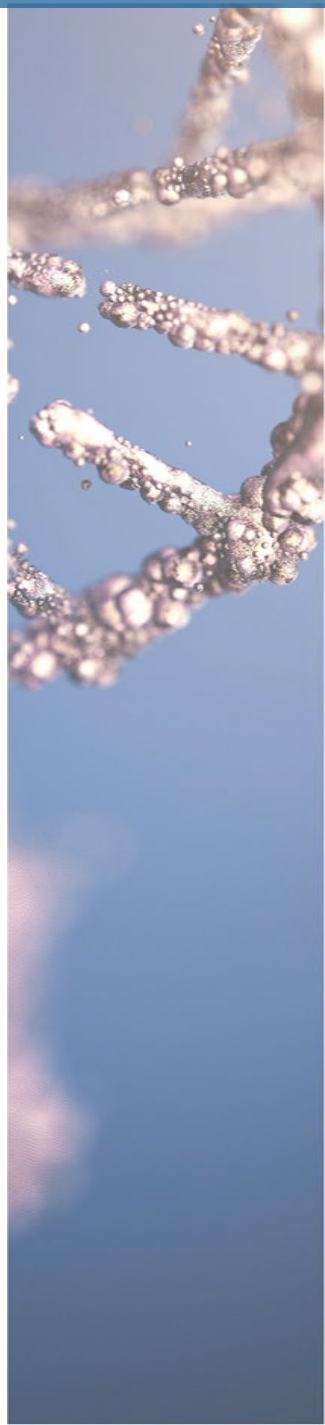
New Guidelines – changes (2)

Macro

- PPE only required if working with GMO that could persist on a person
- Biosafety Cabinet (BSC) are not required within the facility.

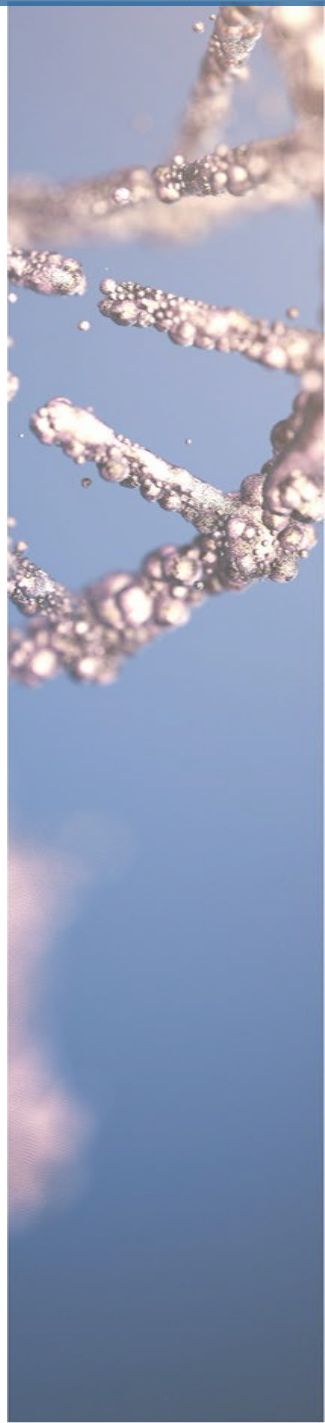
Micro

- mobile phone/personal item policy to be developed
- all staff wear PPE regardless of the activities conducted



New Guidelines – changes (3)

- Inclusion in the plant annex of the use of biological control for the control of insects in room housing plants.
- Changes in the way anteroom are captured in the Guidelines
- Development of an extensive Guidance document and factsheets to support and respond to comments provided during the consultation



New Guidelines – implementation approach

- The OGTR prepares compiled lists of certified facilities for each organisation at each site/campus

Cert identifier	Facility title	Guidelines certified against	Manual condition	Predictive Guidelines	Annex	room the annex applies to
Cert-10232	building 87, Ground floor, room 1-12, Canberra Campus	PC2 Laboratory	None	Micro Guidelines	nil	nil
Cert-10233	building 88, First floor,room 1-12, Canberra Campus	PC2 animal	None	Micro Guidelines	Animal	Room 1-12
Cert-10234	building 89, Ground floor, room 1-12, Canberra Campus	PC2 plant	None	Macro Guidelines	Plant	Room 1-12
Cert-10235	building 88, Ground floor, room 1-12, Canberra Campus	PC2 Laboratory	Manual condition allowing animal in room 4-6	Micro Guidelines	Animal	Room 4-6

- Regulator initiated variations, one for each facility- Flexible process, working with organisations- a minimum of 30 days to respond

New Guidelines – implementation approach (2)

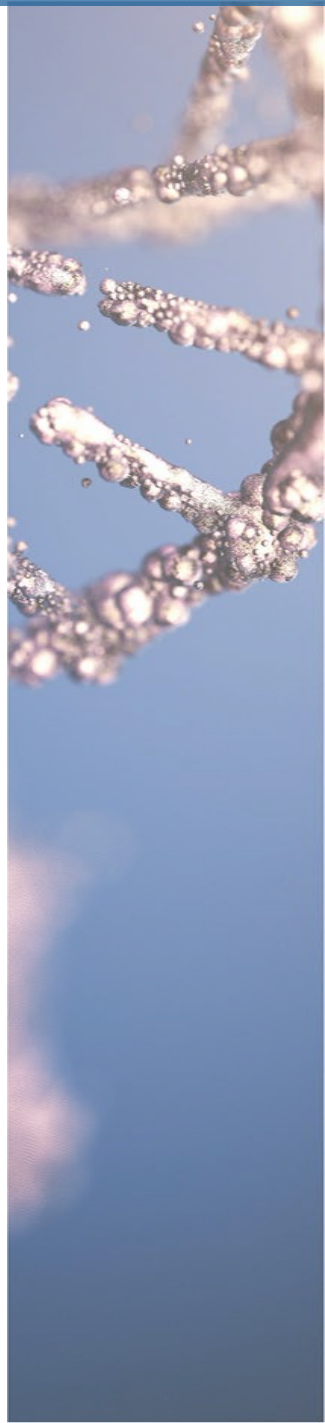
- What you need to do, once we contacted you?

  - check that we have selected the appropriate Guidelines and annex for each facility-a minimum of 30 days to respond

  - Contact us if you have any questions and to arrange the timing of your certifications being transferred to the new Guidelines

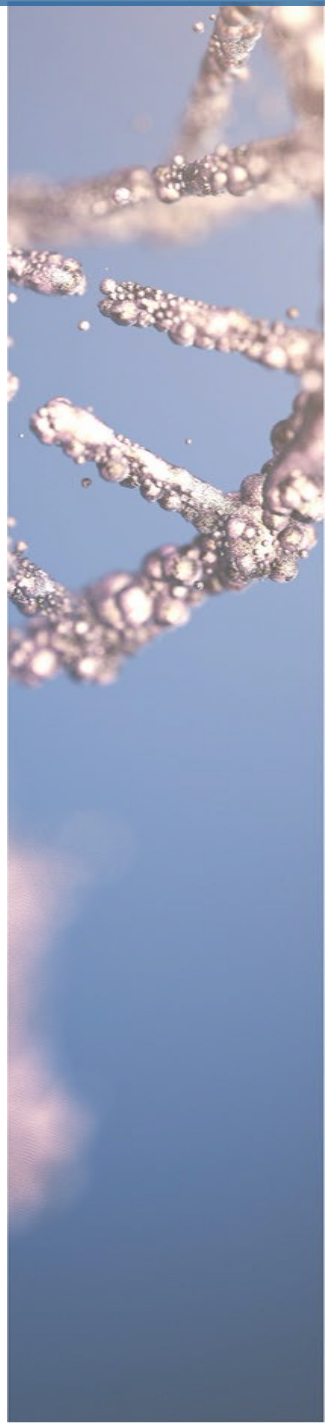
- Once we have received confirmation, we will:

  - Send all new instruments and signs
  - You will have 30 days to affix the signs to your facilities



New Guidelines – implementation approach (3)

- No other amendment will be made to an instrument, only the transfer to a new Certification Guidelines
- Several factsheets will be or are published on our website
- The Guidelines and Guidance document will be hopefully published towards the beginning of next year, and the implementation will start around the beginning a quarter 2.
- The transition to the new Guidelines will take place over 12 to 18 months and will be implemented one organisation at the time



What to expect for the remaining Guidelines

- All guidelines are being reviewed and eventually drafted into rules.
- PC3 and PC2 large scale and PC2 large animal grazing facility and PC1 facility- light amendment
- PC4 are currently under review as it has not been reviewed since 2007
- A primary containment guidelines is also being developed
- PC2 constant temperature guidelines- Survey to sent early this week

