



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Consultation on the regulatory requirements for medical devices containing materials of animal, microbial or recombinant origin

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TGA Health Safety
Regulation

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Introduction

Medical devices are regulated in Australia having regard to the risks (to the individual or to public health) considered in the context of the device's intended use. All devices carry some level of potential risk, and the Therapeutic Goods Administration (TGA) applies scientific and clinical expertise to ensure assessments and decisions regarding supply to Australian patients are made based on the balance between the benefits and the risks.

The risk classification of medical devices considers a range of factors such as potential harm, level of invasiveness, reliance on energy, where in the human body the device is used, terms of use and the end user (e.g., consumers or a person with appropriate knowledge and expertise). Additional evidence to support safety, performance and quality is required for higher risk medical devices in comparison to lower risk medical devices. This approach balances the need to provide patients and the healthcare system with timely access to innovative new technologies with the appropriate level of scrutiny for products.

A risk-based classification system is also used by international regulators including the USA, the European Union, Canada, Japan, and Singapore.

The TGA periodically reviews requirements for medical devices to ensure they continue to be appropriate. When undertaking such reviews, we have regard among other things, to the risks and whether those risks have changed over time, international best regulatory practice, and any emerging issues.

This ensures sustainability of the Australian regulatory system for medical devices, appropriateness and robustness of assessments, minimisation of regulatory burden, and enables timely access to safe medical devices for Australian patients and consumers.

This consultation

This consultation is to obtain feedback on potential changes to the Australian medical device framework in relation to the classification and premarket requirements for non-IVD medical devices that contain tissues, cells, or substances of animal, microbial or recombinant origin.

The TGA has received requests to review the risk classification of medical devices that contain certain materials from animal, microbial or recombinant origin.

We are seeking your views about whether the current classification rule and the corresponding conformity assessment procedures continue to be appropriate given the change in risk status of such products. We seek your feedback on:

1. the risk of certain materials of animal, microbial or recombinant origin
2. microbial and recombinant materials in general
3. accepting evidence from a broader range of comparable overseas regulators for these medical devices.

Background

Classification of medical devices that contain tissues, cells, or substances of animal, microbial or recombinant origin

Currently, under the Australian medical device regulatory framework, the TGA regulates medical devices that contain **tissues, cells, or substances of animal, microbial or recombinant origin** as Class III (high risk) medical devices under rule 5.5, *Schedule 2 – Classification rules for medical devices other than IVD medical devices of the Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

Classification Rule 5.5 states:

5.5 Medical devices containing non-viable animal tissues, cells or other substances, or microbial or recombinant tissues, cells or other substances

(1) This clause applies to a medical device if the device contains:

(a) tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin; or

(b) a combination of tissues, cells or substances of the kind described in paragraph (a).

(2) The device is classified as Class III, unless:

(a) the device contains only tissues, cells or substances of animal origin that have been rendered non-viable; and

(b) the device is intended by the manufacturer to come into contact with intact skin only.

Classification rule 5.5 addresses the risk of Transmissible Spongiform Encephalopathies (TSEs) such as the human version of ‘mad cow disease’. It is generally accepted that TSEs may be transmitted from animals to humans by exposure to contaminated materials. Therefore, it is important to minimise the potential for transmission to humans.

In 2002, when the Medical Device Regulations were established, the risks associated with TSEs were considered high. In this context, classification rule 5.5 included materials of microbial and recombinant origin in addition to materials of animal origin.

In 2002, we also undertook a review of ingredients considered to be low risk for transmitting TSEs. The review considered the risk of each ingredient and the regulatory approach taken by other agencies. As a result of the review, guidance was published clarifying that classification rule 5.5 did not apply to devices containing the following materials:

- bovine milk
- silk
- beeswax
- hair
- lanolin
- sintered hydroxyapatite (process must be validated to demonstrate no evidence of organic material)

- tallow or tallow derivatives
- alcohols
- simple sugars or salts fermented from cultures that do not have any animal reagents
- microbial sourced enzyme cleaners
- honey (deemed not to be an animal-derived substance).

Manufacturers must maintain technical files including risk mitigation steps undertaken for such devices, and this documentation should be made available to the TGA upon request.

In 2014, the TGA published a revised [document](#) outlining the assessment approach for the safety of materials, derived from human and other animal species naturally susceptible to TSEs, and used in the manufacture of therapeutic goods. Due to a range of control measures introduced in many countries, there had been a reduction in the incidence of TSEs. The document outlined criteria that enable some eligible manufacturers to 'self-assess' rather than requiring further TGA evaluation.

In 2022, the TGA assessed the risk of blood transfusion transmission of TSEs. We [concluded](#) that the risk of transmission remains very low and approved the removal of the geographical ban of blood and plasma donors from the UK.

This consultation now seeks to review the regulatory requirements for medical devices containing materials of animal, microbial or recombinant origin.

Alignment with European Union (EU) classification rules

Classification rule 5.5 is specific to the Australian medical device regulatory framework and is not identical to the EU framework. As a result, there are devices which are classified as high-risk devices in Australia but are classified as lower risk devices in the EU. This creates inconsistency and potential regulatory burden for imported products as they are required to undertake further conformity assessment procedures relevant to a Class III medical device prior to being included in the Australian Register of Therapeutic Goods (ARTG) and supplied in Australia. This also delays access to new technology in Australia.

The main difference between the relevant EU and Australian classification rules is the specific inclusion of medical devices that contain microbial or recombinant tissues, cells, or other substances in the Australian classification rules, whereas the EU refers to products of animal origin only (see Attachment A). Other comparable overseas regulators do not classify medical devices containing microbial or recombinant tissues, cells, or other substances as high risk.

We are therefore seeking feedback on the proposal for closer alignment with the EU and whether we should amend our classification rule to align with the EU classification rule. This requires consideration of the risks associated with known products of *microbial and animal origin* and the potential to exclude these devices from classification rule 5.5.

By removing these references, a medical device that contains any of these substances would be classified by other classification rules. However, the safety requirements the manufacturer would need to satisfy would not change. Australian Essential Principle 8.2 specifies the safety requirements for the control of animal, microbial or recombinant tissues, tissue derivatives, cells, and other substances in devices and applies to all device classes. In the EU, General Safety and Performance Requirements 13.2 and 13.3 in the EU Medical Device Regulation align with Australian Essential Principle 8.2 (see Attachment B) and apply to all devices with materials of animal (13.2) and microbial and recombinant origin (13.3), also regardless of class.

Australian Import Permits

Sponsors importing some medical devices that contain tissues, cells, or substances of animal, microbial or recombinant origin are required to apply for an 'import permit' from the Department of Agriculture, Fisheries and Forestry (DAFF) under the *Biosecurity Act 2015*.

Any changes to classification rule 5.5, or the associated TGA guidance, may have an impact on import permit processes, or on importers. In April 2022 DAFF amended the [Biosecurity \(Conditionally Non-Prohibited Goods\) Determination 2021 \(Goods Determination\)](#) and import permits are no longer required for some medical devices that contain tissues, cells, or substances of animal, microbial or human origin. The TGA and the DAFF will discuss the outcomes of this consultation and any possible impacts on import permit processes, before making any recommendations for change to the Government.

Issue 1: Risk of certain materials

Many medical devices contain tissues, cells, or substances of animal, microbial or recombinant origin. In general, these medical devices are regulated as high-risk in Australia, but the risk varies for different materials.

Xanthan gum, Gellan gum, Cellulose, Fish oil, Chitosan, and Alginate are generally considered to be of low risk for human use (TGA Risk Analysis is at Attachment C). Medical devices that contain these materials often contact a patient via a body orifice or via surgical incisions and have varying intended purposes and durations of use. For example, xanthan gum is a thickener derived from bacteria used in numerous medical devices.

Examples of medical devices containing the materials listed above:

Materials proposed to be excluded from classification rule 5.5	Example of medical devices
Xanthan gum	Eye lubricants
Gellan gum	Surgical sealants, wound dressings
Cellulose	Surgical sealants, wound dressings
Fish oil	Polymeric composite surgical meshes
Chitosan	Cartilage biomatrix implant
Alginate	Dental impression material

Consultation question 1

What is the level of risk (potential harm to a person) of medical devices containing **Xanthan gum, Gellan gum, Cellulose, Fish oil, Chitosan, or Alginate**? Does the level of risk (low/medium/high) depend on how and where the material is used?

Consultation question 2

Should **Xanthan gum, Gellan gum, Cellulose, Fish oil, Chitosan, and Alginate** be excluded from classification rule 5.5 on account of their lower risk? If the exclusion from classification rule 5.5 resulted in a lower classification of the device, are there any safety concerns in relation to the material or the device? Provide your rationale.

Consultation question 3

Are the below materials still considered low risk and should they continue to be excluded from classification rule 5.5?

- bovine milk
- silk
- beeswax
- hair
- lanolin
- sintered hydroxyapatite (process must be validated to demonstrate no evidence of organic material)
- tallow or tallow derivatives
- alcohols
- simple sugars or salts fermented from cultures that do not have any animal reagents
- microbial sourced enzyme cleaners
- honey (deemed not to be an animal-derived substance).

Consultation question 4

Are there other materials of animal, microbial or recombinant origin whereby exclusion from classification rule 5.5 should be considered on account of its low risk in medical devices and would a lower classification rule be suitable to ensure the safety of the material and medical device? Provide your rationale.

Example – Jay has a medical device that contains fish oil

Jay produces medical devices that contain fish oil. If this consultation confirms fish oil as low risk, the TGA could ask the Government to exclude these devices from Classification Rule 5.5.

If this is the case, Jay will need to select another classification rule that applies to his device from Schedule 2 of the Regulations. If there are multiple classification rules which are applicable, the highest classification rule will apply.

Jay's device is surgically invasive for short term use. Classification Rule 3.3(2) may apply, in which case, the device would be classified as Class IIa.

Jay could then apply to include his device as a Class IIa device.

Jay would also need appropriate conformity assessment evidence for this device (MDSAP/FDA/Health Canada/EU certificate) as outlined in the guidance - [Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices \(including IVDs\)](#)



Issue 2: Microbial and recombinant materials

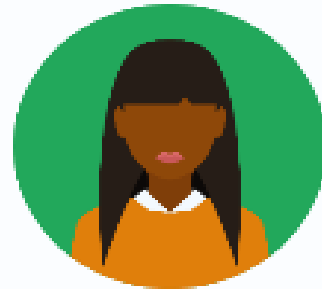
In Australia, medical devices that contain microbial or recombinant tissues, cells or other substances are classified as the highest risk devices under classification rule 5.5. Unlike Australia, comparable overseas regulators do not classify all medical devices containing microbial or recombinant tissues, cells, or other substances as high risk.

We invite views from various stakeholder groups on whether a lower classification of these devices is appropriate.

If it is determined that classification rule 5.5 will not apply to a particular device, then that device would be classified according to the remaining classification rules and its intended use.

Example – Sarah has a medical device that contains a microbially derived enzyme

Sarah manufactures a medical device that contains an enzyme produced by bacteria. Should the classification rule 5.5 be amended to remove the reference to substances of microbial origin, the medical device will be classified using other classification rules from Schedule 2 of the Regulations.



If there are multiple classification rules which are applicable, the highest classification rule would apply.

Sarah's device is surgically invasive for short term use. Classification rule 3.3(2) may apply, in which case, the device would be classified as Class IIa.

Sarah could apply to include her device as a Class IIa device.

Sarah would also need appropriate conformity assessment evidence for this device.

Consultation question 5

Do you have any comments or concerns on the risks of devices containing microbial or recombinant tissues, cells, or other substances in general, and how the TGA regulates these products, considering how these products are regulated in other jurisdictions? If so, please provide further information.

Consultation question 6

Do you have any comments or concerns with the proposal to remove substances of microbial and recombinant origin from classification rule 5.5?

Issue 3: Accepting evidence from comparable overseas regulators

To include a medical device in the ARTG, sponsors must (among other things) hold the required conformity assessment evidence as specified in the [Therapeutic Goods \(Medical Devices— Information that Must Accompany Application for Inclusion\) Determination 2018 \(the Determination\)](#).

The Determination defines a medical device (other than an IVD) that contains tissues, cells, or substances of animal, microbial or recombinant origin as a ‘*specified medical device*’:

specified medical device means any of the following:

- (a) a medical device, other than an IVD medical device, **that contains tissues of animal origin that have been rendered non-viable** (other than one that is intended to come into contact with intact skin only);
- (b) a medical device, other than an IVD medical device, **that contains tissues, cells or substances of microbial or recombinant origin** and is intended for use in or on the human body;
- (c) a medical device, other than an IVD medical device, incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device;
- (d) a medical device, other than an IVD medical device, that incorporates, or intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device.

The Determination restricts sponsors seeking to include *specified medical devices* in the ARTG to only using conformity assessment evidence from either the TGA or the EU.

However, for medical devices that are not ‘*specified medical devices*’, the Determination accepts conformity assessment evidence from a broader range of jurisdictions, namely:

- the TGA
- the EU
- the Food and Drug Administration of the United States
- Health Canada
- the Ministry of Health, Labour and Welfare and Pharmaceutical and Medical Devices Agency of Japan
- Singapore's Health Sciences Authority (HSA).

We seek to understand the risks and benefits of accepting conformity assessment evidence from this broader list of comparable overseas regulators, for medical devices that contain tissues, cells, or substances of animal, microbial or recombinant origin.

NOTE – this consultation is not seeking feedback or proposing to amend the acceptable conformity assessment evidence for all specified medical devices, only those that contain tissues, cells, or substances of animal, microbial or recombinant origin.

Consultation question 7

Do you have any comments or concerns on a proposal to consider alternative conformity assessment evidence for medical devices that contain substances of animal, microbial or recombinant origin, from other comparable regulators beyond the TGA and the EU? If so, please provide further information.

What we invite you to do

In your submission, we ask you to consider and respond to the questions below, and to provide comments on the issues outlined in this consultation paper.

Consultation questions (consolidated)

1. What is the level of risk (potential harm to a person) of medical devices containing **Xanthan gum, Gellan gum, Cellulose, Fish oil, Chitosan, or Alginate**? Does the level of risk (low/medium/high) depend on how and where the material is used?
2. Should **Xanthan gum, Gellan gum, Cellulose, Fish oil, Chitosan, and Alginate** be excluded from classification rule 5.5 on account of their lower risk? If the exclusion from classification rule 5.5 resulted in a lower classification of the device, are there any safety concerns in relation to the material or the device? Provide your rationale.
3. Are the below materials still considered low risk and should they continue to be excluded from classification rule 5.5?
 - bovine milk
 - silk
 - beeswax
 - hair
 - lanolin
 - sintered hydroxyapatite (process must be validated to demonstrate no evidence of organic material)
 - tallow or tallow derivatives
 - alcohols
 - simple sugars or salts fermented from cultures that do not have any animal reagents
 - microbial sourced enzyme cleaners
 - honey (deemed not to be an animal-derived substance).
4. Are there other materials of animal, microbial or recombinant origin whereby exclusion from classification rule 5.5 should be considered on account of its low risk in medical devices and would a lower classification rule be suitable to ensure the safety of the material and medical device? Provide your rationale.
5. Do you have any comments or concerns on the risks of devices containing microbial or recombinant tissues, cells, or other substances in general, and how the TGA regulates these products, considering how these products are regulated in other jurisdictions? If so, please provide further information.
6. Do you have any comments or concerns with a proposal to remove substances of microbial and recombinant origin from classification rule 5.5?
7. Do you have any comments or concerns on a proposal to consider alternative conformity assessment evidence for medical devices that contain substances of animal, microbial or recombinant origin, from other comparable regulators beyond the TGA and the EU? If so, please provide further information.

How to submit your feedback

Your input and feedback will help inform any changes to the regulation of medical devices containing certain materials of animal, microbial or recombinant origin. In addition to the scope of this consultation, we welcome feedback on our consultation process.

You can submit your feedback using our **online survey tool**

<https://consultations.tga.gov.au/medical-devices-and-product-quality-division/consultation-review-medical-devices-animal-origin>

Please direct any queries via email to devicereforms@tga.gov.au.



This survey closes at 23:59pm on 28/7/2023

Attachment A: Australian and EU classification rules

Classification rule 5.5, Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002

Classification Rule 5.5 states:

5.5 Medical devices containing non-viable animal tissues, cells or other substances, or microbial or recombinant tissues, cells or other substances

(1) This clause applies to a medical device if the device contains:

(a) tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin; or

(b) a combination of tissues, cells or substances of the kind described in paragraph (a).

(2) The device is classified as Class III, unless:

(a) the device contains only tissues, cells or substances of animal origin that have been rendered non-viable; and

(b) the device is intended by the manufacturer to come into contact with intact skin only.

EU Classification Medical Device Directive (MDD) - Rule 17

All devices manufactured utilising animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.

EU Classification Medical Device Regulation (MDR) - Rule 18

All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.

Attachment B: Australian and EU safety requirements

Essential Principle 8.2

Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002

8.2 Control of animal, microbial or recombinant tissues, tissue derivatives, cells and other substances

- (1) This clause applies in relation to a medical device that contains:
 - (a) tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable; and*
 - (b) tissues, tissue derivatives, cells or substances of microbial or recombinant origin.**
- (2) If the tissues, tissue derivatives, cells or substances originated from animals, the animals must have been subjected to appropriate veterinary controls and supervision, having regard to the intended use of the tissues, tissue derivatives, cells or substances.*
- (3) If the medical device contains tissues, tissue derivatives, cells or substances of animal origin, a record must be kept of the country of origin of each animal from which the tissues, tissue derivatives, cells or substances originated.*
- (4) The processing, preservation, testing and handling of tissues, tissue derivatives, cells or substances of animal, microbial or recombinant origin must be carried out in a way that ensures the highest standards of safety for a patient, the user of the device, and any other person.*
- (5) In particular, the production process must implement validated methods of elimination, or inactivation, in relation to viruses and other transmissible agents.*

Note: This may not apply to certain IVD medical devices if the characteristics mentioned in subclause 8.2(5) are integral to the intended purpose of the IVD medical device.

EU Medical Device Regulation General Safety & Performance Requirements 13.2 & 13.3

13.2. For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:

- (a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers;*
- (b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device;*
- (c) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.*

13.3. For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

Attachment C: TGA risk analysis

The TGA undertook its own research and analysis of the risk for certain materials: Xanthan gum, Gellan gum, Fish oil, Chitosan, Alginate and Cellulose. The TGA analysis is summarised below:

- Internal consultation determined the potential risk of transmission of infectious agents through medical devices containing such materials. It was determined that these materials pose little toxicological risk to the public. This determination is based on an assessment against the *Ph. Eur* monograph^[1].
- Table 1 below includes references that support the determination that such materials have a low toxicological risk.
- The Department of Agriculture, Fisheries and Forestry (DAFF) was consulted to seek their input on the risk of importing therapeutic goods containing these materials. Their determination was in alignment with TGA that the products that include such materials pose little toxicological risk.

Table1: Risk analysis based on published literature or articles

Material	Origin	Risk analysis
Xanthan gum	Microbial culture (<i>Xanthomonas campestris</i>)	<ul style="list-style-type: none"> - Listed under “Generally recognised as safe*” substance^[3] - Non toxic^[4] - Excipient in pharmaceutical preparations^[5]
Gellan gum	Microbial culture (<i>Pseudomonas elodea</i>)	Common food additive with no safety concerns ^{[6],[7]}
Bacterial cellulose (cellulose)	Microbial culture (Acetic acid bacteria strains)	<ul style="list-style-type: none"> - Non-toxic and biocompatible^[8] - Used in wound dressings^[9] Listed under “Generally recognised as safe*” substance ^[10]
Alginate	<ul style="list-style-type: none"> - Microbial culture - Brown algae 	Listed under “Generally recognised as safe*” substance ^[11]
Chitosan	Animal origin (shrimps)	Used in pharmaceutical excipient and wound healing applications ^[12]
Fish oil	Animal origin (sea animal)	<ul style="list-style-type: none"> - Non toxic^[13] - Listed under “Generally recognised as safe*” substance¹¹

*Generally recognised as safe (GRAS): Designation assigned by the US FDA

- [1] [Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products](#)
- [3] www.fda.gov/food/generally-recognized-safe-gras/microorganisms-microbial-derived-ingredients-used-food-partial-list
- [4] [Xanthum gum materials safety data](#)
(www.inchem.org/documents/jecfa/jecmono/v21je13.htm)
- [5] [Used in sustained release pharmaceutical preparations](#)
(patents.google.com/patent/EP0234670A2/en)
- [6] Re-evaluation of gellan gum (E418) as food additive
(efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5296)
- [7] Gellan gum – uses, benefit and safety (www.healthline.com/nutrition/gellan-gum)
- [8] A review on the toxicology and dietetic role of bacterial cellulose
(www.ncbi.nlm.nih.gov/pmc/articles/PMC5655389/)
- [9] Bacterial cellulose as a material for wound treatment
(www.sciencedirect.com/science/article/abs/pii/S0734975015300227)
- [10] www.fda.gov/food/generally-recognized-safe-gras/gras-substances-scogs-database
- [11] www.fda.gov/food/generally-recognized-safe-gras/microorganisms-microbial-derived-ingredients-used-food-partial-list
- [12] Safety of Chitosan (pubmed.ncbi.nlm.nih.gov/19788905/)
- [13] Safety assessment pubmed.ncbi.nlm.nih.gov/30465900/

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