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Dear Sir/Madam

Proposal for clarifying regulatory requirements for residual claims for disinfectants

Thank you for the opportunity to provide comment to this public consultation on regulatory requirements for residual activity claims for disinfectant products.

CHP Australia is the leading voice and industry body for manufacturers and distributors of consumer healthcare products in Australia, which includes non-prescription medicines. We strive to advance consumer health through responsible Self Care. Our key priorities for the industry include improving health literacy, growing the consumer healthcare products industry and increasing access to medicines where appropriate.

Our responses to the six proposals made as part of this consultation are provided on the following pages. In summary we are broadly supportive of all the proposals however we request further consideration be given regarding:

- Bacteriostatic residual activity
- Products that don't necessarily meet the definition of a disinfectant but the purpose of the product is to provide antimicrobial residual activity.

Proposal for clarifying regulatory requirements for residual claims for disinfectants

Proposal 1: Definition of residual activity
The Regulations do not have a definition for residual activity. Currently, claims made for disinfectants are considered on a case-by-case basis. A potential definition of residual activity could be:

"The capability of a disinfectant product to continue to produce a reduction in the number of viable cells of relevant test organisms on a surface under use conditions defined on the label of the product."

The proposed definition is sufficiently broad to allow for variability of the nature of the surface, the use conditions, test organisms other than bacteria and yeast and the period of residual action as defined on the label. It therefore provides for application of the PAS 2424:2014 and the proposed guidance for extended test provisions.

Further clarity of this definition would be beneficial for industry around:

1. Residual bacteriostatic efficacy or inhibition of microbial growth claims

   Disinfectants and sanitisers making bacteriostatic efficacy claims (which are currently considered to be non-specific claims) are exempt from inclusion in the ARTG. General cleaners making bacteriostatic claims are excluded from operation of the Therapeutic Goods Act and are regulated as consumer goods.

   The Disinfectant Claim Guide indicates *residual activity* is a specific claim. The consultation paper has confirmed for us that TGA have also assessed residual bacteriostatic claims as specific claims, with the examples of a recent residual efficacy claims, including one for residual bacteriostatic action –

   "forms a protective polymer to provide residual bacteriostatic efficacy on high-touch surfaces for up to 24 hours and on low-touch surfaces for up to 30 days"

   As such, we suggest the proposed definition needs to be extended to include not just a reduction of viable cells but also the inhibition of viable cells.

2. The scope of the nature of the antimicrobial agent itself and the form it may take.

   We note that TGA's proposed definition, unlike PAS 2424:2014 method, is not limited to liquid chemical disinfectants. It is unclear the extent of types of surface coatings to which it can apply. Is it limited to liquid surface coatings or can it also be applied to films and other solid coatings that are used as surface protectants? Can the residual activity claim be made by antimicrobial products that don't meet the traditional notion of a disinfectant? It is therefore questioned whether the reference to 'disinfectant' which is defined in the Regulations, should be replaced with the word 'antimicrobial' in the definition of 'residual activity'. This would allow the definition's application to other products with a purpose of residual antimicrobial activity, like protective surface coatings. During the COVID-19 crisis there has been recognition that it is in the public interest to understand the scope of activity of such products, but for such a specific claim to be made on label or in advertising, these products are no longer excluded goods.

   From this same perspective, that of the form of antimicrobial treatments, further guidance would be helpful on what formats of product would be considered excluded under Schedule 1, item 12 of the Therapeutic Goods (Excluded Goods) Determination 2018, that is –

   "sanitation, environmental control and environmental detoxification equipment"

Proposal 2: Testing standards

For testing purposes, adopting the principles set out in PAS 2424:2014 Quantitative surface test for the evaluation of residual antimicrobial (bactericidal and/or yeasticidal) efficacy of liquid chemical disinfectants on hard non-porous surfaces – test method as a preferred methodology for demonstration of residual activity of disinfectants. It is recommended that additional guidance be developed to extend the test provisions to cover organisms other than bacteria or yeast, and periods of greater than 24 hours for residual activity.

CHP Australia are supportive of using the principles established in PAS 2424:2014 method as the basis for a residual efficacy method, along with the development of guidance to extend the current limitations of that method to address:

- other microorganisms other than bacteria and yeast, which should include viruses and fungi
- the periods of residual activity greater than 24 hours or support of periods less than 24 hours.
- reducing the number of abrasion cycles for situations where applicable to very low contact surfaces.

The guidance to be developed might also give consideration to different:

- Types of surfaces – for example soft or textile surfaces.
- Antimicrobial product formats – modifying the test conditions and acceptance criteria to relate to the claimed residual efficacy for both traditional chemical disinfectants but also for surface modifiers.

Surface modifiers physically and molecularly bond with the surface to which they are applied and become an intrinsic part of that material. They can be applied to both porous fabrics (e.g. furniture fabrics) and non-porous surfaces and eliminate viruses and bacteria from the surface via a "mechanical kill action" by rupturing the protective layers of the microbe, as opposed to a "toxic kill action" utilised by disinfectants. The speed/rate of elimination is different to that of a chemical disinfectant. They perform very differently to each other and should be assessed by standards that are appropriate to the mechanism of the product. Unlike disinfectants that provide an almost immediate one-off kill (within the timeframe of application), the surface modifying antimicrobial coating provides an ongoing "killing" ability. This elimination of microbes is not instantaneous but occurs over time. On contact with an antimicrobial coated surface an almost immediate 1-log reduction in microbes occurs. This increases over time, with the surface continually killing the microbes that are deposited. The purpose of a surface

modifiers is to provide a sustained antimicrobial action over days/weeks. Surface modifiers are not intended to be used as an alternative to disinfection, but may be used as a separate step after disinfection.

There is a lack of clarity whether surface modifier type products must comply with TGO 104 requirements. We suggest that these products require their own separate standards and should not necessarily need to pass the usual tests for immediate effect disinfectants as well as the sustained release tests.

Therefore, while a modified PAS 2424: 2014 method will accommodate residual efficacy for many product types, CHP Australia's members would still value the TGA allowing for the use of other appropriate methods to be considered via TGA evaluation on a case-by-case basis, particularly where a method is more specific to the particular product type. TGA's continued facilitation of this approach also allows member companies to access global product development and ultimately leads to greater harmonisation of methods.

For example, methods like the US EPA *Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces*[1].

A suggested method appropriate for surface modifiers would be - ASTM E2149 - 20 Standard Test Method for Determining the Antimicrobial Activity of Antimicrobial Agents Under Dynamic Contact Conditions. This is a suitable test method that can be used on soft textiles and addresses physical stresses that the surface could undergo after application of the product.

Another option to consider is 'reverse' carrier testing. For example, EN 14561 or EN 13697 with carrier disinfected as per instructions for use, stored for x days/weeks then challenged with organisms.

Please refer to the table below for further test method suggestions:

[1] https://www.epa.gov/sites/production/files/2015-09/documents/cloroxpcol_final.pdf

Claim	Standard	Comments
Porous surfaces		
Bactericidal	ASTM E3160-18; or EN ISO 20743	The pass criteria could be modified to a 5-log reduction as for EN 14561. The methods could be modified to test for activity against any bacteria or fungi.
Virucidal	ISO 18184	The pass criteria could be modified if necessary.
Non-Porous surfaces		
Bactericidal	ISO 22196 or JIS Z 2801:2012	The pass criteria could be modified to a 5-log reduction as for EN 14561. The method could be modified to test for activity against any bacteria.
Virucidal	ISO 21702	The pass criteria could be modified if necessary.
Fungicidal	ISO 16869	The pass criteria could be modified if necessary.

In addition, consideration should be given to other types of testing including 'real world' testing. It was apparently conducted and accepted by the US EPA in support of the of the first sustained effect surface coating product approved in the US. 'Real world' testing is often available, performed in locations such as in hospitals, buses, trains, aged care, and on varieties of surfaces such as uniforms, carpets, tiles.

Proposal 3: Acceptance criteria

It is proposed that the acceptance criterion for a claim of residual activity be set at a 3-log difference between the test and the control.

Note that a 3-log reduction in the virucidal test is sufficient to claim efficacy against that virus if cytotoxicity is present, which is a better claim than residual activity. For a residual claim against viruses, it therefore appears that the requirements are not equivalent to that for bacteria, noting that bactericidal efficacy requires a 6-log reduction, but only a 3-log reduction for residual activity. Therefore, a potentially higher standard is applied to residual claims for viruses compared to bacteria.

Feedback is sought on whether a 3-log reduction for residual claims against viruses is reasonable given the acceptance criteria applied to the testing for virucidal activity.

CHP Australia support the TGA proposal that a 3-log difference between the control and the treatment is appropriate for disinfectants. Additionally, this acceptance criteria should be used where the method is modified for viruses. If cytotoxicity is present a 2-log reduction would be appropriate.

The guidance should provide clear instructions for residual activity claims on labelling to ensure they are presented clearly and consistently. The declared maximum residual period claimed on the label must be consistent with the acceptance criteria. For example, "residual efficacy for up to X days/hours" where X is the maximum period at which the acceptance criteria is met. In the case of surface coatings this maximum period might be in terms of weeks, months, or years.

As raised under proposal 1, the TGA may also need to consider acceptance criteria for residual claims of inhibition of viable cells or bacteriostasis. The acceptance criteria for this type of claim might include the period for which the average recovery of organisms from the test substance remains less than the recovery of organisms from the non-active control.

Proposal 4: Limitations on claimed residual activity period

It is proposed that no limitations be placed on the period over which residual activity is claimed, as long as the claims are substantiated by test data.

Feedback is sought on whether a limit should be placed on the period over which residual activity is claimed, and whether claims of 'high touch'

/ 'low touch' conditions and the like should be allowed in conjunction with the residual activity period.

For disinfectant products we need to be mindful of how the user may interpret claims of very long periods residual activity. Could a 365-day residual effect claim be interpreted as 'set and forget' no need to disinfect that surface for another year regardless of the surface type and its use?

Ultimately the effectiveness of the labelling is the key. Therefore, provided the claimed residual activity is consistent with the test method including the organisms subject to the test, the usage instructions, and the surfaces treated CHP Australia is supportive of this proposal.

We support claims of 'high touch' and 'low touch' being made and suggest they are defined in the guidance, ensuring consistency of what is meant and can be substantiated by test data. Other terms and synonyms in use like "multi touch" and "high traffic areas" might also benefit from definition. Additionally, test protocols as part of the extension to PAS 2424 would need to be established within the guidance.

Proposal 5: Restricting residual activity claims to specific organisms
It is proposed that residual activity claims can be made against general bacteria and/or specific organisms, if substantiated by test data.
Feedback is therefore sought on whether residual activity claims should be restricted to specific organisms given some specific organisms are highly pathogenic.

CHP Australia are of the position that residual claims against a spectrum of organisms (bacteria, yeast, fungi and viruses) should be permitted, as long as the data and test methods used support the claims being made.

We suggest that for general bacterial residual activity claims, testing should be performed against the same organisms as those used in the immediate effect disinfectant testing. If specific bactericidal claims are made, then residual activity data should be provided against the same specific organisms. Likewise, specific claims for residual virucidal/fungicidal or other claims should use the same organisms as for immediate effect disinfectant testing. We don't feel that claims need to be restricted if data can be provided to support the claims being made.

We would suggest that restricting the residual activity testing to an allowed select group of organisms would not benefit consumers.

Proposal 6: Allowing residual activity claims
It is proposed that residual activity claims be allowed in the interim, and be assessed on a case by case basis. Should a test method or multiple test methods be defined, the new testing requirements will apply to new listings (i.e. not applied retrospectively to listings already approved).

CHP Australia note and welcome the consultation proposal adopting the principles set out in PAS 2424:2014 test method as a preferred methodology for demonstration of residual activity of disinfectants. While the additional guidance will be designed to extend the test provisions, this still will not address all products types and treatment surfaces which do not lend themselves to testing to the PAS 2424 method. We therefore feel that it is important for TGA to continue to allow and review alternate methodologies for residual activity claims to accommodate these products.

Should an appropriate harmonised test method or methods later be defined it would be important to consider how best to implement it/them at that time. It will be important that:

- consumers are able to effectively compare product claims.
- where methods adopted are not suitable to all product types, flexibility is still provided.
- where multiple methods are adopted they support equivalent claims and/or there is transparency of the methods used.
- there is recognition of the cost burden of testing to the new method and the cost burden of reformulation should a product not pass the new test method.
- where it is necessary to apply the new method retrospectively, a Regulation Impact Statement should be conducted to understand the implications of the change and to determine an appropriate transition provision to minimise the cost burden on industry.