



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**



**Proposed amendments to how the efficacy of certain pool
and spa chemicals is assessed**

Submissions received

July 2022

SPASA comments on 'Proposed amendments to how the efficacy of certain pool and spa chemicals is assessed'.

APVMA has published proposed amendments to how the efficacy of certain pool and spa chemicals are to be assessed. SPASA appreciates the opportunity to comment on the proposed changes to the requirements for demonstrating efficacy of pool and spa sanitisers.

SPASA acknowledges and accepts the need for APVMA to be satisfied a product, when used according to the proposed label directions, would be effective. SPASA appreciates APVMA's efforts to establish criteria that demonstrate the efficacy of proposed products or proposed uses for a product that are acceptable to APVMA, the regulated community, and other stakeholders. However, SPASA does have concerns about total reliance on the OECD guidelines to set the criteria for demonstrating efficacy of swimming pool and spa sanitisers.

The most important function of swimming pool and spa chemicals is to protect the health of people using pools and spas. The guidelines for demonstrating efficacy of swimming pool and spa sanitisers must be focussed on ensuring products used in swimming pools and spas contribute to the protection of human health.

Products used in swimming pools and spas do not work in isolation. Control of contaminating microorganisms in pools and spas requires integrated pool management involving chemicals (including APVMA regulated products such as biocides and products not regulated by APVMA such as acid and flocculants).

Swimming pool and spa products should be assessed realistically against relevant health-based criteria. SPASA questions whether the exposure times stated in Table 1 of the Consultation Document are health based or are based on other criteria, e.g. the results achievable by sanitisers available at the time the guidelines were developed. As an example, SPASA questions why *Escherichia coli* needs to achieve a 4-log₁₀ reduction within 30 seconds while control of *Giardia* requires a 3-log₁₀ reduction over 45 minutes.

SPASA proposes that an Expert Advisory Panel, as recommended in the 'Final Report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia' be convened to evaluate the criteria to be used for assessing the efficacy of swimming pool and spa chemicals and to then propose the relevant criteria against which efficacy can be tested. The criteria should allow authorisation of programs that could be used to achieve the required level of control even though a specific product, when used alone, does not achieve the required level of control.

SPASA does not support the requirement to conduct whole pool studies to assess efficacy but does support whole pool testing to assess dispersion of sanitisers within pools to ensure the sanitiser is capable of being distributed throughout the pool.

Specific issues with the draft guidelines are discussed below.

Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014 is not relevant to current consultation

APVMA has referenced the *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014* and has stated the Determination allows efficacy to be determined by a variety of different means including:

1. Efficacy studies; or
2. Valid scientific arguments; or
3. Demonstrated history of sale and effective use in equivalent uses; or
4. Overseas studies that have been assessed by overseas regulators; or
5. A combination of 2 or more of the above.

There are three issues with referencing the above-mentioned determination, viz.

1. The *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014* does not include products used to sanitise swimming pools or spas (Part 2, Section 3(2)(b)):
 - a. The Determination would need to be modified to include swimming pool and spa sanitisers.
 - b. No details of changes to the Determination have been provided in the consultation documents.
2. The *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014* does not include commercial use products other than those listed in Part 2, Section 3(1)(a)(ii) – (viii).
3. Part 2, Section 4(b) of the *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014* lists the acceptable evidence but is not clear:
 - a. While options (i) to (iv) in Section 4(b) all end with ‘or’ which allows any one of these options to be used, option (v) states a combination of 2 or more of the above options could be used.
 - i. This implies APVMA might require more than a single option to be used as evidence.
 - ii. The need for potentially more than one option or for other options to be required is confirmed in the note below Section 4(b).
 - iii. Section 4(b) should be reworded to clarify if any one of the options is sufficient or if more than one option is required.

SPASA cannot comment on the acceptability of the *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014* without further details of how APVMA proposes to amend the Determination.

Reliance on the OECD guidelines (Guidance Document for Demonstrating Efficacy of Pool and Spa Disinfectants in Laboratory and Field Testing. Series on Testing and Assessment No. 170. Series on Biocides No. 4)

The OECD guidelines at Paragraph 2 state the document ‘describes how applicants could demonstrate’ the efficacy criteria are met. The term ‘could’ indicates the guidelines are not mandatory but provide options for demonstrating efficacy.

SPASA:

- Supports non-mandatory guidance on methods that could be used to demonstrate efficacy; and
- Recommends agreed efficacy criteria/targets be established against which efficacy can be assessed.

The OECD Guidance at Paragraph 5 states 'it is critical that human beings are not exposed to potential microbial infection or chemical health risks' during field testing of a proposed product.

SPASA strongly supports the recommendation that humans not be exposed to potential microbial or chemical health risks. To this end:

- SPASA supports the OECD guidance recommendation that performance be assessed under laboratory conditions.
 - SPASA supports the proposal that 'artificial organic content consistent with a well-maintained pool' be used to simulate bather load (paragraph 14(b)).
- SPASA recommends whole pool testing be done only to assess dispersion of a biocide through the pool rather than attempting to monitor microbial contaminants.
 - Whole pool testing should be done only after efficacy of the product has been demonstrated; and
 - Whole pool testing should not be a pre-requisite for registration provided valid scientific arguments can be supplied to show the available data confirm the product would remain at effective levels throughout a swimming pool or spa when the pool or spa is being used.

The OECD guidelines at paragraph 14(a) state tests should be carried out by a nationally accredited laboratory.

While it is recognised that some countries require 'official tests' to be conducted, this is not a requirement in Australia.

SPASA does not support any requirement for tests to be 'carried out by a nationally accredited laboratory that has no affiliation with or commercial connection to the applicant' (paragraph 14(a)) but does accept microbiological assessments might need to be conducted by suitably accredited laboratories as:

- NATA or other suitably accredited laboratories are not readily available for the field-testing portion of the study;
- The use of NATA accredited laboratories is not required for demonstration of efficacy for other agricultural chemical products; but
- It is recognised that microbiological assessment is a specialised area and use of suitably accredited laboratories for enumeration of pathogens collected could be advantageous.

The OECD guidelines, at paragraph 14(a), state assay methods must be well established.

SPASA does not support the requirement for 'Assay methods for each type of test [to] be well established' (paragraph 14(a)).

- This requirement could prevent development of novel products for which new assay methods might need to be developed.

SPASA does not agree with efficacy of a product being defined by comparison to a specified existing biocide. SPASA does not agree that efficacy be shown to be equivalent to hypochlorous acid/hypochlorite.

- SPASA suggests health-based performance criteria should be established.
 - The performance criteria should be based on the risk posed by the target (or surrogate) organisms.
 - Meaningful exposure times should be developed that can serve as targets for integrated pool management systems designed to protect human health.

SPASA does not believe full pool testing for control of microorganisms should be a pre-requisite for registration of swimming pool chemicals.

- There is no way to ensure pathogens of concern will be present in a swimming pool without intentional introduction of such pathogens.
- Introduction of human pathogens into a swimming pool is complicated by ethics considerations.
- Rather than primarily monitoring pathogens in pools, pool testing should be designed to monitor the dispersion and residual concentrations of biocide.

SPASA supports the concept of a safety margin provided the safety margin reflects good pool management.

- The OECD guidelines suggest a safety margin of 50% of the recommended operating concentration (paragraph 14(c)).
 - This is an acceptable target but there needs to be flexibility if valid scientific argument shows a different safety margin could be used.
 - SPASA supports the requirement for adverse human health effects to not be likely from use of the proposed product or a known product in a proposed situation at the recommended operating concentration.
 - Whatever, safety margin is selected, methods must be available to confirm the required concentrations are present.

Other variables that could affect efficacy that are not adequately addressed by the OECD guideline:

Add inoculum to biocide or biocide to inoculum?

The OECD guidelines, as written, suggest the sanitiser is added to the inoculum preparation. This is appropriate for testing control of a problem, e.g. a faecal event where it is common for a concentrated biocide to be added at the point at which the event occurred.

- This results in significantly elevated biocide concentrations at the site of the event.
- In normal use, the concentration of biocide is maintained at a level to which microorganisms might be introduced.
- The worst-case scenario is a point source release (e.g. faecal event) that is not observed. This could result in a locally high concentration of pathogen(s) that might be controlled or might spread throughout the water.
- Testing should consider the implications of point-source contamination in water containing the required concentration of biocide.

SPASA recommends proponents be allowed to decide if adding inoculum to biocide

Health-Based Criteria

The OECD Guidelines are prescriptive suggestions that do not explain the reason for the criteria stated. As an example, Table 1 of the OECD guidelines lists different reduction requirements and exposure times without explaining why these different reductions and times have been selected:

- Although *Escherichia coli* does not grow in water, the table states a 4-log₁₀ reduction of *Escherichia coli* is required within 30 seconds.
- This contrasts with the requirement for a 3-log₁₀ reduction within 45 minutes for *Giardia* spp even though *Giardia* spp are shed in large numbers in faeces of infected people and are infective at low doses.

To determine health-based efficacy criteria, the risk posed by the microorganisms need to be considered including:

- The rate of replication of microorganisms under different conditions (e.g. temperature);
- The infective dose of target pathogens; and
- The potential microbial load that might be introduced into a pool at a single point and whether the sanitiser at the target concentration, is effective.

SPASA proposes that an Expert Advisory Panel, as recommended in the 'Final Report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia', be convened to determine health-based criteria for testing the efficacy of swimming pool and spa biocides.

SPASA suggests the Expert Advisory Panel include individuals with expertise in pathogens of concern that can occur in pools and spas.

As the peak body for the swimming pool and spa industry, SPASA is willing to work with APVMA to identifying experts who might be able to participate in the Expert Advisory Panel.

Impact of Other Controls

What is the impact of other controls used?

- Water is normally passed through a filter that is capable of removing some contaminants.
- Algaecides and other chemical controls might be added to the pool water that might affect the control achieved.
- While not applied as specific controls, substances added to water to control other characteristics including water pH and turbidity of the water can affect the efficacy of controls and need to be considered in determining effective integrated pool management programs.

SPASA suggests that proponents be allowed to explore options for controlling pathogens and then, if appropriate, seek approval for labels that provide guidance on the whole pool management system required to achieve the target controls.

Other Factors, including Biofilm

Other factors are not considered in the OECD guidelines, e.g. biofilm as a protective 'shield' for pathogens.

- While the OECD guidelines mention sampling for biofilm during testing, the presence of biofilm in inaccessible places (e.g. within filters) is not considered.
- Biofilm protects microorganisms within the film.
- The biofilm can become a constant source of inoculum or could become a point source of contamination if released.
- In either case, the release of microorganisms from an established biofilm can interfere with the observed levels of control.
- The potential presence of biofilm in established pools and spas further complicates whole pool studies.

SPASA does not support the use of whole pools to evaluate efficacy of swimming pool and spa biocides as potential sources of infection, including biofilm in inaccessible areas, can act as ongoing sources of infection.

SPASA supports the development of products that could be used for management of other factors, including removal of biofilms and other harbourages for pathogens and/or the development of biocides that control the organisms that are present within the biofilm, recognising that removal of harbourages, including biofilm, is not within the scope of APVMA regulation.

Conclusions

SPASA supports APVMA's attempts to prepare guidance on the requirements for efficacy of swimming pool and spa biocides and notes the guidance will be helpful to those seeking to register new products as well as all other interested stakeholders.

SPASA does not believe the OECD 'Guidance Document for Demonstrating Efficacy of Pool and Spa Disinfectants in Laboratory and Field Testing' provides sufficient guidance as it does not address the requirements of novel materials.

SPASA recommends health-based criteria:

1. Be developed by a panel of experts knowledgeable in contaminating organisms in water; and
2. The underlying reasons for any proposed criteria be explained so that proponents developing new products:
 - a. Understand the reason for the proposed targets; and
 - b. By understanding the reasoning, have the opportunity to develop testing methods that address those targets.

SPASA does not support the proposal for whole pool testing for microbial contaminants be required for registration. SPASA suggests:

1. Efficacy be demonstrated using appropriate laboratory methods; and
2. Whole pool testing be used for confirmation of the dispersion and residual concentrations of introduced biocides in pools (rather than demonstrating efficacy of the biocide).



Watertech Services International Pty Ltd
Unit 2/27 Ford Road
Coomera QLD 4209 Australia
A.B.N. 85 096 320 482
A.C.N. 096 320 482
Phone: +61 7 5655 6150

**ENVIROSWIM'S RESPONSE TO THE
APVMA'S PROPOSED AMENDMENT TO HOW THE EFFICACY OF CERTAIN POOL AND SPA
CHEMICALS IS ASSESSED**

Enviroswim welcomes APVMA's proposed regulatory changes to how the efficacy of certain pool and spa sanitisers is assessed. Specific performance standards drawing from international best practice supports continued improvement in risk management of disease and strengthening protection of the health and safety of people and the environment.

A mandatory performance-based approach to demonstrate the efficacy of pool and spa sanitisers ensures that only sanitisers proven to meet the criteria can be put on the market. This will safeguard the health of the public and promotes consumer confidence.

Enviroswim supports laboratory and field-testing to prove sanitiser efficacy. Enviroswim's commitment to international best practice is demonstrated by our obtaining of independent testing and certification for our ES3 pool and spa water sanitisation system, including:

1. National Sanitation Foundation to meet NSF50 standards.
2. NATA accredited laboratories to meet efficacy standards, and to assess risk in relation to maintaining water quality for environmental discharge and effectively sanitizing swimming pool water.
3. Field testing in full size swimming pools, including microbiological water sample tests conducted by NATA accredited laboratories, and many thousands of systems in operation both in Australia and internationally.

Enviroswim would be delighted to provide its experience and expertise to the APVMA in considering the proposed regulatory changes to how the efficacy of certain pool and spa sanitisers are assessed.