Submission to

AUSTRALIAN GOVERNMENT REGULATORY TASKFORCE

TASKFORCE ON REDUCING THE REGULATORY BURDEN ON BUSINESS

Government Body

AUSTRALIAN PESTICIDES & VETERINARY MEDICINES AUTHORITY (APVMA)

Enabling Legislation

AGRICULTURAL AND VETERINARY CHEMICALS ACT 1994 (Agvet Code)

Prepared by

AQUAMATICS

Unit 6, 128 Old Pittwater Road
Brookvale NSW 2100
Phone (02) 9939 2444 ♦ Fax (02) 9905 9390
Email mdec@aquamatics.com.au

Manuel de Carvalho, Managing Director

CONTENTS

1.0 INTRODUCTION P 1

The Australian Government has established the Regulation Taskforce to identify practical options for alleviating the compliance burden on business from Commonwealth Government regulation.

This submission makes note of the Commonwealth Government's Agricultural and Veterinary Chemicals ACT 1994 (Agvet Code) and expresses the major concern of how the Australian Pesticides and Veterinary Medicines Authority (APVMA or Authority) administers the regulations and exercises its power.

The submission whilst prepared by Aquamatics, an Australian family business that has been in existence for 30 years and has in the order of 10,000 to 12,000 clients, does actually represent a much wider problem for the whole Pool and Spa Industry.

As a reflection of the wider concern, the peak body for the Industry, the Swimming Pool and Spa Association of NSW (SPASA) would have made its own submission along similar lines but timing and protocol has prohibited a Board motion to participate with the Taskforce. This motion is expected to be passed on 21 December 2005 at the next meeting and will then seek permission from the Taskforce to substitute itself as the author of this submission and participate in further discussions. Please refer to Annexure 'A' for a copy of a letter from SPASA expressing its position of interest.

1.1 SUMMARY OF CONCERNS

The body of this submission will elaborate on the summary below. Supporting evidence is also provided in the annexures.

- The **Agvet Code** does have deficiencies that requires redrafting and or amendments. It should be addressed sooner rather than later to minimise misinterpretation, confusion and vagaries. (refer Section 2.0)

  While there are flaws in the legislation, no one or no organisation contends that there should not be regulation of the Pool and Spa Industry. Most with commonsense would be willing to live with deficient legislation if properly administered. And that is where the main problem lies.

- The **APVMA's core competency and expertise** is in the field of agricultural and veterinary chemicals. It does not understand the complexities and intricacies of pool and spa water chemistry and as a result is going down a path that is and will be detrimental to the whole industry. (refer Section 3.0)

- The **APVMA's method of operation** is draconian, unprofessional, incompetent, uncompromising, dismissive and arrogant. Perhaps allegations that have and may be levelled at other regulators. When there is no scientific or commercial justification to its misguided and unwarranted actions, the description rings true.

Several honest and honourable small businesses with good products and reputations have ceased trading because of the APVMA's misguided and highly questionable actions. Some businesses, like Aquamatics (please refer to Annexure 'B' for a brief history of the business), have spent collectively over $1.5 million dollars defending themselves. Aquamatics eventually won its case at the Administrative Appeal Tribunal.

- The **APVMA's new disinfection guidelines** issued in July 2004 are ridiculously onerous, unrealistic, unjustified and curiously selective in its use. It will stifle creativity and innovation and ensure that no new products will ever be brought to the market.

  The main beneficiaries of the new guidelines are the manufacturers and suppliers of traditional chemicals, such as chlorine. Their market dominance will continue uncontested even if a product is credible, efficacious, ecologically and environmentally more friendly (refer Section 5.0).

- The **APVMA's registration of products** complicates and delays what should be quite often a relatively straight forward process. It hinders business rather than helps it in its endeavour to compete in the market place. (refer Section 6.0)

1.2 THIN EDGE OF THE WEDGE

The extraordinary action undertaken by the APVMA by unjustifiably and without notice issuing Recall Notices in March 2004 (refer Section 4.1) to a small sector of ioniser manufacturers is a microcosm of the problem that the whole industry faces. As noted earlier SPASA shares the concern.

As a result of the its incompetence and ignorance, the APVMA has started a series of events and actions that will sooner rather than later be highly embarrassing for the APVMA, the Federal Government and the whole Pool and Spa Industry. The embarrassment will be self inflicted and will highlight a grossly unprofessional organisation with questionable motives.

Should the APVMA remain unquestioned a $600 million Pool and Spa Industry will be severely damaged. This is not being alarmist or an exaggeration. It will happen if the APVMA is not reigned in.

2.0 LEGISLATION - AGVET CODE P 3

The Agvet Code was passed in 1994 and governs the regulatory framework under which the APVMA exercises its duty for the Government and the public. It tries to ensure that disinfectant and sanitiser products used by the Agricultural, Veterinary and Pool Industries do not pose an unnecessary health risk. A fine and worthy requirement for regulation!

2.1 PREAMBLE

The Act spans some 260 pages defining the powers vested to the APVMA for its to perform its duty. Page 1 of the Act notes that it is -

> An Act to make provision for the evaluation, registration and control of agricultural and veterinary chemical products, and for related matters, for the purposes of the *Agricultural and veterinary Chemicals Act 1994*.

It then goes on to itemise 6 points under the heading of RECOGNISING. This forms the basis of the preamble to the legislation. Of particular interest in the preamble are points (c) and (d), which states as follows:

> (b) ……..
>
> (c) that the furthering of trade and commerce between Australia and places outside Australia, and the present and future viability and competitiveness of primary industry and of a domestic industry for manufacturing and formulating such products, are essential for the well being of the economy and require a system for regulating such products that is cost effective, efficient, predictable, adaptive and responsive; and
>
> (d) that it is desirable to establish a regulatory system that is open and accountable and gives opportunity for public input with respect to the regulation of such products; and
>
> (e) ……...

As will be evidenced in later sections of this submission, the APVMA would appear not to be concerned with these requirements.

2.2 INAPPROPRIATENESS & DEFICIENCIES

The Act is too voluminous to itemise sections in question. Further, Aquamatics nor its executives are qualified lawyers and as a result it would be inappropriate to comment on points of law.

The legislation was drafted with the agricultural and veterinary industries in mind. When it was drafted it was not intended to be used as the regulatory framework for the Pool and Spa Industry.

Although not conclusive, and some may argue irrelevant, the title of the Act and the title given to the authority that enacts it powers makes it clear that the agricultural and veterinary industries was to fall under its control. The Pool and Spa Industry was not contemplated at the time.

It is because the legislation was drafted for other industries that leaves the Pool and Spa Industry with difficulties in the interpretation of some sections.

Vagaries and or loopholes in legislation will be used by honest companies to defend themselves from unjustified actions by any third party.

It is not that the Pool and Spa Industry seeks to avoid legislation but what it does seek is legislation that is applicable to the characteristics of the Industry. There are substantial differences between disinfectants and sanitisers used by the Agricultural and Veterinary Industries and the Pool and Spa Industry.

Pool and spa water chemistry is different and an understanding of that chemistry is needed to properly legislate for its idiosyncrasies, the same comment applies to the APVMA which seeks to force itself on the Industry.

3.0 APVMA - CORE COMPETENCY P 5

There are many highly qualified scientists working at the APVMA. Their qualifications would more than likely lend itself to adapting to the nuances of pool and spa water chemistry.

The reality is that the core competency of the professional staff at the APVMA is in agriculture and veterinary science.

It is the distinct lack of understanding of the Pool and Spa Industry and the APVMA's unwillingness to operate in an open and consultative manner that is causing the substantial problems, with the portent of worse to come.

Many of the events noted in Sections 4.0, 5.0 and 6.0 will highlight the issue of core competency within the APVMA.

3.1 THE GENESIS OF POWER

Regulation of pool and spa disinfectants and products fell under the jurisdiction of the now defunct National Registration Authority (NRA).

The NRA held the role of regulator until about the mid 90's. The APVMA acquired the NRA's portfolio of responsibilities.

There is nothing wrong with the transfer of power in itself or creating another body to carry on duties. It goes wrong when the structure of an organisation does not cater for the duties, and the staff, especially professional staff, is not trained to operate outside of its core competency.

The assumption at the time that scientist within the APVMA, well schooled in agriculture and veterinary science, could easily and properly adapt their experience and qualifications to a completely different set of scientific parameters has proven to be grossly flawed and much to the expense of the Pool and Spa Industry.

The right structure and suitably trained personnel is required to properly regulate any industry. APVMA ignorance and arrogance has already lead to, and is leading to, a burden the Industry cannot operate under.

It is important to reinforce again at this juncture that Aquamatics has no objection to regulation to protect the public's health while still serving business in an efficient, productive manner.

As stated, the problem lies in the method and manner in which the APVMA chooses to exercise its power. The experience of Aquamatics and its fellow ioniser manufacturers over the last 20 months has been nothing short of horrifying and this represents what is in store for the whole $600 million Pool and Spa Industry.

As a precursor to the events of the last 20 months it is worthwhile pointing out two facts, namely:

- Ionisers use the principles of emitting copper and silver ions into a body of water by a process of electrolysis. It must be used in conjunction with an oxidising agent to enhance its sanitising effect. Ionisers accepted around the world as an efficacious means of disinfecting pool and spa water. Europe, UK, USA all accept the use of ionisers as a pool and spa sanitiser.

  Because of the APVMA, Australia is the only country that does not accept ionisers as an efficacious means of sanitising. The APVMA's catch cry is that it is acting for the sake of public health. The APVMA does not have one scintilla of evidence to support its assertion that ionisers represent a threat.

- The European Union is reviewing its regulation of pool and spa water sanitisers, including chlorine.

  In tidying up its regulatory framework and requiring registration of products and systems that have a disinfectant effect, all the countries in the EU recognise that existing products and systems, including ionisers, must have if needed a three to five year moratorium period to meet the standards set by the EU. A common sense approach!

The following sections will clearly demonstrate that the APVMA does not operate in any shape or form with the same degree of common sense.

4.1 MISUSE OF POWER

In the 30 years of Aquamatics being in business there has never been a complaint of a health problem. The system is used not by one or two pools but by about 10,000 to 12,000 pools, including commercial pools. Aquamatics has a system that is efficacious, environmentally friendly and works! It has stood the test of time across a substantial client base, both locally and overseas

Aquamatics and others credible businesses, have been subjected to an abuse of power by the APVMA. There are real concerns about what lies behind the Authority's actions.

Operationally, the APVMA invites people and or organisations to "dob in" companies or products for investigation and regulation.

The ioniser manufacturing sector, approximately eight companies in Australia, was "dobbed in" by some mysterious and undisclosed source. Keep in mind there has never been a reported health problem from pool and spa owners that use ionisers that operate with electrolysis and use a proper oxidising agent. Letters from all State Health Departments have been obtained verifying this fact and are available if required.

There are unanswered questions about the who, what, where and why ionisers were dobbed in. Perhaps ionisers are seen as a threat to the traditional methods of sanitation and perhaps these influential organisation(s) have sought to use a Government Authority to achieve its end? Conspiracies are difficult to prove!

The result of this dobbing in was on 11 March 2004 the APVMA issued Recall Notices to ioniser manufacturers. The requirements of the Recall Notices were, amongst other things, as follows:

- Cease trading until the product is registered and that would only take 2.5 years or more.
- Recall and buy back all its products from the shelves of on-sellers.
- Issue public notices in metropolitan and regional papers advising the public that ionisers were effectively off the market and they had to use chlorine.
- Advise users of the ioniser systems that they should seek the return of their system to the manufacturer and possibly require compensation.

The notices, which came without warning were designed to send a group of legitimate manufacturers out of business. Two companies chose to fight – Zodiac Group (a world wide multinational) and Aquamatics. Some have gone out of business, some rolled over to comply with the APVMA's demands and others have peeled back their operations significantly.

Interestingly, at no time in its deliberation to issue recall notices in March 2004 did it invite discussion with the manufacturers that were to be affected. It also did not it seek any discussion or input from SPASA.

The Taskforce should remember firstly, that letters are held from every State Health Department and secondly, the commonsense used by regulators in the EU.

Aquamatics, and others, made numerous attempts to bring sanity to the situation but to no avail. The APVMA has dismissed facts, scientific evidence and test results done by independent NATA approved laboratories without proper justification.

On numerous occasions it has dismissed NATA results because it has shown chlorine to perform below the Authority's expectations. There is irrefutable scientific evidence to discredit the blind faith that the APVMA shows in its support of chlorine.

Chlorine is an effective sanitiser and Aquamatics is not interested in trying to discredit chlorine, or for that matter, any system or product that works. What it is interested in is reality and fair play.

As an example of the unfounded bias of the APVMA, it is a well known scientific fact that chlorine in the presence of urea has substantially reduced effectiveness.

The APVMA has dismissed test results that Aquamatics' has conducted, through independent NATA laboratories that compared chlorine to its ioniser using normal tap water with urea introduced to the water. Most would accept this as a fairly normal situation in pools and spas. The results correctly showed that chlorine did not disinfect as well as claimed and showed the Aquamatics' ioniser performed very well in those circumstances.

The APVMA has ignored and dismissed that piece of scientific data and all other data in its pursuit of its ill founded cause.

4.2 ADMINISTRATIVE APPEALS TRIBUNAL

Aquamatics lodged an appeal at the Administrative Appeals Tribunal (AAT) in April 2004 objecting to the Recall Notice.

Three hearings later, the last being held for five days in the first week of December 2004, Aquamatics won its appeal with the judgement from the AAT requiring the APVMA to issue Aquamatics with a temporary permit so it could keep trading uninterrupted. Quite rightly the AAT required Aquamatics to pursue registration of its system under the new disinfection guidelines issued by the APVMA on 29 July 2004. The guidelines were issued 4 months after the Recall Notices were issued.

The moving of the goal posts by introducing the new guidelines during the appeal process is discussed further in Section 5.0.

The cost of Aquamatics defending itself at the AAT exceeded $200,000 with costs irrecoverable through the Tribunal. An estimate of costs for the APVMA entourage at the five day hearing alone was about $250,000, and it lost.

Despite the loss the APVMA somehow manages to claim that the AAT supported its position. It continues to denigrate ionisers publicly on its web site through half truths, innuendo and misrepresentation.

4.3 CONFLICTS OF INTEREST

There should be questions raised on the make up of the Board of the APVMA and the advisers it chooses to use as so called industry experts.

The Board has at least one member that is an executive of a major chemical manufacturer and supplier.

Pool and Spa Industry experts that have been used by the APVMA are major suppliers of chemical products. One adviser appears to have been able to register a non-chlorine chemical sanitiser without any scientific test data and information to support efficacy, toxicity and other compliance requirements.

The product is called Aquacadabra Pool Sanitiser and is known to contain a substance called Polihexanide. Polihexanide is also known to cause anaphylactic shock, which can and has caused death. It is believed Polihexanide is banned in Europe.

Questions have been raised with the APVMA about Aquacadabra. To date it has avoided coherent responses to justify the registration of the product.

There are some eight other like products that contain Polihexanide. If the APVMA was truly serious about the role it plays in protecting the health of the public should not these products be subjected to the same type of Recall Notice that ioniser manufacturers endured and be required to be retested under the new test guidelines?

There are many instances of inconsistencies and double standards exercised by the APVMA. Section 5.0 will be of further interest in this regard.

The APVMA issued a new disinfection testing regime on 29 July 2004 after the issuing of the Recall Notices. These guidelines nominate chlorine as the benchmark and are known as:

APVMA Guide for Demonstrating Efficacy of Pool and Spa Sanitisers

Prior to this the APVMA adopted the guidelines used by NSW Health Department for determining efficacy - New Disinfection Process Criteria.

As long as pools have been in existence and sanitation regulations have been in place, in Australia and everywhere else in the world, guidelines similar to those defined by NSW Health have been used without catastrophic health consequences to the millions and millions of pool users around the world.

Despite this fact, the APVMA in justifying the introduction of the new guidelines has said it felt the old guidelines were inadequate to ensure public health. Reasonable if true and uniformly applied to test all disinfection products and systems, new and old.

Having raised the high bar, curiously the APVMA has exempted chlorine and all other products and systems from undergoing the tests. To date ionisers are the only disinfectant system or product required to fulfil the rigours of the new test regime.

The introduction of the guidelines raises many questions of motive that are discussed in Section 5.2, 5.3 and 5.4.

5.1 HOW IT WAS INTRODUCED

The timing of its introduction is of concern. How it was introduced is even more concerning. As required by point (d) of the preamble to the Agvet Code -

> (d) that it is desirable to establish a regulatory system that is open and accountable and gives opportunity for public input with respect to the regulation of such products; and

The APVMA did not make any effort to consult with SPASA. Given the seriousness and significance of the new guidelines it should have been mandatory.

Pool water chemistry is different! Surely the APVMA should have recognised its core competency was not in the Pool and Spa Industry and should have sought advice from the Industry?

Almost single handedly APVMA’s Principal Scientist compiled the guidelines. There are claims that there was expert opinions sought in compiling and agreeing on the standards. The reality was that, and on admission by the APVMA, the expert advice was a couple of telephone conversations with cohorts in a couple of State Health Departments.

The APVMA contains many highly qualified scientists including the Principal Scientist. The APVMA has dismissed test result by questioning the methodology and protocol used by the NATA laboratories. It has rejected test results because it did not have the raw scientific data to confirm the laboratories findings.

There is an argument that the thorough scientific stance is justified to ensure efficaciousness and to protect the public. Commendable and true if uniformly applied!

It is curious that the same scientific thoroughness was not adopted when putting the guidelines together. The Principal Scientist admitted at the AAT that the guidelines were compiled in a rush and benchmark results were taken from publications from web sites.

One of these publications was the World Health Organisation's publication on sanitation standards for drinking water. Other publications were identified as source documents to support its position. The APVMA did not seem to have any use for publications that possibly questioned its views on chlorine or supported ionisers.

The characteristics of a scientist are to question and be satisfied with the scientific results. They should verify the protocol and methodologies used and question the veracity of the data. The APVMA was willing to use this professionalism when confronted by data submitted by ioniser manufacturers but did not exercise the same professionalism when compiling the new set of rules that would impact on a whole industry.

How can WHO drinking water standards have application to pool and spa recreational water? It is highly likely that the testing done by WHO and others were in sterile laboratory conditions using distilled water to test chlorine. A far cry from reality!

Given the date of some of the nominated publications used by the APVMA, it would be quite conceivable that the testing methods used were flawed and are now outdated.

5.2 MOTIVES & BURDEN

A stated reason for the APVMA issuing the new guidelines was that it felt that the old guidelines were inadequate. If that is the case then logically -

- if the old guidelines were inadequate and new ones were required to protect and ensure public health,
- and if all currently registered disinfectants, including chlorine, were passed under an inadequate regime,
- because the inadequate regime does not meet the APVMA's heart felt standard of ensuring public health,
- then it stands to reason that all registered products, including chlorine, should be re-tested to the new standard to ensure public health.

As noted before, the timing of the introduction of the new guidelines was 4 months after the Recall Notices were issued to the ioniser manufacturers.

There appears to be a procedural unfairness in using one set of rules to issue recall notices and change the rules at a later date.

It would not be unfair to question the reason for the new guidelines. Might it be that the APVMA, after its poor preparation and research to justify the hastily issuing of the Recall Notices realised that ionisers actually did disinfect to the standards required at that time. It left itself with no choice but to protect itself by issuing the new guidelines to firstly, justify its attack and secondly, to ensure ionisers would be taken off the market? A theory that may be hard to prove!

The guidelines nominate seven pathogens to be tested. They are:

Bacteria	-	Pseudomona aeruginosa
	-	Legionella pneumophilia
Fungi	-	Trichophyton mentagrophytes (conidia)
Viruses	-	Adenovirus
	-	Rotavirus
Protozoa	-	Naegleria fowleri (cysts)
	-	Giardia muris (cysts)

Only in Australia are these pathogens required to be tested against. To the best of Aquamtics' knowledge, the only exception might be the US where the EPA only occasionally requires testing for Pseudomona aeruginosa, nothing else.

The EPA, especially in California where there are some 3 million pools, is generally regarded as the toughest testing regime to gain approval. The Zodiac Group's product Nature 2 (the subject of a Recall Notice) has been approved by the EPA and everywhere else in the world.

Highly qualified and well respected scientists have told Aquamatics that Sydney Water and hospital disinfectants do not have to undergo such stringent testing.

A reflection of the APVMA's haste and unprofessionalism is the nomination of the Protozoa, Giardia muris. Giardia muris has only ever been found in rodents, never in humans. As a statement of fact, there is not a laboratory in Australia that can test against Giardia muris. As another fact there are only two laboratories in Australia that can test for some of the other pathogens.

Why is it only in Australia that these guidelines are required? Why is it only in Australia that ionisers are treated with such vindictiveness?

Aquamatics has already completed a round of testing and it has cost a ridiculous $50,000. Zodiac has completed its testing and has spent some $200,000.

If the APVMA was to apply the new guidelines fairly and without exception there would be a cost burden to the Industry that would be inconceivable. As well as the huge cost there would not be enough laboratories to cope with the demand.

Precedent was set by the APVMA in March 2004 by issuing Recall Notices to ioniser manufacturers requiring cessation of trading until the registration in 2.5 years. Arguably the APVMA should act in the same manner, fairly and without bias, by issuing notices to every product on the market, registered or not, new or old. Clearly a ridiculous scenario that would bring the Industry to its knees!

5.3 LIMITING THE INDUSTRY

If the APVMA is to follow its edict of new products and systems having to undergo the tests, given the cost and time taken for registration, it virtually ensures that there will never be a new disinfectant introduced to Australia.

The only beneficiaries of this policy are the manufacturers and suppliers of traditional chemical sanitisers. The protection will stifle innovation and creativity in the Industry.

5.4 CURIOUS EXEMPTIONS

The APVMA's edict for the guidelines only to apply to new products raises the question from Aquamatics' perspective that it is not a new product. The business has been in existence 30 years and the product sold has been sold in its current form, with technological improvements, for about 13 years.

The Aquamatics' product is not new but yet is subject to the new regulations. As another illustration of double standards, the APVMA has chosen to exempt a system, known as a Chlorine Dioxide Generator (non-chlorinated) as it is an existing system.

Attached and marked as Annexure 'D' are transcripts of letters (copies held are too difficult to read) from the APVMA to the manufacturer of Zychem Technologies exempting its system from testing. The reasoning is incomprehensible and illogical.

The same reasons for exempting Zychem should apply to Aquamatics and the other ioniser manufacturers.

There are five different disinfection systems (with and without chlorine) available. All deliver a disinfectant outcome on site through a chemical reaction(s).

- Ionisers;
- Ozonators;
- Salt Water Chlorinators;
- Ultra Violet + Hydrogen Peroxide; and
- Chlorine Dioxide Generators.

Despite the similarities, an ioniser is the only system required to be registered. Although the APVMA has clearly stated that it is not willing to guarantee the efficacy of any of the other systems it has chosen to exempt the systems from registration and testing.

The system known as Ultra Violet + Hydrogen Peroxide also presents a situation where there is one rule for one and another rule for another.

An article published in a Commonwealth Government publication - CDI (Communicable Diseases Intelligence), Volume 21, No23, 25 December 1997 notes an incident of infections from a spa in Victoria that used Ultra Violet + Hydrogen Peroxide. The extract is self explanatory –

> *"The outdoor spa pool was being treated with hydrogen peroxide solution. …….. The use of UV-hydrogen peroxide systems is not allowed in public pools in Victoria due to poor performance levels."*

The APVMA was made aware of the problem at the time and since then. The APVMA has chosen to do nothing and when quizzed about its inaction the reasons could be interpreted as it could not be bothered.

Even though the Victorian Government unambiguously states *"The use of UV-hydrogen peroxide systems is not allowed in public pools in Victoria due to poor performance levels."* The APVMA has not acted on the expressed risk to public health but yet acts against ionisers with no evidence.

Interestingly, as part of the tactics of half truths, misrepresentation and innuendo adopted by the APVMA, it has used the reference to the incident published in the CDI article as justification of its actions against ionisers and for continued warnings on its web site.

In both cases the APVMA conveniently fails to mention that the spa used in this particular instance was a Ultra Violet + Hydrogen Peroxide system, mentions ionisers as a sanitiser even though it was not used, and highlights the dangers of infections from spas if the spa is not properly sanitised. The sequence, the flow and the wording is contrived to imply ionisers throughout the web site notice.

The same CDI article notes the deficiencies of the chemical Hydrogen Peroxide Solutions and the threat it poses to public health. Despite the warnings in 1997, the APVMA has chosen to register five such Hydrogen Peroxide Solutions, one as recently as 2004. So much for the APVMA acting in the best interest of the public!

There is no shortage of evidence supporting the assertion that the APVMA appears to be victimising the ioniser manufacturers. There is no shortage of evidence of inconsistencies and double standards. Everything stated in this submission can be readily proven.

6.0 REGISTRATION OF CHEMICAL PRODUCTS P 15

Quite distinct from the registration requirements discussed to date, the APVMA controls the registration of all "registerable" pool sanitiser products.

This sector within the Pool and Spa Industry has its own problems in dealing with the APVMA. The sectors relationship with the APVMA could be said to be a bit more traditional in that companies submit for approval clones or slight variations to products that are already approved or that the criteria for approval is already well known and a well trodden path.

Regardless of this familiarity the sector has continuing issues with the APVMA generally focused on three areas, namely:

- **Constant, numerous and unnecessary changes** to requirements for registration;

- **Extraordinary delays** in approving what would be perceived by the applicants as a rubber stamping exercise; and

- An obsession on **form over substance** in labelling. The APVMA has been known to reject labels because of colour and not the content of the label.

The following is an extract of a facsimile message from one of the chemical suppliers. It describes the frustrations in dealing with the APVMA.

The Taskforce should keep in mind that the APVMA deals with other industries. Stories of their experiences with the APVMA mirror the comments below.

> "…….dealing with the APVMA is becoming a nightmare. Many of the products we sell are "registerable" under APVMA guidelines however most of them would be applied for under the old category 26 (now 6 or 7).
>
> This category is for application of products similar to a currently registered product. Assuming the forms are filled out correctly it is in reality just a rubber stamp job. The estimated period for registration was and currently is 3 months. The actual time used to be 4-6 weeks. It now takes a minimum of 3 months. Even though many of these products have been registered for many years, we now have to provide stability data. We have to provide 11 full colour copies of the label for each individual pack size with our submission. Inevitably there is usually some correction needed (often due to changes in APVMA requirements) which then requires revised submissions and more cost and time.
>
> Very often the APVMA requirements are interpreted differently by individual evaluators causing more confusion to the applicant."

> "In previous years when a product was approved, the applicant would be issued with one approval number. Now, each pack size has its own approval number.
>
> It was the practise when one pack size had limited demand to print labels with just one pack size or even blank and then attach the relevant pack size to the blank label. This is no longer possible, adding substantial cost to printing and stocking of labels. No one in the trade can see the logic of this new requirement.
>
> In a recent application for a chlorine product we wanted to put on the label "..specially formulated for use in…" It was for use in a particular chlorine feeder and we had a particular granular size which was most suited for this machine. Unless we made special application for this we were not allowed to deviate from the standard label. More cost – more time."

The supplier later notes another incongruous interference and burden on the Industry.

> "Talk to anyone in the pool industry and they will all have their own horror stories of dealing with the APVMA.
>
> ……ask about the "No More Ducks". This was a product which discourages ducks from swimming in the pool by changing the surface tension of the water.
>
> The product is a combination of one product which is already approved as safe by the APVMA and another product which does not need to be registered in its own right but is a "safe" product. 12 months and thousands of dollars later it was eventually approved. – Bureaucracy gone mad !!"

Concerns about the new test guidelines discussed in previous sections is commented on.

> "If the new regulations for providing and proving efficacy go through in their current form then Australia will stuck with current products forever. No one in the Australian market could afford to introduce new products.
>
> I understand that the APVMA is now talking about requiring registration for all swimming pool products, even adjusters such as Buffers, water polishers etc……..The time period for registration by the APVMA is already too long due to the work load. Given that for every registerable product used in a swimming pool there are probably 50 other products currently not registerable, you can imagine the work load necessary to approve these products should the APVMA proceed with this idea."

7.0 CONCLUSION P 17

There is a problem with the Agvet Code and it can be fixed over time. Other than the misuse of the legislation to suit the APVMA's modus operandi, the Industry can live with the legislation as it stands and until it is redrafted.

The Taskforce should have concluded by now that the crux of the problem is the APVMA and its culture and attitude, and not legislation

Although not properly documented, and therefore it could be classified as hearsay and dismissed, Aquamatics has been advised of a discussion with one of the senior staff members of the APVMA where the topic was the new test guidelines and other contentious issues between the Pool and Spa Industry and the APVMA. The discussion ended by the APVMA executive expressing its disdain for the Industry along the lines of – *we will do want we want….couldn't give a xxxx about the Industry. It can get xxxxxx!*

If the APVMA was not a Statutory Authority and operated without sanction, it would more than likely been the subject of litigation on the basis of Unconscionable Conduct and it would be a very strong case against it.

The APVMA is not alone in bureaucratic circles with its cultural problem. There are various degrees of culture problems within Government bodies. Arguably the APVMA is as bad as it gets!

Interestingly, the APVMA's reputation for arrogance and bloody mindedness is also well known amongst its public servant peers.

How is the problem fixed?

Immediately and specifically the APVMA must, and it can, repeal the new test guidelines and return the Industry to some normality for testing disinfectants.

On a broader scale and longer term, the APVMA must operate with common sense coupled with a well managed and structured organisation.

As the executives of the APVMA may not see its own faults it is unlikely to be fix the problem itself. The short term remedy is direction from higher authorities with common sense. The longer term solution is educating the public servants that they are there not only there to protect the public (and their own jobs) but to also add positively to Australia and that means business as well. The Business Sector is not the enemy!

The APVMA must reinvent itself to learn to serve the industries it regulates rather than impose its unrealistic, uncommercial and possibly conspiratorial actions.

Preambles (c) and (d) of the Agvet Code says it all!

SPASA LETTER **ANNEXURE 'A'**

SWIMMING POOL AND SPA ASSOCIATION OF NSW LIMITED

ABN 50 076 560 391

22nd November 2005
Ms Vickii Wales
Secretariat - Administrative
Taskforce on Reducing the Regulatory Burden on Business
PO Box 282
Belconnen ACT 2616

Dear Ms Wales,

Our Association, the peak body for the swimming pool industry in New South Wales, is anxious to nominate one of our Board members to present a submission to you detailing some of the regulatory burdens our industry faces.

Constitutionally however, this cannot happen until there is Board endorsement and our next Board meeting is 21st December 2005.

It is understood that one of our Board Members, Manuel de Carvalho of Aquamatics, Brookvale, Sydney, has made contact with you and will be making a submission on behalf of his company. Assuming he receives endorsement from our Board, Mr de Carvalho will become our spokesperson in regulatory matters, however in the interim his submissions will be of a company nature.

We have an issue of some consternation facing our industry with regulations issued by the Australian Pesticides and Veterinary Medicines Authority (APVMA), which are proving burdensome to many within our industry, and which Mr de Carvalho will no doubt elaborate upon.

We do have some issues at a State level in regard to regulations and the ferocity by which some of them are implemented, however we acknowledge that the taskforce is reviewing burdens from a federal perspective.

A registration of interest form on behalf of our Industry Association was forwarded to you electronically this morning. Until there is a confirmed nominee from our Board any information could be sent, addressed to myself.

With thanks and regards,

Brian Hardiman
PO Box 313 Burwood NSW 1805. e: bhardiman@spasa.org.au Tel: (02) 9747 6644

AQUAMATICS HISTORY & PRODUCT **ANNEXURE 'B'**

Aquamatics is a wholly owned Auatralian business that also manufactures all its products in Australia. It markets a unique, non-chlorinated, fresh water purification system known as the **Aquabrite System.**

The business has been in existence for 30 years in one shape or form. It commenced trading as Bridge Projects in 1974. In 1977 Colonel Thomas of Thomas Tube & Filter Company, South Africa, granted the licence to manufacture the Thomas Ioniser to Geoff Hudspith, the previous owner of the business, who pursued the development of the product initially on a part time basis.

A full time commitment to developing the ioniser system commenced some years after the acquisition of the licence. Geoff Hudspith and Les Chedzoy, who is still with Aquamatics, spent many years researching and developing the ioniser to its current status and product range that is available today.

In 1992, Aquabrite the oxidising agent, now used in conjunction with the ioniser was developed by Aquamatics to be used instead of chlorine. Aquabrite is a proprietary blend unique to Aquamatics and it is indeed unique in the world. The combination of the copper and silver based ioniser and the oxidising agent is now marketed, and has been for about 12 years, as the Aquabrite System.

The ioniser systems manufactured by Aquamatics now boasts some 10,000 to 12,000 domestic pools that use the system both here and overseas, including, USA, UK, Europe, Carribean, the Middle East, Thailand, Indonesia, Korea, China, Japan and New Zealand.

About 15% of Aquamatics' business is overseas. Recent promotions in many of the countries noted above have been very well received and very encouraging. The export market has substantial growth potential and may eventually dominate the business.

The Aquabrite System is also used extensively for commercial applications in Australia and Overseas. Here are just a few examples in Australia that illustrate the diversity of use of the systems from pools, to spas (including a ginseng herbal spa), to fountains, cascades and other water features.

- Tadpoles Swim School
- Newmarket Pool
- North Parramatta Swim School
- Trinity Links Resort
- Crest Hotel – ginseng herbal spa
- Quay Apartments – pool and spa
- Warringah Mall – water feature
- Sheraton Towers – water feature
- AMP Centre Circular Quay

LETTER FROM NRA OF 29 JULY 2002
SUBJECT ZYDOX (FC4)

Dear Mr Freedman

I refer to your fax of 22 July 2002 in regard to Zydox (FC4)

Strictly speaking chlorine dioxide products come under the definition of an agricultural chemical product when used for bactericidal, fungicidal, viricidal and sanitizing purposes.

However, as you are probably aware, it is possible to generate chlorine dioxide from precursors such as sodium chlorite and hydrochloric acid using equipment specifically installed for this purpose. The NRA cannot register equipment and does not believe it would be appropriate to register the commodity chemicals used as precursors. This system is therefore not regulated by NRA.

In the case of the "stabilised" chlorine dioxide products such as Zydox (FC4), they also require an activating agent to produce chlorine dioxide. Whilst they have been labelled and marketed more specifically for purposes that constitute an agricultural chemical, in order to place them on an equal footing with the equipment-based system, we have not required registration. We would of course consider registration should any company wish to do so – and these types of products have been registered in the past.

We will review the situation when legislative amendments are passed that allow for other types of "registration" – such as "listing" – for low regulatory impact products. It is hoped that this will occur later this year.

I trust this clarifies the situation for you.

Regards

Pat Robinson
Senior Product Evaluator – Fungicides

LETTER FROM APVMA OF 19 AUGUST 2004
SUBJECT ZYDOX (FC4) – APVMA NEW GUIDELINES

Dear Lionel

The new guideline issued on 28 July 2004 is intended to provide information on data requirements to register new pool and spa sanitizers.

It does not change the requirements for currently registered products or for those that currently do not require registration.

Regards

Colin Byrnes
Manager Fungicides
Pesticides Program