On behalf of the members of Queenslanders Against Water Fluoridation Inc, I wish to place a submission on APVMA’s proposed approval for Profume to be used to fumigate foods; structures associated with foods and non-food uses.

We request that Profume not be allowed to be used on foods, either deliberately or incidentally and that if approved for use in non-food applications that some conditions be placed on the approval to make it safer for workers and bystanders. We feel that APVMA has been given a window of opportunity to prevent harm to people by not allowing the approval for use on foods. Should APVMA proceed to allow the use of Profume on foods we must consider that APVMA is putting the interests of business above the interests of human health.

This is not a frivolous submission, it has been placed with great concern for the implications that approval for use on food will have on human health and we hope that due consideration will be given to the many issues that we have raised.

Fumigation of foods with Fluoride leaving very high levels of Fluoride residues in foods has the potential to adversely impact on human health

APVMA does not seem to be showing sufficient regard for effects on human health by it’s decision to allow foods (all whole cereal grains, all dried fruits and all tree nuts and peanuts) to be allowed to be fumigated with Sulfuryl Fluoride which will result in very high levels of inorganic Fluoride ion residues and smaller amounts of Sulfuryl Fluoride residues.

Fluoride is the major residue in foods fumigated with Sulfuryl Fluoride; one molecule of Sulfuryl Fluoride giving rise to two Fluoride ions in food after Sulfuryl Fluoride reacts with
protein in foods. Fluoride is the active toxic agent of Sulfuryl Fluoride and the toxicological endpoint of concern, but despite this, APVMA is supporting very high allowable Maximum Residues of Fluorides in foods and also has decided not to declare Fluoride as a “defined residue” for monitoring or compliance purposes. APVMA’s decision is that Fluoride will only to be a residue for dietary monitoring but no study has been done on the estimated food intake of Fluoride from fumigated foods and none is likely to be completed before approval given to use Profume on foods and beginning use of foods.

The APVMA Public Release Summary states, “inorganic Fluoride is naturally occurring and is present in the environment, it is not suitable for the purposes of monitoring for compliance”. This is a pathetic excuse for justification for not making Fluoride a defined compliance residue, when it is also stated in the APVMA PRS “research investigating the mode of action of poisoning termites using Sulfuryl Fluoride concluded that disturbances in intermediary metabolism by inorganic Fluoride were the main toxic mechanism”.

The APVMA PRS additionally states that there is no potential for Sulfuryl Fluoride to accumulate (as shown in a study on rats) as it gets rapidly hydrolysed to Fluoride. It is well known however that ingested Fluoride will accumulate in human and animal bodies, but this aspect of increased Fluoride consumption from fumigated foods appears to have been disregarded.

As an example of poor judgment APVMA has shown by not defining Fluoride as a “defined residue” compare if it was Agent Orange with a residue of Dioxin instead of Sulfuryl Fluoride with residue of Fluoride as an example.

APVMA’s position in allowing very high Fluoride residues, by declaring that Fluoride will not be a “defined residue” for monitoring or compliance purposes is unethical and very poor science.

As just an example of what a poor position this is, if Agent Orange were to be used to fumigate dried fruit and it reacted with proteins in the dried fruit leaving high levels of Dioxin then using the APVMA position an allowable level of Agent Orange in the dried fruit would be 0.07mg/ kg and the allowable level for Dioxin would be 5mg/kg or 71 times higher, but no-one would have to bother measuring the Dioxin levels for monitoring or compliance purposes because Dioxins can occur naturally and exist in the environment. This would be despite worldwide recognition that Dioxins are very dangerous chemicals.

If the level of Dioxin should actually be a lot higher than the 5mg/kg level allowed, then that could still be acceptable because Dioxin is not a “defined” residue so should have no legal standing and no company or Government agency would need to be prosecuted or reprimanded. With no legal standing, there would probably be no legal liability either.
APVMA has allowed very high Maximum Residue Limits for Fluoride and then says that Fluoride will not be considered as a residue for monitoring and compliance; this is not only irresponsible it is unjustified

FSANZ online 2006 "Fluoride in foods" shows most foods presently contain very little Fluoride (unless prepared with fluoridated water). Most tree nuts and peanuts do not contain measurable Fluoride levels but when fumigated, will be allowed to contain 30mg/kg (equivalent to 30 ppm; water fluoridated at 1ppm). With very little Fluoride being in most foods at present (unless prepared with fluoridated water), it is not responsible of APVMA to suggest that Fluoride occurs in the environment and to use this a justification to dismiss Fluoride as a residue to be used for compliance purposes.

FSANZ online 2006 data also shows dried apricots, fresh grapes and apples either do not contain Fluoride, or very little Fluoride, yet dried fruits after fumigation would be allowed to contain 5 ppm (5 times more than fluoridated water).

No residue limits have even been set by APVMA for fumigated Hay intended for animal feed or for fumigated pet foods or seeds intended for propagation. The US EPA has set Fluoride residues of MRLs of approximately 120 ppm for many animal foods. The US level was probably set to reflect the actual levels found in fumigated animal food. It would be expected that levels of fumigated animal foods in Australia could also contain Fluoride at this high level, although with APVMA not setting any MRLs any level of Fluoride in animal food could be permissible with no mandatory monitoring of a non-existent MRL required. Animal foods could be repeatedly fumigated with ever increasing levels of Fluoride residue.

Currently APVMA is not allowing Sulfuryl Fluoride to be used on "processed foods" such as flour. Flour has a much greater surface area compared to its volume than the whole wheat grains that the flour is made from, thus if flour is fumigated it absorbs a lot more Sulfuryl Fluoride resulting in very high levels of fluoride ion.

Although APVMA does not propose letting flour and other processed foods be fumigated at this time, APVMA has put forward recommended MRLs of 120 ppm for fumigated wheat germ and a MRL of 75 ppm for fumigated maize flour if processed foods fumigation allowed at a future date. That APVMA has already considered MRLs for some processed foods would indicate that processed foods may be allowed to be fumigated in a second stage application, which once it is no longer a "first time food use" in Australia may be easier to obtain.

The US EPA has approved Fluoride MRLs of 125 ppm in flour and a massive 900 ppm in dried eggs (common fluoride toothpaste contains 1000 ppm Fluoride). As the APVMA is allowing MRLs for dried fruits, whole cereal grains and nuts that are similar to what the EPA has allowed in the US if, Profume use in Australia is extended to processed foods at a later date, it is possible that processed foods in Australia will also allowed very high MRLs similar to those in the US.
Since 1997 the FDA has required that all Fluoride toothpastes contain the warning that children under 6yrs only use a pea sized amount of toothpaste and if more than if than is used for brushing is swallowed that a Professional or Poison Control Centre be contacted immediately. Considering average American toothpaste contains 1000ppm Fluoride ion and APVMA is allowing a MRL of 30 ppm Fluoride in peanuts (and all tree nuts) that equates to consumption of approximately 33 peanuts (peanut being approx pea sized) being a risk of Fluoride over-consumption to a child under 6 years.

The proposed approval for use does not preclude multiple fumigations, which could easily happen with extended storage periods but no additional MRLs were set for multiple fumigation, however there would be little monitoring and higher residue levels than the recommended levels may occur and may not be detected.

There is a dearth of data provided on toxicity of fluoride by the oral route, the only semi-relevant study is an unpublished Anonymous study from 1959 with rats consuming fumigated foods (this study described by the applicant as sketchy and also was prior Good Laboratory Practice) Another study was using ingested corn oil that had had Sulfuryl Fluoride bubbled through. Comment on this study was that it was difficult to interpret. Almost all studies on Sulfuryl Fluoride are animal inhalation studies and the Australian Office of Chemical Health Safety Health Risk Assessment says that the absence of suitable studies with oral exposure (as in foods) is the main deficiency.

No Acceptable Daily Intake (ADI) and the Acute Reference Dose (ArfD) have been provided by APVMA for Fluoride intake, only Sulfuryl Fluoride but can be calculated from APVMA data

- Neither of the only two oral toxicology studies submitted by the applicant Dow were used to determine oral toxicology instead the Acceptable Daily Intake and Acute Reference Intake have each been determined only on an inhalation studies and then only for Sulfuryl Fluoride.

- It would be more legitimate and relevant for Oral toxicology determinations to be made from actual oral intake studies, not inferred from inhalation studies

- APVMA has decided that their ADI for Sulfuryl Fluoride is 0.01 mg/kg body weight (based on 24 month rat study) and the Acute Reference dose for Sulfuryl Fluoride to be 0.3 mg/kg body weight per day. As no ADI or ArfD has been supplied for Fluoride ion (which is the actual toxic agent of concern) calculations can be made using the relative atomic mass of Fluoride compared to the Molecular weight of Sulfuryl Fluoride and the equation where one molecule of Sulfuryl Fluoride gives rise to two Fluoride ions when reacting with protein in food.

- An ADI and ArfD for Fluoride ion calculated using the provided Sulfuryl Fluoride values by APVMA would mean a calculated ADI for Fluoride ion of 0.0037 mg/kg/body weight per day and an Arf D of 0.1117 mg/kg body weight per day. A 20 kg child at this rate should not consume more than 0.07 mg Fluoride a day and a 60 kg adult no more than 0.22 mg Fluoride a day. Consumption of just 100gram of peanuts if it contains Fluoride at 30ppm.
the maximum level allowable, would constitute 3mg of Fluoride, which is well over the calculated Fluoride ADI based on the APVMA recommended ADI for Sulfuryl Fluoride.

**Trial measured residue levels in foods inconsistent with MRLs**

- Information provided on residue trials on Australian wheat is that Fluoride ion residues ranged from less than 0.5 ppm to 2.1 ppm. If this is accurate and a true representation why has an Australian MRL of 7ppm been recommended for wheat? The mean of the Fluoride residue ranges in wheat was reported as being 0.89 ppm. It is believed that this mean figure of only 0.89 ppm would be used to calculate chronic dietary estimates for Fluoride by FSANZ when APVMA will actually be allowing 7.0 ppm for wheat (the wheat germ made from fumigated wheat can contain 10.0 ppm). For a true measure of risk the MRL of 7.0 ppm should be used as the value that APVMA supplies to FSANZ for Fluoride intake dietary estimates if that is what is being allowed, particularly in view that multiple fumigations are allowable on all foods.

- **European and US trials** found Fluoride residues in wheat from 1.2 to 14.3 ppm or up to 7 times higher than that seen in Australian trials. Why the big disparity? Is European wheat and US wheat that different to Australian wheat, or was a lower concentration of Sulfuryl Fluoride used in Australia or a shorter fumigation time actually used that would explain the difference?

- The Executive Summary of APVMA’s Residues Evaluation Report says that the residue trial on Australian wheat was non–GLP or not “Good Laboratory Practice”. Why are these results even being used if the trial is considered to be dodgy? The trials should be redone with the best Laboratory practice available.

- The Residue Report Executive Summary also claimed the range of residues in wheat were within the range of concentrations found in overseas trials. This claim is clearly misleading when the overseas trials found Fluoride residues in wheat up 14.3 mg/kg where Australian wheat was only up to 2.1mg/kg. This is quite a disparity. Levels of UK Organic wheat post fumigation showed levels of 9 to 12 mg, being organically grown, the Fluoride residue must result only from the fumigation.

- Was the Australian wheat used in the trial early harvested wheat, thus less weathered and with a more intact outer coating less penetrable by the Sulfuryl Fluoride gas? It is an agricultural practice to harvest wheat early to diminish pest attack. Additionally wheat can be cleaned of fines or broken wheat. Would have specially cleaned wheat have been used that could explain the discrepant lower results in the Australian trial? If so, these results would not be relevant to later general practice.

- Fluoride residues in fumigated dried fruits ranged from < (less than) 1.4 to 3.1 ppm. It is not understood why the results are presented as “less than” 1.4 ppm when measurements in wheat are shown as ranging from 0.5 ppm. Does this mean the results are not very accurate? Additionally a mean is given of <2.2 mg/kg. It is not known how a mean can possibly be worked out with values just given as “less than” values. It would appear that the mean of “less than” 2.2 mg/kg would be used for dietary Fluoride estimates when APVMA will actually be allowing residue levels of 5.0 mg/kg.
• The residue evaluation report lists a recommended MRL of 5mg/kg on the Commodity group listed as Dried fruit listed as raisins, figs, dates and dried plums. Sultanas are a popular dried fruit and would be much more commonly consumed either directly or in other foods (e.g. fruit cakes, fruit scones, biscuits) than raisins, figs, dates or prunes. Sultanas are packaged as individual serving portions and are popular with children for school lunches. Being a smaller size than raisins and thus having a higher surface area to volume it could be expected to have higher Fluoride residues than raisins and other even larger dried fruits. Why are there no Fluoride residue results provided for sultanas?

• Fluoride residues in nuts (no values given for peanuts and the type of tree nuts not identified by their result) are reported to be from 2.3 to 25.8 mg/kg with a mean rank of 8.79 mg/kg. Once again it is probable than only the mean of 8.79 mg/kg will be used for future Fluoride dietary estimations when APVMA will actually allow residues of 30 mg/kg in tree nuts and peanuts. For the sake of a safety factor for consumers the true possible maximum residue of 30mg/kg that will be allowed should be used as the Fluoride content value of nuts for dietary estimates, not the much lower mean value from trials (the results of which were probably supplied by DOW)

Harm to consumers from increased Fluoride consumption.

• Fluoride is not a nutrient; is has never been proved necessary for life, good health or good teeth. WHO 2004 Fluoride in Drinking Water “for humans essentiality has not been demonstrated unequivocally, no data indicating the minimum nutrition requirements are available”

• Despite there being no evidence that Fluoride is a necessary nutrient, the NHMRC classed Fluoride as a “NUTRIENT” only because of a belief that Fluoride reduces decay. There are now many children’s dental surveys that show the same low levels of tooth decay in areas without water fluoridation as in areas with water fluoridation. Additional fluoride consumed via dietary means would not be justified on the grounds that extra Fluoride is necessary for life or desirable for health.

• The NHMRC has set recommended upper limits of intake for their self declared “nutrient” Fluoride of 10mg fluoride / day for adults and 1.3 to 2.2 mg Fluoride a day for children aged 1 to 8 years old. A child drinking 2 litres of water a day (water fluoridated at 1mg/L) would already be getting 2mg a day and this would be before figuring in any fluoride ingested from any sources such as from swallowed toothpaste, or dental treatments or fluoridated antibiotics, air pollution etc.

• The NHMRC set the values of 10 mg of Fluoride a day intake a day for adults and 2mg a day for children as being acceptable upper intake levels BEFORE the publication of the US National Research Council Report 2006 (Fluoride in Drinking Water). In view of the findings of the 2006 NRC report the acceptable Fluoride intake levels that NHMRC are recommending should be lowered markedly.
The NHMRC is currently claiming that the 2006 NRC report does not relate to Australia as in America Fluoride is allowed in drinking water supplies up to a Maximum Contaminant Level of 4.0 ppm. NHMRC claims that the NRC report is not relevant to Australia as it primarily deals with the health effects of fluoride in the range of 2-4mg/L where fluoridation in Australia is in the range of 0.6-1mg/L. The 2006 NRC report HOWEVER looked at the toxicity of Fluoride in general and determined the allowable Maximum Contaminant level must be lowered, but as yet still not set a new level. The NRC report did not distinguish between artificial water fluoridation, or naturally contaminated.

Furthermore, the NRC 2006 report did not distinguish between various Fluoride concentrations in water; it looked at the toxicity of Fluoride and thus is very relevant to the proposal of ingestion of increased Fluoride from foods. WHO 2004 “Fluoride in Drinking Water; Background Document for development of WHO guidelines for Drinking Water” states "In the USA, 0.2% of the population is exposed to more than 2.mg/litre (US EPA, 1985a)". The 2006 NRC was not just about the 0.2% of the population that are exposed to drinking water with more than 2ppm Fluoride, it would be deceptive of the NHMRC to claim this. The NHMRC recommended acceptable levels of Fluoride intake are too high, they are not protective of human health, and the NHMRC must lower their recommended acceptable intake levels.

- Acute toxicity from Fluoride has been demonstrated in some people at doses as low a 0.3 mg/kg (Gessner BD, Beller M, Middaugh JP, Whitford GM 1994. Acute fluoride poisoning from a public water system. New England Journal of Medicine 330:95-9

- Reports of acute toxicity with Fluoride doses at low as 0.1 mg/kg (Akiniwa, Kenji 1997 Re-examination of acute toxicity of fluoride. Fluoride 30(2) 89-104)

- Increased rates of hip fractures and other bone fractures linked to fluoride consumption have been reported several times. Clinical trials on Osteoporotic patients using doses of Fluoride of 21mg to 25 mg a day showed increased rate of bone fracture (particularly hip) with a time frame of less than a year. Clinical trials with lesser dosages over longer time frames, if done, would be expected to show the same result given several reports linking water fluoridation to increases in hip and other bone fractures.

- JMPR 2005 (Joint Meeting Pesticides Residues – joint WHO and FAO) states that effects on the skeleton, such as inhibition of bone mineralization and formation, delayed fracture healing and reductions in bone volume and collagen synthesis were observed in variety of studies in which rats received Fluoride orally for periods of 3 to 5 weeks

- A double blind trial in the Netherlands had found at least 1% of people consuming Fluoride in drinking water experienced allergic symptoms such as skin rashes, migraines and abdominal pain. Extra Fluoride consumption from foods will place susceptible people at more risk of harm of allergic reactions.

- The Queensland Government with the Australian Dental Association’s assistance is currently distributing to the public a “Fluoride Script” which advises the use of Fluoridated toothpaste for children as young as 6 months who live in areas without water fluoridation.
The Queensland Government also advises that children spit but do rinse the toothpaste away, thus effectively advising it is not harmful for children to swallow toothpaste. This advice from the Queensland Government would mean that children would be ingesting an unknown, but possibly considerable amount of Fluoride in the swallowed toothpaste. It is unlikely that the amount of Fluoride that could be ingested from toothpaste would be accounted for in a Fluoride dietary intake estimate.

- When water fluoridation began in Australia the Fluoride concentration was set, hoping that dental fluorosis would not exceed 10% of the population to try and minimise harm. At one stage dental fluorosis rates in Australia exceeded 50% and measures were put in place to try and reduce the amount of Fluoride (reducing the Fluoride concentration in water, ensuring that toothpaste manufacturers made a special toothpaste for children with a lower concentration of Fluoride and making manufactures and importers of infant formula lower fluoride concentration in their products (or display a warning on the packaging). These measures appear to have had some effect, in reducing the level of dental fluorosis somewhat, but that would be undone and children put at increased risk of developing dental fluorosis if they were to start ingesting Fluoride with common foods. Dental fluorosis in permanent teeth is permanent for life.

- Harold Hodge was the first Scientist in reviews of Fluoride toxicity to report on Fluoride doses that would cause crippling fluorosis. In 1979 he revised his estimate stating Fluoride doses as low as 10mg/day could cause crippling skeletal fluorosis.

- WHO 2004 “Fluoride in Drinking Water” based on fluoride intake studies from China and India states

  1) for a total Fluoride intake of 14mg/day there is clear excess risk of skeletal adverse effects

  2) there is suggestive evidence of an increased risk of effects on the skeleton at total Fluoride intakes above about 6mg/day

In view of the above WHO statements an upper level of no more than 6mg a day of Fluoride should be recommended for adults and proportionally less for children.

- The National Research Council (NRC) 2006 report Fluoride in Drinking Water determined many adverse health effects were linked to Fluoride and decided that the previously held Maximum Allowable Contaminant Level of Fluoride in drinking water of 4ppm was not protective against Skeletal Fluorosis and that this maximum level must be lowered. Assuming an average adult drinks only 2 litres of water a day, this means that risk of adverse health effects occurs with consumption of 8 mg of Fluoride daily.

- Adults who are big tea drinkers can already be consuming amounts of fluoride from their favourite beverage, as tea is a peculiar plant that takes up Fluoride from soil. Adults who are outdoor workers and who drink lots of water could already be breaching intake levels of 10 mg /day just from fluoridated water and tea. Tea as consumed can contain up to 5 ppm. Four 250 ml cups of tea containing 5ppm Fluoride a day could account for an intake of 5mg Fluoride a day just from tea consumption alone.
• Above average consumption of specific food groups (that are approved for fumigation) by population sub-groups (e.g. Vegetarians, Vegans, Seventh Day Adventists) potentially consuming much higher quantities of nuts, dried fruits and wheat and wheat products) would mean greater ingestion rates of Fluoride.

• The US Food and Drug Authority has estimated a four-fold difference in consumption between an average consumer (at 50% percentile) and the 95% percentile consumer for any given food group. Vegans could easily be over the 95% percentile in consumption of tree nuts and peanuts and thus more at risk of foods with high Fluoride residues.

• Population sub-groups who consume more water than average (outdoor workers, athletes, Diabetes insipidus sufferers) or those who have impaired kidney function (and thus unable to excrete fluoride as much) are already or effectively ingesting and retaining more Fluoride than the average person and would be more at risk from consuming extra Fluoride in the foods that they consume. It has been reported that Australian outdoor workers can easily drink 10 litres of water a day.

• The NHMRC in 1991 and 1999 said that health and safety studies on water fluoridation should be done and that total fluoride intake studies should be done and bone Fluoride estimations should be done. These studies have not been done but FSANZ is slated to do Fluoride intake modeling studies next year, but this would almost certainly be after Profume is approved for use. Total Australian Food Studies when performed by FSANZ do not look at pesticide residues every time; if a study is done early 2008 (before Profume fumigation of foods is widespread) it may be another 5 years before pesticide residue consumption is re-visited.

• FSANZ has already done a DIAMOND (Diamond Modeling Of Nutritional Data) computer modeling of Sulfuryl Fluoride to estimate the chronic (long term) estimated dietary exposure of the general population, BUT THIS DATA WAS NOT RELEASED TO THE PUBLIC citing "COMMERCIAL CONFIDENCE". It is not known if a model of Fluoride exposure resulting from Sulfuryl Fluoride use has been done, but one probably has not been done. How can the estimated amount of Sulfuryl Fluoride that the public would consume from foods possibly be deemed as “Commercial Confidence”? The public should have a right to know what and how much they are consuming of potentially hazardous substances.

• When FSANX does do a Food Fluoride intake study, it will probably not take into consideration extra Fluoride exposures from Fluoridated toothpaste/mouthwash ingestion or from Fluoride dental treatments or exposure from fluoridated drugs and thus will be an underestimation of true Fluoride exposure. Additionally FSANZ will probably just use mean fluoride residue results that have been provided rather than the much higher allowable MRL values to calculate maximum possible exposure.

• Considering that Inorganic Fluoride is the major and cumulative residual of Sulfuryl Fluoride, APVMA should had considered the National Research Council (US) report from March 2006 that reported on many adverse health effects linked to Fluoride in drinking water (regardless from artificial fluoridation or from natural contamination up to 4.0 ppm in a very small percentage of water supplies) This recent report does not appear to have been considered, there seems to be no mention of it’s consideration in the Technical reports supplied by APVMA.
• The 2006 NRC report (page 218) states “In humans, effects on thyroid function were associated with fluoride exposures of 0.05 to 0.13 mg/kg/day when iodine intake was adequate and 0.01 to 0.03 mg/kg/day when iodine intake was inadequate. Thus a 60 kg iodine deficient adult has the potential to have its Thyroid function impaired from ingesting as little as 0.6 to 1.8 mg of Fluoride a day. A 20 kg iodine deficient child has the potential for impairment of Thyroid function from ingestion of as little as 0.2 to 0.6 mg Fluoride a day.

• NRC 2006 - from the 1930s to the 1970s Doctors used doses of Fluoride ion as low as 2mg Fluoride a day (range 2 to 10 mg) to lower thyroid activity in patients with Hyperthyroidism. People with normal Thyroid activity could be put at risk of having their Thyroid activity lowered by doses as low as 2 mg Fluoride a day.

• FSANZ Proposal P230 August 2006 is consideration of mandatory fortification with Iodine in recognition of mild Iodine Deficiency states in at least NSW and Victorian children and borderline deficiency in South Australian school -children with Tasmanian children and NT children not studied (Australian National Iodine Nutrition Study 2003-2004). It has been reported that researchers say the mental and physical development of almost half of Australia’s primary school children is at risk from lack of iodine. Adults and children who are iodine deficient will be put at risk from increased consumption of Fluoride from fumigated foods.

• The Office of Chemical Safety relied heavily on the 2005Joint Meeting Pesticides Residues (joint WHO/FAO) JMPR report on Sulfuryl Fluoride. JMPR 2005 states that “the notifier did not submit any studies on metabolites” and “the primary residue in commodities treated with Sulfuryl Fluoride is the Fluoride ion”. Given the lack of studies submitted on metabolites (Fluoride) the American approval for use of Sulfuryl Fluoride on foods appears not to have properly considered inorganic Fluoride as the major residue of Sulfuryl Fluoride.

• JMPR 2005 notes that NO epidemiology studies on health effects of workers at the Sulfuryl Fluoride production facility have been carried out.

• Fluoride crosses the placenta and is transferred from Mother to foetus. Maternal consumption of larger quantities of foods that have been fumigated with Fluoride (such as nuts at 30 ppm Fluoride) will mean that foetuses will be exposed to higher Fluoride exposures.

• Breast Milk of mothers in non- fluoridated water areas has an average of 0.004 ppm it appears that Nature does not intend infants to ingest Fluoride. It is not advisable or acceptable to exposure infants to increased levels of Fluoride as would occur with consumption of rice cereals, and teething rusks made from fumigated wheat and rice.

• APVMA should have considered the Elise Bassin paper in "Cancer Causes Control " 2006 that links Osteosarcoma to fluoride in drinking water (a link previously reported in other human and animal studies) This study found a five fold increased risk of boys developing Osteosarcoma linked to water fluoridation.

• There were apparently no cancer studies required to register Sulfuryl Fluoride as a pesticide in the US.

• APVMA should have considered the American Dental Association and the Centre for Disease Control and Prevention advisories from late 2006 that infants under 12 months of age not consume Fluoride (mainly as in fluoridated water) as part of APVMA's approval
decision process. The advisories resulted from the NRC report with recognition that infants under 12 months of age are at risk of dental fluorosis from Fluoride overdose. APVMA does not appear to have acknowledged this recent development.

- APVMA should have considered the Lancet’s recognition (2006) of Fluoride as an emerging Neurotoxin. There are now a number of studies from China linking Fluoride in drinking water to reductions in IQ. Increased Fluoride ingestion in foods could result in a measure of neurological harm.

- APVMA admits that that there may be a transfer of Fluoride ion into milk, meat and other commodities as a result of fumigated grain being fed to livestock, but NO information has been provided. Grain can constitute up to nearly 100% of livestock animal and poultry diet. Grain fed Animals being fed with Fumigated / fluoridated grain would ingest considerable quantities of Fluoride and may impair the health of animals.

Fluoride accumulates mainly in bone in humans and animals with approximately 99% being stored in bone. FSANZ has already noted that Fluoride residues are of concern in products such as mechanically deboned chicken e.g. chicken nuggets processed chicken products. Bone fragments readily enter the flesh with mechanical deboning and processing and increase the Fluoride level by virtue of the Fluoride that is stored in bones. Mechanically deboned meat would also be a concern. With the rapid increase in sales of poultry products in recent years and if poultry were fed on Fluoride fumigated foods, Fluoride content in the bones of Poultry would increase leading to an increase in human ingestion of Fluoride from poultry consumption.

Potential to harm workers and bystanders

- There is NO KNOWN ANTIDOTE to over-exposure to Sulfuryl Fluoride (DOW MSDS).

- Sulfuryl Fluoride is scheduled as an S6 poison, but the Fluoride chemical mostly used for water fluoridation in Australia is classed as an S7 poison. There is reasonable argument that Sulfuryl Fluoride should be scheduled as S7. The Office of Chemical Safety scheduled as S6 on the grounds of moderate acute toxicity (believed based on one inhalation study and on the additional proviso that APVMA intended to classify it as “A Restricted Chemical” Product. If this were not a proviso it is likely that Sulfuryl Fluoride would have been classed as an S7 poison with more stringent restrictions and not a S6 for general use. Scheduling as S7 would make it harder for non-professional use and access. S7 is the appropriate schedule for this dangerous poison. Even trained operators do not necessarily follow all required safety precautions; the use of a warning agent would give better safety for all concerned.

- Sulfuryl Fluoride is colourless and odourless and also has no warning properties such as eye irritation, thus the Australian Office of Chemical Safety (OCS) Assessment advice and recommendation to APVMA that a suitable stenching agent (a warning gas such as Chloropicrin, a tear gas) MUST be used with Sulfuryl Fluoride, yet APVMA’s proposed label for use shows instead that it "MAY" be used. There is NO compulsion to use a safety
warning agent according to APVMA’s approval requirements. The use of a warning agent must be mandated.

- Re-entry into treated structures is not to be allowed (on the Australian label) until concentration is confirmed to be less than 3ppm, however aerator workers may be exposed to more than 3 ppm without being aware, thus a warning agent such as Chloropicrin should be mandated for the protection of ordinary workers and qualified fumigators.

- The California Profume specimen label shows that if the Sulfuryl Fluoride level remaining in treated structures is more than 1ppm that an approved positive pressure self contained breathing apparatus be used, yet in Australia 3 ppm, 3 times higher than the Californian standard is purported as being safe for re-entry.

- Sulfuryl Fluoride is believed to be 3.2 times heavier than air. After fumigation, the gas is released, often blown out with fans and potentially a risk to humans and animals in the nearby vicinity. Being heavier than air, the gas could flow to lower areas. In small Australian country towns silos are often in the heart of populated areas, thus a considerable number of bystanders could be affected in case of accidents or misuse and even just with normal ventilation of fumigated structures.

- The Department of the Environment and Heritage recognizes from reliable specific animal and vegetation studies that Sulfuryl Fluoride is highly toxic to Zebra fish, Daphnia magna and green algae, yet despite this, the position of APVMA is that there is no risk to animals or the environment. The product label will state that Profume is a highly toxic gas and that it is toxic to fish and wildlife, thus there is a risk.

- In the US since 1993 there have been 13 human deaths resulting from entry into fumigated premises and 335 reports of adverse health effects as self reported by DOW to the EPA. No data has been provided on how many deaths there have been worldwide in the last 40 years it has been used as a fumigant for termites. There is no American National Registry or International Registry for deaths or adverse effects from Sulfuryl Fluoride. A reliable estimate of mortality and morbidity data for Sulfuryl Fluoride is thus unknown.

- In 1986 an elderly couple in the US died from Sulfuryl Fluoride poisoning after their home was fumigated. They were allowed to re-enter their home by the licensed fumigators the day after fumigation, but they suffered ill effects and both died, one 2 days later and the other 7 days later. At the time of the first death Fluoride poisoning was not even suspected. The fumigators apparently did not measure the level of Sulfuryl Fluoride in the home before allowing re-entry. This neglect could happen in any situation. The use of a warning agent may have given the fumigators and the couple some warning of the residual gas.

- Two Neurological epidemiology studies of Sulfuryl Fluoride fumigators have been published, with authors of one study concluding that there was a pattern of effects that merited further investigation and the other study found significant effects with Sulfuryl Fluoride use, when looking at nerve conduction tests, dexterity, pattern recognition and odour recognition (as cited in the Office of Chemical Safety Health Risk Assessment Technical Report). No follow up studies appear to have been done.
The Birth Defect Prevention Act (California Code of Regulations) mandates the listing of Sulfuryl Fluoride. There must be concern then that Sulfuryl Fluoride may cause birth defects.

In the US there has been at least one documented fire in a building under fumigation. Fires in fumigated structures would be a great risk to workers and bystanders. The use of a warning agent could be helpful in a fire situation to alert to the presence of Sulfuryl Fluoride.

Potential problems with trade in food commodities

- Countries that do not allow Sulfuryl Fluoride residues, or have lower allowable MRLs for Fluoride or Sulfuryl Fluoride could be a problem for trade in fumigated food commodities to countries other than the USA.

- If Australian foods are also fumigated with Sulfuryl Fluoride it will be easier for American exporters to get fumigated (fluoridated) foods into Australia. Australian consumption of Sulfuryl Fluoride fumigated USA produce may already be occurring.

- No germination studies appear to have been done for fumigated seeds, it is possible that germination rates could be lowered resulting in losses and increased costs to purchases and a loss of reputation to Australia as a reliable sowing seed exporter.

- APVMA has said that it would be up to DOW to alert all stakeholders of potential risk with residues and trade. This seems to a rather gallant attitude of APVMA to just allow DOW to inform all stakeholders of risks!

- Organic produce will not be able to be stored in the same warehouses / food storage facilities if these facilities will be fumigated.

Potential harm to the Environment

- Sulfuryl Fluoride is being promoted as a more "Greenhouse friendly" replacement for Methyl Bromide, yet no Carbon Dioxide equivalent comparison data for Sulfuryl Fluoride and Methyl Bromide is yet available from APVMA and apparently was not considered. Another Sulphur-Fluoride gas, Sulfur Hexafluoride, is now being recognized as potentially the worst Greenhouse Gas, being 23 thousand times more potent than Carbon Dioxide.

- The California Dept of Pesticide Regulation (CDPR) considers only limited information is available regarding any potential environmental breakdown products of Sulfuryl Fluoride and also that it has a long, or very long lifetime and should, therefore be considered as a Greenhouse Gas. There is no enough known about the potential for Sulfuryl Fluoride as a Greenhouse gas, thus there should not be a rush into using a dangerous substitute for Methyl Bromide.
Sulfuryl Fluoride is promulgated as a more friendly Greenhouse replacement for Methyl Bromide. Although Australian Government has refused to sign the Kyoto Agreement it is a signatory to the Montreal Protocol to restrict use of Methyl Bromide from 2005 to Critical uses only (where no feasible or economic alternative) and for Quarantine purposes. If sale and use of Methyl bromide have already been restricted since 2005 and since it is nearly 2008, there must already be alternatives for Methyl bromide already in use for most purposes. Methyl Bromide is believable allowed for Quarantine purposes until 2015. There is no need to rush into using a Methyl Bromide alternative; especially with it’s potential to harm human health.

Safer alternatives for Sulfuryl Fluoride and Methyl Bromide exist

- It is believed that Sulfuryl Fluoride would not be used as grain fumigant in West Australia due to the improved practices that WA agriculture already employ for “No Tolerance” grain. Some of the WA practices for grain are painting silos white (to reduce temperature), specially sealed Silos, use of low levels of Phosphine gas for longer time intervals and a very vigilant pest resistance-monitoring programme. Perhaps Eastern States should be more vigilant with their monitoring of pest resistance with employment of Western Australian practices.

- The CSIRO Stored Grain Research Laboratory has been investigating use of Carbonyl Sulfide and Ethanedinitrile as alternative fumigants for Methyl Bromide. These could be safer alternatives than Sulfuryl Fluoride.

- Liquid Nitrogen treatment can be used to treat pests and employment of Electogun to kill pests in the walls of storage facilities would be safer alternatives to Sulfuryl Fluoride.

Other issues

- Some of the deaths resulting from Vikane fumigation could possibly be attributed to Suicide. In Australian rural areas Suicide rates have risen with worsening drought and tough financial times. It is possible that premises under fumigation could provide a venue for Suicide. Employment of Chloropricin (a type of tear gas) would make this a possibility more difficult for would be suicides.

- At least one death is known of a licensed and supposedly experienced Vikane fumigator.

- Pets have been killed by Sulfuryl Fluoride fumigation (Vikane). Fumigators were fined for the deaths of pet cats.

- There is no mention of reclamation of Sulfuryl Fluoride, yet it is believed that reclamation of Methyl Bromide is presently occurring. Why is reclamation not being recommended by APVMA, especially for Quarantine purposes where it may be more feasible to use?

- It is believed that Silos and food warehouses would leak, existing structures may not have been purpose built for fumigation. If gas leaks out over the time frame, it would pose a risk to workers and bystanders and additionally may need to be “topped up” with
additional gas. This would pose extra risks to fumigators having to re-enter a fumigated building and later extra contamination of the environment. Why are there no recommendations for work to be done on buildings intended for repeated fumigations to prevent leaks?

**Sulfuryl Fluoride in other countries - foods must be removed prior to fumigation.**

- JMPR 2005 (Joint Meeting Pesticides Residues ...... joint FAO / WHO) states Sulfuryl Fluoride is approved for "food purposes" in the US, also UK, Germany and Italy, but in the UK, Germany and Italy, structures must be EMPTIED of food before fumigation. This would mean that there is almost no Fluoride or Sulfuryl Fluoride in similar foods in these countries.
  - In Canada (April 2006) Sulfuryl Fluoride received registration for use for EMPTY cereal grain mills, EMPTY associated storage facilities and EMPTY food processing plants.

**Hindrance and obstruction to the public getting information about Profume**

APVMA appears to have deliberately put obstacles in the public’s way when attempting to gain information about the use and implications of Profume as a fumigant on foods.

The Profume gazette notice on the APVMA website advised only 28 days from the date of the gazette notice for acceptance of submissions, this is a very limited time for the public to find out about it and respond.

The gazette notice gave very little information and no information at all about Fluoride residues and the very high allowable residues of Fluoride that APVMA was recommending.

Various requests for information were either ignored, delayed or denied by APVMA.

An email to the designated APVMA contact person a week before Profume’s gazettal asked if the product was due to be gazetted the following week and if so, requesting the PRS (Public Release Statement) as soon as it was published. This email was ignored.

When the gazettal notice was published there was no PRS available (PRS should have been completed BEFORE the product was even gazetted seeing gazette notice stated that public submissions would only be accepted for 28 days from the date of the gazette notice)
Request by phone revealed a delay in PRS availability.

There was no written response to advise when it was available and a second phone call 6 days post gazettal revealed it was now available (but PRS was not placed in the correct location, the actual PRS page, but under Industry)
The PRS advised that Full Technical Reports were available for purchase for $30. The reports were requested and paid for, but there was a delay in acknowledging this request was received and then a delay of a week before the reports were provided. The full Technical Report should have been prepared before the gazettal notice placed.

Information was requested of APVMA but a week after receipt there was not even an acknowledgement by APVMA and it was confirmed that APVMA had no intention of providing any information or answers until the date for submission acceptance passed (or too late for the requested information to be used in a submission)

Possible bias on behalf of APVMA towards Industry

One of the questions that had been requested of APVMA, but as yet unanswered, was as to the influence of the APVMA Advisory board into the approval of Profume.

This is of concern to us as we are aware that a new member of the APVMA Advisory board, who was also the Chair of the 2005 NHMRC Drinking Water Treatment Chemicals Working Party, had been heard on radio espousing the virtues of fluoride and making the claim that “dental fluorosis was only cosmetic” This attitude indicates a lack of concern with the well known toxic effects of Fluoride and may result in bias in favour of a company that will contaminate foods with Fluoride. This member is also believed to have associations with the mining industry and the disposal of mining’s hazardous waste.

Considering the fluoride compounds that are put into drinking water are waste products of Bauxite mining / Aluminium smelting and Phosphate rock mining / Superphosphate Fertilizer manufacture this member possibly has a “conflict of interest” and should stand down from the APVMA Advisory Board if dealing with Sulfuryl Fluoride approval.

Of concern too is recognition of the recent appointment of an Advisory Board Member, who is additionally also the Chair of Choice, a company which in March 2007 did a gushing and extremely biased article promoting water fluoridation. We believe that this member would not be impartial, considering the tone of the Choice article that she is associated with.

We request that both of the two members of the APVMA Advisory board who may have a conflict of interest, or who may not be able to make an impartial decision, step down and not have any input into the Sulfuryl Fluoride evaluation and registration process.

It appears that several other members of the APVMA Advisory Board come from the private Agricultural industry sector and may also tend to favour what will benefit the Agriculture industry above potential human health costs.

DOW’s application for Profume use was to kill insects and rodents, but APVMA made no further mention of rodents in it's documentation or in the product label. Perhaps this was done deliberately to advantage Profume approval appearing to make it appear less toxic? The Californian Profume specimen label showed clearly it was to be used to kill rodents.
Conclusions

Fluoride is well known to be a protoplasmic poison and enzyme inhibitor. Fluoride is not only the toxic agent of Sulfuryl Fluoride, acting by disrupting Glycolysis and the Citric Acid cycle metabolic pathways it is also the major residue in foods after fumigation with Sulfuryl Fluoride.

Ingested fluoride accumulates in the body with adults storing about 60% of that ingested. Children can accumulate 80% of the Fluoride that they ingest. Almost all of accumulated Fluoride accumulates in bones. Contaminating foods with fluoride will mean that people will now be ingesting much more Fluoride than ever before and will be accumulating much more fluoride in their bones.

In view of the all of the above comments and described shortcomings of the APVMA support for Profume’s use to fumigate foods it would extremely irresponsible for APVMA to give approval for this use.

Considering Fluoride is the toxic agent of Sulfuryl Fluoride and it's major residue in foods fumigated with Sulfuryl Fluoride and additionally Fluoride is cumulative in animal and human bodies the approval for use on foods should be denied on the following grounds;

• **APVMA cannot ignore Fluoride as a “defined residue” for monitoring and compliance purposes and use just Sulfuryl Fluoride as the defined residue.**

• Sulfuryl Fluoride is a gas, most residues of Sulfuryl Fluoride left in food could be expected to evaporate out of foods (especially if under warm conditions) and leave levels of the original Sulfuryl Fluoride much, much lower than Fluoride that has formed in foods and remains trapped in foods. There should be two MRLs for monitoring and compliance purposes for Sulfuryl Fluoride use, one for Sulfuryl Fluoride and one for Fluoride. It would extremely dishonest to just use Sulfuryl Fluoride as the residue of concern.

• **APVMA cannot allow very high levels of Fluoride residue in fumigated foods (up to 30 times higher than allowed in fluoridated water) when no Fluoride intake studies or modeling studies have been done. Fluoride levels in foods 30 times higher than fluoridated water concentrations must never be allowed.**

• **APVMA must get FSANZ to do food Fluoride intake modeling studies BEFORE it even considers Profume approval.**

• **AS APVMA is proposing very high Fluoride residues in foods these are the Fluoride levels that FSANZ should use for their estimates, not the much lower levels that APVMA says will occur in foods. If the MRLs set by APVMA are not used by FSANZ for the Fluoride intake estimates then APVMA must lower the MRLs to what FSANZ uses for their estimates.**

• Australian Water fluoridation schemes allow Fluoride levels in water only up an absolute maximum of 1.5 ppm (actually done at between 0.6 and 1.1 ppm). The Fluoride level of
water is strictly monitored and authorities would be in breach of Fluoridation Acts if levels of Fluoride in water surpass 1.5 ppm. Unlike water fluoridation, there will very little monitoring of Fluoride contents of foods and then it would be only up to State Health Authorities to monitor, offering very little protection to the consumer.

- Water fluoridation, widespread across Australia means that children are already consuming 2mg of Fluoride a day if they drink 2 litres of 1ppm fluoridated water a day or if they drink other beverages made with fluoridated water. The official guideline used is that children only drink 1.2 litres of fluid a day; this is patently incorrect considering Australia's hot climate. Documented increasing temperatures, attributed to Global Warming will see increase in consumption of fluids. **Water fluoridation and fluoridation of foods cannot co-exist.**

- FSANZ food Fluoride intake studies, when eventually done, will underestimate true Fluoride ingestion by not considering Fluoride exposure from sources other than food. The NHMRC should conduct full Fluoride exposure studies before use of Profume on foods is even considered and also special consideration made of the diets of consumers such as Vegetarians. **As Vegetarians and Vegans are the consumers who are most likely to consume more of foods such as nuts, it is their level of consumption which should be the benchmark.**

- Specific population sub groups such as Vegetarians will be subjected to more exposure to Fluoride by their food choices and discriminated against.

- People who have decreased kidney function (including diabetics and the elderly) are more susceptible to ingestion of Fluoride by virtue of their diminished capacity to excrete Fluoride, this means that more Fluoride accumulates in their bones and puts them at increased risk of skeletal fluorosis (especially the early stages with bone, joint and tendon pain mimicking Arthritis). A safety factor should be included to account for diminished Fluoride excretion capabilities.

- People who have Thyroid Disease or who are Iodine deficient are at increased risk from ingestion of Fluoride, they will be more at risk than the normal population form increased consumption of Fluoride. A safety factor should be employed to give some protection to those who are more susceptible.

- The Acceptable Daily Intake levels of Fluoride as recommended by NHMRC are not acceptable to be protective of human or animal health in view of documented health effects with Fluoride (NRC 2006). The acceptable Fluoride intake levels as recommended by NHMRC should be reduced markedly in view of the NRC 2006 findings.

- APVMA's policy with pet and animal foods appears to be “ANYTHING GOES” with MRLS not even suggested for these commodities. This is not good enough for pet or livestock owners. If Sulfuryl Fluoride were used to fumigate pet and animal foods, there must be MRLs for animal foods set prior to approval for Profume being given.

- Other counties allow Sulfuryl Fluoride to be used to fumigate structures associated with foods, BUT the structures must be emptied of foods first. Why isn't this also Australia's
minimum standard? Are Australian citizens to be used as guinea pigs? No foods should be fumigated with Sulfuryl Fluoride either deliberately or incidentally.

- Approval for use of structures (non-food uses or structures with all foods removed) should have mandated use of a warning agent to be protective of the health of workers and bystanders.

- The maximum re-entry level of Sulfuryl Fluoride should be 1ppm (as in California) not the recommended 3ppm, to be more protective of workers.

- APVMA should request that Profume is scheduled as S7 to ensure that it is a restricted product used only by specially trained personnel. If it is restricted product it must be placed in the restricted products schedule not placed in a lower class because it is just “intended” to be restricted. S7 includes chemicals which “may require special regulations restricting their availability, possession or use and which are too hazardous for domestic use or use by untrained persons”. Sulfuryl Fluoride thus fulfils the requirements of S7. It is irresponsible to place Profume in a lower Schedule especially if done to allow ease of Profume’s approval. S7 scheduling ensures it is restricted product, S6 does not. For the sake of public safety and OHS considerations APVMA must request a higher scheduling.

- The use of a warning agent such as Chloropicrin must be mandated with the use of Profume to help prevent accidental exposure resulting in harm or death.

FSANZ Application A599 3 Oct 2007 states that “MRLs serve to protect public health and safety by minimizing residues in foods consistent with the effective control of pests and diseases” additionally “dietary exposure assessments indicate that setting the MRLs as proposed does not present any public health and safety concerns”

APVMA has assisted the approval of Profume as a food fumigant by allowing very high acceptable levels of Fluoride residue and then saying that Fluoride will not be a defined residue for monitoring or for compliance purposes. APVMA’s position would be of great assistance to DOW getting approval for their product but is at complete odds with FSANZ’s statement that MRLs serve to protect public health.

Profume must not be given approval to be used on foods, to do so would be to the detriment of the health of Australians who would consume fumigated / fluoridated foods, the detriment of animals and their owners and the possible financial detriment of Australian trade.

Submitted by Merilyn Haines, on behalf of Queenslanders Against Water Fluoridation Inc Please advise if references are desired for any issue that has been raised.