

EUROPE'S FOOD SAFETY AUTHORITY SAYS IT'S OKAY TO PUT TOOTHPASTE TOXIN IN FOOD SUPPLEMENTS

EFSA: we're complaining about you again

For the uninitiated, EFSA—otherwise known as the European Food Safety Authority—is Europe's highest authority on food safety. The European institution lurks in the hills of Northern Italy, close to Parma. Generally, when EFSA says a foodstuff is safe, it goes on free sale through all—now 27—European Member States. Conversely, when EFSA says something is not safe, it gets banned or severely restricted.

So, let's now look at EFSA's opinion on sodium monofluorophosphate (SMP). This chemical is essentially a delivery system for fluoride, the reduced halogen that is widely used in oral hygiene products with the intention of reducing tooth decay. Fluorides are used for many other purposes, from dissolving glass, to the preparation of nuclear reactor fuels. Yet EFSA states in its Opinion:

“The present opinion deals only with the safety of sodium monofluorophosphate as a source of fluoride and the bioavailability of the fluoride from this source. The safety of fluoride itself in term of amounts that may be consumed, is outside the remit of this Panel.”

The scientific logic of EFSA avoiding from its remit (with no reasons given) the safety evaluation of “fluoride itself” beats us. In the interests of consumer safety, isn't this the whole point?

What is sodium monofluorophosphate?

SMP is the most common stuff added to toothpaste and other 'oral hygiene' products for the purposes of reducing tooth decay. Advocates of fluoride believe it helps re-mineralise teeth, making them more resistant to decay and helping to rebuild enamel damaged by acids produced by *Streptococcus mutans*, the main bacteria responsible for tooth decay. Fluoride also apparently interferes with the carbohydrate metabolism of these bugs, so reducing the amounts of damaging acids they produce. But, given that these acids are produced mainly when sugar (sucrose) is in the mouth, why not push the public a little harder to out sugar, rather than fluoridating kids and adults alike!

The bit the fluoride supporters don't like to admit is that fluoride also kills *Streptococcus* and other bugs in the mouth. After all, it's been used widely as a pest control agent, with insects and rats being amongst its targets. As you'll see later, we think it's important to understand that tooth decay is an official disease. What's more—at least among the pro-fluoride majority of the dental profession who are eager to get fluoride into as many 'hygiene' products as it can, it's also regarded as a transmissible disease.

There's actually a fair bit of scientific controversy as to just how well fluoride, especially when added to the drinking water supply, stops the rate at which our teeth rot. There are, for example, suggestions of some serious data manipulation in a number of the big studies carried out [1], but this is not the place for this particular discussion. Of course, some would say—as we do—cutting out sugar (sucrose) from your diet and brushing your teeth properly is probably a whole lot better than putting a poison in your mouth and either spitting it out or swallowing it.

The intrinsic toxicity of fluoride is the reason why toothpaste manufacturers often include a warning on the tube which says 'don't swallow'. It's toxic you see, very toxic. There is also quite a controversy as to whether repeated exposure to it might be linked to cancer.

Well surprise, surprise. Before you even get off the first page of EFSA's Opinion, dated 27th November 2008, you stumble across the following:

"... conclusions of comprehensive evaluations indicate that genotoxicity and carcinogenicity are not of concern for fluoride exposure in humans."

That's a little odd, when there's a fair old literature on cancer and mutation risks from fluoride. Not least of all is a large epidemiological study carried out by Japanese scientists on a very large US data set involving over 20 million Americans subjected to varying levels of fluoride in the water supply. They found that there was a positive association between fluoride concentration in two-thirds of the 36 different types of cancer that were recorded [2]. This is not the sort of data you could ignore, surely?

There's also a bunch of other things that fluoride has been implicated in, including increased risk of bone fractures, learning difficulties in children exposed while fetuses, other neurotoxic effects and possibly predisposition to Alzheimer's Disease. But EFSA's selective exploration of the data seems to have bypassed these papers.

New use for toothpaste toxin

Now, here's how the two companies who have petitioned EFSA for approval of SMP propose to use the chemical:

"Sodium monofluorophosphate is intended to be used by both petitioners in food supplements as a source of fluoride in the forms of multi-vitamin, multi-mineral supplements, solid tablets or tablets dispersible in liquid."

This equates to saying: "The stuff we've been telling you for years not to swallow in toothpaste is now safe to take as a supplement. In fact, we now think it's a good idea to add the toothpaste toxin to your daily multi-vitamin."

Is fluoride a nutrient, a toxin or a drug?

The premise of something being both a nutrient and a potential toxin is not new. In fact, one of the most fundamental tenets of toxicology is that all things are toxic, it

just depends on the dose. Theophrastus Phillipus Aureoleus Bombastus von Hohenheim, better known as Paracelsus, came upon this general view some 500 or so years ago.

The real questions of course should be: what dose is safe and what dose becomes toxic, to whom? But, as we've already heard, EFSA isn't too bothered by this as it's 'not within its remit'.

Another issue we should contemplate is: why is EFSA doing risk assessments on a product where the intended use is not nutritional? Why is it evaluating a product that is used to treat a disease—in this case dental caries—that should make all fluoride products used for this purpose fall fairly and squarely under medicines law?

The UK National Health Service website states in its advice to patients [3]:

"If you are prone to dental decay, your dentist may advise the use of fluoride supplements in addition to fluoride toothpaste for extra protection. However, it is very important that fluoride supplements are only taken on the advice and instruction of your dentist."

This is clearly a medicinal use of fluoride. After all, the definition of a medicine under European law is as follows:

"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings" (amending Directive 2004/27/EC).

But medicinal applications are firmly outside the remit of EFSA, which is an authority on food. Medicines are dealt with centrally by another European institution, the London-based European Medicines Agency (EMA). So why is EFSA evaluating fluorides like SMP and calcium fluoride for use in food supplements when they are being used to treat or prevent a disease?

SMP and its other synthetic fluoride cousins are neither essential minerals, nor are they generally regarded as nutrients. There is, however, quite a body of work being generated by the pharmaceutical industry which shows how fluoride can—because of its intimate relationship with calcium—help re-mineralise bones and hence reduce osteoporosis. But, owing to this very same relationship, there's also unequivocal evidence that calcium can be stripped out of bones and teeth and cause skeletal and dental fluorosis. It's a classic double-edge sword that involves the perpetual conundrum of considering risk, benefit and dosage assessments. This is the domain of drug not food regulating authorities.

Drug companies do already have a series of fluoride drugs on the market that aim to get this balance tipping the right way; they deliver fluoride at relatively low doses—logically—beneath those that cause the calcium to be stripped out. Again, it's all rather medical and not at all 'foody'. Get the dose wrong and you could really harm people, especially if they are already living in an area where the drinking water is

fluoridated.

EFSA hasn't touched on the non-tooth decay uses of SMP because the petitioners know their products would have to be regarded as drugs if they did. After all, every medical encyclopedia tells us that osteoporosis is a disease. But the problem for EFSA is; so is dental caries!

So, here we have EFSA evaluating fluoride's safety in food supplements, but EFSA scientists haven't even touched on evaluating how it works, if it works, or if there might be less risky ways of getting the same, or even better, results! We're left thinking it would be uncharacteristically progressive of EFSA to suggest that removing sucrose from childrens' confectionary, which would eliminate the conditions in which oral bacteria (*Streptococcus mutans* in particular) produce enamel-destroying acids, would be more appropriate than offering fluoride as a food supplement. Sucrose could be replaced by other sugars like glucose or xylitol that don't create these conditions. But again, these sorts of considerations are inexplicably outside EFSA's remit. EFSA's desire to compartmentalise its risk assessment work, without looking at any of the benefits of a given foodstuff, is now legendary—and completely irrational! This approach is contrary to the interests of public health and urgently needs reviewing.

Who decides when the rules can be bent? Why are the rules bent when it suits? Why so much leniency and avoidance of known scientific facts when these decisions may endanger public health? Especially when in other cases, EFSA takes an incredibly cautious line, complains of inadequate data to prove safety and gives a slather of negative opinions. Negative opinions have been the fate or likely, soon will be, for a range of beneficial minerals like vanadium and chromium (which compete with anti-diabetic drugs) and silver (which competes with antibiotics).

Scientific junk

We were flabbergasted when we read the basis on which the green light was given to SMP. We remain flabbergasted. In fact, we are unlikely to recover from this condition until EFSA decides to use consistent, rational and objective scientific methods when it undertakes its risk assessments.

In 2005, EFSA set Tolerable Intake Levels (TIL) [4]—in other words the maximum amount you can ingest safely on a daily basis from all sources—that just don't fit either with the science or its methodology already used on essential vitamins and minerals. These are the ones that are actually good for us.

They've conveniently set the following maximum safe levels:

- 1.5 mg/day for children aged 1-3 years
- 2.5 mg/day for children aged 4-8 years
- 5 mg/day for children aged 9-15 years
- 7 mg/day for children over 15 years and adults

We say ‘conveniently’ because we know that they know that countries like Ireland and the UK, who fluoridate all or some of their public water supplies like to do this at about a level of 1 mg /L. So because a 3-year-old doesn’t generally drink more than 1.5 litres of water a day, EFSA feels comfortable its TIL can’t be exceeded. The same goes for an adult. If you are a keen sportsperson and sweat a lot, you could find yourself drinking up to 7 litres a day. Again you wouldn’t have exceeded EFSA’s claimed safe level if you were drinking fluoridated tap water. But, we presume, EFSA would be assuming you don’t swallow your toothpaste.

But hold on a minute; EFSA are meant to be separated from these practical realities. They are meant to be doing the real science and perusing all data that is relevant and making objective judgments about safety using a full complement of available data and the latest risk assessment science!

And this is where we have no option but to use the necessarily harsh term ‘scientific junk’. EFSA have completely ignored a good body of evidence that suggests that dental fluorosis—which it agrees is the most sensitive indicator of fluoride toxicity—occurs in children when the fluoride (natural or synthetic) content of drinking water exceeds around 0.7 mg/L [5,6,7,8].

This 0.7 mg/L threshold level is just under half of the 1.5 mg/L maximum safety level set by the World Health Organization (WHO) for drinking water. The WHO, which actually recommends a maximum artificial fluoridation level of 0.5 – 1.0 mg/L to account for extra fluoride that might be in the diet, has a better excuse. It implies that if it went much lower, there would be a major issue for all those parts of the world where natural fluorides—which seem to be intrinsically safer than artificial ones like SMP—find their way into the drinking water supplies, Ethiopia being a case in point.

Bottom line: why is EFSA saying adults are fine with 7 mg/day, and why are they allowing very young kids to have 1.5 mg a day when the most well accepted data on water consumption [9] shows that 3-year-olds should consume 1.3 litres?

Now for some simple maths: 1.3 (volume of water needed by a toddler daily) multiplied by 1 (the typical amount of fluoride in fluoridated tap water) equals 1.3, conveniently under the 1.5 mg ‘safe level’ set by EFSA. But if the threshold concentration in drinking water as shown by a number of scientific studies is actually 0.7 mg/L, to calculate the daily threshold dose BELOW which you need to be if you want to be safe, you must multiply 1.3 (the amount of water consumed) by 0.7 (the concentration above which dental fluorosis occurs). This gives you 0.91 mg/day. This amount should be at the very least an approximation to the Lowest Observable Adverse Effect level (LOAEL) in risk assessment.

So why isn’t the actual safe level stipulated by the European regulator well below 0.9 mg/day for toddlers? Remember 0.9 mg/day is the threshold! By the time you include an uncertainty factor, it would be inconceivable—assuming use of the

approach EFSA employs for essential vitamins and minerals—to come up with a safe level more than one-tenth of this amount. Therefore: best case scenario, at least for toddlers; the maximum safe level should not exceed 0.09 mg/day.

We'll remind you again, that EFSA's supposed safe level for toddlers is 1.5 mg/day, which is almost 17 times greater than what is probably a much more accurate safe level! And the petitioners want to use SMP to deliver fluoride at levels up to 2 mg/day, 22 times over the safe level we've just determined.

Back to supplements

It's much harder to have a clear view on the safety of SMP for adults, as we're somewhat less susceptible to having the calcium stripped out of our teeth. But we're still quite susceptible to having it stripped out of less visible and hard to monitor areas like our skeletal structure, hence the well researched positive association between fluoride and bone fractures. There's almost certainly a relationship between fluoride and osteoporosis, but that's a hot subject that we're not meant to talk about. Rather like the cancer link. So we won't talk about it (any more).

In looking at the dose range requested by the petitioners, EFSA says:

*“However, when the potential fluoride contribution of sodium monofluorophosphate supplementation is added to the total fluoride daily exposures estimates in Europe for children, fluoride tolerable upper intake levels **will be exceeded in most cases.**”* [our emphasis].

But they still give it a green light? They are seemingly happy that the group most vulnerable to the effects of fluoride—children—get exposed to fluoride supplements? To arrive at this conclusion, EFSA have had to use a completely different approach to that which they've used for the essential vitamins and minerals. With these, EFSA subtracts the highest daily intakes that can be found in a given society from a highly precautionary Upper Level (along the lines, but even more cautious than the one of 0.09 mg/day that we calculated above) to give the supplemental maximum level. This procedure is guided by statements made in Article 5 of the EU Food Supplements Directive (2002/46/EC).

However, in EFSA's fluoride Opinion, EFSA scientists ignore a whole bunch of key literature, they ignore relevant uncertainty factors in creating their Upper Level and they are happy to not subtract highest mean dietary intakes from the Upper Level. All to make sure the petitioners can have a toxin that is intended to treat or prevent a disease in the mouth and may, in the process, expose consumers to significant health risks.

It's hard to explain this in any other way other than the abuse of science to suit big corporate concerns. This is junk science. This is downright dangerous science. If it is none of these, might EFSA care to give us some justification for the radically different approaches used to evaluate this intrinsically toxic biocide as compared with intrinsically safe and beneficial vitamins? Remember: when the latest science tells us

that those of us who don't get into the sun in northern Europe should be taking around 4000 IU of vitamin D3 a day (notably in the winter months), it's astonishing that European risk assessment science has found a way of saying that we shouldn't take more than a twentieth of this (200 IU) daily! That's the amount, proportionately, that your body gets when exposed to less than 30 seconds of sunlight in the midsummer!

Supplementing with a toothpaste toxin is madness, when the product should properly be registered as either a biocide (under the EU Biocidal Products Directive) or as a full blown licenced medicine. Is EFSA really preferring certain petitioners?

Who could trust EFSA to use good science when it appears so ready to alter its risk assessment procedures to suit commercial interests—and allow us (and especially our children) to be poisoned in the process?

While EFSA takes this very cavalier, non-precautionary approach to fluoride on one hand, it then uses ultra-restrictive risk assessments that lead to bans on nutrients that are good for us. But maybe it's that old chestnut: has EFSA, like so many government authorities around the world responsible for licencing of medicines, become vulnerable to pressure from some of the largest corporations on the planet?

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