

Drinking Water, Magnesium and Human Health—What's Next?

By Andrew Warnes

The past several weeks have given the point of use/point of entry (POU/POE) water treatment industry time to let the details of the Baltimore *Symposium on the Health Aspects of Calcium and Magnesium in Drinking Water* soak in. While the results and the impact are yet to be revealed, we can begin to anticipate the potentials and start thinking about the future. The topics are well known by now and the symposium received excellent coverage in the industry press. So what happens next?

One of the most compelling presentations in Baltimore was by an Israeli municipal water authority spokesperson who described the desperate need for renewable sources of drinking water in an arid nation. That country has invested considerably in desalination to meet its water needs and any questions on the part of the public about the safety of drinking water produced by desalination are a serious concern. The Israelis want and need a guideline from a respected entity like World Health Organization (WHO) that would allow them to take appropriate measures to ensure that municipally supplied water is safe. This will also help avoid any public perception of tap water being unsafe due to mineral deficiency. Similar scenarios will play out across the globe wherever desalination is being used to improve lives and meet future water needs.

How do you balance the needs of municipal authorities like these against the beliefs and desires of POU/POE equipment suppliers? From a public health standpoint you can't—particularly when even world renowned experts admit that we don't have totally conclu-

sive proof based upon comprehensive scientific study. In these instances, public health issues trump commercial concerns. WHO stated a desire to have draft recommendations for desalinators by the end of 2006; their general guideline on mineral content is due in 2008. It seems unlikely that the two recommendations will differ greatly, or contradict each other, so we should have a good idea where things are headed by the end of this year.

WHO guidelines for drinking water quality are used by many countries as the basis for national drinking water quality regulations. The U.S. is an exception and requirements to re-mineralize drinking water that has been de-mineralized might not make it to our shores just because WHO recommends it. Regardless, the possibility of sensational press coverage or litigation might make magnesium in drinking water part of the national agenda. It's a possibility that business owners and strategic planners should already be thinking about.

A missed opportunity

Throughout the presentations in Baltimore we heard repeatedly that the studies to date were not totally conclusive, but enough evidence was available to craft a public health recommendation. Dr. Martha Sinclair, a senior research fellow from Monash University in Australia, made a very persuasive argument that without further study, the issue of magnesium was essentially unresolved. Her points included mention of research trials that would need to dose patients with specific levels of minerals and include the elimination of 'confounding factors' like

smoking, diet and exposure to other substances. Such a trial would involve thousands of subjects, millions of dollars and would take years (if not decades) to yield conclusive results.

As an industry, we missed an opportunity to engage the public health authorities with the possibility of joining forces to deliver just the types of data Dr. Sinclair was referring to. As a group we probably have the most extensive collection of data available in the world, including potential research subjects (our customers) who have been drinking softened water for decades and reverse osmosis (RO) water for years. Collectively, we know where these subjects live, how long they have been drinking treated water and in many cases we have annual service records of the hardness levels entering and leaving our products. Our customer records represent a virtual goldmine to researchers (and possibly litigators) and perhaps we should have diverted the discussions into more positive areas by offering to work together. Would manufacturers have given up this data willingly? Could we have delayed any guidelines until conclusive evidence was collected? Unfortunately we'll probably never know the answers to these questions.

So what should I prepare for?

The practical results of the Baltimore symposium are strictly speculative at this point. The issue might blow over completely with no impact to the POU/POE industry. WHO recommendations might be applicable only to municipal desalinators. Scientific minds might hold out for more conclusive data and further

study could reveal no correlation between hardness and cardiovascular disease (CVD). Research might reveal some other cause of CVD that is unknown to us now.

On the other hand, there are beneficiaries if the opposite occurs. We've already heard of a website collecting names for a class action lawsuit against the bottled water industry.¹ So far the mainstream press has not caught on and a BBC story on the subject two years ago failed to start a fire.² Is this a story likely to drive up evening news ratings? Is it a bad situation if you happen to be a mineral water supplier? Given the potential impact of this issue on public perception and in regulatory or legal arenas, we should be thinking about what could happen next.

Can't we just add magnesium back in?

Just adding magnesium back into demineralized drinking water seems like an obvious, relatively easy solution. However, it might not be so simple to do. There is some debate over the legal and regulatory requirements surrounding the addition of substances to drinking water as opposed to removing them. Who regulates this type of thing in the U.S.? An excellent question! Let's look!

Who can do what?

My brief inquiry on the subject brought some surprising answers. They aren't conclusive answers, but adding magnesium or other minerals into drinking water might not be as easy as some of us presumed. Back in 1979, a Memorandum of Understanding (MoU)³ was signed between the United States Environmental Protection Agency (U.S. EPA) and the Food and Drug Administration (FDA) regarding the control of direct and indirect additives to and substances in drinking water. They agreed that the U.S. EPA's responsibilities are as follows:

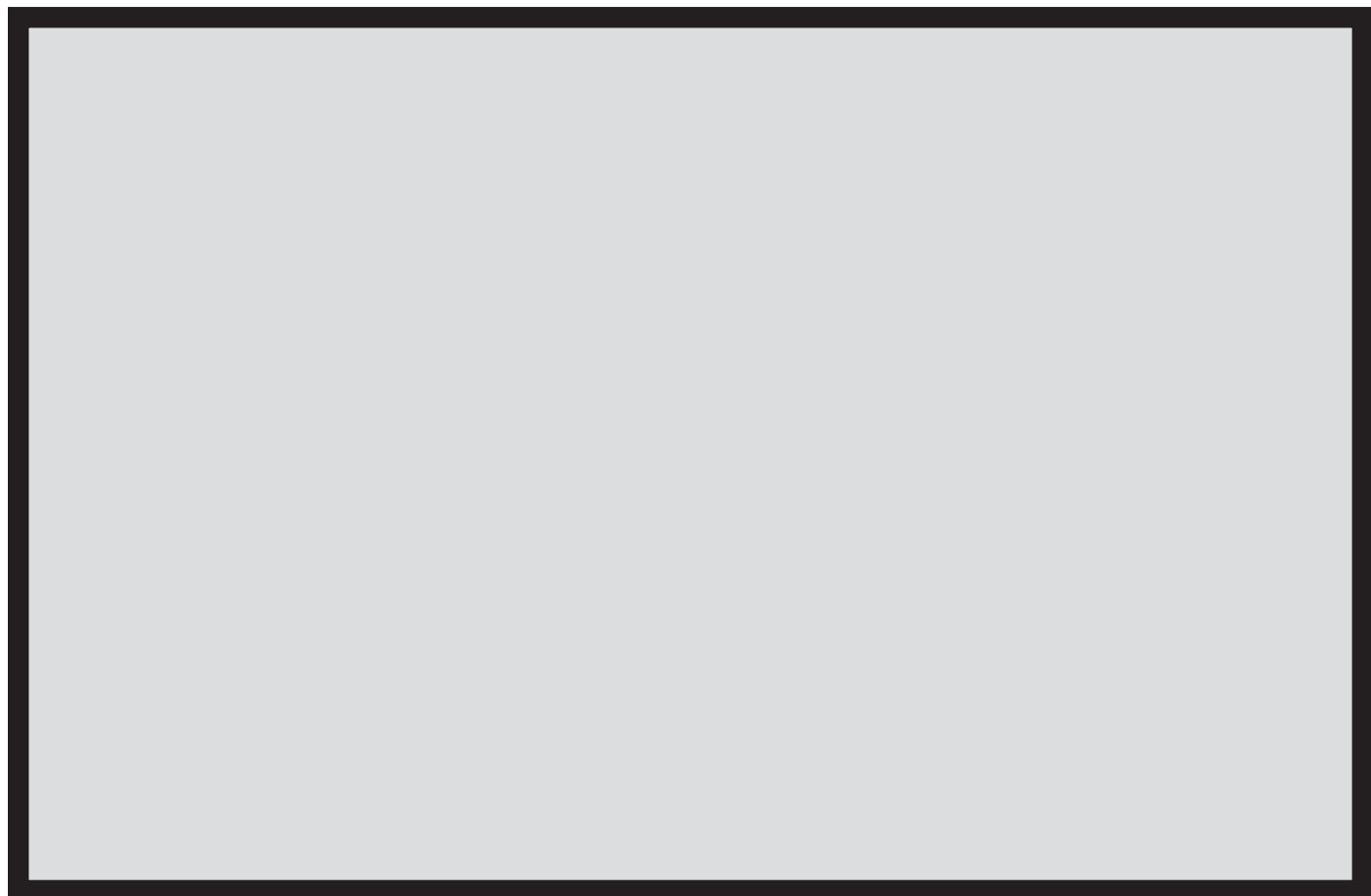
- To establish appropriate regulations and to take appropriate measures, under the *Safe Drinking Water Act* (SDWA) and/or *Toxic Substances Control Act* (TSCA) and *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA), to control direct additives to drinking water (which encompass any substances purposely added to the water) and indirect additives (which encompass any substance which might leach from paints, coatings or other materials as an incidental result of drinking water contact) and other substances.
- To establish appropriate regulations under the SDWA to limit the concentrations of pesticides in drinking

water; the limitations on concentrations and types of pesticides in water are presently set by U.S. EPA through tolerances under Section 409 of the *Federal Food, Drug and Cosmetic Act* (FFDCA).

- To continue to provide technical assistance in the form of informal advisory opinions on drinking water additives under Section 1442(b) of the SDWA.
- To conduct and require research and monitoring and the submission of data relative to the problem of direct and indirect additives in drinking water in order to accumulate data concerning the health risks posed by the presence of these contaminants in drinking water.

The FDA's responsibilities are:

- To take appropriate regulatory action under the authority of the FFDCA to control bottled drinking water and water and substances in water, used in food and for food processing.
- To provide assistance to U.S. EPA to facilitate the transition of responsibilities, including: a) to review existing FDA approvals in order to identify their applicability to additives in drinking water. b) To provide a mutually agreed upon level of assistance in conducting literature searches related to toxicological decision making. c) To provide a senior toxicologist to help U.S. EPA devise new



procedures and protocols to be used in formulating advice on direct and indirect additives to drinking water.

Who has jurisdiction?

It seems relatively clear that U.S. EPA has jurisdiction, but there is more to the story. In the March 1998 issue of the NSF Publication *WaterWorks*, the situation regarding additive regulation was described in depth.

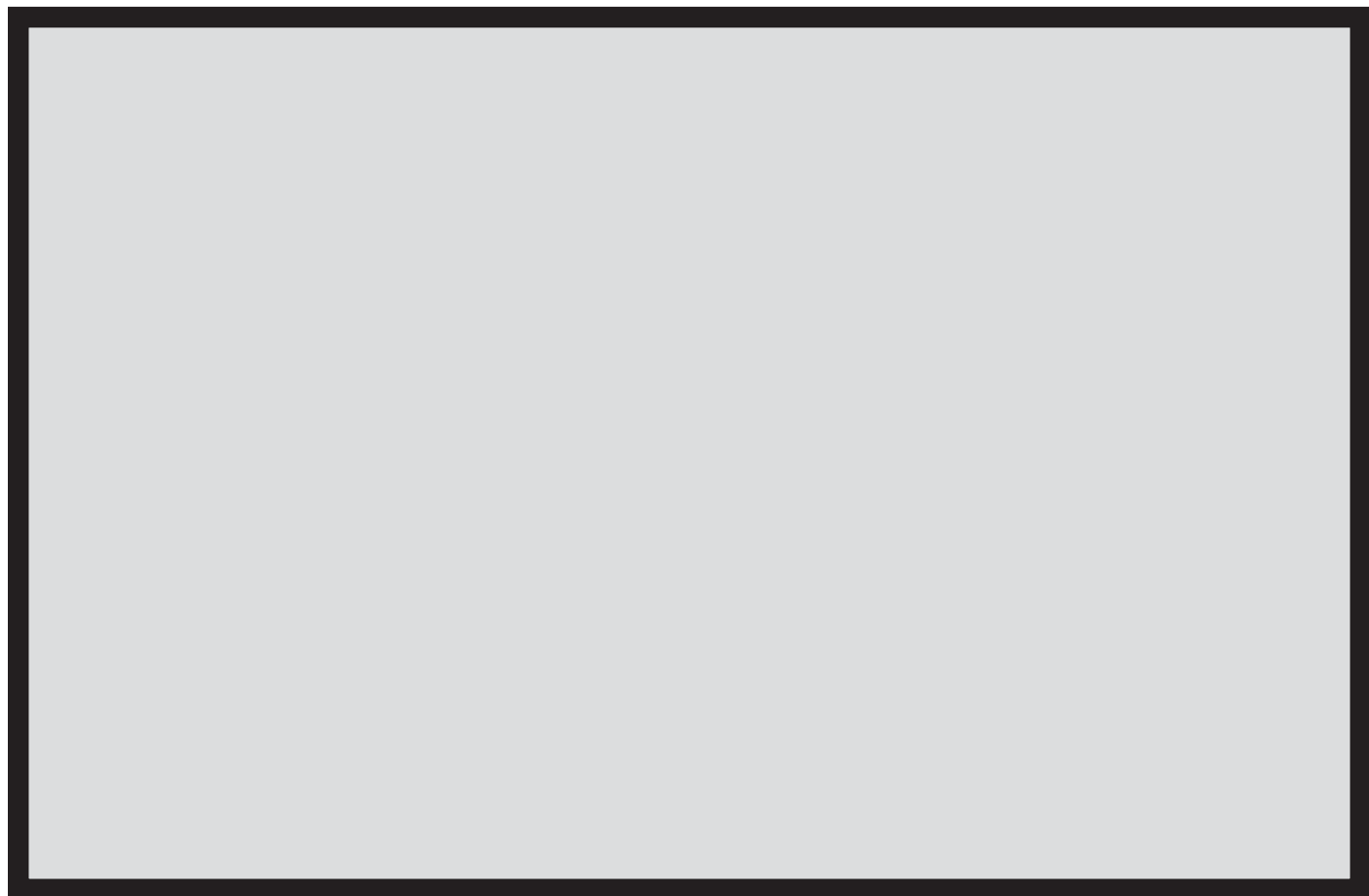
Specifically: "Standards for the chemicals used for treating drinking water and for the system components are not a mandatory part of the federal laws and regulations that guide our national drinking water program. Instead, standards were developed under a voluntary program with input from regulators, product manufacturers and water utilities. Water safety now depends on the state regulators adopting these standards, manufacturers providing products that comply with the standards and water utilities specifying and using products certified to these standards. For many years, the FDA and more recently, the EPA, provided technical assistance to states and to water utilities in the form of advisory opinions on the safety of drinking water additives. These were typically lists of treatment chemicals added directly to water—such as alum, polymers and corrosion inhibitors." "In 1988, when the

EPA discontinued this advisory function, the role of setting standards for additives was taken over by a consortium of stakeholders headed by NSF International. Other consortium members include the American Water Works Association Research Foundation, the Association of State Drinking Water Administrators, the American Water Works Association and Conference of State Environmental and Health Managers (COSHEM no longer exists)." "The original consortium members continue to oversee the implementation of this program, which the states and utilities rely upon to make product specifications and purchase decisions. Two standards for assuring the safety of drinking water additives have been adopted by the American National Standards Institute (ANSI). ANSI/NSF Standard 60: Drinking Water Treatment Chemicals-Health Effects covers drinking water treatment chemicals; ANSI/NSF Standard 61: Drinking Water System Components-Health Effects covers indirect additives. These standards continue to be updated by a voluntary consensus process that represents all stakeholders, including regulatory agencies, industry, water suppliers and consultants."

At this point it might seem that adding magnesium back into drinking water could be covered by ANSI/NSF Standards 60 and 61, with additional at-

tention to be paid to the *Active agents and additives* clauses in ANSI/NSF Standards 42 and 53. The *Active agents and additives* clauses in these standards stipulate that: "Where an active agent or additive is used in the drinking water treatment process, the product water shall not contain that substance (or its degradation products) at a concentration of toxicological significance as given by the USEPA Primary Drinking Water Regulations, by the Health Canada Maximum Acceptable Concentrations, by any U.S. Federal regulatory agency, or at a concentration that exceeds constituent limits of the USEPA Secondary Drinking Water Regulations for all sample points. If the substance does not have a maximum drinking water concentration established by USEPA of Health Canada, a Total Allowable Concentration (TAC) shall be established according to the requirements of ANSI/NSF 61, Annex A."

So far so good. It seems that for the most part, adding magnesium could already be covered by the current ANSI/NSF Standards and testing process but there is at least one additional aspect to additives in the U.S. If a manufacturer is declaring the addition of a beneficial mineral or if a health benefit or claim is being made, there might be a responsibility to comply with FDA dietary supplement



labeling guidelines. According to the FDA,⁴ dietary supplements are defined, in part: "as products (other than tobacco) intended to supplement the diet that bear or contain one or more of the following dietary ingredients:

- a vitamin;
- a mineral;
- an herb or other botanical;
- an amino acid;
- a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- a concentrate, metabolite, constituent, extract or combination of any ingredient mentioned above.

According to the FDA website, under the *Dietary Supplement Health and Education Act of 1994 (DSHEA)*, the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with FDA, nor get FDA approval before producing or selling dietary supplements. Manufacturers must make sure that product label information is truthful and not misleading.

FDA's post-marketing responsibilities include monitoring safety; e.g., voluntary dietary supplement adverse event reporting and product information, such as labeling, claims, package inserts and accompanying literature. The Federal Trade Commission regulates dietary supplement advertising.

Summary

This article is not intended as a guideline for the development of products that add magnesium to drinking water, nor should it be used as such. The author's intent is to discuss the potential impact of the magnesium issue in an open forum. The ramifications of any WHO guidelines on the mineral contents of drinking water and their effects upon human health have yet to be fully understood. For members of the POU/POE industry the impact could vary from zero to severe, but the issue is unlikely to disappear anytime soon. Simply adding minerals back into drinking water after they have been removed might be a more difficult and technically complex process than some envision due to possible regulatory requirements. Current ANSI/NSF Standards and testing protocols should cover the addition of magnesium to drinking water. Products not certified to ANSI/NSF Standards might have an easier job ahead, though both certified and non-certified products are equally required to meet FDA labeling guidelines. The legal aspects of the issue are something probably best covered by a qualified consumer safety professional.

One possible benefit from all of this could be the opportunity for the POU/POE industry to begin offering consumers the perceived and/or real health benefits currently being supplied by the dietary supplement industry. Imagine a world where multivitamins and supplements no longer have to be swallowed as pills and powders—they could be as accessible as the closest tap. Another potential benefit could be more rapid movement into POU/POE technologies that can offer benefits to consumers without altering the mineral content of incoming water supplies. One of my favorite sayings is: "Out of uncertainty and chaos comes opportunity"—perhaps an apt description of the situation the Baltimore symposium has presented us with.

References

1. <http://www.mgwater.com/victims/index.shtml>
2. <http://news.bbc.co.uk/1/hi/health/3396141.stm>

3. To see the MoU please see: <http://www.fda.gov/oc/mous/domestic/225-79-2001.html>

4. To see an FDA labeling guide for industry please visit: <http://www.cfsan.fda.gov/~dms/dslg-1.html#1-1>

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