

## Biocides Directive causes storm of controversy

**It's a substance most embalmers work with just about every day. But it has managed to cause a storm of controversy in the European Union that has gone largely unnoticed in the United States.**

The European Union's Biocides Directive, which was adopted in 1998, is meant to protect the public from harmful substances in biocidal products such as formaldehyde. Some hail the measure as a piece of legislation that has been needed for years and that will finally give embalmers the protection they need. But there are others who argue it could put makers of embalming fluid out of business and threaten the livelihoods of those who practice the craft. It is estimated that there are 2,500 to 3,000 embalmers throughout Europe. All of them, in some way or another, are affected by the directive.

Biocides are chemical products

designed to kill unwanted organisms, and the directive covers 23 different product types, such as disinfectants, preservatives and nonagricultural pesticides. The aim of the directive is to ensure a high level of protection for human and animal health and the environment and to establish, after a systematic evaluation, a list of permitted active ingredients for biocidal products. The directive became effective in May 2000, and its review program is to be implemented over a 10-year period.

Embalming and taxidermy chemicals fall under the fourth group in the directive – "Other Biocidal Products." While biocides on the list to be evaluated can continue to be sold for now under national rule, the companies that make them must supply a dossier that includes safety data information, independent reports, evidence of active ingredients, a chemical breakdown and results of animal testing.

The United Kingdom recently increased its fee for making sure that a dossier includes all the necessary information from \$11,220 to \$18,700, which is nonrefundable, according to Adrian Haler, managing director of the U.K. subsidiary of the

Dodge Co., the leading supplier of embalming fluid to funeral homes in the United States.

According to the Health and Safety Executive's web site, which will be reviewing the status of embalming products in the U.K., the directive is meant to "harmonize the European market for biocidal products and their active substances so that once a product is authorized in one member state under the directive that authorization can be recognized in the other member states," and also to protect people, animals and the environment.

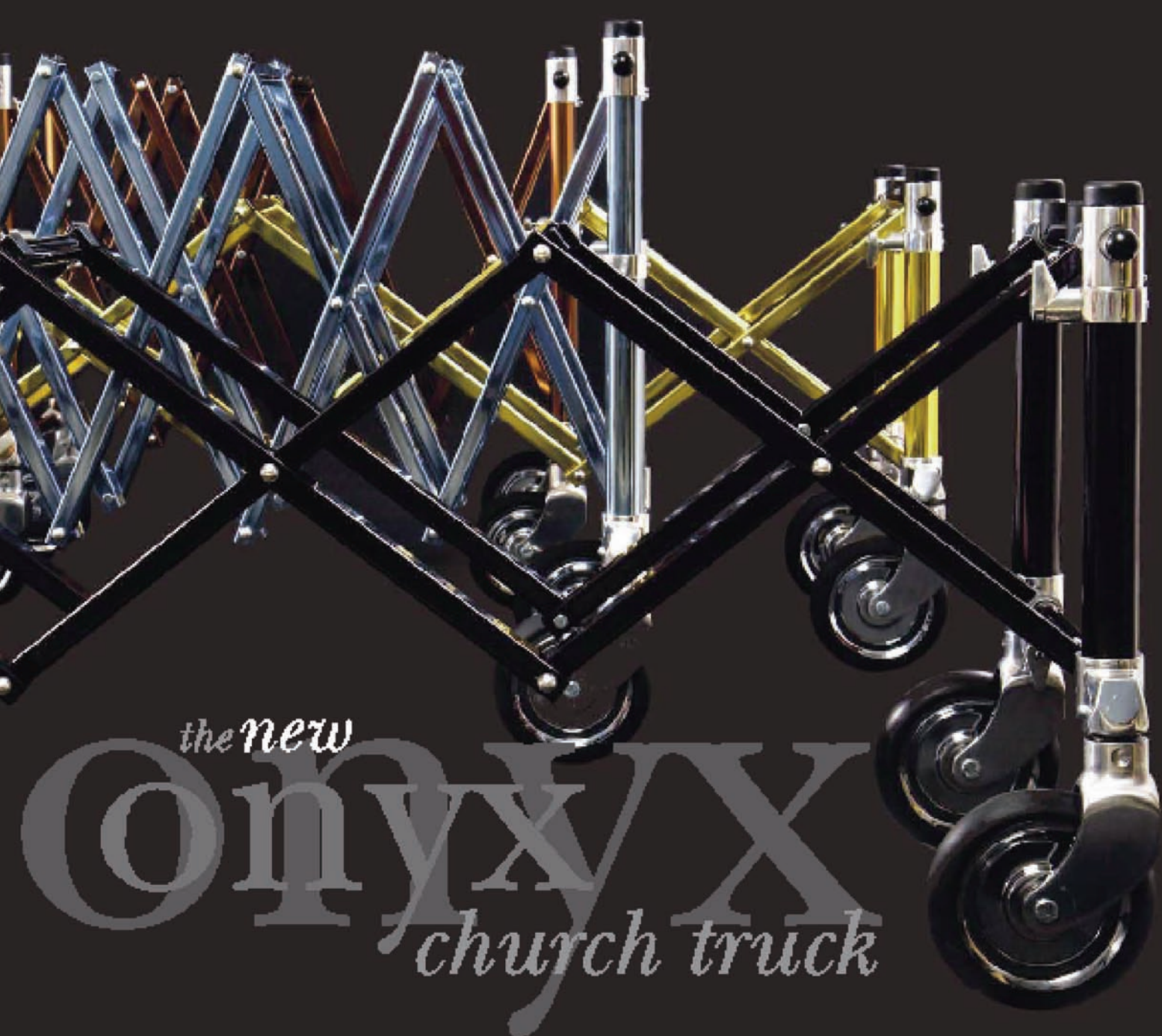
The directive has a whole array of problems, however, according to Haler. "The costs involved are considerably more than the profits one can make," he said.

But determining the costs involved is quite a project. Elena Maidou, a legal and policy officer with the European Commission, said that a task force of companies – the Formaldehyde Registration Group (FAREG) – has notified formaldehyde for a variety of uses, including embalming. "They are the ones who will be covering the cost of the studies for the substance's evaluation, and so far they haven't said anything about having problems to do so," Maidou said. "Dodge may still place formaldehyde on the market thanks to this task force. Until the notified active substances are reviewed and a decision is taken on their acceptance or not, anybody can continue marketing them as biocidal products."

The notifier – in this case FAREG –



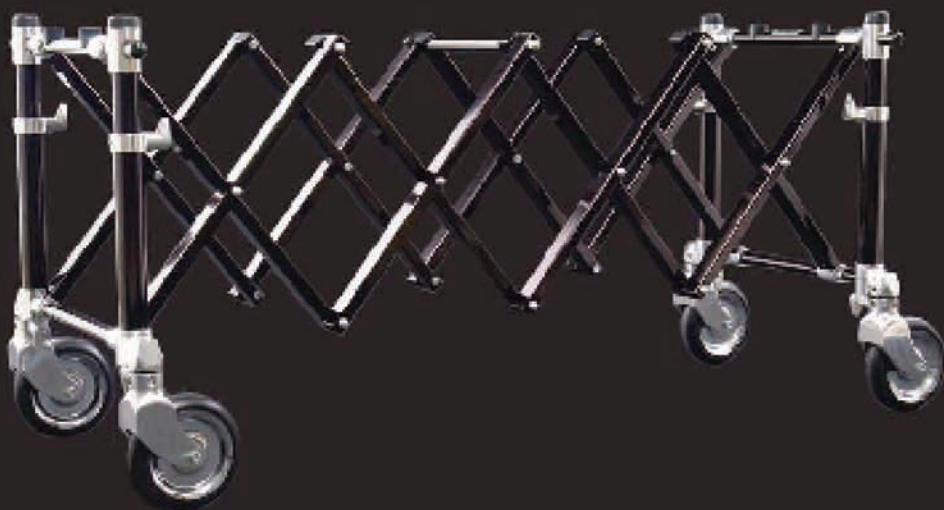
**At least 50 percent of Irish embalmers are already using alternatives to formaldehyde, with no difficulties.** David McGowan, owner of McGowan Funeral Home, Ballina, Ireland



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must initially meet the cost, which includes a product-filing fee of \$189,000. That means FAREG will compile a dossier that includes toxicity and ecotoxicity studies to support the inclusion of formaldehyde in the directive's annex. That dossier will be submitted to Germany, who is the "rapporteur" for the substance, Maidou said.

Germany charges between \$94,500 and \$157,500 for an active dossier evaluation. Formaldehyde has been notified for more than a dozen product types, Maidou noted, including embalming. If Germany finds the use of formaldehyde acceptable, Maidou explained, any interested party may get authorization to market the substance as a biocide. That would require them to apply to a member state of the European Union with the initial information that permitted the inclusion of formaldehyde as an active substance in the active list, plus a dossier on the specific

embalming product that contains formaldehyde, Maidou said. If an individual or company does not own the data, they can buy access to it from FAREG. After getting a first authorization, the party in question could ask other member states to mutually recognize the product in their territories, she said.

However, further costs can be incurred for product testing, literature searches and consultancy and added research. Moreover, despite the positive list of active substances applying to the entire European Union, individual products are being regulated on a per-country basis. Member states are the ones responsible for fixing the amount of fees for the evaluation of active substances and the authorization of biocidal products, and therefore, costs can't be accurately estimated. "There is a very wide difference between what individual countries charge," Haler said. "It's not a level playing field, which it should be. One of the aims

of the directive is to have a harmonized system, and it's far from that. ... There are so many unknowns that the whole thing is ludicrous and unworkable."

Luckily, for the makers of embalming fluid, there is time to sort this all out. A European Commission regulation stipulated that chemicals to be used as biocides were to be identified and notified for evaluation before March 28, 2002. Because FAREG did so, formaldehyde can continue to be used in products until a full dossier has been presented and the active substance reviewed. A dossier must be submitted by Oct. 31, 2008. But that's less than two years away, so it should be no surprise that companies with money to lose are beginning to clamor for reform.

Maidou concedes that "certainly there is always room to fine-tune legislation." She said that's just what the European Commission intends to do when it revises the directive based



*At left, Willbert Honor Collection themes, top to bottom: Michael, Fishermen, Christmas, Purgatory, San Francisco, Her/His II, Kismet. Visit [www.wilbertonline.com](http://www.wilbertonline.com).*

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on the conclusions of a report about the directive's implementation. That report is due to be submitted to the European Parliament and Council at the end of 2007, she said.

The bottom line to all of this is that manufacturers will have to pay for a variety of tests. "I don't think it's likely anyone could afford to get the tests done," Haler said. "They are talking about 350,000 pounds (about \$654,500) for the tests necessary. And if you bump up the price for the chemical, no one will buy it."

Maidou, however, says if it is expensive to support a specific substance, there are reasons. "Either the substance has an unfavorable toxicity/ecotoxicity profile and needs to be thoroughly investigated, involving costly long-term studies on animals, before safe uses may be identified; or the substance has never been examined in the past, or very little, and the entirety of data has to be generated." She added that it

would be wrong to waive data requirements for a substance if no one knows anything about it.

Haler says the directive won't lead to the demise of Dodge's U.K. subsidiary because it could still sell cosmetics, body bags and other items, but he fears that embalming fluid will no longer be a product fixture. "We are all fighting for our livelihoods," he said.

When asked how much money is at stake, Haler could not say. But the Wall Street Journal has reported that Dodge could lose as much as \$3 million in annual sales in Ireland and the United Kingdom.

Haler said that while there have not been extensive tests done on embalming fluid, that it is safe when used properly. He noted that embalmers aren't dying in large numbers, and he laments that the directive would change the way funerals are conducted. "Much of the fuss about formaldehyde is scare mongering - accepted that precau-

tions are needed when using it, which is the same for any other chemical," Haler said. You don't see embalmers in the United States dying in large numbers of cancer, he noted.

### Alternative Viewpoints

David McGowan, owner of McGowan Funeral Home, Ballina, Ireland, thinks the Biocides Directive is a good idea, and he chastised the Dodge Co. for working against it. "I can list, without effort, 10 embalmers, who, sadly passed away having suffered from cancer," he said. "All of these worked with formaldehyde."

McGowan said he used to work with formaldehyde but always had reservations about it. In 1993, he learned about the Champion Co. and its formaldehyde-free fluids and fluids with a low formaldehyde content. Since then, he has been an agent for the company in Ireland and in Britain since 1994.

McGowan said he's been

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embalming in Ireland since 1982. Since then, he said he has never been questioned by any official authority about the chemicals he uses or how he disposes of such chemicals. "In many cases, unqualified personnel work here as embalmers!" he said. "I want to see a change to this hazardous situation. Chemicals used for embalming should be regulated, classified and contain labels and data sheets that are clear and consistent throughout EU member states."

Alternatives to formaldehyde-based fluids are out there, McGowan stresses, and it is his hope that the Biocides Directive will promote their wider use. "At least 50 percent of Irish embalmers are already using alternatives to formaldehyde, with no difficulties," he said. To McGowan, it's upsetting that Halperin chooses to ignore those who warn about the dangers of formaldehyde.

"In my experience, it is possible to embalm without the presence of formaldehyde," McGowan said. "I have used glutaraldehyde for 13 years now and have not had any problems in relation to sanitation of remains. I have witnessed the preservation of remains for up to one month, in the absence of refrigeration."

Peter Ball, a self-employed embalmer in the United Kingdom and secretary of the European Association of Embalmers, noted that the Biocides

Directive also affects glutaraldehyde. "Many embalmers are interested in using other chemicals, but so far have found them significantly less effective than formaldehyde-based formulations," he said. He added, however, that he does not detect any resistance to change and that "safer and more effective chemicals would be welcomed even if a certain amount of education in their use might become necessary."

Although he welcomes the prospect of improving safety in the embalming profession, Ball said some products might become unavailable if the directive is not changed. "Some products will disappear from the marketplace because gross sales are less than registration costs," he said. "The embalmers are involved because the domino-effect of higher costs and removal of some ancillary products from the market could decrease the ability to treat certain types of cases. For example, restorative art procedures with substances that are not as effective in hardening the damaged tissues as efficiently as formaldehyde could easily lead to these techniques becoming ineffective. There is also the possibility of a slowdown in developing markets in Europe where the practice of embalming is in its early stages," he said.

Embalmers are taking notice of the Biocides Directive because there is a

lot at stake for them, even if they don't make and market the fluid. According to Ball, "It is difficult to envisage the continuation of repatriation cases in their present form were the removal of formaldehyde or glutaraldehyde from the marketplace to become a reality. The remains would have to be sealed in a coffin with little prospect of reopening and viewing the deceased on arrival. The interests of Dodge and other companies are the same in that both groups are best served by fighting for the products that will produce the best embalming result possible."

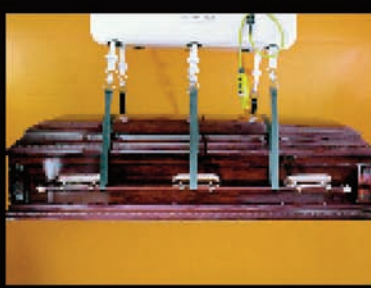
Ball added, "Both, of course, have the interests of their own businesses to look after, and these may not always be the same."

Ball noted that a large number of British embalmers have petitioned the European commissioners to protest the possible disappearance of formaldehyde-based embalming products from the marketplace in favor of less effective chemicals.

For its part, Dodge is conducting a campaign of sorts on behalf of formaldehyde-based fluids in the United States, where its usage is secure, at least for now. John Dodge recently told CBS 4, a Boston television station, that formaldehyde is found in cemeteries only in parts per billion. Edward Luss, another Dodge employee told the station, "The end of formaldehyde would mean an end to



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open casket funerals.”

But according to Joe Sehee with the Green Burial Council, that statement is a lie. “In no state in the U.S. is embalming necessary for a funeral with a viewing,” Sehee said. “Continuing to perpetuate this myth, while perhaps strategic for Dodge in the short term, has potentially devastating consequences for the cemetery and funeral industry.”

Despite the outcry from makers of embalming fluid, the European Commission is standing behind the directive. “The funeral directors’ concerns about the imminent unavailability of formaldehyde were not raised by the companies themselves who notified formaldehyde. Neither have these companies communicated any intention not to submit the data in 2008 (when formaldehyde is scheduled for evaluation); nor expressed any problems with covering the cost of generating the studies and paying the evaluation fee,” Maidou said. “You may ask then why this

pressure campaign; I have every reason to believe that it was initiated by other companies that have vested interests in the embalming sector.”

### Health Risks

Formaldehyde is included on a probable carcinogens list by the Environmental Protection Agency, and some groups believe there is a connection between formaldehyde and nasal cancer and leukemia. “There are a number of people concerned that formaldehyde leaches out of graves and vaults and can pollute underground water systems,” Sehee said. “We don’t have any baseline data that shows it one way or the other, but if we can avoid it, why shouldn’t we use non-toxic chemicals?”

According to an encyclopedia, inhaled formaldehyde can irritate the eyes and mucous membranes, cause headaches, a burning sensation in the throat and breathing difficulties. Studies in animals have shown that animals exposed to large doses of

inhaled formaldehyde over their lifetimes have developed more cancers of the nose and throat, but other studies have shown that smaller concentrations have no carcinogenic effects.

The National Cancer Institute (NCI) states on its web site that since the EPA classified formaldehyde as a probable human carcinogen in 1987, that studies of industrial workers exposed to formaldehyde have shown a greater than normal incidence of nasal cancer and nasopharyngeal cancer, and possibly with leukemia. It goes on to state that the International Agency for Research on Cancer (IARC) classified formaldehyde as a known human carcinogen in 2004. It had previously classified it as a probable carcinogen, but it was reclassified after a working group composed of 26 scientists from 10 countries concluded formaldehyde is carcinogenic to humans. Embalmers and anatomists are at increased risk for leukemia and brain cancer, according to the NCI. In the European Union, it is estimated that more than 1 million people are exposed to formaldehyde in a variety of industries, according to the IARC.

Improper use of formaldehyde-based fluids can lead to heavy fines. In June 2006, the Occupational Safety and Health Administration fined New York Hospital of Queens in Flushing, N.Y., \$112,500 for allegedly failing to protect workers from exposure to formaldehyde. The complaint concerned possible overexposure to formaldehyde for pathology assistants and oral pathology residents working with specimens stored in containers filled with formalin, according to an OSHA news release. Some in the funeral service industry wonder what would happen if there were a class action suit against Dodge or another maker of embalming fluid. The results could be devastating. “There is tremendous liability connected to using known toxic chemicals,” Sehee said. “Can you imagine if there was a class-action lawsuit, if embalmers claimed they were not protected properly? If you are a company and don’t have to expose workers to that



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... if you can take care of that, why wouldn't you do it?"

While the Green Burial Council as an organization is not taking an official stance on the Biocides Directive or trying to advocate legislation, it is trying to educate consumers to show that there are a number of options for end-of-life rituals that are friendly to the environment. And Sehee gets irate when he sees Dodge or any other company misinforming the public. "I can tell you that if (Dodge) continues confusing the marketplace and preventing death care customers from making informed choices, there probably will be any number of groups willing to push for the kind of legislation the EU recently passed," he said. "Dodge, to me, should spend more time developing non-toxic alternatives than in launching PR campaigns to defend their position. This issue comes up in a lot of different industries, and people have a choice to make – stand their ground or move forward. Every sign says at some point we are going to have problems with this. I'm sure there are people who didn't want to get rid of arsenic a century ago," he added, referring to the dangerous substance that was once used by embalmers.

Sehee said he doesn't think it's wise to threaten the industry, but he thinks those in funeral service will need to change their ways as they respond to the wishes of consumers. "I think the situation is sort of analogous to what has happened in the auto industry," he said. "You had some car companies not quite keeping up with the market and the Japanese were there when fuel efficiency was the issue and have put auto companies in a big bind."

And the issue is bigger than Dodge or other makers of embalming fluid, Sehee said. Manufacturers of chemicals are not the ones conducting end-of-life rituals, and while there is some overlap, the interests of each group are not the same. Many people are fed up with how the death care industry shuns the environment, and that is one of the reasons why cremation is on the rise, Sehee said. "All we are saying is let consumers

decide and patronize with their pocketbooks," he said.

One company that is friendly to the environment and that stands to benefit from the Biocides Directive is Aardbalm, an alternative to formaldehyde-based embalming fluid. The product does not fix tissue, but "delays the decomposition process for a window that allows observation of the deceased by the family," said Rupert Street, company secretary. Aardbalm decomposes quickly once it's in the ground and becomes organic matter," Street said.

In a video posted on the Internet, a presenter for the company says that Aardbalm is an organic alternative that produces "better, more natural results." The video claims that the product has no side effects even during prolonged use.

The video states that the embalming process may take a little longer with Aardbalm but adds that it can be injected into the body the same way as any formaldehyde-based fluid and that

the end result is a look that is much more natural. An Aardbalm-treated body is "softer to the touch" and appears more relaxed, the video states.

Formaldehyde-based fluids and Aardbalm cost about the same, the video states. General benefits of Aardbalm include a reduction in dermatitis, irritation of the throat and nose, headaches and depression. The speaker in the video adds that the "aesthetic results achieved by Aardbalm are generally accepted as being very pleasing and have been almost universally well received by the families of the deceased."

Aardbalm was formed in December 1999 but not in response to any legislation, Street said. He said the company has not taken a stance on the Biocides Directive because it does not want to be seen as endorsing something that would be damaging to the funeral industry. What the company is interested in, he said, is "green chemistry" and protecting the environment and people who work in



funeral service.

Since the Biocides Directive, Aardbalm has seen an increased demand for its products. It has made distribution agreements in Australia and the company is in ongoing talks with companies in Canada, the United States and Europe, Street said. The already profitable company sells its product in England, Scotland, Ireland, Australia, Canada, the United States, France and Germany.

### Seeking Reform

The burdens being placed on companies by the directive are too much to bear, according to Haler. "It's very difficult for companies working in this environment," he said. "One doesn't know if one should make investments and that sort of thing. The sort of money one is talking about, there is no way one would get that back."

The Biocides Directive is not an issue that just affects Dodge, Haler stressed. That's part of the reason why

a committee has been established under the auspices of the European Association of European Funeral Directors. The committee will include representatives from various countries, and it will have about \$25,000 to lobby officials at the European Union level, Haler said. "We feel that if we can make enough noise and create big enough waves, then maybe we will have a chance of being listened to," Haler said.

A German legal expert on the committee has agreed to quiz the German authorities whose job it will be to review formaldehyde, Haler said. "So hopefully, we will have a better idea of what will be required," he said. "There are possible avenues that will be explored for the mitigation of the worst effects of the directive." He noted that it's vital for stakeholders to have a pan-European approach. "The problem is that as this is all very new, they seem to be making up the rules as they go," he said.

The committee also will pay close

attention to developments in France, Haler said. "The government (there) seems to have started a campaign to eliminate formaldehyde from the marketplace," he said. "If this is so, and they are successful, this could have a knock-on effect for other European countries," he said.

And in Ireland, Dodge has teamed with Irish funeral directors to pursue a cultural heritage exemption in an effort to ensure that formaldehyde-based embalming fluid can continue being sold. Their argument: Because it often takes several days from the time of someone's death to their burial, embalming fluid plays an important role in the traditional Irish wake. That move received attention in media outlets throughout the world, including the Wall Street Journal.

The arguments that the directive needs to be changed in order to protect the Irish wake are upsetting to McGowan. "As a funeral director and embalmer who takes my profession seriously, I take huge offense at the way (writers) have presented the Irish funeral and wake," he said. McGowan added that, "All articles promote and defend the use of formaldehyde, implying that the Irish funeral as we know it will become extinct," which he disputes.

For now, at least, the battle lines in this fight are drawn. It may be taking place overseas, but embalmers and others in funeral service would be wise to take notice of events as they unfold. It's unclear whether the United States will follow the European Union's lead and come up with a Biocides Directive of its own, but there is a saying that often proves true: What comes around goes around. And in a globalized world, if it is indeed coming, it just might get here quicker than you think. •



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