The Good Times Are Over: and They Are Not Coming Back

by Glenn Roberts, The Roberts Group and Fragrance Materials Association of the US

How many industry professionals reading this column have ever in their lives spoken to a government regulator? My educated estimate is only a few. Now, how many readers have ever spoken to an elected official? I would guess perhaps a few more.

Here we are, an industry facing what it believes to be a critical crisis affecting its future for all time, and only a handful of people have ever spoken with a regulator or elected official. Perhaps there is a connection. Could these things be related?

My theme is: the times are changing. The good times are gone and they are not coming back. Never again will this industry be able to flourish in as much privacy — if not secrecy — as it has until now. Never again will government regulators pay so little attention to this industry, and never again will our customers and our customer's customers take us for granted.

As for the latest news on European ingredient labeling, the fragrance industry will undoubtedly face the labeling of 26 ingredients. And there are many other pending regulatory and legislative actions we need to be aware of as well. For instance: the Chemicals White Paper and the new chemical regulatory Program that's forthcoming in Europe.

There is also a new policy from RIFM and IFRA that addresses how to examine the safety of essential oils. Specifically, it calls for the review of the constituents of essential oils for toxic and systemic effects, in addition to deciding on a case-by-case basis whether or not to review the constituents of essential oils for skin effects.

There is also a new paradigm at FEMA for evaluating the safety of naturals, which also looks at the constituents of the naturally occurring substance.

All industry professionals should also be aware of the new bioterrorism regulations from the US government, which are now under development. These regulations will require every single company that ships product for food use into the United States to register with the government.

Don't panic. The regulations aren't out yet, but it is something to be aware of.

On a more immediate note, everyone in the flavor and fragrance industry should all know that the US Drug Enforcement Agency is now saying that benzaldehyde, when present as a constituent of natural bitter almond oil, must be regulated and reported as a controlled substance.

So, to say the least, there is a lot going on. And, though we have been successful in limiting or forestalling many of these initiatives and many others which many of you may not have heard about (because they never got anywhere), there is a pervasive sense throughout the industry that change is inevitable — and not for the better.

How did we get here? What kind of a system produces such results? Is there any logic here? Adding complexity to the situation is the role of our customers, who often act to implement changes in anticipation of regulatory decisions. Often they take even stronger action than the regulators contemplate. We see this in the case of labeling, where a proposal to require identification of certain ingredients has already led to their ban by some companies.

My message here is a simple one: government regulators can quickly and completely put us out of business. Short of that, regulations can profoundly affect the market for essential oils. So we need to understand regulations and how to influence them. While confusing, irritating, and at times (seemingly) utterly baffling, regulations actually come from a predictable and understandable process.

The workings of the US FDA or the European Union Commission can be understood by the operations of a few basic rules. What I'm going to do is

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outline those rules and discuss how they have affected our industry in the last few years.

Inside the Minds of the Regulators

When I first studied government in college, I learned a simple rule about understanding the workings of large institutions. My professor taught us to ask ourselves, "Who wants to be part of that institution?" In other words, what kind of person wants to be a regulator working for the EU or the FDA? What are the things that motivate a person to go to work for an institution like that? If we can answer that question, we will then have a major insight into understanding how the institution as a whole behaves.

Just as perfumers like to make perfume, and flavorists like to make flavors, regulators like to make regulations. Regulators believe that government regulation of industry is an appropriate thing. Regulators are like school crossing guards — they believe they serve the public, and provide a needed community service. Thus, "industry self regulation" is to many regulators a code word for "let the business people do whatever they want." That's like saying to our school crossing guard let everyone drive as fast as they want whenever they want. So, the first thing we as an industry need to do is stop using code words that mean one thing to us and another thing to regulators and critics.

Regulators are generally no more good or evil than the general population. By and large, they are ordinary God-fearing people with families, pets and mortgages trying to do a reasonable job within the scope of their responsibilities, their resources, and their personal energies. They are more like you and I then any of us realize.

It is important here, then, to remember that flavors, fragrances and essential oils are minor issues for most regulators. There are approximately 20,000 people working for the US Congress, and not one of them is an expert on fragrance. There are thousands of people who work for the US FDA, and not one of them is a full time flavor or fragrance expert — let alone essential oils.

Similarly, there are thousands of people who work for the European Union Commission. Not one of them is a full time flavor or fragrance expert.

On the other hand, as ridiculous as this may sound, you must also ask yourself, how many full time government relations

> How many industry professionals have ever spoken to a government regulator or elected official? My guess is very few.

people work in the essential oil, flavor or fragrance industry? If you exclude the people for whom regulatory work means only interpreting regulations I think the answer you'll come up with is: very few if any.

A new factor to consider amidst all this lack of expertise is the dissemination of regulatory information via the Internet. A couple of years ago the US National Toxicology Program put out a draft report on methyleugenol. In past times, few people would have noticed such a draft report until it got peer reviewed, discussed and finally approved — a deliberately lengthy and cautious process. But now the draft reports go up on the Internet. In the case of methyleugenol, German regulators saw a draft and all hell broke loose.

I think, at this point, it's important to mention zealots. Zealots, we must all be aware, are dangerous people — even if the zealots are on our side. For example, we had a case in the United States of a new pro-business Assistant Administrator at the Department of Agriculture who said that school lunches no longer needed to be tested for salmonella, a serious food born illness. The press went crazy over this arrogant and unwise decision. That decision was revoked in about an hour and a half. As a consequence of that unreasonably zealous action it will be years and years before anybody can touch the now politically explosive question of salmonella testing in the United States — a setback that could have easily been avoided.

In Europe, of course, you have the added complexity of an evolving regulatory system in a multi-state environment. Certainly, Americans often forget how complicated and ever-evolving European processes are. In the United States, regulators for the most part understand and agree with the doctrine that the dose makes the poison. This doctrine contains within it the notion that exposure to materials (such as essential oils), at extraordinarily low levels, has an inherent safety factor built in. On the other hand, in Europe, the precautionary principal prevails. This principal somewhat uncharitably can be summarized as: if you have a question about something not only don't use it but ban it first and ask questions later.

The Industry's Responsibility to Educate

A key factor to keep in mind is that regulators usually believe that they understand the complexities of the industries they regulate. Sometimes that's true; often, however, it is not. This begs the question: if regulators do not understand the industry they regulate, whose fault is that? If we don't take the time to educate

regulators, if we don't speak for our industry, articulately, respectfully and convincingly, we have no one to blame but ourselves when government ignores our views.

We have to get used to the fact that other people see our products and our industry differently than we do. We all laughed when the member of the European Parliament from Berlin said that everybody knows naturals are the most allergenic of fragrance ingredients, but in a recent issue of *Contact Dermatitis*, well-known and highly respected dermatologist Walt Larson proposed a new fragrance mix of synthetics to identify people with fragrance hypersensitivity. He went on to propose, as a safety net, a fragrance mixture of five naturals — just to make sure that everybody with any kind of a fragrance allergy gets caught. (The five naturals he proposes are: jasmine absolute, ylang ylang oil, narcissus absolute, spearmint oil and sandalwood oil.)

How then can an industry like ours be effective in a regulatory environment? There are several basic concepts discussed herein.

Clarity of goals: To be effective in regulatory matters, you must be clear on your goal; you have to know what you are trying to accomplish. This may seem obvious, but you would be amazed how many times industries enter regulatory fights with a general sense that they want to make things better or make them not as bad as they might be, without a clear point that says, "This is the end we're reaching for."

I once worked on a project to pass a 30-page piece of legislation in the US Congress. There were two sentences in that bill that we knew we had to have — we would give up 29.5 pages to get those two sentences, and we would walk away from the bill if we didn't get those two sentences. Because we had that absolute clarity of purpose, we were very strong and very effective throughout the six-plus years it took to get that bill enacted.

We must have that kind of clarity, for example, in ongoing debates over labeling. Is our goal to defeat labeling? Is our goal to accept labeling and defeat the warning label? Is our goal to get the maximum thresholds? Is it our goal to keep the list at no more than 26 ingredients? Or is our goal to avoid reformulations? Or is it just to protect essential oils and if so how do we do that? These goals conflict with each other in varying degrees, and without agreement and clarity on our goals there is very little hope of progress.

We also have to know what is absolutely unacceptable to us. Here it is important that we tell the truth. Many of us have said that any form of fragrance labeling will kill our industry and is, therefore, unacceptable. The fact remains, I am told, that many fragrance companies are right now today submitting briefs without those 26 ingredients. Life goes on, even though we said it would end. What does that do to our credibility? The next time we announce that a proposed regulation is unacceptable and will destroy our industry it may well be that regulators will not believe us as much as we would like.

In order to establish goals and a list of unacceptable outcomes, we need to know who decides for our industry. This is another obvious rule, but a hard one to implement. It's particularly hard in the environment we face on labeling because we have multinational companies, several national associations, a regional association and we have an international association — in addition, of course, to IFEAT and EFEO.

Identifying an industry leader: Who decides for the global industry? Who sets our policies? Who apportions resources? Does that group of decision makers include scientists, political types and lawyers, as well as good representation from the commercial and management side? Are the decisions of that group of people reached quickly and articulated clearly throughout the industry? Are the decisions of that group of people accepted by everyone throughout the industry?

We also need to know with absolute clarity: who's going to make the decision in the government? For example: does the Scientific Committee on Cosmetology make the final decision? Does some mid-level staffer in the Commission make the

decision? Do the member states make the decision? What about the European Parliament? What about the Environment Committee? We need to understand where the focus of the decision-making is so that we can target our efforts in the most efficient way. As an industry, we must always speak with one voice following the guidance and policies established by the recognized industry decision makers. We can't have our scientists saying one thing, political people saying another thing and the commercial people saying a third. It just won't work.

Comprehending the process: It is imperative that we understand the machinations of the regulatory process. In Europe, the complex system is designed to balance interests of the member states, European parliamentarians and the Commission. Concern for public input seems secondary.

In the United States, the process is not so complicated, but adds a formal opportunity for public comment, something I have not seen in Europe. And woe to an agency that ignores those comments, for they can expect that all-so-American response of a lawsuit.

Understanding our opponents: We need to know what we are up against. We need to understand our opponents' strengths and weaknesses. Some opponents are reasonable people that you can sit down with at a table and work things out. You can get to know them and develop a common understanding. There are other opponents (zealots) who are just out to "get" us and there is no point in wasting time trying to make peace with them. With this second group of people, the only thing to do is line up your troops and prepare for a knock-down, drag-out fight.

Nurture political relationships: Just as we nurture customer relations, we need to nurture relations with regulators, journalists and anyone else who can affect our ability to conduct our business. A member of the FMA board taught me an important lesson years ago: nobody likes to do business with strangers. It's true in business, it's true in politics and it's true in regulation. We can't just show up having been invisible for years and suddenly announce that regulators don't understand our industry and don't understand the implications of what they are trying to do. If that regulator can affect you, you need to develop a long-term, stable relationship with him or her — a relationship that's secure enough that, on any given issue, you can go into the regulator's office and say, "No, what you've proposed is wrong and unacceptable and this is why."

Because we are a small, secretive industry with a relatively low visibility politically, we need to work very carefully to form coalitions to expand our strength. Our industry has worked very hard in the United States, for example, in having good relations with CTFA and the SDA, and the folks in Europe have also worked hard to have good relations with COLIPA and AISE.

> If regulators do not understand the industry they regulate, whose fault is that?

On top of this, we need to be realistic in a political environment. For instance, with BSE and foot and mouth disease and God knows what else in Europe, regulators there feel special pressure to be rigorous. This precautionary principal makes the basic good science that we all know and rely upon suspect. Thus, we need to modify our expectations and goals to the political environment in which we live and work. This is particularly hard for our multinational industry, because what is politically feasible in one country may not be politically feasible in another. For example, in Europe we are struggling under the burden of the precautionary principal while in the United States we have so far escaped this burden. So what is a realistic accomplishment in the United States, where there is no precautionary principal, may not be a realistic accomplishment in Europe. It's important for both the Europeans and Americans to remember this fact.

We also need to be creative; we need to come up with new ideas and new solutions for old problems. We need to use our political influence sparingly, but appropriately and forcefully when needed.

The European segment of the industry has done a superb job in a short period of time generating political support within the European Parliament. Hopefully, this effort will be the start of long-term effort at building a permanent network of political relationships.

But we cannot afford the time, money, energy and heartache of building a new political network every time a crisis emerges. All this hard work is for naught if we, as an industry, are not prepared to devote significant amounts of time, money and energy to defending our regulatory status and to defend the integrity of our products. Without such a commitment, we are in for a sorry several years.

Strategies in action: Let me give you a couple examples of how these efforts can be successful. In the United States we faced a significant threat from advocates of multiple chemical sensitivity (MCS). It took our industry a while to figure out how to work together, but in the end we put together an excellent program. In partnership with CTFA, The Fragrance

Foundation and FMA, we found (after a few mistakes) an excellent consultant who has largely neutralized the MCS movement in the United States. And, going back to my point about adequate resources, I have to say that it cost us several millions of dollars to achieve this result. We in the US industry continue to pay for ongoing efforts even though the project is largely wrapped up.

MCS is also an issue in Canada where the Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA) is leading the effort. Again we worked hard to build a coalition. FMA made some financial resources available as well as the work of our US consultant. This has been a big help to the CCTFA. In the end, what turned it around was the CCTFA becoming so infuriated at a ridiculous proposal by the Canadian Mounties to imprison a teenager for wearing a certain hair product that he lost his temper and said in public, "This is crazy!" Because the actions at issue were crazy, the statement by the president of CCTFA was a breath of fresh air that has largely, but not entirely, blown the MCS movement out of the water in Canada.

Conclusion

Now, having said all this, what does this mean for you, the dealers and users of essential oils, in this larger political and regulatory battle? First of all, as I hope all of my fellow industry professionals have come to understand in the last few months, government regulations are clearly relevant to our professional success and future. Government regulation is not just an occasional burp on one's computer screen demanding that a material here or a material there no longer be used. Government regulation has the power to profoundly and permanently change the nature of the industry that we all enjoy so much.

We in FMA welcome the new political activity of EFEO and the French and the American Society of Perfumers. Many members of these and other organizations have played a critical role at important points over the last several months. I personally congratulate all for their successful efforts. I plead with my colleagues to not retreat from this state of activity. We need everyone's ongoing interest, energy and creativity to defend the interests of this industry in Europe, the United States and around the world.

I don't know where the next challenge to our industry will come from; it may be in Europe, it may be in the United States, it may be in Asia or it may be in South America. I do know that more challenges will come. I know that in the future we will look back on these times as the turning point. I hope we see it not as the turning point that marks the beginning of the end of our industry, but as the turning point that marks the beginning of a heightened political sensitivity and willingness to role up our sleeves, invest resources, and defend an industry that has brought taste, beauty and enjoyment to millions of people for hundreds of years.

Indeed, the regulatory and political environment has changed forever. The days when the flavor and fragrance industry can be isolated, unknown, unvisited and unexamined, laboring away quietly, are gone — they are gone forever and they are not coming back. We must be strong, vigilant and aggressive. We welcome everyone's help, support and partnership. Together we can build a strong future for our industry.

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