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Taking the Sting Out of No-Tox®

By Heidi Tolliver-Nigro

Have you ever wondered why so many of this industry's largest and most respected ink manufacturers do not manufacture their own direct food contact inks? Take just a few minutes to talk to Mike Gettis, General Manager of Colorcon, a manufacturer of No-Tox® inks and coatings, and his team and you'll wonder no more.

Colorcon, a division of Berwind Pharmaceutical Services Inc., is a global provider of pharmaceutical technologies and a variety of specialty chemicals, including No-Tox inks, for related industries. Its No-Tox inks are used for packaging, labels, promotional inserts, printed coupons, and similar items that directly contact food and confectionery products.

Because of its expertise, Colorcon does outsource work for many of today's top ink makers, as well as smaller companies, who cannot be named due to confidentiality agreements.

As they sat in the conference room of Colorcon's new manufacturing facility in Chalfont, PA, Mike Gettis and Jerry Napiecek, Manager of Quality Assurance, Technical Services and Regulatory Affairs; Bonnie Kinsey, Senior Sales Coordinator; and Richard Podhajny, Ph.D., Manager of Technology, New Product Development and Quality Control; discussed the little-understood complexities of No-Tox Products with *Ink Maker*, as well as the benefits of moving into the new facility.

JUST SHOOT ME

If you want to understand the complexities of No-Tox manufacturing, it can be summed up in one word: regulation. Whenever ink comes into contact with food, the U.S. Food and Drug Administration (FDA) gets involved, and if you thought today's environmental regulations were strict, wait until you try the regulations for direct food contact!

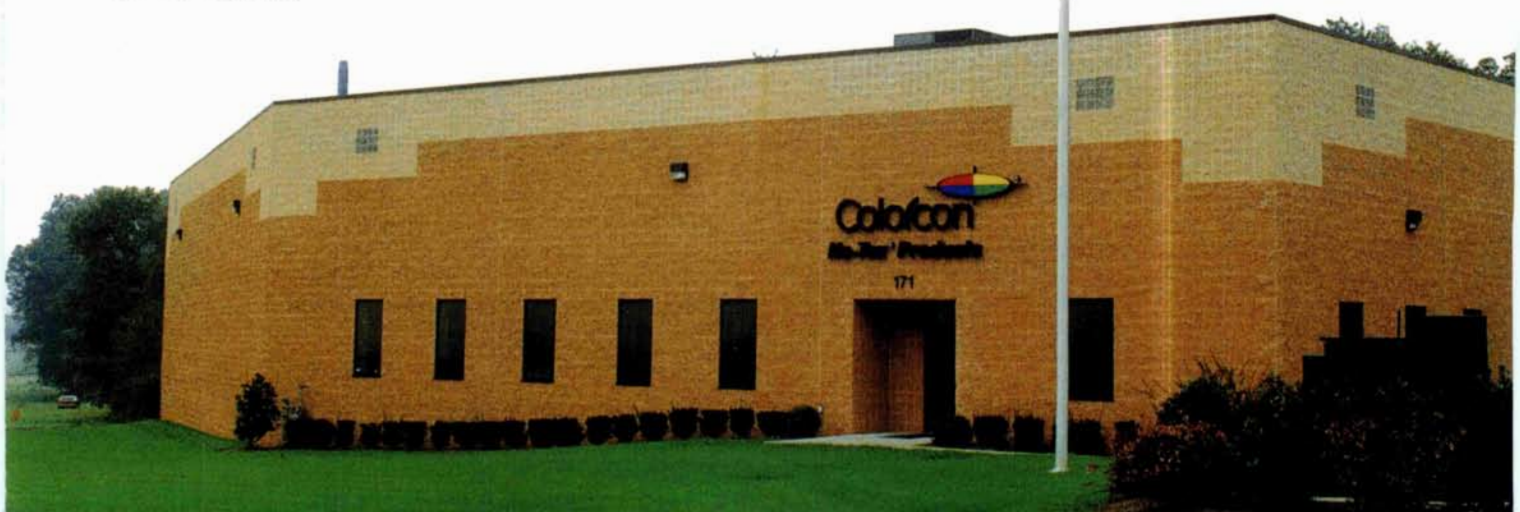
Everything is regulated, from the raw materials to the shipping containers, to the manufacturing processes, to the samples that must be collected and verified, to the seas of paperwork. Even the rodent control devices used on the plant floor must be FDA-compliant.

Making matters even more challenging is that the regulations—and the raw materials to be used—vary depending on the end-use application. In its Guidelines for Direct Food Contact Inserts, for example, Colorcon details the kind of information required to properly develop an application-specific No-Tox ink.

This information includes…

- Type of product
- Whether the product is dry, wet, or greasy
- Coupon insertion and storage conditions (for example, the coupons are hot when inserted, cooled to room tempera ture; or inserted hot, then flash frozen)
- End-use conditions, such as abrasiveness and shelf life of the product
- Colors to be used (bleed resistance varies by color)

(Left to right) Richard M. Podhajny, Ph.D., Manager - Technology, New Product Development and Quality Control; Bonnie L. Kinsey; Senior Sales Coordinator; Lynn G. White, Customer Service Coordinator; Gerald L. Napiecek, Manager - Quality Assurance, Technical Services and Regulatory Affairs; and Mike Gettis, General Manager.



These and many other factors affect the raw materials that will be put into the product. The list of approved raw materials can change on a daily basis, so staying on top of the changing federal regulations is a job in itself. "To get a sense of the complexity, you can view Title 21 on the FDA Web site," says Gettis. "If you were to request a printed copy, you would actually receive three manuals that are each about one-inch thick. Plus, I receive daily updates to review for any last-minute changes."

A DIFFERENT TOOL SET

Few of the raw materials used in conventional inks are used in No-Tox inks. Colorcon is often working with an entirely different—and more expensive—set of raw materials that have undergone rigorous FDA testing.

Wastewater Storage Tank

"We cannot use most conventional pigments in our inks because they aren't approved by the FDA," says Gettis. "For example, there are different grades of titanium dioxide—a commercial grade, a food grade, and a pharmaceutical grade—and we cannot use the commercial grade in direct food contact applications. So knowing the grade of titanium, the purity, and the supplier that produces it are all critical. This can get tricky when working with overseas suppliers because different countries have different standards."

All the raw materials have to be sampled and specifically tested. Although they come with a certificate of analysis from Colorcon's suppliers, Colorcon does its own testing and analysis, as well. This is why it can provide a written guarantee with each order.

This is important—just because ink is approved for one direct food application does not mean that it is approved for all of them. According to Gettis, this is a common but dangerous mistake made by ink manufacturers new to manufacturing direct food contact inks.

"Some companies may mistakenly take an ink for a dry application and put it into a wet and greasy application, thinking that FDA-compliant is FDA-compliant, but it doesn't work that way," he says. "Title 21 has limits on certain raw materials based on their use. For example, there could be migration in wet and greasy food that would not occur in dry food, so the raw materials are quite different."

This requires knowing the true moisture, grease, fat, or oil content of various foods. Colorcon points out that some so-called "dry" products may actually contain fairly high levels of moisture or grease such as "soft" pet foods, breads, cookies, tea, and coffee.

THE PAPERWORK! THE PAPERWORK!

Paperwork that goes along with all that regulation is mind-boggling. The paper trail for orders alone requires its own fleet of filing cabinets—not counting the paperwork for regulatory, technical services, and quality control. At Colorcon's new facility, entire sections are dedicated to storing paperwork, as well as storing raw material and finished product retains. Colorcon keeps all of its paperwork in electronic and hard copy forms.

Even the shipping and warehousing of raw materials is closely monitored. All materials must be shipped in non-recycled, tightly sealed containers. "If a raw material arrives in a container that isn't completely sealed, we refuse it," says Napiecek. "That doesn't happen very often because a supplier who sends us an unsealed container only makes that mistake once."

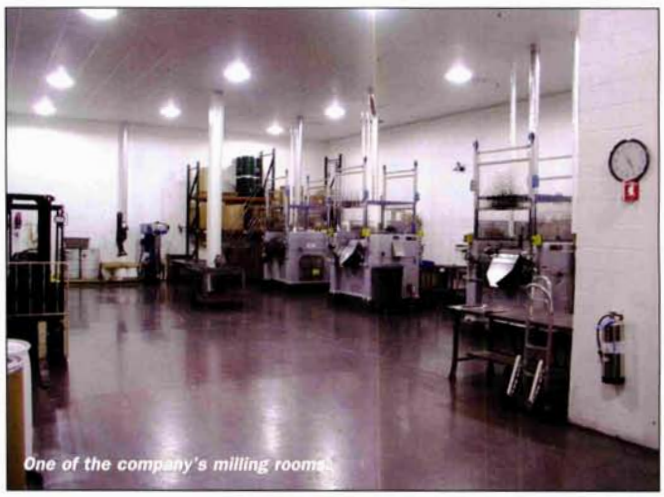
Everything is tracked and recorded, down to the movements of the product within the facility itself. Colorcon even tracks and documents internal labels that go under the batch sheets, labels on the containers of ink, and labels that are put over those labels when the product is packaged for shipment. "We keep track of everything and maintain copies with each order," says Napiecek. "Quality control information has to be present for each batch. We keep all the batch records and all the QC certificates of analysis. The FDA does not require that we submit them, but we must maintain those documents in the event that there is a problem."

And there have been problems. There have been instances when food manufacturers have discovered contamination in their food products. In these instances, Colorcon has been called upon to provide documentation of their raw materials and manufacturing process. In these cases, Colorcon's meticulous recordkeeping continually proves that any contamination must have come from another source. But not everyone has been so lucky. Gettis and his team remember a food manufacturer—not a Colorcon customer—whose ink supplier was not able to provide the proper documentation and was forced to do a large-scale product recall.

For the first year, paperwork is kept at Colorcon's facility. At the end of the year, data is transferred to microfiche at an outsource facility. Physical samples are stored for 2 1/2 years, along with their associated raw materials. Hard copy paperwork is kept for seven years. Colorcon's computer systems are backed up nightly. Needless to say, security is tighter than at the average ink manufacturing plant. Employees enter only with card access and all visitors are required to sign in and wear badges.

WHO WANTS TO BOTHER?

Considering the size of the No-Tox market—which is relatively small compared to commercial and packaging inks market—these are huge headaches for the average ink company to deal with. Plus, most ink manufacturers are used to dealing with drum quantities, not a few gallons



One of the company's milling rooms

here and there. Not to mention that FDA regulations require clean-up procedures in-between each batch. All of which drive the appeal of outsourcing.

"Many ink manufacturers gang batch, from lighter to darker, just doing a rinse in-between," says Napiecek. "But we have to clean each piece of equipment even if we are manufacturing 20 pounds of ink. We can manufacture black ink in a horizontal mill, then get an order for a similar product in white. We have to do it in the same mill. Imagine the clean-up procedures that are involved! But even on white-to-white batches, we still have to strip the entire mill, a four- hour process."

But what, for most companies, is an unusual hardship is an everyday reality for Colorcon and its divisions. Colorcon's core business is the Phar-

maceutical division, which manufactures the pharmaceutical coatings and inks used on pharmaceutical tablets. The Food & Confectionery division serves up edible products to the food industry, including inks that can be printed directly onto pieces of candy. The No-Tox Products Division gets involved in a wide variety of types of products, ranging from semipermanent adhesive tattoos (where skin contact is an issue), to the inside of frozen food packages that need to go from freezer to microwave, to medical devices like syringe barrels or catheters that will be inserted into the body.

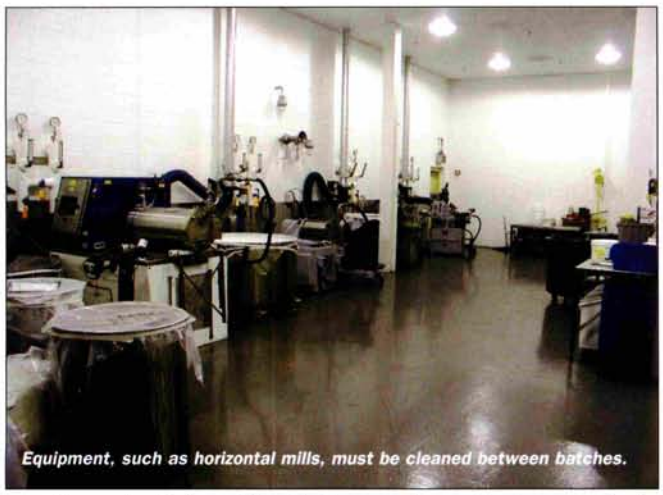
This wide range of experience is extremely helpful in an environment that is not only complicated, but also constantly changing. It is not unusual for raw materials that have been FDA-approved for years to change status. When this occurs, Colorcon must find new raw materials that are appropriate for each given product. The company receives daily updates to the Federal Register, but for an ink company whose primary business is not direct food contact inks, these kinds of changes can slip by them.

Adding to the complexity is that No-Tox ink producers must know as much about substrates as they do about ink. Colorcon recently ran into a situation in which a formulation was suitable for polyolefin film, but not for polyester. This is why Colorcon carefully evaluates the substrates as well as the raw materials for each ink. "These are areas in which traditional ink companies can make mistakes," says Gettis. "They may use the wrong polymer for the wrong substrate—not deliberately, but they just don't know."

This can be especially scary in this age of downsizing and right-sizing. "With fewer and fewer people to deal with these issues, traditional ink companies trying to manufacture direct food contact products have to rely on their suppliers," adds Gettis. "And what happens if they get the wrong information from the supplier? They are in trouble."

EFFECT ON COLOR MATCH

Although Colorcon can protect customers from litigation, there are limits to what No-Tox inks can do. Notably, because of the acute requirements on raw materials—including pigments—it may not always be possible to get an exact color match.



Equipment, such as horizontal mills, must be cleaned between batches.

"We use the Pantone Color Guide as a reference book, and we try to match as many Pantone colors as we can," says Gettis. "But it's not always possible. Customers say, 'I need Pantone 185 Red,' and we give them the closest color match the raw materials will allow. But because the number of pigments approved for direct food contact is very limited, customers must be realistic about what those colors can do. In some cases, we can hit the color on the nose. In others, we can't. But we can generally meet the expectations of the end-use customer."

There are colors that cannot be produced in direct food contact versions, however, including true metallics and all fluorescent colors.

To be able to provide customers with an accurate representation of what the final color will look like, Colorcon does extensive testing on a variety of substrates, including test batches of all custom inks. "We do this testing both to protect ourselves and our customers," says Podhajny. "We don't accept returns unless there is a quality issue."

Because of the exacting raw materials requirements, the development of No-Tox inks is more expensive than traditional inks. When it manufactures a solvent-based flexo ink, for example, Colorcon may use solvent that is two to three times the price of traditional solvent because it's food or pharmaceutical grade.

An employee handles quality contol tasks.

Colorcon's inks also tend to be more heavily pigmented than commercial grade inks, further adding to the cost. "The FDA allows us to use only certain pigments for direct food contact," says Napiecek. "From there, we develop formulations to get reasonable strength and performance characteristics, but we may have to substitute much more pigment. While process ink may contain 10% pigment, our No-Tox products contain more like 20%."

NEW FACILITY BRINGS IT ALL TOGETHER

The new 22,000-square-foot-facility, which Colorcon moved into at the end of May, has dramatically improved the process. Not only does it provide room for expansion, but it has allowed the company to greatly streamline its manufacturing processes, further improve its safety and environmental conditions, and speed up turnarounds.

In the past, the No-Tox division was housed in the same building as the Pharmaceutical and Food & Confectionery divisions, which have different manufacturing, regulatory, and customer requirements. Often, the turnarounds on these products are much longer, so having a dedicated facility has allowed Colorcon to dramatically streamline its processes.

"Before, our other divisions were set up to get product out the door in one to two weeks," says Napiecek. "That was fine for their businesses, but our customers were more demanding. Yet we were restricted to the same processes. Now, we are not restricted by the other divisions' standard operating procedures, so we are able to get product out the door much faster while still being in full compliance with the cGMP [current Good Manufacturing Practices] for our business."

How much faster is turnaround these days? The company has experienced a whopping 60% improvement. It has also experienced a 14% increase in "first time quality measurement"—or how many batches need zero adjustment before leaving the milling facility. The new structure has also allowed Colorcon to cross-train its employees in different departments, from quality control to manufacturing, so even when key employees are off-site, the work can continue undisrupted.

In part, these improvements are due to better communication among the parties. Instead of being spread out across two facilities, all of the No-Tox employees are now within virtual shouting distance of one another. "Just moving materials from one location to another used to cause us to lose half a day," says Gettis. "Or when we needed to ask a question, we'd leave messages and play phone tag. Now, the materials are delivered

right where they need to go. And if an issue comes up, we just gather all the primaries together for a meeting and—bam!—a decision gets made in an hour instead of three days."

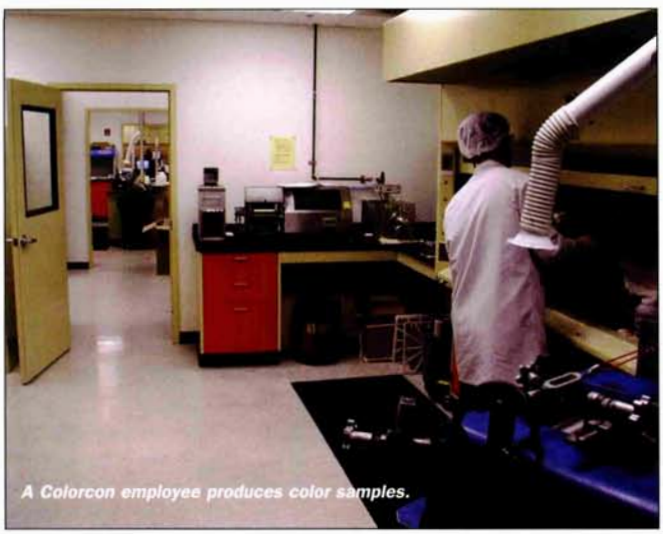
Colorcon has also discovered a nifty trick for speeding up administrative tasks—eliminate the "in" baskets so that paperwork has to be handed to a live person. "You wouldn't believe how much time that saved!" exclaims Podhajny. "With all the automation in this industry, it's amazing how much time we lose through little inefficiencies like that."

The result? Super-fast turnarounds. The company recently received one order for 200 pounds of custom No-Tox offset ink that had to be out the same day. "We got the order at noon, and we had it three-roll milled, tested, packed and in shipping by 3:30 p.m," Napiecek says.

This is particularly impressive when you consider that this custom manufacturing goes on for even the smallest of batches. While most ink makers may custom-manufacture a batch of 200 pounds of ink, Colorcon regularly does it for batches of 20 pounds of ink. Since all of Colorcon's inks are made from scratch—never using flushes—this is a tall order. And FDA regulations require that it do a full clean up of its milling equipment between each batch.

WHY NOT OUTSOURCE?

When you look at all of the costs and complexities of manufacturing

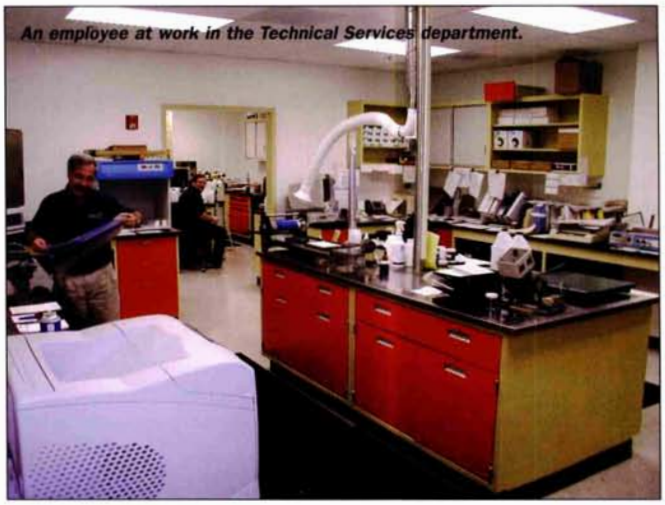


A Colorcon employee produces color samples.

No-Tox ink, it's no wonder that many ink companies choose to outsource this work than to take on these responsibilities themselves.

"No-Tox products require skills, manufacturing processes, regulatory compliance, and many other factors that are way outside traditional ink companies' core competencies," says Gettis. "But that is our business. There are, of course, some ink companies that are still trying to do it all themselves. But they don't have to."

When customers have never purchased No-Tox inks, they are typically stunned by the cost estimates, which can be three to 10 times that of conventional ink depending on the ink type and volume. That's why the first part of Colorcon's customer service responsibilities is to explain exactly what they are getting and what they are paying for. "Usually,



An employee at work in the Technical Services department.

when I give them a price, there is just dead silence on the end of the phone," Bonnie Kinsey jokes. "Then they recover and say, 'Wow! That's a lot.'"

But then she explains all of the factors that go into the manufacture of FDA-compliant No-Tox ink, from the expensive raw materials and exacting manufacturing procedures to the extensive paperwork and monitoring that are required. In its detailed customer information packet, Colorcon includes a sheet detailing a cost comparison between No-Tox products and conventional inks for a typical coupon application so customers can see it broken down by the numbers.

"Sure, companies can forgo using No-Tox inks like ours because of the cost, but if the customer wants a written guarantee, they won't have one," Kinsey explains. "And there have been instances where that has come back to haunt them. Or they can try to manufacture No-Tox inks themselves, but it's often a case of 'you don't know what you don't know.'"

While Colorcon encourages outsource customers to audit their own facilities and cost to determine the ultimate savings from outsourcing, Podhajny points out, "We're getting new customers all the time. And in all the years we've been in business, we've never had any customers go back to doing their own production." He adds that, while some ink companies are still manufacturing their own food contact inks, they would likely save money by outsourcing; they just don't know it because they have no idea how much their own internal cradle-to-grave manufacturing really costs them.

But it's not just costs. Without a doubt, nobody is having as much fun producing direct food contact inks as Colorcon. "I love this job," says Napiecek. "One minute I am talking to a printer about promotional inserts for a cereal box and the next I am talking to a Ph.D. researcher about printing catheters to be inserted into the body. You just never know what you'll be doing when you come in here."

"And it helps when you have such a close-knit group of people," concludes Kinsey. "The majority of our staff have been here 10-15 years, and they are all truly interested in seeing this business succeed. If a manager sees someone overburdened with work in the shipping area, for example, they will go out and help. There are no walls between departments. That is one aspect of the value of Colorcon that the customer never sees."

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