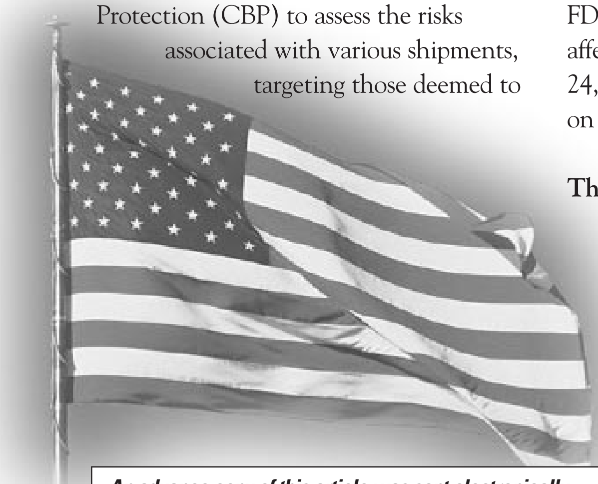
THE ONTARIO Agri-Food Exporter

Winter 2004

THE US *Bioterrorism Act: What it means for your business*

As of December 12, 2003, new border regulations are in place regulating the flow of food and beverage products into the United States. These regulations, imposed under last year's US Bioterrorism Act, give the Food and Drug Administration (FDA) new authority to protect the US food supply from deliberate and accidental contaminations. The regulations are intended to allow FDA and the Bureau of Customs and Border Protection (CBP) to assess the risks associated with various shipments, targeting those deemed to pose the highest risk for adulterations, while moving low-risk shipments through the system quickly. In implementing the regulations, FDA has consulted widely with importers and exporters domestically and internationally, receiving over 450 submissions during the initial comment period. There is still an opportunity for Ontario food companies to provide comments to FDA on how these regulations may affect their business until December 24, 2003 (see "How can I comment on the regulations," page 8).



An advance copy of this article was sent electronically to all those subscribers with a current e-mail address on file with the Export Marketing Unit.

The new regulations

Two key components of the regulations that affect Canadian exporters are first, a requirement to register your food facility with FDA and, second, a requirement to notify FDA of each import (by food type, not shipment) prior to their arrival at the border.

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New notification rules for US Customs

The FDA's new prior notice rules are not the only new rules Ontario exporters need to know about. As of December 5, US Customs and Border Protection (CBP) has also instituted new rules requiring advance electronic notice of all shipments moving across US borders. These new rules are separate from and in addition to any prior notice required by FDA or USDA for food products.

Essentially, the rules require electronic transmission of key cargo data to CBP before shipments arrive at the border. The information will be screened through CBP's Automated Targeting System, which will review shipment data against law enforcement and commercial databases, as well as strategic intelligence. Low-risk shipments will be expedited, while potentially high-risk shipments will be targeted for further inspection.

Customs brokers will be able to provide the CBP electronic notification on behalf of Ontario shippers. Ontario companies should discuss the new requirements with their brokers to ensure that adequate prior notice is being provided.

Under the regulations, shipments via truck must provide electronic notice 30 minutes before arrival in the US for shipments covered under the FAST (Free and Secure Trade) program. For non-FAST shipments, one hour prior notice is required. Rail shipments require 2 hours notice; air and courier, 4 hours; and maritime vessels require 24 hours notice. For more information, please refer to www.customs.gov, or consult with your customs broker.

OMAF *trade events*

Increase your export sales by participating in an OMAF Export Marketing Unit trade-related event. Our seminars, incoming and outgoing missions and trade show participation are all geared to developing and maximizing export opportunities for Ontario companies. Through them, we can help you generate export sales, get in-market exposure, meet buyers face-to-face and gather first-hand information about export markets. If any of these events fit your strategies, contact your client account officer for further details on how your company may participate (see the contact list on page 7).

PROFIT, February 10-11, 2004. Toronto and Buffalo. PROFIT (Program to Raise Ontario Foods International Trade) is a hands-on two-day orientation on exporting to the United States, covering the basic requirements for food exporters. The program features 15 speakers, on topics such as export financing, product labeling, trademarks, US tax laws, US food brokerage, US food distribution, US Food & Drug Administration regulations, US Customs and US customs brokerage. This unique and affordable course focuses exclusively on food and beverage exports. It is ideal for skills upgrade and development for new marketing staff, inside and outside sales staff, shipping and logistics staff, and marketing/sales support staff.

Street Smart, Spring 2004, Toronto. OMAF is working with a major US customer to finalize our next Street Smart program. The one-day Street Smart session begins with short presentations from representatives of the US customer, with the bulk of the day spent in tabletop presentations. This session is geared to export-ready Ontario food companies. Contact your client account officer for participation information, or call the Street Smart hotline at 1-877-406-4754.

Foodex Japan 2004, Tokyo, March 9-12, 2004. Foodex is Japan's premier annual food promotion event and the largest food trade fair in Asia. Foodex 2003 attracted approximately 2,300 exhibitors from 78 countries, and 98,000 visitors representing Japan and Asia's major food and beverage industry players. Exhibitors in the Canadian pavilion reported excellent results. At Foodex 2004, OMAF's Ontario showcase booths within the Canadian Pavilion will provide Ontario exporters with a high-profile opportunity to display their products and interact with potential customers. For more information on this event, contact your client account officer, or Amos Tin, geographic specialist for Asia, at 1-888-466-2372, ext. 63489 or via e-mail at amos.tin@omaf.gov.on.ca.

Food & Hotel Asia 2004, Singapore, April 20-23, 2004. FHA is the leading sourcing ground for professionals in the food and hospitality industry in the region, with a record-breaking 44,000+ attendees participating in the last show in 2002. FHA is made up of seven specialized events that encompass all the significant sectors of the food and hospitality industry. It includes FoodAsia, Wine&SpiritsAsia, BakeryAsia, HotelAsia, HospitalityTechnology, HospitalityStyleAsia and the FHA Culinary Challenge. OMAF has reserved space for Ontario exporters within the Canadian Pavilion, which will provide Ontario exporters with a highly visible presence at the show. For more information on this event, contact your client account officer, or Amos Tin, geographic specialist for Asia, at 1-888-466-2372, ext. 63489 or via e-mail at amos.tin@omaf.gov.on.ca.

This cookie is going south this winter.

What are your products doing?

Ontario exporters are experiencing unprecedented success in selling their products into the US market. Make sure your company is positioned for success with OMAF's PROFIT seminar, a unique and affordable hands-on two-day orientation on exporting to the United States, covering the basic requirements for food exporters. PROFIT focuses exclusively on food and beverage exports,and is ideal for skills upgrade and development for new marketing staff, inside and outside sales staff, shipping and logistics staff, and marketing/sales support staff.

Why should you participate?

- **Save time.** You'll make contact with key export representatives, from OMAF, Export Development Canada, US Customs and Border Protection, US Food & Drug Administration, brokerages, transportation companies and more. Those contacts will save you time—and possibly money—in the future.
- **Build your industry network.** You'll meet other new exporters, as well as new staff of established exporters.
- **Keep up-to-date.** You'll hear the latest on key exporting issues, and being better informed will help you reduce the risk of export headaches. You'll hear from 15 speakers, covering topics such as export financing, product labeling, trademarks, US tax laws, US food brokerage, US food distribution, US Food & Drug Administration regulations, US Customs and US customs brokerage.

A featured component of the February session is a morning spent with the US Food and Drug Administration as they give an overview of the new Bioterrorism regulations that affect food and beverage exports into the US, starting December 12,2003.

Take part in OMAF's highly-regarded PROFIT program, taking place in Toronto and Buffalo February 10-11. Make sure your products head south too! Contact your client account officer for details (see contact information on p. 7).

IN GOOD COMPANY:
Tapping the snack market

This Weston, Ontario-based company had 25 years of experience in producing pita breads. But launching a new product meant tackling an unfamiliar market

The company: Handi Foods Ltd., a manufacturer of pita breads and snacks under the brand Mr. Pita

The challenge: Crack the lucrative—and tough—US snack market with a new snack product

How OMAF helped: Street Smart seminar participation allowed company to meet key buyers; contact with OMAF client account officers provided the company with key market intelligence.

Words to grow by: "Because of OMAF's efforts, we've been availed of the the opportunity to make those face-to-face contacts that result in export success."

Alex Younes calls it his "baby project." He might just as reasonably call it his company's next big idea.

Handi Foods Ltd. is no stranger to successful big ideas. The company has become one of Ontario's premier manufacturers of pita breads under the brand name Mr. Pita, creating a market for their products while establishing one of the strongest brand identities in their niche. Their trademark checkerboard logo is synonymous with pita breads. But when the company developed the idea for Pita Puffs, Mr. Pita's established identity alone wouldn't be enough to make the product a success.

"We developed this concept of the baked not fried snack ten years ago, but back then, the concept was too novel," says Younes. "The second challenge for us was that the snack world is different from the bread world, and tackling that market meant learning a whole new business. We met shut door after shut door, and without slotting money to get our product onto shelves, the concept just couldn't take hold."

An early foray into the US vending machine market looked like it would yield success, but after early growth, established competitors within the field managed to push Mr. Pita out of the machines. "We thought, what do we do next? And then we realized that the way to launch a snack was to appeal to kids," says Younes. The company launched a strategy of targeting school systems with their sensible, healthier snack. This time, the timing was right. The US Senate had mandated that school boards would be required to cut back on snacks high in saturated fats, and that meant that Handi Foods was positioned to offer a benefit that few other snack foods could: a crunchy, appealing snack that kids would enjoy, coupled with a healthier formulation.

The next challenge? "Our size wasn't right," says Younes. "Based on the price point school boards could afford, we had to resize our bag from one ounce to 0.6 ounce. That way, we could stay within their budgets, give the buyers the nutritional buy that they needed and still operate with a fair margin for us." It sounds simple enough, but the resulting sales to the New York City school board and systems in nine other states took time and concentrated corporate effort.

Schools weren't Mr. Pita's only target. The company realized that its product fit nicely with the Jenny Craig diet program, and established a private label deal to supply the product to Jenny Craig in the United States and Canada through its sales representative in the US. It's a deal that resulted in the sale of one million one-ounce snack packages.

"Perseverence was key, because for the first seven or eight years, our Pita Puffs were a great idea in search of the right market," says Younes. "But eventually, the right pieces came together."

Younes credits OMAF with helping to put some of those puzzle pieces into place. On Mr. Pita's complete product line, OMAF has been instrumental in facilitating relationships with major US buyers. "The Street Smart program is outstanding," says Younes. "At the Safeway session, we were able to make direct contact with the buyers, and now we're working with a broker who deals with Safeway to complete that sale. Because of OMAF's efforts, we've had the opportunity to make those face-to-face contacts that result in export success."

Get Street Smart!

It's a familiar story: your company has a terrific product. You think you're a great fit for a major US retail chain. But getting time with the right buyer can seem an impossible task.

That's where OMAF's highly rated Street Smart programs come in. We bring the buyers to you!

What's in it for them? The opportunity to meet with dozens of prequalified, export-ready Ontario companies in our intensive—and sales-proven—table-top sessions.

What's in it for you?

- Hear what key retailers are looking for—right from their top buyers.
- Get the inside scoop on the retail culture of your targeted buyer. Your access to key decision-makers throughout the day will allow you to gather strategic information about price points, packaging and labeling requirements, distribution issues and more—all information that can help ensure the success of your exporting efforts.
- Get up-to-the-minute intelligence on market trends and retailer needs. Retailer presentations identify the company's targeted areas for the upcoming year. You'll find out which items the retailer is focusing on, and what types of products and flavours regional customers are asking for. You'll learn about retailer concerns and policies, such as HACCP requirements, and more.

Watch upcoming issues of this newsletter for details on OMAF's next Street Smart session, and position your company for export success!

The US Bioterrorism Act…

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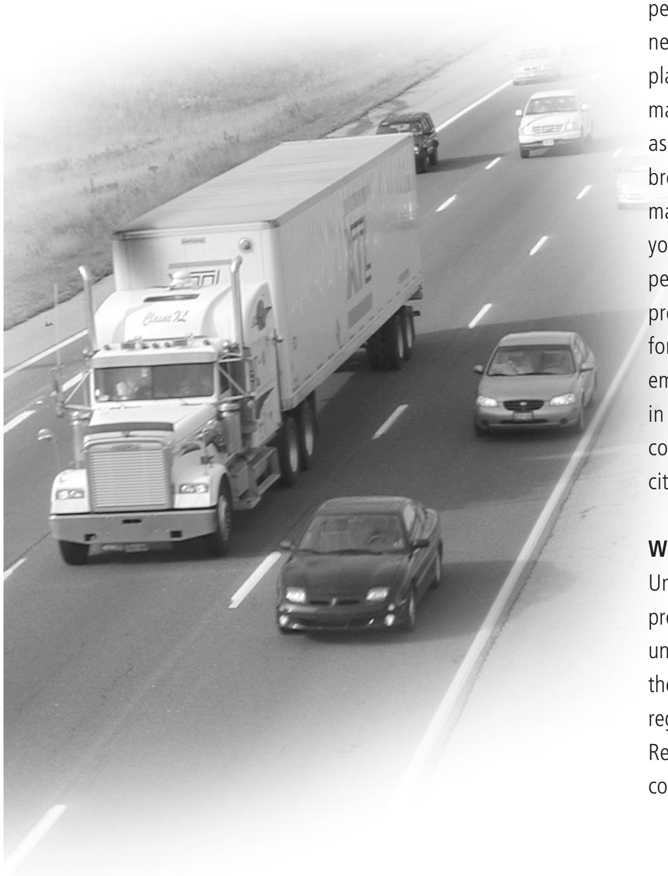
Food facility registration

As of October 16, FDA has had in place an electronic registration system for foreign and domestic food facilities (available online at http://www.fda.gov/furls). Food facilities covered under the regulations were required to register by December 12, 2003. The site is accessible worldwide, around the clock. The registration is a one-time requirement (though changes to facility information must be updated within 60 days of the change taking place). According to FDA, the process should take less than an hour to complete if the facility has its paperwork ready, and registrants will be instantly provided with a unique registration number. There is no charge for registration. (Registrations will also be accepted by fax and regular mail, but confirmation of registration will take significantly longer as FDA personnel must individually input company information and will automatically reject applications that are incomplete or illegible.)
FDA expects 420,000 facilities to register.



Do you need to register? All food facilities that manufacture, process, pack or hold food for consumption in the United States by humans or animals must register. Farms (under certain conditions), restaurants, other food retail establishments, some nonprofit food establishments, certain fishing vessels and facilities such as meat and poultry slaughterhouses that are regulated exclusively by the US Department of Agriculture are exempt. (USDA regulated producers already participate in a USDA registration and prior notice system.) Some foreign facilities are also exempt, if the food from the facility undergoes further processing or packaging by another foreign facility before it is imported to the US.

What is a US agent? As part of the registration process, each non-US facility must designate a US agent. Your US agent functions as the primary link between your registered company and the FDA. Your US agent must have a permanent residence in the US (but is not necessarily a US citizen) and/or operate a place of business in the US. The agent may be an individual, firm, company or association. For instance, your customs broker could act as your US agent, and many are offering this service. However, your agent does not have to be the person registering your company or providing prior notice of importation. As a foreign facility, you may also designate an emergency contact of your own choosing in addition to your agent. This emergency contact does not need to be a resident or citizen of the US.

What happens if you do not register? Under the Act, failure to register is prohibited. Imported food from an unregistered foreign facility will be held at the port of entry until the facility is registered, or refused entry into the US. Registration is a must for any Canadian company seeking to do business in the US.

How do you register? Online registration is strongly recommended, and may be completed at www.access.fda.gov. If you require assistance, the Online Registration Help Desk may be reached by calling 301-575-0156, by faxing 301-210-0247 or by emailing furls@fda.gov. The Help Desk will be staffed on business days from 7 am to 11 pm US Eastern Time. If a facility does not have reasonable access to the Internet, a paper copy of the form may be obtained from FDA by calling 301-575-0156 or by mailing a request to USFDA, HFS-681, 5600 Fishers Lane, Rockville MD 20857, USA.

The FDA suggests that registration should take less than one hour to complete. It has been the experience of previous applicants, however, that input of data can take longer, and that the system times out thereby losing previously input information. Our suggestion is to first download the registration form, complete the hard copy and then log on to the system to input the data electronically.

What information is required? You must register each facility of your firm (see "Defining differences" sidebar, page 6) engaged in activities regulated by the Act. The registration must include:

- The name of the facility, full address and phone number
- The same information for the parent company if the facility is a subsidiary
- The name, address and phone number of the owner or operator
- All trade names the facility uses
- The name of the US agent and contact information. For foreign facilities, this is a mandatory field, without which registrations will not be confirmed.
- Applicable food product categories as identified in FDA's regulation 21 CFR 170.3 (See www.fda.gov for FDA product code builder.)
- A statement certifying that the information submitted is true and accurate and that the person submitting the registration is authorized to do so

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You may also submit:

- An emergency contact name, title, phone number and email address if you wish someone other than your US agent to act as your emergency contact
- Fax number and email address of the facility
- Preferred mailing address
- Type of activity (e.g. manufacturer/processor)
- Title, fax number and email address of the US agent
- Type of storage
- Additional food product categories not specified in 21 CFR 170.3
- "Most/all" food product category (instead of mandatory food product categories)
- Approximate dates of operation, if seasonal
- Fax number and email address of the owner, operator or agent in charge

Optional information provides more avenues through which the FDA can communicate with your company, and can assist the FDA in assessing the risk associated with your shipments.

Prior notice of imported foods

Food importers must provide FDA with advance notice of human and animal food shipments imported or offered for import on or after December 12, 2003. The obligation for prior notice extends to all food samples and food intended for transshipment through the US (see chart below). FDA expects to receive about 25,000 notifications about incoming shipments each day.

What shipments are covered under these regulations? Prior notice applies to food for humans and animals that is imported or offered for import into the United States. Foods excluded from the regulations include those carried into the US by an individual for that individual's personal use; meat food products, poultry products and egg products that are subject to the exclusive jurisdiction of the US Department of Agricultures and food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (for non-business purposes) to an individual in the United States.

When must prior notice be provided? Under the regulation, prior notice must be received and confirmed electronically by FDA no more than five days before its arrival and no fewer than:

- two hours before arrival by land via road;
- four hours before arrival by land via rail; or
- eight hours before arrival by water.

For international mail shipments, notification must be made before the shipment is mailed. When an individual carries or otherwise transports foods (e.g. courier) subject to the new requirement, advance notice of two, four or eight hours is required, depending on the mode of transportation. The food must also be accompanied by confirmation of prior notice for FDA review.

Prior notification must be provided for each article of food within each shipment (see "Defining Differences" sidebar under "article of food," page 6). Individual articles of food within a single shipment may be distinguished by different FDA food codes, different manufacturers, or different packaging thereby changing the quantity size for the same article of food. In these instances, each food article may require the provision of separate prior notifications, even though they comprise the same shipment.

It should be noted that the required time for advance notice has been substantially reduced since the regulations were initially made public last January. Originally, the proposed rule would have required that importers give notice by noon the day before the arrival of food into the US for all modes of transportation. The final regulation requires as little as two hours prior notice, and according to FDA, this could be reduced further in the future as part of the FDA/CBP plan to coordinate border-management activities more efficiently.

How do I provide prior notice? The advance notice to FDA may be submitted electronically in most circumstances using either Customs' existing Automated Broker Interface of the Automated Commercial System (ABI/ACS system) or the FDA Prior Notice System Interface (PNSI). If either means are inaccessible, FDA will post alternatives on the FDA website (www.fda.gov) and accept prior notice by email or fax.

For technical assistance in submitting prior notice, call 301-575-0156, fax 301-210-0247 or email furls@fda.gov. This technical assistance will be available on business days from 7 am to 11 pm US Eastern Time. For assistance with ABI/ACS transmission, contact a CBP client representative or your customs broker.

A confirmation of prior notice will be provided to the transmitter upon successful receipt of the prior notice information. Confirmation, however, is

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FDA Prior Notice Required	FDA Prior Notice Not Required
• Regular shipment of food products to customer in the US • Product shipment to trade show in US • Individual broker/agent bringing food into US for samples or quality analysis • Gift basket being sent to customer in the US • Shipment of live animals into US • Transshipment of food products to Mexico via US	• USDA exclusive products (must comply with USDA regulations including USDA prior notice procedures) • Food for personal use • Food made in a private residence and being carried on person, to a person in US as a gift (non-business)

not a guarantee that prior notice has been successfully provided; FDA will determine this at the port of arrival.

Who must submit prior notice? Any individual with knowledge of the required information may submit the prior notice, included but not limited to manufacturers, brokers, importers and US agents.

What information must be included in the prior notice? The prior notice must include the following information:

- Identification of the submitter, including name, telephone and fax numbers, email address and firm name and address
- Identification of the transmitter (if different from the submitter), including name, telephone and fax numbers, email address, and firm name and address
  NOTE: If the facility's FDA registration number is provided, then only the city and country of the submitter and transmitter are required, instead of the full address.
- Entry type and CBP identifier
- The identification of the article of food, including complete FDA product code, the common or usual name or market name, the estimated quantity described from the smallest package size to the largest container, and the lot or code numbers or other identifier (if applicable). The FDA product code can be determined in consultation with your customs broker, or by going online at www.fda.gov and consulting the FDA code generator.
- For food no longer in its natural state, the manufacturer and registration number
- For food in its natural state, the identification of the grower, if known
- The shipper and registration number (if applicable)
- The FDA Country of Production
- The country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed
- The anticipated arrival information (location, date and time) or, if the food is imported by international mail, the US recipient (name and address)
- The identification of the importer, owner and ultimate consignee, except for food imported by international mail or transshipped through the United States
- The identification of the carrier (using the Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code) and mode of transportation, except for food imported by international mail

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Defining differences

A number of similar phrases and words are used in describing and defining your obligations under the Bioterrorism Act. Here are some critical ones you need to understand:

- **Firm vs facility:** Your firm may have multiple facilities. If all of your facilities operate on one site with one address, you need only register once. If your facilities operate in multiple locations, each separately located facility must be registered separately.
- **Article of food vs shipment of food:** One shipment may include many articles, and each article requires a separate prior notice. So, for example, your shipment may be made up of canned tuna in the following sizes, brand names and manufacturers:

1. Tuna	24/12 oz cans	2,000 cases	Company 1, Brand X
2. Tuna	48/6 oz cans	1,000 cases	Company 1, Brand x
3. Tuna	24/12 oz cans	300 cases	Company 2, Brand Y
4. Tuna	6/ 66 oz cans	2,400 cases	Company 3, Brand X

This constitutes one shipment of food with four separate articles of food, and so for FDA purposes requires four separate prior notices to be filed.

- **Country of origin vs country of production vs country from which shipped:** The country of origin is a phrase used by the CBP. For food in its natural state, it is the country where the article of food was grown or collected, including harvested and readied for shipment to the US. The country of production is an FDA term that refers to the country in which the processed food was manufactured. The country from which an item is shipped is self-explanatory. So, if beans are grown and dried in the US, then rehydrated and canned in China and then purchased for export by a Canadian company that ships the product from Canada to the US, the CBP identifies the country of origin as the US (ie dried beans); the FDA identifies the article of food as canned beans and therefore the country of production is China; and the country from which the article is shipped is identified as Canada.
- **No notice vs untimely notice:** Under the FDA's prior notice regulations, different penalties apply for failure to provide accurate notice as opposed to providing untimely notice. If you fail to provide notice, or provide inaccurate notice, your shipment is subject to refusal at the border. If you provide untimely notice (that is, fail to provide the minimum required notice), your shipment may be refused, unless the FDA has already reviewed the notice and notified the CBP of its response.

Other important distinctions in the regulations include:

- **Paper submissions:** You can register using a paper submission (although electronic submissions are strongly encouraged). However, prior notices must be submitted electronically: no paper submissions are permitted unless otherwise indicated by FDA.
- **Prior notice submissions:** You may opt to use either the ABI/ACS system or the FDA's PNSI, unless your shipment has been refused entry and you are resubmitting your prior notice. In that case, you must submit your prior notice using the PNSI system.

OMAF *staffing changes*

OMAF's Export Marketing Unit has seen some changes in the past months. Long-time Western US representative Gary Cooke has retired, client account officer Wendy Jahn has moved on to a new position with the Ontario Soybean Growers, and client account officer Paul Chessman has taken on new responsibilities for primary agriculture.

Cooke, who represented OMAF and worked with Ontario exporters for 16 years, has retired. As Cooke liked to point out, his region of the US was the starting point for many food trends, and he was always on the lookout for opportunities within those new markets and niches for Ontario products. Through his contribution and hard work, Cooke assisted numerous Ontario companies in their exporting efforts.

Jahn, whose OMAF responsibilities included primary agriculture, will be putting her expertise to work on behalf of Ontario Soybean Growers (OSG) in the new position of general manager. During her time with OMAF, Jahn was involved in leading the development of the Canadian Soybean Export Association's Identity Preservation Standard as a method to distinguish Canadian soybeans from their international competitors.

Following Jahn's departure, OMAF client account officer Paul Chessman has taken on new responsibilities for primary agriculture. Chessman, whose previous role was as a geographic specialist for Europe/Latin America, will take on new challenges in working with Ontario exporters within the primary agriculture area.

Paul Chessman

Gary Cooke

Wendy Jahn

Export Marketing

MARKET DEVELOPMENT BRANCH
Ontario Ministry of Agriculture and Food
1 Stone Road West, 5 SE, Guelph, ON, N1G 4Y2, Canada
Telephone: 519-826-4210 Toll free: 1-888-466-2372
(in Ontario only. Ext. # is last five digits of applicable direct dial #)
Fax: 519-826-3460 Website: www.gov.on.ca/omaf

SECTOR SPECIALISTS

Jim Berry, Client account officer
Beverages,confectionary & snack foods, processed meats
519-826-3767 jim.berry@omaf.gov.on.ca

Diana Campbell, Client account officer
Prepared & dry ingredients, fruits & vegetables, horticulture
519-826-3982 diana.campbell@omaf.gov.on.ca

Paul Chessman, Client account officer
Meat, fish, poultry, game, primary agriculture
519-826-7765 paul.chessman@omaf.gov.on.ca

Kathryn Liotta, Client account officer
Specialty/gourmet, health food, dairy, pet food, delicatessen
519-826-4018 kathryn.liotta@omaf.gov.on.ca

Karen Moore, Client account officer
Bakery, cereals, prepared frozen foods
519-826-3686 karen.moore@omaf.gov.on.ca

GEOGRAPHIC SPECIALISTS

Murray Howatson
Geographic specialist - United States
519-826-3790 murray.howatson@omaf.gov.on.ca

Amos Tin, Geographic specialist - Asia/Pacific
519-826-3489 amos.tin@omaf.gov.on.ca

EXPORT SERVICES

Dean Post, Client information officer
Communications, research, seminars, newsletter, trade show events
519-826-4477 dean.post@omaf.gov.on.ca

Karen Edwards, Marketing assistant
Market research, library
519-826-3768 karen.edwards@omaf.gov.on.ca

Alan Crawley, Supervisor
Marketing communications, research and event co-ordination
519-826-3564 alan.crawley@omaf.gov.on.ca

Dermod Mark, Manager
519-826-3693 dermod.mark@omaf.gov.on.ca

David Clarke, Director
519-826-3510 david.clarke@omaf.gov.on.ca

ADMINISTRATIVE SERVICE REPRESENTATIVES:

Tracey Kiley 519-826-3795
Pat Passmore 519-826-3713
Aida Valois 519-826-3532

REPRESENTATIVES BASED OUTSIDE OF CANADA:

John Porter, Ontario FoodLink: Eastern US
14 Edgewood Drive, Carmel, NY, USA 10512
Phone: 845-276-0072 Fax: 845-276-0074
E-mail: johnporter@rcn.com

Rick Tuma, Ontario FoodLink: Central US
1006 Park Hill Circle
Aurora, Illinois, USA 60504
Phone: 630-820-7144 Fax: 630-820-7144
E-mail: tumarick@aol.com

The US Bioterrorism Act… — *Continued from page 6*

- The Harmonized Tariff Schedule code
- Planned shipment information, except for food imported by international mail. This information includes the airway bill number or bill of lading number, and container number if containerized cargo; the vessel name and voyage number if applicable; the flight number if applicable; the road trip number if shipped by truck; the rail car number if shipped by rail; or the license plate number and state/province if shipped by private vehicle.

To make it easier for the carrier or individual at the port, the carrier should have a copy of the confirmation of prior notice, which includes a prior notice confirmation number, in his/her possession. A new prior notice does not need to be submitted if the estimated quantity changes, however new notice must be submitted in the case of a change of any of the other required information as outlined above. Any change in the prior notice restarts the clock. For instance, if you make a change regarding a truck shipment, it must be received at least two hours before your shipment arrives at the border.

Is there a grace period?
Prior notice rules took effect on Dec. 12, 2003. However, FDA has indicated that a familiarization period will ensue, during which FDA will exercise broad enforcement discretion for the registration and prior notice rules for the first several months after implementation. During this time, FDA and CBP will educate importers about how they can comply with the regulations, and will work with trade associations and foreign governments to ensure that all importers are well informed of the new requirements.
FDA will issue warning letters to those importers not in compliance, and will monitor repeated offenses to discern whether more severe action is warranted.

How can I comment on the regulations? Comments on the initial version of the regulations released last February resulted in significant changes to the regulations. Ontario companies are welcome to comment on the revised regulations directly to the FDA, or to work through the provincial and federal governments in making their concerns known. Comments may be sent to Bobby Seeber, OMAF Senior Policy Advisor (Trade Policy), Policy and Farm Finance Division (phone 519-826-3253; fax 519-826-3492; email bobby.seeber@omaf.gov.on.ca). Comments are due by December 24, 2003.

Defining terms

- **Food** With some exceptions, for the purposes of the Bioterrorism Act, the definition of food which applies is section 201 (f) of the Federal Food, Drug and Cosmetic Act:"(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."
- **Manufacturing/processing** is defined as making a food from one or more ingredients by synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.
- **Packaging** is defined as placing food into a container that directly contacts the food that the consumer receives.
- **Packing** is defined as placing the food into a container other than packaging the food.
- **Holding** is defined as storage of food, for instance warehouses, cold storage facilities, storage silos, grain elevators, liquid storage tanks.
- **Farm** is defined by the FDA as a facility that grows or raises food for consumption on that farm or a farm under the same ownership, or for direct sale to consumers (e.g. by roadside stall). The farm may manufacture, process, pack or hold food, as long as it is consumed on the farm or sold directly to consumers. If a farm in Canada is engaged in the manufacture, processing or packaging of food for commercial sale in the US, it must register the portion of the farm engaged in these activities. Also, any foreign facility, including Canadian farms, whether or not exempt from facility registration, must provide prior notice if it is exporting FDA-regulated food products to the US.

Where can I find out more?

- Watch upcoming editions of *The Ontario Agri-Food Exporter* for updates on these regulations, their implementation and their impact on Ontario exporters.
- Go to the FDA website at www.fda.gov and click on "Bioterrorism Act" under the Hot Topics heading on the right hand of the home page. The FDA site includes Questions and Answers, Powerpoint presentations, Factsheets, Compliance Policy Guides as well as an invitation to comment on the regulations.
- Contact your OMAF client account officer if you require additional assistance or call 1-888-466-2372 ext. 64210. You will be directed to the appropriate client account officer.

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