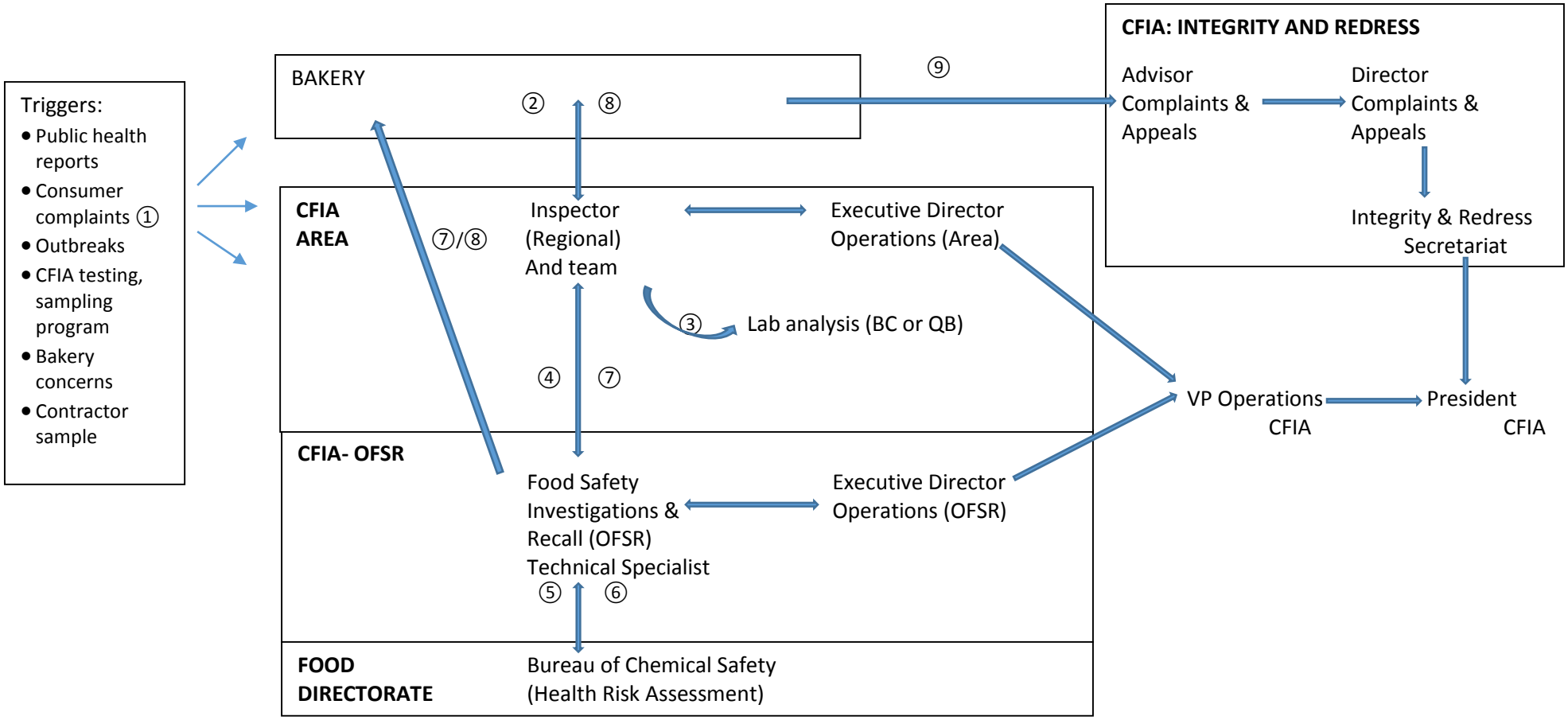
Recall Process (Allergens and Gluten)



Key CFIA websites for further information:

CFIA interactive web-based tool which explains the basic steps of a food safety investigation and recall process.
http://www.inspection.gc.ca/food/information-for-consumers/food-safety-system/basic-html/eng/1374439778888/1374821384212

CFIA Framework for Food Safety Investigation and Response http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/framework/eng/1379341287419/1379343502268

CFIA Food Investigation and Response Manual http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/food-manual/eng/1378402475724/1378403080658

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Recall Process Steps

Step 1	Triggers for an inspection could include: • consumer and industry complaints, • consumer reaction (e.g., anaphylactic reaction) • CFIA inspections and testing and sampling programs (inspector or contractor samples) • information from other government departments, • reports from international partners, and • company-initiated concerns found through its own sampling
Step 2	The trigger would result in a CFIA inspector visit. With the new *Safe Food for Canadian Act* the inspector would review the preventive control plans in place for the company, he/she would use performance measures to ensure the establishment mitigated any risk, and may request information on the traceability of the product. The CFIA must trace food products backwards through the distribution and production systems in order to determine where the problem occurred and trace the food forward to determine what specific products should be recalled. Samples may be collected at the manufacturer, retail level, from consumer. A number of closed samples are obtained. Distribution and product information is collected including where in Canada the food was sold, product codes and expiry/best before dates. The inspector may immediately identify if any potential corrective actions should be taken by the company while samples are sent for analysis. Even with all performance measures taken, the presence of inadvertent allergens may be present due to the levels of adventitious presence of other grains and substances permitted through the *Canadian Grains Act*.
Step 3	CFIA inspector, along with the Area team coordinates the analysis of the suspected product using one of two labs in Quebec or British Columbia. They are responsible for getting the food tested to determine the levels of the allergen.
Step 4	Results of lab analysis are sent to Food Safety Investigations and Recall Office who determine whether there is a potential risk. Currently, there are no maximum limits for allergens. As a result, any levels above zero are sent for further assessment by the Technical Specialist.
Step 5	This information on the presence of allergens or gluten are shared with the Bureau of Chemical Safety at Health Canada to determine whether there is a Health Risk. The Bureau of Chemical Safety conducts a health risk

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	assessment. This assessment is determined by the quantity of the allergy, the market quantity (is it a commonly consumed food), how the product is labeled, where it is distributed, and the type of product (i.e., is it consumed more by children), among other factors. The information is combined and a level 1, 2, 3 or no risk is identified: • High risk (1) would indicated that there is a high risk that eating this product will lead to a serious health problem or death • Moderate risk (2) would indicated that consumption of this product would most likely lead to short-term or non-life threatening health problems • Low and no risk would indicate that no undesirable health effects would occur with consumption of this product.
Step 6	This information is shared back to the OFSR Technical Specialist. The information provided by Health Canada is used to determine whether the product requires one of three class actions: • Class Action level 1—a total consumer recall • Class Action level 2—a retail recall, no public notification • Class Action level 3—managed within company The Food Safety Investigations and Recall Office staff begin the communication process back to the manufacturer.
Step 7 & 8	The decision on whether there is a class action level determination is shared with the Area Food Safety Team and the Inspector, who contacts the manufacturer. If the recall is deemed urgent or must be addressed during non-business hours, the OFSR may contact the manufacturer directly. If the Health Risk is high and a Class Action level 1 has been determined, the Public Health Agency of Canada may be involved. Depending on the level of risk (i.e., class of recall) an alert may be sent to the media as well as publishing the recall information on the CFIA website. The company is responsible for removing the product from sale or distribution if the product is deemed to be a high risk. The CFIA inspector will check to verify that the company has successfully removed the product from the marketplace. If the inspector determines that the company did not proceed with the required actions, Administrative Monetary Penalties may be levied.
Step 9	If the company disagrees with the decision they are able to complete the Complaints, Comments and Compliments Form and submit it along with supporting documents to the Complaints and Appeals Office at CFIA.

Please note that the process may change with Regulatory Modernization, specifically, the inspection will be outcome based rather than prescriptive and information on all recalls will be posted on the CFIA website.