

Helpful Regulatory and Epidemiologic Definitions For Traceback Investigations:

Affidavit - For affidavits provided to FDA -A written statement from a person who has dealt with the goods sampled, knows material facts relating to the movement of the goods or to events affecting their condition, and/or other fact relevant to the goods in question, which is obtained by an FDA employee. The affidavit is signed and sworn to (affirmed as true) by the affiant and then signed by the FDA employee. See IOM Chapter 4 and affidavit forms in that chapter. For affidavits provided by FDA - A written statement signed in the presence of a notary public under a sworn oath that the statement is true. FDA considers such affidavits to be testimony covered by 21 CFR 20.1. See RPM Chapter 10, Requests for Testimony.

Asymptomatic infection - an infection in an individual who does not manifest symptoms.

Attack rate - the number of persons exposed to some factor who become ill divided by the total number of persons exposed to that factor x 100 (expressed as a percent).

BILL OF LADING B/L - The written order from a shipper to a carrier to move goods from one place to another. When available, this is the best source of shipping dates, origin, and name of shipper.

Cases - individuals with an illness of interest (for infectious diseases, usually requires laboratory-confirmation).

Case-control study - a type of epidemiologic study wherein cases and controls are interviewed (or otherwise queried) to determine whether they had been exposed to a list of factors ("exposures") during a defined time interval. Statistically significant differences between cases and controls in their exposures can identify a vehicle responsible for an illness. This type of study is sometimes referred to as a "retrospective study."

Case definition – the characteristics (typically time, place, person, and clinical features or symptoms) of the case being studied. This definition might be different in different phases of an investigation. For example, a broad definition might be used early in the course of an investigation to capture all possible cases; later in the investigation, the definition might be narrowed to capture only definite cases. Often, a "possible" and a "confirmed" case definition are generated, with the latter being, for example, a positive laboratory test result in addition to symptoms.

Chain of custody - a record which establishes the complete chronological disposition of an entity of concern, e.g. a sample or a document.

Cluster - aggregation of relatively uncommon events or diseases in space and/or time in amounts that are believed or perceived to be greater than could be expected by chance.

Cohort study - a type of epidemiologic study in which subsets of a defined population can be identified who are, have been, or in the future may be exposed or not exposed, or exposed in different degrees, to a factor or factors hypothesized to influence the probability of occurrence of a given disease or other outcome. The main feature of cohort study is observation of large numbers over a long period (commonly years) with comparison of incidence rates in groups that differ in exposure levels. Traditional outbreak investigations often begin with a cohort study, with the study population being those in attendance at a particular meal or who had eaten at a restaurant during a particular time and exposure being defined as eating a particular item or meal.

Commercial confidential – trade secrets that are protected by law from public disclosure (e.g., monitoring records, customer lists, and traceback information).

COMMINGLED LOTS - Merchandise arriving off the same carrier with identical markings but covered under two or more entries. Two or more separate shipments of the same product, stored together and bearing no distinguishing marks which enable easy separation. There may be many codes in one shipment.

Confounding -

1. A situation in which the effects of two processes are not separated. The distortion of the apparent effect of an exposure risk brought about by the association with other factors that can influence the outcome.
2. A relationship between the effects of two or more causal factors as observed in a set of data such that it is not logically possible to separate the contribution that any single causal factor has made to an effect.
3. A situation in which a measure of the effect of an exposure on risk is distorted because of the association of exposure with other factor(s) that influence the outcome under study.

CONSIGNEE - Person named in a bill of lading to whom or to whose order the bill promises delivery.

Controls - individuals without the illness of interest.

ENTRY - Delivery or offer for delivery of merchandise into the Customs Territory of the U.S. from an outside point.

Epidemic curve - histogram portraying the date of onset of illness along the X-axis by number of cases of illness along the Y-axis.

ESTABLISHMENT - A place of business or residence, including all accoutrements essential to such business or resident.

Exposure date - the date the implicated product was consumed by the individuals who became ill.

FREIGHT BILL (F/B) - The document stating the transportation charges incurred by the carrier (a bill for the freight charges on a shipment). Next to a B/L, the freight bill is the most authentic document that supports movement of a shipment in interstate commerce.

Grower - Raises livestock, raw agricultural products, or aquaculture products for sale (farms, feedlots, dairy farms, and botanicals).

GUARANTY - A formal and signed agreement between buyers and sellers in which the latter verifies the goods he sells are not in violation of the FD&C Act when shipped. A guaranty that meets the conditions in section 303(c)(2) of the Act protects a good faith purchaser from criminal prosecution based on violations of sections 301(a) or 301(d).

Historical cohort study - a type of epidemiologic study wherein rates of illness are compared between a group of persons known to have been exposed to a factor(s) versus another group not exposed to those factors. Statistically significant differences between exposed and unexposed persons in rates of illness can identify a vehicle responsible for the increased rate of illness. Often employed to investigate outbreaks linked to specific gatherings for which investigators can determine exactly who was present at the event (e.g, outbreaks linked to church suppers).

IMPORT ALERTS - Information to the FDA district offices concerning unusual or new problems affecting imports which gives background and compliance guidance information for each product and problem.

IMPORT BULLETINS - Informational bulletins that generally provide only information on a problem affecting imported products.

IMPORTER OF RECORD - The individual responsible for assuring that imported goods are in compliance with all laws affecting the importation. While the importer may authorize others to carry out certain tasks such as filing, the importer of record holds the bond and is ultimately responsible for the entry.

Incidence - the number of new illnesses that have their onset in a defined period of time.

Incubation period - time from exposure to an infectious agent (or other disease-causing agent) to onset of symptoms.

Infectious dose - the number of organisms required to produce infection.

INTERSTATE (IS) COMMERCE - Commerce between one state or territory and anyplace outside thereof, or commerce within the District of Columbia or within any other territory. Section 201(b) of the Act.

INTRASTATE - Within a state

INVOICE (Imports) - A document that accompanies imported merchandise and contains at least the following information: (a) port of entry or merchandise destination; (b) local consignee, foreign shipper; (c) description of merchandise including any marks; (d) quantity, (e) purchase price, (f) country of origin of the merchandise.

LOT - An amount of a product produced during a period of time indicated by a specific code, or some other unique identifying characteristic. Also, an import entry, group of entries, or a portion of an entry of merchandise that can be clearly defined as appropriate for FDA sampling and examination purposes.

MANIFEST - An itemized listing of a vessel's cargo, with other particulars, for the facility of the customs officers. A document issued by the carrier describing the contents of merchandise being transported.

Manufacturer - Firm or individual responsible for making a product.

95% confidence interval (CI) - a range of values for a given odds ratio or relative risk that expresses how much the "true" odds ratio or relative risk could vary from the one observed 95% of the time. A CI range which excludes "1" is considered statistically significant

Odds ratio - a number that assesses the strength of association between a disease and an exposure of interest; the larger the odds ratio, the greater the association. Used in case-control studies.

Onset date - the date the person first experiences symptoms of the foodborne illness.

PFGE – pulsed-field gel electrophoresis – a molecular method that allows for the specific classification of pathogens by “fingerprinting” the DNA from the pathogen; this method generates visually observable patterns which can be digitized and then compared with other pathogens of the same genus and species. Pathogens with patterns characterized as “indistinguishable” may have similar sources. Two persons or items yielding indistinguishable organisms are more likely

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to be related (i.e., be part of the same outbreak) than if the organisms with different PFGE patterns are isolated.

P-value - the probability that chance, and chance alone, accounted for an observed odds ratio or relative risk. P-values < 0.05 generally connote "statistical significance" (i.e., a less than 5% probability that the observed difference in rates of exposure is random).

Packer/repacker - Packs a product or products into different containers without making any change in the form of the product. Includes packers of raw agricultural products.

PORT (POINT) OF ENTRY - The Customs locations where the consumption entry is made. This may or may not be at the Port of Unloading.

PORT OF LOADING - The location where the final Bill of Lading is issued prior to shipment to the U.S. This may or may not be the country of origin.

PORT (POINT) OF UNLOADING OR DISCHARGING - The location where the merchandise is unloaded from the carrier. This may or may not be at the Port of Entry.

Prevalence - the total number of illnesses that exist during a defined period of time.

Purchase date - the date the implicated product was purchased, but not necessarily consumed. The exposure and purchase date may be the same day (e.g., a person purchases a meal in a restaurant and consumes it immediately).

Receipt date - the actual date a product was received at a firm. This date is important in order to determine which shipments of the product were physically available for sale and consumption on a given day. Sometimes it may be important to know what time of day the product was received.

Relative risk - a number that assesses the increased risk of disease in a group of people with a specific exposure of interest; the larger the relative risk, the greater the risk of infection in the exposed group compared to an unexposed group. Used in historical cohort studies.

Risk factor - an exposure with a significant statistical association with a certain disease.

Seroconversion - a term applied to a person who has produced antibodies to a certain pathogen.

Serology - the use of antibody status to determine whether an individual has been exposed in the past to a specific pathogen.

Shelf life - how long a product can last from the time it is produced, processed, and/or harvested until it is no longer in a condition to be saleable to a customer.

Shipper - Firm or individual responsible for introducing merchandise into interstate or intrastate commerce by way of transport and that does not act as a manufacturer, repacker, distributor.

Statistical significance - often refers to odds ratios or relative risk values, and implies that the probability that chance, and chance alone, accounted for the particular OR or RR is less than 5% (i.e., p-value < 0.05).

Warehouse - A private or public facility for the storage of consumer products, including products reshipped from the producer or grower to the manufacturer or other customer.

WAYBILL - This record accompanies the shipment during transit.

Sources:

MULTISTATE FOODBORNE OUTBREAK INVESTIGATIONS GUIDELINES FOR IMPROVING COORDINATION AND COMMUNICATION, National Food Safety System Project Outbreak Coordination and Investigation Workgroup, February 2001.

ORA Regulatory Procedures Manual – 2011

FDA/CFSAN Staff for the purpose of inclusion in the Traceback Investigations for CORE Network Staff course.