



PRESS KIT

Contents

- **Press Release**

- **Industry Applications**

- **Product Information**

- **List of species identified by *FoodExpert-ID*[®]**

- **Glossary of terms**



PRESS RELEASE

bioMérieux[®] launches its first molecular multi-detection test for food and feed analysis : *FoodExpert-ID*[®]

Marcy l'Etoile, France - February 24th, 2004. bioMérieux announces the launch of *FoodExpert-ID*, the first high-density DNA chip for food and animal feed testing. The *FoodExpert-ID* test, powered by Affymetrix[®] GeneChip[®] technology, will make it possible to verify the animal species composition and the authenticity of raw or processed food and animal feed.

“Our new test, *FoodExpert-ID*, is a real breakthrough for the food and feed industries. By providing rapid multi-species identification, *FoodExpert-ID* will help to improve the safety of food for human and animal consumption, thereby contributing to consumer health protection” says Dr. Christophe Mérieux, Vice President and Director of Medical Affairs and Research at bioMérieux.

Changes in food and feed legislation are creating new needs and imposing new constraints on these industries. *FoodExpert-ID* will respond to these requirements by ensuring accurate labelling and allowing complete traceability throughout the industrial process, from animal feed to the end products released from production sites. The new test will help the food and feed industries comply with European and US legislation, by determining the species composition of a product using the latest advances in molecular biology.

FoodExpert-ID, developed by bioMérieux, is the first molecular high-density multi-detection test designed specifically for the food and feed industries. Using highly innovative techniques and providing extremely accurate results, *FoodExpert-ID* will change the way food and feed analysis can be achieved. The *FoodExpert-ID* offer is based on a high-density DNA chip, the GeneChip, developed by Affymetrix, which supports 80,000 oligonucleotide probes specially designed by bioMérieux. *FoodExpert-ID* combines expertise in genetics, DNA technology, image analysis and bio-informatics, and is the result of a dedicated research programme by bioMérieux.

The innovative breakthrough in *FoodExpert-ID*[®] lies in the test's capacity to detect 33 different species of vertebrate, and to simultaneously identify animal products present in food and feed samples according to two taxonomic criteria: class (mammals, fish and birds) and species (beef, chicken, salmon...). Furthermore, *FoodExpert-ID* can be used to test raw foods as well as products processed at high temperatures and pressures, as is the case for some animal feed. These capabilities, therefore, go beyond conventional food analysis techniques, which can detect only a limited number of species, and which are less reliable when material from more than one species is combined into a single product.

The test report generated by the *FoodExpert-ID* software is based on the unique DNA signature of the product. This report constitutes the "Identity Card" of the animal species entering into the composition of the product, thereby providing an invaluable tool to ensure labelling accuracy. *FoodExpert-ID* contributes to traceability and quality assurance in the food and feed industry through species identification at every step of the manufacturing chain "from farm to fork".

For the first time, *FoodExpert-ID* provides the answers to "open-ended questions" concerning the real composition of food products. It is now possible, for example, not only to confirm that beef raviolis contain beef, but that they contain only beef, or to determine whether cod fillet fish fingers really contain only cod and not any other fish species. In the case of livestock production, *FoodExpert-ID* can be used to verify that feed intended for ruminants contains no animal products, in compliance with European legislation. This new test will therefore contribute to animal feed safety, and will help all food chain partners, from farmers to food manufacturers and retailers, to comply with increasingly stringent food and feed regulations.

FoodExpert-ID has been validated on over 500 food and feed products and government trials are planned to be initiated in the UK, the Netherlands and France before the end of the year.

About bioMérieux[®]

A global leader in disease prevention and management, bioMérieux provides assays, reagents and instrumentation for clinical microbiology, coagulation, immunoassay and nucleic acid diagnostics; and also for product quality control in the agri-food, cosmetics and pharmaceutical industries. With sales of 944 million Euros in 2002, bioMérieux ranks as the eighth-largest biological diagnostics company worldwide. Over 82% of its activity takes place on an international level. Investment in research and development represented over 12% of sales in 2002.

Based at Marcy l'Etoile, France, bioMérieux employs 5450 people throughout the world, including 1550 people in the United States and 3300 in Europe. The Group counts 14 production sites distributed in the United States, Europe and Brazil.

bioMérieux INDUSTRY provides product solutions to quality control and research microbiology laboratories. Applications served include environmental monitoring, sterility testing, pathogen screening, quality indicators, microbial identification, quality control organisms, microbial limits and preservative effectiveness testing.

About Affymetrix®

Affymetrix is a pioneer in creating breakthrough tools that are driving the genomic revolution. By applying the principles of semiconductor technology to the life sciences, Affymetrix develops and commercializes systems that enable scientists to improve the quality of life. The Company's customers include pharmaceutical, biotechnology, agrichemical, diagnostics and consumer products companies as well as academic, government and other non-profit research institutes. Affymetrix offers an expanding portfolio of integrated products and services, including its integrated GeneChip® platform, to address growing markets focused on understanding the relationship between genes and human health. Additional information on Affymetrix can be found at www.affymetrix.com.

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INDUSTRY APPLICATIONS FOR *FOODEXPERT-ID*[®]

The identification of animal species present in human and animal food is crucial if the agri-food industry is to be able to ensure both quality and safety. The industry must comply with increasingly strict regulations concerning food safety, traceability and the accuracy of product labeling.

FoodExpert-ID is the first standardized test commercialized by bioMérieux[®] to address these new regulations. It has four main fields of application:

1. Authenticity of human food composition

The identification of animal species present in human food is important for a number of reasons:

- in order to comply with increasingly strict requirements concerning labeling accuracy,
- for economic reasons, because the price of a product often depends on its composition and because the information provided on the label is a marketing issue for distributors,
- for reasons of health, philosophy or religion. For example, species identification guarantees that a vegetarian product contains no animal material or that a food product contains no pork.

FoodExpert-ID[®] ensures labeling accuracy, confirms the composition of the ingredients and detects cross-contamination that may occur during the manufacturing process.

2. Compliance with human food regulations

Food intended for human consumption must comply with national or European legislation that increasingly includes species identification.

- Directive EC/89/2003 of the European Commission of November 10, 2003, stipulates that labels must include the list of all ingredients representing more than 2% of the total weight of the food product (amendment to Directive EC/13/2000). Member states will have until November 2004 to comply with the legal and administrative measures allowing the sale of products labeled in accordance with this directive, and the agri-food industry will have until November 25, 2005 to meet these standards.
- A European directive (EC/104/2000) requires that the commercial and/or scientific name of the species is included on all fish or fish-based products.

FoodExpert-ID will be the tool of choice for agri-food companies and distributors seeking to validate their products in compliance with regulatory requirements. Its sensitivity threshold validated at 5% (proportion of the relevant species in the composition of the tested product) corresponds to current regulatory requirements, whereas the actual threshold is generally lower. Detection of a species may be followed by a quantitative analysis using other molecular tools.

3. Authenticity of animal feed composition

Over the past few years, general awareness of the importance of animal feed quality has increased and many animal feed manufacturers are now seeking ways to ensure that the level of traceability of their products is identical to that of products intended for human consumption.

- This is particularly true for aquaculture since the composition of fish feed has a strong influence on the organoleptic and nutritional qualities of the fish. The type of fish used to manufacture fish feed is therefore a crucial quality criterion and is often included in the specifications of the product sold to the consumer.

4. Compliance with animal feed regulations

These controls largely concern rendered products (meat and bone meal) that have a high nutritional value and represent a major source of protein for animal feed.

- In August 1994, following the appearance of Creutzfeldt-Jakob disease in humans, linked to the presence of animal by-products in meat and bone meal fed to livestock, the European Commission banned animal protein in livestock feed, followed by a ban on rendered ruminant fat in ruminant feed in June 2001.
- The European regulation, EC/1774/2002, which became law on May 1st, 2003, progressively prohibits the consumption of same-species products, otherwise known as "cannibalism".
- In the United States, the use of animal protein in ruminant feed is strictly regulated by law.

FoodExpert-ID, the first molecular multi-detection test developed by bioMérieux[®], has a high level of sensitivity (validated at 5% of the total weight with a species detection limit of 0.01% of the total weight, depending on the sample). It thus enables the agri-food industry to comply with national and European legislation requiring the identification of species present in rendered products and in animal feed.



FOODEXPERT-ID® - PRODUCT INFORMATION

FoodExpert-ID uses a high density DNA chip, GeneChip®, manufactured by Affymetrix®, which supports 80,000 oligonucleotide probes designed by bioMérieux®. These probes are synthesized on the surface of the chip by photolithography.

The probes are 17 nucleotides long and are complementary to specific regions of the vertebrate cytochrome b gene. *FoodExpert-ID* can identify three classes of vertebrates (mammal, fish and bird) as well as 33 species of animals.

Analysis is based on the detection of DNA sequences common to all species of one of the three classes in the case of class identification or, on the contrary, sequences specific to each of the identifiable species. The specificity of the results is excellent (confirmation of the presence or absence of material from a class or a species), as is their sensitivity (detection threshold: validated at 5% of the total weight, with a species detection limit of 0.01% of the total weight of the sample, depending on the composition). Software developed by bioMérieux interprets the data and issues a "signature" of the product tested, based on its DNA profile.

Product Use

FoodExpert-ID allows the simultaneous detection of products from mammals, birds or fish in a sample and is then capable of identifying 33 species, regardless of whether the food tested is raw or processed (including highly rendered material heated to 133°C for 30 minutes at 3 Atm.).

Conventional tests are not simultaneously species- and class-specific and cannot be used for all types of foods, particularly processed foods. The only products *FoodExpert-ID* is not able to analyze are certain highly processed foods (baby food jars and some canned fish).

***FoodExpert-ID* advantages for users:**

- Semi-automated technique,
- Unambiguous results, through specifically designed software and internal quality assurance,
- Analysis at two taxonomic levels,
- Very high resolution compared to current systems (sensitivity: 0.01% of the total weight, validated at 5% w/w),
- Multi-detection capacity that makes it possible to identify material from several species in the same sample,
- Answers open questions for the first time: "Which animal species are in this product?",
- Same day results,
- DNA analysis provides reproducible results, making it possible to establish an "Identity Card".

Test principle

The *FoodExpert-ID* test is a semi-automated detection test that uses established molecular biology techniques. After having extracted the DNA from a sample, the cytochrome b mitochondrial gene is amplified by PCR. The DNA is transcribed to RNA, fragmented and labeled with fluorescent probes. The labeled RNA is then placed in the Affymetrix® FS400 hybridization unit, with the corresponding *FoodExpert-ID* chip, and the probes on the chip are hybridized in a closed environment. The chip is then scanned in the Affymetrix scanner that detects the fluorescence. The fluorescence pattern provides the DNA signature of the sample tested and is interpreted by sophisticated software. Automated analysis and report preparation are completed in a single working day.

Extraction of DNA → PCR → Transcription → Hybridization on the chip → Scan and Labeling



The test can be carried out in any molecular biology laboratory that has a PCR license.

Quality assurance

Three controls are integrated into the analysis process to verify the overall analysis procedure and to detect any contamination by the environment. One of them, for example, consists of analyzing a sample of known composition, to verify that the process is running correctly. Another control consists of testing a DNA-free sample, to verify the absence of environmental contamination by DNA.

The critical steps in this test are fully automated: hybridization, fluorescence analysis and the interpretation of the data by algorithms, thereby ensuring unambiguous results. The final *FoodExpert-ID* report provides the customer with a product signature based on its DNA profile.

Application examples

There are many applications since *FoodExpert-ID* makes it possible to verify that one or several species are present in the composition of a food product or animal feed and, on the contrary, to verify that other species are absent.

Several examples:

- Food intended for human consumption:
 - Verification of the absence of all animal products in food for vegetarians;
 - Verification of the absence of pork for religious reasons;
 - Verification of tuna species present in processed food (one species is caught in nets that also trap dolphins and birds, whereas another species is fished in a more ecological way, using a hook and line).
- Animal feed:
 - Absence of animal by-products in livestock feed;
 - Absence of material from chickens in meat and bone meal (MBM) for chickens or the absence of pork in MBM for pigs, in order to satisfy the regulation banning cannibalism in animal feed;
 - Identification of animal species (fish or land animals) present in MBM for fish feed, the quality and the price of MBM being linked to its composition.



Species identified by *FoodExpert-ID*®

Mammals

Beef (*Bos taurus*)
Cat (*Felis catus*)
European hare (*Lepus europaeus*)
Goat (*Capra hircus*)
Human (*Homo sapiens*)
Mouse (*Mus musculus*)
Mule deer (*Odocoileus hemionus*)
Pig / Boar (*Sus scrofa*)
Rabbit (*Oryctolagus cuniculus*)
Rat (*Rattus norvegicus*)
Reindeer (*Rangifer tarandus*)
Sheep (*Ovis aries*)

Birds

Chicken (*Gallus gallus*)
Goose (*Anser anser*)
Guinea fowl (*Numida meleagris*)
Ostrich (*Struthio camelus*)
Turkey (*Meleagris gallopavo*)

Fish

Arctic char (*Salvelinus alpinus*)
Atlantic bonito (*Sarda sarda*)
Atlantic cod (*Gadus morhua*)
Atlantic mackerel (*Scomber scombrus*)
Atlantic salmon (*Salmo salar*)
Brook trout (*Salvelinus fontinalis*)
European eel (*Anguilla anguilla*)
European hake (*Merluccius merluccius*)
Greenland cod (*Gadus ogac*)
Japanese eel (*Anguilla japonica*)
Mozambican eel (*Anguilla mossambica*)
Rainbow trout (*Oncorhynchus mykiss*)
Sea trout (*Salmo trutta*)
Skipjack tuna (*Euthynnus pelamis*)
Spotted tunny (*Euthynnus alleteratus*)



GLOSSARY

Animal Feed

A combination of meat and bone meal, vegetable products and compound feed used in any combination to provide nutrition to animals.

Aquaculture

Farming aquatic animals or plants for food / human consumption.

Base pair

One of the pairs of chemical bases joined by hydrogen bonds that connect the complementary strands of a DNA molecule or of an RNA molecule that has two strands; the base pairs are adenine (A) with thymine (T) and guanine (G) with cytosine (C) in DNA, and adenine (A) with uracil (U) and guanine (G) with cytosine (C) in RNA.

Bioinformatics

The use of computers to extract and analyze biological data, particularly in studying the nucleotide sequences of DNA and other nucleic acids.

Bovine Spongiform Encephalopathy

More commonly known as **BSE** or **mad cow disease**; a fatal neurodegenerative disease of cattle, part of the transmissible spongiform encephalopathy family of diseases. BSE is believed to be caused by prions and to have evolved from the sheep prion disease scrapie through the use of sheep protein in animal feed for cattle.

Class

Taxonomic term referring to a level of classification of organisms. Taxonomy down organisms into seven major divisions, called taxa (singular: taxon), as follows: Kingdom, Phylum, Class, Order, Family, Genus, Species. Examples of class level divisions are fish, birds and mammals.

Creutzfeldt-Jakob disease

Rare progressive fatal encephalopathy now usually considered to be caused by a prion and marked by development of porous brain tissue, premature dementia in middle age, and gradual loss of muscular coordination. Named after German psychiatrists, Hans G. Creutzfeldt and Alfons M. Jakob.

Cytochrome B

A cytochrome containing noncovalently bound protoheme (iron protoporphyrin IX; heme b). Cytochromes are a class of hemoprotein whose principle biological function is as carriers of electrons.

DNA

Genetic material found in cell nuclei. Acronym for deoxyribonucleic acid, usually 2'-deoxy-5'-ribonucleic acid. DNA is a code used within cells to form proteins. It is a double-stranded molecule that encodes genetic information.

Genetics

The branch of science which relates to the study of genes and biological inheritance, by which a predisposition to parental traits is passed to offspring at conception.

Hybridization

Complementary base pairing. The hydrogen bonding of two complementary strands of DNA or one each of DNA and RNA to form a double-stranded molecule.

Meat and Bone Meal (MBM)

Meat and Bone Meal is the rendered product from mammal tissues, including bone. It is a by-product of the rendering industry, used to feed cattle.

Microarray

A microarray is a solid surface onto which probes (DNA, RNA, protein) have been synthesised or attached. These arrays are used to capture the complementary targets sequences in samples. Other names for microarrays include: biochip, DNA chip, DNA microarray, and gene array. Affymetrix[®], Inc. owns a registered trademark, GeneChip[®], which refers to its high density, oligonucleotide-based DNA arrays. High density arrays can support up to 400,000 probes in an area of 1 cm².

Mitochondrion

A small intracellular organelle which is responsible for energy production and cellular respiration.

Molecular biology

The study of biology at a molecular level, established in the 1930s. The field overlaps with other areas of biology, particularly genetics and biochemistry. Molecular biology chiefly concerns itself with understanding the interactions between the various systems of a cell, including the interrelationship of DNA, RNA and protein synthesis and learning how these interactions are regulated.

Organoleptic

Effect or impression produced by any substance on the organs of touch, taste, or smell.

Photolithography

Photolithography is the process of transferring geometric shapes on a mask to the surface of a silicon wafer. The steps involved in the photolithographic process are wafer cleaning; barrier layer formation; photoresist application; soft baking; mask alignment; exposure and development; and hard-baking.

Polymerase chain reaction (PCR)

A key technique in molecular genetics that permits the analysis of any short sequence of DNA (or RNA) without having to clone it. PCR is used to reproduce (amplify) selected sections of DNA.

Probe

Short segment of DNA (RNA or protein) with a specific oligonucleotide sequence.

Rendering

Rendering is the process of cooking raw animal material to remove the moisture and fat. Rendering plants handle dead animals, not live animals. The carcasses are treated at extreme temperatures to incinerate the material and to produce raw sources of fat and protein.

Species

Taxonomic term defining a group of genetically distinct, interbreeding organisms. The average genetic differences within a species are less than the average differences between that species and a closely related group of organisms.