From Farm to Fork Solutions for Your Food Safety Requirements







From Farm to Fork Solutions for Your Food Safety Requirements

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Access to safe and nutritious food is key to sustaining life and good health. According to the World Health Organization, an estimated 600 million people fall ill after eating contaminated food with 420,000 deaths every year. Children under 5 years old make up approximately a third of deaths with diarrheal diseases being the most common from the consumption of contaminated food. Food supply chains often cross national borders and good collaboration between governments, producers and consumers with sufficient testing for contamination from foodborne pathogens, toxic compounds and nutritional content helps to ensure the safety and quality of foods.

The food chain typically starts on the farm within the agricultural sector, where most of the food that is eaten passes downstream to food and beverage manufacturers for subsequent processing or transformation and then onto retailers or consumer services until reaching the final consumer. This journey from farm to fork generally passes through various wholesalers and involves other service providers such as transport and warehousing.

Food safety strategy covers not only the safety of food for human consumption, but also animal feed, animal health and welfare, and plant health. The process must ensure that food is traceable as it moves from the farm to the consumer, especially when transported internationally.

Analytik Jena and its parent company in Endress+Hauser offer products that meet the needs of the food industry and the regulations that uphold the high standards. From primary agricultural production to food processing and consumption, it is essential that food quality and safety standards are met and can be met through the collective use of Endress+Hauser and Analytik Jena products.

Primary Agricultural Production

Soils and Fertilizers

The quality of soils and fertilizers used to grow and support the variety of agricultural products we consume today, play a significant role in the quality of the food products we find on supermarket shelves. Analytical instruments from Analytik Jena are designed to meet the high demands of the industry that requires fast and comprehensive chemical analysis of soils and fertilizers, including detection and quantification of toxic metals such as cadmium, lead, arsenic, mercury and chromium that can potentially be passed onto the end consumer.

Analytik Jena's **PlasmaQuant** range of ICP-OES and ICP-MS elemental analyzers are capable of measuring toxic metals to ultra-trace levels and well below those defined in European and other important regulations. The extensive linear range of these products also allows for the determination of the many essential and nutritional elements, including calcium, magnesium, potassium, iron, selenium, zinc, copper, sulfur and phosphorus to name a few.



For laboratories with smaller sample numbers, element requirements or budgets, atomic absorption spectrometers (AAS) are a cost effective option with a lower capital cost compared to ICP techniques. Dual flame and furnace systems are also capable of measuring major, minor and trace elements with a trade-off in sample analysis time.

Measuring the health of the soil used to grow crops and animal feed is vitally important for maximizing yields and keeping toxic metal concentrations to below regulatory levels. The same is true for fertilizers and having the correct N:P:K ratio (nitrogen:phosphorus:potassium) and other essential elements is critical to having to best mix for specific crops, while also being another potential source of toxic metals.

Table 1. Measurement of various elements in soil on the PlasmaQuant® PQ 9000 ICP-OES

Element	Line	Soil Digest Conten	Soil Digest Content in mg/kg		Detection Limit
	nm	Measured	Expected	%	mg/kg
As	188.9790	8.23 ± 0.04	8.5	0.1	0.05
Ca	315.8869	41,800 ± 100	42,000	0.3	-
Cd	214.4410	0.233 ± 0.04	0.24	4	0.015
Cd	228.8018	0.232 ± 0.07	0.235	2	0.03
Cr	267.7160	27.45 ± 0.05	27.6	0.6	0.04
Cu	327.3960	17.5 ± 0.1	17.2	0.2	0.1
K	766.4911	1,890 ± 30	1,900	1	-
Mg	279.0777	5,960 ± 10	6,000	0.1	-
Ni	231.6036	24.73 ± 0.03	24.50	0.1	0.05
Р	177.4340	920 ± 10	900	1	-
Pb	220.3534	23.4 ± 0.2	23.0	0.3	0.35
TI	190.7960	0.17 ± 0.06 (< LOQ)	-	18	0.075 (LOQ 0.22)
Zn	206.2000	60.4 ± 0.2	60.0	0.2	0.025



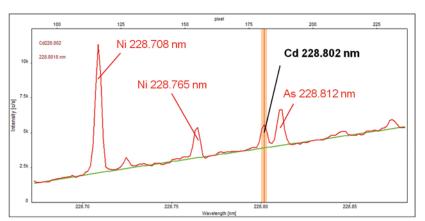
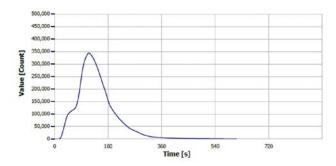


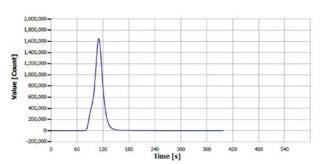
Figure 1. Simultaneous determination of Cd, As and Ni on the PlasmaQuant® PQ 9000 ICP-OES with Automatic Background Correction (in green)

The content of organic carbon in soils and fertilizers is also important as the organic compounds are biodegraded by microorganisms. Organic acids are produced and contribute significantly to the mobilization of heavy metals via complexation and lead to their transfer into lower soil layers and ground water. Elemental Analyzers such as Analytik Jena's **multi EA® 4000** is a fully automated system able to measure Total Inorganic Carbon (TIC), Total Carbon (TC) and Total Organic Carbon (TOC) in fertilizer and soil.

Table 2: Results of the TIC, TC and TOC determination in fertilizer and soil samples

Sample	TIC [%]	TC [%]	TOC [%]
Dolomite	12.41 ± 0.35	12.24 ± 0.35	0.00 ± 0.00
Calcium sulfate	0.82 ± 0.05	0.96 ± 0.05	0.20 ± 0.05
Fertilizer Pellet	0.57 ± 0.06	0.69 ± 0.03	0.13 ± 0.05
Soil Reference Material	11.8 ± 1.54	55.6 ± 2.24	46.7 ± 2.81
Soil Reference Values	12.0	55.8	47.0







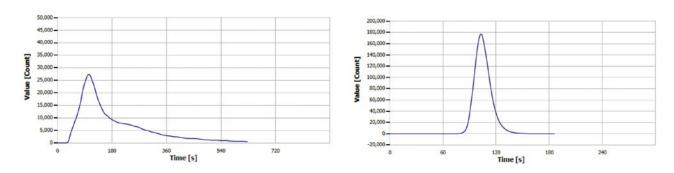


Figure 2. Characteristic measurement curves for Total Inorganic Carbon (left) and Total Carbon (right)

For the characterization of cultivated areas in agriculture, an important parameter is the determination of microbial biomass in soils as well as dissolved organic matter (DOM). They are the basis of the microorganisms' diet. For this purpose, fumigated and non-fumigated soil samples are extracted by aqueous salt solutions (e.g. $0.5 \text{ M K}_2\text{SO}_4$) and the extractable organic carbon (EOC) and extractable nitrogen (EN) are determined by a TOC/TN analyzer like the Analytik Jena **multi N/C® 2100S or multi N/C® 3100.**

Table 3: Results of the Non-Purgeable Organic Carbon (NPOC) and Total Nitrogen (TN) determination in soil samples

Sample name	NPOC [mg/L]	NPOC RSD [%]	TN [mg/L]	TN RSD [%]
Soil sample 1	1.56 ± 0.02	2.2	0.497 ± 0.003	1.1
Soil sample 2	11.6 ± 0.1	1.3	4.81 ± 0.02	0.9
Soil Reference Material	5.26 ± 0.04	1.6	1.22 ± 0.01	0.8
Soil Reference Values	5.18		1.30	

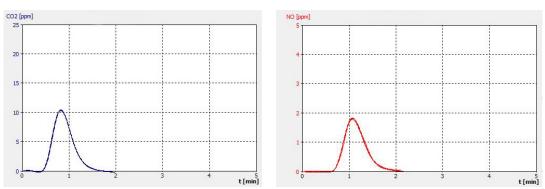


Figure 3: Characteristic measurement curves for Non-Purgeable Organic Carbon (NPOC) and Total Nitrogen (TN) of soil sample 1

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Animal Feed

Animal feed typically refers to foods or forages given to animals and include hay, straw, silage, compressed and pelleted feeds, oils and mixed rations, and sprouted grains and legumes. Feed grains are the most important source of animal feed globally. The two most important feed grains are corn maize for energy and soybean meal maize for protein. Other feed grains include wheat, oats, barley and rice, among others.

Animal feed plays a significant role in the daily uptake of nutrients and fibers to maintain the health of livestock. Besides the organically bound elements, hydrogen, carbon, nitrogen and oxygen that are primarily derived from air and water, there are more than 30 dietary elements necessary for the correct functioning of living organisms.

Phosphorus, potassium and sulphur are regarded as macronutrients in all living systems. Calcium and magnesium are required in relatively large quantities while living organisms need the remaining minerals in trace to minor amounts. Of the trace elements required for normal plant growth, also referred to as micronutrients, Boron, Copper, Iron, Manganese, Zinc, and Molybdenum are regarded as the most important and best understood. The remaining micronutrients play definitive roles in the metabolism of animals and humans, while chloride and sodium are known to have plant growth functions.

Calcium, for example, is the main component of bones and teeth for strength and also helps with blood clotting and proper function of the nervous system. Calcium deficiency can cause osteoporosis metabolic disorder and other problems in humans and animals. Magnesium is important for ruminants to prevent grass tetany, selenium is known to be a major factor in the fertility of cows, and deficiency of manganese causes skeletal deformation in animals and inhibits the production of collagen in wound healing.

On the contrary, toxic elements will have adverse effects on organisms. Examples of such harmful elements include Be, Sb, Bi, Ba, U, Al, Tl, Hg, Cd and Pb. Toxic elements tend to accumulate in organs including the liver, kidneys, pancreas and lungs. For instance, cadmium causes kidney damage and cardiovascular disease while lead affects almost every organ and system in the body, especially the brain and nervous system, with children being most susceptible. Mercury is considered by World Health Organization (WHO) to be one of the top ten toxic chemicals, especially in its methylated form, and has toxic effects on the nervous, digestive and immune systems as well as on lungs, kidneys, skin and eyes. Exposure mainly occurs through consumption of fish and shellfish contaminated with methylmercury.

Looking upstream in the food supply chain, and in particular to the agricultural industry, it is clear that providing the correct balance of macro minerals and trace metals in animal feed helps livestock to thrive and remain disease free. Accurate measurement of elemental composition in food and agricultural products is essential in ensuring product safety and to maintaining adequate levels of nutritional content. With concentrations typically ranging from sub parts-per-billion to high parts-per-million in solution, ICP-OES and ICP-MS are vital tools for providing fast, reliable and routine analysis of samples over a large concentration range.



Table 4: Results for a Hay intra-laboratory reference material, analyzed by ICP-MS following a 400-fold dilution

Element	Measured (mg/kg)	Expected (mg/kg)
²³ Na	0.33%	0.34%
²⁴ Mg	0.19%	0.21%
³¹ P	0.37%	0.39%
³⁹ K	0.34%	0.35%
⁴⁴ Ca	0.54%	0.57%
⁵² Cr	1.8	1.9
⁵⁵ Mn	79.1	81.9
⁵⁶ Fe	498	531
⁵⁹ Co	0.18	0.19
⁶⁰ Ni	1.53	1.61
⁶⁵ Cu	7.5	7.8
⁶⁶ Zn	33.0	34.9
⁷⁵ As	0.27	0.28
⁷⁸ Se	0.047	0.049
¹¹⁴ Cd	0.079	0.083
²⁰² Hg	0.014	0.015
²⁰⁶⁻²⁰⁸ Pb	1.14	1.19



Table 5. Results for an Animal feed reference material, analyzed by ICP-OES following a 2000-fold dilution

Element	Line (nm)	Measured (mg/kg)	Expected (mg/kg)
Al	396.152	0.20%	0.21%
Ca	317.933	12.2%	12.1%
Cu	327.396	0.22%	0.20%
Fe	238.204	0.63%	0.64%
K	766.491	11.0%	11.2%
Mg	285.213	3.99%	3.99%
Mn	259.372	0.14%	0.14%
Na	589.592	3.25%	2.98%
Р	178.224	10.6%	10.5%
S	180.672	4.11%	3.84%
Zn	206.200	4.32%	4.58%
В	249.773	116	120
Со	228.615	< DL	< 20
Cr	267.716	8	< 32
Мо	202.030	6.2	< 20
Ni	231.604	6.4	< 50
V	292.464	< DL	-

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Food processing

Milk production

Historically, food products with a short shelf-life such as dairy were often produced and sold directly to consumers at farm shops and markets or consumed on the farm itself, particularly where subsistence farming was practiced. Therefore, the journey from farm to fork was far shorter and with less handling. However, most milk products that are consumed today pass through many more hands and in greater quantity over a longer period of time before reaching the final consumer. Hence today, appropriate milk heating and pasteurization is of the utmost importance for dairy production, milk product safety and consumer health.

Milk production is a business with small margins but high quality expectations. Based on flow, level, pressure, temperature and analytical sensor signals, milk processes are optimized for cost control while keeping the product quality at a consistently high level. Sufficient heat treatment is a basic requirement for consumer safety and pasteurization methods are usually standardized and controlled by national food safety agencies.

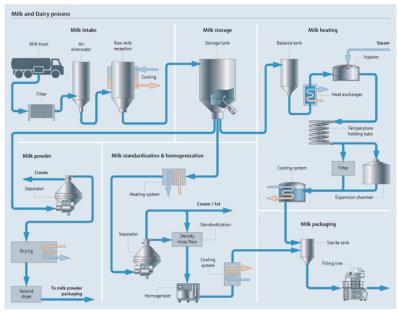


Figure 4. Flow diagram of the milk and dairy process

Milk heating and pasteurization

Milk is an excellent medium for microbial growth and when stored at ambient temperature, bacteria and other pathogens soon proliferate. Milk heating and pasteurization is the reason for milk's extended shelf life and insufficient heating leads to increased bacterial presence and spoilage. The process eliminates pathogenic microbes and sufficiently lowers microbial content to prolong the quality of milk products by reducing pathogens to a level where they are unlikely to cause disease when stored as recommended and consumed before the expiration date.



Diseases prevented by pasteurization can include tuberculosis, brucellosis, diphtheria, scarlet fever, and Q-fever. It also kills the harmful bacteria of Salmonella, Listeria, Yersinia, Campylobacter, Staphylococcus aureus, and Escherichia coli. Pasteurization typically consists of heating milk to a temperature of at least 72°C (162°F) for approximately 15-20 seconds and typically provides a refrigerated shelf life of two to three weeks.

Unlike sterilization, pasteurization is not intended to kill all microorganisms in food. Instead, it aims to reduce the number of viable pathogens so they are unlikely to cause disease. Ultra-heat-treating or UHT processing holds the milk at a temperature of 140° C (284° F) for approximately 4 seconds. During UHT processing, milk is sterilized, and not pasteurized, and allows for storage of several months without refrigeration. The process is achieved by spraying the milk through a nozzle into a chamber filled with high-temperature steam under pressure. After the temperature reaches 140° C, the fluid is cooled instantly in a vacuum chamber and packed in a pre-sterilized airtight container.

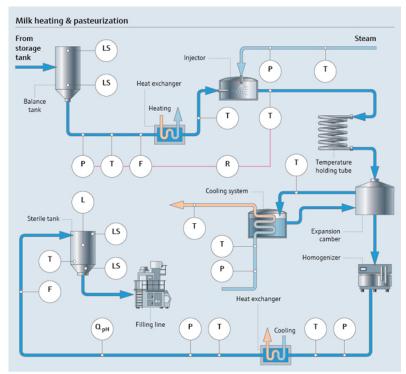


Figure 5. Flow diagram of the milk heating and pasteurization process

On-the-spot milk heating is essential and heat treatment is mainly controlled by three sensor technologies:

- Temperature for the heat control
- Flow velocity to ensure that the impact time is long enough
- Differential pressure across heat exchanger

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Flow measurement in milk heating

Accurate flow sensors ensure the right amount of heat is applied to achieve safe results. The electromagnetic flow-meter carries the main burden of flow measurement in dairy operations and plays a critical role in milk heating. The flow velocity is controlled by an electromagnetic flow meter. The **Promag H100** sensor features integrated temperature and conductivity measurement and provides real-time heat-exchanger control. Integrated conductivity measurement supports phase shift and cleaning operations, and temperature detection in the sensor improves not only the conductivity signal, but also the accuracy of the volumetric flow signal. This is important when transferring milk from one process compartment to the next, as the change of temperature will result in a change in volume and must be compensated for.

Heating control through fast temperature measurements

The critical control point for successful pasteurization is temperature and Endress+Hauser has the fastest temperature sensor for hygienic processes. The **iTherm QuickSens** supplies the correct temperature value three times faster than other sensors. The accuracy and the response time ensures that no energy is wasted and the milk product is not exposed to more thermal stress than necessary, maintaining milk quality and reducing energy costs.

<u>Differential pressure across heat exchanger</u>

Since heat exchangers are used to heat the milk, it needs to be ensured that raw milk does not mix with pasteurized milk. Therefore, the differential pressure across the heat exchanger is monitored as the pressure must always be higher for the pasteurized milk. In case of pinhole leaks in the heat exchanger, the pasteurized milk will be pushed into raw milk and not the other way around. The Endress+Hauser **Cerabar PMP51** digital pressure transmitter with metal membrane is typically used in such hygiene applications. Its Quick Setup with adjustable measuring range allows simple commissioning, reduces costs and saves time.

All these control points have to be connected to legal controls. The Endress+Hauser audit-proof **Data Manager Memograph RSG45** is a flexible and powerful system for organizing process values. The measured process values are clearly presented on the display and logged safely, while limits are monitored and analyzed. Via common communication protocols, the measured and calculated values can be easily communicated to higher-level systems and individual plant modules can be interconnected.



Hg in milk products and fish

Accelerated industrial and agricultural development over recent centuries has seen a considerable increase in exposure to toxic elements such as mercury. Livestock reared freely on pasture are good indicators of environmental pollution from heavy metals as well as a potential source of contamination. Mercury is also a known bio-accumulator with high levels recorded in fish, particularly those at the upper end of the food chain including tuna, shark, mackerel and swordfish. Mercury is also present at dangerously high concentrations in the more toxic methyl-mercury form. Aside from fish and other seafood, a principal source of mercury in human bodies is absorption of matter originating from dental amalgam.

It is widely accepted that mercury affects neurological development within the brain, particularly in infants. Breastfeeding infants are particularly susceptible to toxicity, especially in communities with a high intake of seafood, as methylmercury is excreted in human milk. Therefore, infants nursed for long periods are potentially at increased risk of developing methylmercury toxicity. Conversely, a study by Hapke, 1991 found that cattle are able to demethylate mercury in the rumen and thus absorb less mercury. As a result, cow's milk is found to contain appreciably lower levels of mercury.

Determination of Hg in milk powder and tuna

Low-level concentrations of Hg in milk powder, tuna and fish protein were determined using the contrAA® continuum source Atomic Absorption Spectrometer (AAS) from Analytik Jena.

The contrAA® 800 AAS with HydrEA accessory allows for ultra-trace detection of mercury with detection limits in the parts-per-trillion range, well below concentrations found in milk products. Direct analysis of fish protein without sample digestion is also possible using the exclusive solid AA® accessory in combination with the contrAA® 800 G graphite furnace system.

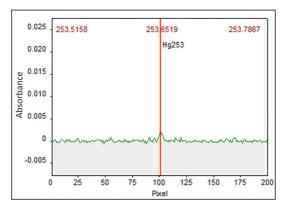
Table 6. Trace-level Hg determination in milk and fish products with the contrAA® AAS

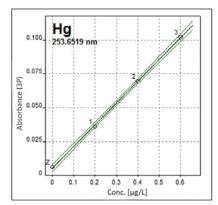
Element	Wavelength [nm]	Sample	Concentration [µg/kg]
Нд	253.652	Lactose powder	< 2
		Tuna fresh fillet	372 ± 15
		Tuna freeze dried	1981 ± 77
		DORM-2*	4330 ± 90

^{*}Fish protein certified reference material, certified content: $4640 \pm 260 \mu g/kg$

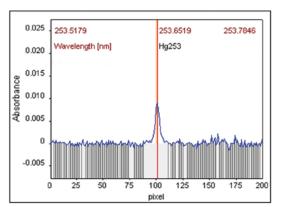
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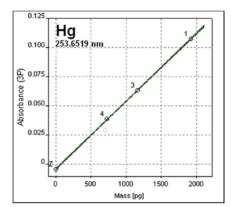






Figures 6a and 6b. Mercury signal in lactose powder (6a) and generated calibration curve (6b) on the contrAA® AAS with HydrEA accessory





Figures 7a and 7b. Mercury signal in fresh tuna fillet (7a) and generated calibration curve (7b) on the contrAA® AAS using direct solid AAS.

Arsenic Species Identification

Arsenic (As) is a naturally occurring element and is present in the air, soil, water and food. Human activities including the burning of coal and other fuels and the use of arsenic compounds in medicines, herbicides and wood preservatives have contributed.

Next to drinking water, rice consumption is a major source of arsenic that concerns approximately 3 billion people. World rice consumption has risen from 156 million in 1960 to 496.6 million metric tons in 2013. Moreover, studies show that arsenic exposure is more critical in rice than in any other food stuff. For example, the arsenic level in rice is 10 times higher than in wheat and barley. The elevated arsenic is due to rice being the only major cereal crop grown under flooded conditions, leading to high arsenic availability and high concentrations close to the root. In addition to direct ingestion, using rice straw for cattle feed increases the risk of arsenic exposure.

According to the World Health Organization guidelines, the permissible level for total arsenic in drinking water is 10 ng/mL. Although no such limit exists for food products, the Food and Agriculture Organization / World Health Organization (FAO/WHO) recommend an intake no greater than $15 \mu g$ per kg body weight per week.



Inorganic arsenic is associated with many adverse health effects, particularly when exposed during pregnancy, infancy and early childhood. The Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration have reported both cancer risks, including lung, liver and kidney, and non-cancer health effects, including cardiovascular disease, diabetes and neurological effects from the long-term exposure to arsenic in rice grain and rice products.

The toxicity of arsenic depends not only on the total concentration, but also its chemical forms as these differ in terms of mobility, toxicity and bioavailability. The soluble inorganic trivalent arsenic (AsIII) and pentavalent arsenic (AsV) are the most toxic forms and are rapidly absorbed by the body. Once absorbed, inorganic arsenic is metabolized by reduction from AsV to AsIII in the blood and is taken up by cells in tissues mainly in the liver. Other common ingested forms including the organic monomethyl arsenic (MMA) and dimethyl arsenic (DMA) have significantly reduced toxicities. Inorganic arsenic is also extensively methylated by intracellular oxidative addition to MMA and DMA and its metabolites are excreted primarily in the urine.

Rice typically contains a high proportion of the inorganic forms of arsenic, emphasizing the importance of arsenic speciation in the analysis of rice samples. Studies have also demonstrated that rinsing rice and cooking rice in excess water can reduce the amount of arsenic present upon consumption. Although, cooking rice with arsenic-contaminated water can increase arsenic ingestion.

High Performance Liquid Chromatography (HPLC) coupled to ICP-MS is the preferred system configuration for the determination of arsenic species in foods and beverages. The HPLC offers fast separation of the main arsenic species in less than 10 minutes while the Analytik Jena PlasmaQuant® MS ICP-MS provides ultratrace detection to $<0.4~\mu g$ of As per kg of rice.

Table 7. Determination of As species in a basmati rice by HPLC-ICP-MS

	AsIII	DMA	MMA	AsV	Sum of the 4 species
Mean [As] (μg/kg)	162	60	ND	95	317
% RSD	4.3	6.7		11.2	5.7

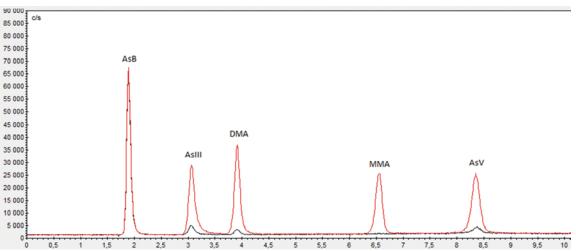


Figure 8: Overlay of 250 µg/kg spike (red) and basmati rice (black) chromatograms

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Animal Species Identification

The identification of non-declared constituents of animal origin is required in order to meet international regulatory standards for compliance with religious and health laws. The adulteration and substitution of food is a concern for various reasons such as public health, religious factors, authenticity and unfair competitive advantage in the food industry. One of the most convenient methods for accurate identification of animal species in processed foods is by the genetic information manifested as DNA. For example, in determining the origin of gelatin in gummy bears, types of meat present in minced meat or the identification of pork traces in rice.

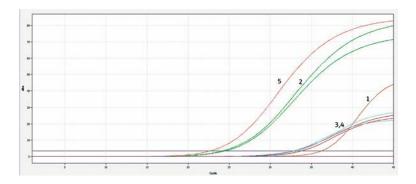
Analytik Jena's InnuPure® C16 touch automated nucleic acid extraction system combined with the innuPREP Food DNA Kit-IPC16 extraction kit allows for the automated preparation, isolation and collection of DNA using pre-filled, sealed reagent plastics. Eluates are analyzed on the high-performance real-time PCR (polymerase chain reaction) thermal cycler qTOWER³ using the innuDETECT Species ID Assays for species identification of goat, sheep, beef, pork, horse, donkey, goat or turkey.

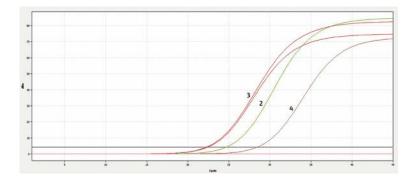
PCR is a technique used in molecular genetics and permits the analysis of any short sequence of DNA (or RNA) even in samples containing only minute quantities. PCR is used to reproduce and amplify selected sections of DNA for analysis. Real-time PCR results presented in table 7 and amplification plots in figures 8a, 8b and 8c identify the actual species of five different cheeses that were investigated with respect to the milk source, including cow, goat and sheep, and were compared against what was the declared on the original packaging. Four of the five cheeses traced back to other sources of milk than what was declared on the packaging.

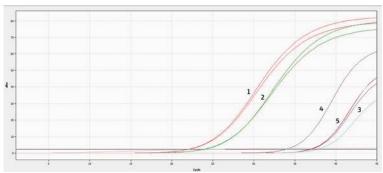
Table 8. Declared versus detected origin of milk source in five different cheeses

Nr.	Declared Milk	Detected Origin		
		Goat	Sheep	Cow
1	Goat	X		х
2	Goat, sheep, cow	х	х	х
3	Sheep	х	х	х
4	Buffalo	х	x	х
5	Cow	Х		х









Figures 9a, 9b & 9c. Amplification plots for cow (a), sheep (b) and goat (c) DNA in various milk sources measured on the qTOWER³.

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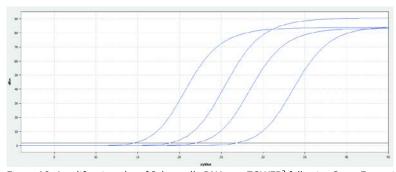
Food borne pathogen detection

Foodborne diseases encompass a wide spectrum of illnesses and are a growing public health problem and result from the ingestion of foods contaminated with microorganisms and may occur at any stage in the process from food production to consumption. The most common symptoms of foodborne illnesses are infections or irritations of the gastrointestinal tract and include vomiting, diarrhea, abdominal pain, fever, and chills. However, other symptoms such as multiple-organ failure or even cancer can result from the consumption of contaminated foodstuff. Diarrheal diseases are the most common illness causing over 550 million people to fall ill and over 230,000 deaths every year. Food safety, nutrition and food security are inextricable linked with unsafe food creating a viscous cycle of disease and malnutrition, and mainly affecting infants, young children, the elderly and the sick.

DNA extraction using **SmartExtraction** technology provides even faster extraction of foodborne pathogens including Listeria, Salmonella, E.coli and Campylobacter. While Analytik Jena's TaqMan® based **innuDETECT Pathogen Assays** makes highly sensitive and routine detection of the pathogens possible.

Table 9: Concentrations of pathogen after standard culturing (1mL used for extraction) and detected Ct values

Nr.	cfu/ml	Ct value
1	8.3 x 10 ⁸	14.08
2	8.3 x 10 ⁷	19.03
3	8.3 x 10 ⁶	22.22
4	8.3 x 10 ⁵	27.27



 $Figure~10: Amplification~plot~of~Salmonella~DNA~on~qTOWER^3~following~SmartExtraction~on~InnuPure ^{\$}~C16~touch$

Summary

Analytik Jena and its parent company Endress+Hauser offer a comprehensive range of elemental analyzers, flow, temperature and pressure sensors, and molecular biological solutions that contribute to the daily assurance that high quality food, meeting both national and international regulatory requirements and considered safe for consumption, is delivered to your table. Analytik Jena and Endress+Hauser are well positioned to offer you a complete Farm to Fork solution for your food safety requirements.

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