LGC AXIO PROFICIENCY TESTING

Prevention is better than cure

The role of proficiency testing in limiting the risk of food recalls

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ISO/IEC 17043

Introduction

This paper covers the potential impact of product recalls in the food and feed sector, highlighting and exploring the three most common causes.

Product recalls are a key concern for all players in the food chain, from supply to sales, from production to testing. Many product recalls involve consumer health risks, which in some cases may have the potential to prove fatal, so even preventative or voluntary recalls can cause a negative impact on the reputation of the brand or product. The costs incurred from this reputational damage and subsequent lost sales come on top of the extensive costs inherent to the recall process and writing off of stock, meaning that a recall can cause significant financial impact to all involved – not to mention the possible health impact for consumers.

Direct costs include notification of consumers and supply chain, product withdrawal and destruction. However, the most significant cost to the company is likely to be litigation expenses and compensation. Recently, renowned food safety advocate Bill Marler called on the companies responsible for an E. coli food outbreak to pay the medical bills and loss of wages of all those affected. The direct cost to a company for a single recall is estimated to average $10 million, a figure that does not even take into account impact on future sales due to reputational damage[1]. Using conservative estimates, the combined direct and indirect impact of recalls costs the food industry $10 billion per year[2].

This paper details the ways in which manufacturers and laboratories can support the quality assurance of food products and establish confidence in their analytical methods, thus protecting consumers and preventing potentially costly and brand-damaging incidents or recalls.

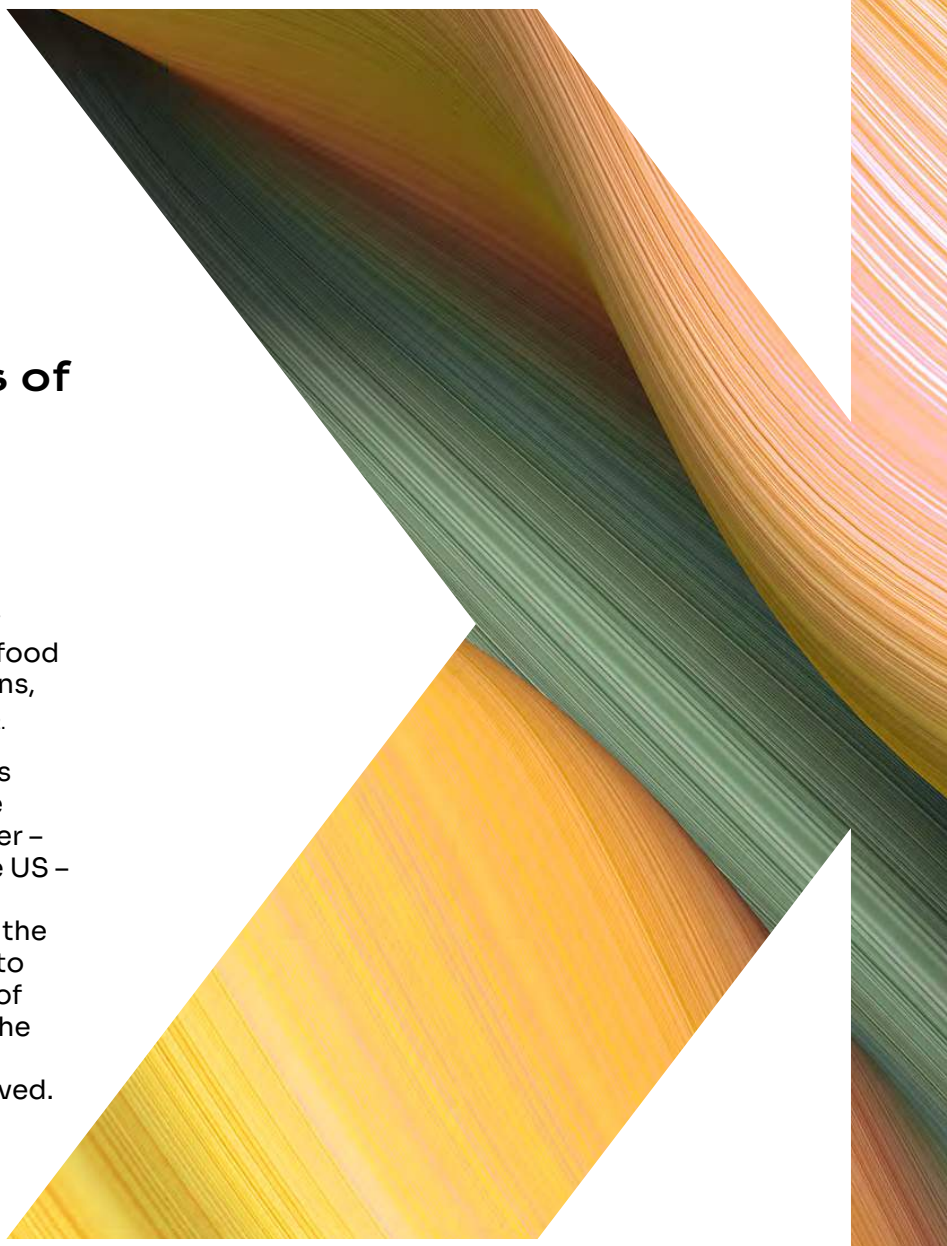
The role of proficiency testing in limiting the risk of food recalls.

In 2017 the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service tallied 456 U.S. food recalls. In its annual report for the same year [3], The Rapid Alert System for Food and Feed for European member states (RASFF) described a total of 3,832 original notifications, of which 942 were classified as alerts, which have the potential to lead to a recall.

The reasons for notifications, alerts, or reminders can be varied, and not all notifications result in a serious risk decision. For example, a notification of unexpected/unlabelled food additives, flavouring or organoleptic flaws/faults does not systematically lead to a food recall. However, notifications of certain physical (presence of foreign bodies), microbiological (pathogenic), or chemical (allergen, toxin, or heavy metal) risks frequently lead to the withdrawal of the products concerned. The three most common causes of withdrawal have remained unchanged for the past four years: allergens, foreign bodies, and pathogenic organisms, Salmonella being one of the most frequently implicated culprits[4].

An effective quality control system can minimise potential hazards that lead to a product recall. These quality control systems should have procedures in place for regularly monitoring the validity of activities undertaken, as stated in ISO/IEC 17025 7.8.2 [5]. Proficiency testing is one of the approved methods to evaluate a laboratory's performance, as it allows laboratories to consistently audit the quality of their output by participating in inter-laboratory comparisons.

Allergens



Introduction

Each year, millions of people around the world have allergic reactions to food[6].

Fortunately, in the majority of instances these result in relatively minor symptoms, although some food allergies can cause severe reactions, and may even be life-threatening[2].

While a very large number of foods have been demonstrated to cause allergic reactions, a smaller number – fourteen in the EU and eight in the US – have been identified as the most common allergenic foods and are the subject of legislation. In addition to accounting for a high proportion of food allergen reactions, they are the sources from which many other products and ingredients are derived.

LGC AXIO Proficiency Testing offers a range of PT samples supporting allergen testing, as part of our Quality in Food Chemistry Scheme (QFCS) find out more: www.lgcstandards.com/QFCS

Allergens

Allergenic ingredients must be declared with an explicit reference to the allergen, to ensure clarity and uniform understanding; any allergen should additionally be emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style or background colour[8].

In addition to the wide range of allergens which may be present in foods, the allergenic activity of a food or ingredient may decrease, remain unchanged, or even increase as a result of food processing. This increases the need for clarity in labelling, thorough control of the production process, appropriate cleaning procedures, and robust methods of analytical testing, including effective use of reference materials and proficiency testing.

For **allergens** see ingredients in **bold.**

Not suitable for **Nut, Peanut** and **Sesame** allergy sufferers due to manufacturing methods.

Suitable for Vegetarians

The improved awareness of food allergens and increased frequency of testing means that incidents and recalls as a result of undeclared allergens or excessive allergen content have increased steadily since 2012, accounting for 9% of UK[9] and 4% of RASFF[10] reported food incidents in 2017.

In order to support monitoring by producers and inspection bodies and to provide foods that are safe for consumers, reliable analytical methods are required for the detection and quantification of food allergens.

Methods of analysis for allergens in food broadly fit into three categories: the analysis of allergenic proteins by either physiochemical methods (mass spectrometry, HPLC, SDSPAGE), immunological methods (ELISA, immunoblotting, dipsticks, protein biosensors) and analysis of DNA by polymerase chain reaction mediated methods (end-point PCR, real-time PCR, DNA microarrays). Although all of these methods are currently available for the determination of allergens in food, the majority of kits for routine analysis are based on immunological methods, for reasons of sensitivity and ease of use.

As the number of combinations of food types, possible matrices and allergens is so large, no single analytical method will fit all purposes. Any analytical method must fulfil the usual validation criteria of robustness, specificity, sensitivity, accuracy and precision. Ideally, the performance of methods will be assessed against a range of sample types, allergen concentrations and both processed and unprocessed materials.

Whilst it is important to validate the analytical method used to ensure it is the correct one, it is also important to validate the execution of the chosen method. Proficiency testing can provide this type of verification, enabling laboratories to put a sample through their entire testing process and compare their results with those produced by other participants. It also allows users to monitor their performance and the performance of their chosen method over time. This then provides confidence in the competence of their analysts and the procedures in place, as well as helping identify areas of improvement.

Incidents and recalls as a result of undeclared allergens or excessive allergen content accounted for 9% of UK reported food incidents in 2017.

Foreign Bodies

Introduction

Requirements for product quality are higher than ever, so counter measures against 'physical contamination' in manufacturing processes are becoming an extremely important topic in all industries.

The term 'physical contamination' should refer to the addition of foreign bodies not directly of biological origin, such as paper, paint or glass, but legally the term refers to all contamination by a non-microbial source, including human hair, parts of insects and cleaning fluids. Physical contamination with foreign bodies is a perennial problem – in the UK the proportion of incidents due to foreign bodies is broadly stable year on year at around 5% (70 to 100 incidents)[11] – and one which appears very difficult to eliminate completely. Usually foreign bodies render the food unfit for human consumption.

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Foreign Bodies

A range of foreign bodies are routinely identified in foods, with metal, plastic and glass accounting for around half of the incidents recorded. That these three material types are detected so frequently illustrates the reason that foreign bodies are difficult to eliminate, since it is not possible to exclude these materials from manufacturing processes, with both equipment and packaging materials commonly made from metal, glass and plastic. Other materials routinely identified as foreign bodies include wood, stone, rubber and materials of animal origin.

Discovery of a piece of plastic in a Snickers bar in 2016 prompted an international recall for manufacturer Mars, due to concern about any similar plastic posing a choking hazard. The precautionary recall, which covered multiple products and 55 countries, was estimated to cost the business millions in product write-offs, recall costs, and lost sales from reputational damage, especially coming as it did just before Easter[12].

Foreign body contamination gives rise to three significant areas of concern: compliance with legislation, the risk of injury to consumers, and brand protection. It is essential that laboratories have confidence in their analytical testing and the proficiency testing schemes that they take part in, as failure to meet the requirements within these three areas could lead to prosecution, legal actions, loss of sales and ultimately the potential closure of the business.

Metal, plastic and glass account for around half of the foreign bodies incidents recorded.

Possible Solutions

The detection of foreign bodies in food can be carried out on the final product or during the production process itself.

Non-destructive techniques, such as X-rays or metal detection, can effectively 'see through' the finished product, though it is often more effective to test the materials during the production process, when a number of different approaches, from the simple to the highly sophisticated, can be more readily applied.

Equipment and methodology are available to enable pieces of metal to be detected in raw materials or foreign bodies to be determined by colour in real time; advanced techniques such as X-ray transmission imaging even have the potential to identify completely concealed foreign bodies and internal defects which have negative effects on food quality. The high sensitivity of the various detection and sorting systems can alter the rate of product rejection and increase the number of so-called false positives, but does reduce the risk of issues with the final product.

As a result of the wide array of testing options available, there is no single 'best' method for detecting foreign bodies in food. The most appropriate method will depend on multiple factors, from the product, packaging, and production process to the cost implications of both success and failure.

Post-hoc analysis, after a foreign body incident has come to light, can be a powerful diagnostic tool for determining the origin of contamination or the point in the production process during which the contaminant was introduced. For example, phosphatase analysis can determine whether insects were present in the product prior to a cooking process and chemical testing can provide presumptive results for the presence of blood. Meanwhile, the analysis of plastic type using FTIR or the determination of elemental composition by X-ray microanalysis can determine which part of the process/ equipment could be responsible for the contamination.

There is no single 'best' method for detecting foreign bodies in food.

A new era for food recalls: Blockchain

Along with analytical testing, technology can also play a role in minimising the impact of a product recall. Blockchain capabilities, which were originally developed to allow the secure exchange of cryptocurrency, have expanded to a swathe of additional industries. This includes food, for which the technology's highly secure but open systems hold great potential for improving supply chain traceability and accountability.

Each ingredient can be tracked from point of origin to final purchase, with a permanent database of the documentation collected throughout, such as livestock health certificates, freight storage temperatures, or wine grape origins.

The integrity of this blockchain data – it can be added to, but existing parts cannot be edited or deleted – allows food manufacturers, having identified hazards through analytical testing, to then locate which part of the production process it originates from within a few seconds13.

The U.S. Food and Drug Administration (FDA) recently released an announcement outlining "A New Era of Smarter Food Safety"[14] that will help to create an enhanced and more transparent food safety system, including a pilot program employing artificial intelligence. These technological advances will improve food surveillance, helping to increase the number, speed and accuracy of notifications and recalls, in order to protect both consumers and brands.

Pathogenic Organisms - Salmonella

Introduction

Salmonella bacteria can be found throughout the environment, but are most commonly encountered in raw eggs and egg products, raw or undercooked meat, poultry, chocolate, fruit and vegetables.

In addition to allergens and foreign bodies, industries involved in food manufacture and production face biological hazards. These include harmful microorganisms, so microbiological criteria are established and applied for a wide range of foods.

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Salmonella

In order to ensure that these criteria are met, testing is carried out throughout the manufacturing process, from raw materials to the finished product, to determine the microbiological quality of the food and ensure that the processes developed to remove microorganisms are effective. Even the environment in which the food is manufactured or prepared is commonly tested for the presence of microorganisms.

One of the most prevalent pathogens that causes problems in food is Salmonella, which is a member of the Enterobacteriaceae family. It is a Gram-negative rod-shaped bacterium commonly associated with the guts of humans and other animals. Although there are only two species of Salmonella, there are over 2,500 different strains, or serovars, according to the Kaufmann and White classification[15].

Salmonella bacteria can be found throughout the environment, but are most commonly encountered in raw eggs and egg products, raw or undercooked meat, poultry, chocolate, fruit and vegetables. Sensitive products such as infant milk powders[16] are particularly stringently monitored for the possible presence of Salmonella (which can survive for several weeks to months, depending upon the environment).

Though foodborne salmonellosis had been decreasing in Europe from 2012 to 2015, the general trend in both foodborne outbreaks and cases related to outbreaks is now showing an increase again, as noted in the 2016 European Union summary report on zoonoses, zoonotic agents and foodborne outbreaks[17].

Additionally, many different Salmonella serotypes are involved in foodborne outbreaks, with no detection method able to identify the entire range of them. The variety of Salmonella serovars responsible for outbreaks each year in the US is catalogued on the Centers for Disease Control and Prevention website[18]; this number seems also to be increasing recently, with eight or fewer serovars mentioned every year from 2006 to 2017, but 14 identified in 2018.

Several infant milk recalls involving Salmonella have recently made headlines, costing hundreds of millions of euros[19]. A 2006 outbreak in chocolate that led to more than 40 people falling ill resulted in Cadbury being fined £1m for food and hygiene offences. The confectionery giant also recalled more than one million of its chocolate bars and assessed the overall cost of the scandal at £20m, due to additional impact on sales[20].

Salmonella testing is the most prevalent food pathogen testing, and a large number of different techniques and commercial kits have been developed over the years. Standard methods consist of an enrichment step followed by streaking onto selective agar plates, and alternative methods are also available, using varied technologies (ELISA, chromogenic agars, molecular detection including PCR, etc.) and a range of protocols (depending on the type and quantity of food matrix).

Choosing the right testing method

Choosing the right testing method is a difficult decision, especially given that no single method will be able to detect all 2,500 serovars of Salmonella in all food matrices. Pathogens, when present, may exist in extremely small numbers and will not necessarily be distributed uniformly throughout the batch. For this reason, testing strategies have been developed to guarantee the absence of Salmonella in the final product. Those strategies include the testing of 25g samples (as defined in regulation), but also the testing of high portion samples (typically 375g) and a wide variety of environmental samples taken at various points in the production line.

Microbiological testing has many challenges, not least the difficulties of working with living organisms whose behaviour may be difficult to predict. Another issue is that microbiological testing is destructive; as such, it is not possible to test an entire batch of product. Instead, samples of the food are taken, which should be as representative as possible of the entire batch.

Challenges arise from not only methodology but also analyst expertise, with the vast majority of routine food samples tested in microbiology labs negative for Salmonella. This lack of familiarity means that analysts may be inexperienced with a positive result from a routine food sample, having had their only practice of positive results from limited reference strains used during quality control tests, rather than examples representative of the high variability within the Salmonella genus.

For this reason it is essential that a Salmonella proficiency testing scheme includes a comprehensive range of different strains and levels, with or without background flora, and occasionally even including atypical strains. This will provide an analyst the opportunity to fully challenge their methods under a number of different scenarios and increase their likelihood of detecting Salmonella in a real sample.

Conclusion

To assure optimum testing performance and reliable analytical results, laboratories can choose from a wide range of methods to test for food adulterants and levels of ingredients. There is no 'one size fits all' technique, and it is very important to consider the specificities of the products to be tested, from matrix to quantity, when choosing a method.

However, even the best method will only give accurate results if correctly implemented by the laboratory. Given the ever-increasing vigilance about food risk, reflected in reported foodborne outbreaks and incidents, it is more important than ever that laboratories scrutinise and assess their own performance. Quality assurance systems need to operate at the highest level of accuracy and reliability, in accordance with standards designed to protect the integrity of analytical testing in the food chain, such as ISO/IEC 17025.

As stated in the ISO/IEC 17025 standard [5], regular use of reference materials and participation in a proficiency testing scheme can provide the confidence required in the execution of a method, by enabling laboratories to test and compare results with the 'true' result, as well as with all other participants' results.

Involvement also allows participants to monitor their performance and the performance of their method over time. This helps provide assurance of the competence of a laboratory's analysts and the procedures it has in place, as well as helping identify areas where improvements can be made, to support ever more effective analysis and safeguard food quality and security.

To guarantee the quality of production and prevent expensive, damaging product recalls (or more critical consequences such as injury, food poisoning or allergic reactions), food industry brands commission a multitude of analyses of their products throughout the manufacturing process, either in-house or by outsourcing testing to third-party laboratories.

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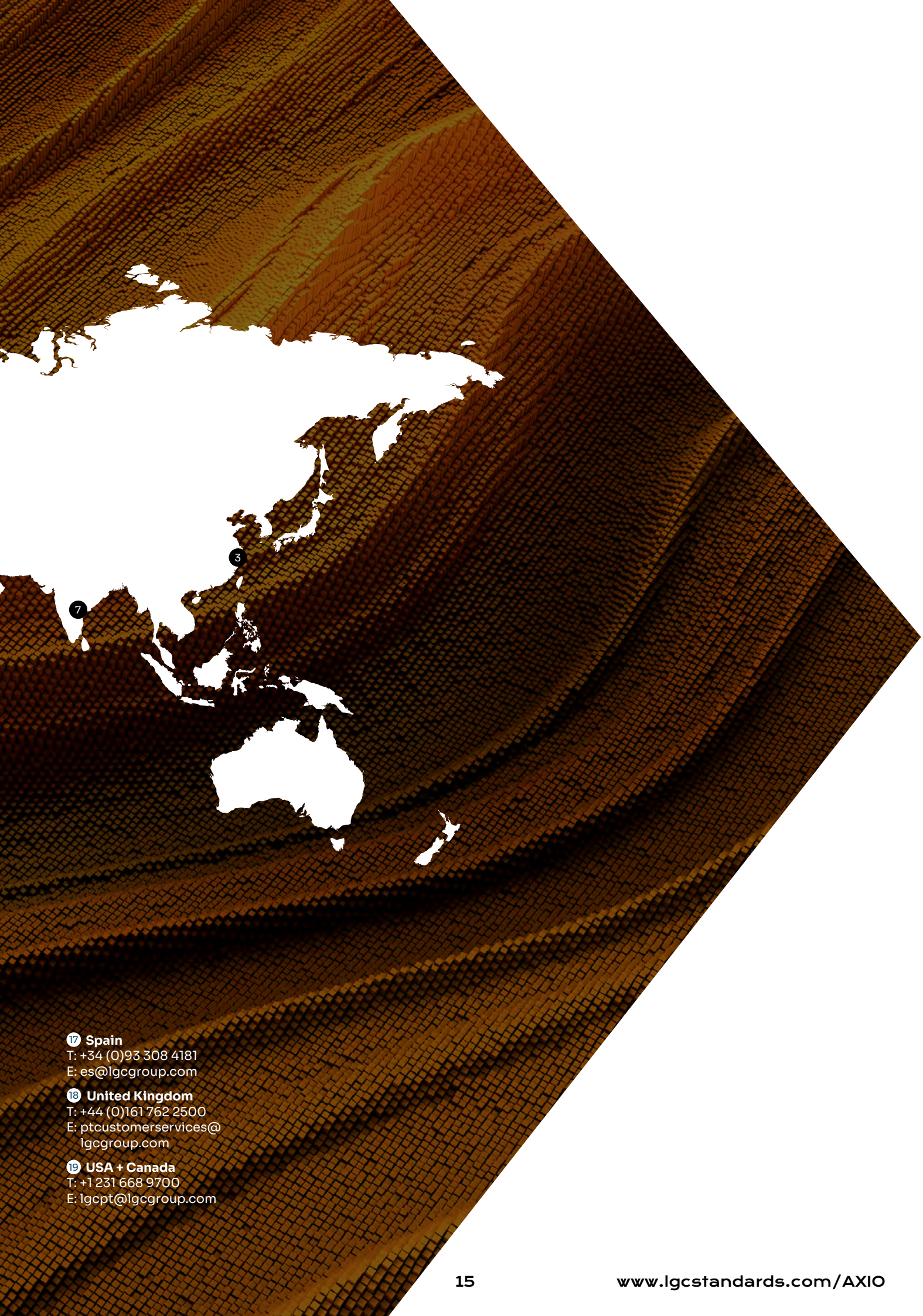

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