Other Service

A. BSCI

BSCI is neither an auditing company nor an accreditation system: BSCI provides companies with a social auditing methodology and report. It does not organise audits itself but provides a network of external accredited, experienced and independent auditing companies. Also, as part of the BSCI approach, social audits only represent one pillar of activity, complementary to capacity building and strong relations with all stakeholders of the supply chain.

BSCI is not a certification scheme: BSCI provides a system that helps companies to gradually improve working conditions in their supply chain. Producers that meet all BSCI requirements are encouraged to go further and achieve our best practice.

B. GOTS

Sustainable fashion, ethical clothing, fair production have many meanings. The Global Organic Textile Standard (GOTS) has a clearly defined set of criteria and is transparent.

GOTS is the worldwide leading textile processing standard for organic fibres, including ecological and social criteria, backed up by independent certification of the entire textile supply chain. GOTS certified final products may include fibre products, yarns, fabrics, clothes, home textiles, mattresses, personal hygiene products, as well as food contact textiles and more.

Having one common standard means textile processors and manufacturers can export their fabrics and garments with one organic certification that is accepted in all major markets. This transparency also gives consumers the power to choose truly organic products sourced from green supply chains.

The information in this section provides a basic overview of GOTS including:

- Philosophy
- Key Features
- Development and Implementation
- Chemicals and Accessories Approval
- Protection
- How to Identify GOTS Goods

C. Global G.A.P.

GLOBALG.A.P (previously EUREPGAP) is the European Retailers standard for Good Agricultural Practices (GAP), which encourages the adoption of commercially viable farm assurance schemes that promote sustainable agriculture and the minimization of agro-chemical inputs.

The European Retailers Group has created and implemented a series of sector specific farm certification standards in response to the demands of clients, retailers and their global suppliers.

Aim of Global G.A.P

The aim is to ensure integrity, transparency and harmonization of global agricultural standards. This includes the requirements for safe food that is produced respecting:

- Worker's health
- Safety and welfare
- Environmental
- Sustainable land use

BSI is certified to audit the GLOBALG.A.P Fruit and Vegetable Protocol. Typically, GLOBALG.A.P audits require two days to complete and we have GLOBALG.A.P approved auditors available to conduct these assessments.

Benefits of GLOBALG.A.P

- Improves processes and practices up to the farm gate
- Helps motivate your workforce
- Leads to improved facilities, training and working conditions
- Can improve productivity
- Encourages sound environmentally farming practices

D. HACCP CERTIFICATION

The HACCP system is a procedure control system guidelines which is applicable to any organization those who are dealing with Manufacturing, trading, supply, retailing, packing, transportation, farming etc of food product.

HACCP (Hazard Analysis and Critical Control Points) is a preventative food safety management system in which every step in the manufacture, storage and distribution of a food product is analyzed for microbiological, physical and chemical hazards.

The effective implementation of HACCP will improve the ability of companies to: protect and increase brands and private labels, promote consumer confidence and conform to regulatory and market needs.

HACCP can be applied to all stages of a food supply chain, from food production and preparation procedures, to packaging and distribution. The Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) both require HACCP programs for juice, seafood and meat and poultry.

HACCP Principals

- Determine Critical Control Points (CCP). For each risk recognized.
- The application of hazard analysis
- Determination of corrective measures in case the watching shows that the CCP is not within the critical limits.
- Establish procedures for verification and certification processes and the HACCP system is effective and it works well. The verification activities should be included authorized persons employed in production
- The establishment and actual management of records and documents
- Establishing critical limits, maximal or minimum value, by which biological, chemical and physical hazards in order to control the pedagogical prevention.
- Determination of processes for monitoring CCPs

E. HALAL CERTIFICATION

OVERVIEW

Halal product certification is the prerequisite for entering the global Halal market. A halal certificate is a document issued by an Islamic organization certifying that the products listed on it meet Islamic dietary guidelines, as defined by that certifying agency. There were 3 types of Halal certificates:

Registration of a site certificate: This type of certificate signifies that a plant, production facility, food establishment, slaughterhouse, abattoir, or any establishment handling food has been inspected and approved to produce, distribute, or market halal food. This does not mean that all food products made or handled at such a facility are halal certified. A site certificate should not be used as a Halal product certificate.

Halal certificate for a specific product with specific duration: This type of certificate signifies that the listed product or products meet the halal guidelines formulated by the certifying organization. Such a certificate may be issued for a certain time period or for a specified quantity of the product destined for a particular distributor or importer. If the certificate is for a specific quantity, it may be called a batch certificate or a shipment certificate. Meat and poultry products, for which each batch or consignment has to be certified, generally receive a batch certificate.
Yearly certification: This may be automatically renewed contingent on passing the annual inspection, through halal compliance and payment of the certification fee
However, there were some surveys showing that entrepreneurs facing certification challenges when entering the global Halal market:

Reaching a consensus on certification requirements that avoids confusing, contradictory and costly requirements that will inhibit development of the Halal industry; Protecting the integrity of Halal certification in order to avoid a loss of confidence by consumers;

Ensuring that claims regarding health and safety are based on science
The relative lack of market information on Halal markets presents a significant challenge to exporters, especially exporters new to these markets.

F. KOSHER CERTIFICATION

1. Introduction

As it says in the German, Man ist was man isst! Man is what man eats. The word kosher is familiar and, at the same time, foreign. One may think of strict rules and religious regulations.

In Hebrew, “Kashrus,” from the root kosher (or “kasher”), means suitable and/or “pure”, thus ensuring fitness for consumption.

The laws of “Kashrus” include a comprehensive legislation concerning permitted and forbidden foods. There are several aspects to these dietary rules. We will consider each aspect in turn.

2.1 Meat and its derivatives

Kosher meat must comply with certain rules.

Kosher Species of Animals:

According to the laws of the Torah, the only types of meat that may be eaten are cattle and game that have “cloven hooves” and “chew the cud.” If an animal species fulfills only one of these conditions (for example the pig, which has split hooves but does not chew the cud, or the camel, which chews the cud, but does not have split hooves), then its meat may not be eaten.

Examples of kosher animals in this category are bulls, cows, sheep, lambs, goats, veal, and springbok.

According to the laws of the Torah, to be eaten, a kosher species must be slaughtered by a "Schochet," a ritual slaughterer. Since Jewish Law prohibits causing any pain to animals, the slaughtering has to be effected in such a way that unconsciousness is instantaneous and death occurs almost instantaneously.

Kashering (Removing the blood) & removing the veins and skin (‘Porschen' or ‘Nikkur'):

After the animal is slaughtered, the Kosher Supervisor and his team treiber the carcass by removing certain forbidden fats and veins. After the meat has been treibered, it is soaked in a bath in room temperature water for a half hour. To draw out the blood, the soaked meat is then placed on special salting tables where it is salted with coarse salt on both sides for one hour.

2.2 Fowl/Poultry and their derivatives

Some birds may not be eaten. These include the eagle, owl, swan, pelican, vulture, and stork - as well as their brood and clutch of eggs (Lev. 11:13-20).

Only birds that are traditionally considered kosher, such as the goose, duck, chicken, and turkey, may be eaten.

2.3 Dairy Products and their derivatives

All kosher milk products must derive from kosher animals. In addition, the milk of impure cattle and game (e.g. donkey milk) is prohibited. Dairy products, of course, also may not contain non-kosher additives, and they may not include meat products or derivatives (for example, many types of cheese are manufactured with animal fats).

Additionally, a number of pre-processed foods contain small portions of milk products, such as whey. According to food product regulations, such tiny additives do not have to be declared on the packaging but may nevertheless render the product non-kosher. This applies especially to bread.

2.4 The prohibition of combining meat and milk

The Torah says: "You may not cook a young animal in the milk of its mother" (Ex.23:19). From this, it is derived that milk and meat products may not be mixed together. Not only may they not be cooked together, but they may not be served together on the same table and surely not eaten at the same time. This rule is scrupulously upheld in observant Jewish households, even in the handling of utensils, which are carefully separated into “fleishig” (meat) and “milchig” (dairy) and separately labeled. By strict observance of these laws, they become an

everyday habit. After meat meals, one must wait one, three, or six hours – depending on one's custom - before eating dairy. After dairy consumption, no interval is required before meat may be eaten.

2.5 Eggs

The eggs of kosher birds are permitted as long as they do not contain blood. Therefore, eggs must be individually examined.

2.6 Fish

Only fish with fins and scales may be eaten, for instance, tuna, salmon, and herring. Shellfish such as shrimps, crabs, mussels, and lobsters are forbidden.

2.7 Fruits, vegetables, cereals

All products that grow in the soil or on plants, bushes, or trees are kosher. However, all insects and animals that have many legs or very short legs are not kosher. Consequently, vegetables, fruits and other products infested with such insects must be checked and the insects removed. A vegetable prone to insect infestation (e.g. cauliflower) must be carefully examined.

2.8 Fruits and Green plants

Certain laws apply specifically to the planting and sowing of vegetables, fruits, and grains. Hybridization of different species: One may not sow two kinds of seeds on a field or in a vineyard. (Lev.19:19/ Dtn.22:19)

Forbidden fruit: Fruits from trees planted within the past three years may not be eaten. (Lev.19:23) New grain: Biblically, no new grain may be eaten, or bread baked from it, before one brings an “omer” of the first fruits of the harvest on the second day of Passover (Lev.23:14)

2.9 Kosher Wine

Gelatin, casein, and bull blood are inadmissible in the kosher wine-making process. Only the bacteria or kosher enzymes from the bowl may be used for fermentation. All devices and utensils used for the harvest or the processing of

the grapes must be cleansed under supervision. Bottles may not be filled multiple times.

In addition, all processing steps must be implemented in agreement with the requirements of “Halacha” (Jewish Religious Law). For example, in the vineyard no other plants may be cross-bred with the grapes (because of the prohibition of hybridization).

2.10 Beverages

Beverages manufactured from grape or grape-based derivatives may only be drunk if the grapes come from a kosher winery, prepared under strict Rabbinical Supervision.

3.0 Conclusion

The process of kosher certification has been radically affected by deep changes in the food industry and by the fact that more than 80% of the products offered by the industry contains pre-processed ingredients. Industrialization presents marvelous opportunities, but the inexorable pace of change in industrial procedures and the complexity of foodstuffs and ingredients also present significant challenges for the kosher certification process.

KIR has risen to these challenges in the course of more than fifty years' experience with food technology.

G. MDR 2020

In the medical industry, regulation has not previously deemed software as a medical device, meaning thousands of health devices and apps using software, such as insulin pumps, are offered within the market without rigorous authorizations. Fortunately, Medical Devices Regulation 2020 (MDR) is expected in May to improve industry standards.

In the medical industry, regulation has not previously deemed software as a medical device, meaning thousands of health devices and apps using software, such as insulin pumps, are offered within the market without rigorous authorizations. Fortunately, Medical Devices Regulation 2020 (MDR) is expected in May to improve industry standards.

This updated set of guidelines declares that some medical devices will require re-assessment to guarantee that they conform to the new regulatory documentation. For example, some equipment previously self-certified must go through requirement re-submission, as well as their clinical information, documentation and labeling updates.

Besides the re-class of several medical devices, the MDR also introduces some changes on the European Database on Medical Devices (EUDAMED), which will now contain more medical device data on certificates and investigations, conformity assessments, and post-market surveillance and vigilance and will be available to everyone, not only public authorities and manufacturers. This data should be delivered and remain up-to-date by manufacturers, even after the device enters the market. Another MDR novelty is the device traceability system based on Unique Device Identification, which allows for the unambiguous identification of a specific device on the market.

The case for Medical Devices Regulation 2020
Technology has advanced enormously over the last decade. Naturally, it has had a significant impact on medical devices and healthcare, improving diagnosis accuracy and treatment times. An example is the increasing number of apps and software used within the healthcare industry. However, technological evolution has also posed new safety challenges.

As technology evolves, so should regulations, achieved in a manner that avoids unnecessary constraint on the use of technology but, ultimately, prioritizes and ensures safety when using these devices.

A principal concern now, and an example of an issue raised by technological evolution that MDR has started to address, is cyber security. Critical Software business development manager, Ana Rita Silva asks: “How can we guarantee that patients are safe, their data can’t be compromised and the devices they use cannot be hacked?”

Challenges posed by Medical Devices Regulation 2020

Although MDR aims to guarantee an increase in safety and transparency, implemented modifications can still pose a challenge for all concerned with the medical devices industry. New classification guidelines will boost the number of devices presented to the evaluation process, which could mean that certification procedures will be more time-consuming, leading to delays in introducing any latest device.

These new challenges will be especially noticeable for manufacturers and certification entities, as more devices require certification from the Notified Bodies to enter the market. Businesses now need to provide more documentation, and added information will be available, even for patients, as everyone will be able to search for their personal and medical details online on EUDAMED. A uniform evaluation of high-risk devices will also be a significant step for the medical devices industry, as it will require conformity from every manufacturer.

Silva comments: “Not everything will change – some regulation will still be applicable, for example, the International Electro technical Commission (IEC) 62304: 2006 / 1: 2015 for medical devices software, IEC 62443 for cybersecurity and International Organisation for Standardization (ISO) 13485: 2016 / 14971: 2007, among others. “So, we can see MDR as an all-inclusive regulation that will encompass standards that already exist, as well as incorporate new ones, with the purpose of answering the challenges that technological evolution has created.”

The importance of partnerships

MDR will significantly increase what is demanded of manufacturers. Examples include changes in technical and clinical documentation, quality management

system improvements, the implementation of Unique Device Identification, and post-market surveillance. Some of these changes will have a direct impact on software design and development processes, and manufacturers may need support to adapt their practices to comply with MDR, as well as achieve certification for their devices.

Silva adds: “From risk analysis, to process modeling, requirements engineering, and product certification, we have more than 20 years’ experience in some of the most demanding industries with the strictest standards, such as aerospace, railway, and space. We are a CMMI level 5 certified company, which allows us to develop safety-critical software with high-quality standards.”

Critical Software also works in verification and validation of software for medical devices, adapting its approach to meet individual customer requirements and preferences.

This background information is useful for manufacturers who need to implement changes in their development processes to be compliant with MDR, coming into effect on 26 May 2020.