QS. Ihr Prüfsystem für Lebensmittel.

IFS Food

IFS Guideline for an Effective Foreign Body Management

VERSION 2

ENGLISH

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CONTENTS

1.	Introduction: Foreign Body Management	3
2.	IFS Food Requirements Regarding Foreign Body Management	
3.	Hazard Analysis for Foreign Body Management	9
	Questions that should be asked regarding every work station and process step	10
4.	Entry of Foreign Bodies via Raw Materials	17
5.	Options for Detecting Foreign Bodies	21
	5.1 Visual inspections by staff	22
	5.2 Sieves and magnets	23
	5.3 Metal detection systems and X-ray inspection systems	27
6.	Handling Foreign Body Incidents and Complaints	34
7.	Training	38

ANNEX

A1	Special Area – Glass as Packaging	42
A2	Risk-Minimising Machine Design and Preventative Maintenance	44
A3	Verification and Validation	46
A4	IFS Requirements – Handling Foreign Body Incidents and Complaints	48

Quality assurance and safe food are the common goal of IFS and QS. To achieve this goal, the highest hygiene requirements must be met in the food chain. For both standards, comprehensive guidelines and supporting documents have been developed together with experts. In addition to the present supporting document, you will find the QS supporting document listeria prevention under the following link.

www.q-s.de/services/files/downloadcenter/2_arbeitshilfen/listerien/QS-Supporting-Document-Listeria-Prevention.pdf

1 Introduction

Glass fragments found in apricot jam

Hair in marmelade

Metal wires in cookies

Consumer reports finger stall in sausage

White rubber parts, approx. 15 mm long in spinach

Synthetic materials in chocolate bars

Dark chocolate shavings - foreign body in the product, bristles from a cleaning brush

Product recall campaign: Warning of glass fragments in baby food

Plastic parts in sausages

Due to metal parts in food, a meat manufacturer must recall its ready-made products sold at a discount supermarket.

1. Introduction: Foreign Body Management

Foreign bodies in food always lead to negative publicity and headlines. They cause not only anxiousness and outrage, but may also be a potential risk to the consumer and lead to official complaints. The increasing perception of foreign bodies being found in food is not just a current fad or a short-lived complaint trend that will lessen in importance in the near future. If anything it is an increasingly important aspect for consumers and the media.

Consumers perceive anything that does not belong to the product as a foreign body*. Experts distinguish between two distinct types of foreign bodies: endogenous foreign bodies that could originate from the product (e.g. cores or bones), or exogenous foreign bodies that do not belong to the product (e.g. plastic parts). This difference is not relevant for the consumer as they do not accept foreign bodies even if they do not pose a direct risk to health, such as small scraps of paper in the product. The consumer expects to receive the product as it has been described and as it is desired – no more and no less.

These guidelines should act as a basis for the interested user in terms of how to handle this sensitive topic within the food industry. The objective is to produce food as safely as possible and to not disappoint consumers. This guideline contains ideas regarding foreign body management and also provides potential solutions.

Its objective is not to set mandatory standards for technical equipment or detectors. Detectors for foreign bodies may be of interest to companies and act as a valuable support, however the decision regarding their use must be made individually on the basis of a hazard and risk assessment. This guideline is intended to help implement an effective and suitable foreign body management for the company. The IFS viewpoint focuses on the prevention of foreign bodies and is meant to raise awareness of the possible sources of contamination. In addition it should lead to sensitised employees who are encouraged to report any contamination risks at an early stage. Based on the information provided by this guideline, companies should be able to better decide how something can be safely used and what monitoring is necessary.

The guideline does not claim to be fully comprehensive, but is based on years of experience from those involved in retail, certification bodies and industry.

*** Foreign bodies are anything that can unintentionally end up in a product during the production process or that cannot be removed and that can be determined via touch. Within the framework of this guideline impurities such as chemical residues and microbiological contamination are not included.**

2 | IFS Food Requirements Regarding Foreign Body Management

2. IFS Food Requirements Regarding Foreign Body Management

When it comes to food – now more than ever before – legislators, retailers, and consumers expect the highest possible levels of safety and quality. For this purpose, it is necessary to professionally monitor and control the whole supply chain (including delivery and production of raw materials and packaging, services, manufacturing processes, storage and transport). For the food manufacturer, this means that implementation of the IFS requirements for foreign body management should not just focus on the requirements expected of the production process, but also take requirements from other chapters into consideration. (See diagram, pg. 7)

Governance and commitment

Corporate policy and company guidelines are the foundation for planning and implementing preventative measures. Even the best system cannot be sustainably integrated without corresponding support. Management must assume responsibility here since product safety and quality are top-management issues.

Food safety and quality management system

A major component in the hazard analysis is the management of avoiding contamination via foreign bodies.

Resource management

A combination of clear provisions regarding personal hygiene and protective clothing as well as effective training for improving competence and awareness play a central part in avoiding foreign bodies, such as jewellery, personal objects, and body hairs.

Operational processes

This section covers the most specific requirements with regard to foreign body management. Only sensible, comprehensive planning and monitoring of all areas within the production process can effectively counteract the risk of contamination.

As part of the purchasing process, quality management criteria with defined requirements and specifications (e.g. critical limits) must be stated in the contractual agreement. A relevant supplier review and evaluation is also important. In this context, note also Chapter 4: Entry of foreign bodies via raw materials.

All production and storage areas, including product packaging, machine design and manufacturing procedures, should be regularly examined for potential sources of contamination. Structural and infrastructure defects (e.g. ceilings, covers, cables, lights, etc.) are often the cause of contamination. In addition, pest contamination particularly through raw materials should be avoided. During repair and maintenance work special care should be taken to ensure that materials such as screws, cable parts and metal shavings can't enter the product unintentionally and equipment must be inspected before restarting operations.

In the requirements for the risk management of foreign materials, particular consideration is given to the risk-based assessment of metal, broken glass, and wood. In general, IFS does not have requirements for specific detectors in this context. The necessity of using such systems is dependent on the results of a hazard analysis for the individual company. If detectors are used, then the corresponding requirements for such systems or methods should be taken into account.

A system of traceability is not just a legal requirement, but is also an important instrument for tracking causes and for limiting damage. In case of contamination through foreign bodies, it must be ensured that the source of contamination is identified as quickly as possible, and that corrective measures are subsequently taken. Details of this investigation must be documented (also see the chapter regarding the handling of non-compliant products).

Site factory inspections

Potential sources of contamination should be recognised early as part of site inspections. Frequent inspections of the surrounding area (e.g. ceilings, lights, walls, etc.) and the examination of equipment and their accessories (e.g. covers, motors, mobile parts, etc.) have proven to be effective measures.

Process and working environment validation and control

An internal (initial) test should be performed if technical aids such as magnetic separators, metal detectors, or X-ray systems are used for detecting and eliminating foreign bodies. Tests must be used to confirm that the planned detection works effectively with subsequent rejection and disposal.

Frequent monitoring and reassessment of the established processes will be carried out to check effectiveness. This is particularly required when modified process parameters or other new insights (e.g. new foreign body risks, complaints and objections) become available.

Management of non-conformities and corrective actions

In order to protect the consumer, effective processes must be in place for returning and recalling products. In case of non-compliant goods, corrective measures must be formulated and documented as quickly as possible. Additionally, any aforementioned detection system must be checked for effectiveness and a system for handling objections/complaints must be implemented, from which effective measures for preventing a recurrence can be readily derived.

Food defence and external inspections

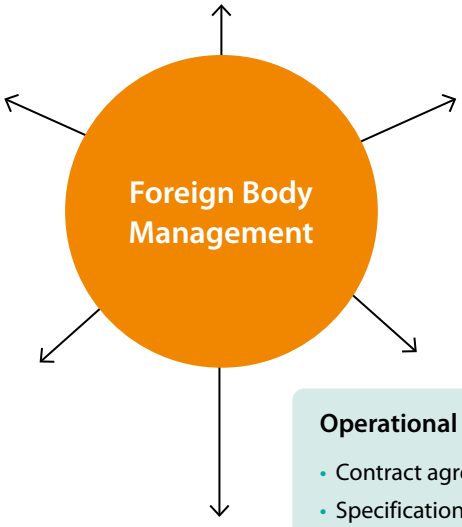
In order to prevent unauthorised people from entering sensitive areas, all entrance areas should be monitored, therefore lowering the risk of product sabotage or falsification.

It is the management's responsibility to ensure the successful interactions of these individual processes.

Which IFS Food requirements are directly related to foreign body management?

Food safety and quality management system

Quality management (incl. HACCP and risk assessment)



Food Defence

Site security

Resource management

- Human resources
- Personal hygiene
- Training and instruction

Governance and commitment

- Corporate policy
- Corporate structure
- Management review
- Review of infrastructure

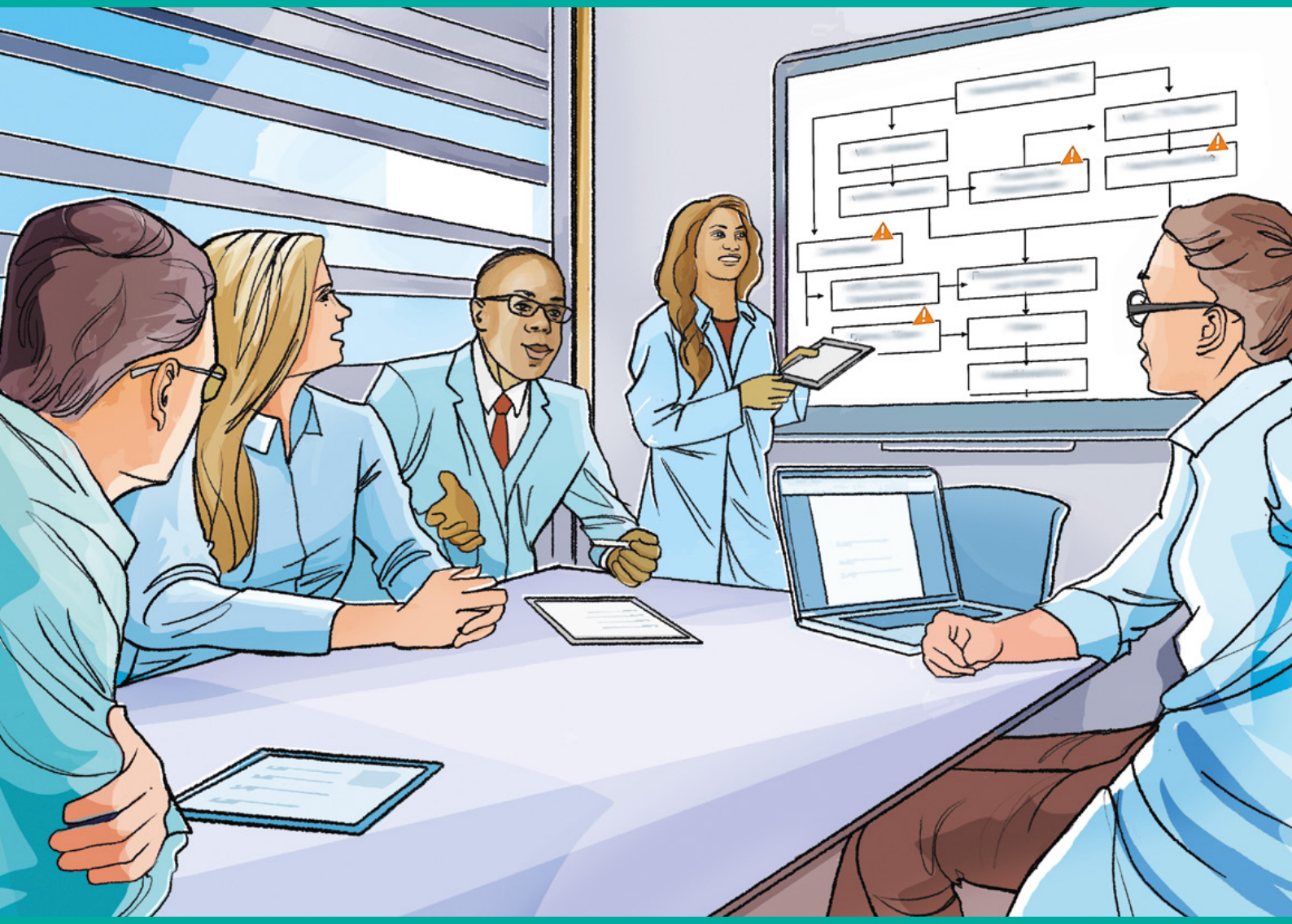
Operational processes

- Contract agreement
- Specifications and formulas
- Purchasing
- Product packaging
- Plant layout and process flows
- Constructural requirements
- Waste management
- Foreign material risk mitigation
- Pest monitoring/control
- Receipt and storage of goods
- Transport
- Maintenance and repair
- Equipment
- Traceability

Measurements, Analysis, Improvements

- Site factory inspections
- Process and working environment validation and control
- Product quarantine and product release
- Management of complaints
- Management of incidents, product withdrawal, product recall
- Management of non-conformities and non-conforming products
- Corrective actions

3 | Hazard Analysis for Foreign Body Management



3. Hazard Analysis for Foreign Body Management

The food manufacturer must determine what health risks may arise for consumers through the consumption of the food produced by his/her company. In such cases, Regulation (EC) No. 178/2002 defines a health hazard as a biological, chemical, or physical agent present in a foodstuff, or condition of this foodstuff that could have adverse health effects. This guideline only covers the physical hazards, namely the foreign bodies.

As part of the HACCP concept, the food manufacturer must carry out a hazard analysis in accordance with Principle 1. As an initial step, the product and typical production methods (flow diagram) must be described in detail so that all potential risks can then be recorded and subsequently evaluated for every process stage.

A hazard analysis should, amongst other things, consider at least the following sources of foreign bodies:

- Suppliers (e.g. raw material extraction from the soil, harvesting equipment, etc.)
- Receipt of goods, storage and preparation
- Processing of raw materials and products (e.g. mixing , cutting, kneading, grinding, heating cooling)
- Transport/logistics (internal/external)
- Packaging (e.g. filling, tubular bag machine, cartoning system, etc.)
- People/material (e.g. accessibility, care, tools, sabotage, protective clothing, personal behaviour, etc.)
- Work environment (e.g. flaking paint, plaster, lights, windows, etc.)
- Rework (clips)

Which specific foreign body sources are relevant is determined through the hazard analysis and depends on the product group/sector.

The possibility and probability of occurrence, as well as an estimation of the effect on consumers must be taken into consideration when evaluating the risk. Whether additional preventive measures are required in order to avoid foreign body contamination (e.g. through frequent hygiene inspections) depends on the resulting risk. Other preventive measures can include equipment within the process to detect foreign bodies (e.g. metal detectors, X-ray inspectors) or separating foreign bodies from the product (e.g. sieves or magnets).

The following question catalogue should assist food manufacturers in recognising and recording potential hazards. It is only intended to serve as an example. It is based on practical experience and does not claim to be entirely comprehensive. The example questions should stimulate examination of all production processes in order to discover potential contamination sources whilst involving all participants. Preventative avoidance of foreign bodies is, and remains, the primary objective of an effective foreign body management system.

Questions that should be asked regarding every work station and process step

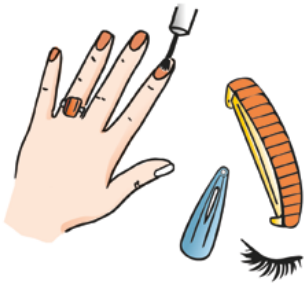
QUESTIONS

Human factors

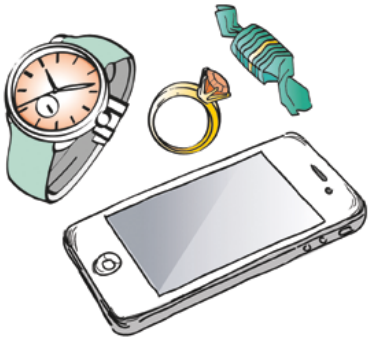
- What work clothing must employees wear?
- Shall a hairnet, astronaut cap, beard protector, protective sleeves or gloves be worn?
- How can hair, including body hair, be covered if working with open products?
- Is it ensured that the hood is put on before the overall?
- What regulations exist for the various sensitive production areas?
- Is an additional disposable overall required?
- Are the procedures for wearing protective clothing adhered to and monitored?
- What procedures regarding personal hygiene are in place regarding foreign bodies?
- What personal objects are allowed to be taken into the production area?
- How is the integrity and completeness of these objects monitored?
- What options are available to lock away these personal objects?
- Are there open, outer pockets?
- Are there any buttons, loops, or eyelets that can become loose?
- Can personal protective clothing itself become a source of contamination (are there loose parts)?
- Is protective clothing suitable for its use?
- Are disposable hygiene items (e.g. gloves, aprons, head coverings) available in a different colour than the product?
- What procedures are in place when temporarily leaving the production area (e.g. canteen, smoke breaks or toilet visits)? Can the outermost layer of clothing (jacket) be removed?
- What procedures are in place for changing clothing and shoes in case of broken glass?
- What clothing regulations are in place for technical department staff?
- How is the transition between the workshop and the production area monitored?
- Is there special outerwear available for welding, angle grinding, or other activities that prevent foreign bodies from being transported from the workshop into the product (e.g. metal shavings)?

EXAMPLES
FOREIGN BODIES

- Hair and beard



- Cosmetics and hairclips



- Personal objects, such as jewellery, mobile phone, sweets, and medications

// Questions that should be asked regarding every work station and process step

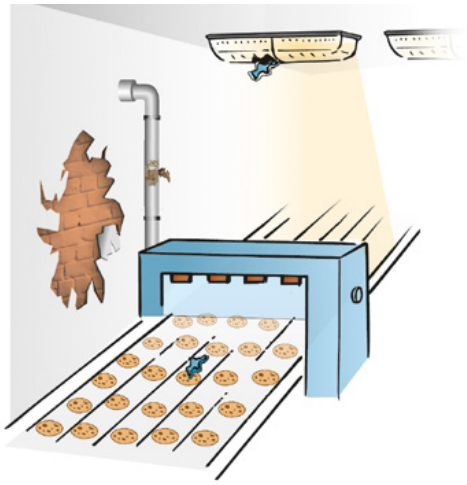
QUESTIONS

Work environment factors

EXAMPLES
FOREIGN BODIES

Work environment

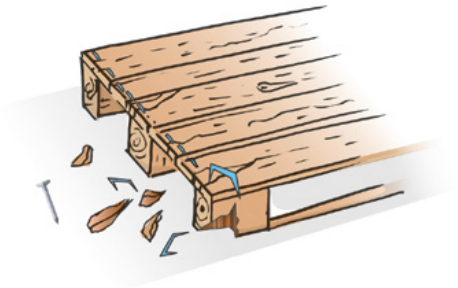
- What surrounding factors must be considered when an open product is processed and it's in an unpackaged condition?
- What is located above the machine/the open product?
  - Can items such as lamps, lines, pipes, pumps, walkways, platforms and ladders be moved or relocated?
  - If they cannot be relocated: are these parts protected (e.g. with breakage-resistant film)?
  - Can this processing area be covered?
- Are glass windows and mirrors equipped with protective film or have break-proof glass?
- Are lamps break-proof?
- Are plastic switches intact?
- During repairs: what risks of contamination exist and how is the product protected?
- How are external companies informed and monitored with regard to the foreign body management requirements?



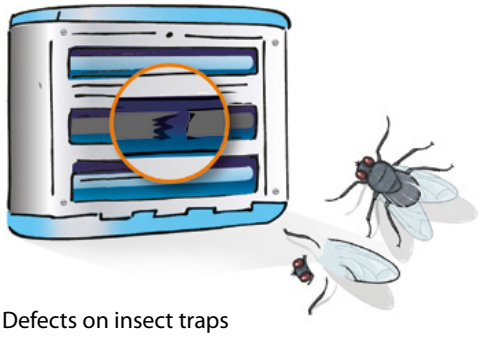
- Insulation material
- Hard plastic and glass from lamps and/or covers
- Rust particles
- Cable ties
- Flaking paint
- Plaster, broken tile elements
- Dust

Pests

- What happens with bait boxes that can no longer be found?
- Are the bait boxes affixed (e.g. secured from falling)?
- Are the fluorescent tubes of electrical fly killers protected against breaking?
- Can electrical fly killers ("booby traps") be replaced with glue-board fly killers?
- Is the fly killer located far enough from an open production line?



- Wood from pallets, frames, doors, or other structures



- Defects on insect traps

// Questions that should be asked regarding every work station and process step

QUESTIONS

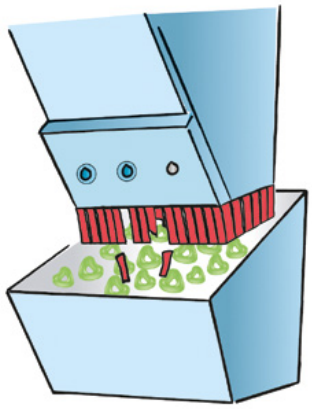
Factors involving machines

EXAMPLES
FOREIGN BODIES

Machines and covers

General

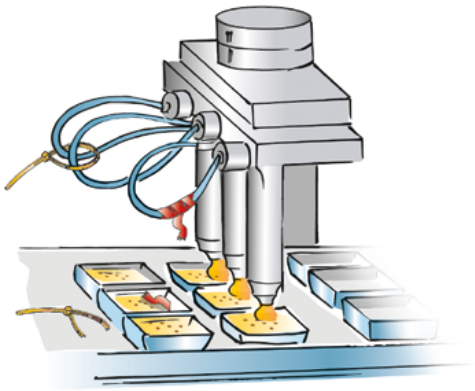
- Is attention paid to a risk-minimising design when planning and purchasing machines (see Annex A2)?
- Is maintenance carried out in a preventative and predictive manner?
- Are checks carried out regarding the wear and tear of materials that are in contact with the product such as conveyor belts, wipers, brushes, and slats?
- Do the maintenance plans include aspects of food safety?
- Who carries out such wear inspections or maintenance checks?
- Is a wear inspection or maintenance check carried out with the assistance of adequate lighting?
- Are cleaning agents used that do not damage the materials?
- Are screws or detachable parts located near the product?
  - If yes, then are these checked regularly?
  - What happens if parts (e.g. screws) are missing?
  - During repairs: Are there containers for collecting small parts?



- Defective slats
- Seals and seal parts
- Colour particles
- Hard plastic on covers, guides and conveyor belts
- Bristles on cleaning brushes
- Oils or dripping liquids from machinery

Equipment and its components

- Is the equipment, along with tipping devices, free of defects?
  - Are there cracks or missing parts in inspection windows and manometers, covers, switches, levers?
  - Can corroded parts contaminate the product and are welded seams monitored?
  - How are the seals monitored in closed systems?
  - Can something fall into the product during the emptying or tipping process?
  - Is the paint or lacquer flaking off?
  - Are the conveyor belts rough, brittle, or frayed?
  - Are conveyor belts a different colour compared to the product?
  - Are the product hoses intact (e.g. not rough or brittle on the inside)?



- Material from conveyor belts or hoses
- Duct tape, cable ties

// Questions that should be asked regarding every work station and process step

QUESTIONS

Factors involving machines

- Which materials are selected for machine covers?
  - Are these selected depending on the application area and purpose (e.g. perforated sheets, unbreakable plastic or bulletproof glass)?
  - Is there a hazard assessment for cracked/damaged covers (e.g. replacing, status tracking, etc.)?
- Is the material for inspection glasses a sensible choice?
- Is contamination of an unsealed product monitored (e.g. punching remnants within the packaging machine)?
  - Are the machine settings frequently monitored?
  - Is the collection vessel frequently emptied?
  - Is packaging from prior production fully removed?
- Is attention paid to product remnants/build-ups and are they fully removed?

Maintenance/Repair/Installation

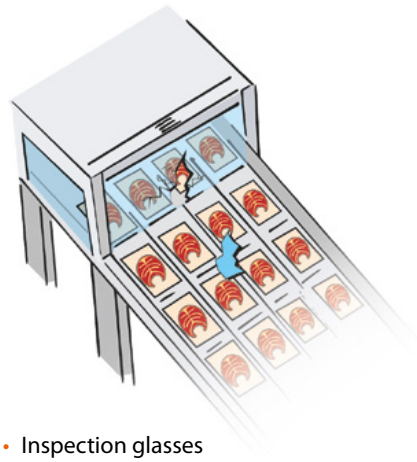
- How is it ensured that all tools and materials are back in the possession of staff/external service providers after work is complete?
- Are parts missing or are too many available?
- Temporary repairs: Is product safety considered and a short-term deadline set for eliminating the problem?
- Temporary repairs: Can tape be replaced with metal-detectable materials like e.g. pipe clamps?
- Is the equipment checked before approval and are Quality Assurance Managers or trained, competent staff involved in this process?
- Are cable ties avoidable? If not, can they be detected and do they have a different colour compared to the product?

Filters and sieves

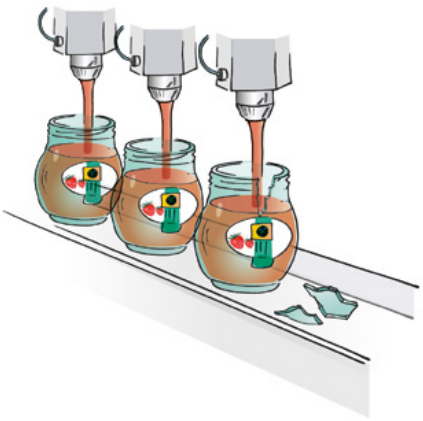
- Are filters and sieves metal detectable or a different colour compared to the product?
- Is there a suitable process for monitoring the filters and sieves in place, and is this process adhered to?

EXAMPLES
FOREIGN BODIES

- Machine parts, such as, e.g. screws, nuts
- Duct tape
- Metal shavings, e.g. due to abrasion



- Inspection glasses
- Covers



- Glass breakage during bottling

// Questions that should be asked regarding every work station and process step

QUESTIONS

Factors involving materials

Raw materials

- Which foreign body contaminants should be expected and how can they be avoided? (See question catalogue Chapter 4 – Entry of foreign bodies via raw materials)

Utensils and tools

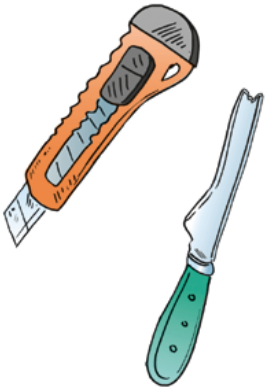
- Which cautionary measures are taken regarding mobile work tools (hand tools) in order to ensure the highest possible level of product safety?
  - Is the number of tools and objects kept to an absolute minimum?
  - Are tools and other items checked for integrity and completeness (e.g. numbered and registered)?
  - Are work tools (e.g. knives, pens, or thermometers) assigned or permanently affixed to work stations?
  - Are all safety knives/cutter knives free from snap-off blades?
  - Are monitoring processes in place and which corrective measures are taken in case of breakage?
  - Are crates and boxes checked for defects and for stickers coming loose?
  - Are crates and boxes stored on upside down, or covered beforehand?
  - Have containers/crates a different colour to the product or are they colour-coded?
  - Are work aids (e.g. shovels, spades, and scrapers) intact, clean, and free of defects?
  - Are these tools a different colour than the product and can they be metal-detected?

Packaging and packaging materials

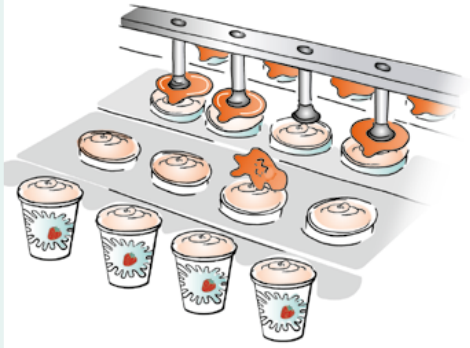
- Can the outer packaging have a negative effect on the product, (e.g. defective outer cartons, film frozen into the frozen goods, rusty containers in the tipping device)?
- Are there procedures for wrapping or opening packaging which help minimise the risk of contamination?
- Is plastic film required for packing? If yes, is it tear-proof/thick enough, temperature-resistant, and a different colour to the product?
- Is the packaging leak-proof and correctly sealed (e.g. leakage test)?

EXAMPLES FOREIGN BODIES

- Broken parts of crates/boxes
- Remnants of stickers



- Knives with snap-off blades
- Worn knives or knives at risk of breakage



- Punching remnants from packaging

// Questions that should be asked regarding every work station and process step

QUESTIONS

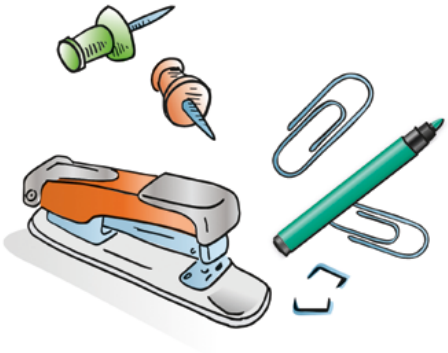
Factors involving materials

- Are screw connections, screw caps and anti-tamper rings checked?
- Can clips or staples in the packaging process be replaced by seals?
- How are pallets (wood/plastic) handled in the receiving goods area and in transition areas? Are they monitored for splinters and pests, and are broken parts removed if necessary?
- What happens in case of broken glass on deliveries? (see also Annex A1 special section: Glass as packaging)

Other utensils

- Are all utensils (e.g. calculators, rulers, pens, etc.) issued by the company and are they registered?
- Are these utensils of a different colour and metal-detectable?
- Are the utensils checked to ensure they are complete and intact?
- How are tools from external maintenance staff checked?
- Have all wooden objects (e.g. sticks, handles and tool elements) been eliminated?

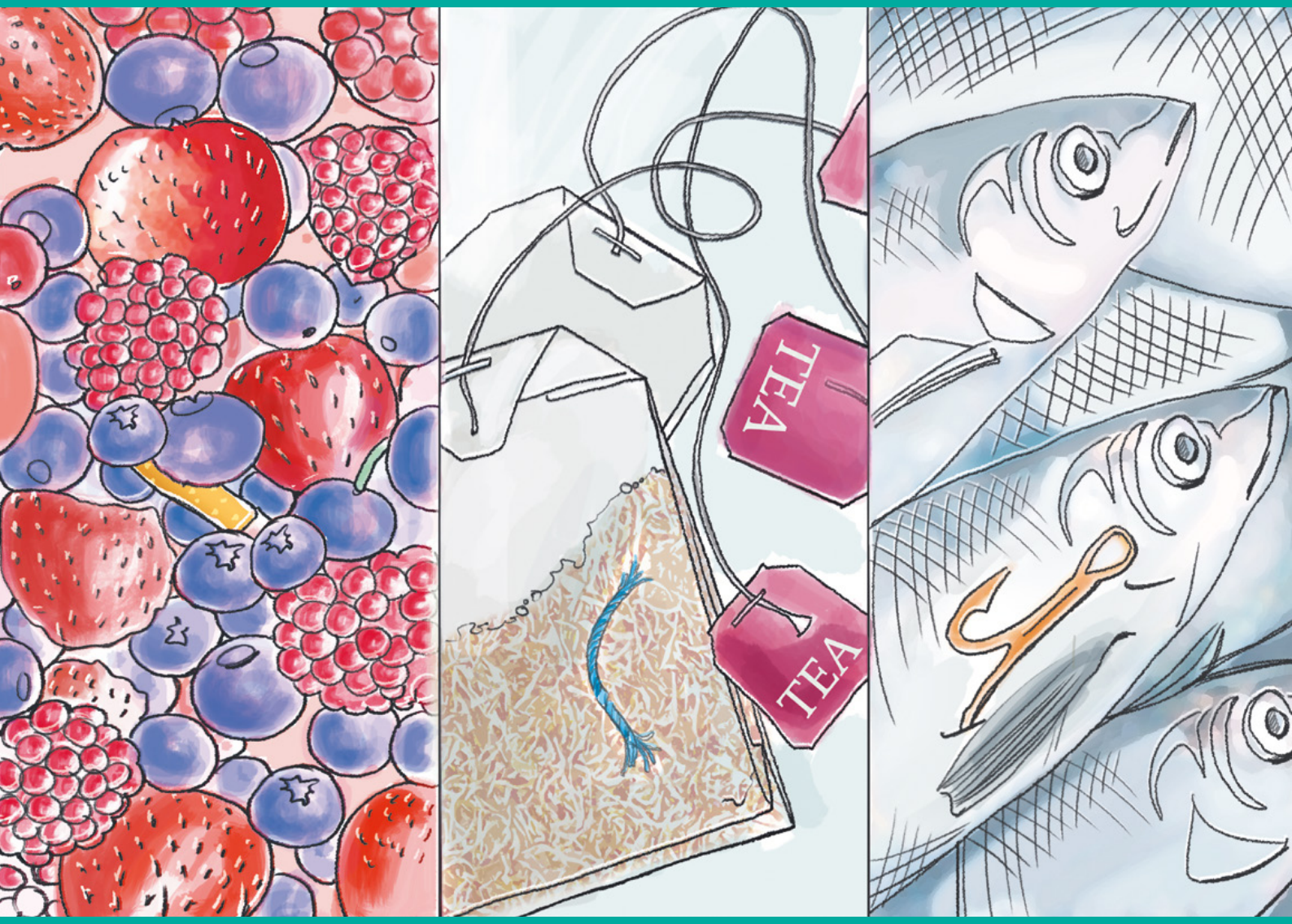
EXAMPLES
FOREIGN BODIES



- Ballpoint pen elements
- Broken pieces from a ruler
- Clips and stapler elements

- Tool parts

4 | Entry of Foreign Bodies via Raw Materials



4. Entry of Foreign Bodies via Raw Materials

Raw materials are often contaminated with foreign bodies by or during the harvesting process. This can include stones from the ground or stems collected during the harvest of the plants. Depending on the product, the foreign bodies can be removed from the product to different degrees.

In-depth discussions are required with the raw material manufacturer in order to recognise the risk posed by the ingredients regarding possible foreign bodies. Only then will it be feasible to carry out the appropriate and required measures to largely reduce the risk of foreign bodies.

It is also very important for the supplier to be informed of discrepancies (foreign bodies found) in their product. This enables evaluation and also adaptation of their own procedures and processes.

Improved communication and effective monitoring of raw materials can be achieved, through trainings for suppliers for example. The purpose is to support a better understanding for the incoming inspections of the respective suppliers' goods. In this respect, the trainings can improve both the communication as well as the understanding for the requirements regarding the raw materials.

The following general questions usually arise with the hazard analysis for raw materials:

1. Supplier selection

1.1 Assessing the quality of raw material suppliers

The following criteria should be clarified in advance:

- Does the supplier have an effective foreign body management system?
- What certifications does the supplier have (e. g. in accordance with recognised GFSI standards)?
- How is the supplier's HACCP concept developed? How is it verified?
- What measures for avoiding foreign bodies have been carried out by the raw material supplier?

1.2 Clarify critical limits and specification

- Which foreign body contaminants are expected?
- How likely is the probability of discovery?
- How can contamination be avoided?
  - Via external foreign bodies (exogenous or extrinsic):

    There must be a zero-tolerance goal for plastic (also in the form of packaging or handling materials), metal, glass, wood, stones, paint and rust.

- Foreign bodies that were carried in with the product (endogenous or intrinsic): Critical limits must be set for items such as shells, blossoms, stems, core splinters from fruit and vegetables, bones, ammunition (also plastic), and hairs from meat.

- Do the critical limits correspond to the latest technology?
- Do the critical limits correspond to consumer requirements and industry standards/Codex Alimentarius/data from associations?
- Can a comparison between different suppliers in regards to quality and critical limits be carried out?
- What options of re-sorting/follow-up treatments are available?
- Are these results integrated into the hazard analysis?

1.3 What foreign body management system does the supplier have, and what can/should be taken into account?

- What preventative actions for foreign body avoidance does the supplier use (e.g. sieves, magnets, detection devices, and inspections)?
- Does the supplier have an adequate foreign body management system (e.g. for hard plastic and glass, knives, cartons, or maintenance related to seals, cords, screws and/or cables)?
- How is the handling of wood monitored?
- What pest control measures are in place?
- Is there a suitable management system for packaging materials with regard to the risks of foreign body contamination?
- What procedures are implemented regarding personal hygiene (particularly jewellery, headdresses)?

The sample questions posed above can be used in the supplier questionnaire. The questions act as written proof of the supplier assessment. A supplier should only be approved after discussion and review through an interdisciplinary team and authorisation through the Quality Assurance department. Approval that is granted solely by the purchasing department should be looked at critically. Specifications the supplier can comply with must be jointly clarified between customer and supplier. If there is a requirement for carrying out preventative actions on the part of the supplier (e.g. detection, separation and/or inspection), they must be outlined as specifically as possible.

2. Incoming goods

Raw materials are sampled within the receiving goods area. The following example questions arise:

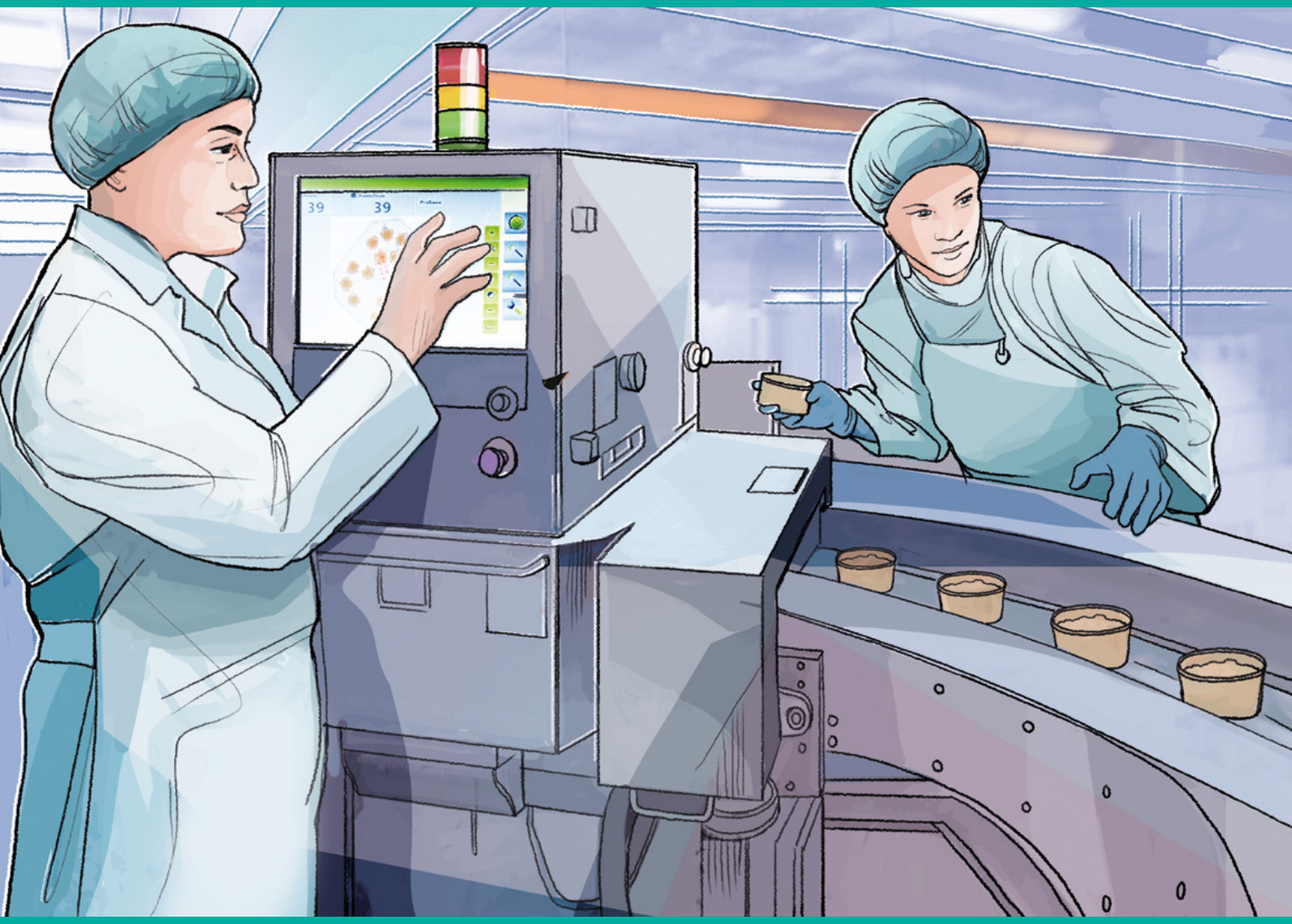
- Are clear procedures in place regarding the quality control of incoming raw materials?
- Do employees have access to the necessary measuring equipment?
- Are employees sufficiently trained and are their qualifications checked or confirmed?
- Is a representative sample of raw material taken in the incoming goods area? Are there defined sampling procedures and are these effectively applied? Is the supplier informed of the results? Is the supplier involved in the initial delivery to experience the procedures and tests "live" in order to be able to initiate measures for improvement?
- Have critical limits been established and are they known?
- Are clearly-defined measures in place if the critical limits are exceeded (e.g. complaint, blockage, quarantine and/or re-sorting)?
- Are all discrepancies documented, communicated and corrective actions taken?

3. Supplier evaluation

A frequent evaluation of the supplier can take place using a supplier questionnaire based on quality, price/conditions, and service (where quality is given most weight). This evaluation should be frequently (at least annually) communicated with the supplier in order to enable continuous improvement.

- Are complaint rates available and are these taken into account during evaluation?
- How is it monitored that the supplier delivers in compliance with the specification (e.g. with sieve analysis or detectors)?

5 | Options for Detecting Foreign Bodies



5. Options for Detecting Foreign Bodies

How do I select the correct detection system?

The hazard analysis and risk assessment reveal which foreign bodies may appear in the product and in what process steps an entry might be expected. Based on this information, systems for inspection or detection should be selected and placed within the most suitable position of the process. The food manufacturer should ask two core questions with regard to every technology:

- Do I have the correct system for the expected foreign bodies (validation)?
- Does the relevant system function properly (verification)?

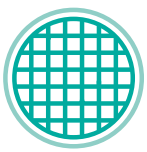
Further information regarding validation and verification can be found in Annex A3 (pg. 46). The methods described here represent only a sample of the most frequently used inspection and detection methods. It is certainly possible that other methods that have not been mentioned here can be useful and effective.

Metal detectors

Magnets

X-ray systems

Visual controls by staff



Sieves

5.1 Visual inspections by staff

Where are visual inspections carried out?

The visual inspection or visual check is an optical test of a product for defects. These can either be in regards to the product (e.g. incoming goods, production, or final inspection) or in regards to the environment (e.g. cleaning, machinery, etc.).

What different kinds of visual inspections exist?

In general, visual inspections can be distinguished between:

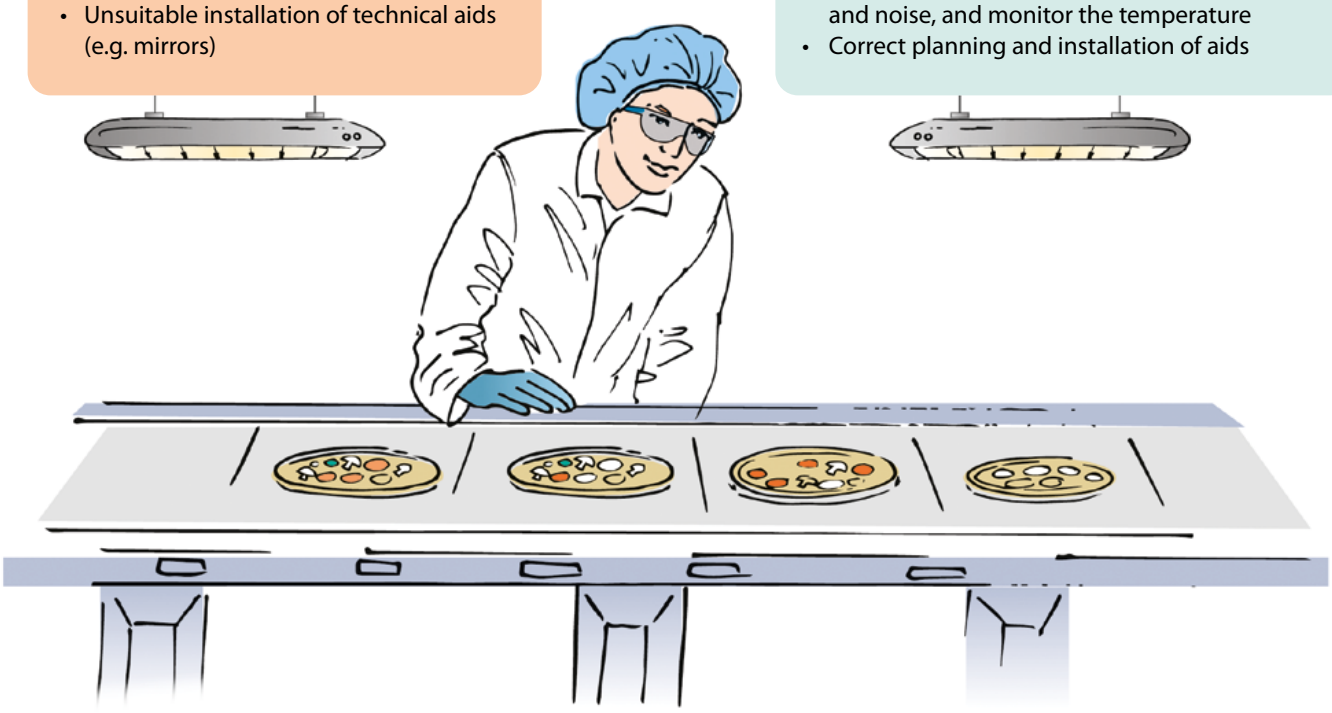
- Direct visual inspection without aids (observing the test area with the naked eye)
- Direct visual inspection with aids (optical aids such as magnifiers, mirrors)
- Indirect visual inspection (with camera systems, e.g. bottle inspection)

Risks/Problems

- Fatigue
- Lapses in concentration
- Pressure to perform (e.g. through high belt speeds)
- Environmental factors (e.g. light, noise or temperature,)
- Unsuitable installation of technical aids (e.g. mirrors)

Measures

- Observe frequency of breaks and staff changeovers
- Adjust conveyor belt speeds
- Ensure an adequate number of employees
- Optimal lighting
- Limit environmental influence such as dust and noise, and monitor the temperature
- Correct planning and installation of aids



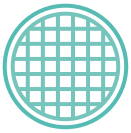
Which influences must be taken into account?

This chapter focuses only on visual checks as an activity carried out by people. Due to the "human factor", these are generally less effective than automated checks. Therefore, major fluctuations may arise depending on the complexity of the product and working conditions. However, inspections only conducted via machines may not always be possible. Regarding checks carried out by people, it is important to ensure that useful and frequent training is given and that a suitable work environment is provided.

The company should always try to ensure that the work conditions for a visual inspection are as good as possible in order to reduce the number of undiscovered defects.

An internal test can be created to monitor the efficiency of detection and for establishing the optimum belt speed at regular intervals. In this case, defined and relevant foreign bodies should be used. The detection rate of these foreign bodies can then be used to establish optimum settings.

5.2 Sieves and magnets

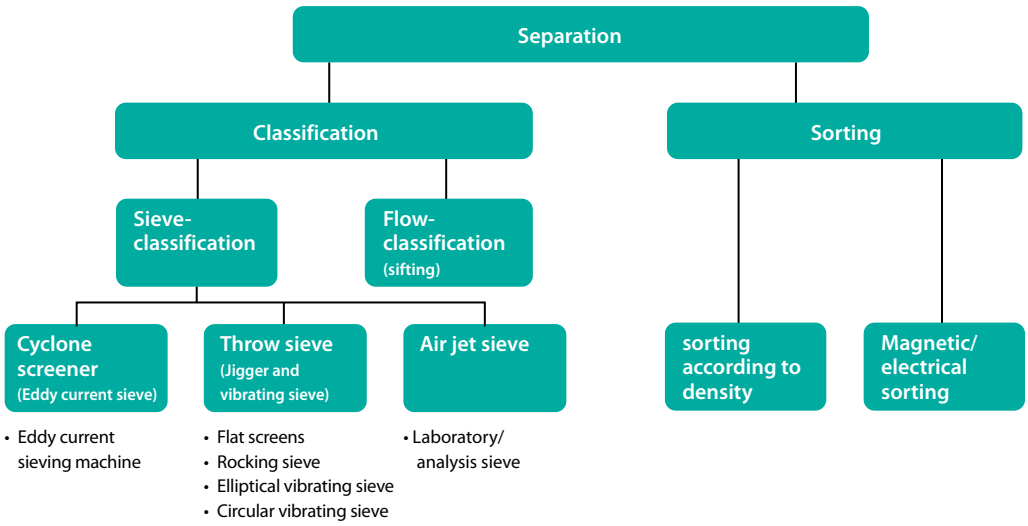


5.2.1 Sieves

When are sieves used?

Within the context of product safety, control sifting should be used to ensure that foreign bodies do not get into the product. In addition, coarse sifting may protect subsequent machinery and equipment from being damaged due to large pieces.

In terms of process engineering, sieving is seen as a separation process that involves the mechanical breakdown of products. This is further divided into classification and sorting.

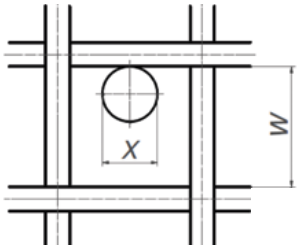


Source based on: AZO GmbH + Co.KG

Which product properties must be taken into account?

In essence, the following properties of liquids and dry product influence the sieving behavior and thus the screening rate: Viscosity, particle size distribution, cohesion forces (interparticular adhesive forces) particle shape and electostatic charge as well as the mesh sizes of the sieve. The screening processes for granulated bulk products can be estimated. A major criterion for this is the ratio of particle size (X) to mesh opening (W) in the sieve floor.

Figure 1



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The open sieving area A0 of a sieve fabric can be established in line with ISO 4783-1:

- Bulk product with grain size x < 100 µm is rather unsuitable for sieving due to adhesive forces between particles (Van der Waals forces). The small particles bond to each other and form agglomerates (clumps) which may block the mesh.
- The electrostatic behaviour of the bulk product has a major influence on the screening rate.
- Product moisture also effects the screening rate greatly
- In the case of liquids the viscosity is the decisive factor

Irregular grain forms can also influence sieving behaviour. Long particles (prism, cylindrical, or rod form) are difficult to sieve and can, depending on their orientation, pass through the sieve even though the particle length is somewhat longer than the gaps in the mesh.

Spherical particles and regular compact forms are easier to sieve.

What influences the flow rate?

Adhesive forces between the particles and associated clumping can have a strong effect on the passage through the sieve. For this reason, tests to determine the respective screening rate are recommended. The quantity of material on the sieve surface is the determining factor for an optimum screening rate. The greater the quantity of material on the sieve netting or sieve surface, the longer the sieving process. Moreover, there is a risk of breakage.

Is the mesh size appropriate for the product?

Depending on the application, mesh sizes of 0.09 mm to 20 mm have proven effective regarding protective and control sifting of bulk products. Mesh sizes up to 4 mm are used for protective and control sifting. Wider mesh openings are used for coarse sifting of larger foreign bodies. Such coarse sieves should be used during the product in-feed of raw materials in order to lower the risk of the sieve breaking due to foreign bodies in subsequent sieving machines. ISO 4783 contains guidelines for selecting the combination of mesh opening size and wire diameter.

What materials are used for the sieves?

Depending on the application, various materials can be used for the sieve netting. Typical sieves used in industrial sieving technology are made of nylon, carbon, and stainless steel, and are used as fabric or perforated plates. During the risk assessment process, the usability of metal sieves with thin wire should be evaluated and particular focus placed on how thin, broken wire pieces can be detected.

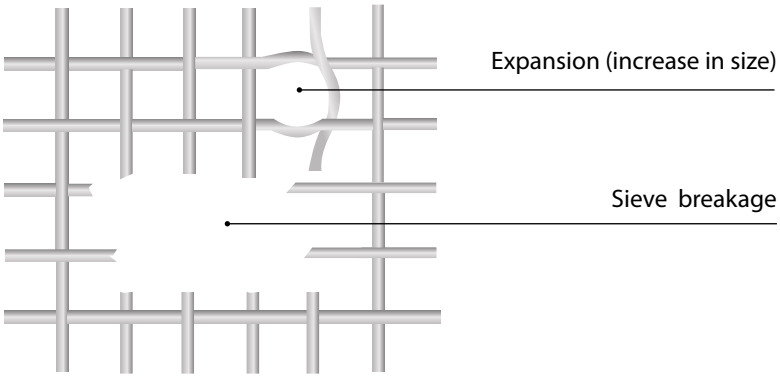
What must be taken into account when monitoring the sieves?

Sieves should be checked frequently for defective meshes and foreign body residues. Frequent visual checks should be carried out across the entire sieve netting and be documented accordingly. In doing so, the mesh gaps covering the entire sieve netting area are checked for defects (sieve breakage) and unacceptable expansions. Defective sieves must be replaced immediately – further use is not permitted. Upon replacement, the product that was being tested prior to the replacement of the sieve should be checked again. If there are foreign bodies on the sieve netting, they should be removed immediately. Sieve breakage can occur due to material fatigue of the sieve netting, sharp-edged, or heavy objects (foreign bodies), but also due to overloading the sieving machine with large quantities of in-feed material.

The following types of damage may occur to sieve netting:

- Sieve breakage due to tearing (e.g. holes appearing as a result of mesh tearing in one or more places)
- Expansion of mesh (e.g. impermissible expansion of individual mesh gaps)

Figure 2



Source based on: AZO GmbH + Co.KG

The potential hazard of wood fragments entering the product should be taken into account when using sieves with wooden frames.

What must be taken into account during cleaning and maintenance?

In order to clean sieving machines, the sieve material is generally removed without a tool when the machine is not in operation. Sieving machines are dry or wet cleaned depending on hygiene requirements. Foreign bodies may be released during the cleaning process when removing the sieve. For this reason, cleaning work should only be performed by trained and supervised staff. Every cleaning procedure should be documented. Brushes with natural or plastic bristles and cleaning wipes made of natural and synthetic fibres are recommended for dry cleaning on the outside.

When using brushes for the inside parts, there is a risk that individual bristles may become detached and subsequently enter the process as foreign bodies. Depending on the degrees of contamination, cleaning agents can be used that are permitted by the manufacturer of the equipment. The sieve netting should be fully monitored for damage after cleaning and only be reinstalled when it is free of defects.

Necessary maintenance work suggested by the equipment manufacturer should be followed accordingly.

5.2.2 Magnets

When are magnets used?

Magnetic separators have various applications and uses. They can separate impurities in a larger spectrum of shapes and sizes than metal detectors and X-ray devices. They are therefore, especially in combination with other metal detection devices, highly efficient for detecting long, thin shaped and magnetizable foreign bodies (e.g. wire pieces).

Where are they used?

Magnets are often located before metal detectors in the production process – this position makes the most technical and financial sense. Additionally, magnets can be used to monitor incoming goods (e.g. flour, grain, or sugar in sack or big bag). Here, the detectors are used to monitor potentially contaminated goods and to prevent larger magnetic foreign bodies such as blades from entering the production process, where they may be shredded further and subsequently may no longer be detectable under certain conditions or could lead to damage down the line.

How are the metal parts found in the product?

Magnet separator systems attract metallic foreign objects when the monitored goods have no magnetic ability and therefore are not attracted to the magnets themselves. Magnet separator systems are therefore not suitable for separating non-ferrous metals, steels and organic materials.

Stainless steel particles which are generated by friction, shear etc. have a modified micro-structure due to the physical stress (alpha-martensite). Thus they have developed magnetic properties which permit separation.

Is the strength of the magnet appropriate for the product?

Magnetic systems must be adapted to the product quantity, flow velocity and specific process applications. In general, the smaller the suspected contaminants the higher the flux density. The same applies to high speeds of fall and large product flows. Therefore, when using magnets in the production process, the focus should be on high flux density and durability, otherwise the magnet will lose the effectiveness in a short period of time. Monitoring the magnet on a regular basis with regard to its performance is a required maintenance measure.

One significant option of verifying and checking magnet performance is using a magnetometer to measure the flux density at regular (monthly) intervals. The current flux density is measured on the magnet's product-facing surface using a Hall probe. The magnet is also checked for deformation and surface damage. When product temperatures are constantly at or above 40°C, a shorter interval between inspections is recommended. The manufacturer's specifications and recommendations should be taken into account.

Is the strength of the magnet still present and suitable?

Revalidation testing has to take place at least on an annual basis with a verifiable measuring device (from the national monitoring authorities) and a tested reference magnet. In this case, the magnetometer is compared on site with the reference magnet, then the magnets are tested by measuring the surface flux density. This method is reliable as it is fully traceable.

Testing methods by attaching and removing metallic test pieces are physically wrong and without reference to the intended purpose – namely to separate small impurities. Shorter monitoring intervals should be chosen at higher product and cleaning temperatures (e.g. in CIP cleaning or steam-based sterilisation).

5.3 Metal detection systems and X-ray inspection systems

5.3.1 Metal detection systems

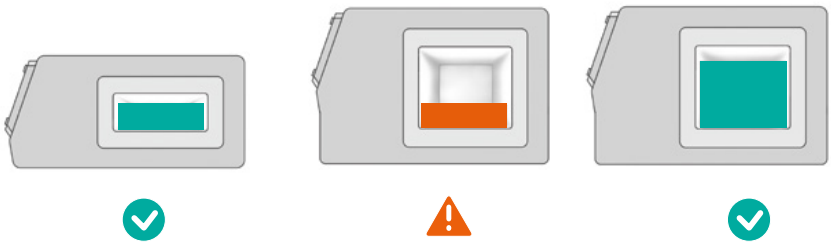
What do I find when using a metal detector?

In principle, metal detectors detect all types of metals. However, magnetic metals (e.g. iron) are more readily recognised compared to non-magnetic metals (non-ferrous metals and non-magnetic stainless steels).

How are the metal parts found in the product?

With a metal detector, the product moves through an electromagnetic field. Metal parts can be detected also within a product as they cause changes to the electromagnetic field. The centre of the device's opening is the point where the electromagnetic field is at its weakest and therefore where the detection capability is also at its lowest. The correct ratio of product dimensions to the tunnel dimension is important and a tunnel that is too large should be avoided.

Figure 3



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What effects do the shape, position and type of metal have on the detection?

The detectability of metal objects depends on the location and the position in which the metal parts pass through the metal detector. A non-spherical metal part (e.g. a piece of wire) triggers smaller or larger signals depending on the direction in which it passes through the detector. Detection becomes even more difficult with metal shavings as the shavings structure is porous, inhomogeneous and generates an even weaker signal than a wire.

In addition, the detection accuracy varies depending on the type of metal and the direction in which it passes through the metal detector. (See Fig. 4)

Figure 4

Iron | Non-magnetic stainless steel | Iron | non-magnetic stainless steel

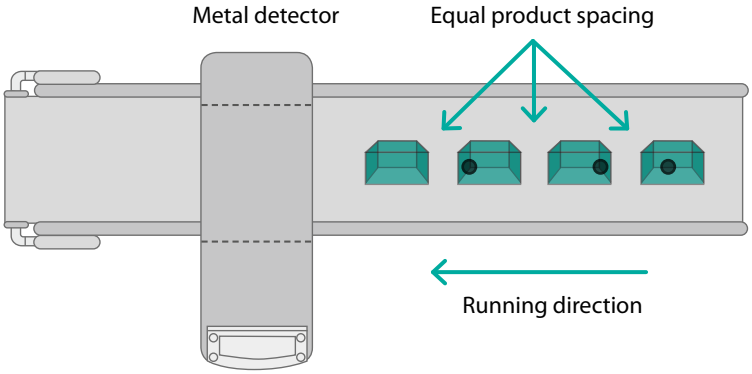
Source based on: © METTLER TOLEDO

Position of the metal part (rod-shaped) with regard to the direction of transport	Iron (Fe)	Non-ferrous metal + non-magnetic stainless steel
lengthways	good	poor
upright or across	poor	good

Has the position of the test sample been correctly chosen?

Since detection sensitivity is at its lowest in the center of the opening, the test sample together with the product should pass through the metal detector in this location. The following diagrams show a potential test procedure:

Figure 5



Is the text sample size and material appropriate for the product?

In general, test samples should be as small as possible in order to detect the widest possible spectrum of metallic foreign bodies. Furthermore, customer specifications have to be taken into account. It should be ensured that the test samples are intact and do not pose any type of contamination risk themselves. If there are doubts about the integrity of the test specimen, it should be replaced.

Is the setting of the metal detector appropriate for the product? If there is a product change, is the program modified accordingly?

The conductivity of a product (= product effect) depends on various factors, such as:

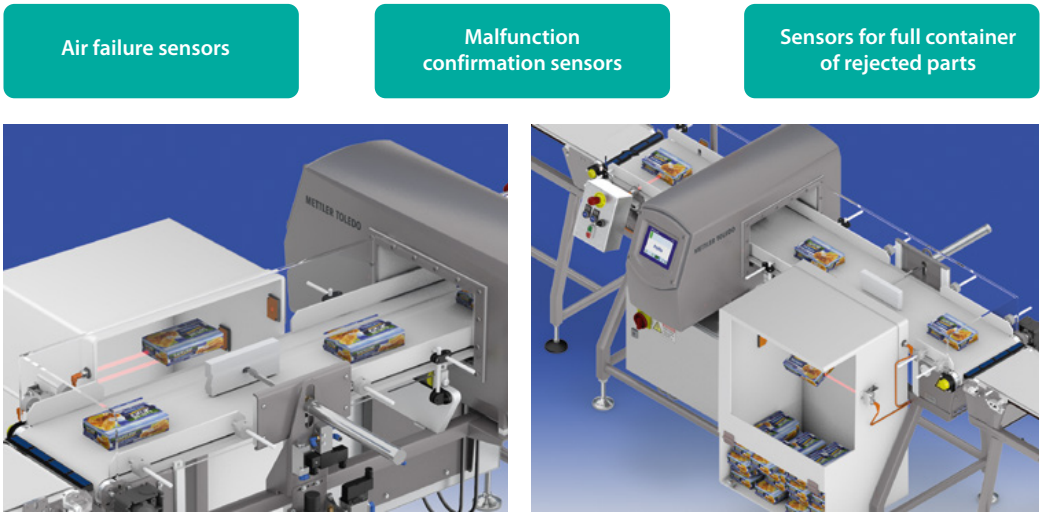
- Moisture and salinity (salt content), texture, and composition
- Temperature
- Product quantity and dimensions
- Packaging materials

Metal detecting devices can minimise product effects through targeted adjustments. If a product change is carried out, then a corresponding programme change should also be paid attention to.

Is the belt speed adapted to the detection and rejection process?

If transportation speeds are exceeded or are too slow, then detection accuracy cannot be guaranteed (please observe manufacturer's specifications). With fluctuating transport speeds (e.g. start-stop operations), there is a risk to fall under the critical transportation speed which could result in the fall of detection accuracy. Products that are within the detector tunnel at this point in time should be inspected once again. It is necessary to ensure that the rejection process is monitored along with the selected belt speed.

Figure 6



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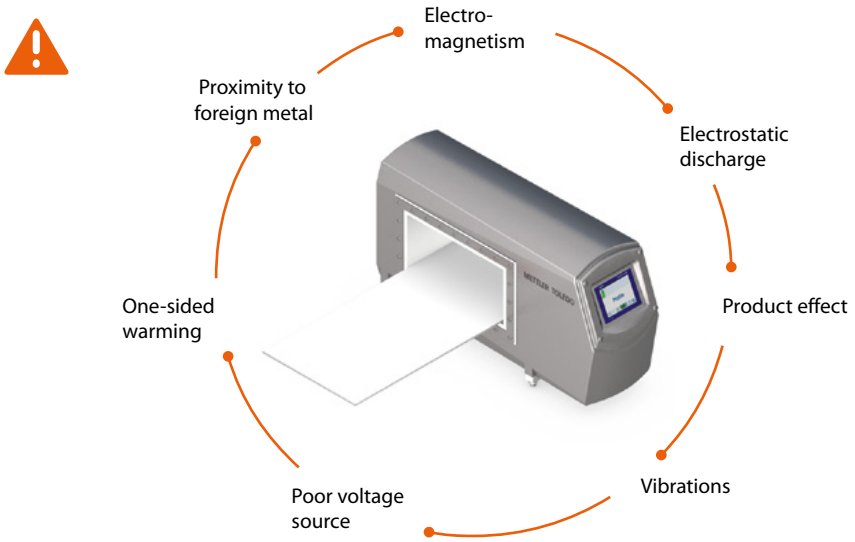
Is there a reporting system/alarm system if the rejection device fails and if the rejection bin is full?

If the rejection bin is full, or the rejection device fails, it is possible that a contaminated product is not properly rejected and will continue in the process. Therefore, the entire rejection process, including the rejection bin and the control sensors should be checked frequently.

Are environmental factors taken into consideration?

Environmental factors can have a negative effect on metal detection. These include: vibration, air humidity, air draft, insulation, electric supply, and interference frequencies.

Figure 7



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Have the manufacturer's specifications and instructions been taken into account?

The manufacturer's operating instructions and guidelines may contain additional or other requirements and should be followed accurately.

Is there suitable documentation?

Appropriate accuracy for the detector should be established and monitored depending on the product. Frequent monitoring must be documented and corrective actions must be established in the event of a malfunction. The following points should be logged in the documentation e.g.:

- Product and line
- Inspector
- Date and time, (if necessary)
- Test sample
- Test result
- Measures in case of discrepancies
- Signature or data collection system

5.3.2 X-ray inspection systems

What can I find using an X-ray inspection system?

Ferrous and non-ferrous metals, as well as stainless steel can be readily recognised with X-ray inspection systems. The technology is also suitable for recognising other foreign bodies such as glass, stone, ceramics, bones, dense plastics, or rubber compounds.

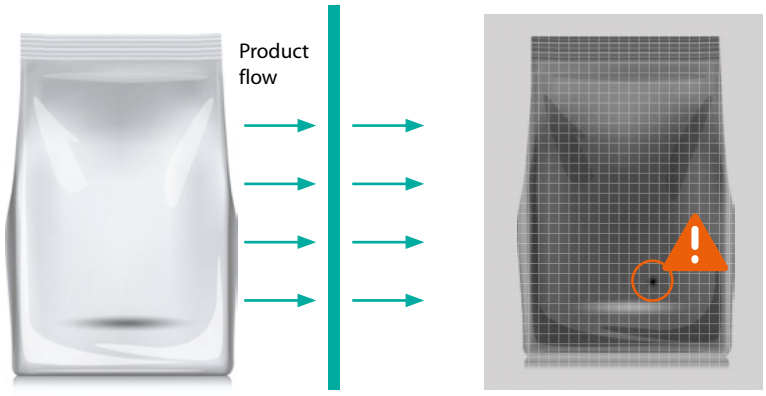
What additional advantages does an X-ray inspection system provide?

X-ray inspection systems can carry out a series of additional quality assurance tests on the production line. These include counting components, recognition of missing or damaged products, monitoring product forms or fill levels, checking seals to ensure they are intact, and the recognition of damaged packaging.

How are the foreign bodies found in the product?

X-ray inspections are used to scan for foreign bodies that absorb a greater quantity of radiation compared to the product within which they are found. The quantity of the absorbed X-ray radiation depends on product thickness and density. Impurities such as glass or metal become visible during an X-ray inspection due to the differing densities. Analysis of the X-ray image is carried out based on an evaluation of the shades of grey: the more homogeneous the product, the better the detection sensitivity.

Figure 8



Source based on: © METTLER TOLEDO

What effects do the shape, position and type of material have on detection?

In general, detection of foreign bodies is only possible if they are denser than the product within which they are located. The following critical limits apply to most foodstuffs containing water:

Density in g/cm³

Water	1.00	Contained in most foodstuffs
Hair	0.32	**Not detectable**
Cherry stone	0.56	
Insects	0.59	
Wood	0.65	
PP	0.90	
Nylon	1.15	
PVC	1.70	**Detectable** Depending on product (homogeneity, thickness, density) and scale of contamination
Teflon	2.19	
Bones	2.20	
Stone	2.52	
Glass	2.60	
Aluminum	2.71	
Iron	7.15	
Steel	7.86	
Stainless steel	7.93	

Typical contaminant sizes that are detected by X-ray inspection systems

Material	Typical contaminant sizes (spherical diameter) in various types of packaging			
	Plastic/paper	Metallised foil	Tins	Glasses
Metal	0.8 mm	0.8 mm	1.2 mm	1.2 mm
Aluminum	2.0 mm	2.0 mm	2.5 mm	2.5 mm
Glass	2.0 mm	2.0 mm	3.0 mm	3.0 mm
Stone	2.0 mm	2.0 mm	3.0 mm	3.0 mm
Bones	3.5 mm	3.5 mm	5.0 mm	5.0 mm
Dense plastic	3.5 mm	3.5 mm	5.0 mm	5.0 mm

Is the belt speed coordinated with the detection and rejection process?

An uneven or irregular transition from and to the transport conveyor of the X-ray device can lead to product backups and problems with the X-ray image processing. Nevertheless, the necessary minimum distance between individual products is generally determined by the requirements for effective rejection and not those for creating images. The correct functioning of the rejection process should be established in conjunction with the selected belt speed.

Is there a reporting system/alarm system if the rejection device fails and if the rejection bin is full?

If the rejection bin is full or the rejection device or process fails, it is possible that a contaminated

product is not properly rejected and will continue in the process. Therefore, the entire rejection process, including the rejection bin and the control sensors should be checked frequently.

Is the size and the material of the test samples appropriate for the product?

Generally, certified stainless steel and glass spheres are used for the verification test as their density can be reliably quantified. Problems may arise if a glass test specimen has a higher density than the glass materials that are used on the production line. In such a case, the glass test specimen will be recognised, but not the glass part of the vessel. With a glass-in-glass application, it is recommended that the glass in production is used for verification purposes. The optimal verification method should be established for every application and test samples should be selected in accordance with the product and the requirements of the customer specification. If there are doubts about the integrity of the test sample, then it should be replaced.

Is the position of the test specimen correct?

Ideally, these should be securely attached to the base of the packaged product. It should be ensured, under any circumstance, that the test sample can be found at every location within the packaging. To do so, the equipment should have stable settings and the ideal test sample size established using a test series.

If a product is changed, is the program modified accordingly?

With a product change, the modified variables of the product and packaging must be taken into account. The product composition (e.g. homogeneity), product density and thickness as well as the packaging material can influence absorption behaviour. With a new product, new foreign bodies can emerge that require a modification to the settings or the image analysis. For this reason, in the case of a product change – if the properties vary – special attention should be paid to the program change.

Have the manufacturer's specifications and instructions been taken into account?

The operating instructions and guidelines from the manufacturer may contain additional or other requirements and should be followed accurately.

Is suitable documentation available?

Appropriate measurement accuracy for the X-ray inspection system should be established and monitored depending on the product. A regular check must be documented.

Corrective actions must be established for disturbances. The following points should be logged in the documentation e.g.:

- Product and line
- Inspector
- Date and time
- Test sample
- Test result
- Action/measures in case of discrepancies
- Signature or electronic data recording

6 | Handling Foreign Body Incidents and Complaints

6. Handling Foreign Body Incidents and Complaints

If, despite all preventative actions and internal controls, foreign bodies are found in products by staff, consumers or authorities, then it is important that a comprehensive analysis is carried out. In this case, the following points should certainly be considered (see Annex A4 – detailed requirements of the IFS Food Standard, pg. 48):

- Management of complaints from authorities and customers
- Management of incidents, product withdrawal, product recall
- Management of non-conformities and non-conforming products
- Information to consumers and authorities
- Corrective actions

Confirmed foreign body incident

A standardised procedure for analysis cannot be described as it depends on the relevant processes, the operating procedures, and the foreign body. The objective is always to determine the origin of the foreign body and to understand how it got into the product. It is necessary to check whether the foreign body is an intact single part (e.g. screw) or a component of a larger object. Here it is important to reassemble the original object (all parts should ideally restore the entire object = origin)

If the origin of a foreign body cannot be determined, then the incident must be documented anyway and the foreign body must be categorised (e.g. product, material, colour, size). In case of re-occurrence at a later point in time, these records could help establish the cause of the contamination.

If it is possible that the foreign body entered the product via raw materials, then the incident should be forwarded to the relevant supplier (traceability and forwarding procedure). The company´s management must carry out a risk assessment if a foreign body is found and consider the following points:

- Where else could parts of the foreign body be found?
- Is the affected product still on site or has it already been delivered?
- How severe is the risk to consumer health/the threat of injury?
- Must an emergency situation be declared?
- Must a recall or a return be initiated?
- Is it necessary to inform customers, certification bodies and/or the authorities?

* Non-conforming products are products that are not in line with quality requirements or the specification.

Customer complaint

If the notification about a foreign body is the result of a customer complaint, then the primary aim is to determine the origins of the foreign body and to prevent further contamination. The further process is the same as if contamination had occurred during the production process.

After clarifying the origin of the object, it has proven to be useful to inform all employees of the incident so that they can support procedures to avoid a recurrence. Additionally, the incident should be mentioned and evaluated in the HACCP team. This increases awareness of foreign bodies and their implications, while also reducing and avoiding the risk of recurrence.

The procedure when handling foreign body finds

* Here it is important to establish the logical link between the foreign body and the results of internal control measures.

7 | Training

7. Training

Having competent and well-trained staff is an important prerequisite for producing safe food.

Along with the standard hygiene training, training in general can be an important preventative tool to increase awareness amongst staff for avoiding risks posed by foreign bodies.

For this reason, a training program is essential in order to increase awareness of contamination via foreign bodies. This training should be conducted:

- at the beginning of the work activity
- when changing the activity/work station
- in case of process and product changes
- when commissioning new equipment or systems

In order to create a training program, a competency matrix can be used to identify the target group and the necessary specific focus. The competence matrix should also include other relevant areas such as the technical department as well as production staff. With the competence matrix, questions can be posed, for example: Which employee is/how many employees are competent to control a certain area such as detectors?

The type and duration of the training differs depending on the content and the risk assessment. Proven training methods include brief on-site training and these should include:

- Improving awareness of employees regarding observation of the work environment for potential contamination through foreign bodies
- Rules of conduct in order to avoid contamination via foreign bodies (e.g. in case of broken glass)
- Handling detection or separation techniques (e.g. metal detectors, X-ray detectors, sieves, magnets, etc.)
- Corrective and preventative actions regarding foreign body management
- Complaints/statistics
- Input from the question catalogue in chapter 3
- Current incidents/press releases
- Language adaptation of the training to the staff. Visual materials and photos are useful in this context.
- Pictures from practical situations

The training is documented e.g. via signature lists or evidence of participation (certificate). After the training, evidences and a system to assess the competence are important. Employee competence can be evaluated with a variety of methods:

- Interview with the employee (e.g. "How do you ensure that...")
- Observing work activity
- Practical and theoretical testing

ANNEX

A1 Special Area – Glass as Packaging 42

A2 Risk-Minimising Machine Design and Preventative Maintenance 44

A3 Verification and Validation 46

A4 IFS Requirements – Handling Foreign Body Contamination and Complaints 48

A1 Special Area – Glass as Packaging

Questions which should additionally be asked regarding glass containers

Packaging specification and receiving goods area

- Are technical data and tolerances established in the packaging specification?
- Are clear procedures available regarding sample sizes and tests to be conducted within the receiving goods area?
- Are the dimensions, weights and tolerances of the containers monitored?
- Is the manufacturer/supplier monitored via frequent audits/assessments?

Storage and de-palletising

- What procedures are in place for storage and de-palletising?
- How are glass breakages handled, and how is it ensured that remaining containers on the pallet are not contaminated?

Machinery and environment

- Is the glass processing line far enough away from other production lines (e.g. shards of glass can be distributed/scattered over a wide area)?
- Is the line and the immediate area checked before operation to ensure that there is no broken glass?
- Are the glasses rinsed out or blown out before bottling?
- Is the pressure and direction of the jet checked frequently?
- Is the blower device/rinsing equipment sufficiently validated?
- What measures are taken if e.g. the pressure falls?
- Are there installations for catching breakage beneath the lines, and are these checked frequently?
- How are glass shards/broken glasses handled?
- What procedures are in place for cleaning the line and the area so that all broken parts are removed (e.g. vacuumed)?
- What procedures are in place for staff (e.g. change of clothing including shoes and hair net) and work items (e.g. brooms, shovels).
- How are cases of broken glass documented?
- Are the settings of the line and the materials optimised in order to minimise collisions between glasses/bottles?

// Questions which should additionally be asked regarding glass containers

- In case of breakage, are sufficient glasses/bottles removed beforehand and afterwards (production line)?
- Can the environment be a potential source of contamination (e.g. windows)?
- Are the X-ray detectors frequently monitored, maintained, and validated?
- Is it ensured that the production line can only be released by a qualified member of staff at the start of production or after a case of glass breakage?

Product release, non-conformities and complaints

- Are the documents from the glass management sufficiently checked before the product is released?
- How are questionable batches handled?
- How are non-conforming products handled?
- What happens with a batch if the origin of a piece of glass cannot be explained?
- How are consumer complaints regarding glass handled and evaluated?
- Is it useful to analyse the glass?

Documentation and training

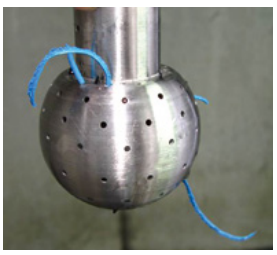
- Are there instructions provided at every relevant work station?
- Are all employees trained in handling glass and breakages?
- How are the documents for incidents of glass breakages controlled?

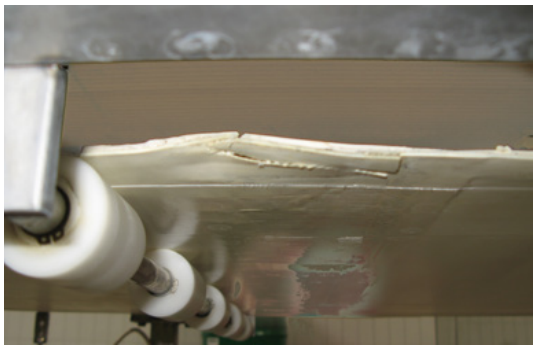
A2 Risk-Minimising Machine Design and Preventative Maintenance

Foreign bodies are often transferred via machines or equipment. Screws and metal parts have been found in foodstuffs, as have cable ties, sealing materials, paint particles and punching remnants. The overwhelming majority of such cases of contamination are due to insufficient maintenance, or maintenance that was carried out too late. In addition to the requirements set out by IFS regarding appropriate maintenance, repair, and equipment, the EU Machinery Directive 2006/42/EC states that all surfaces must be smooth and that preventative maintenance must be performed. This requirement does not just apply to metallic surfaces, but also to all plastics that are in use. Monitoring of all plastics (not just hard plastics) is therefore recommended.

Preventative maintenance

The principle behind preventative maintenance is that, for example, conveyor belts are replaced when the surface material is rough and not only when it becomes brittle, frayed, or broken. At this point contamination has often already occurred (microbial and/or via foreign bodies). It should be considered that maintenance contracts with equipment manufacturers often only cover wear and tear of individual components regarding technical safety (e.g. valves). Further-reaching aspects of food safety are often not taken into account, which means it falls under the responsibility of the company. The company should clarify with the equipment manufacturer where and how the risk of contamination of foodstuffs can be minimised by maintenance activities. Additional factors that should be taken into account regarding maintenance intervals and material wear include amongst others the temperature, mechanical stress, and product composition.





Material

When selecting materials, further aspects must also be considered:

- Glass should if possible be avoided and secured against breakage
- Plastics should be break-proof
- Perforated sheets and grids should be easy to clean

The decisive factor is that the material is appropriate for the purpose. For the painting and coating of machine surfaces and equipment, it must be considered that insufficient strength may cause particles to flake off and enter the product as foreign bodies. Further surface damage may be due to unsuitable cleaning agents. For this reason, every change of cleaning or treatment agents should be discussed with the machine supplier or the supplier of cleaning agents.

Assembly, disassembly and loose parts

During assembly, disassembly, and repairs, there is an increased risk that nuts, screws, tools or other materials may enter the foodstuffs. Tailored solutions should be devised to minimise risk such as containers for temporary storage of small parts. It is very important to make technical staff (also external) aware that a lost screw could have considerable consequences for the company and the end consumer.

A3 Verification and Validation

The company should ask the following questions regarding validation:

- Which processes are required to supply conforming products?
- What scientific findings ensure that the selected process is capable of supplying consistently conforming products?
- How to show that the process functions as intended?
- What are the tools and confirming facts (evidence) that the company has faith in the production process and the products?
- How does the company know that the process remains under control?
- How does the company react to system malfunctions and/or rework processes?

Please note: increased complexity of processes means an increase in the number of validation measures.

Validation:

Definition of validation – IFS Food version 7
"Obtaining evidence that a control measure or combination of control measures is capable of controlling the hazard to a specified outcome."

Validation acts as proof for a specific hazard or risk that the control measure or a combination of control measures are capable of keeping that specific hazard or risk under control. The specific use or application is taken into account here.

Validation acts as evidence that the selected system can keep the specific hazard/risk under control.

Verification:

Definition of verification – IFS Food version 7
"The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended."

Within the food safety and quality management, verification measures must be established to confirm the effectiveness of the HACCP plan. This should take place at least once a year. Amongst other things, the IFS Standard also covers "internal audits, analyses, sampling, evaluations, and complaints by authorities and customers". Verification results are entered into the HACCP plan. It is also important to define specific criteria for the individual verification topics (e.g. CCPs, control measures, flow charts, hazard analyses, preventative programs).

A verification is evidence that the system which was introduced functions as prescribed.

A4 IFS Requirements – Handling Foreign Body Incidents and Complaints

Excerpt from IFS Food Standard version 7

1.2 Corporate structure

1.2.6 The senior management shall ensure that the certification body is informed of any changes that may affect the company's ability to conform to the certification requirements. This shall include, at a minimum:

- any legal entity name change
- any production site location change.

For the following specific situations:

- any product recall
- any product recall and/or withdrawal by official order for food safety and/or food fraud reasons
- any visit from health authorities which results in notifications and/or penalties issued by authorities

the certification body shall be informed within three (3) working days.

4.1 Contract agreement

4.1.2 In accordance with customer requirements, the senior management shall inform their affected customers, as soon as possible, of any issue related to product safety or legality, including non-conformity/ies identified by competent authorities.

4.12 Foreign material risk mitigation

4.12.5 Potentially contaminated products shall be isolated. Access and actions for further handling or checking for these isolated products shall be carried out only by authorised personnel according to defined procedures. After this check, contaminated products shall be treated as non-conforming products.

5.8 Management of complaints from authorities and customers

5.8.1 A procedure shall be in place for the management of product complaints and of any written notification from the competent authorities – within the framework of official controls – , any ordering action or measure to be taken when non-compliance is indentified.

5.8.2 All complaints shall be registered, readily available and assessed by competent staff. Where it is justified, appropriate actions shall be taken immediately.

5.8.3 Complaints shall be analysed with a view to implementing appropriate actions to avoid the recurrence of the non-conformity.

5.8.4 The results of complaint data analysis shall be made available to the relevant responsible persons.

5.9 Management of incidents, product withdrawal, product recall

5.9.2 KO N° 9: An effective procedure for the withdrawal and/or the recall of all products shall be in place. This procedure shall include a clear assignment of responsibilities and a comprehensive information policy for customers and consumers.

5.10 Management of non-conformities and non-conforming products

5.10.1 A procedure shall be in place for the management of all non-conforming raw materials, semi-finished products, finished products, processing equipment and packaging materials. This shall include, at a minimum:

- defined responsibilities
- isolation/quarantine procedures
- risk assessment
- identification including labelling
- decision about the further usage like release, rework/post treatment, blocking, quarantine, rejection/disposal.

5.10.2 The procedure for the management of non-conforming products shall be understood and applied by all relevant employees.

5.10.3 Where non-conformities are identified, immediate actions shall be taken to ensure that food safety and product quality requirements are complied with.

5.10.4 Finished products (including packaging) that are out of specifications shall not be placed on the market under the corresponding label, unless a written approval of the brand owner is available.

5.11 Corrective actions

5.11.1 A procedure shall be in place for the recording and analysis of the non-conformities and non-conforming products with the objective to avoid recurrences by preventive and/or corrective actions. This may include a root cause analysis.

5.11.2 KO N° 10: Corrective actions shall be clearly formulated, documented and undertaken as soon as possible to avoid further occurrence of non-conformities. The responsibilities and the timescales for corrective action shall be clearly defined.

5.11.3 The performance of the implemented corrective actions shall be assessed and the results of the assessment documented.

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