D8.2 –System requirements

Hygienic Design & Hygienic Engineering

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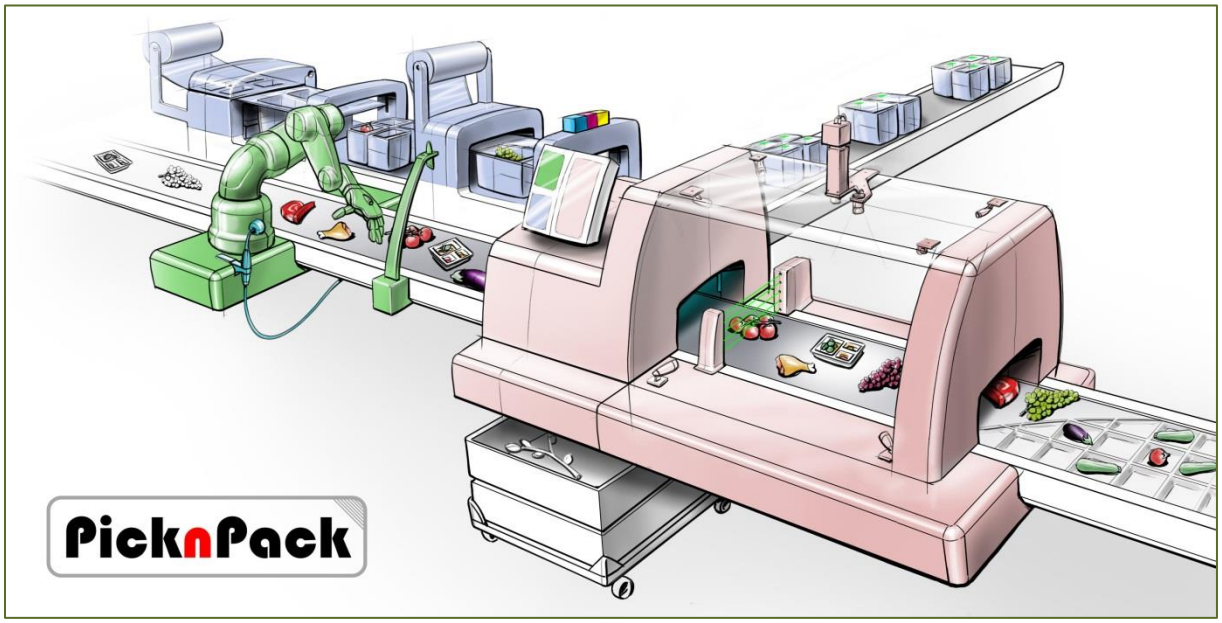

Flexible robotic systems for automated adaptive packaging of fresh and processed food products

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Dissemination level		
PU	Public	X
PR	Restricted to other programme participants (including the EC Services)	
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1 System requirements

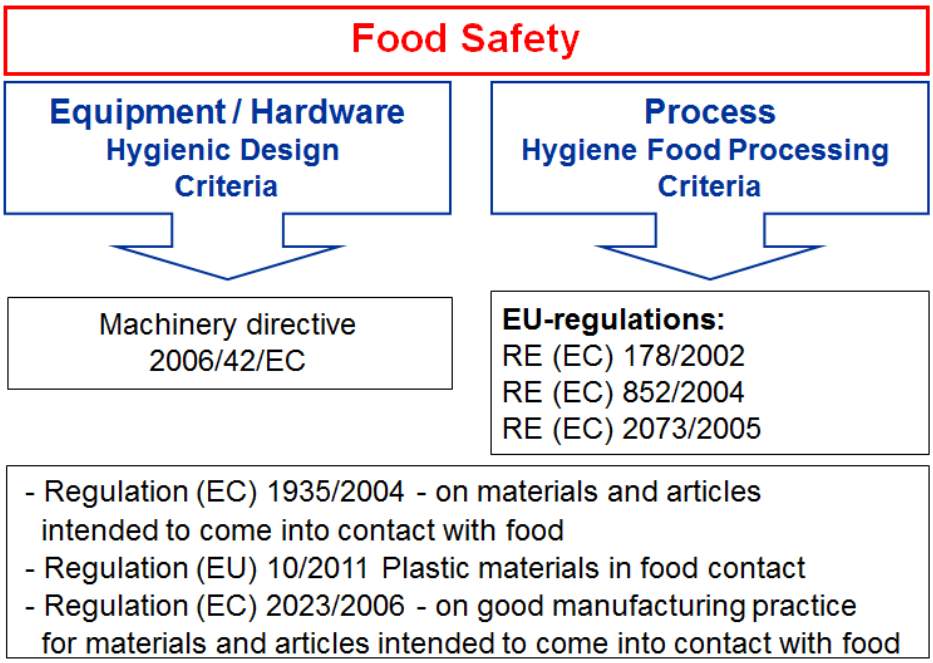

Figure 1: European food safety regulations

As a basic principle the user of a machinery has to be able to run it safely within the respective operating conditions. This applies to all phases of an operation and thereby also for a so-called demonstrator.

A CE-labelling does not have to be done until the machinery is producing “normally” and the transfer of risk to the customer has taken place.

For that special measures have to be taken to guarantee safe operating tests. For this purpose it is necessary to make risk evaluations and to take measures, which ensure that the machinery can safely perform the required tasks, even though the machine itself does not yet appear sufficiently safe. In particular this includes accordingly instructed employees, access controls and perhaps temporary safety measures. Nevertheless if something happens in this period, it has to be possible to prove that the right measures had been taken. This requires a documentation effort which may be already considerably depending on the complexity of the system.

A decisive point is also whether the demonstrator is already run with an output like a normal machine and whether the transfer of risk has taken place.

During the designing process the risk evaluation has to be done according to the Machinery directive. The design of the machinery has to follow the hygienic and safety requirements. If some risks cannot be eliminated completely they have to be written down in the operating instructions. There must also be solutions given to avoid these remaining risks. With these instructions the customer has to do a risk evaluation to ensure the food safety himself.

For this purpose the food industry already has Hazard Analysis and Critical Control Points (HACCP) as its best tool for analysing and managing the food safety risks of any design or design change. This will be done for the development of the PicknPack packaging system when all boundary conditions are known.

The HACCP principle consists of the following:

1. identify any hazards that must be prevented, eliminated or reduced to acceptable levels
2. determine critical control points (CCP's) at the steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable level
3. establish critical limits at CCP's which separate acceptability from unacceptability
4. establish system to monitor CCP's
5. establish corrective action when monitoring indicates that a CCP is not under control
6. establish verification procedure
7. establish documentation

1.1 Packaging technology

Aseptic packing is aimed at products with a long shelf life at ambient temperature. The acceptable presence of relevant microorganisms in such products is very low (e.g. less than one per 10.000 packs).

If the shelf life is short or if the desired shelf life is obtained by cold storage, freezing or in-pack treatments, the product usually contains higher numbers of microorganisms when ready to pack. Such products must be packed hygienically. Thus, a hygienic packing machine should be used. Such a machine must not allow an unacceptable increase in the number of microorganisms present in the product.

It has been decided that the products used for demonstration of the PicknPack flexible packaging system will be packed under hygienic conditions (project meeting Bilbao, 24.-26.4.2013). Therefore all relevant machinery and equipment should comply with the requirements for **hygienic packaging machines.**

1.2 Hygienic requirements

Machine parts / materials in contact with food can be cleaned before each use. Where this is not possible disposable parts must be used.

All product-contact surfaces must be resistant to the product and the cleaning agents at the temperatures used and must be acceptable for contact with food. It is recommended that every surface in the machinery is resistant against the cleaning agents because in practice it cannot be ruled out that the customer will clean all surfaces the same way contrary to orders. The worst case should be considered.

Particular attention must be given to draining of the surfaces of packing machines, and to the control of condensate that may be formed during packing of product. Condensation may occur due to

differences in temperature between product and product-contact surfaces, or due to a too high humidity in the environment. Condensation can also easily occur on interior surfaces like in switchboxes. For this purpose it is recommended to apply a ventilation system for these interior surfaces.

To limit difficulties with cleaning of the product-contact area, moving parts of the machine should as much as possible be situated outside the product area.

A basic checklist for designing a hygienic packaging machine is shown in Table 1. Further information was presented to the project team in the "Hygienic Design"-workshop that was held on occasion of the project team meeting in Bilbao, 26.4.2013.

Table 1: Basic hygienic design check list

1.	**Identify product contact surfaces** The (machinery) surface which are exposed to the product (direct) and from which the product or other materials can drain, drip, diffuce or be drawn into (self returned) the product or product container (indirect).
2.	**Basic rules** • machinery: easy to clean and easy to disinfect (when easy to dismount; disinfect able after remounting) • cleaning: enough flow rate (PIPE: 1.5 m/s; TANK: 1.86-2.24 $m^3/m^2/h$) on all surfaces • prevent ingress of micro-organisms (openings) • prevent growth micro-organisms (dead ends) • avoid void or niche areas • dead ends of pipes only in flow direction < 0.5 times diameter ○ depth / width < 0.5 • validate (test, comparable design, product)
3.	**Surfaces and geometry** • minimise joints (preference: welding) • avoid metal-to-metal contact • avoid sharp change overs or crevices • avoid thread ends • avoid sharps ends (radius> 6 mm) • draining
4.	**Seals**

	• always elastomers • tightening on product side (15% compression) • limited tightening (fixed maximum compression) • enough space for elastomer expansion
5.	**Movable parts** • room for cleaning agents (humidification) • dynamic seal (rotating; moving) • leak detection; shaft cleaning

6.	**Materials**
	• non absorbent
	• non toxic
	• non corrosive
	• stainless steel
	• plastics and rubber (FDA-list)
	  ○ measure stability (water take up; thermal expansion; fillers; time; load)
	  ○ less alteration
	• glue- and lubricants (FDA/NSF list; H 1)

7.	**Fabrication**
	• surface roughness Ra < 0,8 µm
	• welding without distortion:
	  ○ incorrect outlining
	  ○ crevice
	  ○ porosity & inclusion
	  ○ incorrect additives
	  ○ insufficient melting
	  ○ insufficient backing gas
	• insulation (tight from the outside)
	• closed construction

8.	**Direct environment** • be aware contamination by air convection • be aware lubricants (prevent, limit) • be aware construction above (accumulation soil)

For the conceptual design of the layout of the packaging line the following aspects should be taken into consideration:

- Materials not permitted for use: wood, enamelware, uncoated aluminium, uncoated anodized aluminium.
- Inspection windows are made of shatter resistant material and easily removable. Since there are different definitions for the meaning of shatter resistant, a warning system could be applied if there is a chance that splinters can reach the product nevertheless.

- Separation between product contact and non-product contact areas prevents cross contamination during operations. Indirect product contact zone areas are designed as if they were product contact zone areas.
- Separation between product contact areas and non-product contact areas has to be determined by a risk analysis.
- Product contact surface areas: inaccessible surfaces shall allow access by disassembly using simple tools or a tool free design
    - Where access is not possible, the entire assembled unit must be cleanable (i.e. **C**lening **I**n **P**lace).
- Product contact surfaces are constructed to prevent build-up of product residue during operations.
- Surfaces in non-product zones shall be accessible for cleaning and inspection.
- All surfaces near product contact zones are designed as if they were product contact zones.

- Equipment with hollow areas should be avoided, especially in wet operations.
    - If hollow areas cannot be avoided, hollow tube construction, such as framework or blade spacers are fully sealed with continuous, hygienic welds to prevent interior contamination.
    - Since these measures for sealing are also not always viable, hollow areas should be accessible and cleanable as well. The operating instructions should tell the customer how to gain access to critical hollow areas and how to clean them. The interior design of such hollow areas should also follow the requirements of hygienic design if possible.
- No fastener penetrations into hollow tube construction.

- Round framework is used for horizontal framework pieces wherever possible.

- Equipment design has to provide a minimum 300 mm clearance from the floor to allow for cleaning and inspection.
- Equipment should be located a minimum of 760 mm from overhead structures and 920 mm from the nearest stationary object. (Check applicable safety regulations)
- Utility lines are a minimum of 300 mm off of the floor and cleanable.
- Installation for product contact areas and conveyor travel paths will maintain a minimum of 300 mm (400 mm is better) clearance from the floor.
- If minimum distances cannot be reached there is also the alternative option of a distance of 0. In this case resulting fissures have to be sealed adequately and if necessary the seals have to be replaced in regular intervals.

- No bearings, drive, chain guards, control boxes or motors are located in or directly above product contact zones.
- Conduit and other utility supply lines are not routed above product contact areas.

- Fasteners are not used in or above the product zone.
- Control and junction boxes are fastened to the frame via welding or sealed or mounted away from the framework with a stand off and not mounted above product.
- No lap joints. This includes standing off flanged bearings. Bearings should be mounted on the outside of framework. They should be mounted as far from product and product contact surfaces as possible.

- Air used in contact with product or a food contact surface shall be filtered for oil, moisture and/or microbes. (Filtration requirements are based on a risk evaluation).
- Vacuum systems are considered as indirect product contact areas
- Motor fans do not blow air onto or in the direction of product contact surfaces.

- Cooling water, drain lines, drip pans (items with constant flowing water) must be piped and/or directed to a drain.
- Utility supply lines and piping are separated to prevent catch points and to allow for cleaning.

- Belts used as product contact surfaces should be non-absorbent, fully encapsulated (no exposed cloth backs or centers), cleanable.
- Belting is easily removable or the belt tension can be reduced so that the surfaces underneath belting can be easily accessed for cleaning.

- The whole machinery has to be shielded to vermin like rats and birds but especially smaller animals like fruit flies. Housings have to be designed in a way that there is no place where animals can settle. Air slots, seals, etc. have to be judged critically.

- If parts cannot be completely designed according to the requirements of hygienic design leading to remaining risks for the food safety, these risks and the way to prevent them must be documented in the operating instructions.

1.3 Exposure of product

The risk of contamination of product with relevant microorganisms increases with their concentration in the environment. Further, the risk of recontamination depends on the length of time the product and the internal surfaces of the packaging are exposed to the environment.

To control the risk of contamination by microorganisms, several measures can be taken:

- The environment of the packing machine and the product must be kept clean and tidy.
- The length of time that the product and the product side of the packaging materials are exposed to the environment may be reduced to the minimum required for filling and closing of the product container.
- The area where the product or the product-contact surface of the packing material is exposed may be covered by an overhead construction, such as a tunnel or a cover. In this case the product space should be as small as possible but also big enough for a good accessibility.

- ***IF REQUIRED***, the quality of air over the exposed surfaces and product can be controlled. The air may be decontaminated and the ingress of untreated air may be restricted by applying an overpressure. Decontamination of air may be achieved by filtration or by incineration.

If due to flexibility a conveyor belt should be used for both pure food and trays for packaging the hygienic requirements for the outside of the tray must be the same as for the inside to avoid cross-contamination.

1.4 Cleaning / Decontamination

According to risk analysis the selection of the cleaning method depends on which type of product is to be packed.

Compressed air should not be used for cleaning purposes.

Cleaning liquids are usually hot and cold water, detergents, acid /alkali solutions and are often recovered by draining into tanks enabling their re-use. The choice of cleaning agents also depends on the quality of the water (in particular the water hardness).

Preferably, the design should allow In-place cleaning of the product-contact surface, without any dismantling. If this is not possible, each part of the machine must be accessible for cleaning manually, with or without dismantling. If dismantling and reassembling are needed, this should preferably be so easy that it can be done without tools. Decontamination must take place after reassembly. It is recommended that the machine is designed such that cleaning of the surrounding area does not significantly contaminate the machine.

To avoid excessive aerosol formation, high-pressure cleaning should be avoided. Cleaning machinery surfaces and external surfaces with high pressure nozzles will displace dirt from one place to another, in particular in the form of aerosols.

Foam, gel or spray cleaning procedures at low pressures are to be preferred.

The inside of the filling or dosing unit should preferably be cleaned-in-place. Depending on local circumstances, this may be done simultaneously with the process line to which the machine is connected.

The immediate environment of the filler may cause contamination of the product if not adequately cleaned and decontaminated. Special attention may have to be paid to the means for transport of the filled packs (such as conveyor belts or chains) to prevent them from conveying spilled product through the machine.

If an automatic cleaning-in-place is applied, moving parts must be activated during cleaning or be placed in a cleaning position. Dismantled equipment parts as well as cleaning tools should be cleaned in a room that meets the requirements for safe handling of raw materials, intermediate and end products.

A basic principle for the design of food processing lines including cleaning processes is “KEEP IT DRY”. Of course, apart from dry product handling, in most of the cleaning processes in food production

with open machines this is not applicable, since wet cleaning is an effective way to prevented, eliminated or reduced potential hazards. But it should be taken into consideration that less water intake in the machinery and / or machinery environment could be beneficial in order to maintain the hygienic status with reduced effort. In closed machine system it is already implemented.

The water present may cause two major problems. Firstly, it may cause dilution of the chemical used for decontamination. Secondly, when the machine is standing idle (e.g. overnight or in the weekend) with water residues, microorganisms are likely to multiply. The decontamination treatment might be insufficient for inactivation of the large number of micro-organisms that results. Therefore, no significant amounts of water should remain anywhere in the product-contact area of the machine at the end of the cleaning procedure. Hence, the equipment must drain well.

When waste water or cleaning fluids are discharged to the floor the humidity in the environment of the process line is likely to rise. Due to the relationship between microbial growth, moisture, time and temperature this can contribute to microbial growth. Alternatively, the waste water or cleaning fluid can be discharged to dedicated chambers or directly to a drain. The drainage system has to be dimensioned for the expected flow rate. This should be preferably regarded already in the phase of the room planning.

Taking this into consideration leads to alternative cleaning concepts that can be an option for the PicknPack system (open machine system) and that will be discussed with the project team. The concepts “dry machinery environment” is characterised by the following aspects:

- Reduced amount of water used for cleaning
- Cleaning process is monitored
- **C**leaning **I**n **P**lace and **C**leaning **O**f **P**lace of the machinery / equipment
    - COP for parts /equipment that need a longer cleaning time (e.g. dynamic parts) or need a dedicated cleaning procedure
    - COP in washing machines or closed chambers separated from production
    - CIP for larger equipment parts or framework
- Cleaning fluid and waste are collected at the processing line and not drained to the floor
    - E.g. waste water to the drain or chamber attached to the machinery or trolley
- Minimised draining system

1.5 Tracebility

The traceability of food and food ingredients along the food chain (on all manufacturing and distribution steps) is an essential element in ensuring food safety (REGULATION (EC) No 852/2004). Provisions should be taken to ensure traceability of food stuff produced with the PicknPack system.

The tracebility also concerns the product contact surfaces but in contrast to the food ingredients there is no legal regulation for this. It only has to be proven that there is such a system, which is able to trace back the product contact surfaces.