

European Feed Ingredients Safety Certification

Sector reference document on the manufacturing of safe feed materials from starch processing

Version 3.0
Effective from 15 May 2013



Sectors covered by EFISC

The following sector specific sector documents have been developed by the respective European sector organisations in cooperation with EFISC:

AAF	Sector reference document on the manufacturing of safe feed materials from starch processing
FEDIOL	Sector reference document on the manufacturing of safe feed materials from oilseed crushing and vegetable oil refining
EBB	Sector reference document on the manufacturing of safe feed materials from Biodiesel processing

This European Code is open to other manufacturers producing feed materials by the development of a sector specific document.

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a) Introduction

The European starch industry produces a large number of products used for food and feed as an integral part of their overall business plans. Indeed, the starch industry separates the components of cereals, potatoes and peas in order to process them and meet the needs of its numerous customer industries.

It is imperative to the starch manufacturing industry that feed materials are produced in an economic and safe manner and that the products obtained are suitable for human and animal consumption as illustrated by their meeting all current European and national food and feed safety legislation requirements. Many food ingredients obtained by the starch industry are also used as feeding materials. These products are listed in the Feed catalogue (Reg. EU n°68/2013) and can be included in the scope of the operators feed safety management system.

Regarding animal feed materials, Article 20 of the European Feed Hygiene Regulation (EC) n°183/2005/EC, which came into effect on January 1st 2006, allows for the development of Sector Guides by animal feed producers, including feed materials suppliers such as the AAF.

The fact that a HACCP approach to food safety risk management has been widely and successfully implemented in terms of food manufacture has highlighted the potential of such an approach within the feed industry. But a HACCP system alone is not sufficient and if the benefits of such an approach are to become a reality this must be backed by management support, traceability, as laid down in Regulation n°178/2002(EC), communication throughout the business/ sector and the internal monitoring and control of all feed production and distribution processes.

By the universal application of HACCP principles to all stages of production European starch manufacturers are able to provide animal feeds materials of plant origin which are safe for not only for the consuming animal but which also have no deleterious effect upon the safety of a human consumer further up the food chain.

The AAF member companies bring to the attention the following points:

- The plant origin of raw materials processed by the starch industry and the nature of the feed materials limit risks for the feed industry and make risk management easier.
- A strong dynamic of progress is to be noted in the starch industry, which is of benefit to all its customers: indeed, most products of the starch industry are intended not only for feeding materials but also for food, pharmaceuticals and other industries.

- Starch producers very carefully comply with regulations and the quality imperatives of all their customers' fields of activity. These requirements led to the setting up of quality assurance systems, with knock-on effects on all our products.
- The starch industry is therefore very much oriented towards quality control:
 - ISO 22000:2005 and ISO/TS 22002 with a strong focus on HACCP
 - Quality improvement programs integrating the principles of the HACCP method for all products;
 - Extension of ISO certifications and/or HACCP program to all raw materials intended for feeding materials.

Particular attention has always been given to raw materials supplies: increased traceability, quality assurance procedures applying to our suppliers, surveillance scheme (e.g. mycotoxins in wheat and maize), setting up of improvement agreements, audits, etc.



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List of abbreviations used:

As: Arsenic

Cd: Cadmium

CIP: cleaning-in-place

CCP: Critical Control Point

CFU/g: Colony Forming Units per gram

DDT: Dichlorodiphenyltrichloroethane

GMP: Good Manufacturing Practice

HACCP: Hazard Analysis Critical Control Point

HCB: Hexachlorobenzene

HCH: Hexachlorocyclohexane

HCN: Hydrogen cyanide

Hg: Mercury

ISO: International Organisation for Standardisation

MRL: Maximum Residue Limits

PAH: Polycyclic aromatic hydrocarbons

Pb: Lead

PCB: Polychlorinated biphenyls

SO₂: Sulphur Dioxide

T°C: temperature degree Celsius



b) Methodology of the AAF food and feed chain risk assessment

1. AAF made the following crops subject to a food and feed safety chain risk assessment:

- Maize starch
- Wheat Starch
- Potato Starch
- Pea Starch

2. AAF conducted the chain risk assessments according to the requirements as described in chapter 6 of the EFISC Code to good practice for the industrial manufacture of safe feed materials.

AAF will evaluate the food and feed safety assessments of the chains of starch products on a two yearly basis.



c) Listing of Feed Materials

Feed materials from the starch industry meet the statutory definitions of raw materials (Regulation 68/2013 definitions). However, the composition of marketed products may differ, depending on production sites, production tools and processes, and market opportunities.

The following list is a non exhaustive list of the main products of the starch industry intended for use as feed materials by feeding stuffs producers; the definitions below are extracts from Regulation 68/2013 (taking into account industrial language).

Name	Number	Description
○ Maize gluten	1.2.8	Product of the manufacture of maize starch. It consists principally of gluten obtained during separation of starch.
○ Maize gluten feed	1.2.9	Product obtained during the manufacture of maize starch. It is composed of bran and maize solubles. The product may also include broken maize and residues from the oil extraction of maize germs. Other products derived from starch and from the refining or fermentation of starch products may be added.
○ Maize germ meal	1.2.12	Product of oil manufacture, obtained by extraction of processed maize germ
○ Wheat Feed	1.11.6	Product of flour or malting manufacture obtained from screened grains of wheat or dehusked spelt. It consists principally of fragments of the outer skins and of particles of grain from which less of the endosperm has been removed than in wheat bran.
○ Wheat gluten feed	1.11.16	Product of the manufacture of wheat starch and gluten. It consists of bran, from which the germ may have been partially removed. Wheat solubles, broken wheat and other products derived from starch and from the refining or fermentation of starch products may be added.
○ Vital wheat gluten	1.11.18	Wheat protein characterised by a high viscoelasticity as hydrated, with minimum 80 % protein (N × 6,25) and maximum 2 % ash on dry substance
○ Potato pulp	4.8.8	Product of the manufacture of potato starch consisting of extracted ground potatoes.

- Potato pulp, dried 4.8.9 Dried product of the manufacture of potato starch consisting of extracted ground potatoes.
- Potato protein 4.8.10 Product of starch manufacture composed mainly of protein substances obtained after the separation of starch.
- Potato juice, concentrated 4.8.14 Concentrated product of the manufacture of potato starch, consisting of the remaining substance after the partial removal of fibre, proteins and starch from the whole potato pulp and evaporation of part of the water.
- Pea protein 3.11.9 Product obtained from the separated pea fruit water when producing starch, or after grinding and air fractionation, maybe partially hydrolysed.
- Pea solubles 3.11.11 Product obtained from starch and protein wet extraction from peas. It is mainly composed of soluble proteins and oligosaccharides.
- Pea fibre 3.11.12 Product obtained from the separated pea fruit water when producing starch, or after grinding and air fractionation, maybe partially hydrolysed.
- Starch mixture 13.3.3 Product consisting of native and/or modified food starch obtained from different botanical sources.

The above list will be amended, if appropriate, in function of industrial developments within the starch industry, or of an evolution of the EU legislation on feed materials like e.g. a review of the Catalogue of feed materials.

The above list is non exhaustive. Other raw materials (e.g. barley and rice) and other feed materials (that can be specific to a plant or based on market demands) and all food ingredients sold also as feed materials, are considered to be within the scope of the EFISC Code. For all products sold as feeds materials a risk assessment in line with annex 3 needs to be available.

The exact compositions of marketed products sold to the feeding industry can be found in the marketing documents (data sheets) of each starch producer.



d) Overview of the main processes

The below manufacturing diagrams are basic schemes (i.e. examples) for the production of starch from wheat, maize, potato and pea, yet every production site may present distinctive features.

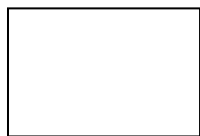
Specific feed materials are underlined in the flow charts. However all other products except ethanol can be used both for feed and food.

They must not be regarded as a standardized process to be applied by starch companies. Each company remains free to decide what design each industrial processing unit should look like.

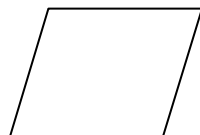
Symbols



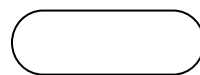
Main Process



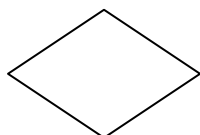
Process step



Material



Process start or terminator



Decision

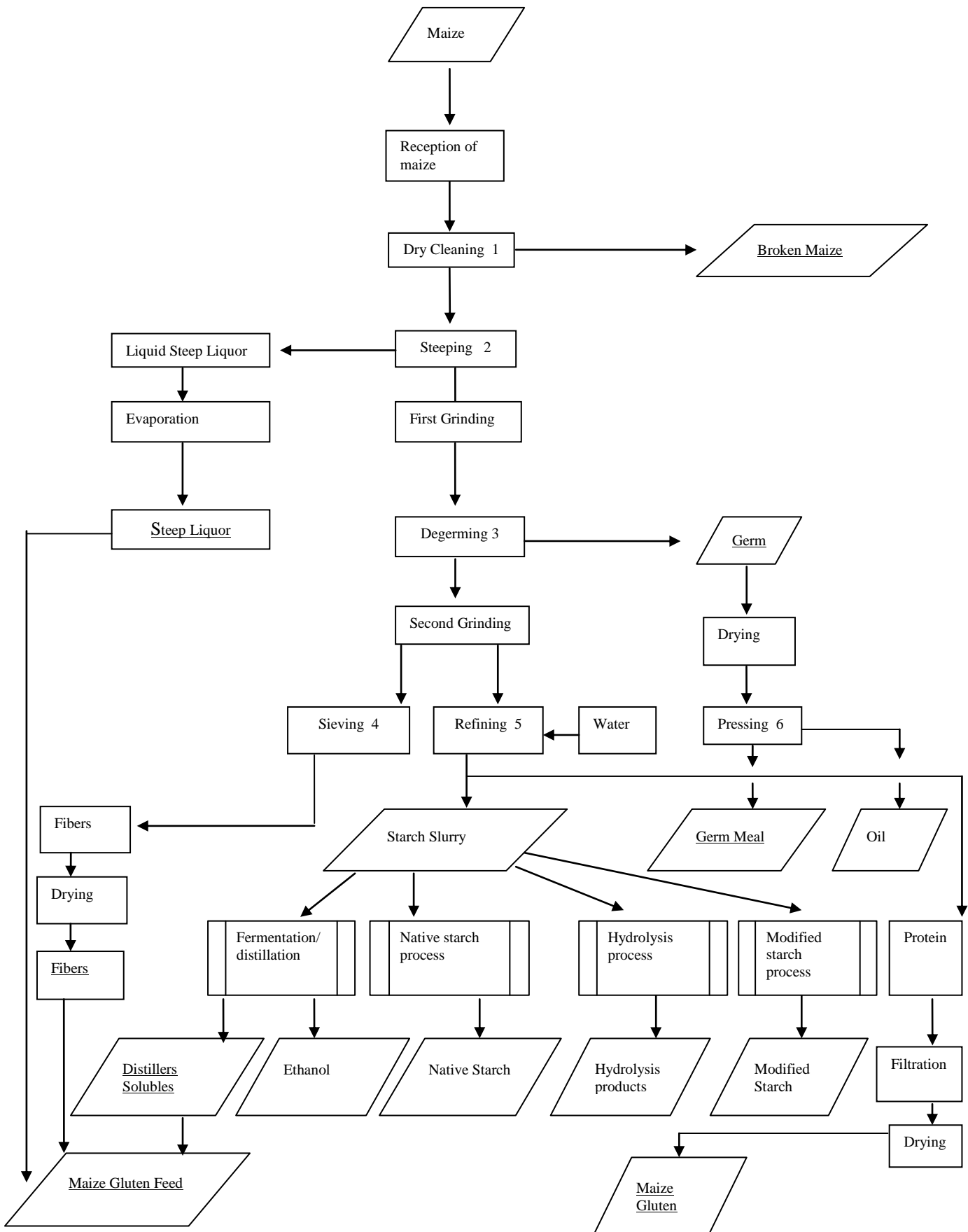


1. MANUFACTURE OF MAIZE STARCH

1. Dry cleaning: sieving and sucking up of impurities and broken grains. The parts non suitable for feed use are eliminated. The parts suitable for feed use are sold as such or incorporated in corn gluten feed.
2. Steeping: corn put into water in order to separate the soluble components (= liquid steep liquor). Micro-organism controlling agent is added to prevent from bad fermentation.
3. Degerming: germ separated from the grain thanks to density difference going through a cycloning.
4. Sieving: product goes through a sieve. Fibres particles stay on the sieve / slurry made of starch and protein goes through.
5. Refining: starch separated from protein thanks to density difference going through a centrifugal extractor.
6. Pressing: oil separated from germ thanks to mechanical pressure.



1. MANUFACTURE OF MAIZE STARCH - BASIC SCHEME

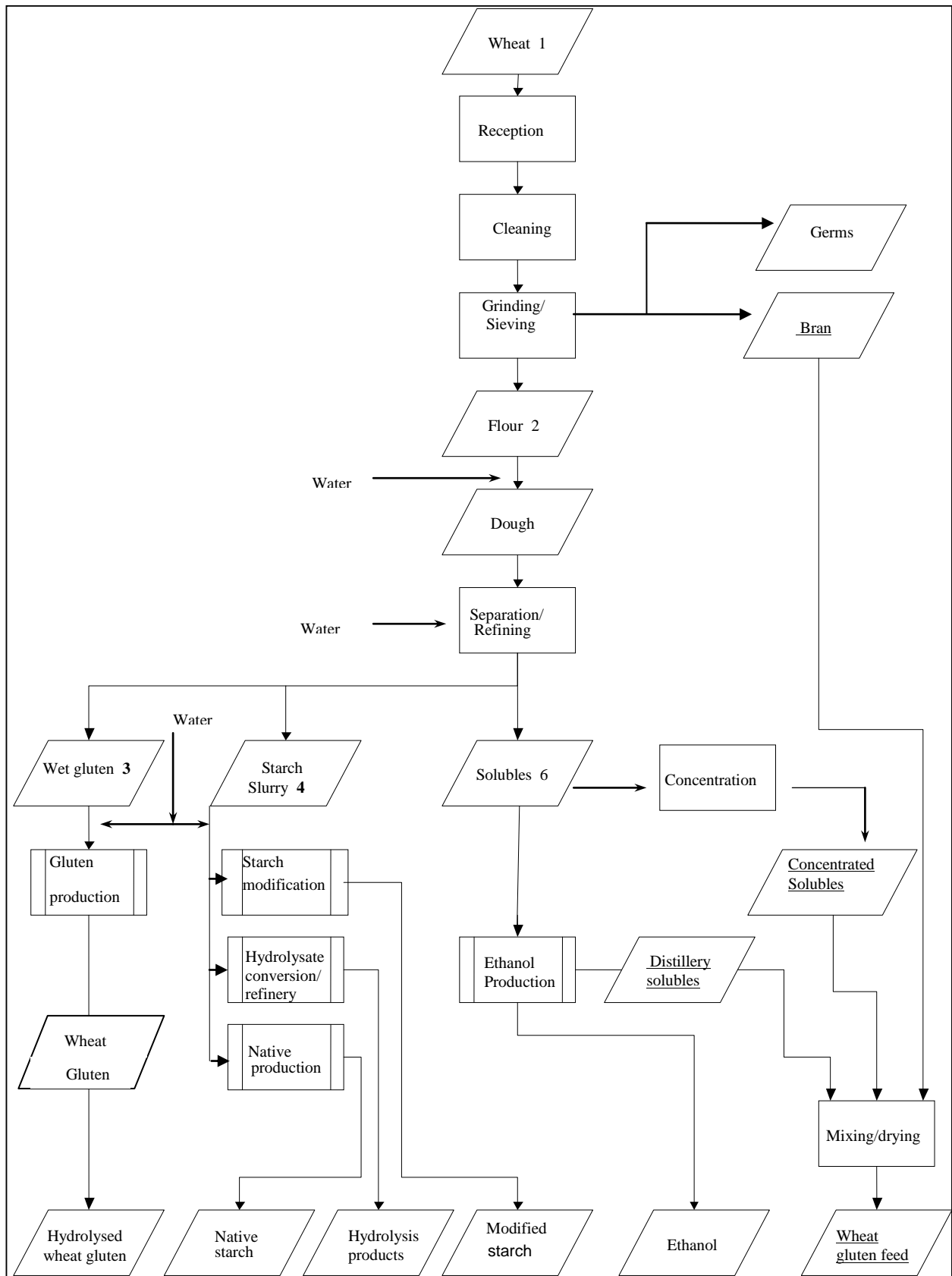


2. MANUFACTURE OF WHEAT STARCH

1. The incoming wheat is cleaned and ground to flour. The wheat bran and eventually also wheat germ are separated from the flour by sieving.
2. The flour is mixed with water to form a dough and the starch and gluten are separated by a physical process.
3. The wet gluten is washed with water to remove residual starch and dried to wheat gluten. The wet gluten can be partially hydrolysed also to produce hydrolysed wheat gluten.
4. The starch slurry is washed with water and can be:
 - Dried to produce native wheat starch;
 - Physically and/or chemically modified and dried to produce modified wheat starches;
 - Hydrolysed by acid hydrolysis and/or enzymes to produce a range of starch hydrolysis products.
5. A fraction of the starch separated during washing can be used in animal feed (liquid wheat starch) or in ethanol production (not shown in the flowdiagram).
6. A fraction of solubles from the separation of starch and gluten can be used in alcohol production, or concentrated and used as such in animal feed (wheat solubles) or added to the wheat bran to produce wheat gluten feed.
7. In ethanol production the starch is enzymatically hydrolysed to sugars and fermented to ethanol with yeast. The ethanol is separated by distillation, and the remaining solubles are concentrated and either used as such in animal feed (distillery grains and solubles) or added to the wheat gluten feed.



2. MANUFACTURE OF WHEAT STARCH - BASIC SCHEME



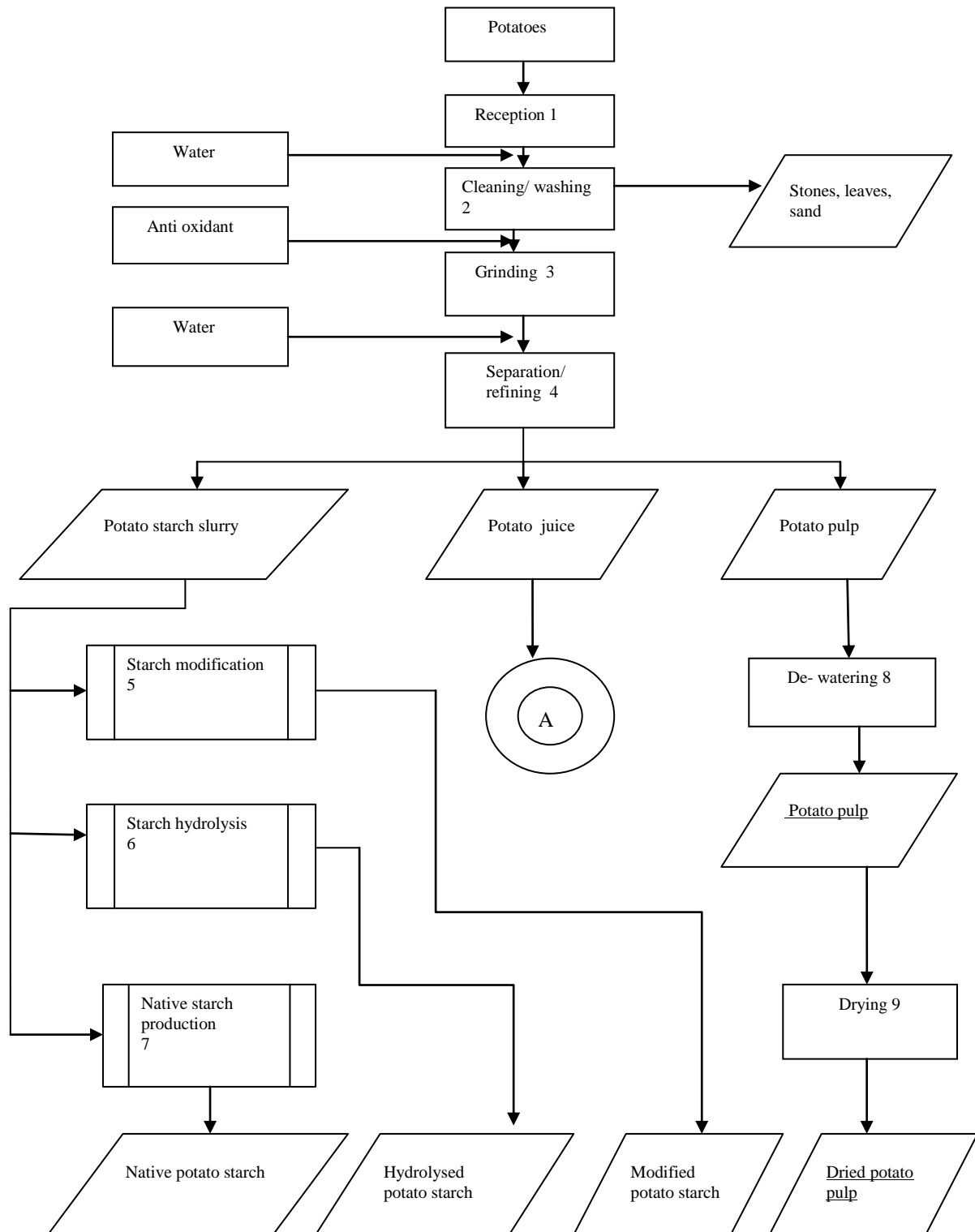
3. MANUFACTURING OF POTATO STARCH

1. At the reception of the potatoes a sample is taken to check on quality.
2. The potatoes are washed and unwanted components like sand, leaves and stones are removed. To prevent excessive foaming some food grade anti foam is added.
3. The cleaned potatoes are grinded and anti oxidant is added.
4. The grinded potatoes are separated with gravity based techniques to potato starch slurry, potato juice and potato pulp.
5. The starch slurry is modified by chemical and/or physical techniques and dried to modified starch.
6. The starch slurry is hydrolysed with acid or enzymes and dried to hydrolysed starch.
7. The starch slurry is de-watered and dried to native potato starch.
8. The potato pulp stream is de-watered mechanically to the feed product potato pulp.
9. The regular potato pulp product can be dried further to dry pellets – dried potato pulp.
10. The potato juice is heated with steam and the protein components coagulate. To prevent excessive foaming some food grade anti foam is added.
11. The coagulated protein is separated by gravity techniques from the potato juice.
12. The protein is dried to the feed product potato protein.
13. Potato protein is mixed with water and acid for the production of potato protein (purified).
14. The mixture of water and coagulated protein is refined to remove the natural glyco alkaloids from the protein.
15. The refined protein is dewatered by gravity techniques.
16. The refined protein is dried to the feed product potato protein (purified).
17. The potato juice is heated to evaporate water and produce condensed potato juice.

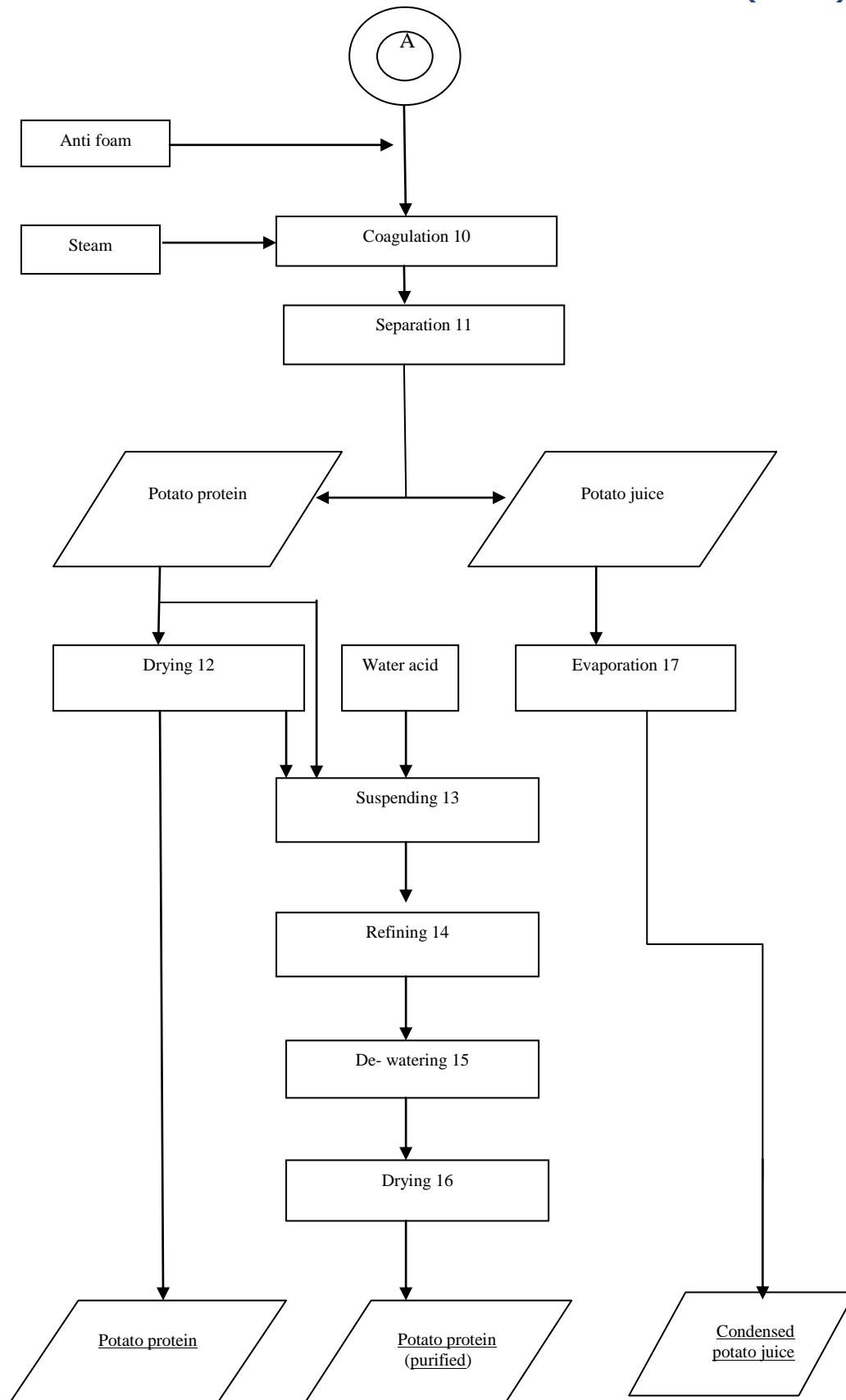
The pH is checked and corrected by pH Regulators in various stages of the production process.



3. MANUFACTURING OF POTATO STARCH - BASIC SCHEME (1 of 2)



3. MANUFACTURING OF POTATO STARCH - BASIC SCHEME (2 of 2)

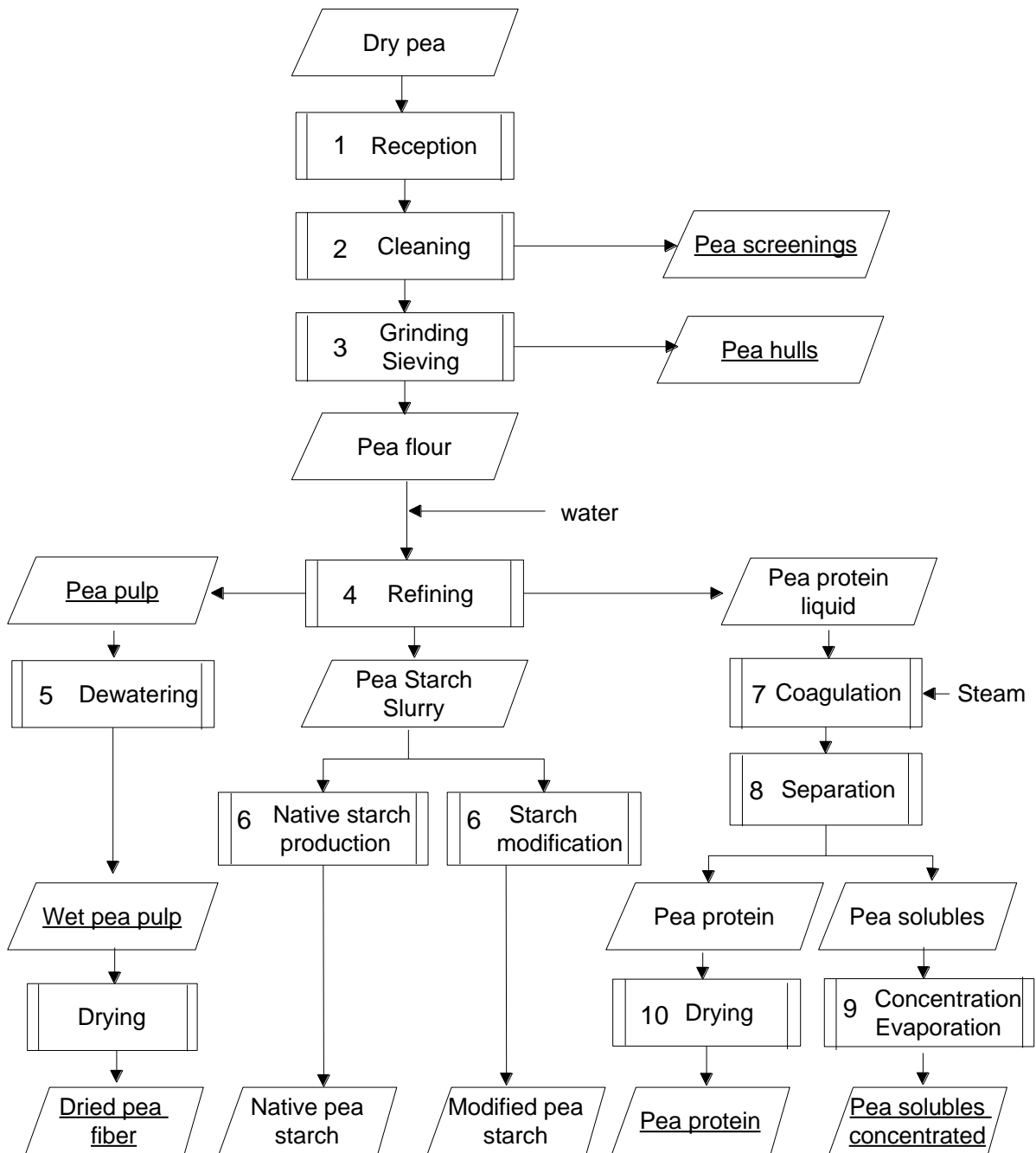


4. MANUFACTURING OF PEA STARCH

1. The incoming dry pea is sampled to check the quality.
2. Pea is cleaned to remove impurities and broken pea by sieving.
3. The cleaned peas are grinded / sieving to flour.
4. The flour is mixed with water to separate by physical process to pea starch slurry, pulp and liquid protein products.
5. Pea pulp fraction is de-watered mechanically to the feed product pea pulp.
6. The pea starch slurry is washed and can be :
 - dried to produce native pea starch,
 - physically and/or chemically modified and dried to produce modified pea starch.
7. The pea protein liquid is heated with steam and the protein components coagulate.
8. The coagulated protein fraction is separated by gravity techniques from pea protein liquid.
9. After coagulated protein fraction separation, the liquid fraction is heated to evaporate water and produce condensed pea soluble.
The pH is checked and corrected by pH regulators in various steps of the production process.
10. The pea protein fraction is dried to obtain pea protein product.



4. MANUFACTURING OF PEA STARCH - BASIC SCHEME



e) Summary of the risk-based approach for the starch sector

In establishing the list of potential hazards, an operator should take due consideration of:

- The Directive of undesirable substances in feed (2002/32/EC).
- The Regulation on genetically modified food and feed (1829/2003/EC).
- The Placing on the market Regulation (767/2009/EC)
- Commission Recommendation on the prevention and reduction of *Fusarium* toxins in cereals and cereal products (2006/576/EC).
- The Regulation on maximum residues levels of pesticides in or on food and feed of plant and animal origin (396/2005/EC).

See the EFISC Code chapter 7 for more information regarding the legislation.

The following list of examples is non- exhaustive and should be adapted according to the circumstances:

Biological hazards

- Relevant Vegetative Pathogens according to the GMP feed regulation and associated microbiological criteria.

Potential Chemical hazards

- Process chemicals, processing aids e.g. enzymes, micro organism controlling agents , pH regulators, antioxidants, mineral nutrients for fermentation
- Biocides
- Mycotoxins
- Phytotoxins
- Heavy metals
- Pesticides residues
- PCB, Dioxins
- Polycyclic aromatic hydrocarbons (PAH)
- Lubricants
- Noxious seeds
- Food contact packaging materials (including printing inks, paper and board, coatings...)
- Pest control chemicals

The use of processing aids is included in the hazards analysis developed by the operator according to the requirements of the section 6 of the EFISC Code.



Physical contamination hazards

- Metal
- Glass
- Hard plastic
- Any other relevant physical contamination.

Radioactivity hazard

- Radionuclides (after a nuclear accident)



f) Risk-based approach for the characterisation of hazards applicable to starch products sold as feed

The following tables present the characterisation of hazards applicable to starch products sold as feed materials. The risk level defined is based on a situation where no control measure is in place and the number obtained is an indicative number. For more understanding of the following risk assessment tables please see EFISC main text, chapter 6 HACCP system.

Those risks cannot be considered as complete and may differ amongst starch producers for example based on the origin of the raw materials and the individual and specific starch manufacturer's processing conditions and the combination of these.

Starch manufacturers have refined the risks to a level appropriate to their specific operating conditions.

Moreover, in these tables, no operational prerequisite programme (OPRP) or critical control point (CCP) is listed due to the fact that the decision leading to the establishment of such OPRP or CCP should be consistent with the reality of each plant or processing line.

Three categories of hazards were considered:

- Biological hazards (B)
- Chemical hazards (C)
- Physical hazards (P)



FEED. Risk assessment of the chain of starch manufacturing

1: GENERAL RISK ASSESSMENT APPLICABLE FOR ANY RAW MATERIAL

1.1 General risk based approach				Ingredient: the raw materials (MAIZE, WHEAT, POTATO, PEA) coming from primary production			
Hazard	Cat.	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies like glass, wood, metals, etc.	P	Low	High	3		In letter stages; general processing steps must be purifying (magnets, screens).	Supplier's specification.
Pesticide residues (authorised) above the MRL, i.e. residues of herbicides, insecticides, fungicides or rodenticides above the MRL	C	Medium	Medium	3	Reg. 396/2005/EC	Active participation in surveillance schemes for contaminant monitoring. A monitoring program should be in place.	Supplier's specification. Traceability from supplier's silo's- attention for the use of post harvest pesticides. Special attention for the geographical origin.
Pesticides residues (unauthorised)	C	Very low	High	2	Directive 2002/32/EC	Active participation in surveillance schemes for contaminant monitoring. A monitoring program should be in place.	Directive 2002/32/EC sets limits for a number of pesticides residues in feeding stuff. Some of the banned pesticides may be present in the environment.
Mycotoxins above the specified limit	C	Medium	High	4	Dir. 2002/32/EC Rec. 2006/576/EC	Active participation in surveillance schemes for contaminant monitoring. A monitoring program should be in place.	Supplier's specification. Traceability from supplier's silo's.
Heavy metals above the specified limit	C	Low	High	3	Reg. 396/2005/EC Dir. 2002/32/EC Rec. 2006/576/EC	Active participation in surveillance schemes for contaminant monitoring. A monitoring program should	Supplier's specification. Special attention for the geographical origin.



FEED. Risk assessment of the chain of starch manufacturing

						be in place.	
Phytotoxins	C	Low	Medium	2	Directive 2002/32/EC limits the maximum content of toxic weed seeds	Active participation in surveillance schemes. A monitoring program should be in place.	Supplier's specification. Special attention for the geographical origin.

1.2 General risk based approach				Ingredient: WATER			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Contaminants present in water such as PFOA and PFOS	P	Low	Medium	2	Regulation 183/2005/EC	A monitoring plan shall be in place for the verification of water of suitable quality for feed production. In latter stages; general processing steps are purifying, i.e. filtration.	For the manufacture of feed water used shall be of suitable quality.
Cross contamination	C	Low	High	3	Regulation 183/2005/EC	The PRP program should prevent cross contamination by use of dedicated water circuits. The chemicals used have to be authorized.	
Pesticide residues (authorised) above the MRL, i.e. residues of herbicides, insecticides, fungicides or rodenticides above the	C	Medium	Medium	3	Reg. 396/2005/EC	A monitoring program should be in place.	



FEED. Risk assessment of the chain of starch manufacturing

MRL							
Pesticides residues (unauthorised)	C	Very low	High	2	Directive 2002/32/EC	A monitoring program should be in place.	
Heavy metals above the specified limit	C	Low	High	3	Dir. 2002/32/EC	A monitoring program should be in place.	
Hydro carbons	C	Low	High	3		A monitoring program should be in place.	
Metal leaching	C	Low	Medium	2		The PRP program should include inert contact materials where applicable and the appropriate construction standards.	
Pathogenic micro - organisms	B	Low	High	3		The PRP program should include dedicated water circuits and the possibility for disinfection treatment. A monitoring program should be in place.	



FEED. Risk assessment of the chain of starch manufacturing

1.3 General risk based approach				Processing agent: CHEMICAL AGENTS (antifoams, acidification or alkalisng agents, SO ₂ and derivatives, enzyme catalysing salts...)			
Hazard	Cat.	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Heavy metals above the specified limit	C	Low	High	3	Dir. 2002/32/EC	Ingredient specification. Contracts containing food adequate requirements.	Purchasing requirements
Cross contamination	C	Low	Medium	2		The PRP program should include on-line process monitoring (pH, sensorial, consumption rates), correct labelling of chemical containers.	



FEED. Risk assessment of the chain of starch manufacturing

1.4 General risk based approach				Processing agent: ENZYMES (particularly those specific to usage in the scope of starch processing)			
Hazard	Cat.	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Cross contamination	B	Low	Low	1		The PRP programme should include on-line process monitoring (consumption rates), correct labelling of enzyme containers.	
Pathogenic micro-organisms	B	Low	High	3		Ingredient specification Contracts containing food adequate requirements.	Purchasing requirements.



FEED. Risk assessment of the chain of starch manufacturing

1.5 General risk based approach				Processing agent: FILTER AIDS (filtering earth, silica, coal, cellulose fibre...)			
	Cat.	Chance	Severity	Risk Class.	Legislation	Control measure	Remarks
Metal leaching	C	Low	Medium	2		Ingredient specification. Contracts containing food adequate requirements.	Purchasing requirements.
Cross contamination	P	Low	Medium	2		Filtration in latter process stages.	
Contaminants from filter aids	C	Low	High	3		Ingredient specification. Contracts containing food adequate requirements.	Purchasing requirements.

1.6 General risk based approach				Materials: MATERIALS IN CONTACT (equipment, packaging...)			
Hazard	Cat.	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Metal leaching	C	Low	Medium	2		Ingredient specification. Contracts containing food adequate requirements.	Purchasing requirements.
Pathogenic micro - organisms	B	Low	High	3		Ingredient specification. Contracts containing food adequate requirements.	Purchasing requirements.



FEED. Risk assessment of the chain of starch manufacturing

1.2 General risk based approach				Utilities: Starch processing			
Hazard	Cat.	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Toxins from pest control materials	C	Low	High	3		A pest control programme must be applied that is suitable for use in the food chain.	Poisoned grain from open boxes could end up in the food chain.
Cleaning agents	C	Medium	Medium	3		Cleaning agents used in the production system should be flushed. Cleaning agents must be authorised for use in the food industry.	
Boiler chemicals	C	Medium	Medium	3		Boiler chemicals used must be suitable for use in the food industry.	
Lubricants from equipment	C	Low	High	3		The PRP program should assure that the contamination of product with non food grade lubricants is avoided and that the risk of contamination with food grade lubricants is minimised. The PRP programme could involve recording of the quantities used.	



FEED. Risk assessment of the chain of starch manufacturing

1.7 General risk based approach				Process stage: MANUFACTURING PROCESS CONTROL			
Hazard	Cat.	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		A system should be in place that removes foreign material; general processing steps must be purifying (magnets, sieving).	
Phytotoxins	C	Low	Medium	2	Directive 2002/32/EC limits the maximum content of toxic weed seeds	Visual inspection of the incoming raw materials is recommended.	
Insects and rodents	B	Medium	Medium	3		The PRP program should address closed buildings, windows and doors. The PRP program should include a pest control program.	Proper sanitation should be in place.
Flying-in birds	B	Low	Medium	2		The PRP program should address closed buildings, windows and doors. The PRP program should include a pest control program.	
Lack of Hygiene	B	Low	High	3		Staff hygiene training shall be provided and the appropriate sanitation, clothing, work instructions and material regarding cleaning foreseen.	Hygiene prerequisite program.
Pathogenic microbiological organisms, including	B	Low	High	3		The PRP programme should provide closed lines. Low probability of growth via	A monitoring program should be in place.



FEED. Risk assessment of the chain of starch manufacturing

Salmonella						raw material by stages with higher temp routes and lower pH ranges. Regular monitoring of finished products.	
Heavy metals above the specified limit	C	Low	High	3	Dir. 2002/32/EC	Knowledge regarding the distribution of chemical contaminants from raw material into the end product, including the concentration factor. Regular monitoring of the finished products.	A monitoring program should be in place.
Mycotoxins above the specified limit	C	Low	High	3	Dir. 2002/32/EC Rec. 2006/576/EC	Knowledge regarding the distribution of chemical contaminants from raw material into the end product, including the concentration factor. Regular monitoring of the finished products.	A monitoring program should be in place.
Pesticide residues above the MRL, i.e. residues of herbicides, insecticides, fungicides or rodenticides above the MRL.	C	Low	High	3	Reg. 396/2005/EC Dir. 2002/32/EC	Knowledge regarding the distribution of chemical contaminants from raw material into the end product, including the concentration factor. Regular monitoring of the finished products.	A monitoring program should be in place.
Direct drying (PAH, nitrous oxides, dioxins)	C	Low	High	3	Dir. 2002/32/EC Reg. 183/2005/EC	Good burner maintenance practices. Avoid formation of soot. An in depth HACCP study should be in place in combination with good maintenance practices. Regular monitoring of the finished products.	A monitoring program should be in place.



FEED. Risk assessment of the chain of starch manufacturing

Cross contamination	C	Low	Medium	2		The PRP programme should foresee dedicated circuits and the dedicated storage of chemicals.	
Lubricants from equipment	C	Low	High	3		Use of food grade lubricants where applicable. Control and registration of the quantities used. Good maintenance programme.	Purchasing specifications.
Cleaning and disinfection agents	C	Low	Medium	2		The PRP programme should address the cleaning and sanitation. The cleaning agents and disinfection agents used should be authorised and suitable for use in the food industry.	Purchasing specifications.

1.8 General risk based approach				Process stage: STORAGE and TRANSPORT CONTROL			
Hazard	Cat.	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Closed process, sieving, staff hygiene, glass procedure, good maintenance practices	Visual checks.
Cross contamination	C	Medium	Medium	3		The PRP program should address the requirements for storage and loading. Verification and control of the previous loads and cleaning regime.	Transport specifications and contractual agreement with service provider.

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Mycotoxins formation	C	Low	High	3	Dir. 2002/32/EC Rec. 2006/576/EC	Appropriate storage control should be in place. The PRP programme should foresee closed storage areas. Humidity & T controls when necessary. The finished product should be monitored on mycotoxins.	Good storage practices for bulk storage Monitoring program should be in place.
Pesticide residues above the MRL, i.e. residues of herbicides, insecticides, fungicides or rodenticides above the MRL.	C	Low	High	3	Reg. 396/2005/EC Dir. 2002/32/EC	The fumigation of silo's to be done by qualified persons. Regular finished products monitoring should be in place.	Good storage practices.
Pathogenic micro – organisms, including Salmonella	B	Low	High	3		Appropriate storage control should be in place. The PRP programme should foresee closed storage areas. Humidity & T controls when necessary. The finished product should be monitored on pathogenic micro-organism, including Salmonella.	Good storage practices for bulk storage Monitoring program.
Insects and rodents		Medium	Medium	3		The PRP programme should provide for a closed storage areas and covered loading area. A pest control system should be in place.	Sanitation and Pest control prerequisite.



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EXAMPLE 2.1: A MAIZE PRODUCT, FOCUS ON RECEPTION, PROCESS, STORAGE AND LOADING STEPS

RISK BASED APPROACH FOR MAIZE PROCESSING				Process stage: RECEPTION (Cereal Maize)			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies like glass, metals, stones, etc.	P	Low	High	3		Closed process, maize cleaning (sieving, magnets), staff hygiene, glass procedure, good maintenance practices.	Visual checks.
Phytotoxins	C	Low	Medium	2	Dir. 2002/32/EC	PRP for incoming raw materials Analysis via monitoring programme. Visual checks. Aggregate sampling.	Product specification.
Heavy Metals above the specified limit	C	Low	High	3	Dir.2002/32/EC	PRP for incoming raw materials. Analysis via monitoring programme.	Purchasing specifications.
Pesticide residues above the MRL (authorised), i.e. residues of herbicides, insecticides, fungicides or rodenticides above the MRL.	C	Medium	Medium	3	Reg. 396/2005/EC	PRP for incoming raw materials taking into account geographical origin. Analysis via monitoring programme.	Purchasing specifications.



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Pesticides residues (unauthorised)	C	Very low	High	2	Directive 2002/32/EC	A monitoring program should be in place.	Directive 2002/32/EC sets limits for a number of pesticides residues in feeding stuff. Some of the banned pesticides may be present in the environment.
Mycotoxins above the specified limit	C	Medium	High	4	Dir. 2002/32/EC Rec. 2006/576/EC	PRP for incoming raw materials taking into account geographical origin. Analysis via monitoring programme.	Purchasing specifications.
PAH, nitrous oxides, dioxins	C	Low	High	3	Dir. 2002/32/EC Reg. 183/2005/EC	Regular monitoring of the incoming material products.	Due to drying of the maize at primary level. A monitoring program should be in place.
Lubricants from equipment	C	Low	High	3		PRP for maintenance. Use of food grade lubricant Recording of the quantities used.	Purchasing specifications.
Pests	B	Medium	Medium	3		Closed buildings. The PRP programme should include pest control	Regular checks on pest activity.



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RISK BASED APPROACH FOR MAIZE PROCESSING				Process stage: PROCESS (Dry cleaning, Steeping, Grinding, Degerming, Sieving, Drying, Mixing, Drying)			
Hazard	Category	Chance	Severity	Risk Class	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Closed process, sieving, dedicated transport lines, dry cleaning of maize, staff hygiene , glass procedure, good maintenance practices PRP for personal hygiene.	Visual checks.
Lubricants from equipment	C	Low	High	3		PRP for maintenance Use of Food grade lubricant Recording of the quantities used.	Purchasing specifications.
Processing aids	C	Low	High	3		On-line monitoring (follow up excessive use of processing aids) pH control, SO ₂ content control, ISO9001 plans, work instructions and training of the personnel.	
Cleaning and disinfection agents	C	Low	Medium	2		PRP for cleaning and sanitation Use of food contact authorized.	Purchasing specifications.
Neoformed compounds (direct dryer)	C	Medium	Medium	3	Dir. 2002/32/EC	Gas specifications. End-product analyses (according to the dryer type).	
Water contamination	B/C	Low	High	3	Reg. 183/2005/EC	PRP for layout of premises and workspace. Analysis via monitoring programme. Disinfection treatment.	
Pests	B	Medium	Medium	3		PRP for Pest control Closed process and buildings.	Checks on pest activity.
Pathogenic Microbiological organisms	B	Low	High	3		Process control (Temperature, pH, Time and Moisture content). Process cleaning instruction. Process monitoring on micro	



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						<p>organisms. Final product monitoring on micro organisms. Drying/evaporating steps: Control moisture content of product. Hygiene prerequisite program.</p>	
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RISK BASED APPROACH FOR MAIZE PROCESSING				Process stage: STORAGE AND LOADING			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Closed process, sieving, staff hygiene, glass procedure, good maintenance practices	Visual checks.
Lubricants from equipment	C	Low	High	3		PRP for maintenance Use of food grade lubricant Recording of the quantities used.	Purchasing specifications.
Pests	B	Medium	Medium	3		PRP for pest control, closed buildings	Regular checks on pest activity.
Pathogenic microbiological organisms, including Salmonella	B	Medium	High	4		PRP for pest control, PRP for personal hygiene, PRP for cleaning and PRP for maintenance, monitoring programme. Control of temperature and ventilation	Good storage practices for bulk storage
Mycotoxins formation	C	Low	High	3	Dir. 2002/32/EC Rec. 2006/576/EC	Appropriate storage control should be in place. The PRP programme should foresee closed storage areas. Humidity & T controls when necessary. The finished product should be monitored on mycotoxins.	Good storage practices. Monitoring program should be in place.
Cross contamination during transport	B	Medium	Medium	3		Cleaning of transport means + verification previous loads	Service provider specification.



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EXAMPLE 2.2: FOR A WHEAT PRODUCT, FOCUS ON RECEPTION, PROCESS, STORAGE AND LOADING STEPS

RISK BASED APPROACH FOR WHEAT PROCESSING				Process stage: RECEPTION (Cereal wheat)			
Hazard	Category	Chance	Severity	Risk Class	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Closed process, Sieving, dedicated lines, Cleaning steps, magnets, glass policy PRP for personal hygiene.	Visual checks.
Toxic plants / seeds Botanic impurities	C	Low	Medium	2	Dir. 2002/32/EC	PRP for incoming raw materials. Analysis. Product specification.	Visual checks.
Heavy metals above the specified limit	C	Low	High	3	Dir.2002/32/EC	PRP for incoming raw materials. Analysis via monitoring programme .	Purchasing specifications.
Pesticide residues (authorised) above the MRL, i.e. residues of herbicides, insecticides, fungicides or	C	Medium	Medium	3	Reg. 396/2005/EC	PRP for incoming raw materials. Analysis via monitoring programme.	Purchasing specifications.



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rodenticides above the MRL.							
Pesticides residues (unauthorised)	C	Very low	High	2	Directive 2002/32/EC	A monitoring program should be in place.	Directive 2002/32/EC sets limits for a number of pesticides residues in feeding stuff. Some of the banned pesticides may be present in the environment.
Mycotoxins above the specified limit	C	Medium	High	4	Dir.2002/32/EC Rec.2006/576/EC	PRP for incoming raw materials Analysis via monitoring programme Raw material specification contracts.	Purchasing specifications.
Lubricants from equipment	C	Low	High	3		PRP for maintenance. Use of food grade lubricant.	Purchasing specifications.
Pest	B	Medium	Medium	3		Closed buildings, PRP for pest control.	Regular checks on pest activity.



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RISK BASED APPROACH FOR WHEAT PROCESSING				Process stage: PROCESS (Dry Cleaning, Grinding, Sieving, Refining, Concentration, Mixing, Drying)			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Closed process, sieving, dedicated lines, cleaning steps, magnets, glass policy in place.	Visual inspection.
Lubricants from equipment	C	Low	High	3		PRP for maintenance. Use of Food grade lubricant.	Purchasing specifications.
Processing Aids	C	Low	High	3		On-line monitoring of usage (follow up excessive use of processing aids) Non toxic processing aids, pH control, ISO9001 plans, work instructions and training personnel.	
Cleaning and disinfection agents	C	Low	Medium	2		PRP for cleaning and sanitation Use of food contact authorized cleaning agents.	Purchasing specifications.
Neoformed compounds	C	Medium	Medium	3	Dir.2002/32/EC	Gas specifications. End-product analyses. (according to the dryer type).	
Water contamination	B/ C	Low	High	3	Reg. 183/2005/EC	PRP for layout of premises and workspace. Analysis via monitoring programme.	
Pest	B	Medium	Medium	3		PRP for pest control. Closed process and buildings.	Checks on pest activity.
Pathogenic microorganisms, including Salmonella	B	Low	High	3		Process control (Temperature, pH, Time and Moisture content). Process monitoring on hygiene indicator micro organisms. Final product monitoring on micro organisms. Drying/evaporating steps: control moisture content of product.	



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RISK BASED APPROACH FOR WHEAT PROCESSING	Process stage: STORAGE & LOAD OUT
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Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Protected storage, sieving, staff hygiene, glass procedure, good maintenance practices.	Visual checks.
Lubricants from equipment	C	Low	High	3		PRP for maintenance. Use of Food grade lubricant.	Purchasing specifications.
Pests	B	Medium	Medium	3		PRP for Pest control.	Checks on pest activity.
Pathogenic microbiological organisms, including Salmonella	B	Medium	High	4		PRP for Pest control, PRP for Personal hygiene, PRP for cleaning and PRP for maintenance. Control of temperature and ventilation. A monitoring programme shall be in place	Good storage practices for bulk storage
Mycotoxins formation	C	Low	High	3	Dir. 2002/32/EC Rec. 2006/576/EC	Appropriate storage control should be in place. The PRP programme should foresee closed storage areas. Humidity & T controls when necessary. Monitoring program should be in place.	Good storage practices for bulk storage
Cross contamination during transport	B	Medium	Medium	3		Cleaning of transport means + verification previous loads.	Service provider specification.



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EXAMPLE 2.3 : POTATO PROCESSING; STARCH AND CO-PRODUCT MANUFACTURING

GENERAL RISK BASED APPROACH FOR POTATO PROCESSING			Process stage: 1 RECEPTION (POTATOES)				
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Bad rotten potatoes	B	Medium	Low	2		Portal control, Inspection truck loads, removal of rotten potatoes.	Visual inspection. Product specifications.
Stones, glass, plastics, wood, metal, carton, sand, soil	P	Medium	Medium	3		Portal control. Inspection of the truck loads. Cleaning of the potatoes and removal of contaminants with sieving and magnets equipment	Visual inspection. Product specifications.
Pesticide residues (authorised) above the MRL, i.e. residues of herbicides, insecticides, fungicides or rodenticides above the MRL.	C	Medium	Medium	3	Dir. 91/414/EC Reg.396/2005/EC	Certified potato growers. PRP for incoming materials. Analysis via monitoring programme.	Product specifications. Regulatory compliance.
Pesticides residues (non authorised)	C	Very low	High	2	Directive 2002/32/EC	A monitoring program should be in place.	Directive 2002/32/EC sets limits for a number of pesticides residues in feeding stuff. Some of the banned pesticides



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							may be present in the environment.
Heavy metals above the specified limit	C	Medium	Medium	3	Dir. /2002/32/EC	PRP for incoming raw materials. Analysis via monitoring programme.	Product specifications. Regulatory compliance.
Natural contaminants (solanine)	C	Medium	Medium	3	Dir. 2002/53/EC	Certified potato growers. Allowed potato varieties listed in National Varieties List. Monitoring solanine content of the potato protein.	Product specifications. Regulatory compliance.
Pests	B	Medium	Medium	3		Closed buildings, PRP for Pest control. Covered storage and loading.	Checks on pest activity.



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GENERAL RISK BASED APPROACH FOR POTATO STARCH PROCESSING			Process stage: (Process (CLEANING/WASHING, GRINDING, SEPARATION/REFINING, DE-WATERING, DRYING, COAGULATION, SUSPENDING, REFINING, DE- WATERING, DRYING, EVAPORATION))				
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Cleaning and washing, dedicated transport lines. Glass procedure.	Visual checks.
Lubricants from equipment	C	Low	High	3		PRP for maintenance. Use of food grade lubricants. Good maintenance practices.	
Water contamination	C	Low	High	3	Reg. 183/2005/EC	Water monitoring. Dedicated water circuits. Chemicals used have to be authorised.	Apply water of suitable quality.
Water contamination	B	Medium	High	4	Reg. 183/2005/EC	Water monitoring, CIP. Dedicated water circuits. Monitoring programme should be in place.	Apply water of suitable quality.
Neoformed chemicals	C	Low	Medium	2		Burner control direct dryers. Gas specifications. End product analysis (according to the dryer type).	
Excessive use of processing aids	C	Low	Medium	2		Online monitoring of the use of processing aids. pH control, control ready product, food grade antifoam. Work instructions and training personnel.	Product specifications, food grade antifoam
Pathogenic microorganisms	B	Medium	High	4		Process control temperature and time. Drying/evaporating steps:	

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						Control moisture content of product. A monitoring programme should be in place.	
Cleaning agents	C	Low	Medium	2		PRP for cleaning and sanitation. Control of consumption rates. Use of Food contact authorized.	Purchasing specifications.
Pests	B	Medium	Medium	3		PRP for pest control.	Regular checks on pest activity.

RISK BASED APPROACH FOR POTATO STARCH PROCESSING				Process stage : STORAGE & LOAD OUT			
Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Protected storage, sieving.	Visual checks.
Lubricants from equipment	C	Low	High	3		PRP for maintenance. Use of food grade lubricant.	Purchasing specifications.
Pests	B	Medium	Medium	3		PRP for pest control. Covered storage and loading.	Regular checks on pest activity.
Pathogenic microbiological organisms, including Salmonella	B	Low	High	3		PRP for pest control, PRP for personal hygiene, PRP for cleaning and PRP for maintenance. Control of temperature and ventilation. A monitoring plan shall be in place	Good storage practices for bulk storage
Cross contamination during transport	B	Medium	Medium	3		Cleaning of transport means and the verification of previous loads.	Service provider specification.



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EXAMPLE 2.4: A PEA PRODUCT, FOCUS ON RECEPTION, PROCESS, STORAGE AND LOADING STEPS

RISK BASED APPROACH PEA PROCESSING				Process stage: RECEPTION (Pea)			
Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Closed process, sieving, magnets, cleaning steps.	Visual checks.
Toxic plants / seeds	C	Low	Medium	2	Dir. 2002/32/EC	PRP for incoming raw materials. Analysis via monitoring programme.	Visual checks.
Heavy Metals above the specified limit	C	Low	High	3	Dir.2002/32/EC	PRP for incoming raw materials. Analysis via monitoring programme.	Purchasing specifications. Regulatory compliance.
Pesticides residues (authorised) above MRL	C	Medium	Medium	3	Reg. 396/2005/EC	PRP for incoming raw materials. Analysis via monitoring programme.	Purchasing specifications. Regulatory compliance.
Pesticides residues (unauthorised)	C	Very low	High	2	Directive 2002/32/EC	A monitoring program should be in place.	Directive 2002/32/EC sets limits for a number of pesticides residues in feeding stuff. Some of the banned pesticides may be present in the environment.
Mycotoxins above the specified limit	C	Low	High	3	Dir. 2002/32/EC	PRP for incoming raw materials. Analysis via monitoring programme.	Purchasing specifications. Regulatory compliance.



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Lubricants from equipment	C	Low	High	3		PRP for maintenance. Use of food grade lubricant	Purchasing specifications. Prerequisite program.
Pests	B	Medium	Medium	3		Closed buildings, PRP for Pest control. Covered storage and loading	Checks on pest activity.

RISK BASED APPROACH FOR PEA PROCESSING	Process stage: PROCESS (Dry cleaning, Grinding, Sieving, Refining, Drying)
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Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Closed process, sieving, dedicated transport lines, dry cleaning of pea. Glass procedure. Good maintenance practices PRP for personal hygiene clothes).	Visual checks.
Lubricants	C	Low	High	3		PRP for maintenance. Use of food grade lubricant.	Purchasing specifications.
Processing aids	C	Low	Medium	2		On-line monitoring (follow up excessive use of processing aids) pH control, work instructions and training personnel.	Purchasing specifications.
Cleaning and disinfection agents	C	Low	Medium	2		PRP for cleaning and sanitation Consumption rates. Use of food contact authorized.	Purchasing specifications.
Neoformed Chemicals (direct drying)	C	Medium	Medium	3		Burner control. Gas specifications. End-product analyses. Indirect dryer.	
Contaminants in water	B/ C	Low	High	3	Reg. 183/2005/EC	Analysis via monitoring programme.	Apply water of suitable quality.



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Pests	B	Low	Medium	2		PRP for Pest control. Closed process / closed workshops.	Checks on pest activity.
Pathogenic microbiological organisms, including Salmonella	B	Low	High	3		Process control (Temperature, pH. Time and Moisture content). PRP for cleaning and sanitation. Drying/evaporating steps: control moisture content of product. Process monitoring on micro organisms. Final product monitoring on micro organisms.	

RISK BASED APPROACH FOR PEA PROCESSING				Process stage: STORAGE AND LOADING			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	P	Low	High	3		Closed process, sieving.	Visual checks.
Lubricants	C	Low	High	3		PRP for maintenance. Use of food grade lubricant.	Purchasing specifications.
Pests	B	Moderate	Moderate	3		PRP for Pest control.	Checks on pest activity.
Pathogenic microbiological organisms, including Salmonella	B	Low	High	3		PRP for personnel hygiene, PRP for cleaning and PRP for maintenance. Control of temperature and ventilation. A monitoring programme	Good storage practices for bulk storage



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					shall be in place.	
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g) Annex Minimum monitoring requirements- Sector Starch

EFISC system participants shall implement a monitoring plan as described in the EFISC Code §4.4.3.

In case insufficient data is available for a risk assessment the following minimum monitoring requirements shall apply. The total minimum number of analysis will depend on the volume of feed materials in tons manufactured in one location as shown in the tables below.

1. Control plan for starch production, their products and co products.

Table A. Corn

Annual production in tons/ Parameter	<200.000	≥200.000
Aflatoxine B1	4-8	6-12
DON	4	6
ZEA	4	6
Dioxin	2	2
Dioxin like PCB	2	2
PCB	2	2
Salmonella	3-6	4-8
Heavy metals (Pb, As, Hg, CD)	4	6
Pesticides*	4	6

*Analysis within inspection of incoming raw materials in unprocessed primary products



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Table B. Wheat

Annual production in tons/ Parameter	<200.000	≥200.000
DON	4-8	6-12
ZEA	4	6
Dioxin	2	2
Dioxin like PCB	2	2
PCB	2	2
Salmonella	3-6	4-8
Heavy metals (Pb, As, Hg, CD)	4	6
Pesticides*	4	6

*Analysis within inspection of incoming raw materials in unprocessed primary products

Table C. Potatoes

Annual production in tons/ Parameter	<200.000	≥200.000
Dioxin	2	2
Dioxin like PCB	2	2
PCB	2	2
Salmonella	3-6	4-8
Heavy metals (Pb, As, Hg, CD)	4	6
Pesticides*	4	6

*Analysis within inspection of incoming raw materials in unprocessed primary products



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Table D. Peas

Annual production in tons/ Parameter	<200.000	≥200.000
DON	4-8	6-12
ZEA	4	6
Dioxin	2	2
Dioxin like PCB	2	2
PCB	2	2
Salmonella	3-6	4-8
Heavy metals (Pb, As, Hg, CD)	4	6
Pesticides*	4	6

* Analysis within inspection of incoming raw materials in unprocessed primary products

