

APPENDIX 3 - Sector reference document on starch processing

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. As these feed materials already meet relevant food safety requirements, they are not part of this sector note.

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:
 - o ISO 9001:2008 (including the guidelines for the application of HACCP program) registration processes initiated since the beginning of the 1990s for most activities of our businesses;
 - o Quality improvement programs integrating the principles of the HACCP method for all products;
 - o 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.

TABLE OF CONTENTS

a) Introduction	1
List of abbreviations used	4
b) Listing of Feed Materials	5
◦ Maize gluten feed or maize feed	5
◦ Maize gluten	5
◦ Maize germ meal	5
◦ Wheat gluten	5
◦ Wheat gluten feed	5
◦ Wheat feed	5
◦ Native starch	6
◦ Potato protein	6
◦ Condensed deproteinized potato fruit juice	6
◦ Pea protein	6
◦ Pea fiber	6
◦ Pea soluble	6
c) Flow charts	7
1. Manufacture of Maize Starch	8
2. Manufacture of Wheat Starch	10
3. Manufacture of Potato Starch	12
4. Manufacture of Pea starch	15
d) Summary of the risk-based approach for the starch sector	17
◦ Biological hazards	17
◦ Potential chemical hazards	17
◦ Physical contamination hazards	18
◦ Radioactivity hazard	18
e) Risk-based approach for the characterisation of hazards applicable to starch products sold as feed	19
◦ Table 1- a general risk assessment applicable for any of the starch industry raw material (wheat, maize, potato, pea)	19
1.1 Raw materials	20
1.2 Water	21
1.3 Processing agents- chemical agents	22
1.4 Processing agents- enzymes	23
1.5 Processing agents- filter aids	24
1.6 Contact materials	24
1.7 Manufacturing process control	25
1.8 Storage and transport control	26

○ Table 2- Focus on the main steps risks (reception, process, storage & loading steps)	
2.1 Maize product	27
2.2 Wheat product	33
2.3 Potato product	37
2.4 Pea product	45

f) Annex 1 Minimum monitoring requirements for starch manufacturing in case no risk assessment and related data is available

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:** Hexachlorocyclohexane
- HCN:** Hydrogen cyanide
- Hg:** Mercury
- ISO:** International Organisation for Standardisation
- MRL:** Maximum Residue Limits
- PAH:** Polycyclic aromatic hydrocarbons
- Pb:** Lead
- PCB:** Polychlorinated biphenyls
- SFM:** Safe, Fair and Merchantable
- SO₂:** Sulphur Dioxide
- T°C:** temperature degree Celsius

b) Listing of Feed Materials

Feed materials from the starch industry meet the statutory definitions of raw materials (Regulation 2009/767 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 or are adapted from Regulation 2009/767 (taking into account industrial language).

- Maize gluten feed or maize feed By-product of the wet manufacture of maize starch. It is composed of bran and gluten, to which the broken maize obtained from screening at an amount no greater than 15 % of the product and/or the residues of the steeping liquor used for the production of alcohol or other starch-derived products, may be added. The product may also include residues from the oil extraction of maize germs obtained also by a wet process.
- Maize gluten Dried by-product of the manufacture of maize starch. It consists principally of gluten obtained during the separation of the starch.
- Maize germ meal Product of oil manufacture, obtained by extraction of dry or wet processed maize germ to which parts of the endosperm and testa may still adhere.
- Wheat gluten Dried by-product of the manufacture of wheat starch. It consists principally of gluten obtained during the separation of starch.
- Wheat gluten feed By-product of the manufacture of wheat starch and gluten. It is composed of bran, from which the germ has been partially removed or not, and gluten, to which very small amounts of the components of the screening of the grain as well as very small amounts of residues of the starch hydrolysis process may be added.
- Wheat Feed By-product of flour 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.

- Native starch Technically pure starch obtained from potatoes, wheat, maize or other cereals.

- Potato protein Dried by-product of starch manufacture composed mainly of protein substances obtained after the production of starch obtained after the separation of starch.

- Potato fibres Dried product of the manufacture of potato starch.
 (= dried potato pulp)

- Condensed deproteinized potato fruit juice By-product of the manufacture of potato starch from which proteins and water have been partly removed.
- Pea protein Product obtained from the separated pea fruit water when producing starch, or after grinding and air fractionation.

- Pea fiber Product obtained from starch and protein wet extraction from peas. It is mainly composed of internal fiber and starch.

- Pea solubles Product obtained from starch and protein wet extraction from peas. It is mainly composed of soluble proteins and oligosaccharides.

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 'Community Guide to good practice for the industrial manufacture of safe feed materials'. 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.

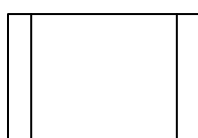
c) Flow charts

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.

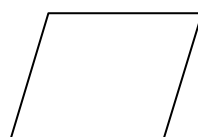
Symbols



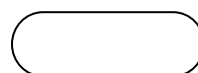
Main Process



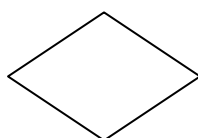
Process step



Material



Process start or terminator

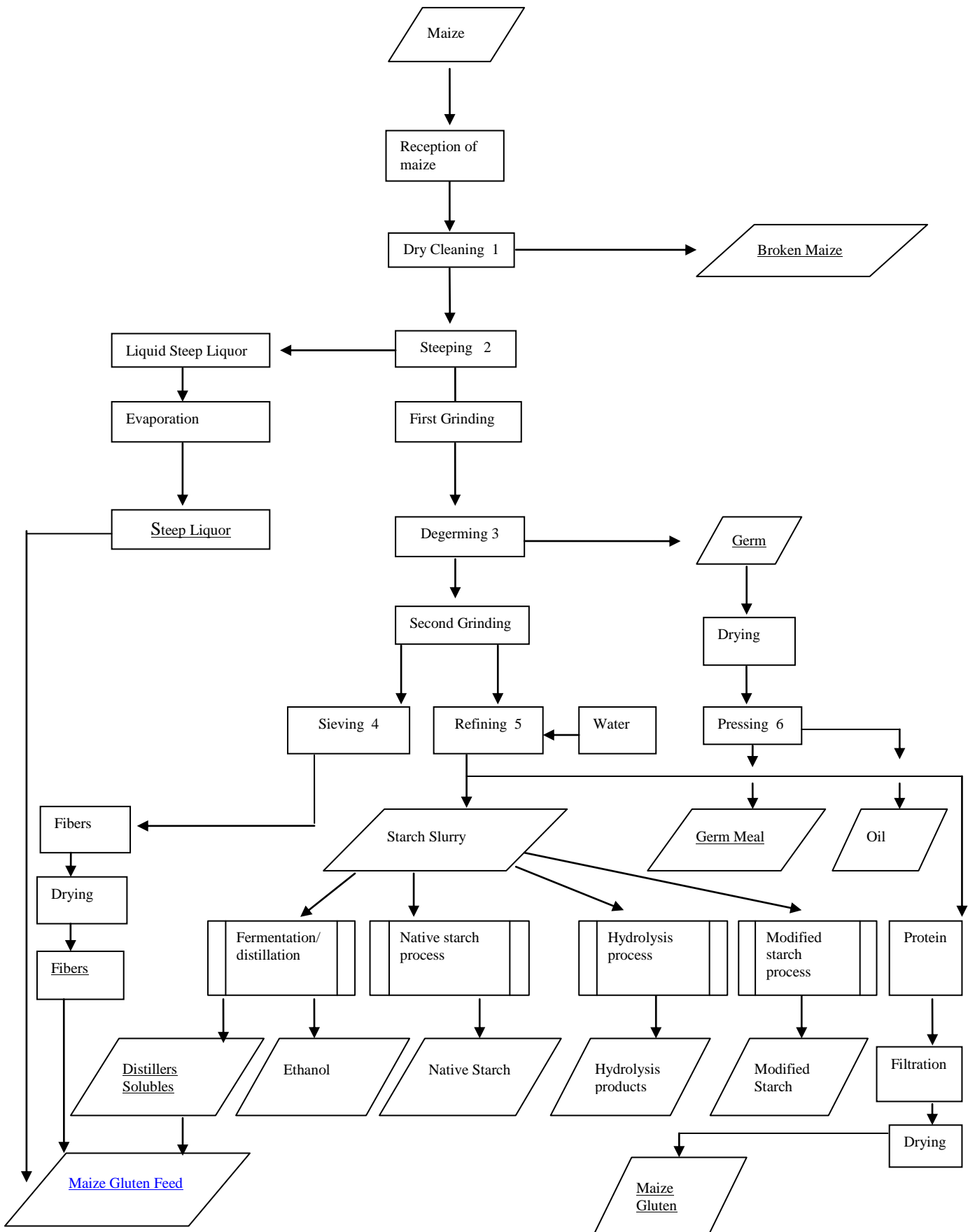


Decision

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.

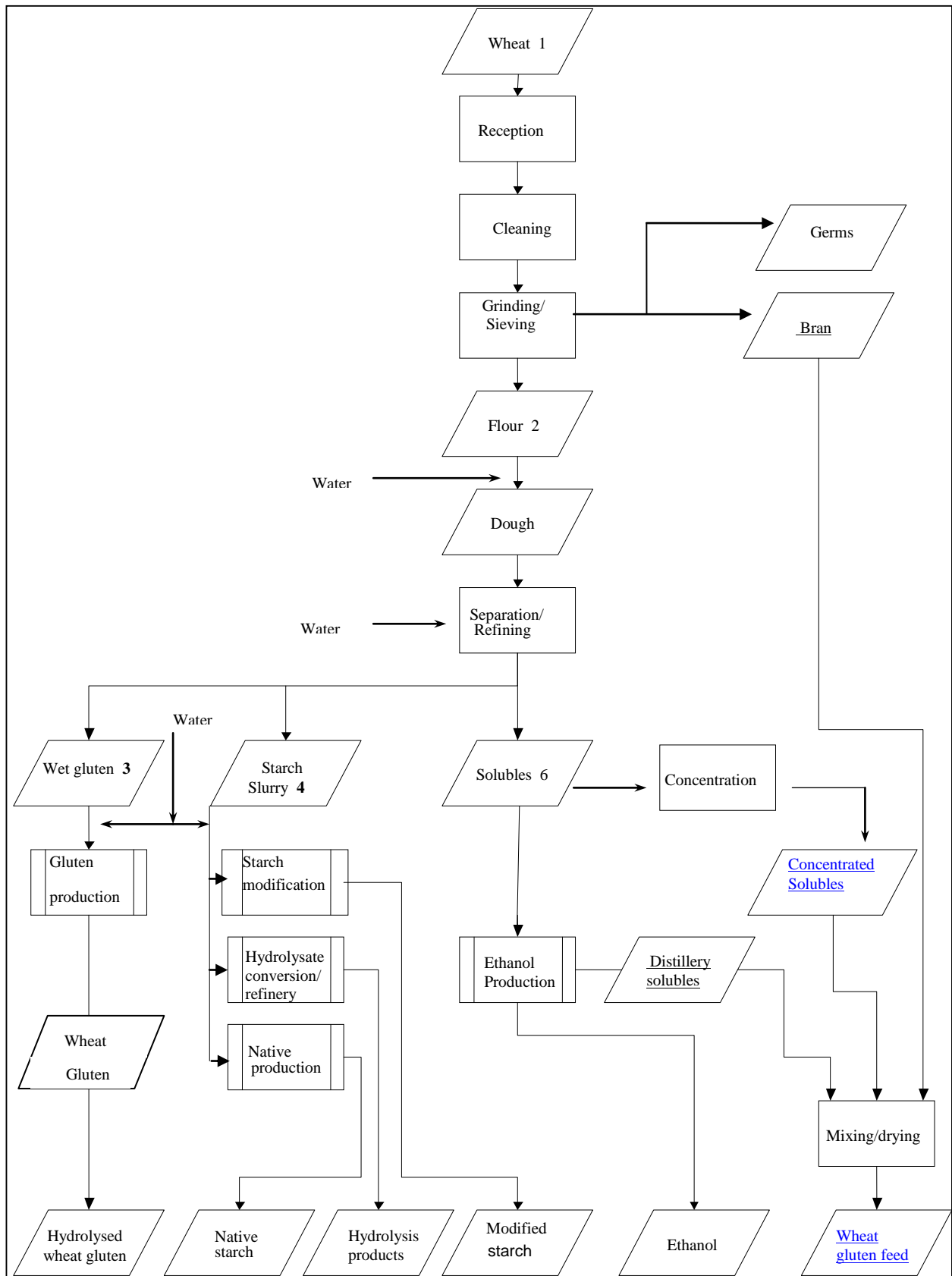
1. MANUFACTURE OF MAIZE STARCH - BASIC SCHEME



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

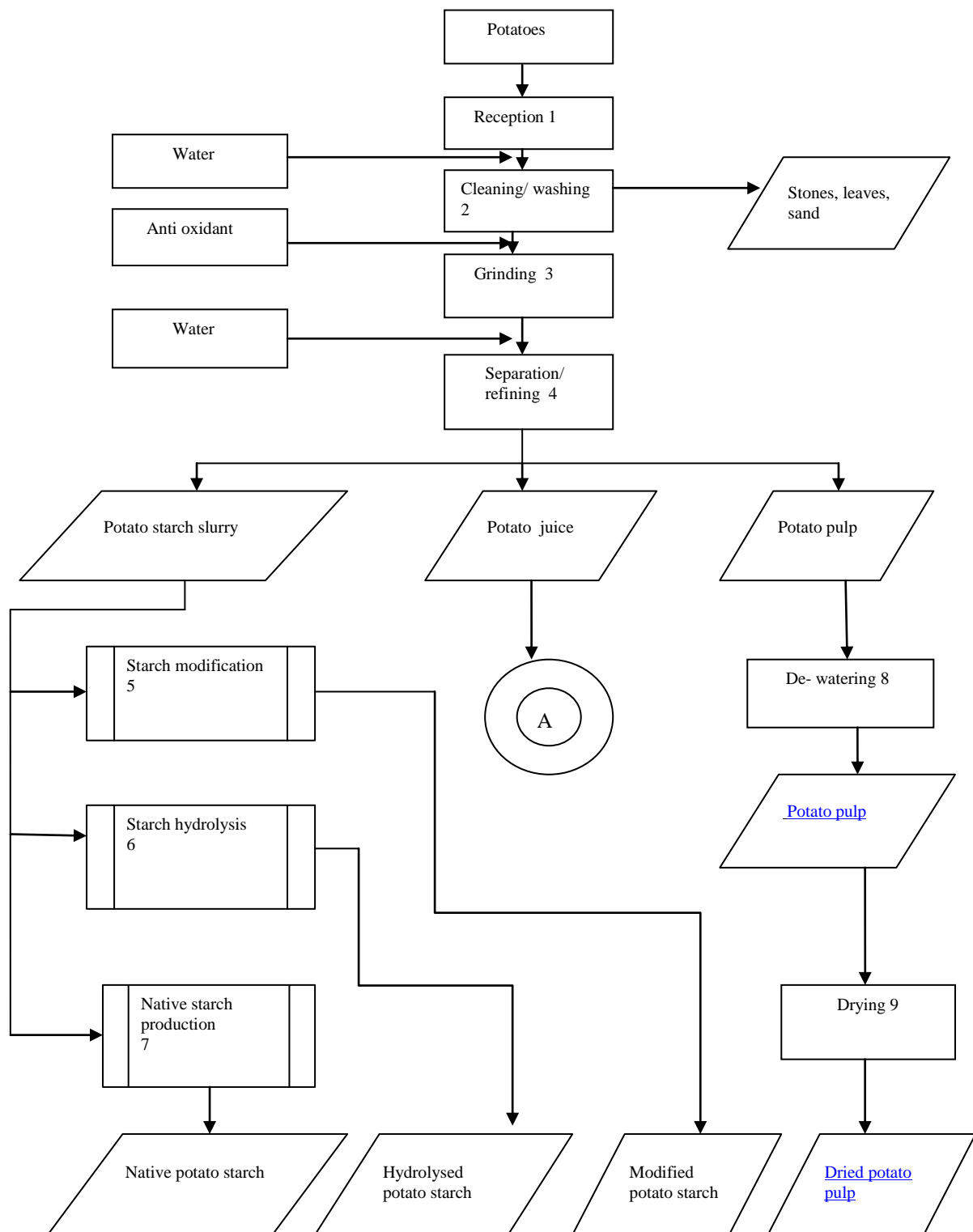


3. MANUFACTURING OF POTATO STARCH

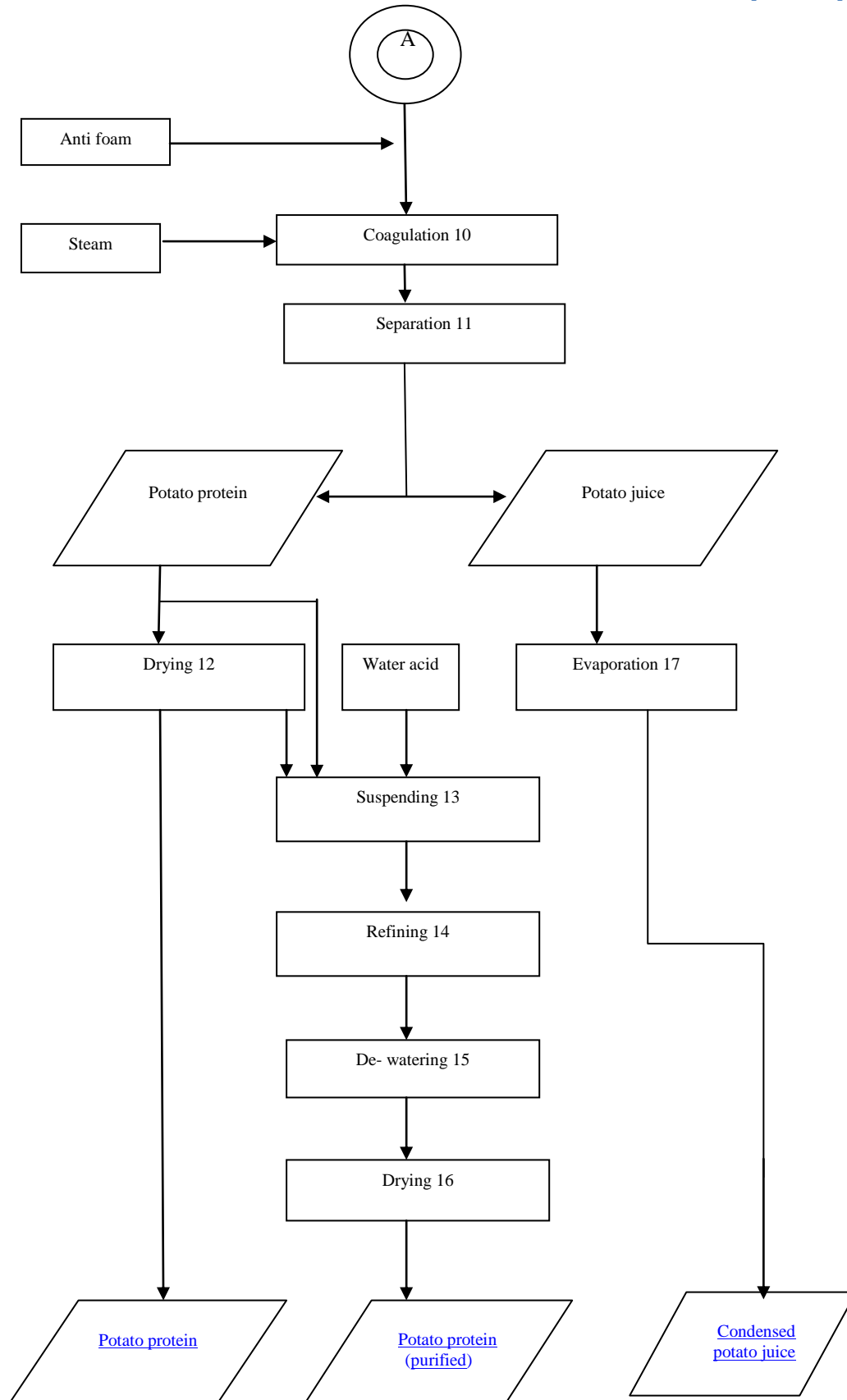
1. At the reception of the potatoes a sample is taken to check on quality.
2. The potatoes are washed and unwanted components like sand, leaves and stones are removed. To prevent excessive foaming some food grade anti foam is added.
3. The cleaned potatoes are grinded and anti oxidant is added.
4. The 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 glycoalkaloids 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)



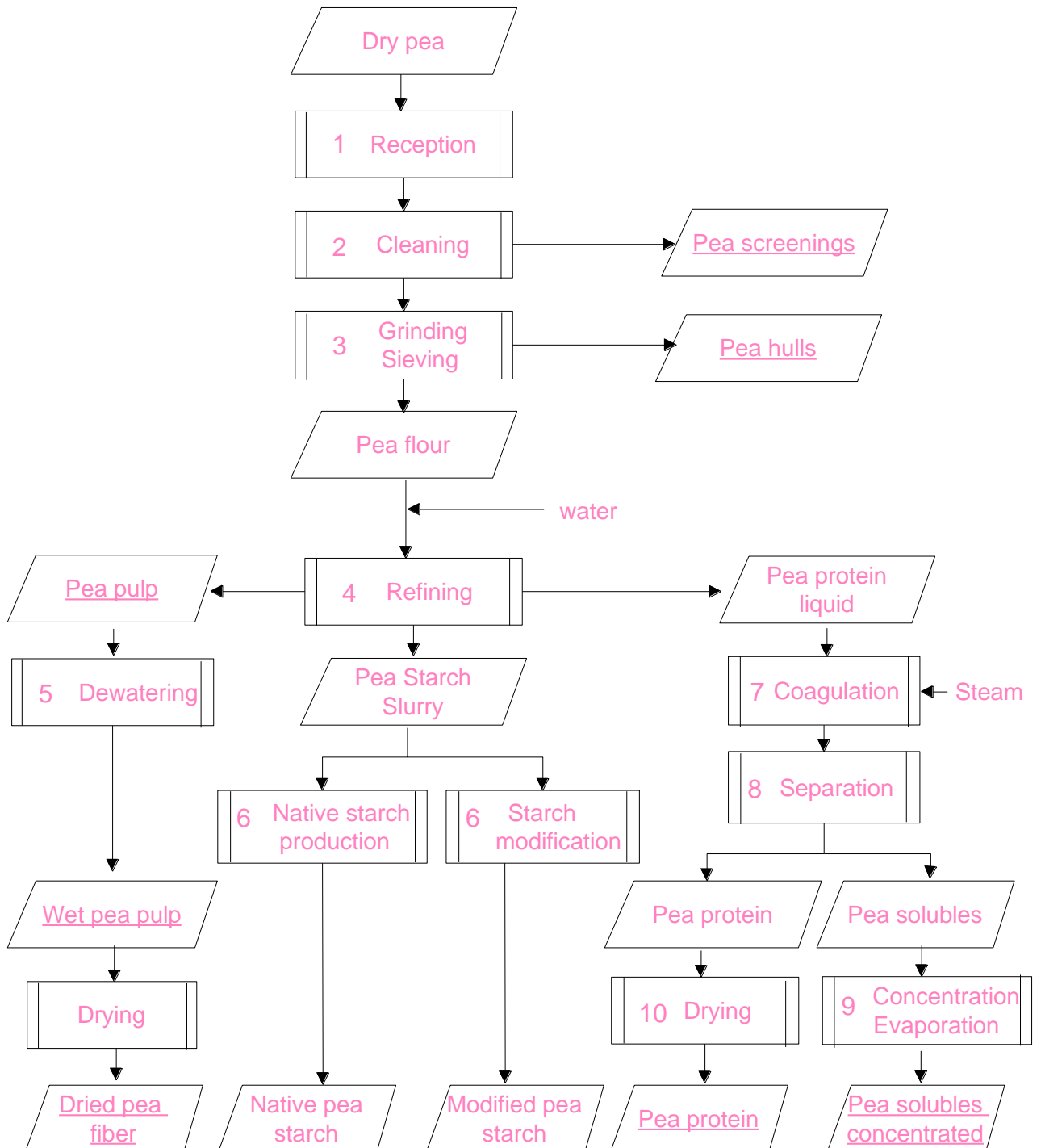
3. MANUFACTURING OF POTATO STARCH - BASIC SCHEME (2 OF 2)



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



d) 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).

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
- 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 guide.

Physical contamination hazards

- Metal
- Glass
- Any other relevant physical contamination.

Radioactivity hazard

- Radionuclides (after a nuclear accident)

e) 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. For more understanding of the following risk assessment tables please see EFISC main text, paragraph 6.

Those risks cannot be considered as complete and may differ amongst starch producers based on individual and specific starch manufacturer's processing conditions.

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

Moreover, in these tables, no CCP is listed due to the fact that the decision leading to the establishment of such CCP should be consistent with the reality of each plant or processing line.

Three categories of hazards were considered:

- Biological hazards;
- Chemical hazards; and,
- Physical hazards.

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: RAW MATERIALS (MAIZE, WHEAT, POTATO, PEA)			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Large	Small	3		In latter stages; general processing steps must be purifying (magnets, screens)	SFM quality + ISO9001 plans
Pesticides, mycotoxins, heavy metals	Chemical	Moderate	Moderate	3	Reg. 396/2005/EC Dir. 2002/32/EC Rec. 2006/576/EC	Active participation in surveillance schemes for contaminant monitoring	SFM quality and/or suppliers specification + ISO9001 plans + traceability from supplier's silo's
Flying-in birds	Biological	Moderate	Moderate	3		Closed buildings	ISO9001 plans
Insects & rodents	Biological	Moderate	Moderate	3			SFM quality and/or suppliers specification + ISO9001 plans + traceability from suppliers' silos
Cross contamination during transport	Biological	Moderate	Large	4		Cleaning of transport means + controlled backhaul	ISO9001 plans and/or suppliers' specification

FEED. Risk assessment of the chain of starch manufacturing

1.2 General risk based approach				Ingredient: WATER			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
General	Physical	Small	Moderate	2		Filtration + compliance with potability standards	In latter stages ; general processing steps are purifying
Cross contamination	Chemical	Small	Moderate	2		Dedicated water circuits	
Pesticides, heavy metals, hydro carbons	Chemical	Small	Moderate	2	Reg. 396/2005/EC Dir. 2002/32/EC	Dedicated water circuits	
Metal leaching	Chemical	Small	Moderate	2		Inert contact materials; construction standards	
Pathogenic micro - organisms	Biological	Small	Large	3		Dedicated water circuits	

FEED. Risk assessment of the chain of starch manufacturing

1.3 General risk based approach				Processing agent: CHEMICAL AGENTS (antifoams, acidification or alkalising agents, SO ₂ and derivatives, enzyme catalysing salts...)			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Heavy metals	Chemical	Small	Moderate	2	Dir. 2002/32/EC	Ingredient specification contracts containing food adequate requirements	ISO9001 plans
Cross contamination	Chemical	Small	Moderate	2		On-line process monitoring (pH, sensorial, consumption rates), correct labelling of chemical containers	ISO9001 plans

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	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Cross contamination	Biological	Small	Small	1		On-line process monitoring (consumption rates), correct labelling of enzyme containers	ISO9001 plans
Toxicity	Biological	Small	Large	3		Ingredient specification contracts containing food adequate requirements	ISO9001 plans
Pathogenic micro-organisms	Biological	Small	Large	3		Ingredient specification contracts containing food adequate requirements	ISO9001 plans

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...)			
Metal leaching	Chemical	Small	Moderate	2		Ingredient specification contracts containing food adequate requirements	ISO9001 plans
Cross contamination	Physical	Small	Moderate	2		Filtration in latter process stages	ISO9001 plans

1.6 General risk based approach				Materials: MATERIALS IN CONTACT (equipment, packaging...)			
Metal leaching	Chemical	Small	Moderate	2		Ingredient specification contracts containing food adequate requirements	ISO9001 plans
Pathogenic micro - organisms	Biological	Small	Large	3		Ingredient specification contracts containing food adequate requirements	ISO9001 plans

FEED. Risk assessment of the chain of starch manufacturing

1.7 General risk based approach				Process stage: MANUFACTURING PROCESS CONTROL			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Moderate	Small	2		Dedicated buildings and circuits. Filters, screens , staff hygiene (clothes), glass procedure, good maintenance practices	ISO9001 plans
Insects and rodents	Biological	Moderate	Small	2		Building proofing, cleaning programs + pest control system as part of the prerequisite programme	Sanitation + ISO9001 plans
Pathogenic micro - organisms	Biological	Moderate	Large	4		Closed lines, low probability of growth via raw material, stages with higher temp routes and lower pH ranges, usage of SO2 + regular monitoring of finished products	Detailed HACCP study + ISO9001 plans+ analyses
Lack of Hygiene	Biological	Moderate	Large	4		Staff hygiene training, appropriate clothing, work instructions regarding cleaning	ISO9001 plans
Heavy metals, mycotoxins, pesticides	Chemical	Moderate	Large	4	Reg. 396/2005/EC Dir. 2002/32/EC Rec. 2006/576/EC	Knowledge regarding distribution of chemical contaminants from raw material into end product. Anticipate harvest events + regular monitoring of finished products	ISO9001 plans+ in depth HACCP + Analyses

FEED. Risk assessment of the chain of starch manufacturing

Direct drying (PAH , nitrous oxides), dioxins	Chemical	Moderate	Moderate	3	Dir. 2002/32/EC Reg. 183/2005/EC	Good burner maintenance practices	Avoid formation of soot + in depth HACCP study + good maintenance practices
Cross contamination	Chemical	Small	Moderate	2		Dedicated circuits, dedicated storage of chemicals	ISO9001 plans

1.8 General risk based approach				Process stage: STORAGE and TRANSPORT CONTROL			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Cross contamination with backhaul products	Chemical	Moderate	Moderate	3		Haulier contractor specification	ISO9001 plans
Mycotoxin formation	Chemical	Small	Large	3	Dir. 2002/32/EC Rec. 2006/576/EC	Good storage control ;closed storage area , Humidity & T controls + regular finished products monitoring	ISO9001 plans
Pesticides	Chemical	Small	Moderate	2	Reg. 396/2005/EC Dir. 2002/32/EC	Disinfection of silo's to be done by qualified persons	ISO9001 plans
Pathogenic micro - organisms	Biological	Small	Large	3		Humidity and temp controls + regular finished products monitoring	ISO9001 plans
Insects and rodents	Biological	Moderate	Small	2		Covered storage and loading + pest control system	Sanitation + ISO9001 plans

FEED. Risk assessment of the chain of starch manufacturing

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

RISK BASED APPROACH FOR MAIZE GLUTEN FEED	Process stage: RECEPTION (Cereal Maize)
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Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Moderate	Moderate	3		Closed process, sieving, magnets	Visual checks
Toxic/Allergenic seeds	Chemical	Small	Moderate	2	Dir. 2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis	Visual checks Aggregate sampling
Heavy Metals	Chemical	Small	Moderate	2	Dir.2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme	Purchasing specifications
Pesticide residues	Chemical	Small	Moderate	2	Reg. 396/2005/EC Dir. 2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme	Purchasing specifications
Mycotoxins	Chemical	Moderate	Moderate	3	Dir. 2002/32/EC Rec. 2006/576/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme	Purchasing specifications
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications
Pests	Biological	Moderate	Moderate	3		Closed buildings, PREREQUISITE PROGRAM for Pest control	Checks on pest activity

FEED. Risk assessment of the chain of starch manufacturing

RISK BASED APPROACH FOR MAIZE GLUTEN FEED	Process stage: PROCESS (Dry cleaning, Steeping, First and Second grinding, Degerming, Sieving, Drying, Mixing, Drying)
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Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Small	Moderate	2		Closed process, sieving, dedicated transport lines, dry cleaning of maize PREREQUISITE PROGRAM for personal hygiene	Visual checks
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications
Processing aids	Chemical	Small	Small	1		On-line monitoring (follow up excessive use of processing aids) pH control, SO ₂ content control, ISO9001 plans, work instructions and training personnel	
Cleaning agents	Chemical	Small	Small	1		PREREQUISITE PROGRAM for cleaning and sanitation Use of Food contact authorized	Purchasing specifications
Neoformed compounds	Chemical	Moderate	Moderate	3	Dir. 2002/32/EC	Gas specifications End-product analyses (according to the dryer type)	
Water contamination	Chemical / Biological	Small	Large	3	Reg. 183/2005/EC	PREREQUISITE PROGRAM for layout of premises and workspace Analysis via monitoring programme	
Pests	Biological	Small	Moderate	2		PREREQUISITE PROGRAM for Pest control Closed process	Checks on pest activity
Pathogenic Microbiological organisms	Biological	Small	Large	3		Process control (Temperature, pH, Time and Moisture content) SO ₂ control Process monitoring on micro organisms	

FEED. Risk assessment of the chain of starch manufacturing

						Final product monitoring on micro organisms Drying/evaporating steps: Control moisture content of product	
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RISK BASED APPROACH FOR MAIZE GLUTEN FEED	Process stage: STORAGE AND LOADING
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Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Small	Moderate	2		Closed process, sieving	Visual checks
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications
Pests	Biological	Moderate	Moderate	3		PREREQUISITE PROGRAM for Pest control	Checks on pest activity
Pathogenic microbiological organisms	Biological	Small	Large	3		PREREQUISITE PROGRAM for Pest control, PREREQUISITE PROGRAM for Personal hygiene, PREREQUISITE PROGRAM for cleaning and PREREQUISITE PROGRAM for maintenance	

FEED. Risk assessment of the chain of starch manufacturing

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

RISK BASED APPROACH FOR MAIZE GLUTEN MEAL				Process stage: RECEPTION (Cereal Maize)			
Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Moderate	Moderate	3		Closed process, sieving, magnets	Visual checks
Toxic/Allergenic seeds	Chemical	Small	Moderate	2	Dir. 2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis	Visual checks Aggregate sampling
Heavy Metals	Chemical	Small	Moderate	2	Dir. 2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme	Purchasing specifications
Pesticide residues	Chemical	Small	Moderate	2	Reg. 396/2005/EC Dir. 2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme	Purchasing specifications
Mycotoxins	Chemical	Moderate	Moderate	3	Dir. 2002/32/EC Rec. 2006/576/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme	Purchasing specifications
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications
Pests	Biological	Moderate	Moderate	3		Closed buildings, PREREQUISITE PROGRAM for Pest control	Checks on pest activity

FEED. Risk assessment of the chain of starch manufacturing

RISK BASED APPROACH FOR MAIZE GLUTEN MEAL	Process stage: PROCESSING (Dry cleaning, Steeping, First and Second grinding, Degerming, Refining, Filtration, Drying)
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Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Small	Moderate	2		Closed process, sieving, dedicated transport lines, dry cleaning of maize PREREQUISITE PROGRAM for personal hygiene	Visual checks
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications
Processing aids	Chemical	Small	Small	1		On-line monitoring (follow up excessive use of processing aids) pH control, SO ₂ content control, ISO9001 plans, work instructions and training personnel	
Cleaning agents	Chemical	Small	Small	1		PREREQUISITE PROGRAM for cleaning and sanitation Use of Food contact authorized	Purchasing specifications
Neoformed compounds	Chemical	Moderate	Moderate	3	Dir. 2002/32/EC	Gas specifications End-product analyses (according to the dryer type)	
Water contamination	Chemical / Biological	Small	Large	3	Reg. 183/2005/EC	PREREQUISITE PROGRAM for layout of premises and workspace Analysis via monitoring programme	
Pests	Biological	Small	Moderate	2		PREREQUISITE PROGRAM for Pest control Closed process	Checks on pest activity
Pathogenic Microbiological organisms	Biological	Small	Large	3		Process control (Temperature, pH, Time and Moisture content) SO ₂ control Process monitoring on micro organisms	

FEED. Risk assessment of the chain of starch manufacturing

						Final product monitoring on micro organisms Drying/evaporating steps: Control moisture content of product	
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RISK BASED APPROACH FOR MAIZE GLUTEN MEAL	Process stage: Storage and loading
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Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Small	Moderate	2		Closed process, sieving	Visual checks
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications
Pests	Biological	Moderate	Moderate	3		PREREQUISITE PROGRAM for Pest control	Checks on pest activity
Pathogenic microbiological organisms	Biological	Small	Large	3		PREREQUISITE PROGRAM for Pest control, PREREQUISITE PROGRAM for Personal hygiene, PREREQUISITE PROGRAM for cleaning and PREREQUISITE PROGRAM for maintenance	

FEED. Risk assessment of the chain of starch manufacturing

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

RISK BASED APPROACH FOR WHEAT GLUTEN FEED				Process stage: RECEPTION, FIBRE EXTRACTION, (CONCENTRATED) SOLUBLES FROM STARCH EXTRACTION OR ETHANOL DISTILLERY			
Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Small	Moderate	2		Closed process, Sieving, dedicated lines, wheat cleaning, magnets, glass policy PREREQUISITE PROGRAM for personal hygiene	
Toxic/Allergenic seeds Botanic impurities	Chemical	Small	Moderate	2	Dir. 2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis	Visual checks Aggregate sampling
Heavy metals	Chemical	Small	Moderate	2	Dir.2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme on raw material and final product (recommendation min 1 x per year) Raw material specification contracts	These can be carried over from wheat and inadequate wheat cleaning steps
Pesticide residues	Chemical	Small	Moderate	2	Reg. 396/2005/EC Dir. 2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme Information about treatments done by the supplier during storage	These can be carried over from wheat

FEED. Risk assessment of the chain of starch manufacturing

Mycotoxins	Chemical	Moderate	Moderate	3	Dir.2002/32/EC Rec.2006/576/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme on raw material and final product (recommendation min 1 x per year) Raw material specification contracts	These can be carried over from wheat and inadequate wheat cleaning steps and have tendency to enrich in wheat gluten feed
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications
Processing Aids	Chemical	Small	Small	1		On-line monitoring (follow up excessive use of processing aids) Processing aids used shall not be toxic pH control, ISO9001 plans, work instructions and training personnel	
Cleaning agents	Chemical	Small	Small	1		PREREQUISITE PROGRAM for cleaning and sanitation Use of Food contact authorized	Purchasing specifications
Neoformed compounds	Chemical	Moderate	Moderate	3	Dir.2002/32/EC	Gas specifications General absence of Chlorine components End-product analyses (according to the dryer type and drying circumstances) (recommendation to check min 1 x per year)	
HCN	Chemical	Small	Moderate	2	Dir.2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme on raw material and final product (recommendation min 1 x per year) Raw material specification contracts	

FEED. Risk assessment of the chain of starch manufacturing

Fluorine	Chemical	Small	Moderate	2	Dir.2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme on raw material and final product (recommendation min 1 x per year) Raw material specification contracts	This can be carried over via wheat raw material
Pests	Biological	Small	Moderate	2		PREREQUISITE PROGRAM for Pest control Closed process	Checks on pest activity
Pathogenic Microbiological organisms	Biological	Small	Large	3		Process control (Temperature, pH, Time and Moisture content) Process monitoring on hygiene indicator micro organisms Final product monitoring on micro organisms (recommendation to check min 1 x per year for pathogens) Drying/evaporating steps: Control moisture content of product	

FEED. Risk assessment of the chain of starch manufacturing

RISK BASED APPROACH FOR WHEAT GLUTEN FEED	Process stage: STORAGE & LOAD OUT
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Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Small	Moderate	2		Protected storage, sieving	Visual checks
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications
Pests	Biological	Moderate	Moderate	3		PREREQUISITE PROGRAM for Pest control	Checks on pest activity
Pathogenic microbiological organisms	Biological	Small	Large	3		PREREQUISITE PROGRAM for Pest control, PREREQUISITE PROGRAM for Personal hygiene, PREREQUISITE PROGRAM for cleaning and PREREQUISITE PROGRAM for maintenance	

FEED. Risk assessment of the chain of starch manufacturing

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

GENERAL RISK BASED APPROACH FOR POTATO STARCH				Process stage: 1 RECEPTION (POTATOES)			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Bad rotten potatoes	Biological	Moderate	Small	2		Portal control, Inspection truck loads, removal	HACCP or ISO 9001 plans
Stones, glass, plastics, wood, metal, carton, sand, soil	Physical	Moderate	Small	2		Portal control, Inspection truck loads. Cleaning potatoes, removal	HACCP or ISO 9001 plans
Pesticide residues, heavy metals	Chemical	Moderate	Moderate	3	Dir. 91/414/EC Reg.396/2005/EC Dir. /2002/32/EC	Certified potato growers Contaminant monitoring	HACCP or ISO 9001 plans
Natural contaminants (solanine)	Chemical	Moderate	Moderate	3	Dir. 2002/53/EC	Certified potato growers, Allowed potato varieties listed in National Varieties List, Monitoring solanine content potato protein	HACCP or ISO 9001 plans
GENERAL RISK BASED APPROACH FOR POTATO STARCH				Process stage: (Process (CLEANING/WASHING, GRINDING, SEPARATION/REFINING, DE-WATERING, DRYING, COAGULATION, SUSPENDING, REFINING, DE- WATERING, DRYING, EVAPORATION))			

FEED. Risk assessment of the chain of starch manufacturing

Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Water contamination	Chemical	Small	Moderate	2	Reg. 183/2005/EC	Water monitoring	HACCP or ISO 9001 plans
Water contamination	Biological	Small	Moderate	2	Reg. 183/2005/EC	Water monitoring	HACCP or ISO 9001 plans
GENERAL RISK BASED APPROACH FOR POTATO STARCH				Process stage: 3 GRINDING			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Excessive use of processing aid	Chemical	Small	Moderate	1		Control process and ready product	HACCP or ISO 9001 plans
GENERAL RISK BASED APPROACH FOR POTATO STARCH				Process stage: 4 SEPARATION/REFINING			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Water contamination	Chemical	Small	Large	3	Reg. 183/2005/EC	Water monitoring	HACCP or ISO 9001 plans
Water contamination	Biological	Small	Large	3	Reg. 183/2005/EC	Water monitoring	HACCP or ISO 9001 plans
Microbial growth	Biological	Small	Large	3		Washing water, CIP	HACCP or ISO 9001 plans

FEED. Risk assessment of the chain of starch manufacturing

GENERAL RISK BASED APPROACH FOR POTATO STARCH				Process stage: 5 DE-WATERING/DRYING Native potato starch			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Neoformed chemicals	Chemical	Small	Moderate	2		Burner control direct dryers	HACCP or ISO 9001 plans

GENERAL RISK BASED APPROACH FOR POTATO STARCH				Process stage: 6 DE-WATERING/DRYING Hydrolysed potato starch			
Hazard	Category	Chance	Severity	Risk	Legislation	Control Measure	Remarks
Neoformed chemicals	Chemical	Small	Moderate	2		Burner control direct dryers	HACCP or ISO 9001 plans
Excessive use of processing aid	Chemical	Small	Moderate	2		Control process and ready product	HACCP or ISO 9001 plans

FEED. Risk assessment of the chain of starch manufacturing

GENERAL RISK BASED APPROACH FOR POTATO STARCH				Process stage: 7 DE-WATERING/DRYING Modified potato starch			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Neoformed chemicals	Chemical	Small	Moderate	2		Burner control direct dryers	HACCP or ISO 9001 plans
Excessive use of processing aid	Chemical	Small	Moderate	2		Control process and ready product	HACCP or ISO 9001 plans

GENERAL RISK BASED APPROACH FOR POTATO PULP				Process stage: 8 DEWATERING POTATO PULP			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Microbiol growth	Biological	Small	Moderate	2		CIP	HACCP or ISO 9001 plans

FEED. Risk assessment of the chain of starch manufacturing

GENERAL RISK BASED APPROACH FOR POTATO PULP DRIED				Process stage: 9 DRYING			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Neoformed chemicals	Chemical	Small	Moderate	2		Burner control direct dryers	HACCP plan

GENERAL RISK BASED APPROACH FOR POTATO PROTEIN				Process stage: 10 COAGULATION			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Microorganisms	Biological	Moderate	Small	2		Steam injection	HACCP or ISO 9001 plans
Excess use of processing aid	Chemical	Small	Moderate	2		pH control, control ready product, food grade antifoam	HACCP or ISO 9001

FEED. Risk assessment of the chain of starch manufacturing

GENERAL RISK BASED APPROACH FOR POTATO PROTEIN				Process stage: 11 DEWATERING			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Microorganisms	Biological	Moderate	Large	4		CIP CCP: temperature dryer	HACCP or ISO9001 plans
GENERAL RISK BASED APPROACH FOR POTATO PROTEIN				Process stage: 12 DRYING			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Neoformed chemicals	Chemical	Small	Moderate	2		Burner control direct dryers	HACCP or ISO9001 plans
GENERAL RISK BASED APPROACH FOR POTATO PROTEIN (purified)				Process stage: 13 SUSPENDING (OPTIONAL)			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Excess use of processing aid	Chemical	Small	Moderate	2		pH control, control ready product	HACCP or ISO9001 plans
Water contamination	Chemical	Small	Large	3	Reg. 183/2005/EC	Water monitoring	HACCP or ISO9001 plans
Water contamination	Biological	Small	Large	3	Reg. 183/2005/EC	Water monitoring	HACCP or ISO9001 plans

FEED. Risk assessment of the chain of starch manufacturing

GENERAL RISK BASED APPROACH FOR POTATO PROTEIN				Process stage: 14 REFINING (OPTIONAL)			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Water contamination	Chemical	Small	Large	3	Reg. 183/2005/EC	Water monitoring	HACCP or ISO9001 plans
Water contamination	Biological	Small	Large	3	Reg. 183/2005/EC	Water monitoring	HACCP or ISO9001 plans
GENERAL RISK BASED APPROACH FOR POTATO PROTEIN				Process stage: 15 DEWATERING (OPTIONAL)			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Microorganisms	Biological	Small	Large	3		CIP, temperature dryer	HACCP or ISO9001 plans
GENERAL RISK BASED APPROACH FOR POTATO PROTEIN				Process stage: 16 DRYING (OPTIONAL)			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Neoformed chemicals	Chemical	Small	Moderate	2		Burner control direct dryers	HACCP or ISO9001 plans

FEED. Risk assessment of the chain of starch manufacturing

GENERAL RISK BASED APPROACH FOR CONDENSED POTATO JUICE				Process stage: 17 EVAPORATION			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Microorganisms	Biological	Moderate	Moderate	3		Process control dry matter, high temperature evaporation step	HACCP or ISO9001 plans

RISK BASED APPROACH FOR POTATO FEED MATERIALS				Process stage: STORAGE & LOAD OUT			
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Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Small	Moderate	2		Protected storage, sieving	Visual checks
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications
Pests	Biological	Moderate	Moderate	3		PREREQUISITE PROGRAM for Pest control	Checks on pest activity
Pathogenic microbiological organisms	Biological	Small	Large	3		PREREQUISITE PROGRAM for Pest control, PREREQUISITE PROGRAM for Personal hygiene, PREREQUISITE PROGRAM for cleaning and PREREQUISITE PROGRAM for maintenance	

FEED. Risk assessment of the chain of starch manufacturing

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

RISK BASED APPROACH PEA PROTEIN				Process stage: RECEPTION (Pea)			
Hazard	Category	Chance	Seriousness	Risk Class.	Legislation	Control Measure	Remarks
Foreign bodies	Physical	Moderate	Moderate	3		Closed process, sieving, magnets, cleaning steps: sieving, magnets	Visual checks
Toxic/Allergenic seeds	Chemical	Small	Moderate	2	Dir. 2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis	Visual checks Aggregate sampling
Heavy Metals	Chemical	Small	Moderate	2	Dir.2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme	Purchasing specifications Regulatory compliance
Pesticides residues	Chemical	Small	Moderate	2	Reg. 396/2005/EC Dir. 2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme	Purchasing specifications Regulatory compliance
Mycotoxins	Chemical	Small	Moderate	2	Dir. 2002/32/EC	PREREQUISITE PROGRAM for incoming raw materials Analysis via monitoring programme	Purchasing specifications Regulatory compliance
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications Prerequisite program
Pests	Biological	Moderate	Moderate	3		Closed buildings, PREREQUISITE PROGRAM for Pest control Covered storage and loading	Checks on pest activity

FEED. Risk assessment of the chain of starch manufacturing

RISK BASED APPROACH FOR PEA PROTEIN	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	Physical	Small	Moderate	2		Closed process, sieving, dedicated transport lines, dry cleaning of pea Glass procedure Good maintenance practices PREREQUISITE PROGRAM for personal hygiene clothes)	Visual checks
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance Use of Food grade lubricant	Purchasing specifications
Processing aids	Chemical	Small	Small	1		On-line monitoring (follow up excessive use of processing aids) pH control, ISO9001 plans, work instructions and training personnel	Purchasing specifications
Cleaning agents	Chemical	Small	Small	1		PREREQUISITE PROGRAM for cleaning and sanitation Consumption rates Use of Food contact authorized	Purchasing specifications
Neoformed Chemicals (direct drying)	Chemical	Small	Moderate	2		Burner control Gas specifications End-product analyses Indirect dryer	
Water contamination	Chemical / Biological	Small	Large	3	Reg. 183/2005/EC	Analysis via monitoring programme	Apply water of suitable quality
Pests	Biological	Small	Moderate	2		PREREQUISITE PROGRAM for Pest control Closed process / closed workshops	Checks on pest activity

FEED. Risk assessment of the chain of starch manufacturing

Pathogenic Microbiological organisms	Biological	Small	Large	3		Process control (Temperature, pH, Time and Moisture content) Cleaning procedures Drying/evaporating steps: Control moisture content of product Process monitoring on micro organisms Final product monitoring on micro organisms	Prerequisite program for cleaning and sanitation
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FEED. Risk assessment of the chain of starch manufacturing

RISK BASED APPROACH FOR PEA PROTEIN				Process stage: STORAGE AND LOADING			
Hazard	Category	Chance	Severity	Risk Class.	Legislation	Control Measure	Remarks
Foreign body	Physical	Small	Moderate	2		Closed process, siebving	HACCP, visual checks
Lubricants	Chemical	Small	Small	1		PREREQUISITE PROGRAM for maintenance. Use of Food grade lubricant	HACCP, Purchasing specifications
Pests	Biological	Moderate	Moderate	3		PREREQUISITE PROGRAM for Pest control	Checks on pest activity
Pathogenic microbiological organisms	Biological	Small	Large	3		PREREQUISITE PROGRAM for Pest control, PREREQUISITE PROGRAM for personnel hygiene, PREREQUISITE PROGRAM for cleaning and PREREQUISITE PROGRAM for maintenance	