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Executive summary

The deliverable D.7.6 “Standard and legislative aspects” concerns the task 7.6 “Standard and legislative aspects” and it is in particular related to the subtask 7.6.1 “Legal authorization and permission requests for the pilot plants” within the Work Package 7 “Safety, Environmental and economic sustainability assessment of the developed processes & products”. This subtask has the aim to define the legal authorizations necessary for the Spanish and Italian pilot plants. Firstly, the deliverable analyzes the processes that will be implemented in the Italian and Spanish pilot plants. In particular the chemical reagents used and the waste and effluents produced by each process will be listed and defined. Successively the document describes the legislative and standard aspects to be taken into account, first introducing the European legislation and standardization framework and then referring to Italian and Spanish legislation. Finally the practical procedures to obtain the environmental authorizations both in Italy and Spain are presented.

1. Introduction

The realization of a pilot plant implies the design and the study of all the processes involved. Starting from the study of the raw materials to the final products, for each step of the process it is necessary to evaluate the quantities in and out, the critical parameters of the process to be controlled, and the effluent and solid waste produced at each stage. The processes and industrial transformations typically generate large volumes of effluents and solid waste. A sustainable process is a process that generates less waste possible, or the waste are further valorized. In the present deliverable, the processes, that will be implemented in the Italian and Spanish pilot plants, are presented and analyzed in terms of the chemicals used and the waste and effluent flows produced. In fact the environmental permits, to be requested to obtain the authorization to proceed with the construction of the plant depend on the waste generated by each process step. Not only for the solid and liquid waste, a pilot plant needs permissions also regarding air emissions, if emissions of volatile organic compounds are present, and the compliance with the rules regarding the storage and use of chemical substances and flammable reagents. In the deliverable the laws regulating all these legislative issues both at European and at national level for each pilot plant are presented and explained.

2. Analysis of the reagents used and waste produced in the pilot plants

2.1. Italian Pilot Plant operations

The Italian pilot plant will treat the agricultural and industrial tomato by-products and the cereal processing by-products. For tomato waste, the starting materials will be cull tomato, tomato plant waste, tomato peels, while for cereals waste the starting material will be wheat bran (see table 1).

Table 1: Starting residues and final product of the Italian pilot plant

Starting residues	Final product obtained
Tomato cull and plant waste	Compost and hydrocompost
Tomato peels	Cutin and lycopene
Wheat bran	Ferulic acid and fibers

From cull tomato and tomato plant waste a final hydrocompost (liquid humic-rich fertilizer) and a solid fertiliser will be obtained. From tomato peels, cutin and lycopene (to a minor extent) will be extracted and from wheat bran, ferulic acid and fibers will be separated.

For the processing of cull and tomato plant waste, the first phase will be the mechanical grinding of the starting residues. Successively, the initial grinded materials can be sent to the anaerobic digestion to produce biogas or supplemented with straw if needed to reach the optimum C:N ratio for composting (25-30), mixed and piled (pile size 1.5 - 3.0 m high x 1.5 – 6.0 wide). A fungal inoculum (not necessary, it can be optional to improve the composting) will be also added at the beginning of composting if required. For the realization of composting the mixing and turning of the materials is important. After composting (3-6 months) the final compost will be split up into two parts, one will be the final compost, while the other will serve for the preparation of humic acid-rich liquid hydrocompost. The compost will be subjected to an alkaline hydrolysis with soda at 120°C for 1 hour. After the hydrolysis, the solid fraction will be separated by means of trommel screen and returned into the composting pile while the liquid fraction will be concentrated to obtain the final hydrocompost.

For the conversion of tomato peels, the tomato processing residues (peels and seeds) will be initially separated from seeds by means of flotation with water. The seeds removed will be sent to the biogas

production or used for oil extraction. The solids particles that remained in the biogas will be put into the composting unit. The tomato peels will be subjected to an alkaline hydrolysis with soda at 130°C for 15 minutes. Then the extraction process continues on the liquid phase, therefore two steps of separation will follow through decanter and centrifugation to eliminate exhausted peels, pulp and suspended solids and to clarify the solution. Even in this case the solids eliminated can be sent to biogas production. After clarifying the solution, the successive step is the pH precipitation, during which the pH of solution will be changed from basic to acid pH (4.5). Finally the solid will be separated through centrifugation. The solid will be the final product (cutin), while the liquid fraction will be sent to biogas production.

In addition to the cutin extraction a small amount of tomato floated peels will be subjected to a lycopene extraction. This extraction will be performed using organic solvents such as ethanol, acetone and ethyl-lactate in small volumes (about 100-250 L for batch). The solvent will be recovered and properly disposed.

The wheat bran will undergo two consecutive enzymatic treatments and a thermal treatment in the same reactor. Then the solution will be filtrated through a decanter, from which the solid fractions can be put into the desiccator to obtain fibers or can be sent to the partner ITENE or can be examined for anaerobic digestion (OWS). Instead the liquid fraction will be subjected to a centrifugation to further purify the solution. The solid obtained by centrifugation can be placed again into the desiccator to obtain fibers, while the liquid will be subjected to a solid phase extraction. First the aqueous solution will be loaded in the column, then the ferulic acid will be eluted with ethanol and finally recovered. The aqueous liquid waste can be used to fungi growth. The solvent ethanol used to elute the ferulic acid will be recirculate and finally disposed.

In the diagram reported in the figure 1, all the implemented processes are showed.

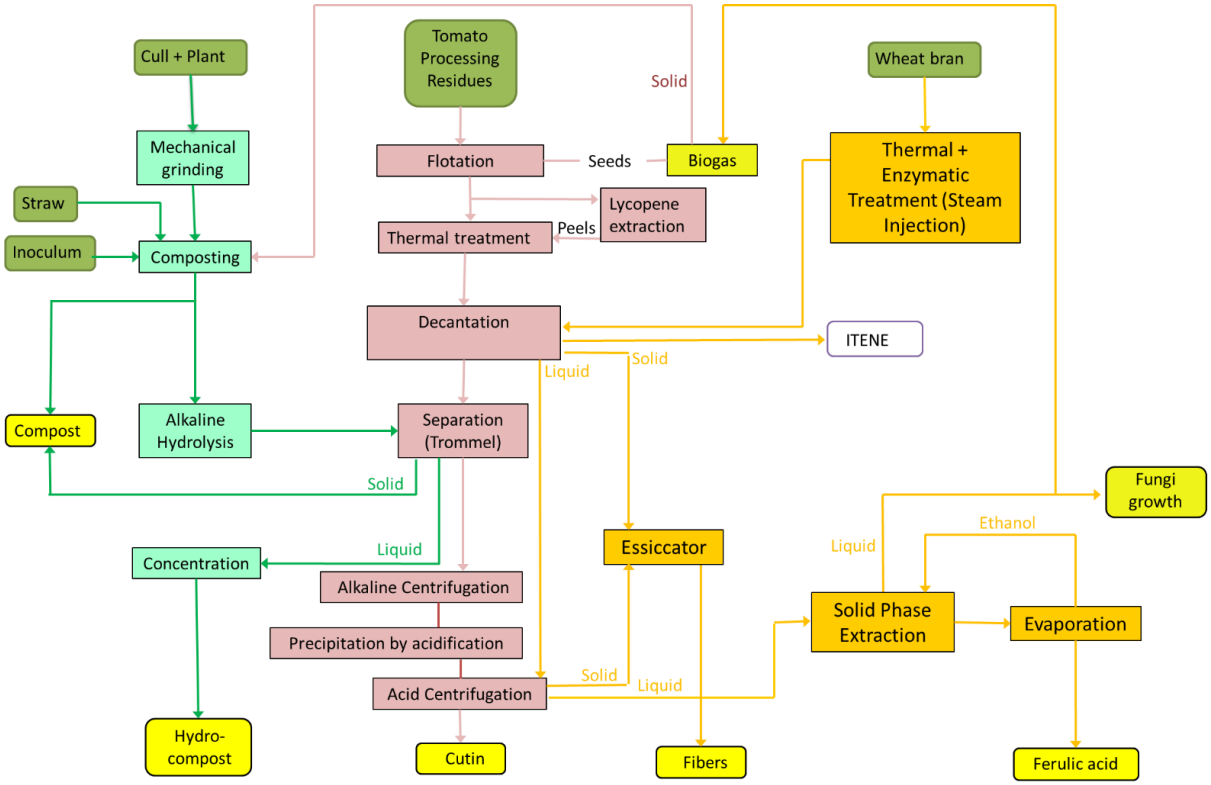

Figure 1: Flow-sheet of the Italian pilot plant

2.1.1 Analysis of chemical used

The chemical reagent used in the treatment of cull and tomato plant waste will be NaOH (3%).
The chemical reagents used in the treatment of tomato peels for cutin extraction will be NaOH and HCl (30%). Instead in the treatments of tomato peels for lycopene extraction the reagents will be the organic solvent ethanol and ethyl-acetate.
The chemical reagents used in the treatment of wheat bran will be phosphate buffers, termamyl, alcalase, pentopan Mono BG, feruloyl esterase and ethanol. The enzymes will be used for the first phases of thermal and enzymatic treatment, while the organic solvent ethanol will be used for the last steps of solid phase extraction.
For the use of soda, the chemical reagents acquired and stored will be sodium hydroxium 30% in water, then for the pilot plant it will be diluted to a concentration of 3% (0.75M) for both alkaline hydrolysis (for cull and tomato plant and for tomato peels). The water used will be well water.
As regarding the organic solvent used both for lycopene extraction and for recovery of ferulic acid, the solvents will be recirculating until exhaustion and then they will be disposed. It is possible to estimate for both cases (lycopene extraction and ferulic acid extraction) that at least 80-90% of the solvent could be recirculated and recovered. Therefore it is possible to estimate a percentage of discard equal to 10%.
In the table 2 reported below a list of the major information about composition, safety measure and chemical-physical properties of the reagents used are detailed.

Table 2: Chemical information of the reagents used in the Italian pilot plant

Information	Soda	Hydrocloric acid	Ethanol	Ethyl acetate
Product	Sodium hydroxide 30% in water	Hydrocloric acid 31% pure	Ethyl alcohol	Ethyl acetate
No CAS	1310-73-2	7647-01-0	64-17-5	141-78-6
Molecular formula	NaOH	HCl	C_2H_6O	$C_4H_8O_2$
Molecular weight	40.01 g/mol	36.46 g/mol	46.07 g/mol	88.11 g/mol
Concentration	30%	31%		
Appearance	Colourless liquid	Colourless, transparent liquid	Clear liquid	Colourless liquid
State	liquid	liquid	liquid	liquid
Colour	colourless	From colourless to slightly yellowish	Colourless	colourless
Odour	odourless	pungent	n.a.	Ether-like, fruity
Odour threshold	n.a.	n.a.	n.a.	
pH	14 (20°C)	<1 (20°C)	n.a.	n.a.
Boiling point	143-145°C	90°C	78-80°C	77°C
Melting point	12-13°C	-52°C	-114°C	-84°C
Freezing point	n.a.	n.a.	n.a.	n.a.
Flash point	n.a.	n.a.	14 °C – closed cup	-3°C
Self ignition temperature	n.a.	n.a.	425°C	427°C
Flammability	Not flammable	Not flammable	Highly flammable	Flammable liquid

Density	1.316 – 1.338 g/ml at 20°C	1.155 g/cm^3 at 20°C	0.7893 g/cm^3 (at 20 °C)	0.902 g/cm^3
Solubility	Completely miscible in water	Completely soluble in water (and other polar solvents)	Miscible in water	Soluble in water (8.3 g/100 ml), ethanol, acetone, diethyl ether, benzene
Hazard information	H314, H290 P260, P280, P303+P351+P35, P305+P351+P33, P310	H290, H314, H335 P261, P280, P301+P330+P33, P303+P361+P35, P312, P403+P233	H225, H319 P210, P280, P305+P315+P33, P337+P313, P403+P235	H225, H319, H333, H336 P210, P261, P305+P351+P338

In the table 3, the quantity of chemicals reagent that will be used in the pilot plant for the different trials are reported.

Table 3: Quantity information about reagents used in the Italian pilot plant

Chemical reagent	NaOH 30% (for cutin extraction)	HCl (for cutin extraction)	NaOH 30% (for hydro-compost)	Ethanol /Ethyl acetate (for lycopene extraction)	Ethanol (for ferulic acid extraction)
Quantity per batch	90 L per batch	30 L per batch	90-100L per batch	100-250 L	100 L

2.1.2 Analysis of resulting effluents

Regarding the effluents produced in the Italian pilot plant, the integrated processes of hydrocompost production from tomato plant and tomato cull, cutin extraction, lycopene extraction and ferulic acid separation, will have a low environmental impact, since practically the only waste produced will be the minor ethanol stream from lycopene extraction and from wheat bran treatment. In fact as it can be seen from the flow-sheet reported in figure 2 the flow of effluents discarded from each phase will be input either into biogas or it will be used for the compost.

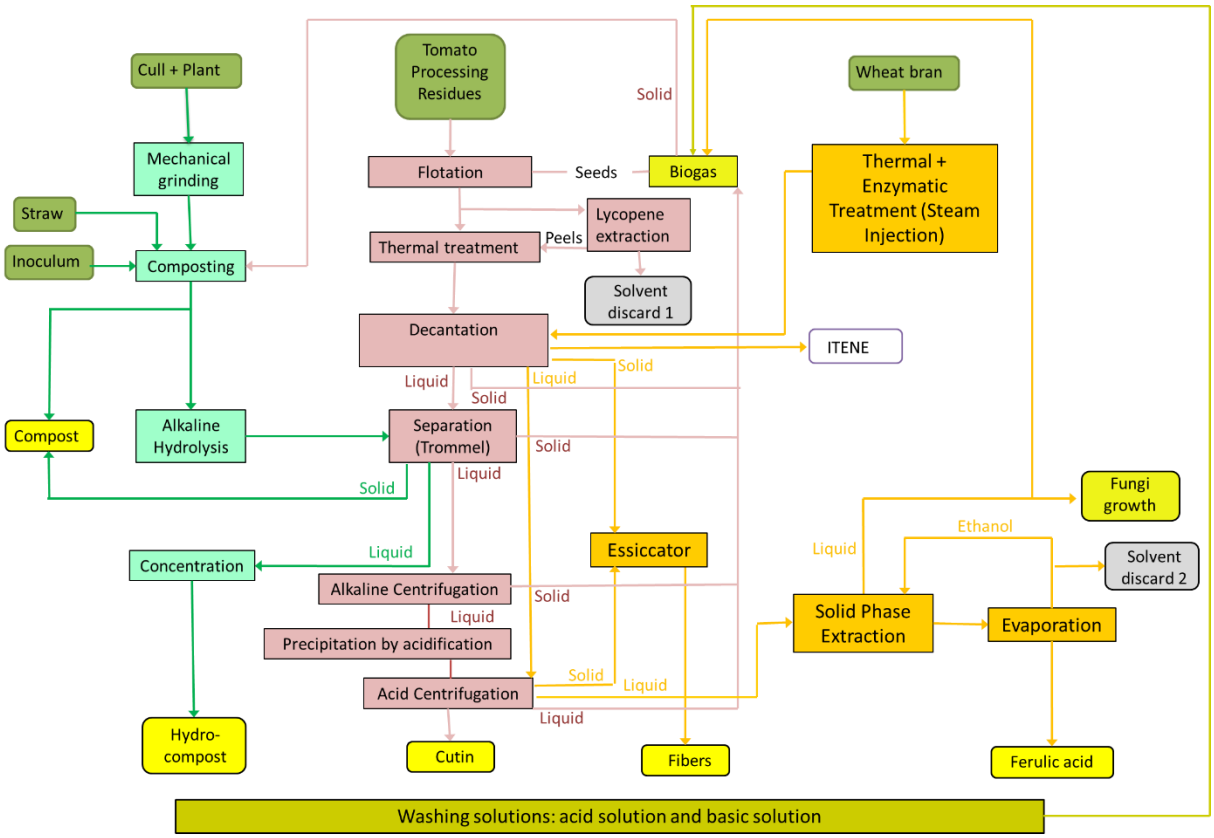

Figure 2: Flow-sheet of the Italian pilot plant with the waste discard and effluents flows

From a detailed analysis of the flow-sheet reported in figure 2 it is possible to conclude/highlight

- Relatively to tomato plant waste and cull tomato treatment: after the alkaline hydrolysis for composting, the solution will be put into the separator (trammel screen) and the solid discarded will be sent to the composting, while the liquid fraction will subjected to a concentration to finally obtain an hydro-compost. In this point no waste will be generated; all the both fractions (liquid and solid) will have a precise collocation and destination in the integrated prototype.
- For cutin extraction in the first phase of flotation the tomato peels will be separated from tomato seeds. The peels separated will be the starting material for the extraction, while the seeds will be sent into the biogas or used for oil extraction. During the following three steps of separation by decanter and centrifuge, the exhausted peels, the residual pulp and some suspended solids will be discarded, while the liquid fraction will be kept for the successive acid precipitation. The solid fraction in all cases will be sent to the biogas production. In the last step of cutin extraction, namely the acid centrifugation, the solid separated will be the final extract (cutin), while the liquid supernatant will be recirculated two times and then will be discarded and sent to the biogas prodcution. Therefore for cutin extraction all the waste fractions will be sent to biogas and no waste will be discard into sewer.
- For the lycopene extraction the organic solvent used will be recirculated and recovered, about only 10% of solvent will be discarded. This is the first critical point in the flow diagram, because in this case the discard will have to be disposed and it could be affected by the regulations relative to emissions in atmosphere.
- For wheat bran treatment, the solid fractions obtained after the decantation and the centrifugation will be sent to the desiccator in order to obtain fibers. So no waste will be

produced. The liquid fraction will be loaded into the separation column for the ferulic acid recovery using ethanol. This is the second critical point of the process. The first aqueous solution used in the extraction will be send to the biogas or in alternative used for fungi growth, while the ethanol after all the possible recirculation and recovery will be discarded; approximately 10% of the total volume used can be estimated to discard. As for lycopene extraction, the discard will have to disposed of and it could affect the limitations relative to emissions in atmosphere.

- Finally in the list of effluents, also the washing solutions that will be used to clean the equipment have to be considered; an acidic solution and a basic solution, depending on the type of product that has been treated on the machine. Since the volume of these solutions will be low, can be sent to the biogas.

In table 4, all the effluents produced by all the different processes are summarized.

Table 4: Summary of the effluents and waste produced ion the Italian pilot plant

Effluent	Physical state (solid or liquid)	Quantity produced	Destination
Tomato cull and plant waste treatment – hydro-compost obtaining			
Discarded fraction after separation in trommel	Solid fraction	10kg/batch	Compost
Tomato peels – cutin extraction			
Discarded fraction from flotation	Solid (seeds)	500 Kg/batch (t.b.d.)	Biogas or oil extraction
Discarded fraction from decanter	Solid fraction	50 kg (t.b.d.)	Biogas
Discarded fraction from trommel	Solid fraction	100 L/batch (t.b.d.)	Biogas
Discarded fraction from alkaline centrifugation	Solid fraction	600 L/batch (t.b.d.)	Biogas
Discarded fraction from acid centrifugation	Liquid fraction	1300 L/batch (t.b.d.)	Biogas
Tomato peels – lycopene extraction			
Discard from lycopene extraction	Organic solvent	10 L/batch	To be disposed Sewer
Wheat bran treatment – ferulic acid separation			
Discarded fraction from decanter	Solid fraction		Essiccator or ITENE to obtain fibers or biogas
Discarded fraction from centrifugation	Solid fraction		Essiccator
Discard fraction from solid phase extraction	Aqueous solution		Biogas or used for fungi growth
Discard from solid phase extraction	Organic solvent	10L/batch	To be disposed Sewer
Washing acid solution	Liquid	t.b.d.	Biogas
Washing basic solution	Liquid	t.b.d.	Biogas

Therefore these integrated processes can be considered a practical and a real example of circular economy, where the waste are minimized and every discarded fractions are instead valorized.

2.2. Spanish Pilot Plant operations

The Spanish pilot plant will treat the by-products of olive oil industry and the by-products of potato processing industry (as shown in table 5). In particular for potato waste, the starting materials will be potato fruit juice, potato peel and potato pulp, while for olive waste the starting material will be what is known as “alpeorujo” that is a blend of the solid and liquid that is going out of the centrifuge when processing olives through a 2-stage process. Olive process can also handled, if needed, the separated fractions obtained in a 3-stage process, which are called “alpechin” (liquid) and “orujo” (solid).

Table 5: Starting residues and final product of the Spanish pilot plant

Starting residues	Final product obtained
Olive residues	Polyphenol extract (mainly hydroxytirosol and oleuropein), Aroma extract, Fibers
Potato fruit juice	Protein concentrate, Aroma extract
Potato peel	Aroma extract, Fibers, Polyphenol extract
Potato pulp	Aroma extract, Fibers, Polyphenol extract

From all materials the project will aim to obtain several products. From olive residues, polyphenolic extracts (mainly composed of known interesting phenols such as oleuropein and hydroxityrosol), fibers and aroma extracts will be obtained. From potato fruit juice, an enriched protein fraction will be recovered, while from the three feeds an aroma extract will be recovered. Also, from potato peel and pulp fibers and polyphenolics extracts can de recovered.

For olive residues, first phase will be mechanical grinding of the starting residues to get homogeneous particle size. Then the residues can be input into the steam explosion stage, where steam will beaded under pressure (up to 10 bars, which lead to temperatures above 200°C) and then released in a fast step to generate a breakdown of the material. The product, which will be partly liquefied at this stage, will be filtered to obtain a liquid and solid fraction. It is important to remark at this point that steam explosion can be considered an optional step, not mandatory, to keep quality of some of the desired products to be obtain, such as aroma extract. Therefore, olive waste can also enter directly on the filtration step without further treatment or just grinding. Liquid fraction will be then ultra-filtered in a membrane, which depending of the molecular cleavage of the membrane will lead to obtain an enriched polyphenolic extract, and also a discarded liquid which will remain as a waste, that will be used as liquid for the fermentation process that we will explain later on with solid fraction. Solid fraction will be driven into a reactor, where an enzymatic treatment will take place at mild temperatures (between 30 and 60°C), with addition of a mix of enzymes and water to allow the reaction to have a good medium to proceed. Water addition can be from 40% of weight to 1000%, although desire is to keep it as low as possible while achieving a good transformation yield. After reaction time has passed, that can be from 1 to 24 hours, solid fraction will be liquefied, so getting a viscosity level similar to a fruit juice or a commercial beverage, and all sugars and other organic materials will become available for extraction. Liquefied fraction can be then filtered to eliminate insoluble solids, which will be used to recover fibers after drying, or can be used for the extraction of macro and micro nutrients for the production of microbiological culture media. Liquid obtained from filtration can be used for 2 processes: first, using a steam stripping equipment, aromatic fraction can

be separated under vacuum to recover mild and fragile organic volatile compounds of interest, such as trans-2-hexanal, octanal, amyl alcohols, etc; second, using the same reactor where liquefaction took place, a solvent can be added to the liquid to recover a polyphenolic fraction. Solvent will be ethanol blended with water, and also solid fraction can be collected if valuable before this step takes place.

Potato fruit juice will follow a similar process to olive in most of its process, as it will be filtered to eliminate solids on it, that will be taken into the enzymatic reactor, while liquid will be taken into ultrafiltration step to obtain from its retentates a concentrated protein fraction, as the water will pass the membranes and will be recovered on the permeate. According to the molecular sieve of the membrane, other organic molecules of lower molecular weight than the proteins (such as sugars, etc) will also go through the membrane. Permeate will be used as a growth media for microorganisms, due to its high content in valuable nutrients. Solid fraction of the potato fruit juice will go through the same enzymatic process of liquefaction as described for olive, with specific enzymes.

Potato peel will be pretreated through ultrasonication, to obtain a mash that can be used for the same enzymatic process of liquefaction, which will also be the entrance to process for potato pulp. Both feeds can also be used directly for the fermentation process, to add required nutrients if needed.

In the diagram reported in figure 3, all the implemented processes are shown.

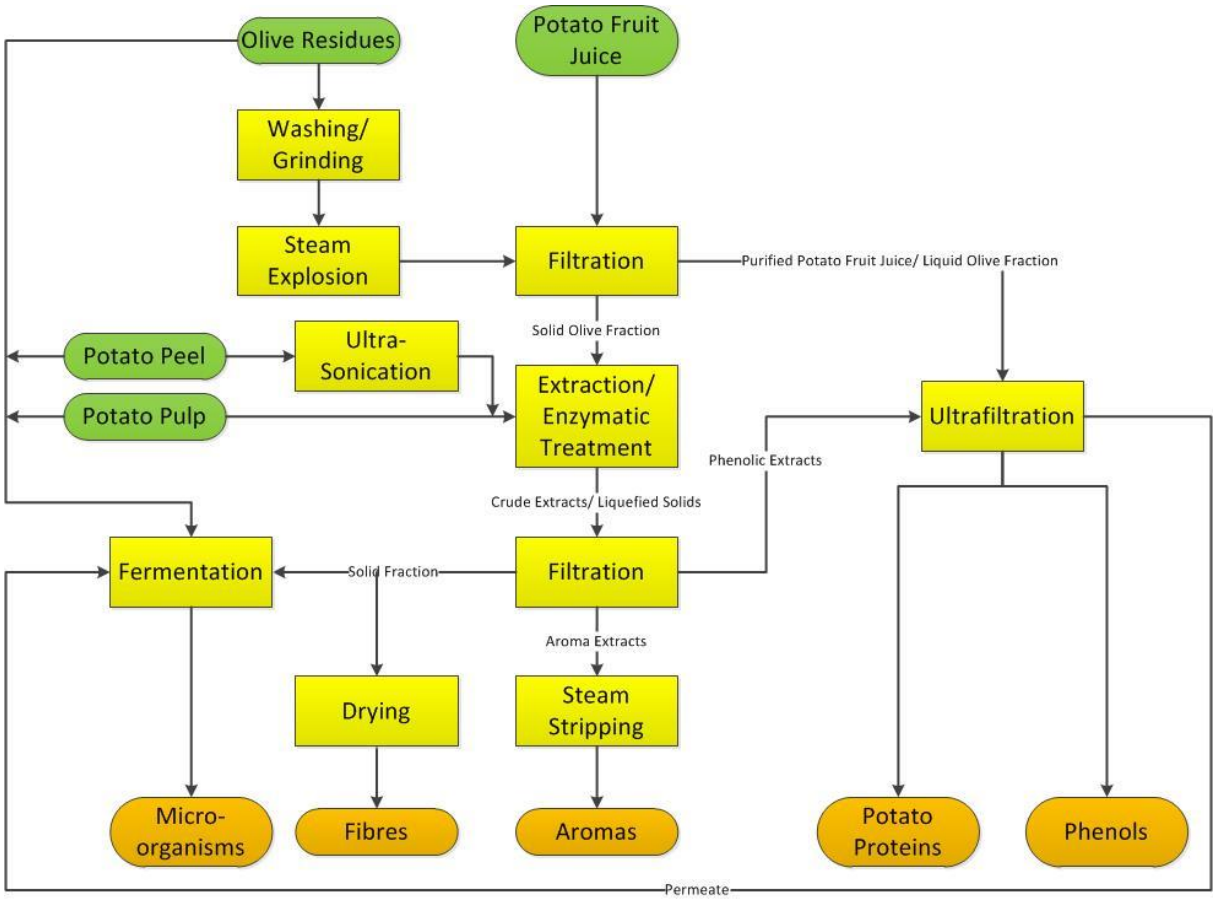

Figure 3: Flow-sheet of the Spanish pilot plant

2.2.1 Analysis of chemicals used

The chemical reagent used are not toxic and present limited hazard level. On all processes some enzymes will be used, although the specific nature of them will be defined during WP2, they will probably come from families of pectinases, cellulases, beta-glucosidases, polygalacturonases, pectinlyases or hemicellulases. Other families can be part of the mix, if the results show the need, such as arabinases, etc. Dosage of enzymes are normally between some ppm and a maximum of 1%, although correct dosage will be defined on WP2. All of them will be used on the enzymatical treatment step.

For extraction, solvent used will be ethanol, probably blended with some quantity of water, up to 30%. Water used will be treated water from Indulleida, which fulfills all normative to be used as human consumption water in Spain [1].

Table 6: Chemical information of the reagents used in the Spanish pilot plant

Information	Ethanol	Enzymes
Product	Ethyl alcohol	Several (hemicellulases, cellulases, pectinases, beta-glucosidases, etc)
No CAS	64-17-5	Several (9012-54-8, 62213-14-3, 9033-35-6, etc)
Molecular formula	C_2H_6O	Organic polimers, complex
Molecular weight	46.07 g/mol	Several, normally over 10.000 g/mol
Concentration		5-10 %
Appearance	Clear liquid	Clear thick liquid
State	liquid	Liquid
Colour	Colourless	Brown to black
Odour	n.a.	n.a.
Odour threshold	n.a.	n.a.
pH	n.a.	5 – 6
Boiling point	78-80°C	100ºC
Melting point	-114°C	0 ºC
Freezing point	n.a.	n.a.
Flash point	14 C – closed cup	> 100ºC
Self-ignition temperature	425°C	n.a.
Flammability	Highly flammable	n.a.
Density	0.7893 g/cm^3 (at 20 °C)	0.9980 - 1.000 g/cm^3 (at 20ºC)
Solubility	Miscible in water	Miscible in water
Hazard information	H225, H319 P210, P280, P305+P315+P338, P337+P313, P403+P235	H344 P261, P285, P304+341, P342+311, P501

Table 7: Quantity information about reagents used in the Spanish pilot plant

Chemical reagent	Ethanol (for extraction)	Enzymes (for enzymatic treatment)
Quantity per batch	Up to 300 L	Maximum 1 L per batch, normally 100-200 mL

2.2.2 Analysis of resulting effluents

According to current workflow of the Spanish pilot plant, the integrated processes for recovery of polyphenolic extracts, aromas and fibers will have a low environmental impact, since practically the

only waste produced will be the exhausted raw materials that will be left after fermentation process, as all processes are connected to take profit of the waste as a raw material for next process.

It is also important to state that there is a wastewater treatment plant available for the use of the project at the installations of Indulleida, so any undesired waste stream or accidental spill has the option to be treated accordingly without any affectation to the external environment of the pilot plant.

From a detailed analysis of the flow-sheet reported in figure 3, it is possible to conclude / highlight:

- Steam explosion process leads to no waste itself.
- Relatively to Ultrafiltration step: the eluate (liquid not used as a product) obtained in the process will be used on fermentation step, due to its good value of organic material, and retentates (liquid with the desired compounds) will be used as product, as process will concentrate them enough. Further processing can lead to evaporation of more water, but it's not likely to used such as process, as the desired compounds (proteins and phenols) are normally heat sensitive and labile to further processing. What is said in this step, also applies to filtration steps in the process.
- Relatively to olive waste or potato waste streams obtained after aroma extraction process: it can be lead to the fermentation vessel to be used as dilution water and adding some organic material valuable to the process. Therefore at this point no waste will be generated
- Relatively to fermentation process, the microorganisms will need the liquid fraction to survive. Process for stabilizing those microorganisms is not drawn in the layout of processing, but it's normally lyophilizate, that will lead to evaporation of water to atmosphere, therefore leading to no waste. It can also be that microorganisms will be recovered through a physical procedure such as centrifugation, and then a liquid waste, really consisting of the exhausted culture media that has been used, will be generated. According to actual processes, that liquid residue can be treated in a wastewater treatment plant to achieve adequate limits to de disposed on continental waters, with no further problems. Another option can be its use as a liquid fertilizer, if chemical analysis show a proper composition.
- Relatively to ultrafiltration, permeate will normally be used on the fermentation process. When it will come from an extraction process, that liquid can contain high amounts of solvent ethanol, and will need to be diluted with water based effluents coming from the rest of processes. There is no approach to recover ethanol although it can be done with a vacuum distiller to recover the azeotrope alcohol/water, that can be reused as part of the extraction solvent.

Table 8: Summary of the effluents and waste produced ion the Spanish pilot plant

Effluent	Physical state (solid or liquid)	Quantity produced	Destination
Liquid after aroma stripping	Liquid	tbd	Fermentation process or Wastewater treatment
Residual liquid after fermentation process, after recovering microorganisms	Liquid	tbd	Wastewater treatment or soil application as a liquid fertilizer
Residual liquid (ethanol/water) from the extraction process and further ultrafiltration	Liquid	tbd	Recovery of azeotropic ethanol/water to be reused as raw material or wastewater treatment plant

3. Regulatory frame for the pilot plants operations

3.1. European legislation and standards

Since the beginning of its work, the Council of the European Union had produced guidelines for the protection of the environment. These directives considered separately each environmental compartment: Directive 75/442/EC on waste; Directive 76/464/EC regulating the pollution of waterways; Directive 84/360/EC on the prevention of air pollution from industrial plants, and many others.

In each of these directives it was already evident not only the intention to reduce and, as far as possible, eliminate all forms of pollution, but also the desire to prevent any action aimed to damage the environmental sector taken into consideration; but what was missing was the interdisciplinary nature of rules.

Over the years, and especially following the awareness of the importance of sustainable development, the European Commission has identified the integrated approach to the evaluation of environmental problems as the most effective tool for achieving the goal of sustainability.

Environmental assessment is a procedure that ensures that the environmental implications of decisions are taken into account before the decisions are made. Environmental assessment can be undertaken for individual projects, such as factory, or for public plans or programmes. The principle is to ensure that plans, programmes and projects likely to have significant effects on the environment are subjected to an environmental assessment, prior to their approval or authorisation. Consultation with the public is a key feature of environmental assessment procedures.

The Directives on Environmental Assessment aim to provide a high level of protection of the environment and to contribute to the integration of environmental considerations into the preparation of projects, plans and programmes with a view to reduce their environmental impact. They ensure public participation in decision-making and thereby strengthen the quality of decisions [2].

The Environmental Impact Assessment (EIA) Directive (85/337/EC) is in force since 1985 and applies to a wide range of defined public and private projects, which are defined in Annexes I and II.

The EIA Directive of 1985 has been amended three times, in 1997 (97/11/EC), in 2003 (2003/35/EC) and in 2009 (2009/31/EC).

The initial Directive of 1985 and its three amendments have been codified by Directive 2011/92/EU of 13 December 2011. Directive 2011/92/EU has been amended in 2014 by Directive, after the publication in 2009 of a report on the application and effectiveness of the EIA Directive. After this publication, the Commission launched a wide public consultation, concluded by a Conference for the 25th anniversary of the EIA Directive. As a result of the review process, on 26 October 2012 the Commission adopted a proposal for a new Directive. The proposal was intended to lighten unnecessary administrative burdens and make it easier to assess potential impacts, without weakening existing environmental safeguards. The proposal was finally converted into the revised EIA Directive 2014/52/EU. [3].

The Directive 96/61/EC, also known as the IPPC Directive (Integrated Pollution Prevention and Control) is the instrument by which the European Union has to implement the principles of industrial pollution's prevention and control and promotion of clean production. The Directive aims to prevent, reduce and where possible eliminate pollution, acting at the origin of the polluting activity [4].

This Directive has been updated in 2008 by the Directive 2008/01/EC on the prevention and integrated reduction of pollution. Finally the last update has been the Directive 2010/75/EU.

This Directive 2010/75/EU on industrial emissions (the Industrial Emissions Directive or IED) is the main EU instrument regulating pollutant emissions from industrial installations. The IED was adopted on 24 November 2010. It is based on a Commission proposal recasting 7 previously existing directives (including in particular the IPPC Directive) following an extensive review of the policy. The IED aims to achieve a high level of protection of human health and the environment taken as a whole by reducing harmful industrial emissions across the EU, in particular through better application of Best Available Techniques (BAT).
The IED is based on several pillars, in particular an integrated approach, use of best available techniques, flexibility, inspections and public participation.
The integrated approach means that the permits must take into account the whole environmental performance of the plant, covering e.g. emissions to air, water and land, generation of waste, use of raw materials, energy efficiency, noise, prevention of accidents, and restoration of the site upon closure. Besides the permit conditions including emission limit values must be based on the Best Available Techniques (BAT), which are defined in the present directive [5].

Another kind of environmental Assessment is the Strategic Environmental assessment, included in the Directive 2001/42/EC, based on the assessment of the effects of certain plans and programs on the environment (SEA Directive). Strategic environmental assessment (SEA) is a systematic decision support process, aiming to ensure that environmental and possibly other sustainability aspects are considered effectively in policy, plan and programme making. In fact the EIA Directive only applied to certain projects. This was seen as deficient as it only dealt with specific effects at the local level whereas many environmentally damaging decisions had already been made at a more strategic level (for example the fact that new infrastructure may generate an increased demand for travel) [6].
The SEA Directive applies to a wide range of public plans and programmes (e.g. on land use, transport, energy, waste, agriculture, etc). The SEA Directive does not refer to policies. The SEA Directive is in force since 2001 and should have been transposed by July 2004.
Plans and programmes in the sense of the SEA Directive must be prepared or adopted by an authority (at national, regional or local level) and be required by legislative, regulatory or administrative provisions [7].

Besides another European Directive correlated to environmental issues is the Directive 2004/35/EC relative to the environmental liability with regard to the prevention and remedying of environmental damage (ELD). The Directive establishes a framework of environmental liability based on the "polluter-pays" principle. The Directive defines "environmental damage" as damage to protected species and natural habitats, damage to water and damage to soil.
The Environmental Liability Directive entered into force on 30 April 2004. The ELD was amended three times through Directive 2006/21/EC on the management of waste from extractive industries, through Directive 2009/31/EC on the geological storage of carbon dioxide and amending several directives, and through Directive 2013/30/EU on safety of offshore oil and gas operations and amending Directive 2004/35/EC [8].

Linked to environment, the waste production is another important aspect to evaluate in order to define process and technologies always more innovative, environmental friendly and sustainable. In the Agrimax project the waste production will be practically due to those discards which cannot be further valorized.

Directive 2008/98/EC of 19 November 2008 sets the basic concepts and definitions related to waste management, such as definitions of waste, recycling, recovery. It explains when waste ceases to be waste and becomes a secondary raw material (so called end-of-waste criteria), and how to distinguish between waste and by-products. The Directive lays down some basic waste management principles: it requires that waste be managed without endangering human health and harming the environment, and in particular without risk to water, air, soil, plants or animals, without causing a nuisance through noise or odours, and without adversely affecting the countryside or places of special interest.
It has intervened to substantially change the legal framework on waste, introducing measures to enhance the principles of precaution and prevention in the management of waste and to maximize recycling/recovery.
The most important provisions regard the identification of criteria to clarify when a waste ceases to be such, which has a significant impact on the internal market and for the promotion and realization of the "recycling society".
The Directive introduces the "polluter pays principle" and the "extended producer responsibility". It incorporates provisions on hazardous waste and waste oils (old Directives on hazardous waste and waste oils being repealed with the effect from 12 December 2010), and includes two new recycling and recovery targets to be achieved by 2020: 50% preparing for re-use and recycling of certain waste materials from households and other origins similar to households, and 70% preparing for re-use, recycling and other recovery of construction and demolition waste. [9].

As regarding the European legislation relative to flammable substances, the Atex Directive and the European Standard EN 13501-2 can be considered regarding the chemical substances and procedures that will be used in the pilot plants.
The ATEX Directive 2014/34/EU deals with the certification of equipment, components and protective systems intended for use in potentially explosive atmospheres. The Directive defines the essential health and safety requirements and conformity assessment procedures, to be applied before products are placed on the EU market. It is aligned with the New Legislative Framework policy, published in the EU Official Journal of 29 March 2014 and entered into force the following day, repealed the previous Directive 94/9/EC with effect from 20 April 2016 [10].
Here, in short, some of the major changes made by Directive 2014/34 / EU from the previous 94/9/EC:
• Expansion of the definitions with the horizontal integration of the New Regulatory Framework;
• Detailed description of the economic operators and their obligations;
• Introduction of the references to the European standardization regulations;
• Reference to Regulation n. 765/2008 regarding the CE Marking; More detailed requirements and procedures by the New Regulatory Framework for notified bodies. Changes therefore do not concern technical aspects [11].

The European Standard EN 13501-2 is part of the harmonized European Fire Standards, which are a set of test standards that have been accepted by all countries within the European Economic Community. This allows manufacturers to produce or import products that have been tested to a common standard without the need to test in each member state. Testing to these standards is now accepted in all EEC countries.
Compliance with the European regulations is mandatory.
The European standard EN 13501-1: Reaction to Fire provides a number of performance criteria to measure the fire characteristics of building products. These cover spread of flame and contribution to fire as well the generation of smoke and the production of burning droplets.

The structural elements are based on EN 13501-2 and the rule encompasses the whole structural element and not just the suspended ceiling. This may consist of the roof and the suspended ceiling or the structural floor and suspended ceiling. The entire element should resist the impact of fire on its structural ability for as long as possible. The length of time this can be maintained is the fire resistance duration and will classify it in one of the classes shown [12].

Finally the European regulation relating to food, food packaging materials and to Risk Assessment (see table 9) will be considered in relation to the final applications of the obtained and extracted substances.

Table 9: European reference legislation

Kind of legislation	Reference Legislation
Environmental	Environmental Impact Assessment (EIA) Directives: 85/337/EC → 97/11/EC, 2003/35/EC, 2009/31/EC → 2011/92/EU → 2014/52/EU Industrial Emissions Directives: 96/61/EC → 2008/01/EC → 2010/75/UE Strategic Environmental Assessment (SEA): 2001/42/EC Environmental liability: 2004/35/EC Waste Framework Directive 2008/98/EC Atex Directive 2014/34/UE European Standard EN 13501-2 Reaction to Fire
Food related legislation	Reg. EC 178/2002; Reg. EC 852/2004; Reg. EC 1333/2008; Reg. EC 1130/2011, Reg. EC 231/2012
Packaging	Reg. EC 1935/2004; Reg EC 2023/2006; Reg. UE 10/2011; UNI EN 1230-2-2009

Food Regulations and Standards

The general principles of food and feed law are outlined in the General Food Law Regulation (Regulation (EC) No 178/2002). They form a horizontal framework underpinning all Union and national measures relating to food and feed. They cover all stages of the production, processing and distribution of food as well as feed produced for food-producing animals.

The general objectives of the law are:

- Guarantee a high level of protection of human life and health and the protection of consumers' interests. Also guarantee fair practices in food trade, taking into account animal health and welfare, plant health and the environment;
- Ensure free movement of food and feed manufactured and marketed in the Union, in accordance with the General Food Law Regulation;
- Facilitate global trade of safe feed and safe, wholesome food by taking into account international standards and agreements when developing Union legislation, except where this might undermine the high level of consumer protection pursued by the Union.

The General Food Law Regulation establishes the principle of risk analysis in relation to food and feed and establishes the structures and mechanisms for the scientific and technical evaluations, which are undertaken by the European Food Safety Authority (EFSA).

Within the context of the General Food Law Regulation, the Regulation EC 1333/2008 lays down rules on food additives to ensure the effective functioning of the internal market whilst protecting consumer health. For those purposes, this Regulation provides for:

- Community lists of approved food additives as set out in Annexes II and III amended by the Reg. EC 1130/2011.
- Conditions of use of food additives in foods, including in food additives and in food enzymes as covered by Regulation (EC) No 1332/2008 (on food enzymes), and in food flavourings as covered by Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods
- Rules on the labelling of food additives sold as such.

EFSA (European Food Safety Authority) evaluates the safety of regulated food ingredients before they can be authorised for use on the European market. They define food ingredients as chemical substances which are used as food additives, food enzymes, flavourings, smoke flavourings and sources of vitamins and minerals added to food. EFSA assesses the safety of new substances and of new proposed uses for currently authorised substances.

There are different application procedures and technical requirements for the various food ingredients.

- Applications for food additives, food enzymes and flavourings (excluding smoke flavourings) are submitted to the European Commission.
- Applications for smoke flavourings are submitted to the national competent authority of a Member State.
- Applications for nutrient sources are sent to the European Commission which then mandates EFSA with the scientific evaluation.

Regarding standards and good manufacturing practices Hazard Analysis and Critical Control Points (HACCP) and ISO certifications are the most relevant aspects to take into consideration in the food sector. HACCP focuses on the sanitation of facilities, equipment and products, all of which must meet government and municipal standards. ISO is a quality control method. Both standards can be implemented either individually or simultaneously. While HACCP focuses primarily on control within the production processes, ISO is broader in nature and takes into account all of the supporting processes as well. Both systems require formal documented processes. It is relatively easy to combine HACCP and ISO into one overall management system that meets both the requirements for ISO 9000 and the requirements for HACCP. In fact, ISO 22000 is a new standard that specifies the requirements for a food safety management system.

Packaging Regulations and Standards

The Framework Regulation EC 1935/2004 lays down rules on materials and articles intended to come into contact with food. Food comes into contact with many materials and articles during its production, processing, storage, preparation and serving, before its eventual consumption. Such materials and articles are called Food Contact Materials (FCMs). Food contact materials are either intended to be brought into contact with food, are already in contact with food, or can reasonably be brought into contact with food or transfer their constituents to the food under normal or foreseeable use. This includes direct or indirect contact. Examples include:

- containers for transporting food
- machinery to process food
- packaging materials
- kitchenware and tableware

The Framework Regulation covers all food contact materials including packaging, machinery and kitchen ware. According to Art.3 of the Framework regulation no food contact materials shall "transfer constituents into food at levels that endanger human health" and is supported by Regulation 2023/2006 on Good Manufacturing Practice (EC 2023/2006).

The specific regulation on plastic materials and articles intended to come into contact with foodstuffs (EC 10/2011) contains a positive list of monomers and additives that can be used in plastic food contact materials. The regulation addresses mono and multilayer plastic articles, as well as coatings on plastic and gaskets of glass jar closures.
Active and intelligent packaging is also generally regulated under the framework regulation EC 1935/2004. In accordance with the framework regulation, it may only release substances into the food that are regulated as food additives or food flavorings. Further, Regulation EC 450/2009 sets additional safety requirements for active and intelligent packaging. As such, a product marketed by companies using active and intelligent packaging has to be accompanied by a declaration of compliance including consumer information at the retail stage.

EFSA evaluates the safety of substances used in food contact materials (FCM) including active and intelligent materials. Applications are submitted to the national competent authority of a Member State, which forwards the application to EFSA.

The European Packaging and Packaging Waste Directive (Directive 94/62/EC) is the main piece of legislation governing packaging and packaging waste in Europe. The Directive was adopted in 1994 and is reviewed every 10 years. The most recent review is in 2015 (Directive (EU) 2015/720). The Directive also contains The Essential Requirements for Packaging that aim to reduce packaging waste and to put forth design requirements that cater to a wide range of packaging materials and packaged goods. Packaging that meets these requirements is guaranteed free circulation in the European Economic Area. EUROPEN provides guidance for its members and other stakeholders on how to comply with the Essential Requirements. The directive has been amended by the following acts:

- Directive 2004/12/EC amending Directive 94/62/EC on packaging and packaging waste
- Directive 2005/20/EC amending Directive 94/62/EC on packaging and packaging waste (extension of deadlines for the attainment of the recycling and recovery targets for the Member States acceding the EU in 2004)
- Regulation (EC) No 219/2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny
- Commission Directive 2013/2/EU amending Annex I to Directive 94/61/EC on packaging and packaging waste
- Directive (EU) 2015/720 of the European Parliament and of the Council of 29 April 2015 amending Directive 94/62/EC as regards the consumption of lightweight plastic carrier bags

The following secondary legislation also apply to the packaging sector:

- **Marking and identification**
  - Commission Decision 97/129/EC: establishing the identification system for packaging materials
- **Data and reporting**
  - Council Directive 91/692/EEC: standardizing and rationalizing reports on the implementation of certain Directives relating to the environment

- Commission Decision 97/622/EC: concerning questionnaires for Member States reports on the implementation of certain Directives in the waste sector
- Commission Decision 2005/270/EC: establishing the formats relating to the database system pursuant to Directive 94/62/EC

- **Derogation for plastic crates and pallets from the heavy metal concentration limits**
  - Commission Decision 2009/292/EC: establishing the conditions for a derogation for plastic crates and plastic pallets in relation to the heavy metal concentration levels established in Directive 94/62/EC (This Decision replaces Commission Decision 1999/177/EC)
- **Derogation for glass packaging from the heavy metal concentration limits**
  - Commission Decision 2001/171/EC: establishing the conditions for a derogation for glass packaging in relation to the heavy metal concentration levels established in Directive 94/62/EC amended by **Commission Decision 2006/340/EC** (prolongation of validity)
- **Notification of draft measures Member States intend to implement within the framework of Directive 94/62/EC**
  - Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.
- **Beverage packaging, deposit systems and free movement of goods**
  - Communication from the Commission (2009/C 107/01)

In table 10 is reported a list of titles and references of harmonised standards under Directive 94/62/EC on packaging and packaging waste.

Table 10: Main European standard applied in packaging

European Standards Organisation	Reference and title of the harmonised standard	Reference of the standard
CEN	EN 13427:2004 Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste	
CEN	EN 13428:2004 Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction	EN 13428:2000
CEN	EN 13429:2004 Packaging - Reuse	
CEN	EN 13430:2004 Packaging - Requirements for packaging recoverable by material recycling	
CEN	EN 13431:2004 Packaging - Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value	
CEN	EN 13432:2000 Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging	

Fertilizer Regulations and Standards

The European Regulation (EC) No 2003/2003 brings into one piece of legislation all the European Union rules that apply to fertilizers. It defines types of fertilizers which have been approved as 'EC fertilizers', based on three main requirements: 1) absence of adverse effects on environment and health under normal use; 2) effectiveness; and 3) existence of sampling and analysis methods.
EC fertilizers (also known as 'national fertilizers') can circulate freely on the EU market, although a safeguard clause allows Member States to restrict the sale of a specific fertilizer if it poses a risk to safety, health or the environment. Non-EC fertilizers may be placed on national markets provided they meet national requirements and can circulate in the EU market under the 2008 Mutual Recognition Regulation. The Fertilizers Regulation establishes a series of specific requirements related to EC fertilizer types listed in the annex to the regulation, such as production method and minimum content of primary, secondary and/or micro-nutrients, as well as provisions concerning identification, traceability, markings, labelling and packaging where relevant.

Although the 2003 Fertilisers Regulation, which aimed at ensuring an internal market in fertilisers, has been effective, it mainly addresses mineral fertilisers and deters the introduction of new types of fertilisers. For this reason, in its circular economy action plan presented in December 2015, the European Commission announced, among other measures, a revised regulation on fertilisers with a view to improving nutrient recycling.

Stakeholders' reactions have been mixed. In the European Parliament, the proposal is being considered by the Internal Market and Consumer Protection (IMCO) Committee. Two further committees are associated: Environment and Public Health (ENVI) and Agriculture and Rural Development (AGRI). The International Trade Committee (INTA) is also to prepare an opinion.

The CEN's Technical Committee 'Fertilizers and liming materials' (CEN/TC 260) sets up European Standards for all kinds of fertilizers and liming materials. Currently the CEN/TC 206 published 92 standard methods mainly included in the CEN standard collection 242/350.

3.2. Italian legislation

Table 11: Italian reference legislation

Kind of legislation	Reference Legislation
Italian	D. Lgs 152/2006 and all its successively updates: D. Lgs 284/2006. D. Lgs. 4/2008, D. Lgs. 128/2010, D. Lgs 205/2010, D. Lgs 219/2010, D. Lgs 46/2014, D. Lgs 20/2015, D. Lgs 68/2015, D. Lgs 115/2015 and D. Lgs 125/2015 (all integrated in the Environmental Unique Text) L. 26 October 1995, n. 447 D. Lgs. 81/2008; D.M. 16-02-07; D. Lgs 85/2016 (Atex)

The Italian legislation has implemented the European Directives on environmental issues, discussed in the previous paragraph, initially with the Legislative Decrees 372/99 (first implementation) and 59/05 (full implementation). Successively the Legislative Decree 152/2006 has been issued. This text with all its successive updates (Legislative Decree 284/2006. D. Lgs. 4/2008, D. Lgs. 128/2010, D. Lgs 205/2010, D. Lgs 219/2010, D. Lgs 46/2014, D. Lgs 20/2015, D. Lgs 68/2015, D. Lgs 115/2015 and D. Lgs 125/2015 all integrated in the Environmental Unique Text) constituted the Environmental Code.
The Environmental Unique Text is constituted by 318 articles, 45 attachments and 10 appendixes and it is divided in 6 parts.

The first Part (Articles 1 to 3) contains the common provisions, such as the scope, purpose and criteria for the adoption of the necessary measures and the general principles.
The second Part (Articles 4 to 52) governs the procedures for the Environmental Strategic Evaluation (the so-called V.A.S.), for environmental impact assessment (the so-called V.I.A.) and for the integrated environmental authorization.
The third Part (Articles 53 to 176) focuses on rules regarding soil defense and the fight against desertification, the river basin districts, the protection of waters against pollution, protection of water bodies and regulation of discharges, water resources management, the relative disciplinary system and related monitoring duties assigned to the supervisory authorities.
The fourth Part (Articles 177 to 266) contains provisions concerning waste management, packaging management, reclamation of polluted sites, the relative disciplinary system and the related monitoring tasks assigned to the supervisory authorities.
The fifth Part (Articles 267 to 298), instead, governs the rules on air protection, reduction of emissions into the atmosphere, civil heating plants, fuels, and the relative system of penalties and the related monitoring tasks assigned to the supervisory authorities.
The sixth part (Articles 299 to 318), finally, contains the rules of refunding protection against environmental damage, prevention and environmental recovery and compensation of environmental damages [13].
With the Legislative Decree 8/11/2006, n. 284, the first set of amendments to the Environmental Code, which has affected Articles 159, 160, 170, 207 and 224, was upgraded.
In 2008 the Legislative Decree 16 January 2008 n. 4 was issued. This decree introduced the principles of environmental law (article 3), rewrote Part II, containing the rules on VIA and VAS, it has modified the discipline of water (part III) and it is primarily intervened in waste legislation.
A further amendment to the Environment Act was produced by Legislative Decree 29 June 2010, n. 128. This decree provided corrections and additions to Part I, Part II and Part IV (rules on the protection of air and reducing atmospheric emissions).
Next to these significant interventions, other measures intervened to change individual parts of the Environmental Code: the legislative Decree 3 December 2010, n. 205, which significantly changed Part IV to implement the Directive 2008/98 / EC on waste and the Legislative Decree 10 December 2010, n. 219, which brought some changes concerning the protection of waters in Part III.
On March 4, 2014 the Legislative Decree n. 46 was issued to implement the European Directive 2010/75/EC on industrial emissions (integrated pollution prevention and control).
The last changes were made with law 20/2015, 68/2015, 115/2015 and 125/2015 [14].

Based on the description of the processes in the previous paragraphs and on the close examination of the Legislative Decree 152/2006, the authorizations necessary for the Italian pilot plant are reported in the table 12 reported below.

Table 12: Environmental Italian authorization

Environmental Matrix	Legislation reference
Draining authorization	Sub-section II of the title IV of the section II of the third Part of D. Lgs n. 152/06
Authorisation to emissions into the atmosphere for plants	Art. 269 of D. Lgs n. 152/06
General authorization to emissions into the atmosphere for plants	Art. 271 of D. Lgs n. 152/06

Communications regarding waste	Artt. 188, 215 and 216 of D. Lgs n. 152/06
Compost authorization	Artt. 183, 195 and 199 of D. Lgs n. 152/2006
Utilisation, storage and disposal of flammable substances	Artt. 287-297 of D. Lgs. 81/2008 D.M. 16-02-07 Atex: D. Lgs 85/2016
Communication or no impediment to noise	Art. 8, paragraph 4 or paragraph 6; of L. 26 October 1995, n. 447
Building/Construction permits	D. Lgs 126/2016 (SCIA)

As regarding the draining authorisations, the subject is discussed in the sub-section II of the title IV of the section II of the third Part of D. Lgs n. 152/2006, namely the articles 124-132.
Pursuant to Article 124 of Legislative Decree no. 152/06, all draining must be previously authorized. In general, the authorization is valid for four years from the time of issue (date of notification of the act); one year before the deadline it must be applied for its renewal. Authorization is granted to owner of which draining originates. The application for authorization must be submitted to the province. The competent authority shall, within ninety days from receipt of the application. The expenses necessary for the carrying out of surveys, investigations, audits and inspections required for the investigation of applications for draining authorization shall be paid by the applicant.
According to article 125, the application for the draining authorization of industrial waste water must be accompanied by an indication of the quantitative and qualitative characteristics of the discharge, and the annual volume of water to be discard, the type of receptor, the identification of points intended to provide control samples, and by the description of the total drain system.

As regarding the authorization to emissions into the atmosphere for plants, the subject is discussed in the articles 269 and 271 of the Environmental Unique Text.
Article 269 establishes that for all plants that produce emissions should be required authorization. The application for authorization must be accompanied by the project of plant, which describes the equipment and activities, the techniques used to control emissions and the amount of these emissions and a technical report describing the overall production cycle.
The authorization lasts for fifteen years. The application for renewal must be submitted at least one year before the deadline. The competent authorities for the control is authorized to carry out all inspections at the facilities which it considers necessary to ensure compliance with authorization.
Article 271 regulates the emission values and the provisions to be applied to equipment and plant activity. The emission values and provisions to apply for channeled and diffused emissions of the plant are identified, based on the best available techniques. The emission limit values are given in the Annex I of Part V. The organic solvents used in the Italian pilot plant (ethanol and ethyl acetate) are included in the Class V and the table with the emission value is the table D, reported in table 13:

Table 13: Emission value [15]

Class	Threshold of significance (expressed as mass flow)	Emission value (expressed as concentration)
Class I	25 g/h	5 mg/Nm^3
Class II	100 g/h	20 mg/Nm^3
Class III	2000 g/h	150 mg/Nm^3
Class IV	3000 g/h	300 mg/Nm^3
Class V	4000 g/h	600 mg/Nm^3

As it can be seen from the values reported in the table, the emission values relative to the Italian pilot plant will be far lower than those reported in the Law.

As regarding the communications relative to waste, the subject is discussed in the article 188 relative to the responsibility in waste management and in articles 215 and 216 relative to self-disposal and recovery operations. In the first case the waste produced by the plant treatments is not discarded directly in the plant but as according to the article 188 is delivered to an intermediary, institutions or company which carries out waste treatment operations, in accordance with Articles 177 and 179. The traceability of waste must be guaranteed from its production until its final destination.
In the case of the Italian pilot plant the waste, which can not be disposed directly in site, is constituted by the exhausted solvents, the disposal of which will be entrusted to an outside company, using an ad hoc contract.
In the second case of self-disposal and recovery, these activities can be carried out directly at the place of production of the waste elapsed 90 days from communication of starting activities to the competent authorities. The technical standards set out in the law (the type, quantity, characteristics of waste, origin, safety provisions….) should be respected. For the Italian prototype, the farm Chiesa already has a biogas plant, where it will be possible to dispose of the majority of the effluents.

As regarding the compost, the sector of composting refers to two main topics of intervention: a) the management of waste and the resulting environmental aspect ruled by Legislative Decree 152/2006; b) the marketing and use of fertilizers. This last aspect will not discuss in this document, since the fertilizer produced in the Italian pilot plant will not be commercialized and sold, but only use for research and study purpose.
In particular in Article 183 of Legislative Decree 152/06, paragraph 1, letter ee the notion of quality compost is defined as a product obtained from the composting of organic waste collected separately, which respects the requirements and characteristics set out in Annex 2 of the legislative decree of 29 April 2010, n. 75. Furthermore, always in the Legislative Decree 152/2006 the responsibilities for the composting plants of the State (Article n. 195, paragraph 2, letter o) and of regions, through the regional plans (Article n. 199, paragraph 12-bis letter c) are established.

For the utilisation, storage and disposal of flammable substances, different reference legislation laws can be considered. The legislative Decree 81/2008 is the Unique Text on health and safety at work. The Title XI is relative to the protection from explosive atmospheres and it includes the articles 287 – 297. After defining the scope and what is an explosive atmosphere ("a mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapors, mists or dusts in which, after ignition, combustion spreads throughout the unburnt mixture "), art. 289 stated that the employer should prevent the formation of explosive atmospheres. If the activities do not allow the prevention of such atmospheres, the employer must take the necessary measures so that explosive atmospheres can be developed in safety (art. 291). To create the security conditions, the employer must identify the areas where explosive atmospheres may arise, properly reported and provide optical / acoustic alarms that signal the start and stop of the plant, both during normal cycle and in case of an emergency (art. 293). The employer must also prepare a document ("document on explosion protection"), in which it will state the identification and assessment of explosion risks identified, the explosive areas identified and the security measures taken (art. 294). Finally, the workers must be informed and trained with regard to the outcome of the risk assessment (art. 294 bis).

The European ATEX Directive 2014/34/EU has been implemented in Italy by the Legislative Decree 85/2016 relating to equipment and protective systems intended for use in potentially explosive atmospheres. According to Paragraph 3, letter E and G of article 1, the concepts of "potentially explosive atmosphere" ("an atmosphere which could become explosive due to local and operational conditions") and "groups of equipment II "(" equipment intended for use in other places liable to be endangered by explosive atmospheres, including devices in categories 1, 2, and 3 of Annex I ") are defined. These definitions meet the operating conditions and the type of equipment that will have in the Italian prototype.
According to this law the devices that will be installed on the Italian pilot plant will be governed by Annex I, paragraph C and Annex II, point 2.3.
The European Standard EN 13501-2 has been implemented in Italy by the Ministerial Decree 16/02/2007. This decree applies to products and construction elements for which is prescribed the requirement of fire resistance for safety in case of fire of the works in which they are inserted. The fire resistance or flame retardancy is the ability of an element to maintain a predetermined time for some parameters in the presence of fire conditions and high temperature.
The products and building elements are classified according to their fire resistance characteristics, according to the symbols and classes indicated in the tables of Annex A.
The project will take account of all legislation relative to flammable substances, and according to the regulations in force, the plant will be equipped with walls, doors and any other components with classification REI 120. Furthermore all equipment that will be installed on the prototype will comply with ATEX regulations.

As regarding the communication or no impediment to noise, the reference Law in Italy is the Law n. 447 of 26 October 1995, that is the Framework Law on Noise Pollution. The Law 447 defines the fundamental principles with regard to the external environment and living environment from noise pollution.
In the law all the issues concerning the noise, the subjects aimed to analyze them and the responsibilities of State, Regions, Provinces and Municipalities are analyzed. In particular Art. 8 shall order the duty to draw up noise impact assessments and acoustic climate assessments for certain types of works.
In paragraph 4 of Article 8 it is specified that applications for the issuance of building permits for new facilities and infrastructures relative to productive activities as well as applications for licenses or authorization of productive activities shall include a noise impact prediction documentation. In case the activities produce emission noise value higher than those foreseen from law (indicated in article 3 paragraph 1 letter a) the application shall include also the indications of the foreseen measures to decrease or eliminate the noise emission caused by the activities or by the plants, as indicated in paragraph 6.

As regarding the building or construction permits, the Italian reference law is the Law 241/1990 of 7 August 1990, which has introduced the certified advisory of starting activity (SCIA). Anyone who intends to start an activity such as a plant installation, business, trade, he must submit the application of SCIA to the company Register of the Chamber of Commerce. In case of Italian pilot plant, it will not necessary to present an application for SCIA, because the pilot plant already exists, and in the Agrimax project it will be only updated and enlarged. For the updating and enlargement it will be used a shed already existing, where the new necessary equipment will be implemented. Therefore, the permits for enlargement and change of use destination will be submitted.

3.3. Spanish legislation

Table 14: Spanish and catalan reference legislation

Kind of legislation	Reference Legislation
Spanish	Ley 16/2002, de 1 de julio, de Prevención y Control Integrados de la Contaminación Ley 21/1992, de 16 de Julio, de Industria Real Decreto 2200/1995, de 28 de diciembre, por el que se aprueba el Reglamento de la Infraestructura para la Calidad y la Seguridad Industrial
Catalan	Llei 3/1998 and Llei 20/2009 Reial Decret Legislatiu 1/2016, de 16 de desembre, pel qual s'aprova el text refós de la Llei de Prevenció i Control Integrats de la Contaminació

Spanish pilot plant will be placed inside the Autonomic community of Catalonia. That fact means that, for environmental legislation, the national and autonomic levels have to be observed, as Catalonia has its own legislation that, in several aspects, is more restrictive than national and European law.

That being explained, the installation has to fulfill the requirements of catalan IIAA (Intervencio Integral de l'Administracio Ambiental), which was placed by Llei 3/1998, de 27 de febrer, de la intervenció integral de l'Administració ambiental. On its article 5, it creates the obligation to declare and evaluate activities according to the annexes that are defined on article 6. Those annexes were updated on Llei 20/2009, del 4 de desembre, de prevenció i control ambiental de les activitats. Actually, all of this laws are coming from the transposition to autonomic laws of IPPC Directive of EU.

As the pilot plant will be placed at Indulleida, it will have to be included on the actual environmental authorization to operate (as Indulleida is included on Annex I of this law), and we will need to define if it's or not a substantial change for the activity. As Indulleida already has installations for treatment of their own wastes, such as trammel for pellet feed production, fiber recovery, etc, a new installation for treatment of vegetable wastes can be considered a non substantial change for Indulleida. For more precise communication, pilot plant, if it should be new, will be included, for our assessment, in annex III, as we can place it inside paragraph 7.1.b, as we want to produce food products on it (although they won't be commercialized) with a production capacity below 300 T/day, as it is shown in table below n. 14 in catalan, which has been retrieved from Llei 20/2009.

Table 15: Catalan legislation for food products

7		INDÚSTRIA ALIMENTÀRIA I DEL TABAC	I.1	I.2		I.3	II	III
				A	B			
1		Escorxadors amb una capacitat de producció de canals (t/d)	> 50				≤ 50, > 2	≤ 2
2		Tractament i transformació per a la fabricació de productes alimentaris a partir de:						
	a	Matèria primera animal (que no sigui la llet), amb una capacitat d'elaboració de productes acabats (t/d)	> 75					≤ 75
	b	Matèria primera vegetal, amb una capacitat d'elaboració de productes acabats (t/d) (valor mitjà trimestral)	> 300					≤ 300
3		Tractament i transformació de la llet, amb una quantitat de llet rebuda (t/d) (valor mitjà anual)	> 200					≤ 200
4		Producció de midó						
5		Instal·lacions d'emmagatzematge de gra i de farina						
6		Carnisseries amb obrador						
7		Fleques amb forns de potencia						> 7.5kW
8		Tractament, manipulació i processament de productes del tabac						
9		Instal·lacions industrials per l'elaboració de greixos i olis vegetals i animals, instal·lacions industrials per l'elaboració de cervesa i Malta, instal·lacions industrials per la fabricació de fècules, instal·lacions industrials per l'elaboració de confitures i almívars, instal·lacions industrials per la fabricació de farina de peix i oli de peix, sempre que a la instal·lació es doni de forma simultània les circumstàncies següents: a) que estigui situada fora de polígons industrials, b) que es trobi situada a menys de 500 m d'una zona residencial, c) que ocupi una superfície de almenys 1 hectàrea. Les activitats incloses en aquest epígraf s'han de sotmetre prèviament a la sol.licitud de la llicència a la decisió de l'òrgan ambiental competent del DMAH respecte a la necessitat o no de sotmetre's a l'avaluació d'impacte ambiental						

Table 16: Environmental Spanish and catalan authorizations

Environmental Matrix	***Spanish legislation***	***Catalan legislation***
Drainings Authorisation	Real Decreto 849/1986, de 11/4/1986, por el cual se aprueba el Reglamento del Dominio Publico Hidraulico Ley 5/1981, de 4 de junio, sobre despliege legislativo en magteria de evacuacion y tratamiento de aguas residuales	Decret Legislatiu 3/2003, de 4 de novembre, pel qual s'aprova el text refós de la legislació en matèria d'aigües de Catalunya
Authorisation to emissions into the atmosphere for plants	Real Decreto 815/2013, de 18 de octubre, por el que se aprueba el Reglamento de emisiones industriales y de desarrollo de la Ley 16/2002, de 1 de julio, de prevención y control integrados de la contaminación	Llei 34/2007, de 15 de novembre, de qualitat de l'aire i protecció de l'atmosfera. Decret 833/1975 de 06-02-1975 pel qual es desplega la Llei 38/1972, de 22-12-1972, de Protecció de l'Ambient Atmosfèric
General authorisation to emissions into the atmosphere for plants	Real Decreto 100/2011, de 28 de enero, por el que se actualiza el catálogo de actividades potencialmente contaminadoras de la atmósfera y se establecen las disposiciones básicas para su aplicación.	Llei 34/2007, de 15 de novembre, de qualitat de l'aire i protecció de l'atmosfera.
Communication or no impediment to noise	LEY 37/2003, de 17 de noviembre, del Ruido REAL DECRETO 1513/2005, de 16 de diciembre, por el que se desarrolla la Ley 37/2003, de	LLEI 16/2002, de 28 de juny, de protecció contra la contaminació acústica DECRET 176/2009, de 10 de novembre, pel qual s'aprova el

	17 de noviembre, del Ruido, en lo referente a la evaluación y gestión del ruido ambiental	Reglament de la Llei 16/2002, de 28 de juny, de protecció contra la contaminació acústica, i se n'adapten els annexos
Communications regarding waste	Real Decreto 833/1988, de 20 de julio, por el que se aprueba el Reglamento para la ejecución de la Ley 20/1986, Básica de Residuos Tóxicos y Peligrosos Real Decreto 952/1997, de 20 de junio, por el que se modifica el Reglamento para la ejecución de la Ley 20/1986, de 14 de mayo, Básica de Residuos Tóxicos y Peligrosos	DECRET 399/1996, de 12 de desembre, pel qual es regula el règim jurídic del fons econòmic previst al Decret legislatiu 2/1991, de 26 de setembre, pel qual s'aprova la refosa dels textos legals vigents en matèria de residus industrials.
Building/Construction permits		Llei 3/1998 and Llei 20/2009 Reial Decret Legislatiu 1/2016, de 16 de desembre, pel qual s'aprova el text refós de la Llei de Prevenció i Control Integrats de la Contaminació
Utilisation, storage and disposal of flammable substances	REAL DECRETO 379/2001, de 6 de abril por el que se aprueba el Reglamento de almacenamiento de productos quimicos y sus instrucciones técnicas complementarias MIE-APQ-1, MIE-APQ-2, MIE-APQ-3, MIE-APQ-4, MIEAPQ-5, MIE-APQ-6 y MIE-APQ-7. BOE num. 112 de 10 de mayo de 2001 ITC MIE-APQ 1: ≪Almacenamiento de liquidos inflamables y combustibles≫	
Food related legislation (includes European legislation on the Catalan part)	Real Decreto 2200/1995, de 28 de diciembre, por el que se aprueba el Reglamento de la Infraestructura para la Calidad y la Seguridad Industrial Real Decreto 140/2003, de 7 de febrero, por el que se establecen los criterios sanitarios de la calidad del agua de consumo humano	REGLAMENTO (CE) No 178/2002 DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 28 de enero de 2002 por el que se establecen los principios y los requisitos generales de la legislación alimentaria, se crea la Autoridad Europea de Seguridad Alimentaria y se fijan procedimientos relativos a la seguridad alimentaria REGLAMENTO (CE) Nº 852/2004 DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 29 de abril de 2004 relativo a la higiene de los productos alimenticios REGLAMENTO (CE) No 1333/2008 DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 16 de diciembre de 2008 sobre aditivos alimentarios

4. Authorizations needed for the pilot plants

4.1. Italian procedures for authorizing the Italian Pilot Plant

The Legislative Decree 152/2006 define the environmental authorizations VIA (environmental Impact assessment) and VAS (Strategic Environmental Assessment). For the plants not subjected to VIA but which they have to submit authorizations indicated in D. Lgs 152/2006 (draining authorizations, authorizations to emissions into atmosphere, communication regarding waste and communication or impediment to noise) the Italian legislation provided for a simplification, the possibility of requiring all the authorizations with a single authorization, the Environmental Unique Authorizations (AUA). This simplification has been introduced by the Presidential Decree n. 59/2013.
According to the article 2 of the Decree Law DM of 18th April 2005 and in accordance with the D.P.R. 59/2013 for the authorization to the new update pilot plant, Chiesa will have to submit the request of release/issue of the unique authorization, including AUA (Environmental Unique Authorization), which it will contain all the required environmental housing licenses, other licenses and the necessary certifications for the realization of the plant as regarding safety and fire prevention.
According to the same D.P.R. and Practical Guidelines issued by the Province of Mantova in July and August 2013, the single application for authorization, including AUA, must to be submitted electronically to the SUAP of its district (Comune) (article 38, paragraph 3 of Law Decree. 112/2008 converted with amendments by Law 133/2008, as implemented by the adoption of the Decree of the President of the Republic n. 160/2010).
The application shall contain all the necessary documents, including all the technical drawings of the prototype and the documents relative to the single provisions of art. 3 c.1 of D.P.R. (Presidential Decree) 59 for environmental securities listed therein and specifically required by Chiesa.

In a second step the SUAP sends letter initiating the proceeding upon official verification of the completeness of the application; therefore it will be responsible to electronically forward all the documents to the other involved Administrations, in particular Province of Mantova, ARPA, Fire Department Area, Ufficio d'Ambito and Parco Dell'Oglio.
The probate Authority for the issue of the AUA is Province of Mantova, which has the following functions:

- To carry out the preliminary investigation for environmental permits under its jurisdiction
- To acquire the provisions regarding the environment authorized by other authority
- To prepare and to adopt the A.U.A., which will contain all the environmental certification of permission required
- To transmit/send the A.U.A. to S.U.A.P, responsible for the area.

Depending on the type of required intervention (based on the detailed project of the prototype) the SUAP calls a conference of services, to which it invites the Province of Mantova, A.R.P.A. and the other Authorities involved in the expression of opinion and Ufficio d'Ambito for the acquisition of the authorization for the drain into the sewer.
The province adopts/implements the provision AUA and the SUAP issue the final provision to Chiesa. Overall the proceeding may not extend beyond 120 days.
Finally within 30 days from the plant installation Chiesa must notify it to the local Chamber of Commerce.

Another possible environmental authorization foreseen from the Italian legislation is the environmental Impact Assessment. In fact the second part of the Legislative Decree 152/2006 deals with the procedures for the Strategic Environmental Assessment (VAS), the Environmental Impact Assessment (VIA) and integrated environmental authorization (IPPC).
The environmental impact assessment (VIA) is an administrative procedure to support the competent authorities (such as the Ministry or Region) designed to identify, describe and assess the environmental impacts of a project, the design of which is subject to approval or authorization [16]. VIA is a preventive and systematic evaluation process of environmental impacts that may result from the territorial transformation activities. The VIA concerns the evaluation of significant and negative impacts of a specific project on the environment and on cultural heritage.
On the basis of the list of projects subjected to VIA, listed in Appendix III to Part II and considering the analysis of the processes that will be implemented in the Italian pilot plant (reported in paragraphs 1.1 and 1.1.2), the Italian prototype for processing tomato and cereals residues should not be subjected to VIA. This possible need (VIA presentation) will be further deepened and evaluated during the course of the preparation of the documentation. In case a VIA would be necessary, the application for VIA will be submitted together with AUA. Before the VIA will be evaluated, successively the procedure for AUA will begin.

4.2. Spanish procedures for authorizing the Spanish Pilot Plant

The procedure to request a Non-Substantial Change for existing installations, consists of:

- All process has to be done on web [17]. All templates are available on the website.
- Prepare all needed information, which includes:
    - Download template for the request of a non-substantial change
    - Prepare a basic project, that includes detailed description and scope of the change and affected installations. This will include drawings of the project, flowchart, etc, to make a proper description of the pilot plant and also it needs to include an environmental assessment of it, with all its planned environmental affectations and program of amends if needed.
    - Mandatory documentation about major accidents that is required according sectorial legislation (food sector)
    - Soil characteristics of the projected activity
    - Appointment of the technical person responsible for the execution of the project
    - Any other document needed for the sectorial law applying to the activity (food sector), in our case an HACCP study will need to be done
    - Declaration of data that are requested confidential
- All digital documents will need to be digitally signed, and in pdf format

All this procedure will need to be done by Indulleida, as juridical entity that will host the pilot plant. It also has, already, authorization for flammables and a storehouse for them in the installations.

It is important to state that Spanish pilot plant will be designed as a food producing plant, therefore all materials and design will need to follow food legislation, that it's included in the reference legislation for that reason.

5. Conclusion

This deliverable has presented the general legislative and standard framework related to the operations of the two pilot plant, with a specific focus on the environmental authorizations necessary to the realization and implementation of the pilot plants. The analysis of the processes that will take place in the two pilot plants and the analysis of the European and national legislations has allowed to define which kind of environmental authorization are needed for both pilot plants. From the analysis of the processes that will be implemented in the Italian pilot plant, it is highlighted that the only critical point will be the organic solvent produced by lycopene extraction and by solid phase extraction. This waste cannot be sent to biogas or used for compost as for all other waste of the processes, but it has to be disposed. However the organic solvent will be used in small volume and they will be recovered and recirculated.

From the analysis of the processes that will be implemented in the Spanish pilot plant, practically the only waste produced will be the exhausted raw materials that will be left after fermentation process, as all processes are connected to take profit of the waste as a raw material for next process. Moreover at the installations of Indulleida there is a wastewater treatment plant available for the use of the project, so any undesired waste stream or accidental spill has the option to be treated accordingly without any affectation to the external environment of the pilot plant.

European legislation has many comprehensive rules on environmental issues and waste. In fact the Council of the European Union had produced guidelines for the protection of the environment. These directives considered separately each environmental compartment. Over the years, and especially following the awareness of the importance of sustainable development, the European Community has identified the integrated approach to the evaluation of environmental problems as the most effective tool for achieving the goal of sustainability.

The Italian legislation has implemented the European Directives on environmental issues in a single Legislative Decree (D. Lgs 152/2006), which constituted the Environmental Code or the Environmental Unique Text.

The close examination of the Italian legislation has revealed that for the Italian pilot plant will probably be necessary only a single authorization, the so-called AUA (Environmental Unique Authorization).

For the Spanish pilot plant, since it will be placed inside the Autonomic community of Catalonia, it will have to observe, for environmental legislation, the national and autonomic levels, as Catalonia has it own legislation that, in several aspects, is more restrictive than national and European law.

Therefore the installation has to fulfill the requirements of catalan IIAA (Intervencio Integral de l'Administracio Ambiental), which was placed by Llei 3/1998, de 27 de febrer, de la intervenció integral de l'Administració ambiental. The authorization needed for the Spanish pilot plant will be the Autoritzacio Ambiental Integrada (AAI), but it will have to be included in actual AAI of Indulleida.

Thanks to the study performed, the correct procedures for the requiring of the environmental authorizations have been identified.

In conclusion the investigation performed in this deliverable has allowed to identify the correct procedures to request all the environmental authorizations necessary for the two pilot plants, that will be realized during the Agrimax project.

6. References

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3] http://ec.europa.eu/environment/eia/eia-legalcontext.htm

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Annex I

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97/11/EC: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31997L0011;
2003/35/EC: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32003L0035;
2009/31/EC: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009L0031;
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Waste Framework Directive 2008/98/EC:
http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=celex%3A32008L0098

Atex Directive 2014/34/UE:
http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=CELEX%3A32014L0034

European Standard EN 13501-2: https://www.en-standard.eu/csn-en-13501-2-fire-classification-of-construction-products-and-building-elements-part-2-classification-using-data-from-fire-resistance-tests-excluding-ventilation-services/?gclid=Cj0KEQjw-73GBRCC7KODl9zToJMBEiQAj1JgfyqHh2ySHJFUIqvBZThIyzZ2x3bXKXnteKGW0zTrDd8aAvxy8P8HAQ

Food related legislation:
Reg. EC 178/2002 : http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32002R0178;
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Reg. EC 1130/2011: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011R1130
Reg. EC 231/2012: http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=CELEX%3A32012R0231
ISO 9000:2015 https://www.iso.org/obp/ui/#iso:std:iso:9000:ed-4:v1:en
ISO 22000:2005: https://www.iso.org/obp/ui/#iso:std:iso:22000:ed-1:v1:en

Packaging:
Reg. EC 1935/2004 : http://eur-lex.europa.eu/legal-content/IT/ALL/?uri=CELEX%3A32004R1935;
Reg. EC 2023/2006: http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=CELEX%3A32006R2023;

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Annex II

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Annex III

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Annex IV

Catalan legislation

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