



Biorefineries for the valorisation of macroalgal residual biomass and legume processing by-products to obtain new protein value chains for high-value food and feed applications

Project number: 887259

D8.2 Inventory of legal requirements applicable to ALEHOOP

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PROJECT INFORMATION

Project full title: Biorefineries for the valorisation of macroalgal residual biomass and legume processing by-products to obtain new protein value chains for high-value food and feed applications

Acronym: ALEHOOP

Call: H2020-BBI-JTI-2019

Topic: BBI-2019-S03-D3


Start date: June 1st 2020

Duration: 48 months

List of participants:

Partner no.	Type of partner	Name	Acronym	Country
1 (Coordinator)	SME	Contactica	CTA	Spain
2	SME	Isanatur	ISA	Spain
3	SME	Biozoon	BZN	Germany
4	SME	Biosurya	BIOYA	Spain
5	SME	Centiv	CENTIV	Germany
6	SME	Garlan	GARLAN	Spain
7	SME	Alginor	ALGI	Norway
8	LE	Nuscience	NUS	Belgium
9	LE	Indukern	IK	Spain
10	RTO	The Flanders Research Institute for agriculture, fisheries and food	EV-ILVO	Belgium
11	RTO	Anfaco	ANFACO	Spain
12	RTO	Tecnalía	TECNA	Spain
13	RTO	Technological University Dublin	TUDublin	Ireland
14	RTO	Universidad de Cádiz	UCA	Spain
15	RTO	Veterinary Research Institute	VRI	Czech Republic
16	RTO	Universidad de Vigo	UVIGO	Spain

DELIVERABLE DETAILS

Document Number:	D8.2
Document Title:	Inventory of legal requirements applicable to ALEHOOP
Dissemination level	PU – Public
Period:	PR1
WP:	WP 8: Regulatory and Market Access Aspects
Task:	Task 8.2: Legal and Ethics Requirements
Author:	Shah, H., Ahmed, L. and Barry-Ryan. C 
Abstract:	A detailed inventory of the relevant National and European regulations affecting the ALEHOOP Project has been prepared to assess the Legal and Ethics requirements. It summarises the legislations that pertain to the allocated work packages along with the relevant partners who are involved in the project. The legislations have been divided into eight large groups depending on their general area of concern. The pertinent partners associated with the work packages admissible to a particular regulation have then been mentioned. Each legislation is accompanied by a summary of the content of the particular legislation along with a link to the legislation.

1. Summary of the legislations with the work packages and relevant partners of alehhop

1.1 General Food Safety and Feed Hygiene Regulations:

<p>REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety</p> <p>Summary: This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety. It lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level and establishes the European Food Safety Authority. It lays down procedures for matters with a direct or indirect impact on food and feed safety.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002R0178&from=EN</p>	
Work Package	Relevant Partners Involved
WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 2	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, GARLAN, IK, ISA, NUS, TECNA, UCA, UVIGO
WP 3	ALGI, BIOYA, BZN, CENTIV, CTA, GARLAN, IK, ISA, TECNA, UVIGO
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 5	TECNA, TUDublin, UVIGO
WP 6	NUS, UCA, VRI
WP 7	BIOYA, BZN, CENTIV, GARLAN, IK, ISA, UVIGO
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>REGULATION (EC) No 183/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 January 2005, laying down requirements for feed hygiene</p> <p>Summary: This Regulation establishes rules for high level of consumer protection with regard to food and feed safety. It lays down general rules on feed hygiene, conditions and arrangements ensuring traceability of feed and conditions and arrangements for registration and approval of establishments. It shall apply to the activities of feed business operators at all stages, from and including primary production of feed, up to and including, the placing of feed on the market; the feeding of food-producing animals; and the imports and exports of feed from and to third countries.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005R0183&from=EN</p>	
WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 2	ALGI, ANFACO, TECNA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 5	TUDublin, UVIGO
WP 6	NUS, VRI, UCA

WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004, on the hygiene of foodstuffs</p> <p>Summary: This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the principles of primary responsibility for food safety rests with the food business operator; it's necessity to ensure food safety throughout the food chain, starting with primary production; it's importance, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain; the general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility; guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles; it's necessity to establish microbiological criteria and temperature control requirements based on a scientific risk assessment; it's necessity to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard. This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0852&from=EN</p>	
WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 2	ALGI, ANFACO
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 7	BIOYA, IK, UVIGO
<p>DIRECTIVE 2009/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009, on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients</p> <p>Summary: This Directive applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients. It shall not apply to extraction solvents used in the production of food additives, vitamins and other nutritional additives, unless such food additives, vitamins or nutritional additives that are listed. However, it shall be ensured that the use of food additives, vitamins and other nutritional additives does not result in foodstuffs containing extraction solvent residue levels dangerous to human health.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0032&from=EN</p>	
WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 2	ALGI, ANFACO, TECNA
WP 3	ALGI, GARLAN, TECNA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 8	ALGI, ANFACO, EV-ILVO, TECNA, TUDublin

1.2 Regulations to Ensure the Protection of Animals, Environment and the Human Health:

<p>REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004, on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC</p> <p>Summary: The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.</p>	
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<p>This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, which in their finished state are intended to be brought into contact with food; or are already in contact with food and were intended for that purpose; or can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R1935&from=EN</p>	
Work Package	Relevant Partners Involved
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 6	NUS, VRI
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006, on good manufacturing practice for materials and articles intended to come into contact with food</p> <p>Summary: This Regulation lays down the rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food and combinations of those materials and articles or recycled materials and articles used in those materials and articles. It shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R2023&from=EN</p>	
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 6	NUS, VRI
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008, on waste and repealing certain Directives</p> <p>Summary: This Directive lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use. It ensures that the waste policy should be able to minimise the negative effects of the generation and management of waste on human health and the environment. It should also aim at reducing the use of resources, and favour the practical application of the waste hierarchy.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0098&from=EN</p>	
WP 2	ALGI, ANFACO, BIOYA, BZN, CENTIV, CTA, GARLAN, IK, ISA, NUS, TECNA, UCA, UVIGO
WP 3	ALGI, BIOYA, BZN, CENTIV, CTA, GARLAN, IK, ISA, TECNA, UVIGO
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 5	UVIGO, TECNA, TUDublin
<p>DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010, on the protection of animals used for scientific purposes</p> <p>Summary: This Directive establishes measures for the protection of animals used for scientific or educational purposes. This Directive establishes measures for the protection of animals used for scientific or educational purposes. It lays down rules on the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures; the origin, breeding, marking, care and accommodation and killing of animals; the operations of breeders, suppliers and users; the evaluation and authorisation of projects involving the use of animals</p>	

in procedures. This Directive shall apply where animals are used or intended to be used in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes.	
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF	
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 5	NUS, TUDublin, UCA, UVIGO, VRI

1.3 Regulations for the Addition of Vitamins and Minerals or Certain Other Substances to Foods and Feed:

<p>3.3.1 REGULATION (EC) No 1925/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006, on the addition of Vitamins and Minerals and of certain other substances to foods</p> <p>Summary: This Regulation aims to regulate the addition of vitamins and minerals to foods and the use of certain other substances or ingredients containing substances other than vitamins or minerals that are added to foods or used in the manufacture of foods under conditions that result in the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/ or would otherwise represent a potential risk to consumers.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1925&from=EN</p>	
Work Package	Relevant Partners Involved
WP 7	BIOYA, BZN, CENTIV, GARLAN, IK, ISA, UVIGO
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>3.3.2 REGULATION (EC) No 108/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 January 2008, amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0108&from=en</p>	
WP 7	BIOYA, BZN, CENTIV, GARLAN, IK, ISA, UVIGO
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>3.3.3 COMMISSION IMPLEMENTING REGULATION (EU) No 307/2012 of 11 April 2012, establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0307&from=EN</p>	
WP 7	BIOYA, BZN, CENTIV, GARLAN, IK, ISA, UVIGO
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>3.3.4 COMMISSION IMPLEMENTING REGULATION (EU) No 489/2012 of 8 June 2012, establishing implementing rules for the application of Article 16 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0489&from=EN</p>	
WP 7	BIOYA, BZN, CENTIV, GARLAN, IK, ISA, UVIGO

WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>3.3.5 COMMISSION REGULATION (EU) No 1161/2011 of 14 November 2011, amending Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 as regards the lists of mineral substances that can be added to foods</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1161&from=EN</p>	
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>3.3.6 COMMISSION REGULATION (EC) No 1170/2009 of 30 November 2009, amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1170&from=EN</p>	
WP 7	BIOYA, BZN, CENTIV, GARLAN, IK, ISA, UVIGO
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI

1.4 Regulations Concerning the Maximum Level of Contaminants in Food and Feedstuff:

<p>3.4.1 COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006, setting maximum levels for certain contaminants in foodstuffs</p> <p>Summary: This Regulation lays down maximum levels to be applied to dried, diluted, processed and compound foodstuff to ensure an efficient protection of public health. It establishes the maximum levels at a strict level which is reasonably achievable by following good agricultural, fishery and manufacturing practices and taking into account the risk related to the consumption of the food. In order to protect public health, this Regulation ensures to keep the contaminants at levels which are toxicologically acceptable.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1881&from=EN</p>	
Work Package	Relevant Partners Involved
WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 2	ALGI, ANFACO
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 8	ALGI, ANFACO, EV-ILVO, TECNA, TUDublin
<p>3.4.2 COMMISSION REGULATION (EU) No 165/2010 of 26 February 2010, amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins</p> <p>https://www.fsai.ie/uploadedFiles/Reg165_2010.pdf</p>	
WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 2	ALGI, ANFACO
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 8	ALGI, ANFACO, EV-ILVO, TECNA, TUDublin

<p>3.4.3 COMMISSION REGULATION (EU) 2015/1006 of 25 June 2015, amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1006&from=EN</p>	
WP 2	ALGI, ANFACO
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 8	ALGI, ANFACO, EV-ILVO, TECNA, TUDublin
<p>3.4.4 REGULATION (EC) NO 396/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 February , on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC</p> <p>Summary: This Regulation establishes, in accordance with the general principles laid down in Regulation (EC) No 178/2002, in particular the need to ensure a high level of consumer protection and harmonised Community provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin. It shall apply to products of plant and animal origin to be used as fresh, processed and/or composite food or feed in or on which pesticide residues may be present.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005R0396&from=EN</p>	
WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 6	NUS, VRI
WP 8	ALGI, ANFACO, EV-ILVO, TECNA, TUDublin
<p>3.4.5 COMMISSION REGULATION (EC) No 149/2008 of 29 January 2008, amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0149&from=EN</p>	
WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 6	NUS, VRI
WP 8	ALGI, ANFACO, EV-ILVO, TECNA, TUDublin
<p>3.4.6 COMMISSION REGULATION (EC) No 260/2008 of 18 March 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annex VII listing active substance/product combinations covered by a derogation as regards post-harvest treatments with a fumigant</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0260&from=en</p>	
WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 6	NUS, VRI
WP 8	ALGI, ANFACO, EV-ILVO, TECNA, TUDublin
<p>3.4.7 DIRECTIVE 2002/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 May 2002, on undesirable substances in animal feed</p>	

Summary: This Directive lays down rules on feeding stuffs are needed to ensure agricultural productivity and sustainability and to make it possible to ensure public and animal health, animal welfare and the environment. It ensures that the maximum levels of undesirable substances that are set apply in general from the date on which the products intended for animal feed are put into circulation or used, at all stages, and in particular as soon as they are imported. This directive states the importance of the contents in products intended for animal feed be reduced, with due regard to the substances' acute toxicity, bioaccumulability and degradability, in order to prevent undesirable and harmful effects.

https://eur-lex.europa.eu/resource.html?uri=cellar:aca28b8c-bf9d-444f-b470268f71df28fb.0004.02/DOC_1&format=PDF

WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 2	ALGI, ANFACO, TECNA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 6	NUS, VRI
WP 8	ALGI, ANFACO, EV-ILVO, TECNA, TUDublin

3.4.8 COMMISSION REGULATION (EU) No 574/2011 of 16 June 2011, amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for nitrite, melamine, Ambrosia spp. and carry-over of certain coccidiostats and histomonostats and consolidating Annexes I and II thereto.

<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:159:0007:0024:EN:PDF>

WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 2	ALGI, ANFACO, TECNA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 6	NUS, VRI
WP 8	ALGI, ANFACO, EV-ILVO, TECNA, TUDublin

1.5 Regulations Concerning Foodstuffs for Particular Nutritional Uses:

DIRECTIVE 2009/39/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009, on foodstuffs intended for particular nutritional uses

Summary: This Directive concerns the foodstuffs whose composition and preparation must be specially designed to meet the particular nutritional requirements of the persons for whom they are mainly intended. The particular nutritional use shall fulfil the particular nutritional requirements of certain categories of persons whose digestive processes or metabolism are disturbed; or of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or of infants or young children in good health.

https://www.fsai.ie/uploadedFiles/Dir2009_39.pdf

Work Package	Relevant Partners Involved
WP 1	ALGI, ANFACO, BZN, BIOYA, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 2	ALGI, ANFACO, TECNA
WP 7	BIOYA, BZN, CENTIV, GARLAN, IK, ISA, UVIGO

WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION DIRECTIVE 1999/21/EC of 25 March 1999, on dietary foods for special medical purposes</p> <p>Summary: This Directive establishes some basic rules concerning vitamin and mineral substances content that can be laid down for products considered to be nutritionally complete for covering the particular nutritional requirements of the intended user; and such rules for nutritionally incomplete foods that can be laid down only for the maximum levels of these substances as appropriate. It lays down compositional and labelling requirements for dietary foods for special medical purposes.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31999L0021&from=EN</p>	
WP 7	BZN, IK, UVIGO
<p>COMMISSION REGULATION (EC) No 41/2009 of 20 January 2009, concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten</p> <p>Summary: This Regulation lays down provisions for Foodstuffs for particular nutritional uses which have been specially formulated, processed or prepared to meet the dietary needs of people intolerant to gluten and marketed as such. It shall apply to foodstuffs other than the infant formulae and follow-on formulae.</p> <p>fsai.ie/uploadedFiles/Reg41_2009.pdf</p>	
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION REGULATION (EC) No 953/2009 of 13 October 2009, on substances that may be added for specific nutritional purposes in foods for particular nutritional uses</p> <p>Summary: This Regulation lists the possible choice of substances that can be safely used in the manufacture of foods for particular nutritional uses which should be available for the categories of nutritional substances. It ensures that the choice of substances should be based primarily on their safety and subsequently on their availability for use by humans and on their organoleptic and technological properties.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R0953&from=EN</p>	
WP 7	CENTIV, GARLAN, IK, ISA, BZN, UVIGO
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION DIRECTIVE 1999/21/EC of 25 March 1999, on dietary foods for special medical purposes</p> <p>Summary: This Directive establishes some basic rules concerning vitamin and mineral substances content that can be laid down for products considered to be nutritionally complete for covering the particular nutritional requirements of the intended user; and such rules for nutritionally incomplete foods that can be laid down only for the maximum levels of these substances as appropriate.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31999L0021&from=EN</p>	
WP 7	CENTIV, GARLAN, IK, ISA, UVIGO
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI

1.6 Regulations Concerning the Labelling, Presentation and Advertising of Foods and Feed:

<p>REGULATION (EC) No 1924/2006 of 20 December 2006, on Nutrition and Health claims made on foods</p> <p>Summary: This Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. It shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1924&from=en</p>	
Work Package	Relevant Partners Involved
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION REGULATION (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council</p> <p>Summary: This Regulation establishes implementing rules for the applications for authorisation submitted in accordance with Article 15 of Regulation (EC) No 1924/2006; and applications for the inclusion of a claim in the list provided for in Article 13(3) submitted in accordance with Article 18 of Regulation (EC) No 1924/2006. It applies to health claims related to the consumption of a food category, a food, or its constituents (including a nutrient or other substance, or a combination of nutrients/other substances), hereafter referred to as 'food'. This Regulation ensures that the applications for authorisation of health claims adequately and sufficiently demonstrate what the health claim is based on and is substantiated by generally accepted scientific evidence, by taking into account the totality of the available scientific data and by weighing the evidence.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0353&from=EN</p>	
WP 8	BIOYA, BZN, CENTIV, CTA, GARLAN, IK, ISA, NUS, TUDublin, UCA
<p>COMMISSION REGULATION (EC) No 1169/2009 of 30 November 2009, amending Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council</p> <p>https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:314:0034:0035:EN:PDF</p>	
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011, on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004</p> <p>Summary: This Regulation provides the basis for the assurance of a high level of consumer protection in relation to food information, taking into account the differences in the perception of consumers and their information needs whilst ensuring the smooth functioning of the internal market. It establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling. It lays down the means to guarantee the right of consumers to information and procedures for the provision of food information, taking into account the need to provide sufficient flexibility to respond to future developments and new information requirements.</p> <p>https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:en:PDF</p>	

WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION REGULATION (EU) No 1047/2012 of 8 November 2012, amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R1047&from=EN</p>	
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION IMPLEMENTING REGULATION (EU) 2018/775 of 28 May 2018, laying down rules for the application of Article 26(3) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, as regards the rules for indicating the country of origin or place of provenance of the primary ingredient of a food</p> <p>Summary: This Regulation lays down the modalities for the application of Article 26(3) of Regulation (EU) No 1169/2011 where the country of origin or place of provenance of a food is given by any means such as statements, pictorial presentation, symbols or terms, referring to places or geographical areas, except for geographic terms included in customary and generic names where those terms literally indicate origin but whose common understanding is not an indication of country of origin or place of provenance. It shall not apply to geographical indications protected under Regulation (EU) No 1151/2012, Regulation (EU) No 1308/2013, Regulation (EC) No 110/2008 or Regulation (EU) No 251/2014 or protected pursuant to international agreements, nor registered trademarks where the latter constitute an origin indication, pending the adoption of specific rules concerning the application of Article 26(3) to such indications.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0775&from=EN</p>	
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015, on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283&from=en</p>	
WP 7	BIOYA, IK, UVIGO
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION IMPLEMENTING REGULATION (EU) 2017/2469 of 20 December 2017, laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods</p> <p>Summary: This Regulation lays down rules for the implementation of Article 13 of Regulation (EU) 2015/2283 as regards the administrative and scientific requirements for applications referred to in Article 10(1) and the transitional measures referred to in Article 35(3) of that Regulation on novel foods. The applications referred to in Article 10(1) of Regulation (EU) 2015/2283 should contain sufficient information and scientific documentation to allow the Commission to verify their validity and enable the European Food Safety Authority (the Authority) to conduct comprehensive risk assessments of the novel foods. They should include detailed descriptions of the safety evaluation strategy, the raw data, information on the relevance of the test material used in the toxicological studies, and detection and characterisation test methods for the engineered nanomaterials.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2469&from=ES</p>	

WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION IMPLEMENTING REGULATION (EU) 2020/1772 of 26 November 2020, amending Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1772&from=GA</p>	
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>REGULATION (EU) No 609/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 June 2013, on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009</p> <p>Summary: This Regulation provides the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes, and total diet replacement for weight control, taking into account Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC. It establishes a Union list of substances that may be added to one or more of the categories of food and lays down the rules applicable to the updating of that list.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0609&from=EN</p>	
WP 1	ALGI, ANFACO, BIOYA, BZN, CENTIV, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA
WP 2	ALGI, ANFACO, TECNA
WP 7	BZN, IK, UVIGO
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>REGULATION (EC) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003, on additives for use in animal nutrition</p> <p>Summary: This Regulation establishes a Community procedure for authorising the placing on the market and use of feed additives and lays down rules for the supervision and labelling of feed additives and premixtures in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' and consumers' interests in relation to feed additives, whilst ensuring the effective functioning of the internal market. It ensures that only those additives approved under the procedure provided for in this Regulation may be placed on the market, used and processed in animal feeding under conditions set out in the authorisation.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R1831&from=EN</p>	
WP 6	NUS, UCA, VRI
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>REGULATION (EC) No 767/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 July 2009, on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC</p> <p>Summary: This Regulation lays down rules on the placing on the market and use of feed for both food-producing and non-food producing animals within the Community, including requirements for labelling, packaging and presentation. It</p>	

<p>shall apply without prejudice to other Community provisions applicable in the field of animal nutrition and shall not apply to water, either taken in directly by the animals or intentionally incorporated into feed. It shall, however, apply to feed designed to be administered in water.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R0767&from=EN</p>	
WP 6	NUS, UCA, VRI
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION REGULATION (EC) No 429/2008 of 25 April 2008, on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives</p> <p>Summary: This regulation establishes implementing rules concerning the procedure for the authorisation of feed additives under Regulation (EC) No 1831/2003, including rules for the preparation and the presentation of the applications and for the assessment and the authorisation of such additives. The rules provide for the requirements to be satisfied by the dossier accompanying the application. The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0429&from=EN</p>	
WP 6	NUS, UCA, VRI
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION REGULATION (EU) No 432/2012 of 16 May 2012, establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health</p> <p>Summary: This Regulation lays down a list of permitted claims made on foods, as referred to in article 13(3) of Regulation (EC) No. 1924/2006, other than the ones referring to the reduction of disease risk and to children's development and health. The list covers several nutrients, substances, food and food categories and sets out related conditions of use of the claim.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0432&from=EN</p>	
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COMMISSION IMPLEMENTING REGULATION (EU) No 828/2014 of 30 July 2014, on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food</p> <p>Summary: This Regulation applies to the provision of information to consumers on the absence or reduced presence of gluten in food. It lays down rules for certain foods that have been specially produced, prepared and/or processed to reduce the gluten content of one or more gluten-containing ingredients or to substitute the gluten-containing ingredients with other ingredients naturally free of gluten. Other foods are made exclusively from ingredients that are naturally free of gluten.</p> <p>https://www.fsai.ie/uploadedFiles/Reg828_2014.pdf</p>	
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>COUNCIL DIRECTIVE (90/496/EEC) of 24 September 1990, on nutrition labelling for foodstuffs</p>	

<p>Summary: This Directive concerns nutrition labelling of foodstuffs to be delivered as such to the ultimate consumer. It shall also apply to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers. This Directive shall not apply to natural mineral waters or other waters intended for human consumption, diet integrators/food supplements. This Directive shall apply without prejudice to the labelling provisions of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (3) and specific Directives as referred to in Article 4 of that Directive.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31990L0496&from=en</p>	
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>DIRECTIVE 2000/13/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 March 2000, on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs</p> <p>Summary: This Directive concerns the labelling of foodstuffs to be delivered as such to the ultimate consumer and certain aspects relating to the presentation and advertising thereof. It applies to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000L0013&from=EN</p>	
WP 8	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI

1.7 Regulations Concerning the Protection of Data:

<p>REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)</p> <p>Summary: This Regulation lays down rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data. It protects fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data. It ensures that the free movement of personal data within the Union shall be neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data. This Regulation applies to the processing of personal data wholly or partly by automated means and to the processing other than by automated means of personal data which form part of a filing system or are intended to form part of a filing system.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN</p>	
Work Package	Relevant Partners Involved
WP 1	ALGI, ANFACO, CTA, TECNA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 9	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
WP 10	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>DIRECTIVE 2002/58/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 July 2002, concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)</p> <p>Summary: This Directive harmonises the provisions of the Member States required to ensure an equivalent level of protection of fundamental rights and freedoms, and in particular the right to privacy, with respect to the processing of</p>	

<p>personal data in the electronic communication sector and to ensure the free movement of such data and of electronic communication equipment and services in the Community. The provisions of this Directive provide for protection of the legitimate interests of subscribers who are legal persons.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0058&from=EN</p>	
WP 1	ALGI, ANFACO, CTA, TECNA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 9	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
WP 10	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>DIRECTIVE 2006/24/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2006, on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC</p> <p>Summary: This Directive aims to harmonise Member States' provisions concerning the obligations of the providers of publicly available electronic communications services or of public communications networks with respect to the retention of certain data which are generated or processed by them, in order to ensure that the data are available for the purpose of the investigation, detection and prosecution of serious crime, as defined by each Member State in its national law. This Directive shall apply to traffic and location data on both legal entities and natural persons and to the related data necessary to identify the subscriber or registered user. It shall not apply to the content of electronic communications, including information consulted using an electronic communications network.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0024&from=EN</p>	
WP 1	ALGI, ANFACO, CTA, TECNA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
WP 9	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
WP 10	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
<p>REGULATION (EC) No 45/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2000, on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data</p> <p>Summary: In accordance with this Regulation, the institutions and bodies set up by, or on the basis of, the Treaties establishing the European Communities, shall protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data and shall neither restrict nor prohibit the free flow of personal data between themselves or to recipients subject to the national law of the Member States implementing Directive 95/46/EC. It ensures that the independent supervisory authority established by this Regulation, shall monitor the application of the provisions of this Regulation to all processing operations carried out by a Community institution or body.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001R0045&from=EN</p>	
WP 1	ALGI, ANFACO, CTA, TECNA
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA

WP 9	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI
WP 10	ALGI, ANFACO, BZN, BIOYA, CENTIV, CTA, EV-ILVO, GARLAN, IK, ISA, NUS, TECNA, TUDublin, UCA, UVIGO, VRI

1.8 Regulations Concerning the Applicable Financial Rules:

<p>COMMISSION DELEGATED REGULATION (EU) No 1268/2012 of 29 October 2012, on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union</p> <p>Summary: This Regulation lays down the rules of application for Regulation (EU, Euratom) No 966/2012. This Regulation provides and ensures for exceptions which reflect the specific operational features of that sector, mainly as regards procurement and the award of grants, notably because these procedures are carried out by the authorities of third countries receiving Union financial support; as regards procurement, such differences should mainly pertain to types of procedures and thresholds from which they apply; and as regards grants, full financing should be allowed in certain cases, mainly to take the reduced co-financing capacity of the beneficiaries into account.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R1268&from=EN</p>	
Work Package	Relevant Partners Involved
WP 2	ALGI, ANFACO, CTA, UVIGO
WP 3	CTA, TECNA, UVIGO
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA
<p>COMMISSION DELEGATED REGULATION (EU) 2015/2462 of 30 October 2015, amending Delegated Regulation (EU) No 1268/2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2462&from=EN</p>	
WP 2	ALGI, ANFACO, CTA, UVIGO
WP 3	CTA, TECNA, UVIGO
WP 4	ALGI, ANFACO, CTA, EV-ILVO, TECNA