RUSTICA

Demonstration of circular bio-based fertilisers and implementation of optimized fertiliser strategies and value chains in rural communities

Deliverable D3.2:

RUSTICA valorisation concepts in the EU legislative framework

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Summary

RUSTICA takes a sophisticated approach to advance highly innovative fertilisers and preservation of soils by transforming leftover materials from the agri-food chain into added-value bio-based[1] products towards optimised circular agricultural models. The project involves six main technologies targeting microbial biomass, NPK-concentrate, insect biomass, -frass, biochar, and compost as (basic-)products in order to develop sustainable solutions for plant nutrient management and soil fertility which will be integrated into five test cases. Not only these five test regions located in Europe and Colombia, but also the global multi-actor approach of the project point to the international dimension of RUSTICA.

Due to its European and international qualification, the project is subject to an array of legal and political rules which directly or indirectly affect exploitation and impact of its results. Contemplating the scope of RUSTICA, reporting on international agreements dealing with environmental affairs and covering both the European Union and Colombia is incorporated into this ***Deliverable 3.2: RUSTICA valorisation concepts in the EU legislative framework.*** Furthermore, attention is drawn to the relations between the European Union and Colombia as a member of CELAC[2] region and the Andean Community taking into account the collaboration and partnership in the project.

To identify legal challenges at the EU level, a more in-depth analysis of EU secondary law with legally binding character on the value chains proposed by the RUSTICA project is undertaken in the course of this deliverable. The study focuses on the variety of feedstocks, the spectrum of processing methods, requirements of products addressing CE-marked fertilisers and those for organic production. In addition, legal sources are scrutinised on their relevance for applications concerning nutrient supply and protection of the environment in agriculture. To this end, prescriptive and voluntary rules are considered for the entire sector. Specifically, light is shed on the EU organic production scheme: farmers have to abide with further strict legal acts, and for access to the EU organic food market, a precisely defined control regime is imposed.

The project strives for ground-breaking news far beyond of day-to-day operations at present. Subsequently, important EU policies are deliberated with particular reference to the *European Green Deal* as its first priority and important strategies related thereto indicating possible avenues of the future for the RUSTICA concept.

[1] "Bio-based" is defined by the terminology of the European Standard EN 16575:2014.
[2] Community of Latin American and Caribbean States

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Acronyms and Abbreviations

AD	Anaerobic digestion
Art.	Article
As	Arsenic
B	Boron
BAT	Best Available Techniques
BEMP	Best Environmental Management Practices
BREF	Best Available Techniques Reference Document
C	Cobalt
Ca	Calcium
CAC	Codex Alimentarius Commission
CAN	Andean Community (Communidad Andina)
CAP	Carboxylic Acid Platform
CAS	Chemical Abstracts Service
Cat.	Category
Cd	Cadmium
CELAC	Community of Latin American and Caribbean States
CJEU	Court of Justice of the European Union
Cl	Chlor
CMC	Component Material Category
CN	Combined Nomenclature
CO	Colombia
COP21	21st Conference of the Parties
Cr IV	Hexavalent Chromium
Cu	Copper
D	Deliverable
Dm	Dry matter
EAFRD	European Agricultural Fund for Rural Development
EAGF	European Agricultural Guarantee Fund
EBC	European Biochar Certificate

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EBI	European Biochar Industry
EC	Ecuador
ECHA	European Chemicals Agency
ECN	European Compost Network
ECN-QAS	European Compost Network Quality Assurance Scheme
ECOFI	European Consortium of the Organic-Based Fertilizer Industry
EEA	European Environment Agency
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EIPCB	European IPPC Bureau
EMAS	EU Eco-Management and Audit Scheme
EMS	Environmental Management System
ESR	Effort Sharing Regulation
ETS	Emission Trade System
Eq	Equivalent(s)
EU	European Union
EUBIA	European Biomass Industry Association
FAO	Food and Agriculture Organisation of the United Nations
Fe	Iron
GA	Grant Agreement
GAEC	Standards of good agricultural and environmental condition
GATT	General Agreement on Tariffs and Trade of 1994
GATS	General Agreement on Trade in Services
GHG	Greenhouse gas emissions
GMO	Genetically modified organisms
ha	Hectare
Hg	Mercury
HS	Harmonised Commodity Description and Coding System 2007
IBI	International Biochar Initiative
ICCD	International Convention to Combat Desertification

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ILUC	Indirect land use change
IPCC	Intergovernmental Panel on Climate Change
IPIFF	International Platform of Insects for Food & Feed
IUPAC	International Union of Pure and Applied Chemistry
IPIFF	International Platform of Insects for Food and Feed
JIRI	Joint Initiative for Research and Innovation of EU-CELAC
JRC	Joint Research Centre
LAC	Latin America and the Caribbean
LDN	Land Degradation Neutrality
LULUCF	Land use, land use change and forestry
Mg	Magnesium
mm	Millimetre
Mo	Molybdenum
Mn	Manganese
MW	Megawatts
N	Nitrogen
N_2	Dinitrogen
N_2O	Nitrous oxide
Na	Sodium
Nandina	Common Nomenclature for the Designation and Coding of Goods of the Member Countries of the Andean Community
NDC	Nationally determined contributions
NH_3	Ammonia
NH_3-N	Ammoniacal nitrogen
Ni	Nickel
NMVOC	Non-methane volatile compounds
NO_2-	Nitrite
NO_3-	Nitrate
NO_x	Nitrogen oxides
NPK	Nitrogen, Phosphorous, Potassium
OECD	Organisation for Economic Co-operation and Development

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P	Phosphorous
p.a.	per annum (annually)
Pb	Lead
PE	Peru
PFC	Product Function Category
pH	Potential of hydrogen (indicator of acidity or alkalinity)
PHA	Polyhydroxyalkanoates
$PM_{2,5}$	Fine particulate matter ≤ 2,5 micrometer
POPs	Persistent Organic Pollutants
K	Potassium
RE	Renewable Energy
REACH	Registration, Evaluation, Authorization and restriction of Chemicals
RED	Renewable Energy Directive
S	Sulfur
SDG	Sustainable Development Goal
SMR	Statutory management requirements
SVHC	Substances of very high concern
SO_2	Sulfur dioxide
t	Tonnes (metric tonnes if not otherwise specified)
TARIC	Integrated Tariff of the European Communities
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
tpa	tonnes per year
TSE	Transmissible spongiform encephalopathies
UN	United Nations
UNCCD	United Nations Convention to combat Desertification in those Countries experiencing serious Drought and/or Desertification, particularly in Africa (UNCCD)
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
UNFCCC	United Nations Framework Convention on Climate Change
UNSD	United Nations Statistics Division

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USDA	U.S. Department of Agriculture
UVCB	Unknown or or variable composition, complex reaction products or of biological materials
VFA	Volatile fatty acids
VOC	Volatile organic compounds
WCO	World Customs Organization
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wide Fund For Nature
Zn	Zinc

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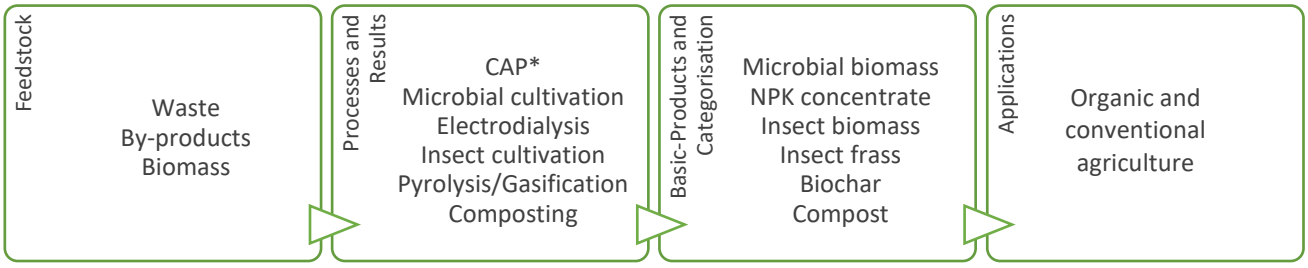
Introduction

RUSTICA aims at boosting the technical validation, demonstration and implementation of bio-based fertiliser and soil improvement methods, thereby using waste and by-products[3] from the fruit and vegetable agro-food system to accomplish closed nutrient cycles. The project encompasses a transdisciplinary multi-actor approach by including six processing options which will be validated in four regions within the European Union (EU) and one in Colombia.

By virtue of its nature, the RUSTICA project is embedded into a multitude of legal and political frameworks. For the areas of this *deliverable 3.2: EU legislation RUSTICA valorisation concepts*, the framework of the EU law is concisely outlined (**chapter one**). It is investigated firstly, with a view on international agreements in the environmental area and secondly, as regards relationships while emphasis is placed on the relations and trade between the EU and Colombia being part of the CELAC region and Andean Community (**chapter two**).

Apart from international affairs, the RUSTICA concept and its value chains are analysed in more detail on legally binding EU secondary law in the sectors waste, by-products and biomass in the context of input/feedstocks. Furthermore, the investigation covers the six processing methods leading to six fertilising (basic-)products. These products are scrutinised with view on the categories of the new EU Fertilising Products Regulation ((EU)2019/1009) and the stipulations of EU organic production, as well as their application in different types of agricultural cultivation (**chapter three**) (**Figure 1**).



**Carboxylic Acid Platform*

Figure 1: Details on RUSTICA concept and value chains
Source: Own depiction based on RUSTICA Grant Agreement (GA)

Depending upon the results concerning the (basic-)products to be developed within RUSTICA, further compounding and blending will be decided in the course of the project in order to achieve optimal solutions for plant supply and soil consistence. Since these prospected product combinations will be defined at later stage of the RUSTICA project, this *D3.2 report* evaluates the six main anticipated fundamental outputs serving as (basic-)products on their own rather than a component of a future mixed fertiliser.

Since the conditions of exploitation and impact for RUSTICA will not solely be affected by current existing legal stimuli and barriers, EU policy and essential strategies indicating priorities and areas of support are outlined in the scope of this work. For this purpose, the European Green Deal, the Circular Economy Strategy, the Bioeconomy Strategy, the Farm to Fork Strategy, and the Biodiversity Strategy of the EU are presented in the context of RUSTICA activities (**chapter four**).

[3] Requirements for by-products are defined, e.g., in Art. 5 of the amended Waste Framework Directive (2008/98/EC) ((EU)2018/851).

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1. RUSTICA - Scope of the analysis and sources of European Union law

The RUSTICA project encompasses not only the European regions Almeria in Spain, Pays de la Loire in France, Flanders in Belgium, Friuli-Venezia Giulia in Italy but also the region Valle del Cauca in Colombia. In this respect, the D3.2 analysis addresses sources of EU law including international agreements (**Figure 2**).

From the three sources of EU law: primary law[4], secondary law[5] and supplementary law[6], this deliverable 3.2 mainly considers unilateral acts of secondary law (EUR-Lex, 2021e). Furthermore, international agreements[7] are concluded by the EU with non-EU countries or international organisations. Even though they are mentioned in the *Treaty on the Functioning of the European Union* (TFEU) (TFEU, 2016), these agreements are not designated as primary or secondary legislation (EUR-Lex, 2021d). They build an own category and following the Court of Justice of the EU (CJEU), they can influence unilateral acts of secondary law which then need to be in accordance with them (EUR-Lex, 2021d) (Ziegler, 2016).

Figure 2: Main sources of law in RUSTICA D3.2 and references in the TFEU
Source: Own depiction based on EUR-Lex (ERUR-Lex, 2021e) (EUR-Lex, 2021d)

Since the project explores waste and by-product resources for fertilising and soil improvement purposes, international agreements (conventions) issuing environmental matters and including the EU and Colombia (EUR-Lex, 2021a) are of specific interest. Furthermore, the EU-CELAC relations (EEAS10, 2021) and the *political dialogue between the EU and Colombia* as a state of the Andean Community which comprises inter alia the *Trade Agreement (EUR-Lex, 2021c)* are indicated in this report.

Unilateral acts of EU secondary law can be categorised relating to their allocation in the TFEU (**Figure 2**) and according to their characteristics. While regulations, directives and decisions are legally binding instruments, opinions, recommendations and the atypical acts are commonly non-binding from the legal perspective (EUR-Lex, 2021f). This D3.2 study mainly focuses on EU legally binding unilateral acts relevant for RUSTICA input, processes and results, product categorisation, and applications (**Figure 1**). In addition, EU policy documents[8] of paramount importance for the project will be part of this RUSTICA Deliverable D3.2.

[4] EU Primary law is mainly composed of the EU Treaties (Treaty on the EU (TEU) (TEU, 2016), Treaty on the Functioning of the EU (TFEU), and the Treaty on the European Atomic Energy Community — Euratom), the Charter of Fundamental Rights, and general principles put in place by the Court of Justice of the European Union (EUR-Lex, 2021e).

[5] EU Secondary law covers two categories of unilateral acts: the five types which are laid down in TFEU Art. 288 and those which are not listed in this Article of the TFEU (EUR-Lex, 2021e).

[6] EU Supplementary law is not defined in the EU Treaties and comprises case-law of the Court of Justice of the EU (CJEU), international law and general principles of law (EUR-Lex, 2021e).

[7] International Agreements are reflected, e.g., in the TFEU (Art. 216) and rules on trade are presented in Art. 207 (EUR-Lex, 2021d).

[8] Including ***The European Green Deal***, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS The European Green Deal; COM/2019/640 final

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2. RUSTICA in the context of EU international policy and law

The project strives for bio-based fertilisers and soil improvement technologies based on waste and by-products in the EU and in Colombia. Thus, international policy and agreements involving the EU, CELAC and specifically the state Colombia are of specific relevance and briefly treated in this D3.2 study.

2.1. International agreements as regards the environment

Since RUSTICA aspires to have fewer adverse environmental impacts than traditional value chains, international agreements and conventions in the sector "environment" are scrutinised in this work.

From 20 chapters constituting the Directory of international agreements in the EU legal database EUR-Lex, chapter 15 comprises "Environment, consumers and health protection". To date, the section "*Environment*" covers 74 documents (EUR-Lex, 2021a) of which those conventions, touching directly or indirectly RUSTICA areas and referring to both the EU and Colombia, are selected and included into this section of the D3.2 report.

2.1.1. Basel Convention[9]

Adopted on 22nd of March 1989, the *Basel Convention*, which introduces rules for transboundary movement of waste, came into force on 5th of May 1992. At the time of writing, it has been signed by 188 parties (UNEP, 2021b) and reported as the "*most comprehensive global environmental agreement on hazardous wastes and other wastes"* while *"other wastes"* - if transboundary moved - are defined in Annex II *"…waste requiring specific consideration*" comprising household waste (Y46) *(UNEP, 1992a),* residues from incinerated household waste (Y47) or plastic waste (Y48) (UNEP, 2019b).

Table 1: Excerpt of Annex IX included in the Basel Convention (2019)

Section and Code	Basel Convention Update 2019 – Annex IX (List B) (Excerpt)
	Wastes arising from agro-food industries provided it is not infectious
B 3060	Wine lees
	Dried and sterilized vegetable waste, residues and byproducts, whether or not in the form of pellets, of a kind used in animal feeding, not elsewhere specified or included
	Degras: residues resulting from the treatment of fatty substances or animal or vegetable waxes
	Waste of bones and horn-cores, unworked, defatted, simply prepared (but not cut to shape), treated with acid or degelatinised
	Fish waste
	Cocoa shells, husks, skins and other cocoa waste
	Other wastes from the agro-food industry excluding by-products which meet national and international requirements and standards for human or animal consumption

Source: UNEP - Secretariat of the Basel Convention (UNEP, 2019b)

[9] *"Convention as a specific term: Whereas in the last century the term "convention" was regularly employed for bilateral agreements, it now is generally used for formal multilateral treaties with a broad number of parties…"* UN Definitions (UN, 2021c)

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A new regime of controlling the international transport of hazardous and other wastes has been established by the *Basel Convention*. Under the premise that exports of these wastes are confirmed by a prior written approval of the importing country and, on the other hand, those that export a waste have no concerns as regards an appropriate management by the recipient, transports can take place if all requirements of the Convention are met (EU, 2021c).

The *Basel Convention* was updated at several times, and since 1998 Annex IX is included (UNEP, 2021c). Annex IX incorporates wastes which will be only covered by Art. 1 paragraph 1(a) defining the scope of the Basel Convention for "*hazardous wastes*" if they are contaminated with *"wastes to be controlled"* as defined in Annex I (e.g., *Y1 clinical waste*) and posing a property of hazardous wastes as defined in Annex III (e.g., *UN Class 9, Code H12 Ecotoxic*). Section *B3 Wastes containing principally organic constituents, which may contain metals and inorganic materials* of Annex IX includes "*B3060 Wastes arising from agro-food industries provided it is not infectious".* The materials compiled by Code B3060 are reflected in **Table 1** (UNEP, 2019b). (Please view also section 3.1.1.4.)

RUSTICA does neither issue hazardous waste nor specifically household waste[10] [11], but agri-food waste is a crucial source of input for the project. Hence, in case of international transports, rules of the *Basel Convention* would need to be taken into account.

For this purpose, it needs to be stressed that the Basel Convention sets principles for waste minimisation and promotes waste management and disposal to be as close as possible to the point of waste origin. Furthermore, it commits the parties to take measures for reduction of transboundary movement of waste (Art. 4) (UNEP, 1992a). Aimed to tailored solutions for organic waste valorisation at intra-regional and inter-regional scale, RUSTICA efforts are towards alternatives to long-distance transports of waste as much as possible.

2.1.2. Stockholm Convention

The *Stockholm Convention on Persistent Organic Pollutants (POPs)* was adopted on 22nd of May 2001 and entered into force on 17th of May 2004. The convention addresses both "measures to reduce or eliminate releases from intentional production and use" (Art. 4) and measures on the reduction or elimination "*of releases from unintentional production* "(Art. 5). In its Annex C, parts II and III, the convention refers to source categories and the potential for a formation and release of POPs in case of incomplete combustion or chemical reactions. Among the source categories of releases from unintentional production are (UNEP, 2019a):

- Part II (a): "*waste incinerators, including co-incinerators of municipal, hazardous or medical waste or of sewage sludge;"*
- Part III (a): *"open burning of waste, including burning of landfill sites;"* (UNEP, 2019a)

Due to its highly innovative approach, the RUSTICA project is expected to provide environmentally friendly added-value solutions to eliminate open burning of organic waste.

[10] Household waste contents are not defined by the Basel Convention. But from about 2 billion of estimated global annual municipal waste generation, the organic fraction is reported as the most important constituting 47% organic waste at present (Chen, Bodirsky, Krueger, Mishra, & Popp, 2020).

[11] Statistical definition of household waste by UNSD and OECD: *"Household waste refers to waste material usually generated in the residential environment. Waste with similar characteristics may be generated in other economic activities and can thus be treated and disposed of together with household waste."* (UN, 1997) (OECD, 2001b)

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2.1.3. Rotterdam Convention

In contrary to the aforementioned *Basel Convention* and *Stockholm Convention*, the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* does not include waste or its treatment. In Art. 3, the scope of the Rotterdam Convention is defined to apply to (UNEP-FAO, 2019):

- *"banned or severely restricted chemicals; and*
- *severely hazardous pesticide formulations."* (UNEP-FAO, 2019)

It was adopted on 10 September 1998 and came into force on 24 February 2004 (UNEP-FAO, 2021) and aims *at "shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals".* Furthermore, it promotes exchange of information about their properties, *"by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties."* (Art. 1) (UNEP-FAO, 2019).

RUSTICA aims at high-level and sustainable bio-based fertiliser solutions to support a thriving organic and conventional agriculture. Thus, albeit the project is not focused on pesticides, due to its scope and scale, its research including a wide variety of substances benefitting crops and promoting healthy soils could result in less pesticide consumption. As such, the project is in line with the Rotterdam Convention.

2.1.4. Convention on Biological Diversity

The *Convention on Biological Diversity* applies since the 29th of December 1993 (UNEP, 2021d). In its preamble the values of biological diversity and its constituents are highlighted (**Figure 3**)(UNEP, 1992b):

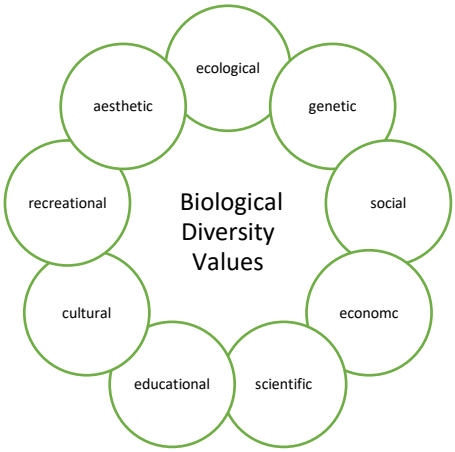

Figure 3: Values of biological diversity
Source: Own depiction based on the Convention on Biological Diversity (UNEP, 1992b)

Its objectives encompass to conserve biological diversity[12], and to use its constituents in a sustainable manner. The balanced and equitable sharing of benefits entailed with the use of genetic resources[13], in particular adequate access to genetic resources and appropriate transfer of the technologies concerned, under

[12] *"'biological diversity' means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems;"* (UNEP, 1992b)

[13] *"'genetic resources' means genetic material of actual or potential value;"* (UNEP, 1992b)

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consideration of all rights over those resources and to technologies, as well as appropriate funding is aimed by this convention (UNEP, 1992b).

The sovereign right of a state to exploit its own resources according to its own environmental law but without infringement of the environment of other states or of areas outside of its national jurisdiction is laid down in the *Convention on Biological Diversity* as well. Transnational and international collaboration is encouraged and the elaboration of strategies, plans and programmes for conservation and sustainable use of biological diversity shall be presented (UNEP, 1992b).

It is referred to identifying and monitoring of ecosystems and habitats with specific properties (e.g., with high diversity), species and communities which are e.g., threatened, and genomes and genes which are of particular economic, scientific or social relevance (UNEP, 1992b).

Conservation of biodiversity shall include inter alia a setup of protected areas and their management, sustainable development in adjoining areas, rebuilt of degraded ecosystems and enable survival and thriving of threatened species, fostering traditional use of biological resources[14] and to prevent threatening through alien species. In addition, the convention emphasizes the necessity of taking measures to encounter the risks related to the use and release of living modified organisms as a product of biotechnology[15] which could influence the maintenance of biological diversity. According to projects which are anticipated to have an undesired effect on biodiversity, procedures including an environmental impact assessment shall be introduced. Moreover, contracting parties shall provide conditions for a facilitated access to genetic resources for environmentally friendly uses to other contracting parties (UNEP, 1992b).

With regard to RUSTICA which elaborates technologies for conversion of waste targeting a sustainable and environmentally friendly agriculture by safeguarding biological resources, the *Convention on Biological Diversity* creates a basis for protection of such resources at the international level.

2.1.5. United Nations Convention to Combat Desertification in those countries experiencing serious drought and/or desertification (UNCCD)

The *United Nations Convention to Combat Desertification in those countries experiencing serious drought and/or desertification*, particularly in Africa (UNCCD), which was adopted in Paris on 17 June 1994, is in force since 26 December 1996.

As the only legally binding international agreement, the UNCCD aims to counteract desertification and the impacts of drought e.g., by means of international cooperation, enhanced productivity of land, preservation and management of land and water resources taking into account sustainability criteria. Thereby, including the local community level is of particular importance (UNCCD, 1994). The Convention links "Combating Desertification" with activities of "*integrated development of land in arid, semi-arid and dry sub-humid areas for sustainable development"* in pursuing the objectives as depicted in **Figure 4**.

Apart from general obligations (e.g., attention should be paid to the creation of a favorable international economic environment for affected country parties), specific obligations are defined for affected country parties (e.g., establishing "*strategies and priorities, within the framework of sustainable development plans")*

[14] *"'biological resources' includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity;"* (UNEP, 1992b)

[15] *"'biotechnology' means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;"* (UNEP, 1992b)

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and developed country parties (e.g., the provision of financial resources and other versions of help to assist affected developing country parties) (UNCCD, 1994).

As an important part of the convention, scientific collaboration and dedicated action plans at the national sub-regional and regional level shall be established for its implementation. Specific regional implementation for Africa, Asia, the Northern Mediterranean, Central and Eastern Europe[16] (Annex V added in 2001) (UNCCD, 2001, 2021b) (UNCCD, 2021a) as well as Latin America and the Caribbean is indicated. Annex III provides guidelines for the latter region (UNCCD, 1994) represented in the RUSTICA project.

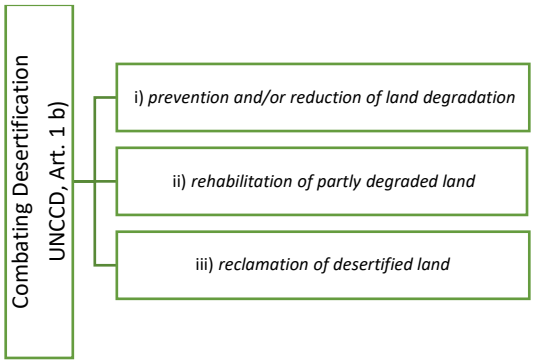

Figure 4: UNCCD: Objectives of activities combating desertification
Source: Own depiction based on UNCCD, Art. 1 b) (directly cited) (UNCCD, 1994)

The region is characterised by particular conditions of wide and vulnerable land areas, the availability of one of the most vast ecosystems worldwide, practices resulting from complex interactions of various factors (e.g. political, economic, biological) and a strong decrease of ecosystem productivity. Taking these characteristics into account, action programmes shall be prepared and reviewed by involving non-governmental organisations and local populations in policy planning and decision making (UNCCD, 1994).

Owing to its individual situation, an affected country party of the region *Latin America and the Caribbean*, may take an action as appropriate, such as *"achieving food security and sustainable development and management of agricultural, livestock-rearing, forestry and multipurpose activities".* Evolving, adapting, adopting and transfer of existing and new environmentally friendly technologies shall be encouraged and international cooperation requirements in support of national efforts shall be identified (UNCCD, 1994).

A new UNCCD 2018-2030 Strategic Framework was adopted in 2017 and is reported as "the most comprehensive global commitment to achieve Land Degradation Neutrality (LDN)". Besides, its contribution to the *Agenda for Sustainable Development 2030* of the United Nations (UN, 2021d) and Sustainable Development Goal 15 (SDG 15), target 15.3: *"by 2030, combat desertification, restore degraded land and soil, including land affected by desertification, drought and floods, and strive to achieve a land degradation-neutral world"* is underlined (UNCCD, 2017) (UNCCD, 2021b).

The EU-international research collaboration of RUSTICA partners takes measures for fertilisers produced in a sustainable way and amelioration of soils envisaging optimisation of soil fertility and reduction of soil degradation. As such, the project is totally in accordance with the UNCCD.

[16] Among the 19 countries of the Central and Eastern Europe Region which are reported to be Parties of the UNCCD, 15 have declared to be affected country Parties. Four (Bulgaria, Latvia, Romania and Slovakia) out of the 15 countries are EU Member States (UNCCD, 2021a).

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2.1.6. United Nations Framework Convention on Climate Change (UNFCCC)

Like the previously mentioned Convention on Biological Diversity and the UNCCD, the United Nations Framework Convention on Climate Change (UNFCCC) has its roots in the "*Earth Summit*" in Rio de Janeiro in 1992 (UN, 2021a). It came into force on the 21st of March 1994 and at time of writing, a membership of 197 countries is reported (UNFCCC, 2021c).

The UNFCCC aims to "*stabilize the concentrations of greenhouse gases in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system*". Furthermore, this level should be accomplished within a timeframe appropriate "*to allow ecosystems to adapt naturally to climate change*", to guarantee "*that food production is not threatened"* and to enable economic development to make progress in a sustainable way (UNFCCC, 1992).

Obligations (Art. 4) resulting from the UNFCCC are, for example, the following (UNFCCC, 1992): development, maintenance and publication of "national inventories of anthropogenic emissions by sources and their removals by sinks of all greenhouse gases" which are not subject to the *"Montreal Protocol"*[17] and the promotion and cooperation of practices and processes including but not limited to technology transfer *"that control, reduce or prevent anthropogenic emissions of greenhouse gases*[18] *in all relevant sectors, including the energy, transport, industry, agriculture, forestry and waste management sectors"* (UNFCCC, 1992).

At COP21, the Paris Agreement was adopted on 12th of December 2015 (UNFCCC, 2021b) and to date, a ratification of 191 parties including the EU and Colombia has been published (UN, 2021b). In particular, by referring to pre-industrial levels, the maintenance of the "*increase in the global average temperature to well below 2°C"* and the pursue of endeavors to "*limit the temperature increase to 1.5°C"* are laid down in the Agreement (UN, 2021a).

Nationally determined contributions (NDC) (UNFCCC, 2021a) of the EU submitted in 2016 were to reduce ≥ 40% domestic greenhouse gas emissions by 2030 in comparison to 1990 (EU, 2015), and by the update from 2020, a commitment to a net reduction of ≥ 55% was published (EU, 2020b). In 2018, Colombia defined a reduction target of 20% for a "business as usual scenario" by 2030 compared to 2010 which could be increased to 30% in case of international support is provided (CO, 2018). In 2020, a maximum of 169.44 million t of CO_2 eq p.a. by 2030 corresponding to a reduction target of 51% compared to the baseline in 2015, was published for Colombia (CO, 2020) (WWF, 2020).

RUSTICA presents a holistic approach and new models to develop and measure the possibilities of converting organic waste into high-value products with low emission effects.

[17] The *Montreal Protocol on Substances that Deplete the Ozone Layer* rules the production and consumption of nearly 100 man-made chemicals referred to as ozone depleting substances (ODS). It covers those chemicals which damage the stratospheric ozone layer if entering into atmosphere. Adopted in 1987, it is the only treaty ratified by each of the 198 UN Member States (UNEP, 2021a).
[18] Except of those controlled by the Montreal Protocol

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2.2. Multilateral and bilateral relations EU - Colombia

There is a variety of relations between the EU and Colombia occurring at different levels (**Figure 5**). For the purpose of this report, light is shed on the partnership of the EU and the Community of Latin America and Caribbean States (Comunidad de Estados de América Latina y el Caribe) (CELAC) as well as further multilateral and bilateral political dialogues involving the EU and Colombia. Specific attention is paid to the Trade Agreement provisionally applied since 2013 presenting provisions for the trade of goods inter alia to be contemplated for RUSTICA products.

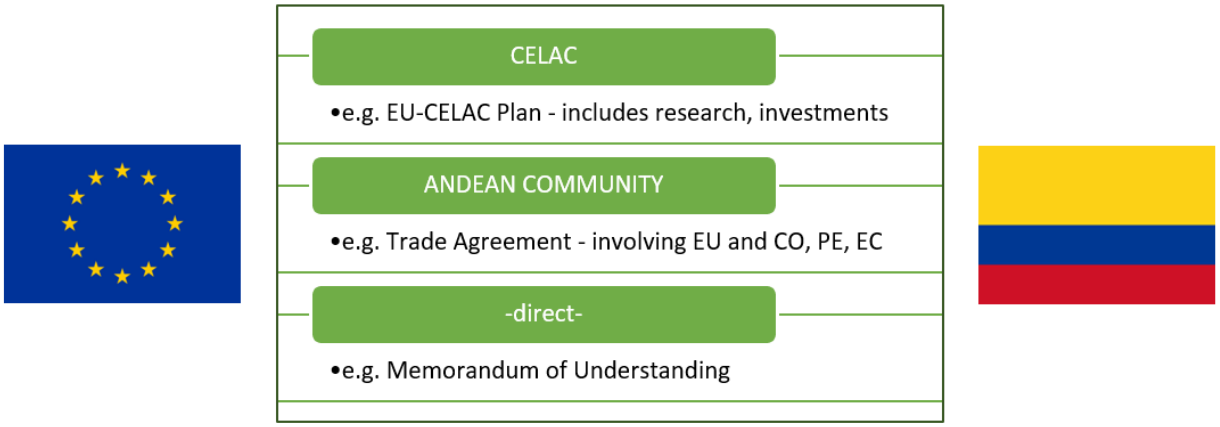

Figure 5: Important routes of EU - Colombia relations
Source: Own depiction based on section 2.2 of this D3.2 report

2.2.1. Bi-regional partnership EU - CELAC

CELAC was established in 2011 and originally composed of 33 partners[19] (NTI, 2021). Because of its relevance as being the "*official counterpart for the region-to-region Summit process and strategic partnership"* of the EU (EEAS10, 2021), the policy is briefly outlined in this RUSTICA report D3.2.

At the occasion of the EU-CELAC Summit in 2015, the Political Declaration on a *'Partnership for the next generation'*, the Brussels Declaration "*Shaping our common future: working together for prosperous, cohesive and sustainable societies for our citizens*" (EUCouncil, 2015a), as well as an *EU-CELAC Action Plan* containing 10 key areas, were adopted. From the aforementioned key areas (EUCouncil, 2015b), the following are of interest to the RUSTICA project:

- *Science, research, innovation and technology*;
- *Sustainable development; environment; climate change; biodiversity; energy;*
- *Investments and entrepreneurship for sustainable development (EUCouncil, 2015b).*

[19] To date (12.04.2021) 32 partners: Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Dominica, Ecuador, El Salvador, Grenada, Guatemala, Co-operative Republic of Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Santa Lucia, Federation of Saint Kitts and Nevis, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago, Uruguay, Venezuela. (Brazil left in 2020.)

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Already in 2010, the EU-CELAC *Joint Initiative for Research and Innovation (JIRI)* was founded and six thematic areas are reported (De Sole, 2019), which are depicted in **Figure 6**. At the Summit in Brussels in 2015, a significant step forward has been made towards a common research area encompassing the three pillars "*researcher mobility, access to research infrastructure and jointly addressing common global challenges*" (EEAS10, 2021).

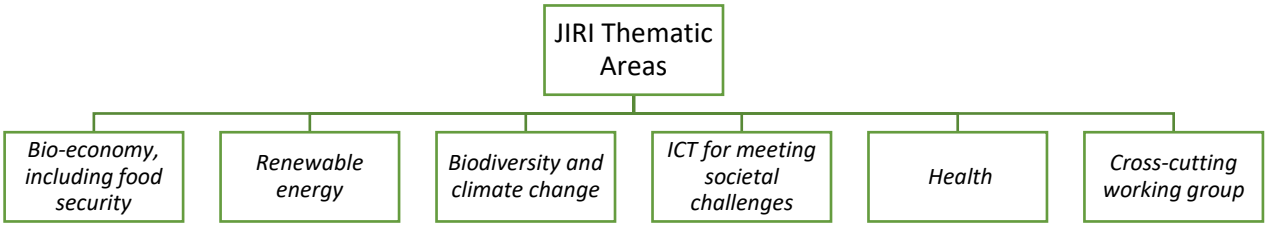

Figure 6: EU-CELAC JIRI Thematic Areas
Source: Own depiction based on De Sole, 2019 (De Sole, 2019)

Both Horizon 2020[20] and Erasmus+ are open to individual researchers and scientists as well as research institutions in the CELAC region (EEAS10, 2021). The RUSTICA project fits into these options.

With view on global challenges, it needs to be pointed out that climate change is one of the major sectors of cooperation between the EU and CELAC countries which is expressed by dedicated programmes and crosscutting actions, e.g., the EUROCLIMA+ Programme. Colombia is among the 18 participating countries (EEAS10, 2021) (EU, 2021a).

A trade volume of €221.6 billion of goods between the EU and LAC has been achieved in 2017. The EU is the third trade partner of LAC and the first investor in the region (EEAS10, 2021).

2.2.2. Political Dialogue, CAN and Trade Agreement EU - Colombia

Besides CELAC, the political relations between the EU and Colombia have a long tradition in other multilateral and bilateral dialogues. Already since 1998, emphasizing democratic principles, an intensification of cooperation and in particular the economic cooperation which included to *"contribute to the sustainable development…"* are determined by the *Framework Agreement on Cooperation between the European Economic Community and the Cartagena Agreement and its Member States*[21] (EU, 1998) (EUR-Lex, 2021b). Today, the Andean Community (Communidad Andina) (CAN) is composed of four members including Colombia (CAN, 2021b). As an example of bilateral relations, the *Dialogue on Human Rights* which also refers to trade-related human rights topics (2012) between the EU and Colombia is documented since 2008 (EU, 2016a) (EU, 2016b). And recently, a *"Memorandum of Understanding on an Agenda of enhanced political and sectoral dialogue and cooperation for the next decade"* including an *"ambitious environmental agenda"* has been signed by the EU and Colombia (EC, 2021o). For the purpose of this D3.2 report, the focus is on the ***Trade Agreement*** between the EU and Colombia as a member of CAN (EC, 2021r).

In 2012, the ***Trade Agreement*** was signed and has been provisionally applied for the CAN members Colombia and Peru since 2013. For Ecuador (EU, 2020a) as a further Member State of the CAN, the agreement applies provisionally since 2017 the way of proceed is the same since the accession to the agreement in 2017 (EC, 2021r). The *Trade Agreement* defines respect for democratic principles and fundamental human rights as a

[20] Colombia is also on the List of Participating Countries in Horizon Europe

[21] In the Cartagena Agreement, the Andean Pact was established in 1969. Today, it is known as the Andean Community (Communidad Andina (CAN)) and represented by the Member States Bolivia, Colombia, Ecuador and Peru. (CAN, 2021b)

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substantial part of it and establishes a Free Trade Area (Art. 3) (EU, 2012) in accordance with Art. XXIV[22] of the *General Agreement on Tariffs and Trade of 1994* (GATT 1994) (WTO, 2021b) and Art. V[23] of the *General Agreement on Trade in Services* (GATS) (WTO, 2021a).

Among the objectives pursued by the ***Trade Agreement*** are the following: trade liberalisation for goods and services in a progressive manner (in compliance with GATT and GATS); trade and investment facilitation including those for payments and capital markets; opening of government procurement markets; protection of intellectual property rights; economic activities under the principles of free competition; effective instruments for dispute settlements; promoting and integrating the objective of "*sustainable development*" into the trade relations; and cooperating for technical assistance and enforcing of the trade capacities in order to contribute to the implementation of this Agreement (EU, 2012) (EU, 2020a).

The parties EU and a state of the CAN confirm their rights and duties under the *Agreement establishing the World Trade Organization* (WTO) (WTO, 2021c), and as it is clearly reflected in the ***Trade Agreement****:* it does not apply to relations between the Members of the *Andean Community* (EU, 2012) (EU, 2020a).

From the 14 Titles of the ***Trade Agreement***, the *Title IX* is related to *Trade and Sustainable Development.* It focuses on international labour standards and environmental issues (Bartels, 2013). The *Title* contains inter alia the following goal: "*The promotion of the conservation and sustainable use of biological diversity and of natural resources"*. The parties corroborate their commitment to international environmental agreements including those mentioned in section 2.1[24]. In addition, e.g., the importance of the issue of climate change is elucidated in *Title IX* (EU, 2012) (EU, 2020a).

The ***Trade Agreement*** applies to fertilisers as well (EU, 2012). Therefore, the scope of products and tariff eliminations are briefly discussed here for goods originating in Colombia to be imported into the EU and vice versa. As regards the tariff nomenclature, the *Harmonised Commodity Description and Coding System 2007 (HS Nomenclature),* also designated as the *Harmonised System* (HS)[25] (WCO, 2018) (WCO, 2021) is under use.

Table 2: Trade Agreement: Main fertiliser categories for EU imports from Colombia

CN 2007	Imports to EU - Description of main fertiliser categories
3101 00 00	Animal or vegetable fertilisers, whether or not mixed together or chemically treated; fertilisers produced by the mixing or chemical treatment of animal or vegetable products
3102	Mineral or chemical fertilisers, nitrogenous
3103	Mineral or chemical fertilisers, phosphatic
3104	Mineral or chemical fertilisers, potassic
3105	Mineral or chemical fertilisers containing two or three of the fertilising elements nitrogen, phosphorus and potassium; other fertilisers; goods of this chapter in tablets or similar forms or in packages of a gross weight not exceeding 10 kg

Source: Trade Agreement EU - Colombia from 2012 amended in 2016 (EU, 2012, 2020a)

[22] GATT 1994, Art. XXIV sets inter alia rules for free trade areas (WTO, 2021b)
[23] GATS, Art. V refers to *"Economic Integration"* (WTO, 2021a)
[24] Except of section 2.1.5: UN Convention to Combat Desertification
[25] HS is defined by the International Convention on the Harmonized Commodity Description and Coding System (HS Convention) which was elaborated by the World Customs Organization (WCO) and came into force in 1998. It is under use in more than 200 countries and enables more than 5000 items to be identified by a six-digit code.

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According to imports to the EU, the Combined Nomenclature (CN) (EC, 2021c) is the instrument for tariff classification[26] in the *Trade Agreement*. Chapter 31 depicts fertilisers and presents five main product categories (**Table 2**) (EU, 2012) (EU, 2020a).

All fertiliser types imported by the EU and originating in Colombia that are integrated into the ***Trade Agreement*** belong to the tariff line staging category "0" which means that customs duties shall be eliminated totally and the fertilisers "*shall be free of any customs duty on the date this Agreement enters into force*" (EU, 2012) (EU, 2020a).

For goods imported into Colombia, the NANDINA nomenclature[27] (CAN, 2017), including the HS and considered as "*one of the most important harmonized foreign trade instruments available to the Andean Community"* (CAN, 2021a), is under use in the *Trade Agreement*. The designations of the five main fertiliser categories in NANDINA (CAN, 2017) correspond to those depicted in **Table 2**, but for fertilisers imported into Colombia covered by the *Trade Agreement* solely sub-categories are deployed in the ***Trade Agreement*** (EU, 2012) (EU, 2020a). Examples of goods are given in **Table 3**.

Table 3: Trade Agreement EU - Colombia: Imports into Colombia - Examples of fertilisers

NANDINA Subheading	Imports into Colombia - Examples of Fertilisers	Category
3101001000	Seabird guano	A
3101009000	Other	A
3105200000	Mineral or chemical fertilisers containing the three fertilising elements nitrogen, phosphorus and potassium	C
3105510000	Containing nitrates and phosphates	C

Source: Trade Agreement EU - Colombia from 2012 amended in 2016 (EU, 2012) (EU, 2020a)

Custom duties on staging category "A" shall be absolutely eliminated and custom duty applies no more to these fertilisers while "C" expresses that custom duties will be eliminated in six equal cuts starting at *"the date this **Trade Agreement** enters into force*" and *"the remaining cuts shall be made on 1 January of the successive years"* (EU, 2012) (EU, 2020a).

Depending on the RUSTICA results new perspectives could be opened with respect to its international collaboration and partnership for a demand and impact of innovative products beyond local and regional deployment.

[26] The tariff classification of the EU is based on two components: 1. Combined Nomenclature (CN) enclosing the HS system and 2. Integrated Tariff (TARIC).
CN is established by Council Regulation (EEC) No 2658/87 is an eight-digitate code encompassing HS and two additional subheading providing information on rates of duties and statistical purposes. TARIC which is also set by (EEC) No 2658/87 is applied for Community measures on imports or exports between Member States. It is located at the 10th and 11th level of the code while the 9th position of the CN remains reserved for national statistics provisions ((EEC)No2658/87).

[27] NANDINA (Common Nomenclature for the Designation and Coding of Goods of the Member Countries of the Andean Community) is in force since 1991 and harmonized at 8-digit level.

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3. RUSTICA Value Chains and EU Secondary Law - legally binding

In this chapter, elements of RUSTICA value chains from resources over manufacturing to products and their application are primarily deliberated in the scope of EU legally binding unilateral acts (**Figure 7**).

Figure 7: RUSTICA elements scrutinised in the context of EU Secondary Law - legally binding unilateral acts
Source: Own depiction based on the RUSTICA concept

3.1. The role of feedstocks

RUSTICA explores an array of resources including but not limited to fruit and vegetable residuals deriving from various stages of the food supply chain or other agricultural cultivation activities (**Figure 8**) and serving as an input towards achieving high-class and environmentally sound fertilisers. Hence, legislation dealing with waste, by-products and biomass is indicated in this section.

Agricultural cultivation	Food processing	Food distribution
• e.g., pruning from orchards and vineyards	• e.g., pomace from grapes and other fruits	• e.g., vegetable waste from the groce market

Figure 8: RUSTICA - examples of input from various stages of the food chain or other agricultural activities
Source: Own depiction based on the RUSTICA concept

3.1.1. Waste

As it is ruled by Art. 3 of the Directive on waste 2008/98/EC "*'waste' means any substance or object which the holder discards or intends or is required to discard;"* (2008/98/EC). The amended Directive explicitly defines biowaste, food waste, municipal waste and by-products (2008/98/EC) ((EU)2018/851) while it is referred to biodegradable waste by the Directive on landfill of waste (1999/31/EC).

As depicted in **Table 4**, the Directive on waste does not apply to non-hazardous agricultural material to be used for farming, forestry or biomass for generating energy. It excludes animal by-products except if they are subject to certain destinations or valorisations (2008/98/EC) and substances containing no animal by-products which qualify for feed materials ((EU)2018/851).

Specific attention to materials from agriculture and relevant for the RUSTICA project will be drawn at later stage of this D3.2 report (e.g., section 3.1.3). Supply chains with animal by-products are subject to thorough health and environmental stipulations if applied to gaining fertilisers under the RUSTICA scheme (e.g., section 3.2.4). Besides, a detailed examination of feeding materials for insects encompassing the "waste aspect" is elaborated in section 3.2.4.

Table 4: Waste fully or partly excluded from 2008/98/EC and (EU) 2018/851

Fully excluded from 2008/98/EC	Partly[28] excluded from 2008/98/EC and (EU) 2018/851
"faecal matter, if not covered by paragraph 2(b)[29], straw and other natural non-hazardous agricultural or forestry material used in farming, forestry or for the production of energy from such biomass through processes or methods which do not harm the environment or endanger human health" (Art. 2(f))	*"animal by-products including processed products covered by Regulation (EC) No 1774/2002, except those which are destined for incineration, landfilling or use in a biogas or composting plant;"*
	"substances that are destined for use as feed materials as defined in point (g) of Article 3(2) of Regulation (EC) No 767/2009[30] of the European Parliament and of the Council and that do not consist of or contain animal by-products."

Source: Own depiction based on legal sources: (2008/98/EC); ((EU)2018/851)

3.1.1.1. Waste hierarchy

The ***waste hierarchy*** (Art. 4) (**Figure 9**) is presented by the Directive on waste to be applied as a "*priority order in waste prevention and management legislation and policy"* (2008/98/EC). The waste hierarchy enshrines five strict definitions[31], starting from the product stage over waste treatment to disposal (2008/98/EC) ((EU)2018/851). On the other hand, the Directive allows also deviations and specific waste streams, if, for example, the ideal environmental outcome can be achieved by including life-cycle-thinking into waste management (2008/98/EC).

In general, there are no specific waste types linked with the waste hierarchy in Art. 4. But as an example how Member States could support the waste hierarchy, "*fiscal incentives for donation of products, in particular food"* is listed in the Annex IVa of the amended Directive (2008/98/EC) ((EU)2018/851).

In literature, the waste hierarchy is acknowledged as well. In a more recent publication, it is interpreted in terms of food waste taking into account the manifold facets of this issue and the following indications: *prevention of waste* includes a measured reduction of waste raw materials, ingredients and products therefrom while *reuse* means inter alia *"sent to animal feed".* Furthermore, anaerobic digestion (AD) and composting are allocated to *recycling,* and generating energy by incineration is put to recovery by the authors (EEA, 2020).

[28] to the extent that other EU legislation applies.

[29] 2(b) refers to "*land (in situ) including unexcavated contaminated soil and buildings permanently connected with land;"*

[30] "***feed materials'*** *means products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures*;" ((EC)No767/2009).

[31] ***"'prevention'*** *means measures taken before a substance, material or product has become waste, that reduce:*
(a) the quantity of waste, including through the re-use of products or the extension of the life span of products;
(b) the adverse impacts of the generated waste on the environment and human health; or (2008/98/EC)
(c) the content of hazardous substances in materials and products;" ((EU)2018/851)
""preparing for re-use' *means checking, cleaning or repairing recovery operations, by which products or components of products that have become waste are prepared so that they can be re-used without any other pre-processing;" (2008/98/EC)*
"'recycling' *means any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and the reprocessing into materials that are to be used as fuels or for backfilling operations;" (2008/98/EC)*
"'recovery' *means any operation the principal result of which is waste serving a useful purpose by replacing other materials which would otherwise have been used to fulfil a particular function, or waste being prepared to fulfil that function, in the plant or in the wider economy…" (2008/98EC)*
"'disposal' *means any operation which is not recovery even where the operation has as a secondary consequence the reclamation of substances or energy…;" (2008/98/EC)*

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RUSTICA proposes, for instance, waste for re-use **if appropriate** and legally permitted for feeding insects without further processing treatments[32]. Technologies like CAP or pyrolysis, able to convert waste into high-value fertilisers, are expected to correspond to *recycling* in the *waste hierarchy*. In addition, developing waste-based fertilisers in the course of RUSTICA to replace other products existing for this purpose may count for *recovery* (2008/98/EC). While excluding recovery for energy purposes, the term "*material recovery*"[33] encloses e.g., recycling and, thus, fits the project activities as well ((EU)2018/851).

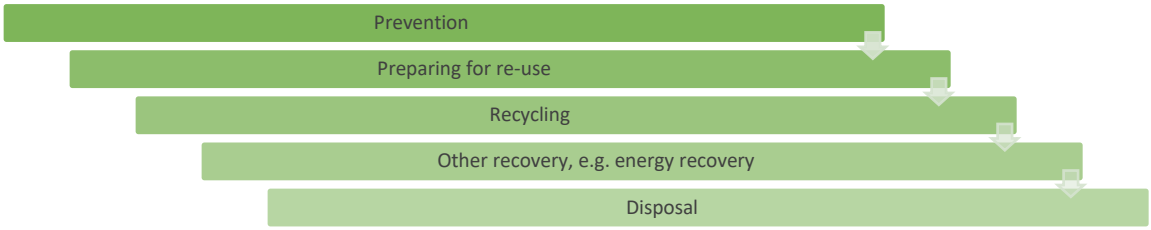

Figure 9: Principles of the waste hierarchy
Source: Own depiction based on terms and definitions of the Directive on waste (2008/98/EC)

3.1.1.2. Waste definitions

Organic waste as under use in RUSTICA is expressed in various terms which are reflected in legal sources of the EU. Although these terms have a common ground, their legal definitions and effects differ clearly. Hence, they are discussed in this D3.2 report.

3.1.1.2.1. Biodegradable waste

Following the Directive on landfill of waste 1999/31/EC, "***biodegradable waste***" means *"any waste that is capable of undergoing anaerobic or aerobic decomposition, such as food and garden waste, and paper and paperboard;"* and a reduction target to 35% for 2020[34] [35]in comparison to the amount of 1995 is laid down by this Directive (1999/31/EC). Efforts shall be undertaken by Member States that waste[36] which is separately collected for re-use and recycling will be no more accepted in landfill ((EU)2018/850).

RUSTICA research on transforming waste into products provides new options for certain biodegradable waste fractions, and as such, it is fully in line with this Directive.

3.1.1.2.2. Biowaste

The definition of "***biowaste***" has been expanded by the amendment (EU) 2018/851 of the Directive on waste and apart from biodegradable garden and park waste, food and kitchen waste from households, canteens, caterers and retail premises, and comparable waste from food processing plants (2008/98/EC), it covers now also biodegradable waste from offices, restaurants, wholesale, and canteens ((EU)2018/851).

Biowaste is a crucial input material for RUSTICA and for the CAP since waste from food processing and distribution, such as wholesale and retail, are incorporated into this legal definition.

[32] Provided that all legal requirements are fulfilled.
[33] *"Material recovery" means any recovery operation, other than energy recovery and the reprocessing into materials that are to be used as fuels or other means to generate energy. It includes, inter alia, preparing for re-use, recycling and backfilling;';" ((EU)2018/851)*
[34] applied if >80% of municipal waste were landfilled in a Member State in 1995 (1999/31/EC)
[35] If the rates were <80% in 1995, the 35% target applied earlier (1999/31/EC).
[36] Including bio-waste as indicated in Art. 22 of (EU) 2018/851

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3.1.1.2.3. Municipal waste

"Municipal waste" refers not only to mixed waste and separately collected waste from households including biowaste but also to waste from other sources if similar in "*nature and composition*" to household waste ((EU)2018/851).

As it is clearly expressed in legislation, municipal waste[37] has to be reduced in landfill ((EU)2018/850) and, at the same time, targets on re-use and recycling (**Table 5**) have to be accomplished ((EU)2018/851) (VOLATILE-D2.6, 2020).

Table 5: Municipal waste: targets for reduction in landfill, re-use and recycling

Target for Municipal Waste in Landfill (EU) 2018/850	Targets for Re-use and Recycling of Municipal Waste (EU) 2018/851
Reduction to 10% or less for the entire municipal waste in landfill by 2035	By 2025: ≥ 55%
	By 2030: ≥ 60%
	By 2035: ≥ 65%

Source: Own depiction based on the amendment ((EU)2018/850) to the Directive on landfill (1999/31/EC) and amendment ((EU)2018/851) to the Directive on waste (2008/98/EC)

Whereas the definition in the amended Directive on waste excludes inter alia production- and agricultural waste, biowaste resulting from food distribution and retail can belong to municipal waste ((EU)2018/851). Thus, from the legal perspective, the RUSTICA concept may contain also biowaste as a fraction of municipal waste on its feedstock side.

3.1.1.2.4. Food waste

Globally, 931 million t of food are wasted per year (UNEP, 2021e). *UN SDG 12.3* requires a reduction of food losses and to halve global food waste per capita in the retail and consumer area by 2030 (UN, 2021d). In the EU ***"food waste"*** means *"all food as defined in Regulation (EC) No 178/2002[38] that has become waste"* ((EU) 2018/851) and the annual amount of food which goes for waste was estimated on 88 million t (EC, 2021j) (FUSIONS, 2016). The term *"food waste"* refers to waste resulting from all stages of the food supply chain ((EC)No178/2002) and does not apply to feed. In contrary to the aforementioned definitions of *biowaste* and *municipal* waste, it captures also food waste from the primary sector ((EU)2019/1597).

Measurement of food waste was introduced by Commission Delegated Decision (EU) 2019/1597. The legal source clarifies that food waste also denotes the inedible parts of food if not separated from the edible ones. Food waste shall be prevented and reduced at the entire food supply chain from the agricultural origin, food manufacture, retail, food service and household. But food which was not harvested, agricultural materials, by-products which count not for waste and animal by-products as reflected in Art. 2 of the Directive on waste (2008/98/EC) are among the items not subject to the rules of this Decision ((EU)2019/1597).

[37] Around 224 million t of municipal waste are reported for the EU-27 in 2019 of which just 17% were composted (Eurostat, 2021) while assumptions of the European Compost Network (ECN) show a content of up to 50% organic waste and a share of 34% biowaste in municipal waste (ECN, 2021a).

[38] *"..."Food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. "Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC. ..."* Art. 2 of ((EC)No178/2002)

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To respond to the food waste problem, the RUSTICA research approach takes different kinds of such waste by using revolutionary methods and technologies towards accomplishing fertiliser innovations superior to the state-of-the art products**.**

3.1.1.3. Waste categorisation and codes

The RUSTICA concept does exclusively address non-hazardous waste and involves novel feedstock strategies. To this end, a first approach on the *List of waste* and its categories is carried out in this D3.2 report.

The *List of Waste* comprising 20 chapters presented by Commission Decision 2000/532/EC (2000/532/EC) has been replaced by amendment 2014/955/EU. Among these chapters, those considered as the most relevant for the RUSTICA project at the moment are listed in **Table 6** (2014/955/EU).

Table 6: Important waste codes proposed for RUSTICA

Waste Code	Waste Chapter or Subcatergory (Excerpt of 2014/955/EU)
02	**wastes from agriculture, horticulture, aquaculture, forestry, hunting and fishing, food preparation and processing**
02 01	wastes from agriculture, horticulture, aquaculture, forestry, hunting and fishing
02 03	wastes from fruit, vegetables, cereals, edible oils, cocoa, coffee, tea and tobacco preparation and processing; conserve production; yeast and yeast extract production, molasses preparation and fermentation
19	**wastes from waste management facilities, off-site waste water treatment plants and the preparation of water intended for human consumption and water for industrial use**
19 06	waste from anaerobic treatment of waste
20	**municipal wastes (household waste and similar commercial, industrial and institutional wastes) including separately collected fractions**
20 03	other municipal wastes

Source: Own depiction based on List of Waste (2014/955/EU)

According to chapter 2, waste subclasses 02 01 including agriculture and horticulture and 02 03 covering fruit and vegetables preparation and processing are to be scrutinised on the allocation of RUSTICA waste.

Chapter 19 encompassing waste from waste management facilities would need to be examined in the course of processes and results if waste is the input material.

For waste from markets and groce markets, chapter 20 municipal wastes and its subcategory *other municipal waste* (20 03) may be taken into account.

3.1.1.4. Shipment of waste

RUSTICA concepts are strongly oriented at building value chains based on locally and regionally available input materials towards a closed loop. In case, transboundary logistics would be needed to supply a site, legal positions on such transports of waste become relevant.

In accordance with international agreements and relationships, such as the "*Basel Convention*" (Recital 4), the "*Stockholm Convention*" (Recital 6), and the "*OECD Decision*[39]*"* (Recital 5) Regulation (EU) No 1013/2006 on shipment of waste is enacted by the EU ((EC)No1013/2006). It applies to shipments between the EU countries, as well as transits, imports and exports between the EU and third countries. For shipments exclusively within

[39] OECD Decision C(2001)107/FINAL (OECD, 2001a)

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Member States, supervision and control shall take place by their own jurisdiction (Art. 33), and exports of waste from the EU to third countries targeting disposal are prohibited while some exceptions are made for the EFTA[40] countries (Art. 34) ((EC)No1013/2006).

Title II ruling shipments within the *Community* either passing third countries or not requires a *prior written notification and consent* for all wastes which are transboundary moved for disposal. For certain wastes to be recovered, this requirement applies as well. (Art. 3(1)(b)(ii)) ((EC)No1013/2006) covers, for instance, Annex IVA which includes e.g., *AC 270 sewage sludge*. Art. 3(2) informs on the *General information requirements* (Art. 18) relevant e.g., for category ***BEU 05 - clean biodegradable waste from agriculture, horticulture, forestry, gardens, parks and cementries*** ((EU)No135/2012) belonging to Annex IIIb and subject to a transport for recovery and exceeding 20 kg. Specific documentation (Annex VII) for tracking is necessary (Art. 18) ((EC)No1013/2006). In case of certain contaminations (e.g., as defined in Annex IIIb of the amended (EC)No 1013/2006), the mere general information requirements are no more accepted ((EC)No1013/2006).

Among others, the Regulation ((EC)No1013/2006) informs on EU exports (for recovery) to "*OECD Decision Countries*"[41] (Art. 38) and as it is laid down : "*waste listed in Annex IIIB shall be subject to the procedure of prior written notification and consent"* (Art. 38(2)(b)).

Prohibitions of exports from the EU to countries where the "*OECD Decision does not apply*" cover hazardous wastes, e.g., those listed in Annex V or mixtures of hazardous wastes and non-hazardous waste (Art. 36 (1)(a)(c)(d)(e)) ((EC)No1013/2006). This ban (Art. 36(1)(b)) of (EC) No 1013/2006 comprises also "other wastes" including e.g., Y46 Household waste as defined in Annex II of the *Basel Convention* (UNEP, 2019b). However, according to Annex V of the Regulation ((EC)No1013/2006), if uncontaminated: "List B" including code B3060 of the Basel Convention[42] (UNEP, 2019b) is exempted from this EU export ban to "*Non-OECD Decision Countries*" (Annex V, Introductory note (2)(3)) ((EC)No1013/2006). In addition, it needs to be highlighted that Annex V, Part 2 of Regulation (EC) No 1013/2006 has been amended in 2015 ((EU)2015/2002) by the complete "List of waste" of Decision 2000/532/EC (2000/532/EC) encompassing non-hazardous (e.g., 20 03 02 waste from markets) and hazardous wastes[43] while the export ban applies mere to the latter ones ((EC)No1013/2006).

With a view on RUSTICA, as indicated above, rules for shipment of waste strongly relate to the type of waste, its categorisation, and the targeted destination.

3.1.1.5. End-of-waste criteria

For waste (2008/98/EC) ((EU)2018/851) that went through a recycling or recovering process to no longer be considered as waste, end-of-waste criteria need to be defined and conditions are set by the amended Directive on waste which have to be met:

Such a substance or object "*is to be used for specific purposes*" ((EU)2018/851) and a market or demand exists for it. The *"technical requirements for the specific purposes and the existing legislation and standards applicable to products*" and its use "*will not lead to overall adverse environmental or human health impacts"*(2008/98/EC).

The elaboration of end-of-waste criteria at the national level is encouraged by the EU legislation ((EU)2018/851). Today, end-of-waste criteria are legally approved for iron-, steel-, aluminium- and copper scraps as well as glass cullet at the EU level (EC, 2021g) (Velghe et al., 2021). While a general methodology how to determine end-of-waste criteria was published by EC the Joint Research Centre (JRC) in 2009 (Delgado Sancho

[40] EFTA (European Free Trade Association) covers Iceland, Liechtenstein, Norway and Switzerland (EFTA, 2021).
[41] E.g., Colombia is member of the OECD since 2020. (OECD, 2021)
[42] Please view also section 2.1.1
[43] Hazardous wastes are marked with an asterisk in the list of 2000/532/EC inserted into Annex V, Part 2 of (EC) No 1013/2006.

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et al., 2009), these criteria still need to be defined on a "*case-by-case basis"* if they are not laid down in legislation at the EU or national level ((EU)2018/851).

To bridge the gap between waste and product and available criteria relating thereto, the use of alternatives, such as standards, certificates and agreements, is proposed in literature (Johansson & Forsgren, 2020). On the other hand, end-of-waste criteria including limits on contaminants were already proposed and debated by the JRC, e.g. for compost and digestate (Saveyn & Eder, 2014) (Zorpas, 2016). However, as a legally binding instrument, Regulation (EU) 2019/1009 ruling the market for CE-marked fertilisers at EU level has established quality requirements for fertilisers including compost as well as digestate and informs on end-of-waste criteria ((EU)2019/1009). The Regulation, which is paramount for RUSTICA value chains, will be extensively studied in section 3.3.1 of this D3.2 report.

3.1.2. By-products

Far-reaching implications can occur by defining terminology in legislation. Hence, this section reflects how *by-products* are embedded into important EU legal frameworks affecting the RUSTICA project. Besides, light is shed on the difference between waste and by-products.

3.1.2.1. By-products and the Directive on waste

By-products are addressed in Art. 5 of the amended Directive on waste encouraging Member States to guarantee that a substance or object resulting from a production process is regarded as a by-product instead of a waste if conditions are met for these substances or objects (2008/98/EC) ((EU)2018/851) which can be summarised as shown in **Figure 10**:

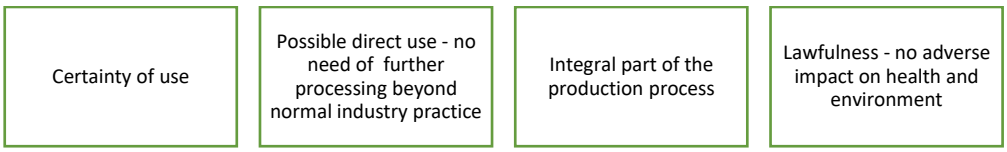

Figure 10: Important requirements for by-products
Source: Own depiction based on the Directive on waste (2008/98/EC) and amendment ((EU)2018/851)

Implementing acts may be adopted by the European Commission. As far as no criteria are set for a by-product at the EU level, Member States may define them based on the stipulations of the Directive on waste ((EU)2018/851).

To depict the legal situation of by-products arising from the food chain is an important element of the RUSTICA project. Therefore, further details will be needed especially on the delimitation of by-products and waste. An explanation is given in the context of food to feed transition which is relevant e.g., for insect cultivation.

Considering food that is no longer intended for human consumption and that does not consist of, contain or is contaminated with animal by-products, four different cases are summarised in the *Guidelines for the feed use of food no longer intended for human consumption* (C/2018/2035) *on routes from food to feed by pointing out the differences between by-products and waste with respect to waste legislation*. The cases can be described as follows:

- Products which are not final products resulting from a food manufacturing process (e.g., sunflower seed expeller or sugarbeet molasse) and complying with Art. 5 of the amended Directive on *waste "should not automatically be considered waste and may fall directly un*der feed legislation"*(C/2018/2035).*

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- *The evidence "that a by-product of non-animal origin", being a non-final product entailed with a* manufacturing process, is not waste according to the *Guidelines*, is assigned to the food business operator. Taking into account that "*food business operators which place such by-products as feed on the market are also registered as feed business operators"* the general need of a *"Certificate as non-waste"* should be redundant (C/2018/2035).

- Under the condition that "*materials of non-animal origin destined for feed"* will be excluded *"from the scope of the Waste Framework Directive*", permission will be given to the *"direct feed use of final food products … without being subject first to waste legislation."* These rules apply to e.g., food products reaching the wholesale and retail level and decided for feed use which fall not under the definition of by-products but waste (C/2018/2035).

- Before entering into force of (EU) 2018/851, final food no longer intended for human consumption, arising from the distribution stage, was subject to EU and national waste legislation prevailing on its use for feed purposes. But these food materials can now pass the Directive on waste (please view also section 3.1.1) and become part of the *feed chain* if conformity is given to the stipulations of feed legislation ((EC)No767/2009) (C/2018/2035).

By-products from food processing and their legal positions are posed by a range of literature sources not only dealing with their re-use in food and feed sectors (Rao, Bast, & de Boer, 2021), but also, e.g., discussing the *"reuse and stimulate industrial symbiosis by reutilizing one industry's byproduct into another industry's raw material…"*(Papageorgiou & Skendi, 2018).

Concerning the RUSTICA project, input materials derived from e.g., fruit and vegetable processing are proposed as by-products. Their use for various technologies and methods will be further verified in the section 3.2.

3.1.2.2. Animal by-products

Because the RUSTICA project includes inter alia insect cultivation, legislation related to animal by-products is a substantial part of this D3.2 analysis.

The Regulation (EC) No 1069/2009 defines *animal by-products* as *"entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen"* ((EC)No1069/2009).

Research of RUSTICA will cover insect breeding in manifold directions and details on legislation in areas, such as input and feeding materials, housing and hygiene and insect output like protein, fat, chitin and frass will be elaborated in more detail in section 3.2.4. However, the project does not focus on animal by-products for feedstock purposes at present. As far as e.g., insect frass would be additionally considered as a feedstock for valorisation via the CAP: such routes may be evaluated (if applicable) at later stage of the project and bearing in mind that a law making procedure is ongoing for frass (ST10820, 2021INIT). (Please view section 3.2.1.)

3.1.3. Biomass

RUSTICA incorporates a multitude of materials from growing, harvesting, manufacturing and distributing of food. As it is already displayed in section 3.1.1, **Table 4**, the Directive on waste does not enclose natural non-hazardous agricultural material used in farming, forestry or for the environmentally friendly production of energy from biomass (2008/98/EC).

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3.1.3.1. Definitions

In contrast to the formerly mentioned legislation on waste, the terms biomass[44] and residues[45] are legally defined by the Directive (EU) 2018/2001[46] on the promotion of the use of energy from renewable sources ((EU)2018/2001). By means of this Directive, biomass may contain among others waste, residues, and products of biological origin from agriculture (**Figure 11**). The Directive further clarifies in the Preamble (117) that agricultural crop residues count for *residues* instead for co-products resulting from fuel production ((EU)2018/2001).

Furthermore, the Directive rules the meaning of the products biofuels[47], bioliquids[48] and biomass fuels[49] and advanced biofuels[50] ((EU)2018/2001).

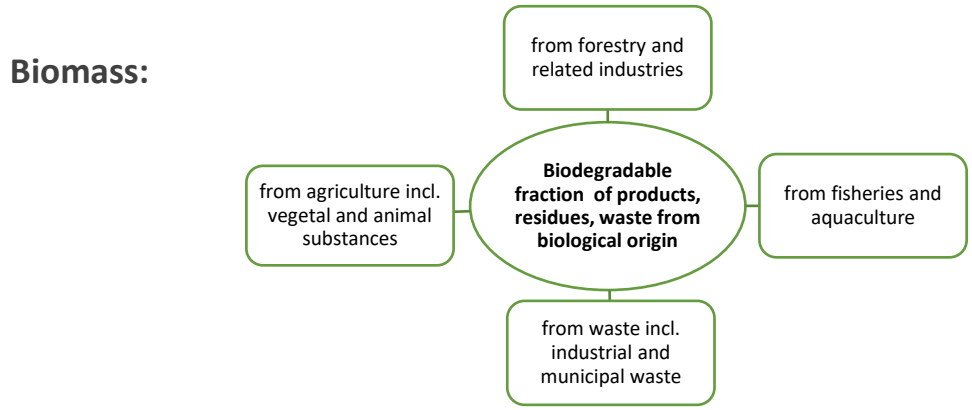

Figure 11: Main contents of biomass based on definition of the RED II (EU) 2018/2001
Source: Own depiction based on the RED II ((EU)2018/2001)

3.1.3.2. Use for energy purposes

As it is laid down by Directive (EU) 2018/2001, a minimum share of 32% in the gross final consumption of the EU Member States energy shall be achieved from renewable sources by 2030. In addition, as a mandatory target for the EU countries 14% or more renewable energy need to be fulfilled by the transport sector by 2030 as well ((EU)2018/2001) (Velghe et al., 2021).

In pursuing the prevention of indirect land use changes (ILUC), the legal source has set a number of measures addressing conventional biofuels and those with a high risk of ILUC. For example: if produced from food and feed crops, the share of biofuels, bioliquids and biomass fuels used for transport purposes may not exceed 7% of the final consumption of energy in the road and rail transport sector for the purpose of calculating the gross final consumption from RE sources in a Member State in 2020 ((EU)2018/2001).

[44] *"'Biomass' means the biodegradable fraction of products, waste and residues from biological origin from agriculture, including vegetal and animal substances, from forestry and related industries, including fisheries and aquaculture, as well as the biodegradable fraction of waste, including industrial and municipal waste of biological origin;"* ((EU)2018/2001)

[45] *"'Residue' means a substance that is not the end product(s) that a production process directly seeks to produce; it is not a primary aim of the production process and the process has not been deliberately modified to produce it;"* ((EU)2018/2001)

[46] also informally referred to as RED II

[47] *"'Biofuels' means liquid fuel for transport produced from biomass;"* ((EU)2018/2001)

[48] *"Bioliquids' means liquid fuel for energy purposes other than for transport, including electricity and heating and cooling, produced from biomass;"* ((EU)2018/2001)

[49] *"'Biomass fuels' means gaseous and solid fuels produced from biomass;"* ((EU)2018/2001)

[50] *"'Advanced biofuels' means biofuels that are produced from the feedstock listed in Part A of Annex IX "* ((EU)2018/2001) which is presented in excerpts below.

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On the other hand, from the 14% target for the transport sector, a progressive contribution of advanced biofuels and biogas is imposed by ((EU)2018/2001) which is illustrated in **Figure 12**.

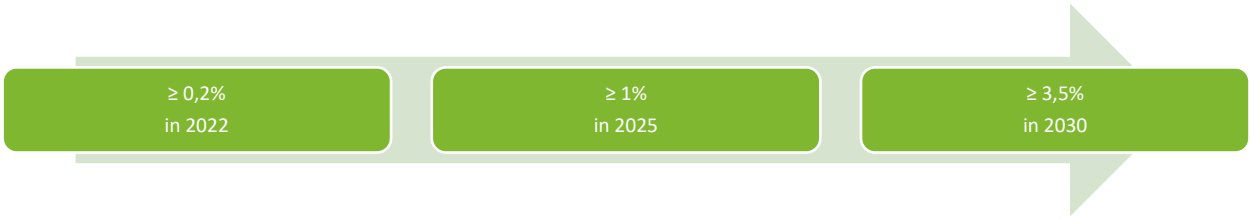

Figure 12: Requested contributions of advanced biofuels and biogas to the target of 14% RE in transport
Source: Own depiction based on the RED II ((EU)2018/2001)

Important feedstocks that are laid down in Annex IX of the RED II and count double for the targets reflected in **Figure 12** but at the same time also relevant for the RUSTICA research on novel fertilisers are inserted in **Table 7** ((EU)2018/2001).

The RED II clearly acknowledges the circular economy and underlines the priority of the waste hierarchy in order to prevent distortions in raw material markets and less appropriate use of waste which could be recycled ((EU)2018/2001). However, the use of certain feedstocks which are of interest for RUSTICA resources is rewarded for generating energy while a same or a similar signal is not provided if secondary materials are gained for fertilisers.

Table 7: Resources (Excerpt) for advanced biofuels double-counting for their share at the EU 14% RE transport target

Resources	Descriptions
Biomass fraction of mixed municipal waste	*"but not separated household waste subject to recycling targets under point (a) of Article 11(2) of Directive 2008/98/EC"*[51]
Biomass fraction of industrial waste	*"not fit for use in the food or feed chain, including material from retail and wholesale and the agro-food and fish and aquaculture industry…"*
Bagasse	--
Grape marcs and wine lees	--
Husks	--
Other non-food cellulosic material	--
Other ligno-cellulosic material except saw logs and veneer logs	--

Source: Own depiction based on Annex IX, Part A of the RED II ((EU)2018/2001)

3.1.4. Emissions and sustainability

The inclusion of sustainability rules is indispensable in the course of introducing novel technologies. Subsequently, legal matters on emissions are part of this D3.2 report.

[51] at least paper, metal, plastic and glass (2008/98/EC)

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3.1.4.1. Emissions and climate law

Among the targets which are laid down in Regulation (EU) 2018/1999 is the 40% reduction target for net greenhouse gas emissions (GHG) by 2030 compared to 1990 ((EU)2018/1999) (please view also section 2.1.6) which is increased to 55% by the *EU Climate Law*. The new legal source refers to the EU target of climate neutrality by 2050 and points out the necessity of improving the carbon sink and accomplishing an elevated volume concerning the net carbon sink in 2030 ((EU)2021/1119).

Table 8: ESR Sectors: GHG emission values 2005 and adjusted values of GHG emission allocation in 2030

Member State	Value for the 2005 GHG emission in tonnes of CO2 equivalent	Adjusted value of annual GHG emission allocation 2030 in tonnes of CO2 equivalent	Targeted GHG Reduction by 2030 relating to 2005 (EU)2018/842
Belgium	81,605,589	53,043,633	35%
Bulgaria	22,326,386	22,326,386	0
Czech Republic	64,965,295	55,870,153	14%
Denmark	40,368,089	24,624,534	39%
Germany	484,694,619	300,570,856	38%
Estonia	6,196,136	5,390,638	13%
Ireland	47,687,589	33,381,312	30%
Greece	62,985,180	52,907,551	16%
Spain	241,979,192	180,055,665	26%
France	401,113,722	252,744,817	37%
Croatia	18,056,312	16,799,301	7%
Italy	343,101,747	230,860,626	33%
Cyprus	4,266,823	3,242,785	24%
Latvia	8,597,807	8,081,939	6%
Lithuania	13,062,124	11,886,533	9%
Luxembourg	10,116,187	6,069,712	40%
Hungary	47,826,909	44,479,025	7%
Malta	1,020,601	826,687	19%
The Netherlands	128,112,158	81,991,781	36%
Austria	56,991,984	36,474,870	36%
Poland	192,472,253	178,999,195	7%
Portugal	48,635,827	40,420,173	17%
Romania	78,235,752	76,671,037	2%
Slovenia	11,826,308	10,174,774	15%
Slovakia	23,137,112	20,360,659	12%
Finland	34,439,858	21,008,313	39%
Sweden	43,228,505	25,937,103	40%

Source: Own depiction based on legal sources: ((EU)2020/2126), Annex I and II and ((EU)2018/842), Annex I

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In correlation to the decarbonisation objectives as determined in (EU) 2018/1999 ((EU)2018/1999), a GHG[52] emission reduction target is set by Regulation (EU) 2018/842 (also called "*Effort Sharing Regulation*") (ESR) at the Member State level for the period of 2021-2030. A decrease of ≥ 30% has to be reached by 2030 in comparison with 2005 for the IPCC (Intergovernmental Panel on Climate Change) source categories energy, industrial processes product use, agriculture and waste[53] [54] ((EU)2018/842). In general, sectors covered by the Emission Trading System (ETS) (2003/87/EC) are excluded by Directive (EU) 2018/842 ((EU)2018/842) (VOLATILE-D2.6, 2020). But since 2021, a certain flexibility is granted to nine Member States[55] for using a limited amount of ETS allowances for balancing emissions in the ESR sectors[56] (EC, 2021a) ((EU)2018/842) (Peeters & Athanasiadou, 2020). A lawmaking procedure for an amendment of (EU) No 842/2018 is currently ongoing proposing an uplift of the EU-wide "30% goal" to 40% by 2030 in comparison with 2005 (COM(2021)555).

By Commission Implementing Decision (EU)2020/2126, annual emission allocations of the Member States are laid down for the period 2021-2030 ((EU)2020/2126). An excerpt of these allocations for 2030 is depicted in **Table 8.**

RUSTICA creates new innovative processing routes for waste, as such striving for reduction of those materials, e.g., in landfill and subsequently for achieving lower GHG emissions.

3.1.4.2. Industrial emissions - their prevention and control

RUSTICA involves an array of materials and technologies including but not limited to the treatment of waste which are also of interest from the perspective of legal requirements on techniques to protect the environment. In this respect, Directive 2010/75/EU on industrial emissions prescribing rules on the prevention and control of industrial emissions comes into play (2010/75/EU). In contrast to the definition of Directive (EU) 2018/2001, the term *biomass* comprises a) products composed of *"any vegetable matter from agriculture and forestry which can be used for fuel purposes to recover its energy content*" and b) waste including e.g., vegetable waste from agriculture and food processing by means of this legal source. The Directive (Art. 3) includes "pyrolysis" into its definitions of "*waste incineration plants*" and "*waste co-incineration plants*" (2010/75/EU).

To operate an installation or (waste-)(co-)incineration plant, Member States shall ensure that these plants are conform with the stipulations of Directive 2010/75/EU and the rules for permissions and registration are fulfilled (Art. 4). The Directive provides specific legal instructions, such as the application of Best Available Techniques (BAT), waste management in accordance with the waste hierarchy, and efficient use of energy (Art. 11) (2010/75/EU).

Contingent to the activity and threshold values[57], the sectors energy industries, production and processing of metals, mineral industry, chemicals industry, waste management, and others like animal waste are reflected in Annex I of this legal source (2010/75/EU). With view on RUSTICA, an excerpt is given in **Table 9**.

[52] Covering carbon dioxide (CO_2), methane (CH_4), nitrous oxide (N_2O), hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), nitrogen trifluoride (NF_3) and sulphur hexafluoride (SF_6) in tonnes of CO2 equivalents ((EU)2018/842)

[53] 2006 IPCC Guidelines for National Greenhouse Gas Inventories include, e.g., 4A Solid Waste Disposal and 4C Incineration and Open burning of Waste (IPCC, 2006);

[54] More details: 2019 Refinement to the 2006 IPCC Guidelines for National Greenhouse Gas Inventories (IPCC, 2019)

[55] Austria, Belgium, Denmark, Finland, Ireland, Luxembourg, the Netherlands, Malta and Sweden

[56] In addition, there is an option for using an amount of credits from the Land use, land use change and forest sector (LULUCF) for ESR purposes (Art. 7) ((EU) 2018/842) Please view also section 3.4.1.3.1.

[57] "*…Where several activities falling under the same activity description containing a threshold are operated in the same installation, the capacities of such activities are added together*. …" (2010/75/EU), Annex I

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As far as RUSTICA will be exploited at large industrial level in these sectors, the aforementioned indications would need to be further verified if applicable for the envisaged activities, e.g.,

- Cat. 1.4: Energy Industries - gasification - biochar
- Cat. 4.1: CAP - carboxylic acid production
- Cat. 5.2: Waste incineration/pyrolysis - biochar
- Cat. 5.3: Waste treatment by composting or in AD combined with CAP
- Cat. 6.5: Recycling of animal-waste from insects

In order to properly implement the Directive on Emissions (2010/75/EU), BAT conclusions are inter alia legally designed for energy industries ((EU)2017/1442), large volume organic chemicals ((EU)2017/2117), waste incineration ((EU)2019/2010) and waste treatment ((EU)2018/1147).

Combustion of fuels with total rated thermal input of 50 MW at minimum if it occurs in a plant with total rated thermal input of ≥ 50 MW or the gasification of coal and other thermal input[58] of ≥ 20 MW if directly connected to a combustion plant are falling under the Commission Implementing Decision (EU) 2017/1442. The Decision lists 75 BAT conclusions but as it is stressed, these are generally applicable but not prescriptive and *"other techniques may be used that ensure at least an equivalent level of environmental protection"* ((EU)2017/1442).

A series of 90 BAT conclusions on large volume organic chemicals is the main constituent of (EU) 2017/2117 addressing emissions to air and water, resource efficiency and residues. However, this Directive does not pose specific details to carboxylic acids from fermentation processes ((EU)2017/2117).

Table 9: Excerpt of Directive 2010/75/EU on industrial emissions - Annex I

Cat.	Sectors (Excerpt) 2010/75/EU	Subcategories
1	**Energy Industries**	*"1.4(b) other fuels in installations with a total rated thermal input of 20 MW or more".*
4	**Chemical Industry**[59]	*"4.1. Production of organic chemicals, such as:* *(b) oxygen-containing hydrocarbons such as alcohols, aldehydes, ketones, carboxylic acids, esters and mixtures of esters, acetates, ethers, peroxides and epoxy resins;"*
5	**Waste Management**	*"5.2. Disposal or recovery of waste in waste incineration plants or in waste co-incineration plants:* *(a) for non-hazardous waste with a capacity exceeding 3 tonnes per hour;"*
		"5.3(b) Recovery, or a mix of recovery and disposal, of non-hazardous waste with a capacity exceeding 75 tonnes per day involving one or more of the following activities, and excluding activities covered by Directive 91/271/EEC: *(i) biological treatment;* *(ii) pre-treatment of waste for incineration or co-incineration;* *When the only waste treatment activity carried out is anaerobic digestion, the capacity threshold for this activity shall be* *100 tonnes per day."*
6	**Others**	*"6.5. Disposal or recycling of animal carcasses or animal waste with a treatment capacity exceeding 10 tonnes per day"*

[58] The Decision (EU) 2017/1442 refers also to biomass as defined in 2010/75/EU (EU), waste co-incineration and gasification.

[59] *".... means the production on an industrial scale by chemical or biological processing of substances or groups of substances..."* (2010/75/EU), Annex I

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Source: Own depiction based on direct citations of the Directive on industrial emissions (2010/75/EU), Annex I

Thresholds for recovery and disposal of non-hazardous waste for incineration are passed by a capacity exceeding 3 t per hour in a waste (co-)incineration plant as referred to in Commission Implementing Decision (EU) 2019/2010 while these limits could also vary in terms of other activities, such as treatment of slags. Manifold environmental parameters, e.g., heavy metals content, are covered by the 37 BAT conclusions of the Decision. The Decision addresses installations primarily not targeting material production ((EU)2019/2010). In addition, rules on other contaminating substances in waste and subsequent required operations exist ((EU)2019/1021).

Treatment of non-hazardous waste is part of Commission Implementing Decision (EU) 2018/1147. It encompasses 53 BAT conclusions. While BAT 1 sets the scene for an environmental management system (EMS) composed of elements like planning, implementation procedures, and performance check, BAT 36 and BAT 37 include composting and BAT 38 stands for emissions to air and enhancement of the overall environmental performance in the context of AD of waste ((EU)2018/1147). (Please view also section 3.2.6.5.)

The European IPCC Bureau (EIPCB) has published a list of Best Available Techniques Reference Documents (BREFs) which is part of Art. 13(1) of 2010/75/EU on information exchange. At the time of writing, this list shows inter alia BREFs on waste incineration, waste treatment (please view also section 3.2.1.5.), slaughterhouses and animal-by products industries[60], and production of large volume organic chemicals (EC, 2021i).

3.2. Routes from manufacturing to fertilisers

To accomplish its objectives and ground-breaking products as depicted in **Figure 1**, the RUSTICA research deals with the six crucial technologies CAP, microbial cultivation, electrodialysis, insects, pyrolysis/gasification and composting. The project deploys several manufacturing routes (**Figure 13**) which will be scrutinised in more detail in this section.

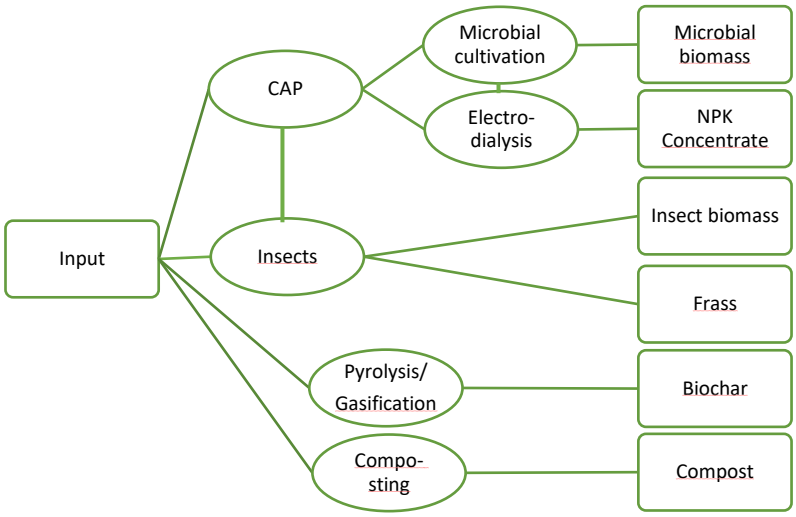

Figure 13: RUSTICA D3.2 analysis: major routes from manufacture to (basic-)products
Source: RUSTICA scheme in the GA (modified)

[60] Currently under revision

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3.2.1. Carboxylic Acid Platform (CAP) - and multi-value resources

A certain optimisation of producing short chain carboxylic acids from organic leftovers took already place in the course of AD for biogas purposes. More recently, comprehensive research was carried out on gaining resources by means of such carboxylic acids and based on AD technologies, e.g., in the EU Horizon 2020 project *"VOLATILE"* (VOLATILE, 2021).

In the RUSTICA project the CAP is at the core since it provides new solutions on gaining valuable substances from various feedstocks towards being further elevated by microbial cultivation or electrodialysis or insect feeding to novel plant nutrition concepts. Since to the best knowledge of the author final legal definitions for the CAP technology are not available at the EU-level thus far, light is shed on various aspects of its use relating to the peculiarities of the input types, current practises of processing and possible consequences for the CAP treatments.

3.2.1.1. CAP - Processing of waste and other inputs

3.2.1.1.1. Waste

If **waste,** as defined by the amended Directive on waste, is recycled or recovered by the CAP for further use and re-introduction of the output into the economy cycle, the general end-of-waste criteria must be fulfilled. As mentioned in section 3.1.1.5, these criteria need to be defined on a "case-by-case" basis if not defined for a specific waste for the entire EU or a Member State (2008/98/EC) ((EU)2018/851). Since in the context of RUSTICA biowaste[61], for example from food processing, and the biowaste fraction of municipal waste[62] (market waste)[63] will be transformed in the CAP, the end-of-waste status has to be clarified.

3.2.1.1.2. By-products

For the purpose that **by-products,** as legally expressed by the Directives 2008/98/EC and (EU) 2018/851, will be transformed into a substrate by the CAP to be further used as an intermediate/substance/product, its use and the compliance with all legal stipulations have to be certain (section 3.1.2) (2008/98/EC) ((EU)2018/851). Unlike treated waste, to evidence an end-of-waste status is not related to the follow-up of legally appointed by-products.

In the course of the RUSTICA project, e.g.,

- Grape pomace
- Other fruit pomace
- Vinasse
- Coffee pulp
- Cacao pulp

are proposed as by-products and planned to be subject to CAP treatment. To date, implementing legal acts to the Directive on waste providing specific details on such by-products could not be found in EU legislation. Therefore, various characteristics of the proposed by-products are highlighted as regards the defined

[61] as defined in (EU) 2018/851
[62] as defined in (EU) 2018/851
[63] May contain food waste

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requirements (Art. 5) in the amended Directive on waste (2008/98/EC) ((EU)2018/851) as well as in other legal contexts and acknowledgements of the term "by-product" [64].

Grape pomace

Following Regulation (EU) No 1308/2013 and by-products, in general wine grape mark may be solely distilled to alcohol, spirits and piquette and not used for wine or any other beverage foreseen to be consumed by humans[65]. Some exceptions exist on pouring of wine onto lees for local specialities[66]. Pressing of wine lees and re-fermentation targeting other destinations than distillation or piquette is prohibited ((EU)No1308/2013). A minimum content of alcohol[67] is dictated for separated by-products in relation to the wine produced ((EU)2019/934) and Member States can grant exemptions from mandatory distillations of processed grapes to certain producers[68] ((EU)No1308/2013). Grape marc is listed in the catalogue of feed ((EU)2017/1017).

According to literature, main products from distillation are sold e.g., as grape seeds and fertilisers. By-products from such distillation are inter alia spread on field, composted or digested to biogas (upon legal permissions) (Lempereur & Penavayre, 2014). Other scientific approaches evaluate, for example, the appropriateness of grape pomace for food components with respect to contaminants limiting a daily intake (Pereira et al., 2020) or analyse options on vermicomposting for residuals from winery for fertiliser and organic soil improvement, but indicating decline of nitrogen in substrates (Nogales Vargas-Machuca, Fernández-Gómez, Delgado-Moreno, Castillo-Díaz, & Romero, 2020). In summary, gaining added value from these materials by CAP is not undermined by these studies.

Fruit pomace

According to the use of fruit pomace or -pulp, it is listed in *EU catalogue of feed materials* ((EU)2017/1017). In addition, apple pomace and citrus pulp have entries in this catalogue. The use of pomace from fruits for food purposes is extensively discussed in literature even under safety and risk aspects (Rao et al., 2021) (Chaouch & Benvenuti, 2020).

For the by-product "fruit residues" from fruit juice production, *Best environmental management practices* (BEMP) are established as a voluntary scheme under the *Community eco-management and audit scheme* (EMAS) ((EU)2017/1508). This BEMP is presented in the **Table 10**.

Table 10: Best environmental management practices for fruit residues from fruit juice production

Environmental performance indicators	Benchmarks of excellence
"Fruit residue exploitation rate (%): total amount of fruit residues used for recovery of valuable products (e.g. pectin, essential oils), as animal feed or as co-substrate in an anaerobic digestion plant."	*"100 % of the fruit residues are used for the recovery of valuable products (e.g. pectin, essential oils), as animal feed or as co-substrate for anaerobic digestion."*

Source: directly cited from COMMISSION DECISION (EU) 2017/1508 ((EU)2017/1508)

[64] Apart from the definition in the Directive on waste, further definitions on by-products could be found in various legal sources, e.g., *"'by-product' means a product which results from preparation of a fruit or vegetable product which has a positive economic value but is not the main intended result;"* (543/2011/EU) for TITLE III Producer Organizations (543/2011/EU) and (EU) 2017/891 for TITLE II ((EU)2017/891)

[65] Financial support is given to distillers provided that the alcohol is solely used for industrial or energy purposes. (Art. 52) ((EU)No1308/2013)

[66] e.g. from Slovakia ((EU)No1308/2013)

[67] From 8% in zone A to 10% in zone C III as defined in (EU) No 1308/2013 ((EU)2019/934)

[68] Disposal of by-products ((EU)2019/934)

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Since the CAP aspires recovery of valuable products from fruit juice pomace as well, there is no obvious contradiction to this BEMP by this RUSTICA employment.

Vinasse

Commonly, descriptions like "*dark-brown slurry with an unpleasant odour*" are written for **vinasse** (Christofoletti, Escher, Correia, Marinho, & Fontanetti, 2013), a by-product[69] from ethanol production. Vinasse is part of the amended *EU catalogue of feed materials* ((EU)2017/1017) and e.g., for betaine, an ingredient which could be derived from vinasse and used in specific food categories like sportsmen food, an authorisation is available as a novel food ((EU)2019/1294). Due to its high sulphur content, anaerobic digestion (AD) to biogas is linked with certain drawbacks while biological treatment is seen as a possible solution (Rodrigues Reis & Hu, 2017).

On the other hand, severe impacts on the environment are reported for vinasse if uncontrollably dispersed to land or discharged into water (Rodrigues Reis & Hu, 2017) (Christofoletti et al., 2013) (Parnaudeau, Condom, Oliver, Cazevieille, & Recous, 2008), triggering the need of exploring new treatment solutions as offered by the CAP of the RUSTICA project.

A REACH[70] dossier (ECHA, 2021a) exists for vinasse indicating it as an odour absorber **(Table 11),** and the way of direct use of this by-product as a component material category (CMC 6) is paved by the new Fertilising Products Regulation ((EU)2019/1009) (please view section 3.3.1). In RUSTICA, it is proposed as an input for fermentation via the CAP and as such, as a precursor for fertilising products of the project.

Table 11: Vinasses - Excerpt of substance identity

Vinasses – REACH Substance Identity (Excerpt)	
Identification	
Display Name:	Vinasses, residue of fermentation
EC Number:	932-215-9
Molecular formula:	Not applicable (a generic molecular formula cannot be provided for this specific UVCB substance).
IUPAC Name:	Vinasses, residue of fermentation

Source: Own depiction based on direct citations of information from the European Chemicals Agency (ECHA, 2021a)

Coffee pulp

As underlined in literature, to achieve coffee as a beverage, 90% of the edible parts of a coffee cherry result either in by-products or waste. In **Figure 14**, a simplified scheme of the main layers of a coffee cherry covering the two beans inside (Iriondo-DeHond, Iriondo-DeHond, & Del Castillo, 2020) is depicted.

Bearing in mind Iriondo-De Hond et al. (Iriondo-DeHond et al., 2020), the contents of cascara (also called husk) include pulp but further rely on the processing methods. Usually, wet- and dry processing are the two main routes for dismantling the cherries to gain the green beans. The simplified processes showing products and the differences in contents of cascara[71] are illustrated in **Figure 15** (Iriondo-DeHond et al., 2020) (Klingel et al., 2020).

[69] 10-20 liters per one liter of ethanol (Christofoletti et al., 2013) (Rodrigues Reis & Hu, 2017)

[70] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) will be further discussed in this chapter.

[71] as defined in literature

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An application to register cascara or husk as a novel food is currently ongoing. A summary of the application of "coffee husk" concludes: it "*would not have a negative impact on human health when used in non-alcoholic, water-based beverage infusions, at the proposed concentration levels*" (EC, 2021l). Other coffee by-products are debated in literature on their suitability for the novel food sector as well. An overview on the progress of legal acceptance as a novel food is given by Klingel et al. for *flowers, leaves, husks, cascara, dried coffee cherries, green unroasted beans, silver skin, used coffee grounds, stems, twigs, wood,* and *parchment* entailed with coffee cultivation and manufacture (Klingel et al., 2020).

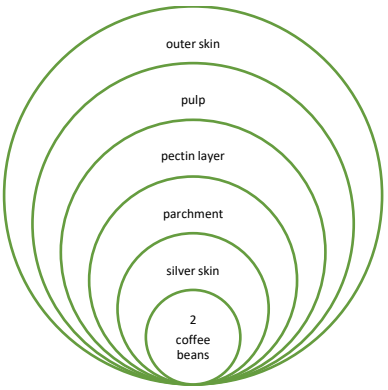

Figure 14: Simplified composition scheme of layers covering coffee beans
Source: Own depiction based on Iriondo-deHond et al. (Iriondo-DeHond et al., 2020) and Klingel et al. (Klingel et al., 2020)

Currently, cascara is predominantly composted but other suggestions are e.g., production of animal feed, biofuel (Iriondo-DeHond et al., 2020), and direct use as a fertiliser (Mazzafera, 2002). In the EU catalogue of feed, coffee skins are incorporated as a "*product obtained from dehusked seeds of the Coffea plant*" ((EU)2017/1017) while *Coffea arabica* L.: Coffee distillate / Coffee extract / Coffee oil / Coffee tincture shall be withdrawn from the market as feed additive ((EU)No230/2013). Even though cascara is used for fertiliser purposes in coffee plant soils, it is described in literature as bulky, and thus causing problems in storage, handling and soil incorporation (Mazzafera, 2002) (Galanakis, 2017).

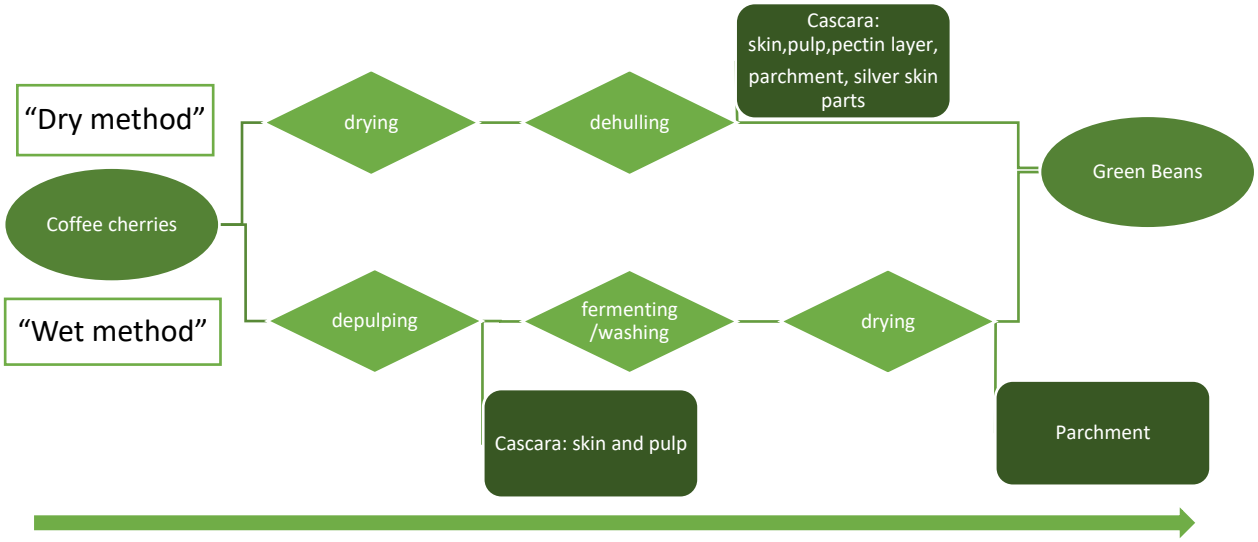

Figure 15: Processing methods of coffee cherries and the differences in cascara contents
Source: Own depiction based on Iriondo-DeHond et al., 2020 (Iriondo-DeHond et al., 2020)

By including coffee pulp into RUSTICA research and the CAP, tailor-made fertiliser building blocks are targeted in terms of quality and application convenience

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Cocoa pulp

Since just around 30% of the cocoa fruit are made up by the beans, cocoa production and processing have to cope with a range of by-products and wastes. After removing the beans three main classes of by-products cocoa pod husk, pulp, and cocoa shell (**Figure 16**) remain for further exploitation (Figueroa, García, & Vega, 2020).

For the by-product pulp juice, arising from the cacao processing industry, production of industrial alcohol and alcoholic beverages is reported as an important utilisation. Besides, cocoa pulp in various forms is listed as a novel food in EU legislation ((EU)2020/206).

Animal feed or fertilisers are the popular destinations for pod husks and shells (Pavlović, Miškulin, Aladić, & Jokić, 2019). With regard to the *EU Catalogue of Feed Materials*, cacao husks, hulls and meal from cocoa beans have been listed in this compendium ((EU)2017/1017). If processed or unprocessed cocoa shells build a component for a CE-marked fertiliser, it requires a labelling "toxic for dogs and cats" ((EU)2019/1009).

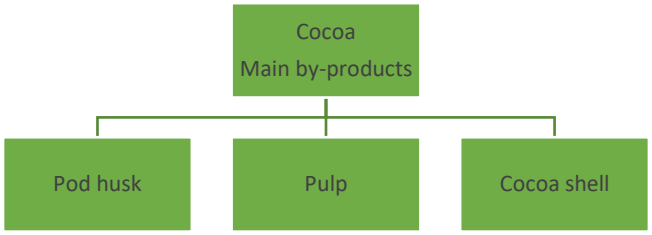

Figure 16: Main cocoa by-product classes
Source: Own depiction based on Figueroa et al. (Figueroa et al., 2020)

Thus, if cocoa by-products will be converted in the RUSTICA CAP towards producing fertilisers conform to the new Fertilising Products Regulation ((EU)2019/1009), the stipulations on labelling have to be met.

3.2.1.1.3. Animal by-products

As indicated before, legislation on **animal by-products** would need to be considered given that e.g., insect frass (please view also section 3.1.2.2) will be fed as an input material into the CAP. Under the premise that animal by-products as defined by the Regulation ((EC)No1069/2009) would be used for the CAP, also the subsequent value- and supply chains as well as final fertilisers will be determined by rules of legislation corresponding to materials of animal origin.

3.2.1.1.4. Biomass

Considering the previous section 3.1.1, the amended Directive on waste excludes faeces, straw and other natural non-hazardous agricultural materials if *"such biomass*" is used in "*farming, forestry or for the production of energy"*. It applies to animal by-products, e.g., if composted or digested to biogas (2008/98/EC) and can be circumvented if substances without animal by-product ingredients meet the definition of Art. 3(2)(g) of the Regulation of placing on the market of feed ((EC)No767/2009) ((EU)2018/851).

On the other hand, the term *biomass* (section 3.1.3) as defined in RED II assembles not only biodegradable residuals and wastes but also products if they are of biological origin and e.g., from agriculture or from industrial or municipal waste ((EU)2018/2001). As such, "*agricultural materials"* not covered by the amended Directive on waste (2008/98/EC) ((EU)2018/851) may legally qualify for energy purposes while a priority for a route of processing them e.g., via CAP towards high class circular bio-based fertilisers is not explicitly pointed out in the aforementioned legal acts thus far.

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3.2.1.2. Manufacture by CAP from the chemicals' perspective

Since output of CAP fermentation combines carboxylic acids and nutrients, the legal options and constraints for substances and mixtures are a crucial part of this section of the D3.2 report.

3.2.1.2.1. REACH – a central step to market access

The Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and its amendments refer to stipulations on substances[72] ((EC)No1907/2006) and mixtures ((EC)No1272/2008) thereby covering their "*manufacture, placing on the market or use*". The amended Regulation ((EC)No1907/2006) is composed of 15 Titles, 17 Annexes and 13 Appendices. The Titles and their designations in the legal act ((EC)No1907/2006) are listed in the Annex of this report.

REACH acknowledges sustainability[73] (Luit, Waaijers-van der Loop, & Heugens, 2017) but it does not apply to waste[74] [75]as it is not recognised as a substance, mixture or article by means of Art. 3 of the Regulation. But if derived from a recovery process and after the status "ceased to be waste" by means of the amended Directive on Waste (2008/98/EC) ((EU)2018/851) is attained, the substances/mixtures/articles resulted from these processes are covered by all REACH Titles in case ≥ 1 t are generated in the EU or imported into the common market unless there isan exemption. Such an exemption from Title II (Registration of substances) could be taken into account, for example, for a recovered substance which is exactly the same as a previously registered substance serving as an input for the recovery process while all legal requirements relating thereto (e.g., information) need to be fulfilled ((EC)No1907/2006).

Whereas the definition of "substance" does not indicate terms like recovery or recycling, the European Chemicals Agency (ECHA) has published the *Guidance on waste and recovered substances*, clarifying that even mechanical processing can count for recovery after the output has ceased to be waste (ECHA, 2010).

Depending on its composition, further use, and position in RUSTICA value chains, the CAP output could also serve as an intermediate[76] as defined by REACH. In consequence, rules relating thereto are briefly mentioned. Three different types of intermediates are addressed by Regulation ((EC)No1907/2006):

- non-isolated intermediates
- on-site isolated intermediates

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[72] *"substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;" EC No 1907/2006, Art. 3*

[73] REACH, Preamble, Recitals 3, 4, and 131 ((EC)No1907/2006)

[74] *defined as follows: "'waste' shall mean any substance or object in the categories set out in Annex I which the holder discards or intends or is required to discard;" (2006/12/EC)*

[75] Directive (EC) 2006/12, Annex I includes *e.g., "Q14 Products for which the holder has no further use (e.g. agricultural, household, office, commercial and shop discards, etc.)" (2006/12/EC)*

[76] *"intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):*
(a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;
(b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;
(c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;" ((EC)No1907/2006)

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- transported on-site isolated intermediates.

While non-isolated intermediates are out of the scope of the REACH Regulation (Art. 2(1)(c)), on-site isolated and transported on-site isolated intermediates are excluded from Title II, Chapter 1 (General obligations on registration and notification), Art. 5-7. Conversely, if manufactured outside and imported into the EU by a representative, all duties for importers have to be fulfilled according to Title II. Rules for research apply for intermediates as well (Art. 8-9). Nevertheless, registration has to be made (Art. 17) and information must be given for onsite-isolated intermediates produced ≥ 1 tpa., such as name of the manufacturer, identity and class of substances, as far as no additional testing is needed for submission by the manufacturer. Art. 49 confirms exemptions, e.g., from dossier evaluation (Title VI) but entitles the competent authorities in Member States to control and to gain additional information. Transported on-site isolated intermediates need to meet additional conditions, for instance, the substance is completely contained by technical means during its entire lifecycle (Art. 17-18). In contrast to e.g., substances being placed on the market, intermediates do not fall under Title VII covering authorisation of substances of very high concern (SVHC) ((EC)No1907/2006).

SVHC and their authorisation are a critical part of REACH. These substances should be strictly controlled and substituted by appropriate alternatives in the future (Title VII). At present (05.10.2021), the list of substances subject to an authorisation in Annex XIV shows 54 entries in the amended REACH Regulation ((EU)No143/2011C) ((EU)No125/2012) ((EU)No348/2013) ((EU)No895/2014) ((EU)2017/999) ((EU)2020/171C) ((EC)No1907/2006C) ((EU)2020/171) and 219 substances are published by ECHA on the "*Candidate List of substances of very high concern for Authorisation"* (ECHA, 2021b). In addition, users others than the manufacturers, importers, distributors or consumers have to abide by the framework of REACH for downstream users[77] and processes. Title V discloses various duties for this group ((EC)No1907/2006). (Please view also sections 3.2.2 and 3.2.3)

Multiple input materials of biological origin are under research in the CAP of the RUSTICA project. For the carboxylic acids and nutrient contents triggered by the CAP fermentation, it is of interest if REACH sets specific rules benefitting substances of bio-based origin or granting exemptions for specific purposes or applications.

In general, the REACH Regulation does not make a differentiation in legal supply chains if there are dedicated bio-based elements incorporated or not (Luit et al., 2017). On the other hand, for certain substances/products/sectors REACH and its amendments indicate bypassing as regards selected Titles provided that all legal requirements of REACH ((EC)No1907/2006) and other relevant areas are met. With view on RUSTICA, a set of these cases is exemplified in **Table 12**.

In case a substance counts for biocidal or plant protection products and is registered for this sectoral purpose, it is regarded as being registered and if all legal requirements are fulfilled, it can be exempted from additional registration in REACH ((EC)No1907/2006).

RUSTICA value chains connected to the CAP follow the direct routes to microbial biomass and NPK concentrate. As a further pathway, output of the CAP will be taken into account for feeding insects. REACH offers partially exemptions for feeding stuff if all legal conditions relating thereto are met. As far as research on CAP will lead to *low-risk substances* as defined in Annex IV of the Regulation ((EC)No1907/2006) ((EC)No987/2008), exemptions from Titles II, V and VI could be verified.

[77] "*downstream user: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture ((EC)No1272/2008), in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;*" ((EC)No1907/2006)

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Table 12: REACH - Excerpts of exemptions from certain Titles

Description	REACH Source
The provisions of the Titles II, IV, V, VI and VII shall not apply as far as the substance is used • ***in feeding stuffs if in compliance with (EU)No 178/2002*** • *as an additive in feeding stuffs covered by Regulation (EC) No 1831/2003* • *in animal nutrition covered by Directive 82/471/EEC*	Articles 2(5)(b) 2(6)(d)
Exempted from Titles II, V, VI: *"Substances included in Annex IV, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;"* *e.g. Glycerides, C_{10-18} (CAS No. 85665-33-4)*	ANNEX IV
Exempted from Titles II, V, VI: *"Substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;"*	ANNEX V
"1. Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight." *"2. …or to storage of another substance, mixture or article"*	
"4. A substance solely intended to provide a specific physicochemical characteristic functions as intended."	
"5. By-products, unless they are imported or placed on the market themselves."	
"6. Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption."	
"7. The following substances which occur in nature, if they are not chemically modified: *Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal.[78]"*	
"8. Substances which occur in nature[79]…"	
"9. The following substances obtained from natural sources[80]…vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C_6 to C_{24} and their potassium, sodium, calcium and magnesium salts; glycerol." "...if occurring in nature and not chemically modified."	
"12. Compost, biogas and digestate"	

Source: Own depiction based on direct citations from the REACH Regulation ((EC)No1907/2006) and its amendments ((EC)No1272/2008) ((EC)No987/2008) ((EU)2019/1691)

Annex V gathers substances of which registration is regarded inappropriate under certain conditions. Hence, criteria to be finally evaluated are e.g., incidental reactions of the new CAP technology and the handling of by-products. Furthermore, attention needs to be paid to rules on "*substances which occur in nature*" which do not apply to chemically modified fermentation products. "*Substances obtained from nature*" which are not

[78] It is referred to by the Fertilising Product Regulation (EU)2019/1009, please view also section 3.3.1.

[79] *"...other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Regulation (EC) No 1272/2008 or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f)."* ((EC)No1272/2008) ((EC)No987/2008)

[80] *"...if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f):..."* ((EC)No1272/2008) ((EC)No987/2008)

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chemically modified are addressed by Annex V as well ((EC)No1907/2006) ((EC)No987/2008) ((EC)No1272/2008). (Please view also section 3.2.2)

On the other hand, *substances obtained from natural sources* including, e.g., fatty acids from C6 to C24 ((EC)No987/2008) will be of interest for the RUSTICA investigations on CAP with regard to rules on exemptions from registration under REACH. But it has to be accentuated that for hexanoic acid a REACH dossier is available (ECHA, 2021d).

3.2.1.2.2. CAP versus digestate

Looking at RUSTICA and targeting bio-based fertilisers via CAP towards a circular bioeconomy, it needs to be stressed that regulatory stipulations and exemptions (**Table 12**) were laid down concerning REACH for digestate which is either not waste or has ceased to be waste. ((EU)2019/1691).

Commission Regulation (EU) 2019/1691 amending the REACH Regulation describes digestate as follows:

"Digestate is a residual semisolid or liquid material that has been sanitised and stabilised by a biological treatment process, of which the last step is an anaerobic digestion step, and where the inputs used in that process are biodegradable materials originating only from non-hazardous source segregated materials, such as food waste, manure and energy crops. Biogas resulting from the same process as digestate or from other anaerobic digestion processes, as well as compost resulting from the aerobic decomposition process of similar biodegradable materials, are already listed in Annex V to Regulation (EC) No 1907/2006. Therefore, digestate that is either not waste or has ceased to be waste should also be listed in that Annex, as it is inappropriate and unnecessary to require that substance to be registered and as its exemption from Titles II, V and VI of Regulation (EC) No 1907/2006 does not prejudice the objectives of that Regulation." ((EU)2019/1691).

In the RUSTICA project, CAP aims at anaerobic treatment and converting organic materials, e.g., food waste, with non-hazardous characteristics into a nutrient-rich material targeting final deployment as a fertiliser. Considering the legal definition of digestate and its status in the REACH Regulation, the novel and highly innovative CAP process and its output could be further verified in terms of meeting rules as applied to digestate.

3.2.1.3. CAP and feed business operation

In order to explore the CAP and its applications as comprehensive as possible, materials in the scope of the process will be ascertained according to their suitability for feeding, notably for insect nutrition purposes.

To ensure safe and healthy feed without negative environmental effects, Regulation (EC) No 178/2002 and its amendments *laying down general principles and requirements of food law* outlines rules on feed for food-producing animals and non-misleading labelling for feed presentation. As defined by this legal act: *"Feed" or "feedstuff" means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.* ((EC)No178/2002)*"*

Responsibilities of feed business operators, such as fulfilment of safety requirements along the feed chain ((EC)No178/2002) and liability for defective feed as determined in 85/374/EEC (85/374/EEC) are documented in this legal source ((EC)No178/2002). Traceability of any food, feed, food-producing animal or substance or material employed for feed shall be guaranteed by the feed business operator along the supply chain from production over processing to distribution ((EC)No178/2002).

More specific rules on feed to be placed on the market are established in Regulation (EC) No 767/2009 and its amendments. This legal act expands requirements on feed safety and presentation as laid down in (EC) No 178/2002 to non-food producing animals. This applies to traceability of feed ingredients and responsibilities of feed business operators as well ((EC)No767/2009). Feed business must comply with hygiene standards as drawn

up in (EC) No 183/2005 ((EC)No183/2005) and if more oriented to food business: (EC) No 852/2004 would apply ((EC)No852/2004). A list of materials restricted or prohibited for feeding (e.g., faecal materials) is subject to Annex III of the Regulation (EC) No 767/2009 ((EC)No767/2009). An overview on important legal (basic) acts affecting feed business operation is given in **Figure 17**:

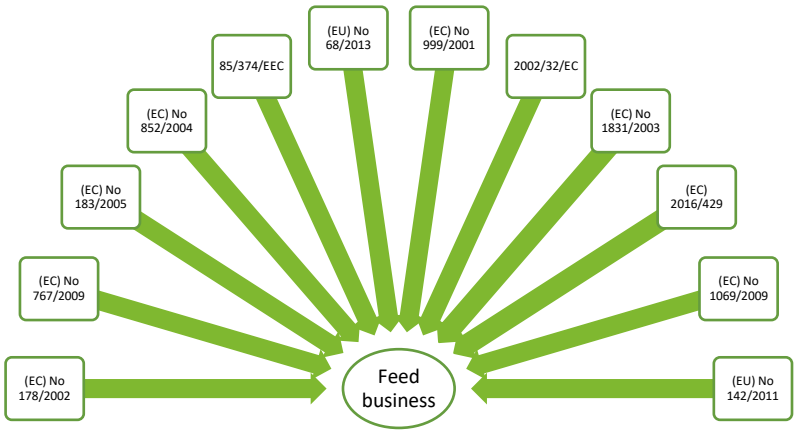

Figure 17: Examples of important legal acts in the scope of feed business operation
Source: Own depiction based on legal acts as mentioned in section 3.2.1.3.

Aside from the aforementioned constraints on feeding materials, further legal sources need to comply with if feed(-stuff) is placed on the market. Prominent examples are Directive 2002/32/EC and its amendments on undesirable substances in animal feed dictating maximum levels on contents like inorganic contaminants and nitrogenous compounds (e.g., nitrite((EU)No1275/2013)) (2002/32/EC) (VOLATILE-D2.6, 2020). Direct and indirect impositions on feed business result also from the Regulation for combating *Certain Transmissible Spongiform Encephalopathies* (TSE) ((EC)No999/2001) and the Regulation on transmissible animal diseases ((EU)2016/429). Finally, it needs to be stressed that the Animal by-product regulation ((EC)No1069/2009) and its implementing Regulation ((EU)No142/2011) are *"KEY"* for each feed business dealing with such products.

As far as feed additives will be produced and market entrance at the EU level is envisaged, an authorisation is necessary and the additive needs an entry in the *European Union Register of Feed Additives* as laid down in Regulation (EC) No 1831/2003 ((EC)No1831/2003) and its amendments. Commonly, the Catalogue of feed material is a voluntary instrument, but if addressed by feed business, the requirements of this legal compendium originally established by the amended Regulation (EU) No 68/2013 ((EU)No68/2013) need to be met (VOLATILE-D2.6, 2020).

Since animal feed material under RUSTICA is mainly foreseen to nutrition of insect cultivation, more details on feeding are elaborated in section 3.2.4.

3.2.1.4. CAP and its role in the final fertiliser product

Albeit the CAP serves as a source of nutrients and building blocks which will be further treated by several methods to enable high-level bio-based fertilisers, the activities including its input materials will be relevant for final applications in the light of their legal stipulations.

Whereas traceability in the supply chain is prescribed by legislation on chemicals and feed business sector as mentioned above, restrictions on waste and proven origins of products including their precursors are also of utmost importance in the legal frameworks of plant nutrients applications, such as CE-marked fertilisers ((EU)2019/1009) (section 3.3).

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3.2.1.5. Emissions: current status

Emissions are an important matter for new technologies like the CAP. Whereas GHG emission savings for generating energy by means of biogas based on biowaste substrate are legally defined ((EU)2018/2001) (VOLATILE-D2.6, 2020), such values are not yet available for the CAP if extracting nutrients from an anaerobic AD process and the follow-up treatments by microbial cultivation and electrodialysis.

Depending on the feedstocks, functions and level of upscale of the CAP, rules for industrial emissions (2010/75/EU), e.g., the already indicated BATs for waste treatment may come into play ((EU)2018/1147). Scrutinising BREF for waste treatment reveals that innovative processes of converting organic waste to carboxylic acids are already elucidated but focusing on routes leading to polyhydroxyalkanoates (PHA) rather than fertilisers (Pinasseau, Zerger, Roth, Canova, & Roudier, 2018). (Please view also section 3.1.4.)

3.2.2. Microbial cultivation and -fertiliser

In pursuing a dedicated and optimised product for an ideal plant nutrition, CAP output will be subject to microbial cultivation in RUSTICA.

The corresponding fermentation process leads to microbial biomass and subsequently to microbial fertiliser which consists of such dried biomass and acts as a direct fertiliser. Conversion rates up to 100% are reported in literature if microbial biomass is produced from inorganic nutrients, and the function of the microbial fertiliser gained from this process is to feed microbiome as a substrate in soil or growing media enabling biomass mineralisation to supply the plant. Like other organic fertilisers, nutrients, e.g., N/P/K are delivered to a crop, but additional highly beneficial properties, such as slow-release and tailored nutrient supply, better nutrient exchange capacity and soil water retention are in the portfolio of microbial fertilisers (AVECOM, 2021a) (Spanoghe et al., 2020).

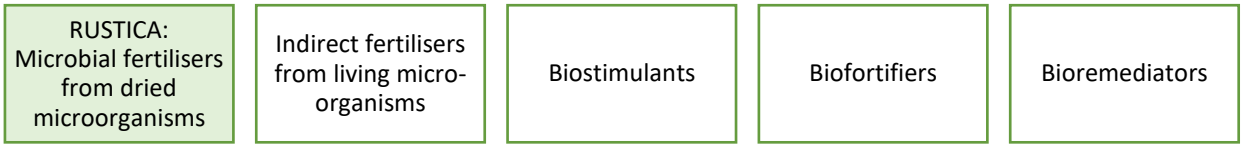

Figure 18: Microbial fertilisers and other typical deployments of microorganisms for plant nutrition and soil support
Source: Own depiction based on literature: (Sakarika et al., 2020), (Spanoghe et al., 2020), (F.-J. Zhao & McGrath, 2009)

Conversely, fertilisers composed of living organisms[81] taking the role of biocatalysts by mobilising nutrients, e.g., in the manner of N-fixation or P-solubilization and, thus, working as an indirect fertiliser are scientifically debated as well (Sakarika et al., 2020) (Spanoghe et al., 2020) (Thomas & Singh, 2019) (Stamenković et al., 2018).

According to literature, further deployments for microorganisms are biostimulants[82] (Please view section 3.3.) providing plant growth promoting substances enabling the plant e.g., to better cope with stress factors, and in certain cases microorganisms have multifunctional properties by tackling both nutrient availability and stress problems (Sakarika et al., 2020) (Stamenković et al., 2018). Biostimulants are distincted between a microbial and a non-microbial group in legislation ((EU)2019/1009) (section 3.3.1) and literature. The variety of

[81] In literature sources also referred to "microbial fertiliser", "biofertilisers" (Stamenković, Beškoski, Karabegović, Lazić, & Nikolić, 2018) or "microbial biofertilisers" (Thomas & Singh, 2019).

[82] Legally defined in the Fertilising Products Regulation (EU) 2019/1009 by *amending Regulation (EC) No 1107/2009: "plant biostimulant' means a product stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere: (a) nutrient use efficiency; (b) tolerance to abiotic stress;(c) quality traits; (d) availability of confined nutrients in soil or rhizosphere." ((EU)2019/1009) (No1107/2009)*

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biostimulants in agriculture including legal definitions and scientific approaches is thoroughly analysed by Rouphael and Colla (Rouphael & Colla, 2020).

Further areas of bridging the gap between nutrients bound in soil and the need of plants are biofortification and bioremediation. The former is reported as *"…increase micronutrient concentrations in the edible parts of plants through breeding or the use of biotechnology"* in scientific publications (F.-J. Zhao & McGrath, 2009). Bioremediators include microorganisms pursuing neutralisation of contaminants in soil and other environments (Gouma, Fragoeiro, Bastos, & Magan, 2014) (Sakarika et al., 2020). **Figure 18** reflects certain terms outlined in literature in the context of microbial fertilisers and other support of microorganisms on plants and soil.

3.2.2.1. Legal position and influence of microorganism types, substrates and processes

A comprehensive legal framework has been established in the EU for genetically modified organisms (GMO) including microorganisms (EC, 2021b). But for the purpose of RUSTICA microbial fertiliser production, no GMO will be under use (AVECOM, 2021b). A general legal obligation on registration or evidence of safety relating to such ("non-GMO")-microorganisms is not enacted at the EU level (e.g., Recital 59) ((EU)2019/1009).[83]

Depending on the composition of CAP, output materials serving as a substrate for microbial biomass and their legal situation concerning the amended REACH Regulation ((EC)No1907/2006), this legal source needs to be further taken into account for the subsequently occurring processes in the supply chain or for users of such products as well.

On the other hand, commitments under REACH ((EC)No1907/2006) arise not only from the legal status of the substrate but also from the activities undertaken in the scope of the process itself leading to microbial protein/-biomass. In this regard, exemptions of Annex IV and Annex V need to be studied on their relevance for the entire group of gained substances. Whereas some exemptions are reported on living or dead organisms in the ECHA Guidance on REACH, Annex V (ECHA, 2012):

- *"… whole living or unprocessed dead organisms (e.g. yeast (see Attachment 2), freeze-dried bacteria) or parts thereof (e.g. body parts, blood, branches, leaves, flowers etc.) are* ***not considered as substances*** *…"* (ECHA, 2012 – Guidance on Annex V, Entry 7 & 8 - general considerations)

it is clearly pointed out that fermentation products yielded from a process of chemical modification cannot benefit from an exemption (ECHA, 2012).

- *"Examples of substances that are not covered by this exemption 113 include but are not limited to, e.g.* ***fermentation products*** *which are isolated by other means as those given in Article 3(39)114. In these examples, the substances have undergone chemical modification, i.e. solvent extraction (bonemeal), fermentation products (enzymes), or are dangerous and thus* ***not exempt from registration****." (ECHA, 2012 – Guidance on Annex V, Entry 8)*

The ECHA Guidance document discusses also yeast and a variety of possible roles and functions including its extracts in a process and the decisive point of the type of the process resulting either in a naturally occurring substance or not (ECHA, 2012).

- *"Yeast extract could be considered a naturally occurring substance if, following lysis of yeast cells by mechanical processing, it is isolated by manual, mechanical or gravitational means, by dissolution in* ***water, by flotation, by extraction with water, by steam distillation or by heating solely to remove***

[83] Some microorganisms, e.g., *baculovirus* are listed under the Regulation (EU) No 528/2012 and its amendments which set rules for biocidal products ((EU)No528/2012) (ECHA, 2020). It is further referred to microorganisms in (EU) 2021/1165 covering organic production.

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> ***water*** *… (see Article 3(39))"* **but:** *"… chemical lysis of the yeast by other means than those of Article 3(39), either by the* ***yeast's own enzymes or manenhanced*** *for example (but not exclusively) by adding salt or enzymes, and followed by isolation (typically involving centrifugation). Under these circumstances, the yeast extract is* ***not*** *a naturally occurring substance … "* (ECHA, 2012 – Guidance on Annex V, Attachment II)

Although not mentioned in Art. 3 of the REACH Regulation, the ECHA document underlines that fermentation cannot be interpreted as an operation occurring in nature (ECHA, 2012):

- *"Since fermentation is not specifically listed in Article 3(39), it cannot be understood as one of the operations allowed for the sake of keeping within the definition of processed substances which occur in nature. Furthermore, due to the controlled (bio)chemical transformation taking place,* ***'fermentation mass' cannot be understood as an 'unprocessed' substance*** *in accordance with Article 3(39)."* (ECHA, 2012 – Guidance on Annex V, Attachment II)

If necessary, the RUSTICA project plans further preparation of components to a final fertiliser product. In this respect, if no manufacturing process or distribution is carried out and no exemption applies, *Title V Downstream users*[84] of REACH addresses users of substances or mixtures covered by this legal act ((EC)No1907/2006).

A downstream user by means of REACH has a set of rights and duties. Such rights comprise inter alia to forward information to a manufacturer or any other supplier who delivered a substance with the objective to declare this an identified use. Such information shall be in a proper manner allowing a supplier to elaborate an exposure scenario. Among the duties stipulated for downstream users are e.g., the preparation of a chemical safety report and information of ECHA if there are uses beyond of the exposure scenario and no further exemption applies ((EC)No1907/2006). In the *Guidance for Downstream Users,* ECHA identified various roles for this type of users which are e.g., formulator, re-filler, industrial end-user, article producer and professional end-user (ECHA, 2014).

3.2.2.2. Microbial fertiliser - technologies and definitions

Hitherto, a legal definition for "*microbial fertiliser*" could not be found at the EU level, and as mentioned above, in literature the term is used in a versatile manner even combined with other attributes like "bio". Investigations in this direction were also made, e.g., by Malusa and Vassilev who figured out that no legal definition exists at the international and EU scale. They extensively debate the necessity of appointing parameters for defining "biofertilisers" (Malusa & Vassilev, 2014). A definition of microorganisms targeting various purposes covered by the term "*biofertilisers*[85]" is also published by the European Biomass Industry Association (EUBIA) (EUBIA, 2021). So far, however, the term is not part of the new Fertilising Products Regulation ((EU)2019/1009).

RUSTICA research on microbial fertiliser represents neither a biostimulant nor an indirect fertiliser containing living organisms. Besides, biofortification and bioremediation are not specifically addressed thus far.

The project aims for a high-quality organic and direct fertilising product with new characteristics advantageous for plant uptake, benefitting the soil and favourable for the environment.

[84] *"Downstream user: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;"* ((EC)No1907/2006)

[85] *"Biofertilisers are defined as preparations containing living cells or latent cells of efficient strains of microorganisms that help crop plants' uptake of nutrients by their interactions in the rhizosphere when applied through seed or soil…"* EUBIA, 2021

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3.2.3. Electrodialysis and NPK concentrate

RUSTICA research on CAP anticipates a multitalented output to be further refined by electrodialysis targeting NPK concentrate as a final high quality fertilising product.

Electrodialysis, a mass separation process disengaging ions from a solution (EMIS, 2010), has a long tradition, and studies on this technology were already carried out in the first half of the 20th century. Strong endeavours led to an upscale of the method from pilot to commercial scale in the 1950s (Bazinet, Lamarche, & Ippersiel, 1998) while desalination of nature water by electrodialysis is known "*as a relatively mature operation process*" since the 1970s (Wang, Zheng, Wang, Wang, & Wang, 2016).

Further progress was made during the time and applications in the food and beverage industry, such as demineralisation of cane sugar, deacidification of fruit juices and stabilisation of acids in oenological treatments can be found in literature. An important step forward was taken by introducing the bipolar membranes enabling, for example, the dissociation of water molecules and recovery of acids in a concentrated version (Bazinet et al., 1998). Today, deployments of electrodialysis are also in recovery processes of wastewater and waste management (Kulkarni, 2017) targeting inter alia isolation of volatile fatty acids (VFA) and nutrients from these effluents or concentration as a follow up of digestate from sludge (Gurreri, Tamburini, Cipollina, & Micale, 2020). Remaining challenges for electrodialysis, such as low yield of carboxylic acids from anaerobic fermentation (W. Zhao et al., 2021) or extraction of VFA from complex substrates like mesophilic anaerobic fermentation media without loss of nutrients, and approaches to tackle them are extensively discussed in scientific publications (Brown, Tuffou, Nicolau, Dinsdale, & Guwy, 2020).

Extraction of nutrient elements from complex mixtures of CAP and their valorisation is part of RUSTICA. Therefore, legal criteria of separating ions through electrodialysis from ionic mixtures resulting from CAP will be further enlightened with regard to REACH regulation and publications of ECHA.

3.2.3.1. Ionic mixtures - view on the REACH Regulation

While the term "electrodialysis" could not directly be spotted in REACH Regulation ((EC)No1907/2006) and its amendments, ECHA provides information on ions (ECHA, 2021e) and ionic mixtures (ECHA, 2012). As far as a substance includes a cationic and an anionic part, analytical data must be delivered for each ion in terms of identification and quantity in case of this substance is subject to REACH (ECHA, 2021e).

About Annex V presenting a number of exemptions from certain Titles of REACH ((EC)No1907/2006), ionic mixtures are referred to in the *Guidance* of ECHA relating thereto. In Entry IV, the document (ECHA, 2012) indicates exemptions for *"substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when (b) a substance solely intended to provide a specific physicochemical characteristic functions as intended."* As an example for such a substance, water[86] as a solvent which is added to a salt leading to a solution with ionic pairs in equilibrium is presented by the publication (ECHA, 2012).

The ECHA *Guidance* document gives further details on requirements of exemptions as regards ionic mixtures (salts, acids and bases) in its Attachment 1 relating to Entry IV (b): Ionic pairs in equilibrium resulted in an aqueous solution which are not considered to be "*manufactured, imported or placed on the market*" would be exempted from REACH registration under specifically defined conditions (ECHA, 2012). Such conditions are, e.g.,

[86] which is exempted from registration under REACH (Annex IV)

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- "All starting substances (salts, acids and bases) of the aqueous solution must be registered[87];"
- "None of the salts in the aqueous solution is isolated from the solution; and"
- "The salts remain in their ionic form in the solution." (ECHA, 2012)

if the solution is imported. For downstream users ((EC)No1907/2006) (ECHA, 2014), the points two and three apply. In this respect, if any salt will be eliminated from the solution, the downstream user's position is getting lost and alters into a "manufacturer" role triggering the consequence that the isolated substances have to be registered under REACH (ECHA, 2012).

3.2.3.2. Macronutrients for fertiliser purposes

By means of RUSTICA research, the plant macronutrients N/P/K will be separated from a heterogeneous CAP mixture containing various carboxylic acids. The research aims at accomplishing purified liquid inorganic compositions at the highest level enabling their optimal uptake by plants and eliminating adverse economic and environmental effects, such as the use of primary fossil-based resources for fertiliser manufacture. To identify further legal drivers and bottlenecks on the routes to the market, it will be examined how the bio-based RUSTICA novelty resulting from sophisticated electrodialysis processes will suit into the new Fertilising Products legislation ((EU)2019/1009) (section 3.3.1) and meet the requirements of organic farming (section 3.3.2).

3.2.4. Insects - from feeding to utilisation

Multiple valorisation routes for leftover materials of the agri-food chain are in the scope of the RUSTICA Project. One direction of these routes leads to the exploration and exploitation of novel fertilisers originated from insects.

The emerging insect farming sector poses new perspectives, e.g., in terms of generating proteins and expects a dynamic development in Europe (Cadinu, Barra, Torre, Delogu, & Madau, 2020) (Lähteenmäki-Uutela & Grmelova, 2016) which would need to go hand in hand with a reliable legal framework. To investigate the current situation, legal sources on cultivation of the specific bugs species are analysed in this D3.2 report.

In the scope of conducting research on insects and their appropriateness for fertiliser purposes, RUSTICA links waste and by-products directly or via the CAP technology with cultivating of various types of such invertebrates in pursuing two main output component classes: firstly, insect biomass and secondly, frass. These two categories are also set in literature for the bioconversion of organic waste by insects while building blocks of frass are described as *"predominantly insect frass and to a lesser extent, shed exoskeletons, dead insect parts, and potentially uneaten feedstock"* (Fowles & Nansen, 2020).

To identify legal bottlenecks, important steps starting from nurture over terminating the insect life to achieve resources for circular bio-based fertilisers are deliberated in this section.

3.2.4.1. Animal care and nutrition

Since 2017, the term "*farmed insects*[88]*"* is legally established at the EU level ((EU)2017/893) and amends the Regulation (EC) No 999/2001[89] *on prevention, control and eradication of certain transmissible spongiform*

[87] Registered and known in the EU

[88] *""Farmed insects" means farmed animals, as defined in Article 3(6)(a) of Regulation (EC) No 1069/2009, of those insect species which are authorised for the production of processed animal protein in accordance with point 2 of Part A of Section 1 of Chapter II of Annex X to Regulation (EU) No 142/2011."* ((EU)2017/893)

[89] *Regulation (EC) No 999/2001 applies to fertilisers, their precursors and intermediates as well.*

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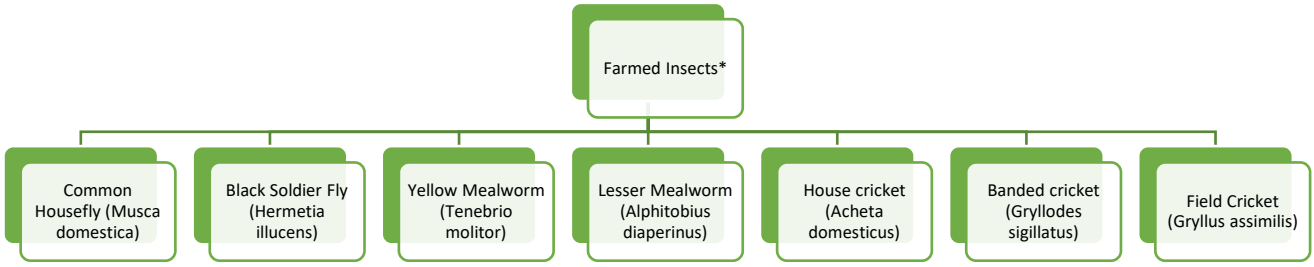
encephalopathies (TSE) ((EC)No999/2001). It corresponds to "*farmed animals*"[90] as defined in the Animal by-products Regulation ((EC)No1069/2009) and at the same time, it covers those insect types that are permitted for *"processed animal protein"* to be fed to food producing animals by means of Regulation (EU) No 142/2011 implementing (EC) No 1069/2009. The seven species assembled to "*farmed insects*, reflected in (EU) No 142/2011 and legally authorised to be converted into this class of protein for feed targeting the food chain are depicted in **Figure 19** ((EU)2017/893).

To prevent and encounter a negative impact of invasive alien species in the EU, legislation ((EU)No1143/2014) has been enacted, and a list compiling such organisms is drawn up in order to protect biodiversity, ecosystems and humans against such distortions. The EU insect sector is bound to these stipulations and, hitherto, one type of insect (*Vespa velutina nigrithorax* de Buysson, 1905 – Asian Black Hornet) is part of the amended "Union list" ((EU)2016/1141) and as such, *"not eligible for farming purposes*" (IPIFF, 2021a).

Regardless if there is a use in the direction of food, feed or fertilisers, due to their definition as *farmed animals* (Lähteenmäki-Uutela & Grmelova, 2016) (IPIFF, 2021a) feed business operators supplying the sector and holders of insect species need to adhere to general and specific feed materials and rules, respectively.



*for processed protein to food producing animals

Figure 19: Farmed insects for processed protein fof food producing animals
Source: Own depiction based on the legal sources: ((EU)2017/893) amending ((EU)No142/2011) and ((EC)No999/2001)

As it is undoubtedly expressed, the use of faecal matters is prohibited for animal feeding, and the ban covers all processed versions as well ((EC)No767/2009). Furthermore, "solid urban waste[91]" is not permitted to be fed to animals ((EC)No767/2009) ((EU)No568/2010). At this occasion, it needs to be mentioned that to the best knowledge of the author, this term neither could be found in the amended Directive on waste (2008/98/EC) ((EU)2018/851) nor in the Animal by-product Regulations ((EC)No1069/2009) ((EU)No142/2011).

On the other hand, Regulation (EC) No 1069/2009 authorises a range of products from its "*Category 3 materials*[92]", such as eggs, milk, honey, rendered fats, collagen and gelatine[93] free of any disease and "*foodstuffs containing products of animal origin, which are no longer intended for human consumption"* under certain conditions. But it forbids (insect-)feeding with e.g., processed protein derived from the same species and other

[90] Definition of farmed animals: *"…any animal that is kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins or any other product obtained from animals or for other farming purposes"* ((EC)No1069/2009).
[91] The term "solid urban waste" is not defined in (EC) No 767/2009 and its amendments but it excludes catering waste.
[92] Depending on the level of risk to public and animal health (EC) No 1069/2009 subdivides three categories of animal by-products. Category 1 posing the highest risk collates, for example, animals killed in the context of TSE eradication measures, and Category 2 gathers, e.g., manure, non-mineralised guano and digestive tract content; ((EC)No1069/2009)
[93] As defined in (EU) No 142/2011, Annex X: only if treated as laid down (EC) No 852/2004: *"processing" means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;"* if fed to farmed animals ((EU) No 142/2011)

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Category 3 materials (IPIFF, 2021a), herbage in contact with organic fertilisers or soil improvers within 21 days[94], and catering waste[95] or products derived therefrom ((EC)No1069/2009).

The amended Regulation (EU) 999/2001 ((EC)No999/2001) prohibits animal-derived protein ((EC)No1923/2006) including processed animal protein, hydrolysed protein of animal origin, blood products, and dicalcium- and tricalcium phosphate of animal origin to non-ruminants ((EU)No56/2013). But certain exceptions could apply, e.g., when the hydrolysed protein or blood products are gained from non-ruminants, fishmeal is derived from non-mammals, and dicalcium- and tricalcium phosphate is appropriately labelled ((EC)No1923/2006).

In **Table 13**, a set of input materials (non-exhaustive) is displayed which is not permitted for feeding to farmed insects.

Owing to the inclusion of input from the retail sector, "*former foodstuff*" from the fruit and vegetable origin is subject to this RUSTICA D3.2 report. Apart from the constraints of the *Animal by-product Regulations* ((EC)No1069/2009) ((EU)No142/2011), *former foodstuff*[96] is heeded in the amended *Catalogue of Feed materials* as well, but no distinction is made e.g., between vegetable and animal origin. Apparently, catering waste is excluded by the Catalogue ((EU)2017/1017). As agreed in the aforementioned EU Guidelines C/2018/2035 and in literature, foodstuff containing no meat and fish but formerly offered for human consumption *("former foodstuff"),* such as over date packaged food from the retail sector, can be used for animal (C/2018/2035) and, more specific, insect feeding (Lähteenmäki-Uutela & Grmelova, 2016) (IPIFF, 2021a).

RUSTICA intends to investigate a set of fruits and vegetables, e.g., tomatoes, cucumbers and melons not suitable for food deployments including their leaves and stems for insect cultivation taking into account the requirements of feed law ((EC)No767/2009). According to IPIFF, "*Fruits and vegetables and their derived products*" count for substrates which commonly serve as substrates for insect production (IPIFF, 2020). Contemplating law in the waste sector, the amendment of the Directive on waste ((EU)2018/851) provides options on materials as far as they are in compliance with (EC) No 767/2009. (Please view also section 3.1.1)

[94] Except of manure, guano, milk inclusive derived products, and digestive tract content if free of any risk and disease ((EU)No142/2011), Annex II, Chapter II

[95] *'catering waste' means all waste food, including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens;* (EU) No 142/2011, Annex I

[96] *"'Former foodstuffs' means foodstuffs, other than catering reflux, which were manufactured for human consumption in full compliance with the EU food law but which are no longer intended for human consumption for practical or logistical reasons or due to problems of manufacturing or packaging defects or other defects and which do not present any health risks when used as feed. The setting of maximum contents as referred to in point 1 of Annex I to Regulation (EC) No 767/2009 shall not be applicable to former foodstuffs and catering reflux. It shall apply when further processed as feed."* ((EU) 2017/1017), Annex, Part A, point (3)

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Table 13: Examples of materials prohibited for feeding of farmed insects

Examples of materials prohibited for feeding to farmed insects	Legal Sources
"Faeces, urine and separated digestive tract content resulting … irrespective of any form of treatment or admixture."	(EC) No 767/2009
"Solid urban waste, such as household waste"	(EU) No 568/2010
"Catering waste and products derived therefrom"	(EU) No 1069/2009
"Processed protein from the same species"	(EU) No 1069/2009
***"Herbage in contact with organic fertilisers or soil improvers"…* within 21 days**	(EU) No 1069/2009
"Processed animal protein ... to farmed animals" (some exeptions are made)	(EC) No 999/2001

Source: Own depiction based on the legal sources: ((EC)No767/2009), ((EU)No568/2010), ((EC)No999/2001), ((EC)No1069/2009)

Furthermore, by-products from food manufacture, such as pulps from olives, cocoa and coffee are foreseen for RUSTICA insect dietary purposes. Considering the current *Catalogue of Feed Materials* ((EU)2017/1017) amending ((EU)No68/2013) and materials planned for feeding in the project, the list shows entries of olive pulp, cocoa by-products (e.g. husk and shells) and coffee skins.

Besides, output from CAP will be subject to RUSTICA research on insect feeding. Looking at chapter 12 of Annex, Part C of the List of Feed Materials, "*Products and by-products obtained by fermentation using micro-organisms, inactivated resulting in absence of live micro-organisms"* are depicted. Feed materials not aligned to 12.C of the list and arisen from a fermentation process or containing microorganisms, may be placed on the market with living microorganisms under conditions, e.g., as follows ((EU)2017/1017) (Part A(6)): Their use in feed materials or compound feed does not multiply the microorganisms and is not connected to a function fulfilled by microorganisms as defined in Annex I of the Regulation on Feed Additives ((EC)No1831/2003) ((EU)2017/1017). The voluntary character of the catalogue is already pointed out in section 3.2.1 as well as the commitments of a feed business operator in case of taking advantage of the compendium ((EU)2017/1017).

Opposed to the *Catalogue of Feed Materials,* all feed material needs to be consistent with the Directive 2002/32/EC and its amendments (please view also section 3.2.1) establishing maximum levels of undesirable substances[97] in animal feed (2002/32/EC). A range of general limits for feed materials and maximum amounts for specific applications are legally prescribed in Annex I of the amended Directive 2002/32/EC. The seven main groups of such substances and examples thereto are reflected in **Table 14**.

Ruling undesired substances, the amended Directive 2002/32/EC not only applies to feed materials but also e.g., to feeding stuff[98], feed additives and premixtures therefrom (2002/32/EC). As far as feed additives will be produced and market entrance at the EU level is envisaged, an authorisation is necessary and the additive needs

[97] *""undesirable substance" shall mean any substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for animal feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production."* (2002/32/EC)

[98] *""feedingstuffs" shall mean products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding."* (2002/32/EC)

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an entry in the *European Union Register of Feed Additives* (EU, 2021b) as established by Regulation (EC) No 1831/2003 ((EC)No1831/2003) and its amendments.

Table 14: Seven main groups of undesired substances in animal feed

Undesired Substances/Name of Section	Examples of undesired Substances	Legal sources
Inorganic contaminants and nitrogeneous compounds	e.g., Arsenic, Lead, Mercury	(EU) No 2019/1869
Mycotoxins	e.g., Aflatoxins B1	(EU) No 574/2011
Inherent plant toxins	e.g., Hydrocyanic acid	(EU) No 574/2011
Organochlorine Compounds (except dioxins and PCBs)	e.g., Aldrin, DDT	(EU) No 574/2011
Dioxins and PCBs	e.g., Dioxins	(EU) No 744/2012
Harmful botanical impurities	e.g., Datura sp., Ambrosia spp. (seeds)	(EU) 2015/186
Authorised feed additives in non-target feed following unavoidable carry-over	e.g., Decoquinate	EU 2015/186

Source: Own depiction based on Directive 2002/32/EC, Annex I (2002/32/EC) and amendments ((EU)No574/2011) ((EU)2019/1869) ((EU)No744/2012) ((EU)2015/186)

Ruling undesired substances, the amended Directive 2002/32/EC not only applies to feed materials but also e.g., to feeding stuff[99], feed additives and premixtures therefrom (2002/32/EC). As far as feed additives will be produced and market entrance at the EU level is envisaged, an authorisation is necessary and the additive needs an entry in the *European Union Register of Feed Additives* (EU, 2021b) as established by Regulation (EC) No 1831/2003 ((EC)No1831/2003) and its amendments.

Feed additives comprise substances, micro-organisms or preparations aimed at functions as legally defined in (EC) No 1831/2003 which can be summarised as follows ((EC)No1831/2003):

They *"shall satisfy the nutritional needs of animals and favourably affect:"*

- *"the characteristics of feed and animal products"*
- *"the environmental consequences of animal production"*
- *"animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs or have a coccidiostatic or histomonostatic effect."((EC)No1831/2003).*

Specific legal rules on feed additives for insects could not be found thus far ((EC)No1831/2003) and following IPIFF, currently, such additives need to be authorised for ***"all animals"*** (IPIFF, 2020). With view on the CAP, its wide variety of expected outputs and inter alia targeting insect feeding, an excerpt of the aforementioned *Register* by focusing on technical additives and subcategory "*preservatives*[100]*"* and sensory additives, such as *"flavouring compounds*[101]*"* (EU, 2021b) as laid down in Annex I of the Regulation ((EC)No1831/2003) is depicted in **Table 15.**

[99] *""'feedingstuffs" shall mean products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding."* (2002/32/EC)

[100] *"preservatives: substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites;"* (EC) No 1831/2003)

[101] *"flavouring compounds: substances the inclusion of which in feedingstuffs increases feed smell or palatability." ((EC)No1831/2003)*

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Table 15: Examples of carboxylic acids as additives for the preservation and flavouring of feed

Category/ Functional Group	Sub-classification	Code/ Additive	Expiry date of authorisation	Legal base	Date of first entry
1a	Preservatives	E 260/ Acetic acid	Application submitted	Following the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted	07.11.2005
2b	Flavouring compounds	2b08002/ Acetic acid	06.02.2027	Commission Implementing Regulation (EU) 2017/53 of 14 December 2016	23.01.2017
1a	Preservatives	E 270/ Propionic acid	Application submitted	Following the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted	07.11.2005
1a	Preservatives	E 280/ Lactic acid	Application submitted	Following the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted	07.11.2005
2b	Flavouring compounds	2b08004/ Lactic acid	06.02.2027	Commission Implementing Regulation (EU) 2017/56 of 14 December 2016	23.01.2017
2b	Natural or corresponding synthetic chemically defined flavourings	-- CAS No 107-92-6 / Butyric acid / Flavis No 08.005	Application submitted	Following the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted	07.11.2005
2b	Flavouring compounds	2b08007/ Valeric acid	06.02.2027	Commission Implementing Regulation (EU) 2017/53 of 14 December 2016	23.01.2017
2b	Flavouring compounds	2b08009/ Hexanoic acid	06.02.2027	Commission Implementing Regulation (EU) 2017/53 of 14 December 2016	23.01.2017
2b	Flavouring compounds	2b08010/ Octanoic acid	06.02.2027	Commission Implementing Regulation (EU) 2017/53 of 14 December 2016	23.01.2017
2b	Flavouring compounds	2b08011/ Decanoic acid	06.02.2027	Commission Implementing Regulation (EU) 2017/53 of 14 December 2016	23.01.2017
2b	Flavouring compounds	2b08012/ Dodecanoic acid	06.02.2027	Commission Implementing Regulation (EU) 2017/53 of 14 December 2016	23.01.2017

Source: European Union Register of Feed Additives 2021 (Excerpt) (EU, 2021b), and legal sources: ((EC)No1831/2003), ((EU)No305/2014), ((EU)2017/53), ((EU)2017/56)

Ruling undesired substances, the amended Directive 2002/32/EC not only applies to feed materials but also e.g., to feeding stuff[102], feed additives and premixtures therefrom (2002/32/EC). As far as feed additives will be produced and market entrance at the EU level is envisaged, an authorisation is necessary and the additive needs

[102] *"'feedingstuffs" shall mean products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding."* (2002/32/EC)

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an entry in the *European Union Register of Feed Additives* (EU, 2021b) as established by Regulation (EC) No 1831/2003 ((EC)No1831/2003) and its amendments.

Feed additives comprise substances, micro-organisms or preparations aimed at functions as legally defined in (EC) No 1831/2003 which can be summarised as follows ((EC)No1831/2003):

They *"shall satisfy the nutritional needs of animals and favourably affect:"*

- *"the characteristics of feed and animal products"*
- *"the environmental consequences of animal production"*
- *"animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs or have a coccidiostatic or histomonostatic effect."((EC)No1831/2003).*

Specific legal rules on feed additives for insects could not be found thus far ((EC)No1831/2003) and following IPIFF, currently, such additives need to be authorised for ***"all animals"*** (IPIFF, 2020). With view on the CAP, its wide variety of expected outputs and inter alia targeting insect feeding, an excerpt of the aforementioned *Register* by focusing on technical additives and subcategory "*preservatives*[103]*"* and sensory additives, such as *"flavouring compounds*[104]*"* (EU, 2021b) as laid down in Annex I of the Regulation ((EC)No1831/2003) is depicted in **Table 15**.

Regulation (EC) No 183/2005 deals with hygiene rules for animal production determined for the food chain ((EC)No183/2005). As such, insects solely bred for fertiliser production might be excluded by this legal source. Regulation (EC) No 852/2004 encompassing food safety and hygiene rules for food business operators is important for insect farming addressing human consumption. It provides no specific orders for the non-food producing insect sector but sets forth treatments for former animal-based food stuff ((EC)No852/2004).

An array of legal sources is related to animal health, and subsequently to human health in the EU. In this direction, the amended (EU) No 2016/429 on transmissible animal diseases applies to insect farming as well ((EU)2016/429) while EU welfare rules including minimum standards for animal farming (98/58/EC) are not legally dictated to production of insects (IPIFF, 2021a).

Whereas rearing of insects is legally allocated to the primary sector, killing of them alters their status and law on animal by-products (EC) No 1069/2009 and (EU) No 142/2011 then applies. If, for instance, processed animal proteins are produced, the activity needs to be approved by the national competent authority (IPIFF, 2020).

3.2.4.2. Use of Insect Biomass

Unlike insect business delivering e.g., human diets and animal feed, the highly innovative RUSTICA insect valorisation approach covering the entire insect production output for fertiliser purposes lacks comprehensive and dedicated literature at the moment. EU legal frameworks dictate rules on the spectrum of applications for invertebrates. In this respect, options, constraints and perspectives for insect cultivation are investigated in terms of insect biomass for nutrient supply of plants in this section.

3.2.4.2.1. Entire insect bodies

Protocols of strong endeavours to launch insects on the market as a *Novel food* are available (IPIFF, 2021b), and food safety of *dried Tenebrio Molitor larva* in compliance with the Regulation on Novel Foods (EU) 2015/2283 ((EU)2015/2283) has been confirmed by the European Food Safety Authority (EFSA) (EFSA, 2021). Commission

[103] *"preservatives: substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites;"* (EC) No 1831/2003)

[104] *"flavouring compounds: substances the inclusion of which in feedingstuffs increases feed smell or palatability." ((EC)No1831/2003)*

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Implementing Regulation (EU) 2021/882 amending (EU) 2017/2470 ((EU)2017/2470) sets stipulations for the first insect definitly registered as a *Novel Food* in the EU and delivers an authorisation to the French Company SAS EAP Group ((EU)2021/882).

Feed materials in the List of the amended Annex, Part C, of the *Catalogue of feed* comprise terrestrial invertebrates in both versions: living and dead while the latter is excluded if (EC) No 1069/2009 applies to a process related thereto ((EU)2017/1017). Further prescriptions are imposed to feeding of invertebrates to farmed animals (e.g. not to be delivered to ruminants). If consistent with national law, insects can be fed to pets ((EU)No142/2011) .

Terrestrial invertebrates without health and safety risks are aligned to Category 3 materials of (EC) No 1069/2009 (Art. 10 (l)). The Regulation installs options and constraints on **organic fertilisers** and **soil improvers** for these materials, e.g., in its Art. 32. Such stipulations are, for example, pressure sterilization and origin from an approved production site ((EC)No1069/2009).

3.2.4.2.2. Insect proteins

If insect protein is derived from killed insects, a permission by the competent national authority in accordance with Art. 24.1 und Art. 44.1 of (EC) No 1069/2009 is necessary as well ((EC)No1069/2009). Specific attention needs to be drawn to the term of *"processed animal protein"* which is defined in Regulation (EU) No 142/2011, Annex I:

"'Processed animal protein' means animal protein derived entirely from Category 3 material, which have been treated in accordance with Section 1 of Chapter II of Annex X (including blood meal and fishmeal) so as to render them suitable for direct use as feed material or for any other use in feedingstuffs, including petfood, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, milk-derived products, colostrum, colostrum products, centrifuge or separator sludge, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, including eggshells, tricalcium phosphate and collagen;" (EU) No 142/2011, Annex I(5)

Annex X, Chapter II, Section 1 of the Regulation (EU) No 142/2011 commands the "*processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV"* if non-mammalian processed animal protein (except of fishmeal) is generated. For example, processing method 1 "pressure sterilization" applies to particles which need to be reduced to ≤ 50 mm. Heating is required to a "*core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars".* In addition, all air has to be removed by pressure and replaced by steam ("*saturated steam*") in the sterilization chamber. Heat treatment is allowed as the "*sole process or as a pre- or post-process of the sterilization phase"*((EU)No142/2011).

Processed animal protein for organic fertilisers and soil improvers has to be mixed with an ingredient preventing its use for feeding purposes unlessan appropriate packaging is used for excluding such purposes ((EC)No1069/2009). Ingredients permitted for mixing are e.g., lime, manure, urine, digestate or mineral fertilisers and should be in line with good agricultural practice and avoid feeding of the materials (Annex XI) ((EU)No142/2011).

To enable identification, a specific labelling is prescribed in Annex VIII of (EU) No 142/2011: "*organic fertilisers or soil improvers/no grazing of farmed animals or use of crops as herbage during at least 21 days following application'"* while certain exemptions apply to packages ≤ 50 kg or big bags below 1000 kg. Records need to be kept for at least two years on the applications on land, amounts delivered, dates of application and contact of livestock. Such documentation is not compulsory if e.g., manure, digestive content or milk-related products are applied ((EU)No142/2011).

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Hydrolysed proteins are defined in Annex I of (EU) No 142/2011 as *"polypeptides, peptides and aminoacids, and mixtures thereof, obtained by the hydrolysis of animal by-products".* Annex XI, chapter II enables Category 3 material as a starting material for producing proteins others than "*processed animal proteins*" to be deployed as components of organic fertilisers and soil improvers if treated by the methods 1-5 or 7 of Annex IV ((EU)No142/2011) (EBIC-ECOFI, 2021).

3.2.4.2.3. Insect fats and oils

Opposed to restrictions of processed animal proteins for feeding purposes, feeding of fats is reported not to be part of the "feed ban" imposed by the amended (EU) 999/2001 ((EC)No999/2001).

While scientific analyses on insect fats and oils highlight their valorisation outside the food and feed areas, such as cosmetics (Verheyen et al., 2018) and biodiesel (Kalu-Uka et al., 2021), to the best knowledge of the author, profound information on the appropriateness and maturity of these materials for fertiliser purposes is not available at present.

As far as belonging to *Category 3 Material* and foreseen to be used as organic fertiliser or soil improver by means of (EU) No 1069/2009 ((EC)No1069/2009), insect fat and oil has to undergo treatment of one of the processing methods 1-5 or 7 of Chapter III, Annex IV of (EU) No 142/2011 as well ((EU)No142/2011).

3.2.4.2.4. Chitin and chitosan

After cellulose, chitin is the second largest polysaccharide available worldwide. It can be found in a wide range of organisms, and, hitherto, it is mainly gained from crustaceans at the commercial level. Apart from fungi as the second most important source of chitin, increasing attention is drawn to insects and their potential as sustainable and non-seasonal suppliers of chitin and its conversion into the more soluble biopolymer chitosan. Hahn et al. conducted a detailed study on chitosan by de-acetylation of insect chitin (Hahn et al., 2020).

The use of chitin and its derivatives in agriculture is comprehensively discussed in literature. A positive effect on plant growth (e.g., for grapevine), nutrient contents comparable to other organic fertiliser ingredients, and an influence on tolerance to abiotic stresses are inter alia extensively evaluated by Sharp (Sharp, 2013). Stimulating of plant growth by chitin or chitosan because of their positive effect on *soil biomass and on the association of symbiotic organisms with plants* rather than a direct effect on the plant itself is pointed out by Winkler et al. (Winkler et al., 2017).

No direct indication on the terms "chitin" or "chitosan" could be identified in the Animal by-product Regulations. However, if treated as a part of an invertebrate body and accepted as a *Category 3 Material* targeting organic fertilisers and soil improvers as laid down in Art. 32 of (EU) No 1069/2009, the processing methods 1-5 and 7 of Annex IV and the rules of Annex XI of (EU) No 142/2011 would apply.

3.2.4.3. Frass and new options

A range of studies were already undertaken on the use of insect frass for fertiliser application. Trials conducted with frass from mealworm (Tenebrio molitor L.) fully or partly replacing mineral NPK fertiliser and barley as a crop resulted in a "great potential to be used as a partial or a complete substitute for mineral NPK fertiliser" (Houben, Daoulas, Faucon, & Dulaurent, 2020). Furthermore, it can be deduced from attempts with composted frass from the black soldier fly (Hermetia Illucens L.) and combined with mineral NPK fertiliser for maize nutrition in Kenya that the high fertiliser value of that frass and *"its integration with mineral NPK fertiliser could be a solution for improved soil health and sustainable production of maize"* (Beesigamukama et al., 2020). The potential and effects of frass and its combination with inorganic fertilisers on plant productivity and soil quality by pointing out the role of insect nutrition for frass application in terms of electrical conductivity and contaminants are discussed in literature as well (Chavez & Uchanski, 2021).

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Pondering the EU legislation: pursuant to Art. 22 of (EU) No 142/2011, *placing on the market and use of organic fertilisers and soil improvers*, especially if these materials are supplied to land have to be conform with Art. 15(1)(i)[105] indicating that measures may be set for implementing details relating thereto and Art. 32(1) e.g., considering materials of categories 2 and 3 of (EC) No 1069/2009 ((EC)No1069/2009). Other details are legally clarified, e.g., in Annex XI of the Regulation ((EU)No142/2011) implementing the Regulation on Animal by-products ((EC)No1069/2009) .

According to a draft for a Regulation amending (EU) No 142/2011, rules are proposed for frass e.g., in the context of processed manure and an entry to be made for setting rules as regards its use for organic fertilisers in Annex XI of the Animal by-products implementing Regulation ((EU)No142/2011) and its alignment to standards as under use for processed manure (ST10820, 2021INIT) (ST10820, 2021ADD).

Currently, frass could be considered for CE-marked fertilisers via compost (CMC 3) and digestate (CMC 5) ((EU)2019/1009) if an endpoint is defined in the manufacturing chain in compliance with the Animal By-Products Regulation ((EC)No1069/2009). (Please view more details also in section 3.3.1)

At time of writing, endpoints in the manufacturing chain are defined in Art. 3 of Regulation (EU) No 142/2011 and its amendments for "*certain derived products to be placed on the market"* and "*other than imported*" as reflected in **Table 16** ((EU)No142/2011).

Table 16: Certain derived products and endpoints in the manufacturing chain ((EU) No 142/2011, Art. 3)

Derived Product	Legal reference defining specific requirements for endpoints in the manufacturing chain
Biodiesel	(EU) No 142/2011, Annex IV, Chapter IV, Section 3, point 2(b)
Processed pet food	(EU) No 142/2011, Annex VIII, Chapter II, point 7(a)
Dog chews	(EU) No 142/2011, Annex XIII, Chapter II, point 7(b)
Hides and skins of ungulates	(EU) No 142/2011, Annex XIII, Chapter V, point C
Wool and hair	(EU) No 142/2011, Annex XIII, Chapter VII, point B
Feathers and down	(EU) No 142/2011, Annex XIII, Chapter VII, point C
Fur	(EU) No 749/2011, amending (EU) no 142/2011, Annex VIII, Chapter XIII
Fish oil for the production of medicinal products	(EU) No 749/2011, amending (EU) No 142/2011, Annex XIII, Chapter XIII
Gasoline and fuels	(EU) No 294/2013, amending (EU) no 142/2011, Annex IV, Chapter IV, Section 3, point 2(c)
Oleochemical products derived from rendered fats	(EU) No 294/2013, amending (EU) No 142/2011, Annex XIII, Chapter XI
Renewable diesel, jet fuel, propane and gasoline	(EU) No 2017/1261, amending (EU) No 142/2011, Annex IV, Chapter IV, Section 3, point 2(f)

Source: Own depiction based on legal sources: ((EU)No142/2011), ((EU)No749/2011), ((EU)No294/2013), ((EU)2017/1261)

Detailed information on animal by-products in the context of endpoints in the manufacturing chain is given by the *European Consortium of the Organic-based Fertilizer Industry* (ECOFI). The guide describes a procedure for an application by submission of a dossier to EFSA via the national competent authority which needs to be in compliance with the legal stipulations of Art. 16(e) and Art. 20 of Regulation (EC) No 1069/2009 (ECOFI, 2019).

[105] *"Measures for the implementation may be laid down to the application to land of certain animal by-products, organic fertilisers and soil improvers;" ((EC)No1069/2009)*

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3.2.4.4. LCA and emissions

The aforementioned global, European and national GHG emission reduction targets are also of interest if it comes to emissions prompted by the emerging EU insect production sector. To the best knowledge of the author, GHG rules specifically issuing insect cultivation could not be detected thus far in legally binding EU legislation.

On the other hand, a range of studies involving insect farming are already undertaken to explore the effects of this sector on emissions and climate change. Oonincx et al. investigated five species of insects[106] on their GHG (CO2, CH4, and N_2O) and NH_3 emissions in comparison to pigs and beef cattle. The authors concluded that the GHG emission of four insect types in terms of kg of mass gain was significantly lower than for pigs and achieve just around one percent of the GHG emissions caused by ruminants (Oonincx et al., 2010). A number of 22 life cycle assessment studies on insect production was evaluated by Smetana et al.: if food by-products or waste are used as a feedstock, the results in terms of global warming potential impacts for all the functional units are in the range from -6,42 CO2 eq. as favourable for the environment to 5,3 CO2 eq. per kg dm[107] (Smetana, Spykman, & Heinz, 2021).

3.2.5. Pyrolysis/gasification and biochar

For thousands of years, mankind has applied charcoal for cooking, heating and other applications like feed materials (Conte, Schmidt, & Cimò, 2016). Roots indicating a long history were also discovered by means of "*Terra Preta*", an anthropogenic soil of high fertility and organic matter contents of pre-Columbian origin in Central Amazonia (Bezerra et al., 2019) (Glaser, Lehmann, & Zech, 2002).

More recently, since the 1990s, due to its positive effect as regards global warming and soil constitution, charcoal has attracted growing scientific interest (Conte et al., 2016) (Glaser et al., 2002). The term "biochar" for deployments explicitly targeting soil was introduced in scientific literature in the first decade of the 21st century designating a particular type of soil conditioner (Bezerra et al., 2019) (Conte et al., 2016) (Lehmann, Gaunt, & Rondon, 2006).

Various definitions are suggested for *biochar* in literature and to the best knowledge of the author an official legal statement drawing the exact outline of this material group at the EU level could not be identified thus far. Van Laer et al. referred to the comprehensive definition of the JRC of the European Commission in its report "*Biochar Application to Soils*", which is herewith cited as follows (Verheijen, Jeffery, Bastos, Van der Velde, & Diafas, 2010) (Van Laer et al., 2015):

"Charcoal (biomass that has been pyrolysed in a zero or low oxygen environment) for which, owing to its inherent properties, scientific consensus exists that application to soil at a specific site is expected to sustainably sequester carbon and concurrently improve soil functions (under current and future management), while avoiding short- and long-term detrimental effects to the wider environment as well as human and animal health" (Verheijen et al., 2010).

Following the Guidelines of the European Biochar Certificate (EBC), "*Biochar is a porous, carbonaceous material that is produced by pyrolysis of plant biomasses and is applied in such a way that the contained carbon remains stored as a long-term C sink or replaces fossil carbon in industrial manufacturing. It is not made to be burnt for energy generation (EBC, 2012) ."*

[106] *Tenebrio molitor*, *Acheta domesticus*, *Locusta migratoria*, *Pachnoda marginata,* and *Blaptica dubia*

[107] With exception of one study which significantly deviate from the majority and expresses 4.5-12 kg CO2 eq. per kg dm (Smetana et al., 2021)

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3.2.5.1. Feedstocks and consequences

Apart from the processing conditions, feedstocks are reported to be the most important element determining the characteristics of biochar, and in principle, each organic input could be converted to biochar by pyrolysis (Verheijen et al., 2010). In any case, the choice and legal status of the resource significantly influences the situation of the entire value chain.

If waste[108] is the feeding material for the process, the output is considered waste as well. An "*end-of waste status*" is necessary and criteria have to be defined (2008/98/EC) ((EU)2018/851) before the biochar can be placed on the market. As far as agricultural waste streams are under use which are usually discarded, the process is waste treatment and for the resulting biochar the aforementioned end-of-waste status needs to be defined as well (Van Laer et al., 2015).

Alternatively, by-products could be supplied to manufacture of biochar. In case of by-products as referred to by the amended Directive on waste (2008/98/EC) ((EU)2018/851) are under use, it needs to be stressed that criteria would be required at the European or national level to exactly define such a by-product. Furthermore, a marketed by-product (like a product) has to be registered under the REACH Regulation as far as no exemption applies ((EC)No1907/2006) (ECHA, 2012). If all legal stipulations are met, biochar accomplished by means of a by-product or a product, such as a crop specifically grown, is not waste but a product if representing the main or sole output of the manufacturing activity. According to literature, if the main objective is another article it will be a by-product (Van Laer et al., 2015) or waste (Conte et al., 2016) for energy as the main output.

In addition, feedstocks from animal by-products and their endpoints in the manufacturing chain as discussed prior to this section could be debated as regards organic input material for biochar. However, to date, this is not in the scope of the RUSTICA project.

Eventually, attention needs to be drawn again to the term "*biomass*" (please view also section 3.1.2) in the context of biochar. By virtue of its legal definition the term comprises a miscellaneous assortment of products, residues and waste laid down for energy purposes in the Renewable Energy Directive ((EU)2018/2001). Stringent orders are made as with regard to sustainability of biomass for fuel purposes, such as targets on GHG emission savings ((EU)2018/2001). If biochar production is related to biomass for generation of energy, the RED II stipulations would need to be deliberated.

To explore the RUSTICA value chain on biochar, pruning from orchards and vineyards and remainders, such as leaves and stems from vegetable and fruit yields including cocoa fruit pods are proposed. As far as these things are commonly treated as waste (Van Laer et al., 2015) and no exemption applies to a transformation process into biochar from the Directive on waste (2008/98/EC) ((EU)2018/851), production activities need to follow these rules from starting point along the process to final output. Conversely, if by-products instead of waste will be fed to the biochar plant, subsequently rules thereto will apply.

3.2.5.2. Processing and rules on quality

Generating biochar commonly occurs by means of pyrolysis or gasification process and the production of *char* is entailed with *liquids* and *syngas*. Pyrolysis means to chemically decompose an organic substance through heating by excluding oxygen. However, a totally oxygen-free environment cannot be achieved in practise so that oxidation to a minor degree always takes place (Verheijen et al., 2010). Different conditions, such as processing temperature and process duration governs the output, and in particular the ratio between the three

[108] as defined by the Directive on waste 2008/98/EC

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aforementioned constituents (**Table 17**). This D3.2 report focuses on biochar while liquid and gaseous fractions are neglected in the course of this work.

Table 17: Biochar: the effect of processing conditions

Type of Processing	Tempe-rature	Important Determinants	Liquids	Biochar	Syngas
Torrefaction[109] (Van Laer et al., 2015)	< 300 °C	Biomass residence time up to one hour	5%	80%	15%
Slow Pyrolysis (Verheijen et al., 2010)	~400 °C	Very long residence time of solids	30%	35%	35%
Intermediate Pyrolysis (Verheijen et al., 2010)	~500 °C	Moderate hot vapour residence time of 10-20 s	50%	20%	30%
Fast Pyrolysis (Verheijen et al., 2010)	~500 °C	Short hot vapour residence time of ~1 s	75%	12%	13%
Gasification (Verheijen et al., 2010)	~800 °C	Long vapour residence time	5%	10%	85%

Source: Own depiction based on Verheijen et al. (Verheijen et al., 2010) and Van Laer et al. (Van Laer et al., 2015)

Owing to the chemical alteration of the feedstock triggered by the pyrolysis or gasification process (Verheijen et al., 2010), the stipulations of the REACH Regulation are relevant again for the recovered waste or obtained material. As already mentioned, waste is not subject to REACH ((EC)No1907/2006) and placing on the market of waste-based biochar needs specific end-of-waste criteria based on the general requirements of the amended Directive on waste (2008/98/EC) ((EU)2018/851). Unlike the exemptions for brown and black coal as a *"solid fuel formed by plants and a substance occurring in nature"*, *ECHA Guidance on Annex V* emphasizes that *"Charcoal obtained by thermal decomposition of wood is not regarded as a substance which occurs in nature (ECHA, 2012)".* As published by the European Biochar Industry (EBI), biochar is incorporated into the REACH dossier of charcoal (**Table 18**) (EBI, 2020) .

Table 18: REACH Dossier of Charcoal and indications on biochar (Excerpt)

REACH Dossier of Charcoal - Registration of biochar	
Origin	**Registration Number**
wood	EC# 240-383-3
coconut shells	EC# 271-974-4

Source: Own depiction based on ECHA, 2021 (ECHA, 2021c); EBI, 2020 (EBI, 2020)

In absence of comprehensive legal frameworks bolstering the market of biochar, tremendous efforts have been made to develop standards and confer certificates enabling measurable levels of quality at the global, European and national level. The standard (version 2.1) of the *International Biochar Initiative* (IBI), located in the United States, comprises inter alia ≥ 10% of organic carbon in the biochar product, a hydrogen to organic carbon ratio of below 0,7, and a declaration of the contents, such as total moisture, -ash and -nitrogen. In addition, limits on contaminants and pollutants may not be exceeded (Meyer et al., 2017) (Vereš, Koloničnýa, & Ochodeka, 2014). The *European Biochar Certificate* (EBC) stands for a voluntary standard in the EU, but it is mandatory for biochar

[109] *"Torrefaction is a form of partial or incomplete pyrolysis and as such, yields a solid product that is not considered to be a char-like material, with significantly less recalcitrant carbon and lower stability. Hence, it has limited potential to be used in soil applications. (Van Laer et al., 2015)"*

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marketing in Switzerland. It requires e.g., certain characteristics of the product, recovery or incineration of pyrolysis gases, and conformity with the positive list of the permitted feedstocks. Furthermore, accredited laboratories are committed to analyse biochar batches in compliance with the EBC regulatory. Moreover, inspections of production sites with a capacity of more than 50 tpa are conducted by independent national agencies at one time per year (EBC, 2012) (Van Laer et al., 2015).

3.2.5.3. The Future: biochar and CE-marked fertilisers

At time of writing, biochar is mentioned in the new EU Regulation on Fertilising Products (EU) 2019/1009, e.g., in the context of waste recovery (Recitals 19 and 58). But the European Commission has adopted a draft to add biochar as a CMC 14 to the Fertilising Products Regulation (EU) 2019/1009 at 7th of July 2021 (EC, 2021s) (C(2021)4764). More details thereto will be given in section 3.3 of this report.

3.2.5.4. Emissions in the context of biochar

Since paramount for each manufacture and use of products, it is briefly referred to emissions in this section.

To accomplish the aforementioned objectives of the *Paris Agreement* and target of climate neutrality in the EU by 2050, strong efforts on emissions sinks are of vital importance. In literature, the quality of biochar as a net emission technology is comprehensively described (Vereš et al., 2014). Such merits are, for instance, a continuous and clear measurable carbon sequestration and water conservation superior to other methods like minimum tillage as a technique for arable land. Another implication which can result from biochar deployment are low expenditure for the climate mitigation which belongs to the types of feedstocks, processing or installations (Verde & Chiaramonti, 2021). It is noteworthy that the strengths of biochar are also acknowledged by the IPCC, and, depending on the pyrolysis temperature, a fraction of biochar carbon remaining up to 89% after 100 years has been calculated in the *2019 Refinement to the 2006 IPCC Guidelines for National Greenhouse Gas Inventories* (IPCC, 2021b). The properties of biochar are not explicitly highlighted in the Directive 2003/87/EC and its amendments as important instruments of the EU Emission Trade Systems (ETS) (Van Laer et al., 2015). But a reference is made to biomass: "*the emission factor of biomass shall be zero*" in Art. 38 of the Implementing Regulation (EU) 2018/2066, and charcoal is included in Annex VI as a fuel material having no emission factor ((EU)2018/2066).

With view on an upscale of pyrolysis and gasification technologies involving biochar and energy production to industrial level, the resulted complexity of the legal aspects are of interest. If biochar feedstock and technology would be embedded into the legal context of originating from waste incineration (which includes pyrolysis) or large-scale gasification, e.g., technical prerequisites and BAT conclusions (2010/75/EU) ((EU)2019/2010) ((EU)2017/1442) would need to be scrutinised on their relevance for the entire site concept. (Please view also section 3.1.4.2)

3.2.6. Composting - from treatment to product

In order to ensure that nutrient cycles can be closed, the RUSTICA project integrates composting as a mature technology into the sphere of its activities. Composting is the technology to be finally decided upon results of the five innovations and towards striving for perfect solutions on plant nutrition and soil health rather than an already existing rigid concept. Such solutions may include blending and compounding of various components towards tailored recipes for orchards, vineyards, greenhouses and open field agriculture.

In this respect, legal facets addressing compost with view on input components and their origin, quality requirements including standards, the position in the REACH Regulation ((EC)No1907/2006), emissions, and CE-marked fertilisers are indicated in this RUSTICA D3.2 report.

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3.2.6.1. Input components

Following the publications of the European Compost Network (ECN), around 30.5 million t of compost are generated annually from biowaste in Europe (ECN, 2021b). A separate collection or separation at source of biowaste all over the EU becomes mandatory by the end of 2023 as it is introduced by the amendment ((EU)2018/851) of the Directive on waste (2008/98/EC). Art. 22 clearly encourages Member States to take initiatives in compliance with the waste hierarchy (please view section 3.1.1.1) as well as protection of human health and the environment to foster the *"recycling including composting …"* of biowaste targeting "*relevant high-quality standards*". Furthermore, *home composting* shall be encouraged as well as promotion of materials produced from biowaste. Moreover, the development of European Standards for biowaste subject to a recycling process, such as composting, through European standardisation organisations will be requested by the European Commission ((EU)2018/851). End-of-waste criteria for compost are proposed by the EC JRC (Saveyn & Eder, 2014) but not finally implemented at the EU level (Luit et al., 2017).

Considering the recycling targets for municipal waste, rules are established for treatments of *"municipal biodegradable waste"* resulting in compost. If an application to land takes place, it counts for recycling in a Member State provided that the effects are *"benefits to agriculture or ecological improvement*" (Art. 11a) ((EU)2018/851).

Stringent hygiene measures are prescribed if animal by-products will be composted ((EC)No1069/2009) ((EU)No142/2011). But, so far, such materials are not foreseen to be investigated for compost as a "basis product" under the RUSTICA research which does not exclude its later involvement into fertiliser blends.

3.2.6.2. Quality requirements

Details on materials nationally permitted for composting, categories of compost, applications and quality are comprehensively discussed in literature (Saveyn & Eder, 2014) (ORBIT, 2008). Based on "*existing experiences in countries with running quality assurance schemes*" the ECN introduced a *European Quality Assurance Scheme* (ECN-QAS) covering compost and digestate (ECN, 2021c) (**Figure 20**).

Figure 20: ECN-QAS (European Compost Network Quality Assurance Scheme) Label
Source: European Compost Network (ECN, 2021c)

ECN-QAS aims at harmonisation of requirements and available quality assurance schemes for compost and digestate throughout Europe. The four main building blocks of the certification by ECN-QAS are (ECN, 2021c):

- *"Suitable Input Materials:* → *Positive list*
- *Operation Quality:* → *Check list*
- *Product Quality:* → *Product control*
- *Product use:* → *Application, recommendation and declarations (ECN, 2021c)"*

The European Environment Agency (EEA) has evaluated availability/level of quality management systems and national quality standards for compost in Europe and reports eleven EU countries[110] that have fully or partly

[110] Austria, Belgium, Czechia, Estonia, Finland, France, Germany, Ireland, Italy, Netherlands, Sweden (EEA, 2020)

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established compost quality management and assurance systems mainly based on ECN-QAS. National quality standards for compost are identified in 20 EU countries[111] of which 13 Member States* have incorporated these rules into their national legislation. Such national quality standards may refer to limits on heavy metals and impurities which differ widely between countries or regions (EEA, 2020).

3.2.6.3. Compost in the scope of the REACH regulation

As mentioned before, compost is covered by Annex V and exempted from Titles II, V and VI of the REACH Regulation ((EC)No1907/2006) ((EU)2019/1691). Thus, no obligation to register exists, commitments of downstream users do not apply, and evaluations of dossiers are redundant if all legal requirements are fulfilled. Notwithstanding, if a company can take advantage by means of an exemption, appropriate information must be delivered to the competent authorities upon request evidencing that the exemption for the substances is justified (ECHA, 2012). Moreover, no exemption is reported e.g., from Title VII Authorisation of SVHC and Title VIII Restrictions on certain dangerous substances ((EC)No1907/2006) ((EU)2019/1691).

3.2.6.4. New perspectives: the Fertilising Product Regulation

As the new Fertilising Products Regulation is enacted, compost gained a novel perspective to valorise waste into a high quality EU CE-marked fertiliser ((EU)2019/1009). This Regulation sets inter alia limits on contaminants which will be further ascertained in section 3.3 of this D3.2 report.

3.2.6.5. Compost and emissions

Pertaining to GHG emissions, the IPCC infers that composting of food waste leads to *"significantly lower emissions than landfilling"* while those from yard waste composting are "roughly comparable" to landfill. But the advantages of a decreased need of synthetic fertilisers and the GHG emissions entailed with their production, transport and use are not encompassed by these estimations and calculations. As it is published by IPCC, a possible reduction of fertiliser requirements by 20% at minimum is outlined by USDA[112] research, and subsequently, considerably lower GHG emissions through composting (IPCC, 2021a).

Legally prescribed measures and technologies to reduce industrial emissions (2010/75/EU) encompass biological treatment of waste and include aerobic treatments with stipulations and instructions for composting. For example, BAT 36 deals with "*monitoring and/or control of key waste and process parameters",* such as input properties, and BAT 37 underpins the need of reduction of odour and various emissions to air by means of "*semipermeable membrane covers"* and "*adaptation of operations to the meteorological conditions*"((EU)2018/1147). (Please view also section 3.1.4.)

[111] Austria*, Belgium*, Croatia, Czechia, Denmark, Estonia*, Finland*, France*, Germany*, Hungary, Ireland*, Italy*, Lithuania, Luxembourg*, Netherlands*, Poland, Portugal, Slovenia*, Spain*, Sweden* (EEA, 2020)

[112] U.S. Department of Agriculture (USDA)

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3.3. Fertilising products - requirements for different farming types

Research of RUSTICA includes a broad spectrum of resources to be deployed for plant nutrition and support of soil. As reflected in section 3.2 of this report, six essential technologies of the project are studied in order to attain six (basic-[113])products: **microbial biomass NPK concentrate, insect biomass, -frass, biochar,** and **compost**.

Therefore, particular attention has to be drawn to the new Fertilising Products Regulation ((EU)2019/1009) which replaces (EC) No 2003/2003 ((EC)No2003/2003), introduces new fertilising concepts, and establishes new pathways for entering the *Internal Market* of the EU by CE-marked fertilisers qualifying as ***"EU Fertilising Products"***[114] [115] ((EU)2019/1009) (EC, 2021d).

At the same time, specific rules are laid down for materials and products targeting fertiliser purposes in organic agriculture. These stipulations are fundamental if RUSTICA products will be applied under the premise of EU organic production ((EU)2018/848).

In this respect, both avenues to fertiliser application will be scrutinised for the RUSTICA (basic-)products in this section 3.3.

3.3.1. EU Fertilising products (CE-marked fertilisers)

While Regulation (EU) No 2003/2003 primarily refers to fertilisers which originate from inorganic materials based on chemical synthesis or mining ((EC)No2003/2003), the new Regulation (EU) 2019/1009 presents conditions targeting legal harmonisation for organic and recycled materials as well ((EU)2019/1009).

Regulation (EU) 2019/1009 entering into force at 16.07.2022 enables not only products as fertilisers typically delivering nutrients to a plant but also enhancing the efficiency of their uptake or quality of soil, to access the EU *Single Market*. To this end, seven main product function categories (PFCs) are defined: **PFC 1: fertiliser (including mineral, organo-mineral and organic fertilisers), PFC 2: liming material, PFC 3: soil improver, PFC 4: growing medium, PFC 5: inhibitor, PFC 6: biostimulant, PFC 7: fertilising product blend** ((EU)2019/1009) based on component material categories (CMCs). Both will be further discussed on possible allocations of RUSTICA results in this D3.2 report.

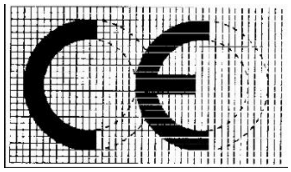

Figure 21: CE marking label as depicted in Regulation (EC) No 765/2008
Source: Regulation (EC) No 765/2008

Basic principles on CE marking and stipulations on accreditation of conformity assessment bodies, which apply to non-food products, are described in Regulation (EU) No 765/2008. According to general principles, Art. 30 expresses inter alia that "*CE marking shall be affixed only by the manufacturer or his authorised representative",*

[113] As mentioned before: upon need, these products might be mixed, blended or compounded at later stage of the project in order to excellently serving plant and soil.

[114] "*'EU fertilising product' means a fertilising product which is CE marked when made available on the market;*" ((EU) 2019/1009)

[115] "*'fertilising product' means a substance, mixture, micro- organism or any other material, applied or intended to be applied on plants or their rhizosphere or on mushrooms or their mycosphere, or intended to constitute the rhizosphere or mycosphere, either on its own or mixed with another material, for the purpose of providing the plants or mushrooms with nutrient or improving their nutrition efficiency;* " ((EU)2019/1009)

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and in total responsibility for the conformity, such marking is merely permitted for products fulfilling all legal requirements relating thereto. The CE marking label is illustrated in **Figure 21**. Art. 4 indicates rules for appointment of single national accreditation bodies which shall be conducted by Member States. These accreditation bodies are authorised to award a conformity assessment body by an accreditation certificate (Art. 5) whereas any competition between these two organisations has to be excluded (Art. 6) ((EC)No765/2008). The European Commission and other Member States shall be notified on bodies authorised to conduct *"third party conformity assessment tasks"* in accordance with the Fertilising Products Regulation ((EU)2019/1009).

As it is underpinned in (EU) 2019/1009, the manufacturer shall be solely responsible for inducing and conducting a conformity assessment (Art. 6). Furthermore, the Regulation ((EU)2019/1009) points out the necessity of compliance with existing law on standardisation ((EU)No1025/2012) and an adaption of Decision No 768/2008/EC modules to be chosen for conformity assessment procedures. By using five modules (A, A1, B, C, D1) (No768/2008/EC), four different application procedures are linked to various CMCs and PFCs in Annex IV of the Fertilising Products Regulation ((EU)2019/1009). For example, Modul D1 Quality assurance of the production process (EN ISO 9001:2000) (No768/2008/EC) may be used for each EU fertilising product except of PFC 1(C)(I)(a)(i-ii)(A) Straight or Compound Solid Inorganic Macronutrient Ammonium Nitrate Fertiliser of High Nitrogen Content containing ≥ 28% N or blends therefrom. Finally, an EU de*claration of Conformity* made by the manufacturer shall attest that all requirements of the Regulation are met (Art. 16), and the product has to be labeled and packaged appropriately (Art. 6,8,11,18 and Annex III) ((EU)2019/1009).

Distributors are committed, e.g., to verify and evidence accompanied documents of delivery. In case of imports from third countries, the manufacturers have to meet the requirements as well, and the importer has to ensure that conformity with law exists (Recital 31) (Art. 8) ((EU)2019/1009).

Plant protection products are not in the scope of the Fertilising Products Regulation ((EU)2019/1009), and if a product serves both fertilising and plant protection as ruled by (EC) No 1107/2009 law, the latter ((EC)No1107/2009) shall apply (recital 23) ((EU)2019/1009).

End-of-waste criteria (Art. 19) are laid down for materials containing waste as defined in the Directive on waste (2008/98/EC) in compliance with the Regulation ((EU)2019/1009) and it is indicated how a material *has "ceased to be waste from the moment that the EU declaration of conformity was drawn up*" ((EU)2019/1009).

The new Fertilising Product Regulation covers exclusively CE marked products but does not impede the placing on the market of non-harmonised fertilising products in the EU (Recital 5) ((EU)2019/1009). If intended to be used beyond national borderlines, such fertilising products need to comply with Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in another Member State ((EU)2019/515).

3.3.1.1. Component Material Categories (CMCs)

As indicated above, RUSTICA basic-products will be examined on their perspectives to tie into CMCs.

3.3.1.1.1. Overview

Today, eleven CMCs which are solely permitted to constitute an EU fertilising product are listed in Annex II of the Regulation. The CMCs and their input materials shall not contain substances of which maximum limits are laid down for PFCs (Annex I) in amounts that would *"jeopardise the EU fertilising product's compliance"* with these rules ((EU)2019/1009) .

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Table 19: EU Fertilising Product CMCs

Fertilising Products Regulation (EU) 2019/1009, Annex II	
CMC	**CMC Designation**
CMC 1	Virgin material substances and mixtures
CMC 2	Plants, plant parts or plant extracts
CMC 3	Compost
CMC 4	Fresh crop digestate
CMC 5	Digestate other than fresh crop digestate
CMC 6	Food industry by-products
CMC 7	Micro-organisms
CMC 8	Nutrient polymers
CMC 9	Polymers other than nutrient polymers
CMC 10	Derived products within the meaning of Regulation (EC) No 1069/2009
CMC 11	By-products within the meaning of Directive 2008/98/EC
	Law making procedure ongoing:
CMC 12	Precipitated phosphate salts and derivates
CMC 13	Thermal oxidation materials and derivates
CMC 14	Pyrolysis and gasification materials

Source: EU Fertilising Products Regulation, Annex II ((EU)2019/1009); ongoing law making procedures (C(2021)4743) (C(2021)4751) (C(2021)4764); (EC, 2021s)

At the time of writing, lawmaking procedures are still ongoing for CMC 12 (C(2021)4743), CMC 13 (C(2021)4751), and CMC 14 (C(2021)4764) (EC, 2021s) to be incorporated into the list of CMCs in Annex II of the Regulation ((EU)2019/1009). An overview on the CMCs is given in **Table 19**.

3.1.1.1.2. RUSTICA products in the context of CMCs

With view on the aforementioned six RUSTICA (basic-)products, the CMCs contents are analysed in this section.

a) CMC 1 Virgin materials and substances

CMC 1 covers a broad spectrum by using the designation “virgin materials and substances” but excludes waste, substances or mixtures which have ceased to be waste and substances formed from precursors which have ceased to be waste in accordance with national transposition of Art. 6 of the Directive on waste (2008/98/EC) in one or more Member States. Furthermore, e.g., by-products as referred to in the Directive on waste (2008/98/EC), animal by-products ((EC)No1069/2009) and compost are not in the scope of CMC 1 ((EU)2019/1009).

In order to be accepted as CMC 1 material or substance, a registration under the REACH Regulation is required and a registration dossier including inter alia a chemical safety report (Art. 14) ((EC)No1907/2006) has to be presented confirming the use as a fertilising product if the substance/material cannot benefit from an exemption of Annex IV or points 6, 7, 8, or 9 of Annex V of REACH ((EC)No1907/2006) ((EU)2019/1009).

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In addition, if the long-term availability of micronutrients is envisaged by a substance or mixture, precise conditions are dictated to the function of chelating[116] or complexing[117] agents. This applies to inhibitors[118] of nitrification, denitrification or urease as well if they are used to stop or delay specific microbial activities or enzymes in a CMC 1 material or substance by means of the Fertilising Product Regulation ((EU)2019/1009).

With regard to products envisaged by RUSTICA research, CMC 1 would be of interest, e.g., for NPK concentrate. By inspection of the value chains of the project, especially the type of feedstocks will play a crucial role.

b) CMC 2 Plants, plant parts or plant extracts

Plants, parts of them or extracts therefrom form an own category CMC 2 if they are just mechanically e.g., by cutting, grinding etc., treated. Processes aligned to CMC 2 include also drying, frost or freeze-treatment or an extraction by water or supercritical CO_2 ((EU)2019/1009).

RUSTICA processes and products go beyond these treatments and as such, CMC 2 may be not primarily addressed by the output of the project.

c) CMC 3 Compost

If used as an *EU Fertilising Product* under CMC 3, compost may contain biowaste as defined in the Directive on waste (2008/98/EC) from "*separate biowaste collection at source*" and derived products in compliance with Art. 32 of the Animal By-Products Regulation (EU) No 1069/2009 of which the endpoint in the manufacturing chain has been determined in accordance with Article 5(2) ((EC)No1069/2009) ((EU)2019/1009).

CMC 3 also encompasses "*unprocessed living or dead organisms or parts thereof*". If they are processed only *"manual, mechanical or gravitational routes, dissolution in water, flotation, extraction with water, steam distillation or heating solely to remove water, or extraction from air by any means"* it is within the scope of CMC 3. However, deviating from these rules e.g., the organic fraction of mixed municipal household waste even if separated by methods like biological and/or mechanical treatment and animal by-products without a determined endpoint in the manufacturing chain are not permitted (CMC 3 (1.)(c) ((EU)2019/1009). But options are given (CMC3 (1.)(e)) for such an input if it

- *"has previously been composted or digested, and*
- *contains no more than 6 mg/kg dry matter of PAH_{16}*[119]" ((EU)2019/1009).

As far as additives are under use ((EU)2019/1009), a REACH dossier is necessary unless advantage can be taken from an exemption of registration as provided in Annex IV or Annex V (points 6,7,8, and 9) of the Regulation ((EC)No1907/2006). CMC 3 requires hygiene rules by separating input and output materials and certain temperature profiles, e.g., depending on the compost process duration up to 70 °C (**Table 20**). Macroscopic impurities above 2 mm by means of glass, metal and plastics may not exceed 5 g/kg dm of the sum of the three impurity types, and the aforementioned PAH_{16} content have to be ≤ 6 mg/kg dm in the compost. Stability criteria

[116] *"The chelating agent shall be an organic substance consisting in a molecule which: (i) has two or more sites that donate electron pairs to a central transition metal cation (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn), magnesium (Mg), calcium (Ca) or cobalt (Co)), and (ii) is large enough to form a five- or six- membered cyclic structure."* ((EU) 2019/1009), Annex II

[117] *"The complexing agent shall be an organic substance forming a flat or steric structure with one di- or tri- valent transition metal cation (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn) or cobalt (Co))."* ((EU) 2019/1009), Annex II

[118] Inhibitors are explained in PFC 5: *"An inhibitor shall be an EU fertilising product the function of which is to improve the nutrient release patterns of a product providing plants with nutrients by delaying or stopping the activity of specific groups of micro-organisms or enzymes."* ((EU) 2019/1009), Annex I

[119] *"Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene." ((EU) 2019/1009)*

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need to be met, e.g., by achieving a self-heating factor by maximum temperature ≥ Rottegrad III[120] ((EU)2019/1009).

Table 20: EU Fertilising Product Regulation: Four different options for temperature profiles in CMC 3

CMC (EU) 2019/1009	Options for temperature profiles
CMC 3	70 °C or more for at least 3 days
	65 °C or more for at least 5 days
	60 °C or more for at least 7 days
	55 °C or more for at least 14 days

Source: Own depiction based on the Fertilising Products Regulation ((EU)2019/1009)

Since RUSTICA includes compost, the aforementioned CMC requirements need to be met if it will be placed on the market as an EU Fertilising Product.

d) CMC 4 Fresh crop digestate

Prerequisites for plants or plant parts grown for biogas purposes are allocated to CMC 4. Hygiene rules are designed and for additives REACH needs to be considered ((EU)2019/1009).

RUSTICA does not focus on biogas production and fresh crop digestate. Thus, CMC 4 would be not in the foreground if it comes to decisions on exploitation of the products of the project.

e) CMC 5 Digestate other than fresh crop digestate

Opposed to CMC 4, for digestate falling under CMC 5 conditions are laid down e.g., for biowaste (CMC 5(1.)(a)) and derived products ((EC)No1069/2009) (CMC5 (1.)(b)) with a defined endpoint in the manufacturing chain enabling their use as an input material for anaerobic digestion addressing an EU Fertilising Product ((EU)2019/1009). In case, an endpoint of the manufacturing chain is not defined for an animal by-product (CMC 5(1)(c)(iii)), an option (CMC 5(1.)(e)) requiring previous composting or digesting and a content of less than 6mg/kg of PAH_{16} [121] is given by the Fertilising Products Regulation. Furthermore, a registration under REACH is necessary for non-exempted digestion additives ((EU)2019/1009).

Additionally, CMC 5 dictates various selectable hygiene concepts including certain temperature profiles. These concepts either involve composting or pasteurization[122] while the latter will be compulsory if animal by-products are concerned. Rules for digestate contents as regards PAH_{16} [123] (CMC 5(4.)) and macroscopic

[120] The Rottegrad self-heating factor is an indicator for the maturity of a compost. The Rottegrad classification was introduced by U.S. Composting Council, 1997 (Pecorini et al., 2020)

[121] *"Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene." ((EU) 2019/1009)*

[122] *"A biogas plant must be equipped with a pasteurisation/hygienisation unit, which cannot be by-passed for the animal by-products or derived products introduced with a maximum particle size of 12 mm before entering the unit, with: (a) installations for monitoring that the temperature of 70 °C is reached during the time of one hour; (b) recording devices to record continuously the results of the monitoring measurements referred to in point (a); and (c) an adequate system to prevent insufficient heating." ((EU) No 142/2011)*

[123] *"Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene." ((EU) 2019/1009)*

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impurities (CMC 5(5.)) are identical with those of CMC 3 compost (CMC 3(4.)). Stability criteria need to be met, e.g., a residual biogas potential of ≤ 0,25 l biogas/g of volatile solids ((EU)2019/1009).

RUSTICA does not involve digestate at present. But it is important to emphasize that, for example, CAP could be combined with certain hygiene installations and measures addressing pasteurization of critical feedstocks as required for digestate (OWS, 2021).

f) CMC 6 Food industry by-products

In CMC 6, the Regulation sets an own category for food industry by-products and releases conditions for the following products: *food industry factory lime; molasses; vinasse; distillers grains; plants, plant parts or plant extracts and lime from drinking water production*. A REACH dossier ((EC)No1907/2006) is requested for these by-products if they are not covered by an exemption ((EU)2019/1009).

Even though RUSTICA does not directly use food industry by-products as a fertilising product, such by-products play an important role as a feedstock or precursor of the products of the project. As previously reflected in this D3.2 report, e.g., vinasse to be valorised by CAP is of interest for RUSTICA value chains towards a final product. Therefore, RUSTICA products resulting from these value chains might be assessed more in terms of other CMCs rather than in CMC 6.

g) CMC 7 Micro-organisms

If an EU Fertilising Product will be placed on the market in accordance with PFC 6 A (Microbial Biostimulant), microorganisms "*including dead or empty-cell micro-organisms and non-harmful residual elements of the media on which they were produced*" are permitted as ingredients by excluding all production processes except of drying and freeze-drying. At present, CMC 7 lists four groups/types of microorganisms: *Azotobacter* spp., *Mycorrhizal fungi, Rhizobium* spp., and *Azospirillum* spp. ((EU)2019/1009).

RUSTICA involves microbiome to be used in microbial fertilisers. So far, the Regulation ((EU)2019/1009) covers a limited number of microorganisms in direct relation to microbial biostimulants of PFC 6 A. While at the moment, the RUSTICA microbial cultivation and microbial fertilisers go beyond of the CMC 7, this fact will be evaluated again upon results at later stage of the project.

h) CMC 8 Nutrient polymers

According to CMC 8: polymers for the purpose of controlling nutrient release by the constituting monomers[124] may be solely composed of monomer substances which are in accordance with CMC 1, points one as regards exclusion of certain components (e.g., waste and animal by-products) and two informing on requirements of REACH documents ((EU)2019/1009).

Hitherto, RUSTICA (basic-)products are not explicitly reported to nutrient polymers in the meaning of CMC 8. Hence, at the moment CMC 8 is not at the foreground for the project.

i) CMC 9 Polymers other than nutrient polymers

To control water penetration into nutrient particles, to increase the water capacity retention and to bind material into an EU Fertilising Product of PFC 4 (Growing Medium) may be the exclusive purposes of polymers[125] if deployed under CMC 9. Further conditions like biodegradability and toxicity are defined in this category ((EU)2019/1009).

[124] REACH Regulation (EC) No 1907/2006 needs to be considered.
[125] REACH Regulation (EC) No 1907/2006 needs to be considered.

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To date, there is no RUSTICA (basic-)products preference on "non-nutrient" polymers. Therefore, other CMCs might be closer than CMC 9 for the results of the project.

j) CMC 10

Derived products as defined in Regulation (EC) No 1069/2009 *"having reached the end point in the manufacturing chain as determined in accordance with that Regulation"* are aligned to CMC 10. The Regulation undoubtedly refers to the necessity of a Table reflecting the products concerned and specifications thereto (in compliance with Art. 42(5) ((EU)2019/1009).

Owing to its valorisation of insects, CMC 10 is of utmost importance for RUSTICA. In pursuing the use of both insect biomass, and frass as the leftover from insect production, legal consistency in this sector creates a reliable environment for exploitation and thriving impact.

k) CMC 11 By-products within the meaning of Directive 2008/98/EC

A by-product belonging to CMC 11 has to be in compliance with the definition of Directive 2008/98/EC by excluding animal by-products as defined in (EC) No 1069/2009, polymers, compost or digestate. A REACH dossier ((EC)No1907/2006) is necessary except if an exemption applies. After 16th of July 2022, a CMC 11 by-product may only be placed on the market if it is conform to criteria established by delegated acts as indicated by Art. 42(5) ((EU)2019/1009).

At current stage, a final statement cannot be made if RUSTICA intends to place by-products resulting from its production processes onto the market by means of CMC 11. As mentioned before, side streams (from food processing) are proposed for by-products which will serve as precursor of RUSTICA products. Their role and possible legal position would need to be finally discussed upon availability of results.

l) Ongoing lawmaking procedures

At the time of writing, lawmaking procedures for CMCs 12, 13, and 14 are in progress. While CMC 12 and 13 are not in the scope of RUSTICA, **CMC 14 pyrolysis and gasification materials** are subject to research in the project.

Recital 58 of the EU Fertilising Products Regulation refers to recycling and biochar and a lawmaking procedure addressing this innovation is reported ((EU)2019/1009). The Document C(2021)4764 provides (draft-) conditions for "*Pyrolysis and Gasification Materials*" and a CMC 14. It sets rules for various input materials, such as mixed municipal waste and animal by-products and put in place the relevance of the REACH Regulation (C(2021)4764).

The incorporation of biochar being a main output of the RUSTICA project into the EU Fertilising Products Regulation is pivotal for the exploitation and facilitates the way to the EU market.

3.3.1.2. Product Function Categories (PFCs)

The necessity of establishing PFCs, in order to ensure that quality and safety requirements are tailored to the different uses of EU Fertilising Products, is highlighted in Recital 6 of the Regulation. Annex I encompasses structure and contents of the PFCs ((EU)2019/1009) which are studied on their relevance for the RUSTICA project.

3.3.1.2.1. Overview

Claimed functions of EU Fertilising Products and the requirements associated thereto are divided into seven main PFCs ((EU)2019/1009) which are illustrated in **Figure 22**.

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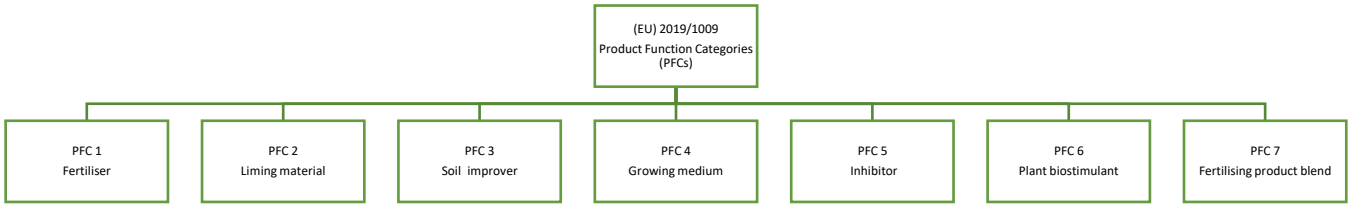

Figure 22: Seven main PFCs of the EU Fertilising Products Regulation
Source: EU Fertilising Products Regulation ((EU)2019/1009) and VOLATILE D2.6 (VOLATILE-D2.6, 2020)

The main PFCs are further subdivided in the legal act and indicate specific requirements, such as nutrient contents and limits on contaminants and pollutants. Restrictions laid down in Annex I apply to the aforementioned CMCs and those limits may also not be exceeded by their input materials ((EU)2019/1009).

3.3.1.2.2. RUSTICA products in the context of PFCs

RUSTICA research expects a wide range of results. Each PFC is deliberated on aspects to be taken into account for the RUSTICA results, notably for the six (basic-)products.

a) PFC 1 Fertiliser

The Regulation defines fertiliser as follows: "*A fertiliser shall be an EU fertilising product the function of which is to provide nutrients to plants or mushrooms.*" The main category PFC 1 is subdivided into further categories ((EU)2019/1009) which are displayed in **Figure 23.**

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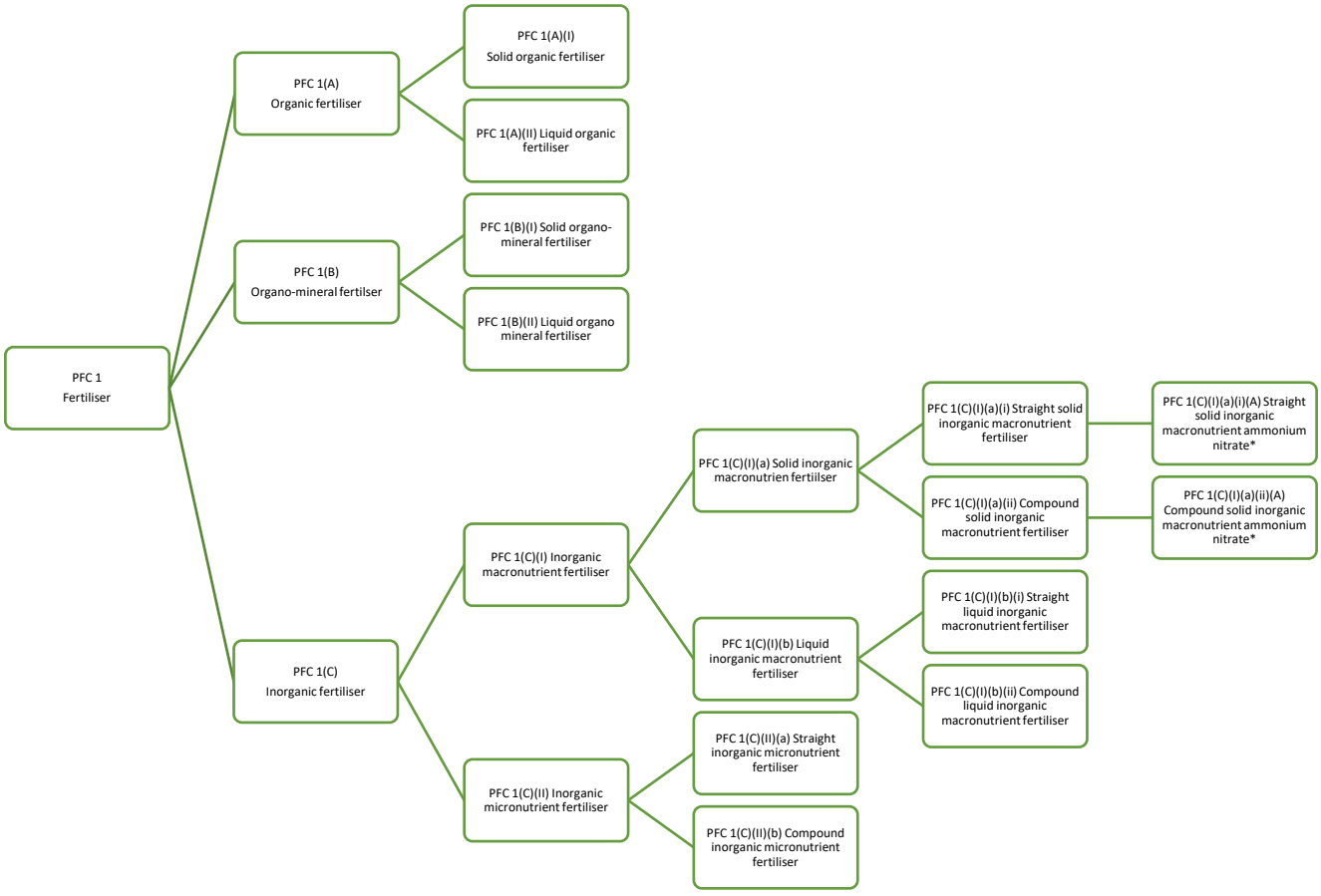

*ammonium nitrate fertiliser of high nitrogen content

Figure 23: EU Fertilising Products: Fertiliser (PFC 1) and its subcategories
Source: Own depiction based on EU Fertilising Products Regulation ((EU)2019/1009)

To ensure protection of human health and the environment, the Regulation ((EU)2019/1009) establishes comprehensive indicators on safety for the three subcategories organic, organo-mineral, and inorganic fertiliser. Safety requirements associated with the subcategories are e.g., limits on contaminants. Important indications on such contaminants ((EU)2019/1009) are shown in **Table 21**.

A ***PFC 1(A)*** *Organic fertiliser* may consist of organic carbon ($C_{(org)}$)[126] and nutrients of solely biological origin. For both solid and liquid organic fertilisers, minimum contents for primary macronutrients NPK by means of N, P_2O_5, and K_2O are defined which are in the range of 1% to 2.5% by mass for each individual nutrient depending on e.g., the number of declared primary nutrients. Furthermore, a minimum organic carbon content of 15% by mass for PFC 1(A)(I) and of 5% for PFC 1(A)(II) has to be achieved ((EU)2019/1009).

Apart from the contents of an organic fertiliser, an *organo-mineral fertiliser* belonging to **PFC 1(B)** may be constituted by "*one or more inorganic fertilisers, as specified in PFC 1(C)*". Contents for primary nutrients are required in the range of 2-2.5% for a single nutrient while the total of primary nutrients has to reach 8% for solid and 6% for liquid organo-mineral fertilisers. As far as PFC 1(C)(I)(a)(i-ii)(A) is in the co-formulation, "*an organo-mineral fertiliser shall not contain 16 % or more by mass of nitrogen (N) as a result of ammonium nitrate (NH_4NO_3)*" ((EU)2019/1009).

[126] C(org) is defined by the EU Fertilising Products Regulation: *"as organic carbon (C_{org}) = organic matter × 0,56"* ((EU/2019/1009)

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Table 21: EU Fertilising Products - important limit values on contaminants in PFC 1 Fertiliser

Contaminant	PFCs and Limit values			
	1(A) g/kg dm	1(B) g/kg dm	1(C)(I) g/kg dm	1(C)(II) g/kg micronutrients[127]
Cadmium (Cd)	1.5	3-60[128]	3-60[129]	200
Hexavalent Chromium (Cr IV)	2	2	2	--
Mercury (Hg)	1	1	1	100
Nickel (Ni)	50	50	100	2,000
Lead (Pb)	120	120	120	600
Inorganic arsenic (As)	40	40	40	1,000
Biuret ($C_2H_5N_3O_2$)	0	12	12	--
Copper (Cu)	300	600[130]	600[131]	--
Zinc (Zn)	800	1,500[132]	1,500[133]	--
Perchlorate (ClO_4-)	--	--	50	--

Source: Own depiction based on EU Fertilising Products Regulation ((EU)2019/1009)

Inorganic fertilisers systematized in **PFC 1(C)** are defined as: *"…shall be a fertiliser containing or releasing nutrients in a mineral form, other than an organic or organo-mineral fertiliser."* As far as an inorganic fertiliser contains more than 1% carbon which is not evoked by specific substances and mixtures, such as chelating or complexing agents as referred to in CMC 1, tests on pathogens (*Salmonella spp.* and *Escherichia coli* or *Enterococcaceae)* are dictated by the Regulation ((EU)2019/1009).

Two major inorganic subgroups: macronutrient **(PFC 1(C)(I))** and micronutrient fertilisers **(PFC 1(C)(II))** are formed which significantly differ in allocated types of substances to be composed of ((EU)2019/1009).

- **PFC 1(C)(I):** N,P,K (primary macronutrients) Ca, Mg, Na and S (secondary macronutrients)
- **PFC 1(C)(II):** B, Co, Cu, Fe, Mn, Mo and Zn (micronutrients) ((EU)2019/1009)

If it comes to minimum contents of nutrients in inorganic macronutrient fertilisers, the requirements vary considerably pertaining to each single nutrient, the number of nutrients and state of aggregation of the product. For example, a total of at least 18% by mass as the *"sum of all declared primary and secondary macronutrient*

[127] Limit values of contaminants expressed in mg, in relation to the total micronutrient content expressed in kg including boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn) ((EU) 2019/1009)
[128] Depending on the P content: if below 5% P2O5(-equivalent) content by mass: 3 mg/kg; if ≥ 5% than 60 mg/kg ((EU) 2019/1009)
[129] Depending on the P content: if below 5% P2O5(-equivalent) content by mass: 3 mg/kg; if ≥ 5% than 60 mg/kg ((EU) 2019/1009)
[130] Limits shall not apply if intentionally added to compensate a soil deficiency and declared in accordance with Annex III of (EU) 2019/1009
[131] Limits shall not apply if intentionally added to compensate a soil deficiency and declared in accordance with Annex III of (EU) 2019/1009
[132] Limits shall not apply if intentionally added to compensate a soil deficiency and declared in accordance with Annex III of (EU) 2019/1009
[133] Limits shall not apply if intentionally added to compensate a soil deficiency and declared in accordance with Annex III of (EU) 2019/1009

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contents" needs to be achieved for a straight[134] **(PFC 1(C)(I)(a)(i))** or compound[135] **(PFC 1(C)(I)(a)(ii)** solid[136] inorganic macronutrient fertiliser. As already mentioned, deviating from these categories, a specific N-content (28% at minimum) is mandatory for **PFC 1(C)(I)(a)(i-ii)(A)** while limits are set for Cu (10 mg/kg) and Cl (200 mg/kg)**.** Straight (**PFC 1(C)(I)(b)(i))** and compound **(PFC 1(C)(I)(b)(ii))** liquid[137] inorganic fertilisers shall contain a total of ≥ 7% as the *"sum of all declared primary and secondary macronutrients((EU)2019/1009)."*

Nutrient contents to be achieved are legally set for inorganic micronutrient fertilisers as well. Eight different types of straight inorganic micronutrient fertilisers **(PFC 1(C)(II)(a))** are defined, and, for instance, a micronutrient salt fertiliser shall contain "*10% by mass of a water-soluble micronutrient"*. A sum of 2% by mass in liquid fertilisers and 5% by mass in solid fertilisers for all declared micronutrients has to be available in a compound inorganic micronutrient fertiliser **(PFC 1(C)(II)(b))** ((EU)2019/1009).

In principle, organic, organo-mineral and inorganic fertilisers are interesting categories for RUSTICA. Huygens et al. concluded that there is a potential application for "pyrolysis and gasification materials" under PFC 1 (Huygens, Saveyn, Tonini, Eder, & Delgado Sancho, 2019). As accentuated by the designation RUSTICA "NPK concentrate", rules on inorganic macronutrient fertilisers might be specifically scrutinised. PFC 1(A) requirements will be also among the options which could be verified for materials authorised by CMC 10. For compost, firstly attention is drawn e.g., to PFC 1(A), but, secondly, in pursuing highly innovative RUSTICA products the PFC 1(B) could also be debated as an alternative. Ultimately, the PFCs would need to be studied again upon availability of the final products of the project.

b) PFC 2 Liming material

A **PFC 2** liming material is defined by the Regulation as it *"shall be an EU fertilising product the function of which is to correct soil acidity* ((EU)2019/1009)*."*

At current stage of the RUSTICA project, it cannot be finally evaluated if RUSTICA output can be used as a liming material which does not exclude that in the course of research progress an achievement may reveal characteristics of pH value adjustments in accordance with PFC 2.

c) PFC 3 Soil improver

"To maintain, improve or protect the physical or chemical properties, the structure or the biological activity of the soil to which it is added" is the required function of a soil improver as defined in **PFC 3**. The Regulation differentiates *organic soil improvers (PFC 3(A))* which shall be built up by 95% material of biological origin and *inorganic soil improvers (PFC 3(B))* embracing all other soil improvers. In addition, limits for pathogens are set for PFC 3(A). With view on level of contaminants permitted in soil improvers, limits are determined as reflected in **Table 22** ((EU)2019/1009).

[134] May contain either only one macronutrient from N, P, K, Ca, Mg, Na, S or only one primary macronutrient from N, P, K, and one or more secondary macronutrients from Ca, Mg, Na, S. ((EU) 2019/1009)

[135] May contain either more than one primary macronutrient from N, P,K or more than one secondary macronutrient from Ca, Mg, Na,S but then no primary macronutrient from N, P, K. ((EU) 2019/1009)

[136] "'solid form' means form characterised by structural rigidity and resistance to changes of shape or volume and in which the atoms are tightly bound to each other, either in a regular geometric lattice (crystalline solids) or in an irregular manner (an amorphous solid);" ((EU) 2019/1009)

[137] "liquid form' means a suspension or a solution, where a suspension is a two-phase dispersion in which solid particles are maintained in suspension in the liquid phase, and a solution is a liquid that is free of solid particles, or a gel and includes pastes;" ((EU) 2019/1009)

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Table 22: EU Fertilising Product PFC 3 Soil Improver - limits on contaminants

	Limits on Contaminants in mg/kg dm							
PFC	**Cd**	**Cr IV**	**Hg**	**Ni**	**Pb**	**As**	**Cu**	**Zn**
3(A)	2	2	1	50	120	40	300	800
3(B)	1,5	2	1	100	120	40	300	800

Source: Own depiction based on EU Fertilising Products Regulation ((EU)2019/1009)

Contemplating RUSTICA research and innovation, as already indicated above, stipulations on soil improvers might be inter alia of relevance for biochar which is highlighted in literature as well (Huygens et al., 2019). However, this does not preclude studying this option for other results of the project.

d) PFC 4 Growing medium

As regards the definition of **PFC 4**, it *"shall be an EU fertilising product other than soil in situ, the function of which is for plants or mushrooms to grow in."* Rules for maximum contents of contaminants reveal that limits in mg/kg dm for Cd, Cr IV, Hg, and As match those of inorganic soil improvers **PFC 3(B)** but lower limits apply to Ni (50 mg/kg dm), for Cu (200 mg/kg dm) and Zn (500 mg/kg dm). Moreover, limits on pathogens need to be obeyed ((EU)2019/1009).

RUSTICA involves a broad spectrum of applications in agriculture and horticulture. Therefore, legal points of PFC 4 Growing Media as an alternative to soil are of interest for the project. In particular, light is shed in literature on the promising use of pyrolysis and gasification materials for soilless growing media (Huygens et al., 2019). But more details also with view on other output of the project can be debated in the course of available results.

e) PFC 5 Inhibitor

As previously mentioned, the role of **PFC 5** Inhibitors is defined to delay or stop microbial activity or enzymes to improve nutrient release patterns of EU fertilising products supplying plant nutrients. PFC 5 assembles three different types of inhibitors ((EU)2019/1009):

- **PFC 5(A)** Nitrification Inhibitor to *"…inhibit the biological oxidation of ammoniacal nitrogen (NH_3-N) to nitrite nitrogen (NO_2-)…"*
- **PFC 5(B)** Denitrification Inhibitor *to "… inhibit the formation of nitrous oxide (N_2O) by slowing down or blocking the conversion of nitrate (NO_3-) to dinitrogen (N_2)…"*
- **PFC 5(C)** Urease Inhibitor to *"…hydrolytic action on urea (CH_4N_2O) by the urease enzyme, primarily targeted to reduce ammonia volatilisation* ((EU)2019/1009)."

In contrary to its predecessor (EU) No 2003/2003 ((EC)No2003/2003), the new EU Fertilising Products Regulation informs on the function but does not list specific substances, mixtures or compounds linked to the designation "inhibitor". But at the current point of the RUSTICA research, it's too early for a final statement if inhibitors will have any meaning for the project or not.

f) PFC 6 Plant biostimulant

The legal definition (section 3.2.2) of a **PFC 6** Plant biostimulant clearly delineates its function *"which is to stimulate plant nutrition processes independently of the products' nutrient content…"* exclusively targeting at least one of the following properties: "*a) nutrient use efficiency, b) tolerance to abiotic stress, c) quality traits or c) availability of confined nutrients in the soil or rhizosphere*." Contaminants in a plant biostimulant of **PFC 6** may not be above the limits as inserted in **Table 23** ((EU)2019/1009):

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Table 23: EU Fertilising Product PFC 6 Biostimulant - limits on contaminants

	Limits on Contaminants in mg/kg dm							
PFC	**Cd**	**Cr IV**	**Hg**	**Ni**	**Pb**	**As**	**Cu**	**Zn**
6	1,5	2	1	50	120	40	600	1500

Source: Own depiction based on EU Fertilising Product Regulation ((EU)2019/1009)

Different conditions are laid down for **PFC 6(A)** Microbial Biostimulant and **PFC 6(B)** Non-microbial Biostimulant. Following the EU Fertilising Products Regulation, *"a microbial plant biostimulant shall consist of a micro-organism or a consortium of micro-organisms referred to in CMC 7 in Part II of Annex II."* To be accepted as a **PFC 6(A)**, a comprehensive list of limits on pathogens applies. **PFC 6(B)** refers to any other biostimulant and sets limits on micro-organisms to be tested: *Salmonella spp*. and *Escherichia coli* or *Enterococcaceae* ((EU)2019/1009).

To date, plant biostimulants are not in the first row of the RUSTICA (basic-)product concept. But this fact does not exclude that research results of the project could be further evaluated on their appropriateness for this purpose.

g) PFC 7 Fertilising product blend

Aside from single categories, the EU Fertilising Products Regulation enables blending of PFCs. An EU Fertilising Product of **PFC 7** *"shall be composed of two or more EU fertilising products of PFC 1 to PFC 6".* But it's unambiguously stressed that for each component EU fertilising product "*compliance with the conformity assessment procedure applicable to that component EU fertilising product"* has to be evidenced. The nature of each component EU fertilising product shall not be altered by the blending process and no adverse effects on health and environment shall be entailed with the blending. An own EU declaration of conformity is necessary for a **PFC 7** blend and labelling has to be made accordingly ((EU)2019/1009).

Owing to the RUSTICA propositions, blending of products is envisaged by the project. In this respect, PFC 7 may have a key role to be assessed if RUSTICA results will be placed on the market as EU fertilising products.

3.3.2. Fertilisers for EU organic production

For RUSTICA research and developments targeting added value and sustainable solutions, the legal framework for fertilising products in organic farming is of particular interest.

3.3.2.1. General information

The portray from organic production of Recital one of the Preamble of Regulation (EU) 2018/848 includes inter alia "*an overall system of farm management and food production that combines best environmental and climate action practices, a high level of biodiversity, the preservation of natural resources and the application of high welfare standards and high production standards…*((EU)2018/848)*".*

As it is expressed in Recital 4 of Regulation (EU) 2021/1165 *authorising certain products and substances for use in organic production and establishing their lists* implementing Regulation (EU) 2018/848, certain fertilisers, soil conditioners, and nutrients for plant nutrition may be used for organic production, and they should be authorised by the European *Commission in accordance with "point (b) of Article 24(1) of Regulation (EU) 2018/848*[138] *and establish their list."*

[138] Art. 24 (1)(b) refers to fertilisers, soil improvers, and nutrients ((EU) 2018/848)

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Details of this list are relevant for the exploitation of RUSTICA for organic farming purposes.

3.3.2.2. RUSTICA products and provisions of organic farming

Art. 2 of Regulation (EU) 2021/1165 underlines that just substances and products listed in the Annex II of the Regulation are permitted to be used as a fertiliser, soil conditioner and nutrient in organic farming. Furthermore, this legal source clearly declares that an application for this purpose may solely take place if compliance with the current EU Fertiliser Regulation (EC) 2003/2003, "*the relevant applicable Articles*" of Regulation (EU) 2019/1009, and the Animal by-products Regulations (EC) No 1069/2009 and (EU) No 142/2011 exists ((EU)2021/1165).

In addition: *"Preparations of micro-organisms may be used to improve the overall condition of the soil or to improve the availability of nutrients in the soil or in the crops* ((EU)2021/1165)." provided that the rules of Regulation (EU) 2018/848, in particular *Chapter III Production Rules* and Annex II, are fulfilled ((EU)2021/1165). In this context, it needs to be clarified that GMOs are not permitted, neither for microorganisms nor for any other organisms falling under the EU organic farming legislation (Art. 11) ((EU)2018/848).

Table 24: Excerpt of list of substances and products for organic production ((EU) 2021/1165, Annex II)

Compound products or products containing only materials listed hereunder (excerpt) ((EU) 2021/1165, Annex II)	Description, specific conditions and limits
Dejecta of worms (vermicompost) and insect frass-substrate mixture	*"where relevant in accordance with Regulation (EC) No 1069/2009"*
Composted or fermented mixture of vegetable matter	*"Product obtained from mixtures of vegetable matter, which have been submitted to composting or to anaerobic fermentation for biogas production"*
Products or by-products of animal origin as below: Hydrolysed proteins 1)	*"1) Not to be applied to edible parts of the crop"*
Products and by-products of plant origin for fertilisers	*"e.g.: oilseed cake meal, cocoa husks, malt culms"*
Hydrolysed proteins of plant origin	
Inorganic Micronutrient Fertilisers	*"until 15 July 2022: as listed in accordance with Part E of Annex I to Regulation (EC) No 2003/2003;* *from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply"*
Biochar - pyrolysis product made from a wide variety of organic materials of plant origin and applied as a soil conditioner	*"only from plant materials, when treated after harvest only with products included in Annex I* *until 15 July 2022: maximum value of 4 mg polycyclic aromatic hydro-carbons (PAHs) per kg dry matter (DM)* *from 16 July 2022, the relevant limits for contaminants set in Regulation (EU) 2019/1009 apply"*

Source: Own depiction based on direct citations of (EU) 2021/1165 ((EU)2021/1165)

Moreover, it is determined that fertilisers, soil conditioners, and plant nutrients *"may only be used according to the specifications and restrictions of use of those respective Union and national legislations* ((EU)2021/1165)." In accordance with Art. 31 of (EU) 2018/848, products and substances authorised for fertilisers, soil conditioners or nutrients in organic production can indicate a reference informing on that fact ((EU)2018/848).

Taking into account the RUSTICA activities, an excerpt of Annex II ((EU)2021/1165) is given in **Table 24**.

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Considering Table 24, the rules on insect frass are crucial for RUSTICA, because of the option to opening a gate to organic production if all legal requirements, e.g., those of the Animal by-products Regulation (EU) No 1069/2009 are fulfilled ((EC)No1069/2009). Rules on composted vegetable matter may be debated for the (basic-)product "compost" of the project. Hydrolysed proteins from animal origin can be taken into account with view on insect cultivation while conditions for hydrolysed proteins of plant origin which could be entailed with CAP may be discussed as well. Annex II refers to by-products, but there is no indication on fertilisers using "by-products" as a precursor in this legal source ((EU)2021/1165). Albeit NPK concentrate is envisaged as a main (basic-)product of electrodialysis, research on inorganic micronutrient fertilisers is thereby not excluded. To enter the EU organic farming sector, RUSTICA biochar production would need to be coupled, e.g., to limits of contaminants and rules on plant protection as laid down in Annex I of (EU) 2021/1165 ((EU)2021/1165).

3.4. Fertiliser application and various agricultural areas

RUSTICA results will be validated for various agricultural areas. These areas can be summarised in fruit production, greenhouse cultivation, and open field production. In more detail, the former stands for orchards and vineyards while vegetables will dominate the RUSTICA applications in greenhouses and open field tests. At the EU level, a range of legal sources influences fertiliser applications to agricultural crops being either grown by conventional farming or organic production methods. Besides, additional more restrictive legal positions are designed for the organic sector ((EU)2018/848).

3.4.1. General Rules

Hitherto, important terms of nutrient supply by means of fertilisers are dictated at the more national or regional level in the EU (Amery & Schoumans, 2014) (Kuhn, 2017). Nonetheless, legally enshrined protection of the environment led to settings implicating fertiliser supply on crops in the EU (Keessen et al., 2011). In addition, pecuniary support on agriculture is increasingly bound to certain farming practices, which directly or indirectly involve use of fertilisers (Garske, Stubenrauch, & Ekardt, 2020).

3.4.1.1. Common Agricultural Policy and legal indications

Originally established in 1962, the Common Agricultural Policy of the EU applies in all of the Member States. It strives for reliable food supply and support of farmers, mitigation of climate change and sustainability in natural resource management thereby fostering rural communities, areas, and landscapes as well as economic development and jobs in agriculture and related sectors (EC, 2021m).

To address the peculiarities of agriculture against other types of business, the Common Agricultural Policy initiates and implements measures to bolster the income of farmers by means of direct payments, to balance challenging market situations, and to enable national and regional programmes on rural development (EC, 2021m). The financing relies mainly on two funds, the European agricultural guarantee fund (EAGF) as the "first pillar" for direct income and market support and the European agricultural fund for rural development (EAFRD) as the "second pillar" (EC, 2021n). Effects on fertiliser application as it is planned by the RUSTICA research can be entailed with provisions laid down in the legal acts creating the conditions of EU farming and subsequent positions in the food chain. Today, in the area of legally binding secondary law main instruments are reported as shown in **Figure 24** (EC, 2021m).

Recitals 53-60 of the Preamble of the Regulation **(EU) No 1306/2013** explain the principles of "cross-compliance" which have to be met by farmers in order to obtain "*full payment of some supports"* on their direct income. These principles encompass land management as well as agricultural production and -activity and they are acknowledged by basic "*standards on environment, climate change, good agricultural and environmental*

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condition of land, public health, animal health, plant health and animal welfare." Art. 93 indicates the rules of "*statutory management requirements*" (SMR) and "*standards of good agricultural and environmental condition"* (GAEC) laid down in Annex II of the Regulation ((EU)No1306/2013). From the perspective of fertiliser application: SMR 1 respect to the Nitrate Directive (91/676/EEC), GAEC 1 buffer strips at water courses, GAEC 3 protection of groundwater against dangerous substances (80/68/EEC, Annex I) (80/68/EEC), GAEC 4 minimum cover of soil, GAEC 5 minimum land management as regards erosion, GAEC 6 upholding of soil organic matter level through suitable methods including prohibition of burning arable stubbles with exception of measures on plant health, SMR 2 considering conservation of wild birds, and SMR 3 rules on safeguarding natural habitats, wild flora and fauna ((EU)No1306/2013) (Garske et al., 2020) are of relevance but govern in general more indirectly the nutrient management for crops.

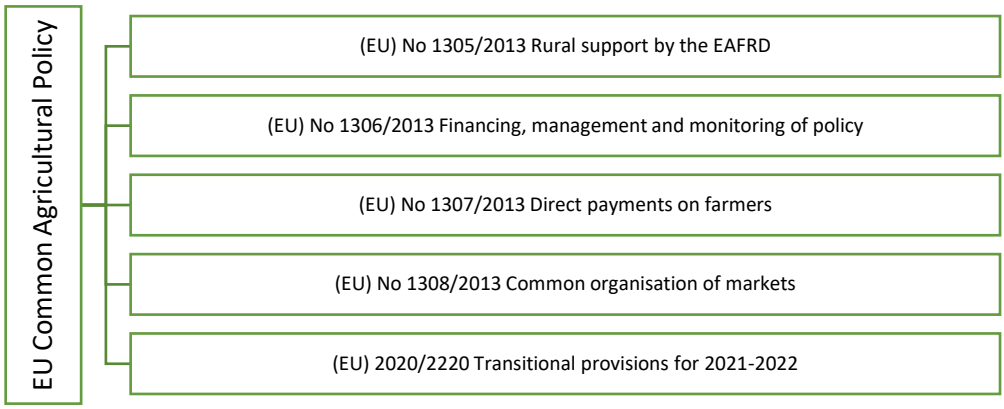

Figure 24: EU Common Agricultural Policy - Important legally binding instruments
Source: European Commission (EC, 2021m)

Rules *for "Payment for agricultural practices beneficial for the climate and the environment"* as reflected in Art. 43-46 of Regulation **(EU) No 1307/2013** require the methods "*crop diversification, maintaining existing permanent grassland and having ecological focus areas on the agricultural area*" or equivalent agricultural practices defined in Annex IX of the Regulation ((EU)No1307/2013) (Garske et al., 2020). The practices equivalent with *ecological focus area* which can be chosen are, for example, "*Production on arable land with no use of fertiliser (mineral fertiliser and manure) and/or plant protection products, and not irrigated, not sown with the same crop two years in a row and on a fixed place* ((EU)No1307/2013)".

Among the objectives of the rural development are "*ensuring the sustainable management of natural resources, and climate action*" and the six priorities (Art. 5) laid down in Regulation **(EU) No 1305/2013** advocate e.g., enhanced management of fertilisers and soils as well as prevention of soil erosion. Furthermore, the legal source promotes *"the supply and use of by-products, wastes and residues and of other non food raw material, for the purposes of the bio-economy".* In Art. 28, the Regulation designs the voluntary "*Agri-environment-climate"* measure and EAFRD payments thereto (Giannakis, Kushta, Bruggeman, & Lelieveld, 2019). The requirements are beyond of others, such as "cross-compliance" in Title VI of (EU) No 1306/2013 and relevant minimum standards on fertiliser use (Garske et al., 2020). In addition, options are opened to organic farming ((EU)No1305/2013). Financial support connected to the Water Framework Directive (2000/60/EC) and to Directives 92/43/EEC (92/43/EEC) and 2009/147/EC (2009/147/EC) (Natura 2000) is related to conditions, in particular the measures may not be covered by other support schemes ((EU)No1305/2013).

Agricultural markets and their common organisation are subject to Regulation **(EU) No 1308/2013**. The legal act provides general rules and solutions for market threats and disturbances (e.g., diseases and pandemics), refers to competition, and addresses imports and exports with third countries. Contemplating the EU internal

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market: market intervention, marketing standards and producer organisations are main areas directed by the Regulation ((EU)No1308/2013).

To be recognised as a producer organisation, *"promoting, and providing technical assistance for, the use of environmentally sound cultivation practices and production techniques, and sound animal welfare practices and techniques"* may be taken as an objective (Art. 152). Operational programmes on aid in the fruit and vegetable sector in **(EU) No 1308/2013** may aim at *"environmental measures, particularly those relating to water, and methods of production respecting the environment, including organic farming*" (Art. 33). Marketing standards may cover *"the type of farming and production method including oenological practices and advanced systems of sustainable production;"* (Art. 75(3)(g)). If a Member State considers a producer organisation as representative: rules can be expanded to other market operators for a limited period. These rules need to be bound to at least one objective which can be, for example, rules on production more stringent than those at EU and national level, protecting the environment, and measures on the protection of organic farming (Art. 164). Specific support programmes in the wine sector comprising inter alia "*restructuring and conversion of vineyards"* may refer to enhanced management techniques of vineyards, *"in particular the introduction of advanced systems of sustainable production"* (Art. 46(3)(d)) ((EU)No1308/2013).

The Regulation **(EU) No 1308/2013** is implemented and supplemented by a multitude of legal acts ((EU)No1308/2013). 543/2011/EU dealing with fruits and vegetables highlights marketing standards and quality requirements along the food supply chain rather than production methods (543/2011/EU). On the other hand, Regulation (EU) 2017/892 determines the prerequisites for eligible investments under the national framework for environmental actions in the fruit and vegetable sector (Art. 3). Such actions may include "*investments beneficial for the environment"* (Art. 3(1)(b) which, for instance, *"could achieve a reduction in the environmental risks linked to the use of certain production inputs, including plant protection products or fertilisers;"* (Art. 3(3)(c)) ((EU)2017/892).

Transitional provisions which apply until 2023 are laid down in Regulation **(EU) 2020/2220** amending the legal sources illustrated in **Figure 24**. Following Art. 58(a), to encounter the detrimental consequences of the COVID-19 crisis, additional resources shall be made available for the EAFRD. A share of ≥ 37% of these resources *shall be reserved in each rural development programme for measures, such as environment and climate investments* ((EU) No 1305/2013, Art. 59(6), and as an example, "*soil conservation, including the enhancement of soil fertility through carbon sequestration* (Art. 58a(4)(c)) ((EU)2020/2220)".

In summary, legislation of the Common Agricultural Policy endorses activities and programmes pursuing environmentally and climate friendly agricultural cultivation methods. It fosters measures of sustainable production including reduction of inputs like fertilisers from a more general perspective. Waste valorisation and the bioeconomy are mentioned and carbon sequestration is legally supported. But solutions, such as the revolutionary RUSTICA concept are not yet fully incorporated into the legal sources.

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3.4.1.2. Water, water treatment, and soil

Among the most prominent frameworks, stipulations on quality of different types of water and limits on contents, such as substances used as plant macro- and micronutrients are discussed relating to the consequences of fertiliser application.

As the overarching legal source, *Directive 2000/60/EC establishing a framework for Community action in the field of water policy* addresses inter alia protection of surface waters and groundwater (2000/60/EC), and there is a number of legal acts which refer to various types of water and/or its treatments (Amery & Schoumans, 2014). A set of these legal sources is inserted in **Table 25**.

Table 25: Important legal sources related to water and water treatment

Legal Source	Designation (short version)	Indications (examples)
2000/60/EC	"Water Framework Directive"	Surface-, ground and transitional waters: e.g., national responsibilities
2006/118/EC	"Ground water Directive"	Qualtity standards: e.g., for nitrate: 50 mg/l (max.)
(EU) 2020/2184	"Drinking water Directive"	Chemical parameter: e.g., for nitrate: 50 mg/l (max.)
2008/105/EC	"Surface water Directive"	Environmental quality standards: e.g., for cadmium and its compounds
2006/7/EC	"Bathing water Directive"	Quality standards and limits on microorganisms
2008/56/EC	"Marine Strategy Framework Directive"	Qualitative descriptors on environmental status: e.g., on eutrophication
91/271/EEC	"Urban Waste-water Treatment Directive"	Re-use of sludge from waste water treatment and monitoring of disposal
86/278/EEC	"Sewage sludge Directive"	Applications in agriculture and limits on contaminants (e.g., heavy metals)
91/676/EEC	"Nitrates Directive"	Reduction of water pollution and limits on application of nitrate by manure

Source: Own depiction based on Amery and Schoumans (Amery & Schoumans, 2014) and legal sources in Table 25

As pointed out in Art. 11 and in Annex VI, Part A of 2000/60/EC measures are required under several legal acts including but not limited to the "*Sewage sludge Directive*" (86/278/EEC) and *Council Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources* (2000/60/EC).

Unlike legal rules on sewage sludge which is not within the scope of RUSTICA, provisions of Directive 91/676/EEC count for the output of the project (91/676/EEC).

To protect all waters against pollutions at the general level, EU countries are required to introduce "*code(s) of good agricultural practices*" which are voluntary (Art. 4). To this end, the Directive presents ten items (Annex II) as regards fertilisers and soil management which should be addressed as far as they are relevant for a country or region. These items (Annex II) (91/676/EEC) can be summarised as reflected in **Table 26.**

In case waters could be affected by pollution (Art. 3) and an EU country did not induce an action as defined in Art. 5 of the Directive (91/676/EEC), an identification of waters is required on criteria, such as a concentration or possible concentration of nitrate and the legally defined limit in surface waters taken into account for drinking water use. A content of more than 50 mg/l of nitrate in groundwaters and the status of eutrophication

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in freshwater bodies, estuaries, coastal and marine waters are among these criteria as well (Annex I). All identified areas of land which drain into such waters in a Member State need to be designated as "vulnerable zones" (Art. 3(2)) (91/676/EEC).

Art. 5 (91/676/EEC) establishes action programmes as regards the vulnerable zones. These programmes shall consider scientific and technical data on nitrogen contributions from agriculture and other origin as well as the state of environment in regions of this Member State. In pursuit of Art. 3(4), if such programmes are introduced throughout the entire country, it is exempted from the obligation to identify "vulnerable zones" (Art. 3(4)) (91/676/EEC).

Table 26: Nitrate Directive - Code(s) of Good Agricultural Practice: Summary of items to be addressed

Item n°	Nitrate Directive: Item Areas to be addressed
1	Time periods of non-proper fertiliser application to land
2	Fertiliser application to land including extreme slopes
3	Fertiliser application in case of water-saturated, flooded, frozen and snow-covered soils
4	Terms for fertiliser applications in close proximity to water courses
5	Measures to prevent water pollution through run-off and seepage of manures and liquids
6	Methods of fertiliser application to "maintain nutrient losses to water at an acceptable level"
7	Land use management with crop rotation systems and a ratio of permanent to annual tillage crops
8	Minimum amount of vegetation cover to utilise the soil N and prevent nitrate pollution
9	Fertiliser plans and documentation of fertiliser use
10	Prevention of water pollution through irrigation effects beyond of crop roots

Source: Own depiction based on Nitrate Directive (91/676/EEC), Annex II

Mandatory measures to implement the action programmes shall include the aforementioned *codes of good agricultural practices* as far as they are not replaced by stipulations in Annex III of the Directive. Examples of these stipulations concerning the application of fertilisers are (91/676/EEC):

- Prohibition of fertiliser application to land during certain periods
- Limitations to fertiliser applications in accordance with good agricultural practice and specific conditions in a vulnerable zone (e.g., soil- and climate conditions, land use practices)
- Balancing nitrogen demand of crops, -availability in the soil, and -supply by fertilisers
- Application of ≤ 170 kg N/ha/year to land as the amount of manure (91/676/EEC).

As regards the amount of 170 kg N/ha, Member States may deviate from this number upon a justification, e.g., crops with high nitrogen uptake. The justification will be examined by the European Commission (91/676/EEC). Currently, derogations are granted, for instance, to Denmark, The Netherlands, Ireland, and Belgium (Flanders) (EC, 2021h).

Application of fertilisers resulting from RUSTICA would be subject to the EU legislation on nitrate and in a broader sense to regulatory on water while specific limits on nitrogen application are mainly defined for manure.

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3.4.1.3. Emissions with view on agriculture

Comprehensive efforts are made and rules are laid down in the EU in order to reduce emissions and mitigate climate change. To this end, measures are designed specifically for the land use sector.

3.4.1.3.1. Rules from ESR and LULUCF

The ESR (EU) 2018/842 covers also GHG emissions from the agricultural sector ((EU)2018/842), notably enteric fermentation of ruminants (methane), manure management (methane and nitrous oxide), rice cultivation (methane) and agricultural soil management (mainly methane and nitrous oxide) (Agridata, 2021) to accomplish the GHG reduction targets. (Please view also section 3.1.4.)

Apart from the legal frameworks on ETS and ESR, the Regulation (EU)2018/841 *on the inclusion of greenhouse gas emissions and removals from land use, land use change and forestry in the 2030 climate and energy framework* (LULUCF) ((EU)2018/841) is considered as a "third pillar" (Böttcher, Zell-Ziegler, Herold, & Siemons, 2019) in the EU legal framework to achieve the climate neutrality by 2050 and the intermediate objective of ≥ 55% by 2030 (EC, 2021t).

The Regulation ((EU)2018/841) clearly refers to the UNFCCC and the Paris Agreement (e.g., Recitals 3 and 4) and sets commitments on the contributions of EU countries in the LULUCF sector for a period covering 2021-2030 (Art. 1) ((EU)2018/841) in order to achieve the objectives of the International Agreement (UNFCCC, 2015). It applies to emissions and removals of the GHGs carbon dioxide, methane, and nitrous oxide (Annex I, section A) ((EU)2018/841) in the land accounting categories: *"afforested land", "deforested land", "managed cropland", "managed grassland",* and *"managed forest land"*. The category "managed wetland" will be included as of 2026 (Art. 2) and, for example, the land use category "managed cropland" comprises (Art. 2(1)(a)(iii)) ((EU)2018/841):

- *"cropland remaining cropland*
- *grassland, wetland, settlement or other land, converted to cropland, or*
- *cropland converted to wetland, settlement or other land;"* ((EU)2018/841)

With regard to a certain flexibility as defined in Art. 12 and 13 (e.g., options for transfer of removals between Member States), it has to be ensured by each EU country *"that emissions do not exceed removals, calculated as the sum of total emissions and total removals"* for all of the aforementioned land accounting categories on its entire state territory for the periods from 2021-2025 and 2026-2030 (Art. 4) ((EU)2018/841). This stipulation is also called "no-debit" rule (EC, 2021t) (Böttcher et al., 2019). Since 2021, LULUCF emissions need not only to be monitored but also measured (Ekardt, Wieding, Garske, & Stubenrauch, 2018).

LULUCF and land use emission reduction are comprehensively addressed in literature (Böttcher et al., 2021) (Savaresi & Perugini, 2019). For example, measures are proposed to avoid emissions from mineral agricultural soils and support carbon sequestration. Such measures comprise, e.g., *"minimised CO2 release from microbial mineralisation by reducing soil disturbance and managing soil physical properties"* (Böttcher et al., 2021).

On the other hand, as it is revealed in literature: "*emissions from livestock farming (except from grazing land) and fertiliser application in the agricultural sector are therefore part of the targets within the ESR* (Ekardt et al., 2018)".

RUSTICA targets not only fertilising of plants but also improvement of soil. As such, the project is expected to develop materials beneficial for GHG emission reduction by means of the ESR and LULUCF legislation.

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3.4.1.3.2. Emission ceilings and reduction commitments

Targeting levels of air quality that do not lead to adverse effects on human health, Directive (EU) 2016/2284 defines obligations of the Member States on "*anthropogenic atmospheric emission*" reduction. Detailed premises for pollutants are put in place and reduction targets for sulfur dioxide (SO_2), nitrogen oxides (NO_x), non-methane volatile organic compounds (NMVOC), ammonia (NH_3), fine particulate matter ($PM_{2,5}$) are set ((EU)2016/2284) (Giannakis et al., 2019) (Hu & Schmidhalter, 2021).

In Recital 6 of the Preamble, the Directive ((EU)2016/2284) refers to the revised Gothenburg Protocol (UNECE, 2021a) for emission reduction commitments concerning the year 2020 and thereafter (UN, 2013a). It further points out that 2005 functions as a base year for the aforementioned pollutants and groups of pollutants ((EU)2016/2284). The estimated emission levels 2005 of the EU as a Convention Party are reflected in **Table 27**.

Table 27: Estimated EU Emission levels 2005 (Revised Gothenburg Protocol)

Convention Party (revised Gothenburg Protocol, Decision 12/2)	Estimated emission levels in 2005 in 1000 t				
	SO_2	NO_x	VOC[139]	NH_3	$PM_{2,5}$
European Union	7,828	11,354	8,842	3,813	1,504

Source: Own depiction based on the revised Gothenburg Protocol (UNECE, 2021a), ECE.EB.AIR/114, Annex II, Tables 2-6 (UN, 2013a)

As stressed in Recital 7 ((EU)2016/2284), the national emission ceilings of 2001/81/EC (2001/81/EC) shall be aligned with international commitments of the EU and the Member States. To this end, the national emission reduction commitments for each year in the period 2020-2029 equal the values of the revised Gothenburg Protocol (UNECE, 2021a) (UN, 2013a) ((EU)2016/2284). The reduction commitments of the EU-28 laid down in Directive (EU) 2016/2284 are depicted in **Table 28** ((EU)2016/2284).

The Directive (EU) 2016/2284 imposes drawing up and updating "*National air pollution control programmes*" (Art. 6) including but not limited to evaluate the relevance of national emission sources for the air quality, to reduce pollutant emissions in pursuing the reduction targets, and to boost decrease of black carbon towards lower fine particular matter. A review (Art. 13) on progress towards the objectives shall take place by 2025 ((EU)2016/2284) (Giannakis et al., 2019).

Table 28: Emission reduction targets for EU-28 compared with 2005 ((EU) 2016/2284)

For any year in Time Period	Emission reduction targets for EU-28 compared with 2005				
	SO_2	NO_x	NMVOC	NH_3	$PM_{2,5}$
2020-2029	59%	42%	28%	6%	22%
From 2030	79%	63%	40%	19%	49%

Source: Own depiction based on (EU) 2016/2284, Annex II, Tables A and B ((EU)2016/2284); UN ECE/EB.AIR/114-Annex II-Tables 2-6 (UN, 2013a); (Hu & Schmidhalter, 2021);

Measures to control **ammonia emissions** embrace farming practices and fertilisers (Annex III, Part 2). Thereby, four main points are set by the Directive ((EU)2016/2284):

[139] The revised Gothenburg Protocol, Table 5 refers to volatile organic compounds. (UN, 2013)

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1. Elements of the *UNECE Framework Code for Good Agricultural Practice for Reducing Ammonia Emissions* of 2014 (UNECE, 2021b) (UN, 2015) shall be considered by a national *advisory code of good agricultural practice* (Giannakis et al., 2019). At minimum, the elements "*a) nitrogen management taking into account the whole nitrogen cycle b) livestock feeding strategies c) low-emission manure spreading techniques d) low-emission manure storage systems e) low-emission animal housing systems f) possibilities for limiting ammonia emissions from the use of mineral fertilisers"* have to be focused by the measures ((EU)2016/2284).

2. National nitrogen budgets may be initiated by Member States to observe alterations of nitrogen[140] losses in agriculture following the rules of the *UNECE Guidance Document on Nitrogen Budgets* ((EU)2016/2284) (UNECE, 2021b) (UN, 2013b).

3. To lower ammonia emissions from inorganic fertilisers, ammonium carbonate shall be prohibited. Urea shall be replaced by ammonium-nitrate based fertilisers. In case urea will be further used for fertiliser purposes, methods achieving ≥ 30% ammonia emission reduction in comparison to the reference methods of the UNECE Framework Code (UN, 2015) are required. In addition, organic fertilisers shall substitute inorganic fertilisers. As far as the latter will continue to be deployed, spreading shall be done in a holistic approach including crop or grass land need of nitrogen and phosphorous, nutrient level in soil and deliveries from other fertilisers ((EU)2016/2284).

4. Specific attention is paid to terms of livestock manure including e.g., emission reduction from slurry and solid manure application by spreading tailor-made to nutrient requirements of plants ((EU)2016/2284).

Measures to control **emissions of fine particulate matter and black carbon** include an authorisation of "Member States to ban open field burning of agricultural harvest residue and waste and forest residue." The implementation of such bans shall be monitored by the EU countries and exemptions shall be very limited. Beyond of that, a *national advisory code of good agricultural practices* may be established for appropriate harvest residue management in a Member State to improve soil structure through integrating harvest residues including enhanced techniques, to indicate alternative uses, and to lift up the "*nutrient status and soil structure through incorporation of manure as required for optimal plant growth, thereby avoiding burning of manure (farmyard manure, deep-straw bedding)* ((EU)2016/2284)".

RUSTICA value chains starting from waste and by-products present perspectives for harvest residues by not simply incorporating them into soil but valorising them into high-class fertilisers towards an optimum for plants, soil and the environment.

3.4.1.4. Protection of biodiversity

To protect biodiversity, the "Natura 2000" network has been established by the amended Directive 92/43/EEC in order to safeguard and preserve habitats and wild flora and fauna. Criteria are laid down for identifying sites of Community importance and designation as "special area of conservation" (Annex III). In addition, "*special protection areas*" resulting from the "Birds Directive" (2009/147/EC) are covered by "Natura 2000" (2009/147/EC), the world's biggest network on protected areas. The network covers more than 18% of the land and over 8% of the sea area of the EU (EC, 2021f). Outstanding examples of natural habitats posing typical properties shall be established (92/43/EEC) at least in one of the nine *bio-geographical regions* of the EU territory: *"Alpine, Atlantic, Black Sea, Boreal, Continental, Macaronesian, Mediterranean, Pannonian and Steppic"* (EC, 2021e).

[140] including ammonia, nitrous oxide, ammonium, nitrates and nitrites ((EU) 2016/2284)

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There are no striking rules on tighten restrictions laid down for fertilisers in these legal sources. But it can be inferred that agricultural production will be affected in the protected areas which commonly also include nutrient management (Garske et al., 2020). This might apply to RUSTICA products as well.

3.4.2. Organic farming

Since RUSTICA research targets efficient and effective fertilisers based on secondary resources towards environmentally friendly products and closed loops, the requirements of fertiliser application in organic production are examined for the purpose of this D3.2 report. Moreover, organic production is investigated from the international perspective in the context of EU rules.

3.4.2.1. Rules for organic production in the EU

Whereas rules on protection of water and reduction of emissions pertain to the entire EU and its agricultural sector, the Common Agricultural Policy addresses agriculture in general and provides the setting for specific areas, Regulations (EU) 2018/848 and (EU) 2021/1165 earmark conditions for fertiliser application in organic agriculture ((EU)2018/848) ((EU)2021/1165). The logo for organic production of the European Union is depicted in **Figure 25**.

Figure 25: Organic production logo of the European Union
Source: Regulation (EU) 2018/848, Annex V ((EU)2018/848)

Regulation (EU) 2018/848 (Recital 20) votes for restrictions of external inputs in EU organic production and an authorisation to be granted in accordance with the legal source prior to their use. Products, such as fertilisers, to be permitted for organic production shall be bound to precise stipulations and restrictions (Recital 33) and Recital 63 stresses inter alia that fertilisers and soil conditioners should be used as less as possible ((EU)2018/848). Recital 81 refers to certain fertilisers which are not in the scope of the regulation, but due to their importance they are subject to authorisation under this Regulation and to be labelled accordingly ((EU)2018/848).

General principles (Art. 5) are including but not limited to "*the responsible use of energy and natural resources, such as water, soil, organic matter and air*", soil-related crop production, and as already mentioned, the use of GMOs[141] and products related thereto is not accepted. External inputs shall be used as far as internal materials or methods are not available and in terms of fertilisers, their use shall be limited to "*low solubility mineral fertilisers*" (Art. 5(g)(iii) ((EU)2018/848).

As it is clearly underlined, production of organic crops shall occur "*in living soil, or in living soil mixed or fertilised with materials and products allowed in organic production, in connection with the subsoil and bedrock*". Exceptions are made for crops naturally grown in water and "*sprouts by moistening of seeds and the obtaining of chicory heads including by dipping in clear water.*" In addition, cultivation of seedlings and transplants in containers for further transplanting are permitted, as well as growing of ornamentals and herbs to be sold in

[141] Except for veterinary medicinal purposes ((EU) 2018/848)

pots. However, typical hydroponic production is not allowed in EU organic production (Annex II, 1.1-1.4) ((EU)2018/848).

More detailed rules on soil management and fertilisation (Annex II, 1.9) strictly prescribe, e.g., "*multiannual crop rotation including mandatory leguminous crops as the main or cover crop for rotating crops and other green manure crops*" for arable land. In general, soil fertility shall be preserved and advanced by *"livestock manure or organic matter, both preferably composted, from organic production."* Green houses or perennial cultures except of such for fodder purposes shall use short-term green manure crops and legumes as well as plant diversity. If nutrient demands of plants cannot be addressed by methods like those described in this paragraph 1.9, fertilisers and soil conditioners covered by the Regulation (Art. 24) shall be applied as less as possible. The total amount of nitrogen resulting from livestock manure[142] in conversion and organic production units shall not be more than 170 kg/ha and year. As already indicated, to advance the overall condition of the soil or availability of nutrients, the use of preparations of micro-organisms is permitted. Such preparations and plant-based ones can be put in place for compost activation as well. But: *"Mineral nitrogen fertilisers shall not be used* ((EU)2018/848)*."*

3.4.2.2. Stipulations on organic fruits and vegetables for EU imports

The RUSTICA project explores and validates sophisticated technologies on fertiliser production and application in the context of conventional and organic farming not only in the EU territory but also in Colombia. In terms of exploitation and further collaboration in the course of the project and after its lifetime, it is of interest which traits need to be achieved by fruits and vegetables resulting from the innovations in plant nutrition of the project outside of the EU and to be placed on the *Common Market*.

3.4.2.2.1. General perspectives

An array of legal acts applies to trade of fruit and vegetables concerning imports to the EU, which are, for example, laid down in legal sources of the *Common Agricultural Policy* (e.g., ((EU)No1308/2013)) and with view on the project: also specifically in the *Trade Agreement* between the EU and Colombia (EUR-Lex, 2021c). While including the entire agricultural sector is obviously far beyond of this work, some aspects of organic production taking into account the international collaboration in the RUSTICA project are briefly thematised in this D3.2 report.

3.4.2.2.2. Imports to the EU organic food market

At time of writing, important rules on imports of organic products from outside of the EU are enacted and documented in Commission Regulation (EC) No 1235/2008 ((EC)No1235/2008) and its amendments which, in turn, rely on (EC) No 834/2007 on organic production and labelling of organic products ((EC)No834/2007).

Two different types of imported products are anchored in the Regulation (EC) No 834/2007. While Art. 32 delineates *"Import of compliant products*", the conditions for *"Import of products providing equivalent guarantees*" are portrayed in Art. 33 of this Regulation. Major requirements for each type to be placed on the market ((EC)No834/2007) are depicted in **Table 29.**

A strict control system is established to imports of products targeting the market of organic foods in the EU. Both *compliant products* and those *providing equivalent guarantees* must follow production and labelling rules as described in the Regulation (EC) No 834/2007. These rules comprise, for example, the prohibition of GMO

[142] The limit covers: *"farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrement, including poultry manure, composted farmyard manure and liquid animal excrement."* ((EU) 2018/848)

covering products generated with them or therefrom in main areas of organic agriculture[143] and compulsory labelling of the code number of control authority or -body.

In addition, *compliant products* need to be conform with objectives and principles laid down in Title II of the Regulation. Such objectives are e.g., striving for *products of high quality* and a *high-level of biodiversity*. Specific farming principles include, for instance, the use of recycled wastes and by-products originated from plants and animals for growing plants and livestock ((EC)No834/2007).

Table 29: Comparison of major import requirements laid down in (EC) No 834/2007

Compliant Products	Products providing equivalent guarantees

• in accordance with
  • Title II Objectives and Principles for Organic Production
  • Title III Production Rules
  • Title IV Labelling
  • Implementing rules relating thereto
	• Production compliance with production stipulation equivalent to
	  • Title III Production Rules
	  • Title IV Labelling

• Control of operators incl. exporters by control authorities recognised by the European Commission and accreditation by European Standard EN 45011 or ISO Guide 65	• Control measures equivalent to rules laid down in Title V Controls • Submission of activities along the entire supply chain (production to distribution) by the operator to a control system applying rules equivalent to Titles II, III, IV and V in a third country or to another control system in a third country recognised by the European Commission. • Considering Codex Alimentarius CAC/GL32[144] is part of both control routes.
• Availability of *documentary evidence* at any time at the operators' level to identify the operator conducting the last operation and enabling verification of compliance with rules of control bodies	• Availability of a *certificate of inspection* for the product concerned from recognised control authorities or bodies of the third country evidencing that rules of control as laid down in Art. 33 are fulfilled

Source: Own depiction based on Art. 32 and Art. 33 of Regulation (EC) No 834/2007 ((EC)No834/2007)

More details on the two aforementioned product classes of imported products addressing the EU organic market are provided in (EC) No 1235/2008 and its amendment. Concerning *Products providing equivalent guarantees*, Annex III of this Regulation presents a list of third countries based on Art. 7 which meet the requirements of Art. 33(2)[145] of Regulation (EC) No 834/2007.

Art. 10 ((EC)No1235/2008) refers to *"recognised control bodies and control authorities for the purpose of equivalence"* and a list of these bodies and authorities is covered by Annex IV with reference to Art. 33(3) of (EC) No 834/2007. To become part of this list, a specific procedure including a technical dossier is prescribed for the applicant by the legal act. Information has to be provided by the interested control body/-authority on

[143] "food, feed, processing aids, plant protection products, fertilisers, soil conditioners, seeds, vegetative propagating material, micro-organisms and animals" (EC) No 834/2007

[144] As a joint initiative of the World Health Organization (WHO) and the FAO, the CODEX ALIMENTARIUS COMMISSION (CAC) was founded to define international standards, guidelines, codes and further advisory on food. These are collated in the CODEX ALIMENTARIUS. Reference "CXG 32-1999" indicates "GL-32 Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods" (FAO-WHO, 2021) (FAO-WHO, 1999).

[145] *(EC) No 834/2007, Art. 33(2): "The Commission may, in accordance with the procedure referred to in Article 37(2), recognise the third countries whose system of production complies with principles and production rules equivalent to those laid down in Titles II, III and IV and whose control measures are of equivalent effectiveness to those laid down in Title V, and establish a list of these countries. The assessment of equivalency shall take into account Codex Alimentarius guidelines CAC/GL 32."*

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its activities in a third country and the production standards and controls in the concerned country as well as their conformity to Titles III, IV and V of the Regulation (EC) No 834/2007 ((EC)No834/2007) ((EC)No1235/2008).

Due to the international orientation of the project embracing a consortium partner from Colombia, stipulations for this country are of particular interest. Subsequently, control bodies and authorities for imports from Colombia to EU as listed in Annex IV[146] of (EC) No 1235/2008 and its amendments are depicted in **Table 30** by taking into account code numbers and related product categories ((EC)No1235/2008).

Table 30: Imports from Colombia to the EU organic market: Control bodies/-authorities and product classes

Control body/authority	Code	Product Categories[147]					
		A	B	C	D	E	F
Agreco R.F. Göderz GmbH, DE http://agrecogmbh.de	CO-BIO-151						
Bio Latina Certificadora, PE http://www.biolatina.com	CO-BIO-118						
CERES Certification of Environmental Standards GmbH, DE; http://www.ceres-cert.com/	CO-BIO-140						
Certificadora Biotropico S.A, CO www.biotropico.com	CO-BIO-186						
Certificadora Mexicana de productos y procesos ecológicos S.C., MM; http://www.certimexsc.com	CO-BIO-104						
Control Union Certifications, NL http://certification.controlunion.com	CO-BIO-149						
Ecocert SA, FR http://www.ecocert.com	CO-BIO-154						
Florida Certified Organic Growers and Consumers, Inc. (FOG), DBA as Quality Certification Services (QCS), US; http://www.qcsinfo.org	CO-BIO-144						
IBD Certificações Ltda., BR http://www.ibd.com.br	CO-BIO-122						
IMOcert Latinoamérica Ltda., BO http://www.imocert.bio	CO-BIO-123						
Kiwa BCS Öko-Garantie GmbH, DE www.kiwabcs-oeko.com	CO-BIO-141						
Letis S.A., AR http://www.letis.org	CO-BIO-135						
Mayacert, GT http://www.mayacert.com	CO-BIO-169						
Organización Internacional Agropecuaria, AR http://www.oia.com.ar	CO-BIO-110						
Servicio de Certificación CAAE S.L.U., ES http://www.caae.es	CO-BIO-178						
Soil Association Certification Limited, UK http://www.soilassociation.org/certification	CO-BIO-142						

Light green shaded fields = category encompassed by control body

Source: Own depiction based on legal sources: ((EC)No1235/2008) and amendments ((EU)2016/1330); ((EU)2018/949); ((EU)2020/2196); ((EU)2017/2329); ((EU)2019/446; (EU)2020/25);

[146] With reference to Art. 10 of Regulation (EC) No 1235/2008 and Art. Art. 33(3) of (EC) No 834/2007

[147] A: Unprocessed plant products; B: Live animals or unprocessed animal products; C: Unprocessed aquaculture products and algae; D: Processed agricultural products for use as food; E: Processed agricultural products for use as feed; F: Vegetative propagating material and seeds for cultivation; (EC) No 1235/2008, Annex IV

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4. RUSTICA in the mirror of EU priorities and strategies

The RUSTICA project strives for ground-breaking news and future-oriented solutions in the fertiliser sector towards tailor-made nutrition for agricultural needs in five model-regions across Europe and beyond. To create and amplify the impact of the project, European policy instruments are pivotal for a successful innovation. Accordingly, the European Green Deal and important sector-related strategies are briefly reflected in this D3.2 report.

4.1. The European Green Deal

From six new priorities (EC, 2021q) presented by the European Commission in 2019, the European Green Deal is the first one and at the same time it constitutes the new growth strategy of the EU (EC, 2021p) (VOLATILE-D2.6, 2020). The European Green Deal laid down in Communication (COM(2019)640) is composed of four main sections **(Figure 26)** and presents a roadmap with key actions.

Figure 26: The European Green Deal - four main sections
Source: Own depiction based on the European Green Deal (COM(2019)640)

The objectives of accomplishing no net emissions of greenhouse gases in 2050 and an economic growth which relies no more on resource use are highlighted in the **first section**. Furthermore, the protection, conservation and enhancement of the EU's natural capital are endorsed by the strategy (COM(2019)640). By turning waste into secondary resources, thereby reducing the use of primary sources, and measuring the environmental impact, RUSTICA research is fully in accordance with these goals.

A clean and circular economy is addressed inter alia in **section two** and a decarbonisation of e.g., production of chemicals is targeted while a new circular economy action plan which is available since 2020 specifically responds to resource intensive sectors but offers guidance for all sectors. Besides, a fair and healthy food system with no adverse effects on the environment is outlined by the Green Deal including the announcement of the *"Farm to Fork"* strategy which was published in 2020 as well (please view section 4.4). To protect biodiversity and to identify main reasons of losses therein including measurable objectives and measures to address them, the 2030 biodiversity strategy has been launched in 2020 (please view section 4.5). Furthermore, a chemicals strategy is announced targeting sustainability and safety. Financial incentives are indicated e.g., by means of tailored taxation of organic vegetables and fruits. Research on circular bio-based sectors will be bolstered by partnerships linking industry with EU countries (COM(2019)640). By converting nutrients from agro-food residuals into high-quality fertilisers, the RUSTICA idea clearly fits into these policies of preserving natural resources and fostering partnerships in the bio-based sectors.

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Promotion and implementation of environment, climate and energy policies in the world are part of the global policy of the EU while continuity will be guaranteed that the *Paris Agreement* is the essential multilateral framework in combating climate change (**section three**). Diplomatic and financial tools will be deployed for "*green alliances*" with international partners including Latin America and efforts are enhanced to strengthen sustainable development commitments of EU trade agreements. To address sustainability, the EU can establish standards which are valid for global value chains, thus, trade, e.g., with environmental products and services could be become easier (COM(2019)640). With regard to the international partnership with Colombia in the RUSTICA project, the EU policy can directly influence the impact of the project in the global context.

Perusing **section four** of the *European Green Deal*, it is including but not limited to an involvement of the public and all stakeholders for building the *Climate Pact* as a fundamental platform to achieve local alterations. As it is further stressed, not only urban but also rural regions are endorsed in multiple directions to build their strategies. Pecuniary support is given e.g., by funds which will redound to access options in the circular and bio-economy in rural areas (COM(2019)640). RUSTICA will be validated in five rural regions of which four are located in Europe and one in a third country. Financial support schemes could be taken into account for the exploitation of the RUSTICA project results in these regions and beyond.

To underpin the strategy, a set of key actions has been defined in a roadmap for the period 2020 to 2021. Bearing in mind the RUSTICA efforts on innovations, it will be referred to the Green Deal and its roadmap also in the following sections of chapter four in this D3.2 report.

4.2. EU Circular Economy Strategy

Starting from waste and by-products, the RUSTICA project embodies the idea of circularity by combining agricultural cultivation and innovative fertiliser processing technologies. In consequence, the strategy "*Towards a circular economy: A zero waste programme for Europe"* which was established in 2014 (COM(2014)398), is part of this D3.2 report.

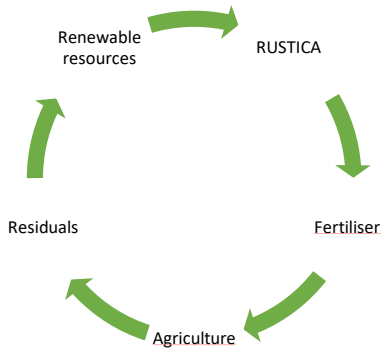

Figure 27: Example of a simplified RUSTICA cycle
Source: Own depiction based on RUSTICA concept

Shifting from linear to more circular economic models would benefit the European economy in its efforts to encounter the challenges of global pressure on resources and increasing risks in terms of reliable supply. To elevate competitiveness and robustness and, in turn, reduction of dependence on uncertain deliveries, re-introduction of resources into production and use as often as possible by eliminating waste is a direct response thereto. By contributing to "*decouple economic growth from resource use and its impacts*", such models can open the anticipation of maintaining sustainable growth at the long-term (COM(2014)398).

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In accordance with the roadmap of the Green Deal (COM/2019/640), a *New Circular Economy Action Plan* has been launched in 2020. As it is reported in the plan, resource extraction and processing are responsible for around 90% of biodiversity loss and water stress while a severe increase of material consumption, e.g., biomass and generation of waste at the international level is expected in the future. To meet these challenges, the plan outlines inter alia the necessity of a speed up for achieving a new growth model following the principles of regeneration, less resource consumption and "*double its circular material use rate in the coming decade*" (COM/2020/98).

The plan further promotes a sustainable product policy framework including, for example, more recycled matter in products without a compromise in terms of performance and safety. *"Circularity in production processes"* is highlighted, e.g., by linking the Bioeconomy Action Plan and its implementation (please view section 4.3) with the *"circular bio-based sector"* (COM/2020/98).

Seven "*key product value chains"* are identified by the *New Circular Economy Action Plan* of which "*food, water and nutrients"* dealing with biological resources and renewable bio-based materials in the context of the Bioeconomy Strategy and its Action Plan, (section 4.3) is of particular relevance for the RUSTICA research. Prominence is given to the food value chain (please view also section 4.4), and an "*Integrated Nutrient Management Plan*" is announced by the European Commission with regard to enhancement of sustainability in usage of nutrients and vitalising the markets for nutrients resulting from recovery processes (COM/2020/98).

In pursuing *"less waste and more value*", the European Commission strives inter alia for an optimal internal market for secondary raw materials. To this end, the development of further end-of-waste criteria at the EU level for selected waste streams will be evaluated with view on national transformation of the legislation already conducted on by-products and the end-of-waste status. Transnational efforts to harmonise the national rules are encouraged (COM/2020/98).

The *New Circular Economy Action Plan* also advocates the global transition to a circular economy and features, for instance, that attention is paid in Free Trade Agreements to the uplifted goals of the circular economy (COM/2020/98).

RUSTICA creates value chains from waste to high-value bio-based fertilisers able to close loops **(Figure 27)**, save fossil resources and gain secondary raw materials. As such, the project represents the ideals of the strategy.

4.3. EU Bioeconomy Strategy

Already in 2012, the strategy *"Innovating for a Sustainable Growth: A Bioeconomy for Europe*" which contains the "*conversion of renewable resources and waste streams into value added products"* was published by the European Commission (COM(2012)60) (COM/2018/673) (Wiedemann, Hiessl, & Rusu, 2020).

RUSTICA is a model *par excellence* for the bioeconomy since introducing novel valorisation routes for organic waste materials resulting in added-value fertilisers. Accordingly, more details are given on this strategy in this section of the D3.2 report.

As mentioned before, the Bioeconomy is addressed by the *Green Deal* (COM(2019)640), and it is strongly referred to by the New *Circular Economy Action Plan* from 2020 (COM/2020/98).

To address challenges, such as *finite resources, climate change, weaken ecosystems*, *a worldwide growing population* and at the same time to refresh the European economy in terms of sustainability and global competitiveness, the aforementioned *Bioeconomy Strategy* was updated in 2018 (COM/2018/673) (Wiedemann et al., 2020).

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Taking a broader approach, the 2018 update *"A sustainable Bioeconomy for Europe: Strengthening the connection between economy, society and the environment"* expands the scope of sectors mainly focused by the economic and industrial use of biological resources from four to five by adding services. On the other hand, as demonstrated in **Figure 28**, it explicitly points out connecting land and marine eco systems and the primary sectors with the previously mentioned industrial and economic activities (COM/2018/673) (Kardung et al., 2021) (VOLATILE-D2.6, 2020) (Wiedemann et al., 2020).

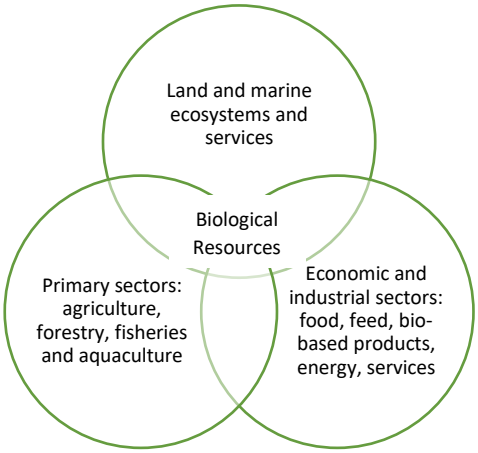

Figure 28: EU Bioeconomy Update 2018: Interlinks and Intersections
Source: Own depiction based on RUSTICA concept

Nonetheless, after reviewing, the five aims laid down in the strategy from 2012 are still relevant in the 2018 update of the strategy (COM/2018/673) and briefly featured in this D3.2 report.

1. **Food and nutrition security** is crucial and a speed up of the transformation into food and farming systems with characteristics, such as "*sustainable, healthy, nutrition sensitive, resource-efficient, resilient, circular and inclusive"* is demanded by the strategy. The conversion of organic waste, residues and food discards into high-value bio-based products, e.g., by bio-refineries which could help farmers to gain additional turnover in compliance with the objectives of the Circular Economy (COM/2018/673).

2. The **sustainable management of natural resources** is required, in particular with view on biodiversity loss and threatened ecosystems. More capacity to observe the status of these resources and to project evolvements is required (COM/2018/673).

3. **Less dependence from non-renewable resources** is important to meet the EU energy and climate targets and the role of the bio-based sector is emphasized in the context of the Paris Agreement. More innovation in industrial bio-based processes will be an important factor for the development of circular bioeconomies (COM/2018/673).

4. As the world-wide challenge, **mitigation and adaption to climate change** is paramount and a sustainable and circular bioeconomy can play a key role in terms of a GHG neutral Europe. To unlock the potential of the circular economy, the contribution of e.g., *"more resource efficient, active and sustainable primary production practices on land"* needs to be promoted (COM/2018/673).

5. **Strengthening European competitiveness and creating jobs** is a central goal pursued by the strategy. Appropriate frameworks including but not limited to enabling vibrant uptake of innovations and market growth for bio-based products, for example, by public procurement or standardisation activities could foster this objective (COM/2018/673).

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The updated strategy proposes three major action areas (COM/2018/673) (Kardung et al., 2021) in order to respond to these objectives which are **(Figure 29)**:

Area 1	Area 2	Area 3
"*Strengthen and scale up the bio-based sectors, unlock investments and markets*"	"*Deploy local bioeconomies rapidly across Europe*"	"*Understand the ecological boundaries of the bioeconomy*"

Figure 29: EU Bioeconomy Update 2018: Three main action areas
Source: Own depiction based on the EU Bioeconomy Update 2018 (COM/2018/673)

These areas are underpinned by 14 actions (COM/2018/673). Bearing in mind the scope of RUSTICA, the actions are summarised as follows:

Pertaining to **area one**, the mobilisation of *"public and private stakeholders in research, demonstration and deployment"* of circular bio-based solutions, establishing a *"€100 million Circular Bioeconomy Thematic Investment Platform"* (Kardung et al., 2021), and provision of *"voluntary guidance to the deployment of bio-based innovations"* based on studying and analysing drivers and bottlenecks are highlighted. Furthermore, the promotion/development of standards and enhancement of labels on bio-based products based on reliable data indicating environmental and climate performance, facilitation of evolving "*new sustainable biorefineries"* and confirmation of their nature and potential are part of the first area. (COM/2018/673) (VOLATILE-D2.6, 2020).

Area two involves inter alia "*sustainable food and farming systems*" in a circular bioeconomy and a "*Strategic Deployment Agenda"* therefor. To endorse unfolding of local bioeconomies in urban, rural, and coastal areas, pilot actions through instruments and programmes of the European Commission are mentioned in this area. A *European Bioeconomy Forum for Member States* will be introduced and promotion of education/training and skills will take place (COM/2018/673) (VOLATILE-D2.6, 2020).

Better knowledge on the bioeconomy by integrating biodiversity and ecosystems for its deployment within safe ecological boundaries and provision of such knowledge by the *Knowledge Centre for Bioeconomy* are subject to **Area three**. More capabilities, e.g., for observation and reporting to constitute a monitoring system not only across the EU but international coherent to track the route of progress on a sustainable bioeconomy. In addition, voluntary guidance for conducting the bioeconomy within required ecological limits and an improved incorporation of the advantages of valuable biodiversity ecosystems in the primary sector inter alia by supporting of *"agro-ecology*" and solutions based on micro-biome. (COM/2018/673) (VOLATILE-D2.6, 2020).

By virtue of its comprehensive activities towards bio-based fertiliser solutions derived from "leftovers" in the agri-food chain, the RUSTICA project addresses the aforementioned objectives of the EU Bioeconomy Strategy. Actions, e.g., promotion of standards/labels for bio-based products are of specific interest for the project.

4.4. EU Farm to Fork Strategy

Targeting innovative and affordable solutions on plant nutrition and soil health, sustainable food systems as reflected in the *Farm to Fork Strategy*, are focused by RUSTICA. Thus, this strategy which is among the key actions of the Green Deal Action Plan is part of the D3.2 report.

A reduction of GHG emissions by 20% in the period from 1990 to 2017 took place in EU agriculture, and its role for accomplishing the GHG reduction target of 55% by 2030 compared to 1990 towards climate neutrality in the EU by 2050 is a fundamental part of the strategy. In this respect, the strategy discusses to recompense e.g., farmers and other representatives of the food chain if already moved to sustainable methods and paving the

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way for others. Likewise, decreasing of excess fertilisation and stepping up of organic farming is underlined in the document (COM/2020/381).

In the context of sustainable food production, it is referred to advanced biorefineries for manufacturing of e.g., bio-fertilisers providing new options by means of a circular bio-based economy which are currently rather unexploited by the farming sector (COM/2020/381).

Furthermore, an excess of nutrients in the environment, in particular nitrogen and phosphorous, is rebuked which is caused by a surplus resulting from nutrients not entirely taken up by crops. A decrease of nutrient losses ≥ 50% by maintenance of soil fertility and leading to less use of fertilisers by 20% at minimum are targeted by 2030. Environmental and climate legislation are mentioned as regulatory instruments to detect the nutrient charges to be lowered with the help of the EU countries in order to attain the aforementioned objectives. Sustainability in management of nutrients encompassing lifecycles of nitrogen and phosphorous as well as following the guidance of balanced fertiliser application are relevant thereto (COM/2020/381).

With reference to nutrient pollution, an integrated nutrient management action plan will be elaborated by the European Commission in collaboration with the Member States. The increase of precise fertilisation and sustainable agriculture methods preeminently in areas with concentrated livestock as well as converting organic waste into fertilisers are subject to this collaboration as well. Implementing measures of the Member States are (COM/2020/381):

- Inclusion into the *Common Agriculture Policy Strategic Plans*
- *Investments*
- *Advisory services*
- *EU space technologies (Copernicus, Galileo) (COM/2020/381).*

Issuing food waste, the strategy invokes, for example, policies on recovery, waste management, biodiversity, and bioeconomy (COM/2020/381). Due to its concept RUSTICA research is dedicated to tailor-made solutions in order to tackle the aforementioned problems of food waste and nutrient pollution.

Apart from sustainable farming in general, organic farming is addressed by RUSTICA as well. It is not only appreciated by consumers but also highlighted in terms of jobs and market growth while benefitting biodiversity. Beyond of the *Common Agricultural Policy*, an *Action Plan for the Development of Organic Production* has been launched by the European Commission to step up in this sector and to meet the goal of 25% organic farming in the farmland of the EU by 2030 (COM/2020/381).

Action plan for the development of organic production

Significant progress has been made in organic farming in the EU representing an area which has been expanded by almost two thirds in a decade and achieved 13.8 million ha in 2019. Today, it stands for 8.5% of the entire agricultural territory in the EU. To further stimulate the sector and to attain the 25% target[148], the European Commission has established an *Action Plan for the Development of Organic Production* (COM/2021/141), also referred to *"Organic Action Plan" (EC, 2021k)*.

The Plan relies on three axes (**Figure 30**) which are underpinned by 23 actions (COM/2021/141). These actions are indicated in summary within this D3.2 report.

[148] This target is also laid down in the European Green Deal.

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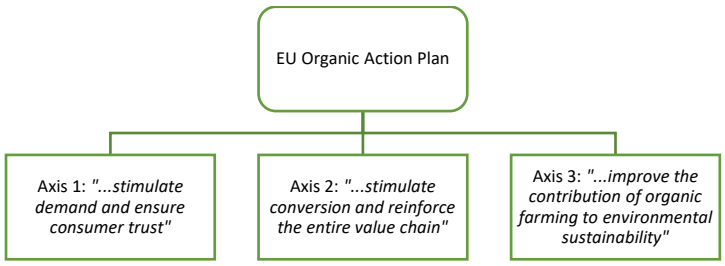

Figure 30: Summary of the three axes of the EU Organic Action Plan
Source: Own depiction based on EU Action Plan for the Development of Organic Production (COM/2021/141)

Eight actions are beneath **axis 1** which address e.g., promoting EU organic farming and labelling with the logo, expanding *Green Public Procurement* and "green canteens", strengthening organic school schemes, preventing food fraud, and enhancing traceability by digital technologies (COM/2021/141).

In the scope of **axis 2**, financial support by the Common Agricultural Policy to shift to organic farming is reflected. Furthermore, sector analysis leading to more market transparency, backing of food chain management and producer organisation, supporting appropriate processing and trade, and taking steps forward in animal nutrition are part of the second axis (COM/2021/141).

Sustainability aspects of organic farming are gathered by **axis 3** and concrete actions are dealing with less climate and environmental impact, improving biodiversity and crop yields, substituting critical input and plant protection materials while voting for more animal welfare. In addition, the *Organic Action Plan* adverts more efficiency in the use of resources and reveals measures, such as less water pollution by nutrients and diminishing nutrient release (Action 23) (COM/2021/141).

RUSTICA includes research on the appropriateness of its output for the organic sector. Strong efforts are made in the project to investigate benefits for agricultural crop yields, biodiversity and environment.

4.5. EU Biodiversity Strategy

Because of the RUSTICA approaches on environmentally friendly plant nutrition, healthy soil ecosystems and organic farming, EU policy on biodiversity is part of this D3.2 report.

To protect the environment and nature with its variety of ecosystems, the *EU Biodiversity Strategy for 2030* which is part of the *Green Deal Action Plan* introduces concrete and detailed plans as well as measures thereto (COM/2020/380).

Five main "*drivers of biodiversity loss*" are identified by the strategy (COM/2020/380) and shown in **Figure 31**.

The strategy responds to these challenges: a protection of 30% of the EU land area at minimum and ≥ 30% of the sea area should take place by means of a legal framework by 2030. In addition, 10% of the protected areas not only at land- but also at the seaside should be strictly protected. This requires a proper management including determining objectives linked to measures and their monitoring (COM/2020/380).

An "EU Nature Restoration Plan" is set by the strategy and mentions, e.g., a proposal of the European Commission for "*EU nature restoration targets in 2021*" with legally binding character in order to renovate destroyed ecosystems. By defining a more natural agriculture, the strategy links with the Farm to Fork Strategy and Common Agriculture Policy, but provides additional targets, such as ≥ 10% of agricultural area "under high-diversity landscape features." These features may comprise hedges, buffer strips and non-productive trees by contributing to more carbon sequestration and restrain soil from erosion and depletion (COM/2020/380).

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Advantages of organic farming, such as more job creation per hectare than conventional agriculture, are emphasized as well as the 25% target for organic agriculture in the EU by 2030 as defined in the *Farm to Fork Strategy* (COM/2020/381) (please view section 4.4). Moreover, the strategy acknowledges the value of soil as a non-renewable resource, its fertility and its role in nutrient cycling while clearly describing the increasing risk of desertification in Europe. With regard to "zero pollution", the targets of the Farm to Fork Strategy, e.g., 50% less nutrient losses by 2030, are incorporated into this strategy as well (COM/2020/380).

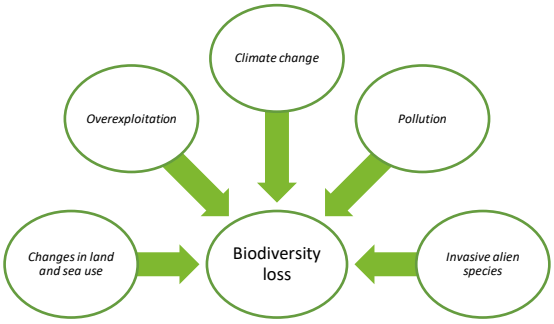

Figure 31: EU Biodiversity Strategy 2030: "Five main direct drivers of biodiversity loss"
Source: Own depiction based on EU Biodiversity Strategy (directly cited) (COM/2020/380)

As it is disclosed by the strategy, the EU lacks a broad framework to guide the implementation of commitments as regards biodiversity at various political levels. Hence, the necessity of prioritising support to amplify EU environmental legislation is underlined by the strategy (COM/2020/380).

Apart from the European level the strategy encourages tackling biodiversity issues at the global dimension as well. For instance, partner countries all over the world will be endorsed to reach the international objectives and to combat environmental crime, as well as biodiversity loss (COM/2020/380).

The RUSTICA project bundles an array of measures to tackle loss of biodiversity in Europe and beyond. Especially, to reduce nutrient losses while maintaining or lifting up quality and fertility of soil is focused by the project.

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5. Conclusions and recommendations

Highly ambitious objectives, such as integrating five novel and one established technologies, are linked with the implementation of RUSTICA in Europe and worldwide. The project not only aims at demonstrating the technical feasibility but also upscaling to pilot level. Validation will take place inter alia by means of application tests in order to identify robust options enabling a vigorous impact of the project.

Achieving these goals and maximising the impact will depend on many factors while one of these factors will be the legal and political environment relevant for the project during and after its lifetime. As playing a crucial role for the launch of RUSTICA bio-based products onto the market, EU legislation and policy including international aspects are studied in this D3.2 report. Conclusions and recommendations can be made as follows:

5.1. RUSTICA in the context of EU and international policy

5.1.1. International agreements as regards the environment

Major efforts of RUSTICA are reflected in the purposeful elaboration of international recognised and affordable plant nutrition and soil support systems while at the same time prioritising utmost benefits of the environment. From the six prominent Conventions as overarching international agreements highlighting the protection of the environment and being part of this D3.2, the ***Basel Convention*** establishes rules for the transboundary movement of wastes. For example, waste from the agro-food industries (Annex IX, Code B3060) would be subject to the rules of hazardous waste if contaminated with "wastes to be controlled" as defined by the Convention which indicates a strictly defined control regime in case of transports of such waste become necessary. Conversely, a more detailed description of household waste commonly covering very heterogenous fractions could support international waste management. Combating intentional or unintentional production of POPs as laid down in the ***Stockholm Convention*** is in accordance with the RUSTICA project and its endeavors on evolving alternatives to open burning and inappropriate combustion. RUSTICA research may not exclude resilient plants and additional effects of its products on plant protection able to substitute hazardous products as addressed by the ***Rotterdam Convention***, as such the objectives of the Convention will be relevant for the project. Because of its innovative measures, the project has the potential to significantly reduce pollution of the natural environment, enhance preservation of (genetic) resources, and foster biodiversity which is totally conform with the **Convention on Biological Diversity**. Preserving of land and water by elevating soil quality and capacity not only in Europe but also worldwide is at the core of RUSTICA intentions. Hence, the project totally complies with the objectives of ***United Nations Convention to Combat Desertification in those Countries Experiencing Serious Drought and/or Desertification (UNCCD).*** Undoubtedly, the RUSTICA approach represents a proper symbol in pursuing a reduction of greenhouse gas emissions as agreed by the ***United Nations Framework Convention on Climate Change (UNFCCC)***.

5.1.2. Multilateral and bilateral relations EU - Colombia

The multilateral and bilateral relations between the EU and Colombia are the solid fundament enabling co-operation at different levels. The way to scientific collaboration is paved inter alia by the bi-regional partnership ***EU-CELAC***, and the ***Trade Agreement*** signed by the EU and Colombia as a Member of ***CAN*** serves as the comprehensive basis for establishing common standards from the economic, environmental, and social perspective. Among the goods ruled by the ***Trade Agreement*** are multiple fertiliser categories, as such providing an opportunity to be verified for the impact of the developments envisaged by the RUSTICA project.

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5.2. RUSTICA value chains and EU secondary law - legally binding unilateral acts

5.2.1. The role of feedstocks

5.2.1.1. Waste

Various terms are examined for describing the feedstocks of the RUSTICA project. As far as ***waste*** is concerned, the ***Directive on waste 2008/98/EC*** is a central legal source to be considered. The amendment ***(EU) 2018/851*** has introduced an option for feeding if a substance meets the requirements of feed materials as defined in ***(EC) No 767/2009*** provided that it is totally free from animal-by products. Furthermore, ***2008/98/EC*** excludes *natural non-hazardous agricultural materials* if e.g., used in farming or for the production of energy. To establish valorisation systems as covered by the RUSTICA approach at the farm level and/or in combination with generation of energy, an extension of this exclusion addressing bio-based fertilisers could be supportive. With regard to the ***waste hierarchy***, the legally ***(2008/98/EC)*** defined term "recycling" covers both reprocessing for the original or for other purposes and as such, there is no difference between accomplishing added-value in a process or simply reaching the status of origin. In particular for operations on organic waste, such a distinction could be relevant. The definitions of waste elucidated in this D3.2 comprise e.g., ***biodegradable waste*** as defined by the ***Directive on Landfill 1999/31/EC*** while this legal source and its reduction targets would be relevant for the project if waste otherwise ending up in landfill is diverted. Reduction ***((EU)2018/850)*** and recycling targets ***((EU) 2018/851)*** for ***municipal waste*** play a role for the project as well. ***Biowaste*** which includes food processing waste and ***food waste ((EU)2018/851)*** including all food ***((EU) No 178/2002)*** that has become waste represent central terms for feedstocks of the RUSTICA conversion processes. Scrutinising the ***List of waste (2014/955/EU)***, the waste codes under use deviate from international waste codes, such as those of the ***Basel Convention.*** Furthermore, a broad spectrum of waste categorisation is laid down in legislation on **shipment of waste *((EU) No 1013/2006)*** and its amendments***.*** A harmonisation of ***waste codes*** at European and international level could be a factor for facilitated waste management. In addition, their alignment to chemical nomenclature or product identification codes (e.g., in custom tariffs) could lead to new views on identification and traceability in reprocessing. To re-enter the economic cycle, ***end-of-waste criteria*** as referred to by the ***Directive on waste*** are indispensable for a waste. Therefore, it could boost RUSTICA if ***end-of-waste criteria*** for building waste-based value chains of the project will be defined at the EU level.

5.2.1.2. By-products

General characteristics are defined for ***by-products*** in ***2008/98/EC.*** The amendment of the ***Directive on waste*** indicates also conditions for establishing criteria for by-products at the national level where such criteria are not set at the Union level. But the availability of detailed criteria valid throughout the EU by means of legally binding legislation would be highly supportive for RUSTICA value chains envisaging marketable substances based on the feedstocks proposed for by-products in the project.

5.2.1.3. Animal by-products

In principle, ***animal by-products*** as defined in ***(EC) No 1069/2009***) are not foreseen as a feedstock for the RUSTICA valorisation routes. The project focuses on fruit and vegetable leftover materials for input to all of its value chains, and legal analyses result that undoubtedly, e.g., catering waste (as covered by the Animal by-products Regulations) is prohibited for insect feeding. If frass would be intended for research (e.g., for CAP): it should be considered that establishing legal rules for frass at the EU level is currently ongoing.

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5.2.1.4. Biomass

A definition of ***biomass*** is laid down e.g., in the RED II ((EU)2018/2001). The Directive rewards certain resources by double-counting for advanced biofuels if contributing to the RE target in transport. While e.g., agri-industrial waste is already excluded from this incentive if permitted for feeding purposes, it would be advantageous for the project if such rules on exclusion would apply for the RUSTICA bio-based fertiliser models as well.

5.2.1.5. Emissions

The RUSTICA project envisages drawing up of high-class conversion systems for redundant organic materials often discarded to landfill or inappropriately deposited in landscape. By means of its waste-based novel value chains, the project takes strong efforts to achieve a reduction of GHG emissions in accordance with EU-wide and national targets ***((EU)2018/842)((EU)2018/841)***. Stipulations on industrial emissions ***(2010/75/EU),*** e.g., as regards waste treatment would need to be considered in the course of technology upscale and exploitation at the more industrial level.

5.2.2. Routes from manufacturing to fertilisers

5.2.2.1. CAP and multi-value resources

A thorough definition of the ***CAP*** in EU legislation, taking into account its unique properties of generating valuable resources from waste or by-products, could accelerate the way to the market. Furthermore, a clear acknowledgement of ***bio-based*** substances by the ***REACH Regulation (EC) No 1907/2006*** and its amendments including but not limited to labelling could indicate the distinguished features of such materials. Since the technology uses anaerobic treatment processes, discussing legal aspects of ***CAP*** nutrient output in the context of anaerobic digestion should not be excluded. Provided that all legal requirements are met, pursuing of certain options in the feeding sector could be further encouraged for the ***CAP.*** Whereas GHG savings of biogas production from biowaste are legally established in the ***RED II***, the potential of the ***CAP*** on emission reduction is not yet completely anchored in legally binding EU legislation.

5.2.2.2. Microbial cultivation and -fertiliser

A more comprehensive legislation on "NON-GMO" micro-organisms and more details on biotechnological processes including fermentation relating to the ***REACH Regulation*** could be useful for supporting ***microbial fertilisers***. In addition, establishing conditions specifically for microbial fertilisers in the ***Fertilising Products Regulation (EU) 2019/1009*** could bolster the marketing of these products.

5.2.2.3. Electrodialysis and NPK concentrate

Generating ***NPK concentrate*** by means of ***electrodialysis*** is subject to the ***REACH Regulation*** as well. As a follow-up process of the CAP in the project, the technology and the facets of its legal positioning would need to be further discussed as regards incentives and promotion of new circular bio-based inorganic fertilisers. The implementation of such acknowledgements, e.g., in the ***REACH Regulation*** and ***Fertilising Products Regulation*** would be supportive for the RUSTICA project.

5.2.2.4. Insects - from feeding to utilisation

Strong progress has been made in legal matters for ***insect cultivation*** in recent time, in particular if used for the food and feed sectors. Stringent rules apply to nutrition of farmed insects. For example, ***"solid urban waste"*** ***((EU) No 568/2010)*** is defined in legislation on feed material and prohibited for animal (insect) diets. Since this term is not reflected in the Waste Framework Directive, a harmonisation of the terms could facilitate actions in

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the intersection area of waste and feed. Furthermore, conditions are laid down for invertebrates to be accepted as a *Category 3 material* and prerequisites for the use of these materials as ***organic fertilisers*** and ***soil improvers*** (e.g. **((EC) *No 1069/2009 and amendments*)** by means of the project. New rules for ***frass*** as a processed manure are under development in the context of stipulations for fertilisers as defined in the Regulation ***(EU) No 142/2011*** which are of particular relevance for the project. Specific legislation aligned to conditions of ***farmed insects*** targeting solely fertiliser applications as it is subject of RUSTICA could endorse such innovations.

5.2.2.5. Pyrolysis/gasification and biochar

The ***EBC*** as a voluntary standard for ***biochar*** in the EU provides a regime covering e.g., input materials, terms of production and control. A set of legal frameworks is available for ruling pyrolysis and gasification from the more energy perspective ***(e.g., 2010/75/EU).*** Hence, a legislation on such processes tailored to production of ***biochar*** could advance its upscale. This applies to the merits of ***biochar*** on carbon sequestration as well. As it is published by ECHA, opposed to brown or black coal, charcoal is not considered as "*a substance which occurs in nature"* by means of the ***REACH Regulation***. ***Biochar*** is reported to be incorporated into the ***REACH dossier of charcoal*** facilitating its marketing throughout the EU. In the course of the ongoing law-making procedure for biochar as a ***CE-marked fertiliser***, further significant progress is expected for ***biochar*** which is of utmost importance for the RUSTICA project.

5.2.2.6. Composting - from treatment to product

Composting *is clearly acknowledged in the* ***Directive on waste (2008/98/EC)*** for recycling of ***biowaste*** and legal provisions are made if recycling targets of ***municipal waste*** need to be addressed. The mature technology is also reflected in legal frameworks on industrial emissions ***(2010/75/EU)***, and implementing rules e.g., by means of ***BAT conclusions*** are set. As regards quality of compost, there are different options reported. Apart from voluntary standards unified by the ***ECN*** at the European level, nationally established legal prescriptions on composting rules are reported. Beyond these options, terms for compost are included in the new legislation for ***CE-marked fertiliser (EU)2019/1009***. As such, more than one gate is open for this technology. As it is further reported, composting can be favourable in terms of GHG emissions, especially if replacement of mineral fertilisers is considered.

5.2.3. Fertilising products requirements for different farming types

5.2.3.1. EU Fertilising Products (CE-marked Fertilisers)

The ***Fertilising Products Regulation (EU)2019/1009*** presents a revolutionary concept for fertilisers in the EU. In order to be permitted for placing on the market, an ***EU Fertilising Product*** needs to pass a ***conformity assessment procedure*** and to affix a visible ***CE-marking label***. At the time of writing, the Regulation comprises ***11 CMCs*** of which ***CMC 1*** is of specific interest for the project (e.g., for NPK Concentrate). However, restrictions expressed by this CMC would require tailor-made solutions as regards the feedstocks and building blocks for production addressing this ***CMC 1***. As implied above, ***CMC 3*** provides rules for compost to be obeyed by the project if targeting this route. ***CMC 3*** also refers to composting of materials subject to the Animal by-product Regulations which is crucial for the insect cultivation of the project. ***CMC 5*** defines the frame for digestate including hygiene and sanitation requirements for input components. Such requirements could be further debated with view on the CAP. ***CMC 6*** defines food industry by-products. Such by-products are of interest as precursor or building-blocks in the RUSTICA value chains rather than a final output product of the project. Nonetheless, expanding the list by further food industry by-products, such as those proposed in RUSTICA could back the project, e.g., if it would be referred to as a building block. ***CMC 7*** presents a list of micro-organisms permitted for biostimulants. An expansion of the list as regards micro-organisms authorised for microbial

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fertilisers as under research in RUSTICA would be a valuable factor for the project. ***CMC 8*** encompasses nutrient polymers steering nutrient release which is currently not at the forefront of the research of the project. ***CMC 10*** refers to derived products and (EC) No 1069/2009 which is relevant for the project and to date, a list of products is announced by the ***Regulation (EU)2019/1009***. ***CMC 11*** requires detailed criteria by delegated acts for by-products as defined by ***2008/98/EC*** as of 16.07.2022. These rules will be important for the consideration of by-products and their use in the project. An ongoing law-making procedure for ***Pyrolysis and Gasification Materials*** and ***CMC 14*** establishes the legal options and constraints for biochar as an ***EU Fertilising Product***.

Seven main ***PFCs*** subdivided into a multitude of categories are presented by ***(EU) 2019/1009***. From a general view, all of the three major subcategories ***organic fertilisers (PFC 1.A)***, ***organo-mineral fertilisers (PFC 1.B)*** and ***inorganic fertilisers (PFC 1.C)*** allocated to ***PFC 1 Fertilisers*** are of interest for the RUSTICA research while e.g., arguments for compost voting for the former and criteria of NPK concentrate indicating the latter would need to be finally assessed. Among others, the potential of biochar can be further discussed, for example, not only in terms of ***PFC 1*** but also for **soil improvement *(PFC 3)*** and, in particular as regards **growing media *(PFC 4)***. A specific indication of ***microbial fertilisers*** in ***PFC 1*** could be a new option for the project. As far as RUSTICA product properties and qualities reveal pH adjustments and proximity to ***PFC 2 (liming material)*** or could function as an ***inhibitor (PFC 5)*** the requirements of the PFCs will be extensively assessed. An expansion of ***PFC 6 Plant Biostimulant*** considering a limited number of micro-organisms ***(CMC 7)*** for ***PFC 6.A*** would need to be finally evaluated upon availability of project results. ***PFC 7*** is crucial for the RUSTICA project since targeting fertiliser blends.

5.2.3.2. Fertilisers for organic production

As pointed out in **Regulation (EU) 2021/1165** certain fertilisers, soil conditioners, and nutrients for plant nutrition can be used for organic production if they are in accordance with all legal requirements, and in particular comply with provisions of the current ***Fertiliser Regulation (EC) 2003/2003,*** the ***Fertilising Product Regulation (EU) 2019/1009*** and the ***Animal by-product Regulations.*** Bearing in mind the RUSTICA output, rules are defined e.g., for insect frass, compost of vegetable origin, inorganic micro-nutrient fertiliser, and biochar. However, the legal definition of specific waste-based circular routes, e.g., for CAP output, microbial protein and inorganic macronutrient fertilisers could benefit the project in the organic agriculture sector.

5.2.4. Fertiliser applications and various agricultural areas

5.2.4.1. General view

Fulfilment of certain standards, e.g., as regards the environment is required in farming if supported by the ***Common Agricultural Policy (e.g., (EU) No 1306/2013)***. The legislation engages with other legal acts and programmes (e.g., Natura 2000) and promotes sustainable agriculture. In summary, support from the ***Common Agricultural Policy*** is coupled to proper management in the entire sector. Reference is made to the bioeconomy and valorisation of waste and by-products relating thereto. But to boost the impact of RUSTICA, a more specific incorporation of the new innovative processes and products envisaged by the project into the ***Common Agricultural Policy*** and their financial incentivisation would be a valuable support.

Detailed orders on fertiliser management are laid down in the ***Nitrate Directive (91/676/EEC)***. While quantitative application is addressed for manure as a nitrogen fertiliser, it could lead to new prospects for the project if established rules will be verified in terms of the project innovations and their properties. Obligations are defined for Member States to reduce GHG emissions including those from agriculture ***((EU)2018/842)***, and the LULUCF sector ***((EU)2018/841)*** has a “no-debit” rule. Furthermore, commitments to ***reduce anthropogenic atmospheric emissions*** as defined in ***(EU)2016/2284*** address agriculture as well. All these stipulations provide

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a basis for further assessing the novel RUSTICA approach and its circular value chains in this context. The project aims at a broad and complex output towards environmentally friendly plant and soil support and at the same time tackling environmental affairs already by using the selected (waste-)feedstocks. It would need specific and more local analysis how RUSTICA could respond to areas subject to ***Natura 2000*** and its legal bases, e.g., ***(92/43/EEC)***.

5.2.4.2. Organic farming

Overall, it can be summarised that ***EU organic production*** favours "internal fertilisers" from a farm itself and promotes to use additional fertilisers from outside as less as possible ***((EU)2018/848)***. If the latter would become necessary, the legal source opts for the application of "*low solubility mineral fertilisers",* and *"mineral nitrogen fertilisers shall not be used* ***((EU)2018/848).***" RUSTICA research aspires to reach a novel product portfolio which could be beyond of traditional fertiliser categorisation schemes. In this respect, the requirements of ***organic production*** could be more extensively discussed upon availability of project results. On the other hand, EU rules on **organic production** ***(e.g., (EC)1235/2008)*** are not only defined for EU countries but also e.g., for Colombia as the home of the international project partner of RUSTICA. Accordingly, for the exploitation and impact of the project, this legal background can be considered.

5.3. RUSTICA in the mirror of EU priorities and strategies

5.3.1. The European Green Deal

The European Green Deal (COM(2019)640) and its objectives prepare a solid fundament for RUSTICA and its endeavours to transform redundant leftover along the food chain into valuable resources. The project is a vibrant example for exploring new methods to decouple economic growth from the use of resources and advocating decarbonisation for its value chains. Due to implementing new technologies targeting environmentally and climate friendly fertilisers for improvement of agricultural cultivation in Europe and worldwide, RUSTICA also addresses the global policy as laid down in ***the European Green Deal***. By specifically encompassing rural regions, the project could serve as a catalyst for establishing climate friendly fertiliser systems there.

5.3.2. EU Circular Economy Strategy

By means of presenting feedstocks serving as an alternative to traditional resource extraction and introducing circular models, RUSTICA evolvements could help to decrease biodiversity loss as it is caused by exploitation of resources. The project matches the ***Circular Economy Action Plan (COM(2020)98)*** requesting to double circular materials use within the next decade. An optimisation of markets for secondary raw materials as indicated by the ***Plan (COM(2020)98)*** can be interpreted as a strong signal for the project and its output. Moreover, lifting up the position of circular materials in international trade agreements could be an argument for the further elaboration of the impact of the project.

5.3.3. EU Bioeconomy Strategy

It can be simply said, RUSTICA is entirely conform with the five objects of the updated ***Bioeconomy Strategy (COM(2018/673)*** e.g., by producing sustainable fertilisers for food security, by developing improvements for preservation of soil, by using waste as feedstock to reduce resource dependence, by resource efficient primary production to adapt to climate change, and by development of new business models for growth and employment. Furthermore, the project involves stakeholders and promotes its research values. Taking a

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regional approach, the project offers unique opportunities to engage in activities complying with a local bioeconomy, and delivers knowledge and training on its research results.

5.3.4. EU Farm to Fork Strategy

The RUSTICA project is in line with the ***Farm to Fork Strategy (COM(2020)381)***, in particular, research on biofertilisers is directly addressed by the strategy. It aspires nutrient systems tailored to the crop thereby preventing nutrient loss and pollution while at the same time novel solutions on food waste are elaborated. The project pursues an optimal and balanced nutrition of plants and management of healthy soils. Therefore, a general but not specific reduction of fertilisers by 20% would be a challenge for the project. On the other hand, the project complies with the ***Action Plan for the Development of Organic Production (COM(2021)141)*** and in particular with Axis 3 including but not limited to efforts on the development on materials to replace unsustainable input, promoting resource efficiency, and decreasing nutrient pollution in water and soil.

5.3.5. EU Biodiversity Strategy

As regards biodiversity loss, the ***EU Biodiversity Strategy for 2030 (COM(2020)380)*** has identified five main factors, e.g., overexploitation and pollution. The RUSTICA project plans to demonstrate the replicability and scalability of its research on sustainable nutrient management systems at the European and international level. By reducing the burden of waste and transforming it into valuable fertilisers, the research of the project fosters the reduction of adverse effects on (natural) environment and biodiversity. In addition, it creates an excellent knowledge platform to advocate the merits of new value chains taking into account conservation of soil, fossil resources and biodiversity by its stakeholder approach assembling not only local experts but also global actors.

Owing to its European-international partnership, the project is directly linked with challenges, such as preserving terrestrial and aquatic ecosystems, protecting biodiversity, and encountering desertification in Europe and beyond. In this respect, the EU Biodiversity Strategy 2030 and international agreements of the EU concerning the environment present a political and legal guidance thereto.

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Annex

Table 31: The 15 Titles of the REACH Regulation

Title No	Title
I	GENERAL ISSUES
II	REGISTRATION OF SUBSTANCES
III	DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING
IV	INFORMATION IN THE SUPPLY CHAIN
V	DOWNSTREAM USERS
VI	EVALUATION
VII	AUTHORISATION
VIII	RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES AND MIXTURES
IX	FEES AND CHARGES
X	AGENCY
XI	COMPETENT AUTHORITIES
XII	ENFORCEMENT
XIII	TRANSITIONAL AND FINAL PROVISIONS
XIV	COMPETENT AUTHORITIES
XV	ENFORCEMENT

Sources: REACH Regulation (EC) No 1907/2006 ((EC)No1907/2006) and its amendments

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