nenuPHAr products

1. Flexible transparent film packaging
2. Thermoformed food plastic tray
3. Roll-on bottle and applicator
4. 3D printing filament
5. Stand up pouch for dry food
6. Plastic cup, container for compote
7. Medical Devices (meshes/sutures)
8. Agro-textile

First STOP: REACH regulation

Registration, Evaluation, Authorization and Restriction of Chemicals for (bio)chemical content

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH, Regulation 1907/2006/EC)

(Bio)plastic products must follow these criteria due to its own (bio)**chemical content** and/or the use of chemicals during processing methods. REACH Regulation assesses hazardous and toxicological substances as well as the circulation and/or banning of substances on the market.

TITLE II > GENERAL ISSUES

Article 1 - *Aim and scope*

The purpose of this Regulation is to **ensure a high level of protection of human health** and the **environment**, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

TITLE II > REGISTRATION OF SUBSTANCES

Article 6 - *General obligation to register substances on their own or in mixtures*

1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or in mixture, in quantities of **one tonne or more per year** shall submit a registration to the Agency.

3. Any **manufacturer or importer of a polymer** shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met: (i) the polymer consists of 2 % (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s); (ii) the total quantity of such monomer substance(s) or other substance(s) makes up **one tonne or more per year**.

Article 7 – *Registration and notification of substances in articles*

All substances being in mixtures or in articles must submit a registration when:

- Their quantities are totalling over one ton or more per year;
- They are intended to be released under normal or reasonably foreseeable conditions of use;

The substance registration submitted shall be accompanied by detailed information about its characteristics and composition explained in **Annex VI** to **Annex XI.**

Annexes VI to XI specify the information that shall be submitted for registration and evaluation purposes. For the lowest tonnage level, the standard requirements are in Annex VII, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the information requirements will differ, according to tonnage, use, and exposure. The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.

Article 13- *General requirements for generation of information on intrinsic properties of substances*

An assessment of the chemical content of substances must be regularly reviewed, in particular for human toxicity and ecotoxicological tests in compliance with the principles of Good Laboratory Practice (GLP; Directive 2004/10/EC). In addition to Article 13, this assessment should be performed by the steps defined in Article 14- *Chemical safety report and duty to apply and recommend risk reduction measures:*

- Human health hazard assessment
- Physicochemical hazard assessment
- Environmental hazard assessment
- Persistent, bio-accumulative and toxic (PBT) and very persistent and very bio-accumulative (vPvB) assessment.

If a substance meets the criteria as a PBT or vPvB, the "chemical safety report" shall include additional steps as well as a "safety data sheet" with recommendations of measures to control and mitigate the risks that had been identified.

Plant protection products and biocidal products are out of the REACH registration needs (Art. 15 in Chapter 2) if they are not considered as PBT or vPvB according to its own procedure guidelines (Regulation 1107/2009 **Annex II**)

Roadmap 1: FOOD CONTACT (i)

Flexible transparent film packaging | Thermoformed food plastic tray
Stand up pouch for dry food | Plastic cup, container for compote

Regulation (EC) No 1935/2004

Materials and articles intended to come into **contact with food**, including active and intelligent food contact materials and articles.

Special requirements for active and intelligent materials and articles: Substances to be released into the food or the environment surrounding shall be authorised and used in accordance with the relevant Community provisions applicable to food → INGREDIENT (Art. 6(4)(a) of Directive 2000/13/EC)

CARVACROL (≥95%) : Approved for use in and on foods (Regulation (EC) No 1334/2008)

Labelling: the glass/fork symbol demonstrates that foodstuffs contained within a Food Contact Materials (FCM) are safe for human consumption

ANNEX I: List of groups of materials/articles with specific measures: 10. **PLASTICS**

Commission Regulation (EC) 2023/2006

Good manufacturing practice (GMP) for materials and articles intended to **come into contact with food**: Quality assurance tool that give retailers the necessary control along the supply chain to ensure consistency and the delivery of quality, safe products.

ANNEX: Detailed rules on good manufacturing practice
B. Quality assurance system **for plastic recycling processes** covered by Regulation (EC) No 282/2008.

Commission Regulation (EU) 10/2011

Plastic materials and articles intended to come into contact with food

CHAPTER II > Compositional Requirements > **SECTION 1** > Authorised substances
Article 5 - **Union list** of authorised substances (see Table)
SECTION 2 > General requirements, restrictions and specifications

SML: specific migration limits → **migration test methods** → Art.11 Regulation (EC) No 882/2004
Unless specific detection limits have been set for particular substances or groups of substances, a detection limit of **0.01 mg/kg** shall apply. (Art. 11)

Substance name	Use as additive or polymer production aid	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation	SML [mg/kg]	SML(T) [mg/kg] (Group restriction)	Restrictions and specifications
Cellulose	YES	YES	0.01		
Other cellulose derivatives/compounds (ethylcellulose; cellulose, regenerated; ethylhydroxyethylcellulose; cellulose acetate butyrate)	YES	NO	0.01		
Starch, edible	YES	YES	0.01		
Hydroxyethyl starch; starch, hydrolysed	YES	NO	0.01		
Polyethyleneglycol	YES	YES	0.01		
Crotonic acid	YES	YES	0.01	0.05 expressed as crotonic acid	
3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	NO	YES	0.01		The substance is used as product from bacterial fermentation.
Poly(R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate	NO	YES	0.01		*
Glucose	NO	YES	0.01		
Glycerol	YES	NO	0.01		
Tri-n-butyl acetyl citrate	YES	NO	0.01	60 expressed as sum of substances	

* Only to be used either alone or blended with other polymers in contact with all foods under contact conditions of up to 6 months and/or 6 months and more, at room temperature or below, including hot fill or a short heating up phase. The migration of all oligomers with a molecular weight below 1 000 Da shall not exceed 5.0 mg/kg food.

Roadmap 1: FOOD CONTACT (ii)

Flexible transparent film packaging | Thermoformed food plastic tray
Stand up pouch for dry food | Plastic cup, container for compote

Commission Regulation (EU) 10/2011

Plastic materials and articles intended to come into contact with food

CHAPTER II > Compositional Requirements > SECTION 2 > General requirements, restrictions and specifications

OML: Overall migration limit → Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding **10 milligrams of total constituents released per dm² of food contact surface (mg/dm²)** (Art.12)

Plastics materials/articles intended to be in contact with food for **infants and young children** (Commission Directives 2006/141/EC and 2006/125/EC) shall not transfer their constituents to food simulants in quantities exceeding **60 milligrams of total of constituents released per kg of food simulant.**

Article 6 -**Derogations for substances not included in the Union list**

2. By way of derogation from Art. 5, colorants and solvents may be used in the manufacture of plastic layers in plastic materials and articles subject to **national law**.

3. The following substances not included in the Union list are authorised subject to the rules set out in Arts. 8, 9, 10, 11 and 12:

(b) mixtures obtained by mixing authorised substances without a chemical reaction of the components;

(c) when used as additives, natural or synthetic polymeric substances of a molecular weight of at least 1 000 Da, **except macromolecules obtained from microbial fermentation**, complying with the requirements of this Regulation, if they are capable of functioning as the main structural component of final materials or articles;

(d) when used as monomer or other starting substance, pre-polymers and natural or synthetic macromolecular substances, as well as their mixtures, **except macromolecules obtained from microbial fermentation**, if the monomers or starting substances required to synthesise them are included in the Union list.

Article 9 - **Specific requirements on substances**

Substances in **nanoform** shall only be used if explicitly authorised and mentioned in the specifications in Annex I.

CHAPTER III > Specific Provisions for Certain Materials and Articles

Article 13 - **Plastic multi-layer materials and articles**

A plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may:

(a) not comply with the restrictions and specifications set out in this Regulation (except for vinyl chloride monomer as provided in Annex I); and/or

(b) be manufactured with substances not listed in the Union list or in the provisional list.

3. Substances under paragraph 2(b) shall not migrate into food or food simulant, in accordance with Art. 11.

A **plastic layer** made by Substances not listed in the Union list which is not in direct contact with food and is separated from the food by a functional barrier shall not belong to either of the following categories:

(a) substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' (**CMR**)

(b) **substances in nanoform.**

5. The final plastic multi-layer material or article shall comply with the specific migration limits set out in Article 11 and the overall migration limit set out in Article 12 of this Regulation.

Article 14 - Multi-material multi-layer materials and articles: Same conclusions as Art. 13)

Additives at **NANO-scale** (such as cellulose nanocrystals, CNC) are not allowed for their use in packaging intended to come in contact with food, even in a multi-layer configuration without direct contact with food.

Roadmap 2: COSMETICS (i)

Roll on bottle: ball dozes and applicator

Regulation (EC) 1223/2009

Cosmetic Products: Rules to be compiled with any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health.

Article 3 - **Safety**

A cosmetic product made available on the market shall be **safe for human health** when used under normal or reasonably foreseeable conditions of use, taking account the following:
(a) presentation including conformity with Directive 87/357/EEC;
(b) labelling;
(c) instructions for use and disposal;
(d) any other indication or information provided by the responsible person (Art. 4)

Article 8 **- Good manufacturing practice**

1. The manufacture of cosmetic products shall comply with good manufacturing practice with a view to ensuring the above objectives.
2. Compliance with GMP shall be presumed where the manufacture is in accordance with the relevant harmonised standards.

Article 19 – **Labelling**


Reference to attached information

Period after opening


Date of minimum durability

ANNEX I- **COSMETIC PRODUCT SAFETY REPORT (CPSR)**

The cosmetic product safety report shall contain:
4. *Impurities, traces, information about the* ***packaging material****:* (i) The purity of the substances and mixtures; (ii) in the case of traces of prohibited substances, evidence for their technical unavoidability; (iii) the relevant characteristics of packaging material, in particular purity and stability.

Commission Implementing Decision 2013/674/EU

Guidelines on Annex I

3.4. Impurities, traces, information about the packaging material

3.4.1. Purity of substances/mixtures: Include data on the purity of raw materials and identification of the toxicologically relevant unintended substances in the CPSR for product safety assessment.

3.4.2. Evidence of the technical unavoidability of traces of prohibited substances: Traces generated by the degradation of substances within the final product, by preservation or transport problems, or by the interaction of raw materials should be avoided through GMP, or re-formulation.

3.4.3. The relevant characteristics of packaging material:

Reference to Regulation (EC) No 1935/2004 could be useful. Materials that have been developed for food packaging have often already been tested, so relevant information on stability and migration may be available. Additional testing may not be required. However, **more evaluation may be needed for new or novel packaging**.

Safety of the finished product can be affected by: (i) interaction between the cosmetic product and the packaging material; (ii) barrier properties of the packaging material; (iii) substance migration from/to the packaging material.

The information on relevant characteristics of the packaging materials in direct contact with the product should allow an Estimation of potential risks through packaging relevant characteristics: (i) **composition** of the packaging material, including technical substances such as additives; (ii) technically unavoidable **impurities**; (iii) possible **migration** from the packaging.

Studies on interactions/suitability: **NO standard procedures for cosmetic products**.

Roadmap 2: COSMETICS (ii)

Roll on bottle: ball dozes and applicator

COSMETICS EUROPE - ADVISORY DOCUMENT

Information Exchange on Cosmetic Packaging Materials Along the Value Chain in the context of the EU Cosmetics Regulation EC 1223/2009- 13 June 2019

METHODOLOGY

1. Description of General Chemical Composition of all specific items or materials.
Ensure compliance with:

> **REACH**: It is mandatory to declare and identify the presence of Candidate list Substances of Very High Concern when present ≥ 0.1% w/w (i.e. ≥ 1000 mg/kg)
> **PPWD** 94/62/EC: Heavy Metals : <100 ppm for the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium.

2. Identification of all those components / materials which are potentially capable of transferring chemical substances to the cosmetics formulation.

3. Communication of adequate information needs about substances identified in 2 to allow the cosmetic product safety assessor to evaluate their impact (if any) on the safety of the cosmetic formulation. Actions recommended in this approach:

Chapter A. If possible, the supplier declares and documents **compliance with food contact legislation/ standards**.

"safe for food, safe for cosmetics": In general terms, materials safe for food packaging are safe for cosmetic packaging. However, if cosmetic formulations can not be represented by existing food simulants or if migration assessment using appropriate simulants mimicking the cosmetic product exceed OML and/or SML values, packaging materials must be assessed as if they were a NON-FOOD contact compliant structure.

Chapter B. Where **food contact compliance cannot be claimed**, the supplier provides relevant information for the safety evaluation of the packaging by other means.
Reason(s) for non compliance :

- Presence of non-approved substance(s)
- Presence of approved substance(s) not respecting purity criteria of food contact legislation
- No evaluation of migration (by testing or other means of assessment)
- Presence of substance(s) above the SML/OML
- Material/item not manufactured according to EU GMP (EC) 2023/2006 (or an equivalent)

If the non-compliance is related to a specific substance, its identity (chemical name, CAS Number) and concentration in the packaging material/component should be communicated.

If the substance is present in the material/component at a very low level at which it can be considered as posing no appreciable risk to the safety, it may not be necessary to provide such information. Please see Annex 3 ("**Threshold for Toxicological Concern**", TTC) for guidance on relevant cut-off levels. If a TTC approach cannot be taken, substances should be communicated if they are present above **1 ppm**.

Chapter C. The supplier addresses substances that are of specific concern under to the cosmetic product safety assessor (i.e. banned or restricted under the Cosmetic Regulation Annex II, Annex III and CMR substances as well as substances classified as skin sensitisers).

By the moment, NENU2PHAR identified substances do not fall under Chapter C assumption.

Information generated under the approach described under Chapter A and B is addressing systemic toxicity concerns and does not allow evaluation of local effects (skin irritation, skin sensitisation) of substances migrating into the cosmetic formulation.
Migration of skin sensitisers into the formulation needs to be known to the cosmetic product safety assessor to carry out a predictive safety assessment.

Roadmap 3: 3D PRINTING

3D Printing Filament

Directive 2011/65/EU

Restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) with a view to contribute the protection of human health and the environment, including the environmentally sound recovery and disposal of EEE waste.

Article 4 - **Prevention**

Member States shall ensure that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, **does not contain the substances listed in Annex II**. For the purposes of this Directive, no more than the maximum concentration value by weight in homogeneous materials as specified in Annex II shall be tolerated.

According to current information, NENU2PHAR products do not contain any of the substances listed in the Annex II of Directive 2011/65/EU.

3D printed products in themselves may be used to produce medical devices, food contact and agrotextile components, etc. which fall within the scope of **specific EU product legislation**. Therefore, manufacturers must ensure that 3D printed products meet the requirements of the applicable EU legislation, carry out the necessary conformity assessment procedures, compose a technical file, draft the EU declaration of conformity and affix the CE marking, before placing them on the EU market.

Roadmap 4: MEDICAL DEVICES (i)

Implantable medical devices: knitted meshes / sutures.

REGULATION (EU) 2017/745

Medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Article 2 - *Definitions*:

Implantable device: Any device, including those that are partially or wholly absorbed, which is intended: (i) to be totally introduced into the human body, or (ii) to replace an epithelial surface or the surface of the eye; by clinical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device

Nanomaterial: Natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm; Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials**;**

Article 5 - *Placing on the market and putting into service*

A device shall meet the general safety and performance requirements set out in **Annex I** which apply to it, taking into account its intended purpose.

Demonstration of conformity with the general safety and performance requirements shall include a **clinical evaluation** (Art. 61).

Article 8 - *Use of harmonised standards:* Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

Article 10 - General obligations of manufacturers

Manufacturers shall fulfill the following requirements

Establish a System for Risk Management (Annex I > Sec.3)	Conduct a Clinical Evaluation (Art. 61 & Annex XIV + PMCF#)	Draw up Technical Documentation (Annexes II & III)	Draw up Declaration of Conformity (Art. 19)
Draw up a summary of safety & clinical performance. Public via Eudamed. (Art.32)	Establish Conformity Assessments (Annexes IX to XI)	Comply with UDI* system and registration obligations (Arts. 27, 29 & 31)	CE Marking (Art. 20)

Establish a Quality Management System

#PMCF: Post-Market Clinical Follow-up

*UDI: Unique Device Identification

Article 18 - *Implant card and information to be supplied to the patient with an implanted device.*

Sutures & staples (among others) are exempted from the obligations laid down in this Article

Roadmap 4: MEDICAL DEVICES (ii)

Implantable medical devices: knitted meshes / sutures.

REGULATION (EU) 2017/745

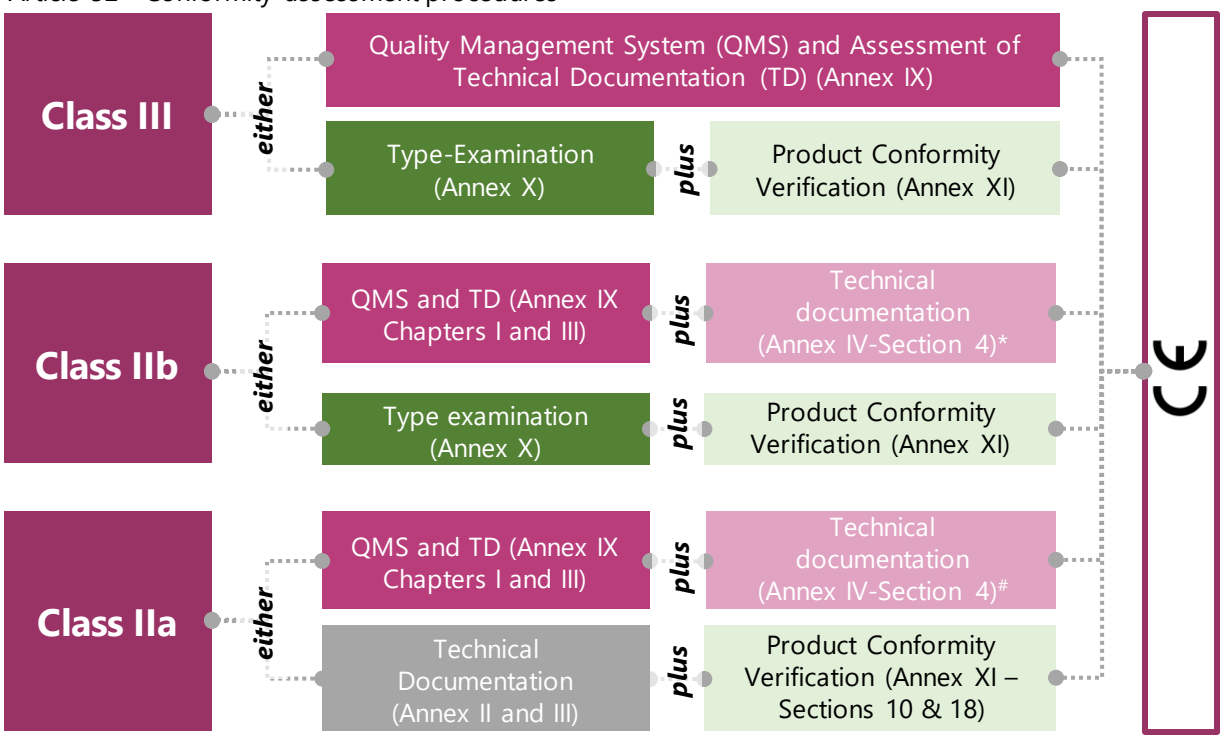
CHAPTER V > Classification and Conformity Assessment > SECTION 1

Article 51 - *Classification of devices*: Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with **Annex VIII**.

Application	Use	Classification
Rule 6: Surgically Invasive Devices	Transient (< 60 min)	Class IIa
Rule 6 + Intended to have a biological effect or to be wholly or mainly absorbed	Transient (< 60 min)	Class IIb
Rule 7: Surgically Invasive Devices	Short-term (60 min -30 days)	Class IIa
Rule 7 + Intended to have a biological effect or to be wholly or mainly absorbed	Short-term (60 min -30 days)	Class III
Rule 8: Surgically Invasive Devices	Long-term (> 30 days)	Class IIb
Rule 8 + Intended to have a biological effect or to be wholly or mainly absorbed	Long-term	Class III
Rule 19: All devices incorporating or consisting of nanomaterial	High or medium potential for internal exposure	Class III
	Low potential for internal exposure	Class IIb
	Negligible potential for internal exposure	Class IIa

CHAPTER V > Classification and Conformity Assessment > SECTION 2

Article 52 - Conformity assessment procedures



* at least one representative device per generic group. For Class IIb implantable devices, except sutures and staples (among others), the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device.

\# at least one representative device for each category of devices.

Roadmap 4: MEDICAL DEVICES (iii)

Implantable medical devices: knitted meshes / sutures.

REGULATION (EU) 2017/745

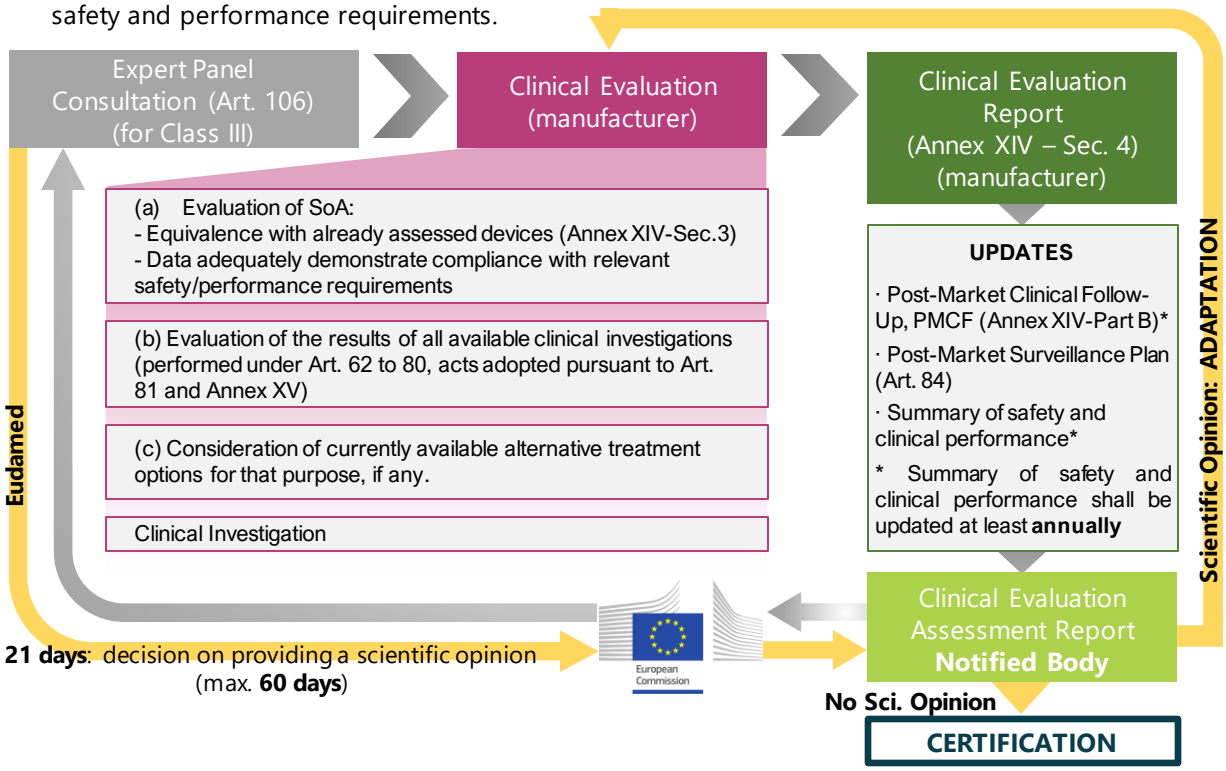
CHAPTER V > Classification and Conformity Assessment > SECTION 2

Article 54 - *Clinical evaluation consultation procedure for certain class III and class IIb devices.*

Class III implantable devices: In addition to the Art. 52 procedures, a notified body shall also follow the procedure regarding **clinical evaluation consultation** (Annex IX - Section 5.1 or Annex X – Section 6) when performing a conformity assessment.

CHAPTER VI > Clinical Evaluation and Clinical Investigations

Article 61 - *Clinical evaluation.* Confirmation of conformity with relevant general safety and performance requirements (Annex I) shall be based on **clinical data** providing sufficient **clinical evidence**, including where applicable relevant data (Annex III). The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements.



CLINICAL INVESTIGATION shall not apply to **implantable devices and class III devices** that are **sutures**, **staples**, dental fillings and braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors. Clinical evaluation is based on sufficient clinical data and is in compliance with relevant product-specific common specifications (CS), if available.

ANNEX I > General Safety and Performance Requirements > CHAPTER II > Requirements regarding Design and Manufacture

Particular attention shall be paid to:

- Choice of materials/substances used (toxicity and, where relevant, flammability)
- **Compatibility** between the materials/substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, **absorption, distribution, metabolism and excretion**.
- Impact of processes on material properties;
- Results of biophysical or modelling research the validity of which has been demonstrated beforehand (where appropriate);
- Mechanical properties of the materials used and surface properties; and confirmation that the device meets any defined chemical and/or physical specifications.

Roadmap 4: MEDICAL DEVICES (iv)

Implantable medical devices: knitted meshes / sutures.

REGULATION (EU) 2017/745

ANNEX I > CHAPTER II >Requirements regarding Design and Manufacture

Substances: Reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. **Special attention shall be given to nanomaterials**.

Devices that are invasive and come into direct contact with the human body shall only contain the following substances in a **concentration that is above 0,1 %** weight by weight (w/w) where justified (Sec. 10.4.2):

(a) substances which are **carcinogenic, mutagenic or toxic to reproduction** ('CMR'), (cat. 1A or 1B, Annex VI-Part 3 Regulation (EC) No 1272/2008)

(b) substances having **endocrine-disrupting properties** (Art. 59 of Regulation (EC) No 1907/2006 or, Art. 5(3) of Regulation (EU) No 528/2012

Devices composed of substances intended to be introduced into the human body, and that are ***absorbed by or locally dispersed*** in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in **Annex I to Directive 2001/83/EC**.

For devices manufactured utilising non-viable biological substances other than human and animal origin, the ***processing, preservation, testing and handling*** of those substances shall be carried out so as to provide safety for patients. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

DIRECTIVE 2001/83/EC

ANNEX I > Analytica, Pharmacotoxicological and Clinical Standards and Protocols in respect of the Testing of Medicinal Products → MODULE 4: NON-CLINICAL REPORTS

The pharmacological and toxicological tests must show the **potential toxicity of the product** and any dangerous or undesirable toxic effects that may occur under the proposed conditions of use in human beings; these should be evaluated in relation to the pathological condition concerned;

Pharmaco-kinetics means the study of the fate of the active substance, and its metabolites, within the organism, and covers the study of the absorption, distribution, metabolism (bio-transformation) and excretion of these substances.

Single-dose Toxicity (single administration)

Repeat-dose Toxicity (repeated administration. Effect of dosage)
Generally, 2 tests: short-term (2-4 weeks) and long-term (duration depending on conditions of clinical use)

Geno-toxicity Study of mutagenic and clastogenic potential reveals the changes which a substance may cause in the genetic material of individuals or cells. They present a serious hazard to health (including mutations leading to cancer). These studies are **obligatory for any new substance**.

Carcino-genicity: Tests to reveal carcinogenic effects shall normally be required for any medicinal product whose expected clinical use is for a prolonged period of a patient's life; and recommended for some medicinal products if there is concern about their carcinogenic potential

Reproductive and developmental toxicity Studies the effect on adult male or female reproductive function, studies of the toxic and teratogenic effects at all stages of development from conception to sexual maturity as well as latent effects, when the medicinal product under investigation has been administered to the female during pregnancy. Omission of these tests must be adequately justified.

Local tolerance Determine whether medicinal products are tolerated at sites in the body, which may come into contact with the medicinal product as a result of its administration in clinical use. The testing strategy shall be such that any mechanical effects of administration or purely physico-chemical actions of the product can be distinguished from toxicological or pharmaco-dynamic ones.

Roadmap 5: AGRO-TEXTILE (i)

Agro-textile tape for woven groundcovers
(industrial and consumer market).

REGULATION (EC) 1107/2009

Rules on the authorisation of **plant protection products** in commercial form and for their placing on the market, use and control, ensuring a high level of protection of both human and animal health and the environment, while **improving agricultural production**. It includes active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants.

Definitions

- **Active Substances:** Substances, including micro-organisms, having general or specific action against harmful organisms or on plants.
- **Safeners:** Substances added to a plant protection product to eliminate or reduce phytotoxic effects.
- **Synergists:** Substances to enhance activity of an active substance.
- **Co-formulants:** Substances used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists.
- **Adjuvants:** Substances which consist of co-formulants or preparations (one or more co-formulants) to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties.

CHAPTER II > Active Substances, Safeners, Synergist and Co-Formulants

Subsection 1 > Requirements and conditions for approval

The assessment of the different plant protection products shall follow the criteria defined in **Annex II**. It is also mentioned that the consequent residues generated should not have any toxicological, ecotoxicological, environmental, biodiversity, or drinking water relevance effects. Available analytical standards shall be use for measuring these effects.

Subsection 2 > Approval procedure

The application must be submitted together with a complete **dossier** according to Art. 8, which contains information about the *uses, results of tests and studies*, as well as the person or institute that has carried them out. Information about the **consequent residues** should be also mentioned. The Authority shall send and make available to the public the applicant an assessment report once the plant protection product meets the approval criteria. Where appropriate, the Authority shall address in its conclusion the **risk mitigation** options identified.

ANNEX II: Procedure and criteria for the approval of active substances, safeners and synergists

1. Evaluation (based on scientific principles)
2. Decision-making criteria (submit further dossier information about conditions and restrictions if any)
3. Criteria for the approval of an active substance:
   - Dossier Submission.
   - **Efficacy**: Only be approved if its use in realistic conditions is sufficiently effective.
   - Relevance of metabolites.
   - **Composition**: The specification shall define the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/ diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.
   - **Methods of analysis**: They shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise (detection of quantities > 1g/kg).
   - **Impact on human health** (considering endocrine disrupting properties, fate and behaviour, persistence or biodegradation, bioaccumulation, toxicity in the environment)
4. Candidate for substitution (following a comparative assessment, art 50)
5. Low-risk active substances (classification of those which will pose only a low risk to human and animal, health, and environment, Art. 47)

Roadmap 5: AGRO-TEXTILE (ii)

Agro-textile tape for woven groundcovers
(industrial and consumer market).

REGULATION (EC) 1107/2009

ANNEX II: Procedure and criteria for the approval of active substances, safeners and synergists

Relevant Requirements for Impact on Human Health

Fate and behaviour in the environment - An active substance, safener or synergist shall only be approved where it is not considered to be: POP, PBT and/or vPvB. It shall only be approved if:

- the risk assessment demonstrates risks to be acceptable in accordance with Art. 29(6) under realistic proposed conditions.
- on the basis of the assessment of Community/internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.
- a residue definition can be established for the purposes of risk assessment and for enforcement purposes.
- the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with Art. 29(6).

Persistent organic pollutants (POP)

Persistent = Degradation of 50% (DT50) >2 months in water; > 6 months in soil; > 6 months in sediment.

Bioaccumulation = bioaccumulation factor in aquatic species is > 5,000 or the partition coefficient n-octanol/water (log Ko/w) is > 5, or evidence that substance present other reasons for concern, such as high bioaccumulation in other non-target species, high toxicity or ecotoxicity

Potential for long-range environmental transport:

- measured levels in locations distant from the released sources are of potential concern;
- monitoring data show that long-range environmental transport of the substance may have occurred via air, water or migratory species;
- environmental fate properties and/or model results demonstrate that the substance has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For a substance that migrates significantly through the air, its DT50 in air >2 days.

Persistence = half-life > 60 days in marine water; >40 days in fresh or estuarine water; >180 days in marine sediment > 120 days in fresh or estuarine water sediment, or >120 days in soil.

Bioaccumulation = bioconcentration factor > 2,000. (based on measured data on bioconcentration in aquatic species)

Toxicity

- the long-term no-observed effect concentration for marine or freshwater organisms is < 0.01 mg/l,
- the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) (Regulation (EC) No 1272/2008), or
- other evidence of chronic toxicity, as identified by the classifications STOT

Persistent, bioaccu-mulative and toxic (PBT)

Very persistent & very bioaccu-mulative substance (vPvB)

Persistent = half-life > 60 days in marine water, fresh or estuarine water; >180 days in marine, fresh or estuarine water sediment, or >180 days in soil.

Bioaccumulation = Bioaccumulation = bioconcentration factor > 2,000.

Roadmap 5: AGRO-TEXTILE (iii)

Agro-textile tape for woven groundcovers
(industrial and consumer market).

REGULATION (EU) 2019/1009

Rules on the making available on the market of **EU fertilising products**

Article 4 - *Product requirements*

An EU fertilising product shall: (i) meet the requirements set out in **Annex I** for the relevant **product function category**; (ii) meet the requirements set out in **Annex II** for the relevant **component material category**; and (iii) be labelled in accordance with the **labelling** requirements set out in **Annex III**.

Article 50 - Biodegradability review

By 16 July 2024, the Commission shall carry out a review in order to assess the possibility of determining **biodegradability criteria of mulch films**, and the possibility of incorporating them into component material category 9 in Part II of Annex II (Polymers other than nutrient polymers)

Other important information to take into account: CMC 3: COMPOST in →

ANNEX II > Component Material Categories (CMCs) > PART II > Requirements related to CMCs

An EU fertilising product may contain compost obtained through aerobic composting of, e.g., bio-waste within the meaning of Directive 2008/98/EC resulting from separate bio-waste collection at source.

The aerobic composting shall consist of **controlled decomposition of biodegradable materials**, which is predominantly aerobic and which allows the development of temperatures suitable for thermophilic bacteria as a result of biologically produced heat. Batch shall be forced to material homogenisation. During the composting process, all parts of each batch shall have one of the following **temperature-time profiles**:

- 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, or
- 55 °C or more for at least 14 days.

The compost shall contain:

a) no more than 6 mg/kg dry matter of PAH_{16};
b) no more than 3 g/kg dry matter of **macroscopic impurities above 2 mm** in any of the following forms: glass, metal or plastics; and
c) no more than 5 g/kg dry matter of the sum of macroscopic impurities referred to in (b).

From 16 July 2026, the presence of plastics above 2 mm within the maximum limit value referred to in point (b) shall be no more than 2,5 g/kg dry matter. By 16 July 2029 the limit-value of 2,5 g/kg dry matter for plastics above 2 mm shall be re-assessed in order to take into account the progress made with regards to separate collection of bio-waste.

The compost shall meet at least one of the following **stability criteria**:

(a) ***Oxygen uptake rate:***

- Definition: an indicator of the extent to which biodegradable organic matter is being broken down within a specified time period. The method is not suitable for material with a content of particle sizes > 10 mm that exceeds 20 %,
- Criterion: **maximum 25 mmol O_2 /kg organic matter/h**;

(b) ***Self heating factor:***

- Definition: the maximum temperature reached by a compost in standardised conditions as an indicator of the state of its aerobic biological activity,
- Criterion: **minimum Rottegrad III**.

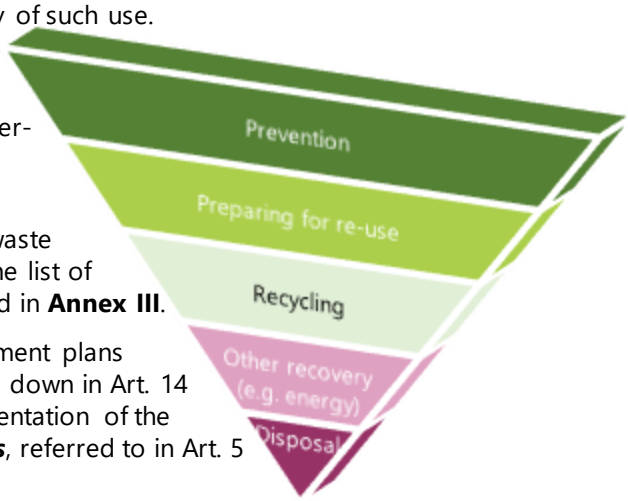
Although both introduced regulations do not completely fit with the intended application, an alignment with all the highlighted statements shall be accomplished during the project implementation to an agile and successful market uptake of NENU2PHAR agro-textile products

END-OF-LIFE Roadmap (i)

Final disposition and Biodegradability of NENU2PHAR products

Waste Framework Directive 2008/98/EC (WasteFD)

This Directive lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use.



Article 4 - *Waste hierarchy*: Priority order in waste prevention and management legislation and policy.
Article 6 - End-of-waste status: When waste has undergone a recovery, including recycling, operation.

Article 7 - *List of waste* → Decision 2000/532/EC.
A Member State may consider waste as hazardous waste where, even though it does not appear as such on the list of waste, it displays one or more of the properties listed in **Annex III**.

Article 28 - *Waste management plans*: Waste management plans shall conform to the waste planning requirements laid down in Art. 14 of Directive 94/62/EC and the strategy for the implementation of the ***reduction of biodegradable waste going to landfills***, referred to in Art. 5 of Directive 1999/31/EC.

Packaging and Packaging Waste Directive 94/62/EC (PPWD)

Article 1 – Objectives: harmonize national measures concerning the management of packaging and packaging waste to prevent any impact thereof on the environment of all Member States as well as of third countries or to reduce such impact, thus providing a high level of environmental protection, and to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community. It follows WasteFD waste hierarchy.

Article 6 - Recovery and recycling → targets:
By 31 December 2025 a minimum of 65 wt.% of all packaging waste will be recycled (a minimum of **50 wt.% of plastic**).
By 31 December 2030 a minimum of 70 wt.% of all packaging waste will be recycled (a minimum of **55 wt.% of plastic**).

ANNEX II > Essential Requirements on the Composition and the Reusable and Recoverable, including Recyclable, Nature of Packaging

Packaging recoverable in the form of composting: Packaging waste processed for the purpose of composting shall be of such a biodegradable nature that it does not hinder the separate collection and the composting process or activity into which it is introduced.

Biodegradable packaging: Biodegradable packaging waste shall be of such a nature that it is capable of undergoing physical, chemical, thermal or biological decomposition such that most of the finished compost ultimately decomposes into carbon dioxide, biomass and water. Oxo-degradable plastic packaging shall not be considered as biodegradable.

This Directive acknowledges that bio-based plastics can help to minimise the environmental impacts of plastic packaging and to make packaging more sustainable and beneficial from a life-cycle perspective. Member States are encourage to promote the use of bio-based recyclable packaging and bio-based compostable packaging.

Directive 2019/904 (Single-use Plastic Directive, SUPD)

Article 1 – *Objectives*: Prevent and reduce the impact of certain plastic products on the environment, in particular the aquatic environment, and on human health, as well as to promote the transition to a circular economy with innovative and sustainable business models, products and materials, thus also contributing to the efficient functioning of the internal market.

Article 2 – *Scope*: Applies to the single-use plastic products listed in the **Annex**, to products made from oxo-degradable plastic and to fishing gear containing plastic.

END-OF-LIFE Roadmap (ii)

Final disposition and Biodegradability of NENU2PHAR products

Directive 2019/904 (Single-use Plastic Directive, SUPD)

Article 3 - *Definitions*: For the purposes of this Directive, the following definitions apply:

- **Plastic**: material consisting of a polymer as defined in point 5 of Art. of Regulation (EC) No 1907/2006, to which additives or other substances may have been added, and which can function as a main structural component of final products, with the **exception of natural polymers that have not been chemically modified**;
- **Single-use plastic product**: product that is made wholly or partly from plastic and that is not conceived, designed or placed on the market to accomplish, within its life span, multiple trips or rotations by being returned to a producer for refill or re-used for the same purpose for which it was conceived;
- **Biodegradable plastic**: plastic capable of undergoing physical, biological decomposition, such that it ultimately decomposes into carbon dioxide (CO_2), biomass and water, and is, in accordance with European standards for packaging, recoverable through composting and anaerobic digestion;

Article 15 - Evaluation and review: The Commission shall carry out an evaluation of this Directive by 3 July 2027, submitting a report which shall include, among other issues:

- an assessment of the scientific and technical progress concerning criteria or a standard for **biodegradability in the marine environment** applicable to single-use plastic products within the scope of this Directive and their single-use substitutes which ensure full decomposition into carbon dioxide (CO_2), biomass and water within a timescale short enough for the plastics not to be harmful to marine life and not to lead to an accumulation of plastics in the environment.

NOTE:

GO!PHA, an Industry Organization, representing the PHA Industry and its downstream market participants, has requested the European Commission through different position papers to clarify that PHA produced via the cultivation of microorganisms, and having identical structures and chemical compositions as naturally occurring ***PHA***, are ***classified as Natural Polymers within the scope of the SUPD***.

GO!PHA