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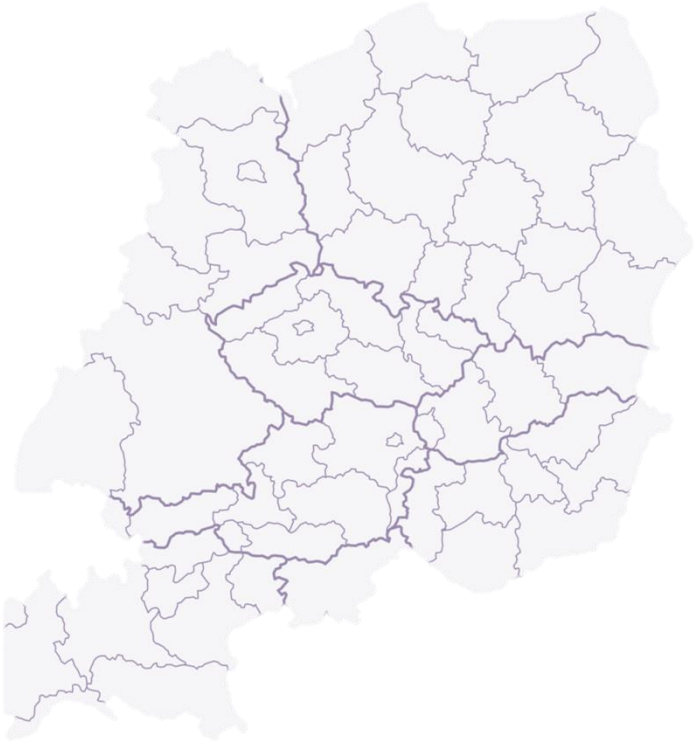
Nanotechnology for Chemical Enterprises -how to link scientific knowledge to the business in the Central Europe space



10 Operating Procedures for SMEs on the Responsible Management of Nanomaterials

Federchimica *

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*Corresponding Author contact:
Dania Della Giovanna: d.dellagiovanna@federchimica.it
www.nanoforceproject.eu

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Warning

The present document was not intended to examine and solve all the critical aspects that companies may come across in the development of their operations concerning the responsible management of Nanomaterials inside companies, but rather to supply indications concerning the support to operations.

For any further clarification, please contact the competent offices of the Federation.

The legislative texts reported in the document do not by any means replace those published in the official version in paper form. On this point, it should be noted that:

- Only the community legislation published in paper form in the Official Journal of the European Union is authentic; the documents related to the community legislation are taken from the EurLex site, and possible internal revisions
- Only the national legislation published in paper form in the Official Journal of the Italian Republic is authentic; the documents related to the national legislation are also the result of internal revisions.

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CONTENT

1 Nanomaterials

This chapter contains an overview of Nanomaterials, their definition and laws and regulations in this field.

Nanomaterials are chemicals that due to their dimension in the 10-9 m range exhibit novel and improved characteristics and properties (such as increased strength, different reactivity or conductivity) compared to the same materials in a "bulk" form that is without nanoscale.

Nanomaterials have the potential to improve the quality of life and to contribute to industrial competitiveness in Europe. However, the new materials may also raise environmental, health and safety concerns.

The risk management in the handling of Nanomaterials is the subject of technical-scientific activities on behalf of the European Community, and many opinions have been published by the "Scientific Committee on Emerging and Newly Identified Health Risks" (SCENIHR).

The overall conclusion so far is that even though Nanomaterials are not per se dangerous, there still is scientific uncertainty about the safety of Nanomaterials in many aspects and therefore the safety assessment of the substances must be done on a case-by-case basis.

Information on nanotechnologies in general can be found on the following site http://ec.europa.eu/nanotechnology.

1.1 Classification of Nanomaterials

On 18 October 2011 the Commission adopted the recommendation 2011/696/EU on the definition of a Nanomaterial. According to this recommendation a Nanomaterial means:

"a 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 1nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness, the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%".

The definition will be used primarily to identify materials for which special provisions might apply (e.g. for risk assessment or ingredient labelling), if necessary. These provisions are not part of the definition, but could be embedded into the existing legislation currently under revision

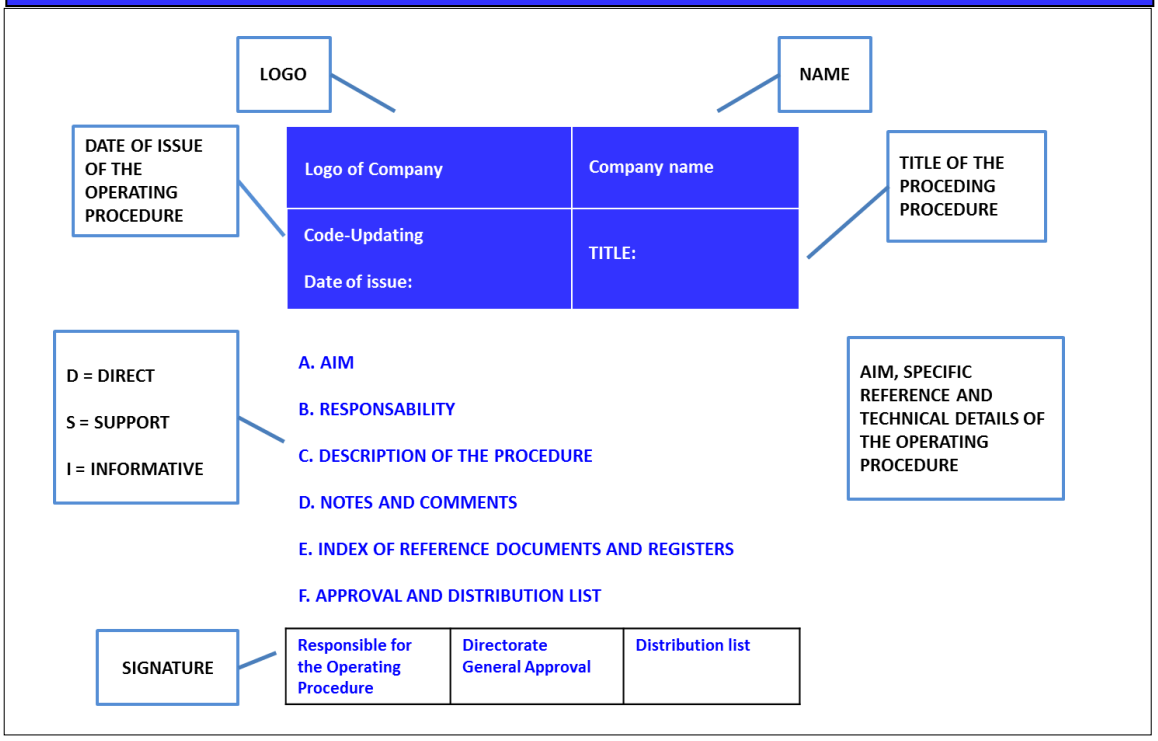
Nanomaterials are not intrinsically hazardous per se but there may be a need to take into account specific considerations in their risk assessment. Therefore, one purpose of the definition is to provide clear and unambiguous criteria to identify materials for which such considerations apply.

It is only the results of the risk assessment that will determine whether the Nanomaterial is hazardous and whether or not further mitigating action is justified.

2 How to implement the 10 Operating Procedures

This chapter describes the general criteria for the operating management of Nanomaterials in a SME. Tab. 1 illustrates the structure of the Operating Procedure.

TAB. 1: Structure of the Operating Procedure



Tab. 2 illustrates the contents of the points from A to F.

TAB. 2 Contents of the Points from A to F of the Operating Procedure	
A. AIM	Description of the objective of the procedure and its scope
B. RESPONSIBILITY	Identification of the departments responsible for the different activities that follow the flow chart, identifying the following types of responsibility: a) D = Direct b) S = Support c) I = Informative
C. DESCRIPTION OF THE PROCEDURE	Schematic description of the Operating Procedure
D. NOTES AND COMMENTS	Specific reference and supplementary technical details
E. INDEX OF REFERENCE DOCUMENTS AND REGISTERS	List of registers and documents adopted and used by the Procedure
F. APPROVAL AND DISTRIBUTION LIST	Signature of the Responsible of the Operating Procedure and of the Directorate General

Tab. 3 illustrates the matrix of the organizational functions and Operating Procedures they are involved in.

TAB. 3: Matrix of the 5 Organization Functions and the 10 Operating Procedures	
FUNCTION	**OPERATING PROCEDURE**
General Directorate	✔
Plant	3.1 - Qualification of raw materials and intermediates 3.2 - Management of the productive process; maintenance and control of equipment and measurement instruments; treatment of non compliant products 3.3 – Risk identification, assessment and management for health and safety at work 3.4 – Waste management 3.5 – Management of direct and indirect environmental aspects 3.6 – Plant design
Research and Development	4.1 - Design and development of new products and pilot tests
Procurement and Logistics	5.1 – Selection and management of suppliers in compliance with health and safety principles 5.2 – Safety in the carriage of goods
Commercial Department	6.1 - Responsibility for marketed products containing Nanomaterials

3 6 Production Procedures

3.1 Qualification of Raw Materials

Logo of Company	Company name
Code – Updating Date of issue:	TITLE: Qualification of Raw Materials and Intermediates

A. AIM

The present procedure defines tasks and responsibilities for the management of the qualification process of Nanomaterials as raw materials and intermediates, with a view to ensuring the suitability of the production process and making sure that they are compliant with qualitative and safety requirements

B. RESPONSABILITY

In charge of Operating Procedure: **Procurement and Logistics**.
Responsibilities for the different concerned areas in detail.

Organizational Function	D	S	I
Directorate General			√
Quality Environment Safety		√	
Human Resources			
Research and Development		√	
Plant		√	
Production			√
Production Control		√	
Technical Services/Engineering			√
Maintenance			√
Procurement and Logistics	√		
Procurement			
Warehouse/Transport/Distribution			√
Commercial			
Sales			√
Marketing		√	
Customer Services			√

Responsability:
D = Direct
S = Support
I = Informative

C. DESCRIPTION OF THE PROCEDURE

QUALIFICATION PROPOSAL

Procurement generates proposals about the qualification of a raw material whenever there is a new and documented demand for the supply and use of Nanomaterials, in particular in the event of:

- Need to introduce new Nanomaterials;
- Change of suppliers or of economic conditions for supplies;
- Change in qualitative and quantitative characteristics;
- Variations in the production process that have an impact on raw materials
- Change in production specifications
- Change in safety legislations and/or internal procedures of use;
- Variations in supply guarantees.

The minimum requirements to be met are the following:

- Safety Sheet;
- Identification requirements (CAS number, etc.) and Analytical Certificate;
- Declaration about possible restrictions of the use of substances during the process, dictated by safety requirements;
- Technical sheet;
- Type of packaging and transport conditions
- Details of analytical methods used by the supplier for the characterization of the Nanomaterial, in particular, to evaluate:
  - Size (granulometry);
  - Inner/outer structure;
  - Chemical nature
  - Chemical and physical properties;
  - Concentration.
- Declaration of conformity with safety and environmental standards in force produced by the supplier (Note 2).

Evaluation of the Nanomaterial

Procurement, in the event of a variation in the chemical-physical or qualitative properties of the product, in the conditions of use and the handling standards and procedures, requires that:

Production:

- should ascertain, with the support of Research and Development, the compatibility of the product with the productive process based on its impact on the operation of the plant and on the output and quality of the final product;

Production Control:

- should characterize the product and ascertain its compliance with production quality specifications;
- should check whether the methods and equipments needed for lab tests are available; in case there are shortcomings, ask the supplier to provide a technical support or obtain an analysis service;

Quality Environment Safety:

- should carry out a new risk assessment;
- should disseminate the new updated Safety Sheet;

Marketing:

- should assess the compatibility of the final product with customers needs and economic requirements.

Procurement draws up and updates the document of the Approval and Validation Plan including information related to:

- Information details by the Supplier;
- Evaluation of the Nanomaterial.

In the event that all the evaluations that are conducted have been proved consistent with the specifications and the supporting departments that are involved have validated the Nanomaterials within their competence, **Procurement** endorses the Approval and Validation Plan of the material, updates the Register of Validated and Certified Products (Note 1) and informs the organization.
In the event that there are elements that are not in accordance with specifications, **Procurement** informs **Production, Research and Development** and **Quality Environment Safety** with a view to agreeing with the supplier upon the necessary actions and reach the certification of the product.

APPROVAL AND VALIDATION PLAN

Procurement, with the support of **Quality Environment Safety, Production, Production Control, Research and Development,** develops the approval and validation plan for raw materials/intermediates aiming at ensuring the management of all the activities necessary for the product qualification explained as follows

Information by the Supplier

Procurement, after qualifying the potential supplier (see "Operating Guidelines for the qualification of external companies", developed by Federchimica in June 2011) invites the potential supplier to provide all the safety and technical information details that are necessary for the qualification of the Nanomaterial, as well as a representative sample for its characterization

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D. NOTES AND COMMENTS

1. The Approval and Validation Plan is a register to collect the information that is necessary for the approval of the raw material and/or intermediate that is purchased. The Register of Approved and Validated Products is a list of products that have an endorsed approval and validation plan. The Register reports the validity date of the approval that was granted.
2. The supplier shall ensure that all substances contained in the product are pre-registered, registered and/or authorized in accordance with the requirements laid down in regulation (EC) n.1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorization and restriction of chemicals (REACH). Moreover, it ensures that any requirement prescribed by REACH in terms of the delivery of the product shall be met

E. INDEX OF REFERENCE DOCUMENTS AND REGISTER
• Approval and Validation Plan; • Register of Approved and Validated Products

F. APPROVAL AND DISTRIBUTION LIST:		
Function in charge of the Operating Procedure	**Directorate General approval**	**Distribution List**

3.2 Management of the Productive Process, Maintenance and Control of the Equipment and Measurement Instruments, Treatment of non Compliant Products

Logo of Company	Company name
Code – Updating Date of issue:	TITLE: Productive Process Management; Maintenance and Control of the Equipment and Measurement Instrument; Treatment of non Compliant Products

A. AIM

Describe and regulate the planning, management and control of productive processes that use Nanomaterials, so as to obtain a product that is compliant with quality requirements and ensure deliveries according to the volume and time schedule requested by the customer.

B. RESPONSABILITY

In charge of Operating Procedure: **Production.**
Responsibilities for the different concerned areas in detail.

Organizational Function	D	S	I
Directorate General			√
Quality Environment Safety			
Human Resources			
Research and Development			
Plant			√
Production	√		
Production Control		√	
Technical Services/Engineering		√	
Maintenance			√
Procurement and Logistics			
Procurement		√	
Warehouse/Transport/Distribution		√	
Commercial			
Sales		√	√
Marketing			√
Customer Services			√

Responsability:
D = Direct
S = Support
I = Informative

C. DESCRIPTION OF THE PROCEDURE

PRODUCTION PLANNING

Production, with a view to planning the management of the plants and updating the production plan (Note 1), requires that:

- **Warehouse/Transportation/Distribution,** with the support of the Sales Department, should quantify the availability of the finished product at the warehouse and define the time schedule for the customers' deliveries;
- **Procurement** should ensure that the raw materials/intermediates and the packagings that are necessary for production are available at the warehouse within the time schedule indicated in the production plan.

PRODUCTION MANAGEMENT

Production, with a view to providing and arranging the resources that are necessary for the plant management, in keeping with the production plan, legislations and safety procedures, is in charge of:

- Assigning operators to the tasks necessary for the operation of the plant, identifying the work shifts and organizing handing over procedures;
- Supplying the staff working at the plant with updated operating instructions and with the specific safety training (Note 2);
- Checking the availability of personal protective equipments and the safety and environmental protection management procedures;
- Making the production equipment available;
- Updating, if necessary, the process documentation(Note 3);
- Checking the availability of the updated Quality Specifications of the product;

Production, with a view to making the plant and equipment suitable for the planned production requires that:

- **Technical Services/Engineering** should make sure that all necessary arrangements are made for the plant to manage production in safety, as provided for by the risk analysis of the process. It also requires to ensure, with the support of **Maintenance,** the proper operation of the systems involved in the management of abnormalities (Procedure 3.5);
- **Maintenance,** with the support of **Technical Services/Engineering**, should check the maintenance and control of the equipment and of measurement instruments, so as to ensure their reliability and operational availability, in accordance with production plans and in line with any prescribed technical or safety requirement (Note 2);
- **Production Control** should be engaged in quality analyses on the finished product so as to ascertain the compliance with quality requirements and identify non-compliant products. It also requires to make resources available for carrying out environmental monitoring analyses as foreseen by the updated environmental monitoring plan (Procedure 3,5).

In the event the product is considered to be NON COMPLIANT, **Production,** with the support of **Quality Environment Safety**, decides either to further process or to segregate the product with a view to disposal as waste. Furthermore, **Production**, with the support of **Technical Services/Engineering,** is responsible for identifying why a product is not compliant, define corrective actions and introduce product improvement projects.

D. NOTES AND COMMENTS

1. The production plan is a table that contains the following details for each product: estimated quantity, production date, updated quality specifications.
2. **Quality Environment Safety,** in collaboration with the supporting departments within their competence, performs a risk assessment of the activities that involve the handling and use of the raw materials and finished products, based on the Safety Sheet of the product and on additional technical information derived from the literature and provided by the supplier himself.
   In the specific case of Nanomaterials, studies by national and international authority aimed at defining exposure risks and relative precautionary measures to be adopted at the workplaces are still under way. The supplier himself may be asked to produce proof of consolidated practices used in the production process of the raw material and his experience in the sector.
   In the absence of definite information, the "Precautionary Principle" has to be adopted. Typically, the principle provides an outline of a series good practices:

   - Good Management Practices
     Educate workers through training programmes on safe procedures to be followed in handling Nanomaterials so as to reduce the risk of inhalation and/or contamination.
     Provide information on the risks related to the use of Nanomaterials.
     Promote the practice of handwashing before eating or before leaving the workplace.
     Provide for monitoring measures (e.g. decontamination procedures) to ensure that Nanomaterials are not carried outside the working area.
     Provide appropriate spaces to have showers and to change one's occupational chothing so as to prevent the contamination of other areas (including one's domestic environment) due to the Nanomaterials that may settle on the occupational clothing.
   - Good Practices for Workers
     Upon receipt of the product check the conformity with the text reported on the label.
     Follow the Safety indications reported on the label.
     Make sure to wear a suitable protective equipment and handle the product with care, to avoid any leaks and/or ruptures.
     Avoid to handle Nanomaterials out-of-doors, in particular if they are in the "free particulate" state.
     Clean the working areas at the end of each operation, using filtration systems (absolute filters).
     Avoid to store and consume food or beverages in the places where the Nanomaterials are handled.

3. **Production** with the support of **Technical/Engineering Services** and of **Quality Environment Safety**, draws up the process documentation, consisting of a collection of documents related to the management of the plant that in outline may be subdivided in 4 sections:
   - Management of the production process:
     - Principles of manufacturing
     - Organization of the equipment

- Flowsheet of the material
- Process data
- Peculiarity of the Nanomaterials that are used/produced (size, physical shape, other)

- Safety and environmental protection:
  - Instructions related to the management of Safety and environment as a result of the risk analysis that is performed
  - Adoption of personal protective equipment (PPE) and check whether they are appropriate
  - Management of emissions into the atmosphere, generation of waste (liquid and solid) and their segregation
  - Indication on how to manage possible risk situations (spills or others)
- Instructions for the operators.
  - Detailed and chronological description about what the operator has to do to implement the process
- Quality:
  - Specifications and analytical procedures
  - Management of the process control and finished product samples.

4. **Maintenance** with the support of **Technical Services/Engineering** and in collaboration with **Production**, provides for the planning of Preventive Maintenance, Safety Planning Maintenance and Corrective Maintenance (Note 4), assigns priority to the interventions, issues work permits, assigns maintenance operations and checks/accepts the work that has been done.

5. Maintenance plans, subdivided into preventive, planned and corrective, are documents that contain the description of the interventions to be undertaken on the plants, with the priorities and the dates of execution and completion; for each scheduled operation, they also contain the technical details, the internal staff to be involved or the indications for assigning the job to qualified external firms.

E. INDEX OF REFERENCE DOCUMENTS AND REGISTER

- Register of production;
- Documentation of the process;
- Plans of maintenance;
- Plan of environmental monitoring.

F. APPROVAL AND DISTRIBUTION LIST:

Function in charge of the Operating Procedure	Directorate General approval	Distribution List

3.3 Risk Identification, Assessment and Management for Health and Safety at Work

Logo of Company	Company name
Code – Updating Date of issue:	TITLE: Risk identification, Assessment and Management for Health and Safety at Work

A. AIM

The present procedure is aimed at managing risks for Health and Safety at work in accordance with provisions of reference legislations and is implemented for all activities that involve the handling of Nanomaterials that are performed either regularly or occasionally by the staff working for the plant.

B. RESPONSABILITY

In charge of Operating Procedure: **Quality Environment Safety**.
Responsibilities for the different concerned areas in detail.

Organizational Function	D	S	I
Directorate General			√
Quality Environment Safety	√		
Human Resources			√
Research and Development		√	
Plant			√
Production		√	
Production Control		√	
Technical Services/Engineering		√	
Maintenance		√	
Procurement and Logistics			
Procurement			√
Warehouse/Transport/Distribution			√
Commercial			
Sales			
Marketing			
Customer Services			√

Responsability:
D = Direct
S = Support
I = Informative

C. DESCRIPTION OF THE PROCEDURE

The employer with the collaboration of **Quality Environment Safety**, plans and implements risk assessment policies in the working places in accordante with Lgs. D. 81/2008 and s.m.i. throughout the activities carried out in the plants, with the support of the corporate departments that are involved in the manipulation of the Nanomaterials, including the setting up of an ad hoc working party (Note 1) and through previous consultation with the workers' representatives for safety.

The process of identifying hazards, assessing and controlling risks, is based on a method approach that is validated by all departments involved, that include:

- Data and information collection related to Nanomaterials;
- Identification of hazards (Note 2)
- Risk assessment depending upon the existing/submitted control measures, adopted control measures, exposure to hazards, the likelihood of a failure in control measures and the harmful consequences;
- Acceptability of residual risks (Note 3)
- Drawing up/updating of a Document on Risk Assessment; (Note 4);
- Drawing up/updating of Safety management programmes, to identify further control measures that are deemed to be necessary and assess whether they are sufficient to bring risks down to an acceptable level;
- Revision of the identification process of hazards and evaluation/control of risks;
- Evaluation of the extent of risks of exposure to Nanomaterials
- Identification of protection and prevention measures with the support of the involved departments for each assessed task (Note 5).
-

Quality Environment and Safety is in charge of revisions of the risk assessment plan and whenever there are documented changes that affect environmental safety/management such as:

- Variations of the working process conditions
- Changes in the process or production plants
- Introduction of new substances or variations in the qualitative features of the material
- Entry into force or changes in procedure and/or legislations related to environmental safety/management
- Change in working tasks
- Findings from audits that highlight risk situations that are assessed in different manners
- Occurrence of serious accidents at work
- Notifications, complaints and relevant cases of non-compliance that have a serious impact on safety.

The updated plan is submitted to the involved corporate departments and to the Representatives of Workers engaged in Safety.

Quality Environment and Safety, with the approval of the **Directorate General** and with the support of corporate departments involved in the handling of Nanomaterials, prepares the following plans:

- Training and information;
- Distribution of Personal Protective Equipment (PPE);
- Audit;
- Supervision/measurement (Procedure 3.5).

Quality Environment and Safety, with the support of the involved organizational functions, draws up/updates the register concerning training (Note 6) and, if deemed appropriate, possible documents on the distribution of PPEs, audits, collection of audit reports.

D. NOTES AND COMMENTS

1. The working group is set up by the employer, in accordante with Leg. D. 81/2008, involving the operator in charge of the prevention and safeguard service and, if necessary, the competent physician. External consultants may be convened as well as the supplier of the Nanomaterial in the event that the company should lack the suitable experts.
2. With a view to identifying among the risk and/or hazard sources highlighted through the data collection the ones that entail an exposure to Nanomaterials for the workers in charge, the following will have to be examined: operating modes manual, automatic, instrumental also with protected cycle; the extent of operations throughout the working day depending upon the time needed and the quantity of the materials that are used; the organization of the activity with respect to the time spent in the working environment and in overlap with other processing activities; the safety measures and/or prevention/protection systems that are scheduled for the execution of productive activities. The exposure to Nanomaterials has to be reduced to a minimum based on the “Precautionary Principle” limiting the period of exposure and/or the number of people exposed and/or the concentration of the Nanomaterials themselves.
3. Potential residual risks that still persist after the adoption of control measures should be addressed, taking into account operating modes, exposure characteristics and existing protection and safety measures.
4. The Risk Assessment Document is approved by the Directorate General and by the Competent Doctor respectively, the Representatives of Workers engaged in Safety are informed about the outcome of the risk assessment and the improvement measures that are planned.
   The Risk Assessment Document is available for consultation (control authorities, representatives of workers dealing with safety, departments involved in the assessment process).
5. Action plan, with the following priorities, should the hazardousness of the substance/mixture be confirmed as follows:
   - Elimination or reduction through the replacement with other agents or processes which, in the conditions of use, are not or are less harmful for public health;
   - If point one is not possible, planning of appropriate working processes and technical checks, as well as use of appropriate materials and equipment;
   - Provision of appropriate organizational measures and collective protection measures at the source of the hazard;
   - Personal protection measures, including PPEs, whenever the exposure cannot be prevented through other means;
   - Worker’s health surveillance (in accordance with articles 229 and 230 of Lgs.D. 81/2008 and modifications).

Moreover, it is necessary to highlight the importance of:

- Training and information of the workers;
- Adoption of procedures on the installation and maintenance of control systems (i.a. ventilation systems) in the working places where the exposure to Nanomaterials is expected;
- Programmes on the information and training of the workers, on the handling of Nanomaterials, on safety sheets and, if provided, on the correct use, through training, of Personal Protection Equipment (PPEs).

6. The Training Register contains the training activity of the staff carried out at the company or at external institutes, and it includes the outcome of any possible learning test.

E. INDEX OF REFERENCE DOCUMENTS AND REGISTER

- Risk Assessment Document;
- Register of training.

F. APPROVAL AND DISTRIBUTION LIST:

In charge of the Operating Procedure	Directorate General approval	Distribution List

3.4 Waste Management

Logo of Company	Company name
Code – Updating Date of issue:	TITLE: Waste management

A. AIM

The present procedure is aimed at describing the management methods for the waste that is produced in the plant, including the whole cycle, from their generation at the plants or in the laboratories, up to the phases of transportation, recovery and/or disposal (Note 1).

B. RESPONSABILITY

In charge of Operating Procedure: **Quality Environment Safety**.
Responsibilities for the different concerned areas in detail.

Organizational Function	D	S	I
Directorate General			
Quality Environment Safety	√	√	
Human Resources			
Research and Development		√	√
Plant		√	√
Production			
Production Control			
Technical Services/Engineering		√	√
Maintenance			
Procurement and Logistics		√	√
Procurement			
Warehouse/Transport/Distribution			
Commercial			
Sales			
Marketing			
Customer Services			

Responsability:
D = Direct
S = Support
I = Informative

C. DESCRIPTION OF THE PROCEDURE

Quality Environment Safety for each waste type produced at the site:

- Identifies and classifies each single waste, with the support of Production/Production Control/Research and Development (in the event of waste produced in a laboratory);
- Identifies, qualifies and manages suppliers, waste disposal plants, road haulers holding transport permits and disposal/recovery of the produced waste permits, in particular: keeps the contacts with waste disposal plants managers and haulers making sure that they are reliable with respect to the treatment/transportation of the waste in compliance with the authorizations provided by the standards (Note 2);
- Requires that **Procurement** should authorize the selection of waste disposal operators and/or hauliers; similarly for waste produced in a laboratory it requires the authorization of **Research and Development** or **Production Control**;
- Requires that **Production** should authorize the choice of waste disposal plants and/or haulers, and similarly for waste produced at the laboratory asks **Research and Development** or **Production Control** for an authorization;
- Looks preliminarly over the plants and technologies used by the waste disposal plant and/or hauler and writes the report concerning the inspection, similarly, it carries out checks to ascertain whether the haulage vehicles are suitable for handling the specific waste that is produced;
- Manages and updates internal lists of the waste disposal firms and of the qualified hauliers (Note 3);
- Defines the methods for the temporary storage of waste in the storing areas of the site, identifying them with caution signs;
- Keeps/updates a list of the generated waste, sorted according to the different types of waste;
- Verifies the validity of the authorizations for the treatment plants and membership to the Register of Haulers engaged in Waste Disposal, making sure that these subjects are authorized to handle the specific EWC codes for the waste to be disposed of;
- Organizes, with the support of **Warehouse/Transportation/Distribution,** the planning of the loading and carriage of the waste;

With the support of the departments involved in the waste management:

- Promotes the training of the employees on all aspects connected to safety, such as handling, storage and transportation of the waste;
- Adopts specific procedures for handling and loading waste on vehicles.

The waste that originates from laboratory activities is managed by the respective departments: **Research and Development, Production Control**.

The departments that are involved in waste issues manage, based on legislations in force:

- Waste identification forms prepared by **Production** based on the indications provided by **Quality Safety Environment**;
- Forms stamped and signed by the recipient;
- Loading and unloading registers;
- Annual declaration (M.U.D./SISTRI).

The **Technical Services/Engineering** with the support of **Quality Environment Safety** and of **Warehouse/Transportation/Distribution** identifies the storage areas, marks the boundaries and prepares the relative signs (name of the waste, EWC code, identified risks).

D. NOTES AND COMMENTS

1. Waste: any substance or object which the holder wants to get rid of or has decided to or is under the obligation to get rid of (including contaminated materials and substances collected in containers).
2. Requirements for the waste disposal firm/hauler:
   - Hold a regular authorization and ensure full compliance with the provisions laid down in the authorizations and in laws and regulations that can be implemented to the waste disposal and transportation activities;
   - Be in possession of means and facilities to be used for the carriage and the disposal of the waste that are compliant with the requirements provided by legislation and with prescriptions reported on the authorization documents.
3. Internal documents that list the waste disposal operators and haulers considered to be suitable for the waste management.

E. INDEX OF REFERENCE DOCUMENTS AND REGISTER

- National Register of qualified waste disposal operators
- - National Register of qualified waste haulers
- - List of waste
- - Form concerning waste identification,
- - Forms stamped and signed by the recipient of the waste;
- - Loading/unloading registers;
- - Annual declaration (M.U.D./SISTRI).

Literature and Legislative References:

- Safety for goods transport of goods (PR procedure - 7.2 of the present Documentl)
- Directive 91/689 (hazardous waste definition)
- Decree 52/97 (hazoudous substance)
- Decision 2000/532/EC
- Legislative Decree 28/02/2006 (hazardous substances)
- Regulation 1272/2008(CLP)
- Legislative Decree 65/2003 (hazardous preparations)
- Directive 94/62/EC (packagings)
- Law n. 70/94 (MUD)
- Ministerial Decree. 1 April 1998, n. 145 (Waste Transportation Forms)
- Ministerial Decree 1 April 1998, n. 148 (Waste Loading/Unloading Registers)
- UNI EN ISO 14001:2004
- Decision 2000/532/EC
- Legislative Decree 3 April 2006 n. 152 (Environment Single Text) and successive amendments.

F. APPROVAL AND DISTRIBUTION LIST:		
Function in charge of the Operating Procedure	**Directorate General approval**	**Distribution List**

3.5 Management of Direct and Indirect Environmental Aspects

Logo of Company	Company name
Code – Updating Date of issue:	TITLE: Direct and indirect Environmental aspects managementi

A. AIM

The present procedure indicates the management methods of direct and indirect environmental aspects generated by corporate activities that may entail the exposure of Nanomaterials to the environment.

B. RESPONSIBILITY

In charge of Operating Procedure: **Quality Environment Safety**.
Responsibilities for the different concerned areas in detail.

Organizational Function	D	S	I
Directorate General			√
Quality Environment Safety	√		
Human Resources			√
Research and Development		√	
Plant			√
Production		√	
Production Control		√	
Technical Services/Engineering		√	
Maintenance		√	
Procurement and Logistics			
Procurement			
Warehouse/Transport/Distribution		√	
Commercial			
Sales			
Marketing			
Customer Services			

Responsability:
D = Direct
S = Support
I = Informative

C. DESCRIPTION OF THE PROCEDURE

INDENTIFICATION OF THE OVERALL ENVIRONMENTAL ASPECTS

Quality Environment Safety: identifies the overall environmental aspects related to all activities of the site and collects information concerning:

- Potential effects of the spreading of Nanomaterials to the surrounding environment (water/ground/air),
- Environmental aspects dealt with in laws and prescriptions applicable to the site,
- Quantitative data on inbound and outbound material movements,
- Management procedures and practices concerning the environment received from suppliers of Nanomaterials.

IDENTIFICATION OF SIGNIFICANT ENVIRONMENTAL ASPECTS

Quality Environment Safety looks into the environmental aspects generated by specific activities together with each corporate department involved in the handling of Nanomaterials.

Identified environmental aspects are classified between ***significant*** or **not *significant*** based on significance criteria (Note 1).

The activities of identification/evaluation and registration are repeated:

- When new information on treated products becomes available;
- When changes to the production systems and loading/unloading systems are introduced;
- When treatment procedures of liquid waste and emissions into the atmosphere are changed.

OPERATING AND PREVENTIVE CONTROL OF ENVIRONMENTAL ASPECTS

Quality Environment Safety asks the departments that perform activities which generate significant environmental aspects to ensure compliance with applicable laws and regulations through determining/updating operating instructions and specific procedures on controlling processes and mantaining the efficiency of the plant. In particular, the following items have to be inspected:

- State of the unit (clean, tidy-looking, healthy);
- Control of the operations under way (analysis of the working environment);
- State of working order of the plants with respect to environmental impact factors (aspirators, emission abatement systems).

FUNCTIONING OF THE PLANT IN ABNORMAL CONDITIONS

Quality Environment Safety asks the departments with significant environmental aspects to be planned, with the support of **Technical Services/Engineering** and **Maintenance,** to adopt the necessary interventions to curb the effects deriving from abnormal events that may take place during the operation of the plants or of the laboratories (plan for curbing abnormal events).

In particular, actions are needed in the event of unforeseen operations that entail a significant variation in environmental protection measures and that have an impact on the objectives and prescriptions of the environmental system, such as: more production of waste or emissions, increased consumption of raw materials, malfunctionings or failures.

Useful interventions for these aims are:

- Changes in the Production Programme or its discontinuation;
- Changes in the Treatment Plant Functioning Programme;
- Recourse to third parties for treatment;
- Different methods to keep effluents under control;
- Recycling of the flows to be treated;
- Temporary storage.

In the event of situations that may seriously harm the environment or the people, **Production** informs **Quality Environment and Safety** and the **Directorate General** and activates the emergency plan.

CONTAINMENT SYSTEMS

Quality Environment Safety asks the departments that need containment systems such as:

- Sequestration and emission reduction systems (dust, aerosol, gas/steam/vapors);
- Waste water treatment plants;
- Management system for rain water and grey water;
- Installations for the segregation, storage, disposal of waste;

to develop a monitoring and maintenance plan with the support of **Techical service/Engineering** and **Maintenance.**

SUPERVISION AND MEASUREMENT ACTIVITY

Quality Environment Safety asks **Production Control** to perform the necessary laboratory measurements to monitor environmental parameters through the use of validated methods and on the basis of an analysis plan agreed upon with the involved departments (environmental monitoring plan). The execution of the monitoring analysis plan can be assigned to a recognized external laboratory.

The outcomes of the measurements, notified by the laboratory through an analytical report to the involved departments, are reported in the register of environmental aspects and compared with the established threshold values.

In the event that threshold values are exceeded, the responsible manager of the involved department informs **Quality Safety Environment** that develops the actions needed to go back to the right parameters.

D. NOTES AND COMMENTS

1. Significance criteria are:
   - Managerial performance criteria: they indicate the ability by the company, in an effective and correct manner, to manage activities that are related to the environmental aspect;
   - Environmental impact criteria: they indicate the nature of the environmental impact associated to the aspect, allowing both for the extent it has and the conditions of the social-environmental context where the impact reveals itself.

E. INDEX OF REFERENCE DOCUMENTS AND REGISTER

- Emergency plan
- Plans for the containment of abnormal events
- Plan for the maintenance and monitoring of containment systems
- Environmental monitoring plan

Literature and legislation references:

- ISO 14001 (EMAS–6 Guidelines: guidance for identifying environmental aspects and evaluate their significance).
- Legislative Decree 152/2006 – Environmental legislation

F. APPROVAL AND DISTRIBUTION LIST:

Function in charge of the Operating Procedure	**Directorate General approval**	**Distribution List**

3.6 Plant Design

Logo of Company'	Company name
Code – Updating **Date of issue:**	**TITLE: Plant design**

A. AIM

The present procedure is aimed at describing the design approaches adopted for plants used for producing Nanomaterials through synthesis or blending processes.

B. RESPONSABILITY

In charge of Operating Procedure: **Technical Services/Engineering**.
Responsibilities for the different concerned areas in detail.

Organizational Functions	D	S	I
Directorate General			√
Quality Environment Safety		√	
Human Resources			√
Research and Development		√	
Plant			√
Production		√	
Production Control			√
Technical Services/Engineering	√		
Maintenance		√	
Procurement and Logistics			
Procurement		√	
Warehouse/Transport/Distribution			
Commercial			
Sales			√
Marketing		√	
Customer Services			√

Responsability:
D = Direct
S = Support
I = Informative

C. DESCRIPTION OF THE PROCEDURE

DESIGN

The **Technical Services/Engineering** based on indications supplied by **Research and Development**, by **Marketing** and by **Quality Environment Safety** carries out a preliminary feasibility study for the development of a new plant or for the changes to the existing one. The basic details that are necessary for the study include:

- Planned production volumes
- Type of production (batch or continuous and definition of the various steps)
- Type of inbound and outbound material movements
- Physical state (size) of the Nanomaterial (as a raw material and/or finished product/intermediate;
- Loading systems of the Nanomaterials (based on packagings of the supplier)
- Use of other raw materials/production intermediates
- Conveying gas emissions to suitable abatement systems
- Types of generated waste and waste water (liquid, solid, gaseous)
- Types of waste drain systems (liquid / solid)
- Types of packaging for finished products
- Preliminary risk analysis

The feasibility study is aimed at identifying an estimate of the cost of the intervention to be implemented, (+/- 30%) and carrying out and analysis on critical aspects. **Quality Environment Safety** supports the **Technical Services/Engineering** and takes care of aspects related to applicable legislations concerning permits or other activities that are necessary and cogent for the implementation of the project (Directive on large extent risks, Emissions into the atmosphere, noise or odour impact, etc..).

In the following phase, the project is further developed through detail engineering which provides indications concerning:

- Planimetry;
- Piping;
- Equipment for the loading of raw materials, synthesis/blending and unloading of finished products;
- Containment systems:
- Control and treatment of liquid and gaseous emissions (Note 1);
- Storage of solid waste.

PROJECT ASSESSMENT

Technical Services/Engineering, with the support of other functions: **Production**, **Marketing**, **Research and Development**, **Quality Environment and Safety and Procurement**, evaluates the progress of the project depending upon the economic and technical feasibility. In the event that the project is not consistent with the established objectives, the team suggests either to stop the process and plans changes and improvements or to abandon the project.

IMPLEMENTATION

Technical Services/Engineering, with the support of **Procurement, Maintenance** and **Research and Development** is in charge of**:**

- Controlling the purchase of materials and equipment and check whether they match with the specifications established during the design phase;
- Managing the installation of the equipment and the testing of the plant;
- Drafting the operating instructions;
- checking safety and environmental conditions with the support of Quality Environment and Safety (Note 2);
- Managing the emissions of the plant.

SETTING IN MOTION

Technical Services/Engineering with the support of **Production** and **Research and Development** manages the activities of qualification and approval of the installation, so as to check whether they comply with established project requirements and with applicable technical standards.

The procedure provides the following steps:

- To plan a setting in motion scheme through a planning of activities to carry out any control that appeared to be critical in the Risk Assessment phase;
- To test all the equipments that make up the plant and, in particular, the automatic components and the machineries that are managed either manually or by the control system;
- To plan the introductory production campaign with the following objectives:
  - Prove that all systems and safety devices of the plant are reliable and in working order;
  - Check whether the productive process is repeatable and compliant with the objectives to be pursued (product quality, composition of the gaseous emissions that are conveyed, characteristics of the waste).

At the end of the introductory campaign, after a review of the results, **Technical Services/Engineering** draws up the setting in motion report, which contains all the assessments and the data collected in this phase, possible open actions, the state reached in the preparation of the definitive documentation indicating for how long the documents have to be retained and who the managers responsible for the implementation is.

Technical Services/Engineering asks **Quality Environment and Safety** to draw up all necessary documents to process the files required by applicable legislation.

The definitive report with the validation is approved by **Production** and represents the formal act whereby the plant is accepted (report of plant acceptance).

D. NOTES AND COMMENTS

1. In assessing the sequestration plants, it is necessary to consider that at present there are no absolute filtration technologies.

E. INDEX OF REFERENCE DOCUMENTS AND REGISTER

- Report on setting in motion
- Report on plant acceptance

Legislative and literature references

- ISO 14001 (EMAS–6 Guidelines: guidance for indentifying environmental aspects and the evaluation of their significance.
- Legislative Decree 152/2006 – Legislation concerning the environment

Operating Procedure of this Document

3.3 – Risk identification, assessment and management for health and safety at work**;**

3.5 – Management of direct and indirect environmental aspect ;

4.1 – Design and development of new products and pilot test;

5.1 Selection and management of suppliers in compliance with health and safety principles.

F. APPROVAL AND DISTRIBUTION LIST:

Function in charge of the Operating Procedure	**Directorate General approval**	**Distribution List**

4 Research and Development Procedures

4.1 Design and Development of New Products and Pilot Test

Logo of Company	Company name
Code – Updating Date of issue:	TITLE: Design and Development of New Products and Pilot Test

A. AIM

The present procedure defines the criteria to be adopted when developing Nanomaterials or new products that employ Nanomaterials with the aim to reduce risks for health, safety and the environment.

B. RESPONSABILITY

In charge of Operating Procedure: **Research and Development**.
Responsibilities for the different concerned areas in detail.

Organizational Function	D	S	I
Directorate General			√
Quality Environment Safety		√	
Human Resources			
Research and Development	√		
Plant			√
Production		√	
Production Control		√	
Technical Services/Engineering		√	
Maintenance			
Procurement and Logistics		√	
Procurement		√	
Warehouse/Transport/Distribution		√	
Commercial			√
Sales		√	
Marketing		√	
Customer Services		√	

Responsability:
D = Direct
S = Support
I = Informative

C. DESCRIPTION OF THE PROCEDURE

EXPLORATIVE SURVEY

Research and Development, with the aim to review the threats and the opportunities linked to the development of a new product (Note 1), define the scope for preliminary enquiries, formulate the working assumptions and define the priorities for a test plan ask:

- **Marketing** to carry out a market analysis in the sectors where there are applications for the Nanomaterials to identify the needs of the new product in terms of:
  - Economic considerations,
  - Market geography,
  - Qualitative requirements of the product,
  - Types of application
- **Quality Safety and Environment** to assess in advance the profiles of toxicology and eco-compatibility for the process and the products to be manufactured (Note 2)

DEVELOPMENT AND PILOTE TESTS

Research and Development plans and manages the laboratory tests necessary to the acquisition of data and information that are not available in literature, to be processed and evaluated and used at a later time of the project (Note 3). In this phase, **Research and Development** asks:

- **Quality Environment Safety** to collect the chemical-physical, toxicological and eco-toxicological data from recognized sources that are necessary for the risk assessment of the product;
- **Production Control** to take steps to characterize the samples produced in a small scale. In the event that analytical methods for a first check of the qualitative requirements defined through the explorative research are not available, Production Control is in charge of acquiring the necessary analytical technology or can resort to qualified external bodies.

Based on the results obtained, **Research and Development,** with the support of **Marketing,** decides whether to go on with the activity or repeat the research and setting up phases with new conditions, or, as an alternative, stop the project.

If the review of the laboratory findings supplies sufficient indications on the validity of the new product, **Research and Development** goes on with the planning of the activities and the change of scale into pilot plant and/or semi-industrial plant. In this phase, the following aspects have to be assessed:

- With the support of **Technical Services/Engineering**: technologies to be adopted, production output, continuous or batch process, etc.;
- With the support of **Procurement**: qualified suppliers for raw materials;
- With the support of **Production Control**: analytical support methods, methods for controlling the process, the finished product, the emissions, solid and liquid waste;
- With the support of **Production Control** and **Quality Environment Safety**: identify and control emissions deriving from the process; identify the waste (liquid, solid, gaseous).

Research and Development is in charge of preparing, on a pilot scale, one or more representative samples to be used for:

- Completing the toxicological and eco-toxicological profile of the product through recognized methods and register the product in accordance with applicable legislation, with the support of **Quality Environment Safety**;
- Samples for prospective customers, with the support of **Customer Services** and **Sales**;
- Identification of the packaging and transportation modes with the support of **Warehouse/Transportation/Distribution**;
- Registration of the product for specific applications with the support of **Quality Environment Safety**;
- Definition of the productive process and management of generated waste with the support of **Technical Services/Engineering**, **Quality Environment Safety**, **Procurement** and **Logistics** (Waste).

During all the activities, procedures on patent protection for the innovations under study can be activated.

Research and Development, with the support of **Production,** and **Marketing**, based on the collected data, the replies obtained with the tests performed by prospective customers and the final processing operations:

- Verifies the technical and economic objectives that have been reached;
- Suggests to go on with the new product on an industrial scale.

Research and Development, with the aim of completing the collection of information necessary for the development and definition of the product, asks:

- **Technical Services/Engineering** to prepare the technical specifications for production;
- **Marketing** to prepare the quality specifications of the finished product;
- **Production Control** to formalize the analytical methods for the control of the product, the process and the generated environmental aspects.

FILE PROCESSING AND REGISTRATION OF THE PRODUCT

Research and Development, with the support of **Quality Environment Safety** and **Marketing,** takes care of drafting the specific File of the Product that contains the necessary information to place the product on the market and to register it in accordance with applicable legislation (Note 4).

D. NOTES AND COMMENTS

1. The type of research of the new products depends upon the final product, which can be:
   - Obtained by synthesis (synthesis of new molecules with identity and CAS definition);
   - Blending/formulation (already existing Nanomaterials that are formulated or blended with other components);
   - Applicative (already existing Nanomaterials that are studied for new types of application);
2. An environmentally responsible design should allow for the aspects related to the interaction of Nanomaterials with the environment, both when they are used and when they are released.
   - Modelling of transport mechanisms;
   - Final disposal of Nanomaterials.
3. Based on the type of product to be developed, the activities to be planned may include:
   - Literature review to collect available information.
   - identification of the product and raw material profile.
   - Data banks and other available information.
   - Support with information supplied by potential suppliers.

   To identify the profile of the new product/formulation, the following information may be useful for a more accurate definition of the project and its development:
   - Chemical-physical /toxicological and eco-toxicological profile of similar products.
   - Classification of the severity of the hazard and state of the raw material registrations.
   - State of the product registration on the reference markets (Reach and other schemes).
   - Initial product screening and/or new application (in vitro, read-across, QSAR).
4. Indications necessary for the marketing of the product in accordance with applicable legislation:
   - Classification, labelling and basic data: see CLP regulation
   - Safety sheets (REACH regulation and regulation 453/2010/EU);
   - Instructions for use and applications , obligations and procedures to be adopted.
   - Packaging: indications on the types to be adopted and procedures for the recycling/disposal
   - Information for consumers
   - Precautions taken for Health and Safety.

E. INDEX OF REFERENCE DOCUMENTS AND REGISTER

- Dossier of the product;
- Collection of production specifications;
- Quality specifications of the finished product.

Riferimenti normativi e di letteratura

- ISO 14001 (EMAS–6 Guidelines: guidance for identifying environmental aspects and the evaluation of their significance.
- Legislative Decree 152/2006 – Legislation concerning the environment
- Regulations REACH and CPL:
- Specific regulations on product applications.

Operating Procedure of this Document **3.3** – Risk identification, assessment and management for Health and Safety at work; **3.5** – Management of direct and indirect environmental aspect ; **5.1** – Selection and management of Suppliers in compliance with Health and Safety principles; **6.1** – Responsibility for marketed products containing Nanomaterials.
F. APPROVAL AND DISTRIBUTION LIST:

Function in charge of the Operating Procedure	**Directorate General approval**	**Distribution List**

5 Procurement and Logistic Procedures

5.1 Selection and Management of Suppliers in Compliance with Health and Safety Principles

Logo of Company	Company name
Code – Updating Date of issue:	TITLE: Selection and management of Suppliers in compliance with Health and Safety principles

A. AIM

Define and manage the eligibility of the suppliers of the Nanomaterials as raw materials and ensure the information flow with respect to safety and environment. Management of the Vendor list and Complaints.

B. RESPONSABILITY

In charge of Operating Procedure: **Procurement**.
Responsibilities for the different concerned areas in detail.

Organizational Function	D	S	I
Directorate General			
Quality Environment Safety		√	
Human Resources			
Research and Development		**√**	
Plant		√	
Production		√	
Production Control		√	
Technical Services/Engineering			√
Maintenance			√
Procurement and Logistics			√
Procurement	√		
Warehouse/Transport/Distribution		√	
Commercial			
Sales		√	
Marketing		√	
Customer Services			√

Responsability:
D = Direct
S = Support
I = Informative

C. DESCRIPTION OF THE PROCEDURE

Procurement collects the orders of raw materials placed by the departments in charge:

- Production for feeding the plants,
- Research and Development for the laboratory studies and the tests in pilot plants.

COMMERCIAL EVALUATION

With a view to selecting and qualifying suitable suppliers and managing the corporate vendor list (Note 1), **Procurement** requires that the **Commercial Department** should carry out an evaluation of the features of potential suppliers (see "Operating guidelines on the Qualification of External Companies", published by Federchimica in June 2011)

TECHNICAL EVALUATION

Procurement with the support of **Production, Production Control, Technical Services/Engineering, Quality Environment and Safety** and **Research** and **Development** provides a technical evaluation of potential Suppliers, implementing the following criteria:

- Quality of the raw material and its impact on the process and final product;
- Compliance with the requirements concerning Safety and Environmental Aspects;
- Punctuality and compliance with delivery terms and conditions;
- Complete set of accompanying documents and analysis certificates;
- Operating support to the supplier in the management of Nanomaterials (information on the management of provided materials, analysis and safety characterization approaches, critical parameters);
- Engineering aspects to be adopted in the productive process to guarantee safe handling of the product;
- Performance related to the management of complaints;
- Supplier certification (quality system of the supplier).

Procurement: concerning the abovementioned evaluation with the aim to include the supplier in the Vendor List (Register of commercial and technical evaluations of suppliers).

In the event of unsuitable suppliers, **Procurement** gets in contact with the suppliers to ask for products that perform according to the required standards. Moreover, it enquires into alternative possible suppliers to ensure regular supplies.

Procurement agrees upon prices and other terms with the selected supplier (e.g. payment terms, transportation costs, validity of the agreement). Before starting supplies, **Procurement** starts the procedure to include a new supplier in the Vendor List and also is in charge of informing **Production, Production Control, Warehouse, Transportation and Distribution, Quality Environment and Safety, Technical Services/Engineering.**

COMPLAINT MANAGEMENT

Whenever a problem of any nature sets in (concerning **Production, Quality or Logistics)**, such as raw material non compliant with requirements, risk of accidents with environmental impact, non

compliant packaging, delayed deliveries, wrong invoices or other issues, **Procurement** submits a complaint to the supplier with the support of involved departments, also attaching any document that may clarify the nature of the problem. Any samples of the non compliant material are collected by **Production Control** and remain available until the complaint is dealt with.
The complaints are stored in the specially provided Register of complaints, with precise indications as to date, raw material, supplier, corrective action required/taken by the counterparty. Only when the supplier clarifies the problem that originated the complaint and implements the corrective action that is undertaken, the procedure is closed and the possible counter-samples that are collected may be disposed of.

AUDIT ON SUPPLIERS

Procurement organizes and manages possible inspections that may take place at the supplier's premises and that are implemented with the support of all departments that may be involved (**Quality Environment Safety**, **Production** and **Marketing**).
The inspections at the supplier's premises (Audits) can be performed both during the qualification phase and based on the following decision elements:

- Strategic nature of the product/supplier
- Critical aspects of the product
- Quality of the finished product
- Lower overall rating
- Suppliers who are deemed to be non eligible but Procurement and Logistics wants to keep
-

Procurement is in charge of the inclusion of the information obtained through the inspections into any proper document.

DEALING WITH ORDERS

Procurement, in order to get the goods ready for production at the warehouse, requires that Warehouse, Transportation and Distribution should submit the purchase order in due time so as to ensure the availability of the raw material for the plant operations.
Procurement processes the order with suppliers who are included in the Vendor List. Orders are then stored and archived.

D. NOTES AND COMMENTS

1. . Vendor List: official corporate document with the indication of suppliers qualified for the supply of raw materials and intermediates. In the document, all details necessary to the identification of the supplier, possible audits that are carried out, information concerning supplied products (quality requirements, safety data, etc..) shall be collected.

E. INDEX OF REFERENCE DOCUMENTS AND REGISTER

- Dossier of the product;
- Collection of production specifications;
- Quality specifications of the finished product;
- Register of the commercial and technical evaluations of the suppliers;
- Vendor list.

Operating Procedure of this Document

3.1 – Qualification of Raw Materials and Intermediates;

3.2 – Management of the productive process; maintenance and control of the equipment and measurement instruments, treatment of non compliant products;

6.1 – Responsibility for marketed products containing Nanomaterials.

F. APPROVAL AND DISTRIBUTION LIST:

Function in charge of the Operating Procedure	Directorate General approval	Distribution List

5.2 Safety in the Carriage of Goods

Logo of Company	Company name
Code – Updating Date of issue:	TITLE: Safety for the carriage of goods

A. AIM

The present procedure aims at ensuring that transportation and distribution activities of products and waste generated by the production activity are compliant with requirements provided by applicable laws concerning the handling of hazardous goods.

B. RESPONSABILITY

In charge of Operating Procedure: **Procurement and Logistics (Waste).**
Responsibilities for the different concerned areas in detail.

Organizational Function	D	S	I
Directorate General		√	√
Quality Environment Safety		√	
Human Resources		√	
Research and Development		√	
Plant			
Production		√	
Production Control			
Technical Services/Engineering			
Maintenance			
Procurement and Logistics	√		
Procurement			
Warehouse/Transport/Distribution		√	
Commercial			
Sales			√
Marketing			√
Customer Services			√

Responsability:
D = Direct
S = Support
I = Informative

C. DESCRIPTION OF THE PROCEDURE

Procurement and Logistics (Waste) with the support of **Quality Environment and Safety** manages the transportation and distribution modes of products classified in ADR provisions, through the adoption of requirements contained in applicable legislation and international technical standards regulating the Carriage of Dangerous Goods.
With a view to classifying the products for transportation, it is necessary to have an expert in dangerous goods within the organization in accordance with Legislative Decree n° 40 of 4/02/2000. This expert may be an external consultant who complies with the requirements set out in the decree.

IDENTIFICATION OF DANGEROUS GOODS

Procurement and Logistics (Waste) requires that **Quality Environment Safety** should manage the internal list of products classified according to ADR; this document, besides the commercial name, also includes some other details related to the severity of the hazards and risks concerning the product, the conduct to be followed during the carriage of the goods, the handling and the management of emergencies ensuing accidents.
This internal list, besides a check-list containing all elements necessary to the carriage, the official denomination of the material, the UN number, the group class of the packaging, the identification number on the label, the Kemler number, the main and secondary hazard (if any).

EVALUATION AND CHECK OF THE CONTEINER, THE VEHICLE AND THE MATERIAL USED FOR THE TRANSPORTATION, LOADING AND UNLOADING OPERATIONS

Procurement and Logistics (Waste), in order to ensure that dangerous goods are carried only by vehicles that are technically suitable and fitted with equipments provided by ADR asks Warehouse/Transportation/Distribution to evaluate and inspect the transport means and equipment employed for the transportation, loading and unloading operations.
It is necessary to use packaging/containers that are suitable for the carriage of hazardous goods with a specific interest (for example UN approved packaging).
For specific controls on single products, reference is made to internal specific check-lists.

VOCATIONAL TRAINING

Procurement and Logistics (Waste) asks **Human Resources** to organize, with the support of **Quality Environment Safety,** training activities for the staff in charge of the handling materials.
The staff in charge of handling operations needs at least the basic training on ADR and the specific training (including the one concerning the present procedure. Furthermore, training activities on Safety issues, exposure risks to the products subject to handling procedures in the event of accidents during the loading/unloading and as well as the preparation on how to intervene in emergency situations.

URGENT PROCEDURE

Procurement and Logistics (Waste) requires that **Quality Environment and Safety**, in the case of an incidental event occurring during the loading, unloading and handling phases of ADR materials, should inform in writing the advisor for safety in transport, if previously appointed, who has to submit a proper accident report within 30 days from the occurrance of the accident to the legal representative of the company and to the Department of Transport, Navigation and IT and Statistical Systems of the Ministry of Infrastructures and Transport and of the Ministry of the Interior – Department of the Fire Brigades, Public Rescue Service and Civil Defense (see art. 11, par. 7, of Lgs. D. no 35/2010) with a view to organizing, based on the submitted reports, a national databank on accidents during transportation.

The incidental event is treated like a "non compliance" with the procedure, therefore it is included in the Register of non compliant cases by **Procurement and Logistics** (Waste) that subsequently manages the corrective/preventive action plan.

With respect to the incidental event, the following aspects are considered:

- Dinamycs of the accident,
- Nature and severity of danger for the goods involved,
- Possible reaction among the different materials,
- Conduct of the individual operators,
- Concurrent use of equipment for loading and unloading,
- Loading and unloading procedures,
- Adverse phenomena or other factors.

CHOICE AND USE OF SUBCONTRACTORS OR OTHER OPERATORS

Procurement and Logistics (Waste), with the support of **Quality Environment Safety,** verifies that the waste disposal operators and the Suppliers who deliver ADR goods are in possession of the following requirements provided for in existing legislative provisions:

- Compliance of the employed vehicle with ADR provisions with respect to the carried goods,
- Suitability of the equipment of the transport means
- Suitability of the driver and other crew members on board,
- Compliance of the signalling procedures on board.

Handling/transportation operations are authorized only in the event that the required provisions are complied with.

MANAGEMENT OF INBOUND MATERIALS

Procurement and Logistics (Waste), requires for products that fall within the ADR transport provisions that **Quality Environment and Safety** should add their trade name in the ADR list; it subsequently should inform the organizational functions involved in handling operations that they shall ensure compliance for loading/unloading operations.

MANAGEMENT OF OUTBOUND MATERIALS

Procurement and Logistics (Waste) identifies the transport procedures for the outbound ADR goods in accordance with the existing legislation and classifies it by indicating:

- Class of danger;
- Kemler Danger Number;
- UN identification number.

APPOINTMENT AND TASKS OF THE TRANSPORT SAFETY CONSULTANT

Procurement and Logistics (Waste**),** within the meaning of provisions of Legislative Decree n°40 of 4/02/2000 and of Legislative Decree 35/2010 provides the **Directorate General** with the decision-making elements necessary for the appointment of the consultant for safety in the carriage of dangerous goods (Note 1).

D. NOTES AND COMMENTS

1. If the company doesn't fall within the exemptions granted for the shipment of ADR materials with respect to the quantity of materials handled and number of journeys, the **Directorate General** appoints the Consultant for safety of transport with the following tasks:
   - In the event of an accident, write a specific report to be submitted to the General Directorate and to the Ministry of Transport – Department for Inland Transport (through the Provicial Office of the Vehicle Licencing Agency) and to the Ministry of Interior (see above).
   - The Dangerous Goods Transport Safety Advisor is required to write - within 60 days from his appointment and by the end of February of each year following the year of reference – a "report" concerning each operation related to the activity of the firm, the corporate management system aimed to ensure optimum safety conditions in the field of transport, loading and unloading of hazardous goods (see art. 11, par. 5 of Lgs. D. no 35/2010). The compulsory "report" is also required whenever events occur which modify the practices or the procedures that underlie the report itself, that is provisions in the field of transport, loading/unloading of hazardous goods. The "report" shall be submitted to the legal representative of the company and retained by him for at least 5 years and be produced upon request to the Local Office of the Department of Transport, Navigation and IT and Statistical Systems of the Ministry of Infrastructure and Transport (see art. 11, par. 6, of Lgs. D. no 35/2010) that is the competent body that ensures compliance with the provision for which the legal representative is responsible.

E. INDEX OF REFERENCE DOCUMENTS AND REGISTER

- Register of non compliant cases
- Plan of corrective/preventive actions
- Report of the consultant for Safety in transports

Reference Provisions and Literature

- Legislative Decree. 40 of 4/02/2000
- Legislative Decree. 35/2010

F. APPROVAL AND DISTRIBUTION LIST:

Function in charge of the Operating Procedure	**Directorate General approval**	**Distribution List**

6 Commercial Procedure

6.1 Responsibility for Marketed Products Containing Nanomaterials

Logo of Company	Company name
Code – Updating Date of issue:	TITLE: Responsability of a product, contain Nanomaterials, on the market

A. AIM

Describe the procedures and responsibilities concerning the supply of products containing Nanomaterials to the customers, making sure that the safety information is communicated in an effective manner and the necessary technical support is available.

B. RESPONSABILITY

In charge of Operating Procedure: **Commercial.**
Responsibilities for the different concerned areas in detail.

Organizational Function	D	S	I
Directorate General			
Quality Environment Safety		√	
Human Resources			
Research and Development		√	
Plant			√
Production		√	
Production Control			
Technical Services/Engineering			
Maintenance			
Procurement and Logistics			
Procurement			
Warehouse/Transport/Distribution		√	
Commercial	√		
Sales		√	
Marketing			
Customer Services		√	

Responsability:
D = Direct
S = Support
I = Informative

C. DESCRIPTION OF THE PROCEDURE

Commercial manages the product on the market for all aspects related to communication and relationships with the Customer.

SAMPLING AND APPLICATION TESTS FOR CUSTOMER

The Commercial Department requires that:

- **Customer Service** should:
  - receive requests of product samples from prospective customers (Note 1);
    - **Warehouse/Transport/Distribution** should:
  - manage the shipment of the sample, in accordance with procedure 5.2, taking care of the packaging, the labeling with indications on the severity of danger (if applicable);
- **Sales** should:
  - ensure submission of the Safety Sheet of the product and any other available information for the safe use of the product.

In the event that the customer needs to develop tests based on own applications, it is necessary to evaluate the risk conditions that may occur, with the support **of Quality Environment Safety,** involving the Safety Department of the same customer.

PACKAGING, LABELLING AND TRANSPORTATION OF THE PRODUCT

The **Commercial** Department requires that:

- **Sales** should:
  - collect order requests and enter them in the Register of Orders after having looked into the specific needs of the customer in terms of volume and delivery schedule
- **Warehouse/Transport/Distribution** should:
  - manage required samples and supplies, in accordance with procedure 5.2 and to communicate them to Production, that plans the production and transportation according to the conditions established at the moment of the purchase order
- **Logistics** should:
  - provide the correct labelling on the packaging, consistently with the severity of danger classification of the product and the choice of the hauler within the meaning of applicable legislation (procedure 5.2).

DISSEMINATION OF SAFETY AND TECHNICAL DOCUMENTATION

The **Commercial** Department for products that are distributed depending upon samples and tests requires that:

- **Warehouse/Transport/Distribution** should:
  - submit the Safety Sheet to customers at the moment of the first supply, and redistribute it, updated with the support of Quality Environment Safety, every time there are significant variations (Note 2); when the safety sheet has been submitted, the submission is entered in the register of safety sheet submission;
    - **Research and Development** should:
  - perform, with the support of **Quality Environment Safety,** a risk assessment concerning the

use of the product at the customer's premises, based on basic available information and based on the obtained information, with the support of **Customer Services,** examine the inclusion of the product in the client's processes. The results are disseminated to the clients who require them.

To offer a better customer service, further information items may be provided, such as:

- Good practices adopted in the production phase;
- Analytical methods of detection in the environmental matrices (water, air, soil);
- Waste management

CUSTOMER TECHNICAL ASSISTANCE

The activity of customer service is provided by **Customer Services**, that can rely on the support of **Research and Development**.

Based on requests, it may turn out that laboratory studies and tests are necessary to verify whether products in specific applications are suitable.

The service offered to support customers in application problems and to promote the correct use of Nanomaterials is agreed upon through procedures in writing that define the necessary level of collaboration and communication.

COMPLAINTS MANAGEMENT

The **Commercial** Department assigns the complaint management to **Customer Services** that relies on the support, depending upon the issues raised by the customer, of **Sales, Quality Environment Safety** or **Production**.

Each complaint is entered in the Register of Complaints, with the indications of the customer, lot/batch of production and details about the ascertained non compliance.

Based on the request ,**Customer Services** involves the support departments, identified based on competence, aiming to plan the solution of the raised issue. Once the complaint is overcome, the Register of Complaints is updated and the file may considered to be closed.

D. NOTES AND COMMENTS

1. Customers may submit a request based on many different reasons, for example: interest in a subsequent purchase contract, need of qualitative/ behavioral audits following a change in the characteristics, specific application needs;
2. The Safety Sheet has to be drawn up in the language of the customer who receives it in accordance with applicable legislations.

E. INDEX OF REFERENCE DOCUMENTS AND REGISTER

- Register of Orders
- Register of Safety Sheet delivery
- Corrective/preventive action plan
- Report by the transport safety consultant
- Register of complaint

Operating Procedure of this Document

5.2 – Safety in the carriage of goods.

F. APPROVAL AND DISTRIBUTION LIST:

Function in charge of the Operating Procedure	**Directorate General approval**	**Distribution List**