C4 **GREEN-SAFETY - More than safety for bionanoproducts**

Eusebio Gainza Lafuente

Biopraxis Pharmaceutical, Spain

Abstract

The big handicaps that bio-nanotechnology innovation implies may cause, under the current norms and uses if the markets, that it would be no possible to reach that those innovations get to the citizens and user in a short term. Due to this, integration and collaboration during the whole value chain or product cycle, from R&D to final consumer, is indispensable for the success of these new generations of bio-nanoproducts, also to ensure their safety during the whole life cycle.

In this way, we are conscious of this situation and of the different regulatory levels existent in the EU for different products with European labels, which are the following:

- Eco-label: Regulation (EC) No 1980/2000 of the European Parliament and of the Council and its norms for ulterior development
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and related regulations
- Council Directive 89/391/EEC. It establishes a set of base rules in order to protect the health and safety of workers

As a consequence, and taking into account that products made offside EU don't need to complete the Council Directive 89/391/EEC, a New system of European label, Green Safety, is needed, and it should include the following aspects for all the products sold in the EU:

- Procedures & tools to fully manage environmental and safety regulations.
- To redesign working environments & processes to consider environmental and safety regulations as well as the "design for all" paradigm, when designing new tools, equipment & machines
- Guidelines for workplaces that are friendly to ageing/disabled staff

- New workplaces designed, tested & scored as "more safety and comfortable" (by a significant number of test population)
- To define new business models based on new technologies to include these changes in a profitable way to future products and production systems.
- Development of a family of standards for sustainability and safety management including standards to measure & assess new products, production & services

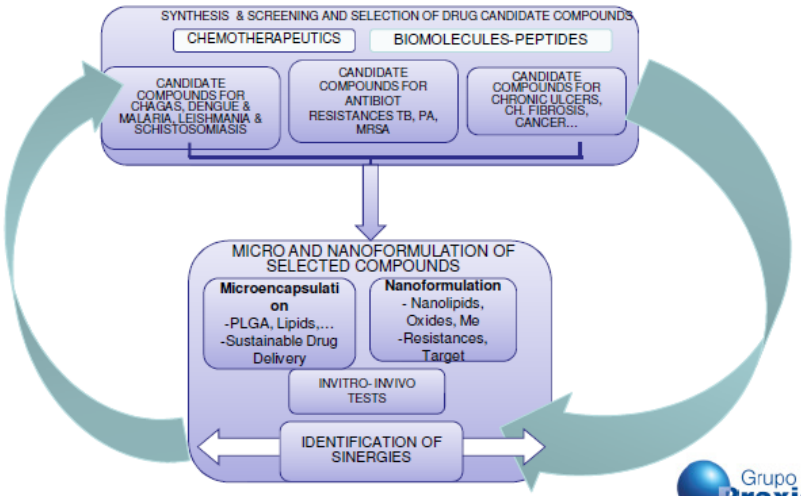
European Technology Platform on
Industrial Safety
Safety for Sustainable European Industry Growth

"GREEN-SAFETY more than Safety for Bionanoproducts"

Angel del Pozo and Oihane Ibarrola
(Chemical Engineers)
Eusebio Gainza Lafuente
Dr. Chemical Engineer
BIOPRAXIS PHARMACEUTICAL
Research Manager

Grupo Praxis

The coordinated interaction of bio&nano technologies origin of new products



Grupo Praxis

Safety Directives
(Global approach)

- Safety Directives of
  - Machines
  - Electromagnetic risks
  - Medical Devices 93/42/EEC
  - GMP for pharmaceutical products
  - High Accidents (Seveso)
  - ……
- Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work

Obligatory Directives

Enviromental
(Directives& Regulations)

- Directives of Water Quality
- Directives of Air Quality
- Directives of Wastes Recycling
- Directives of Dangerous Materials & Wastes: 67/548/EEC and1999/45/EC
- Directives….
- Regulation (CE) 1980/2000 Eco-Label Certification
- Regulation (CE) 834/2007 Organic Aliments Certification

Voluntaries Regulation of Labels

March 17, 2014

Grupo Praxis

Eco-label: Regulation (EC) No 1980/2000 of the European Parliament and of the Council

o The eco-label aims to promote products with a reduced environmental impact compared with other products in the same product group. The following are excluded from the Regulation scope: foodstuffs; drinks; pharmaceutical products; medical devices; substances or preparations classed as dangerous & products manufactured by processes likely to significantly harm human beings and/or the environment.
o The environmental requirements are defined with reference to the Life Cycle Assessment matrix given in Annex I to the Regulation and are subject to the methodological requirements set out in Annex II.
o Eco-label criteria must be established by product group by the European Union Eco-Labelling Board (EUEB) and published in the Official Journal of the European Union.
o The products must fulfill the following conditions:

- Applying for the award of a European eco-label and certificated by European Authorities is possible for products made in EU and off-side EU.
- Applications of an eco-label are subject to payment of a fee and annual fee.
- Any product whith eco-label is recognisable by the 'daisy' logo
- The eco-label products must complete as minimum the European Regulation.
- The Commission and the Member States must promote the use of the eco-label by means of awareness-raising actions and information campaigns.
- They must ensure coordination between the Community scheme and existing national schemes.

March 17, 2014

Grupo Praxis

Example: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Medical devices
The design and manufacture of medical devices is subject to essential requirements concerning protection of the health and safety of patients and users of these devices.
Essential requirements
Medical devices **must not compromise the clinical condition or the safety of patients** and not present any risk to the persons implanting them, or to other persons. These devices must achieve the performances intended by the manufacturer. They must be designed in such a way as to withstand the storage and transport conditions.
Harmonised standards shall implement and transpose by Member States, which shall also include the monographs of the European Pharmacopoeia.
All devices must be subjected to a conformity assessment procedure by independent bodies contributing to the application of procedures which represent a minimal risk.
Placing on the market and free movement, under MS control only if the MDs meet the requirements of this Directive and do not compromise the safety and health of patients
European databank is to store the data on registration of manufacturers; certificates issued, amended, suspended, withdrawn or refused; and obtained in the vigilance procedure and on clinical investigations. The manufacturer must immediately inform the competent authorities of any incident causing death or damage to the health of a patient, Member States must take all appropriate measures to withdraw from the market devices conforming to the Directive which are liable to compromise the health and/or safety.

Safety Directives (Global approach)

Depending on the level of risk of the product, the CE marking is affixed to a product by the manufacturer or authorized representative who decides whether the product meets all the CE marking requirements. If a product has minimal risk, it can be self-certified where manufacturers a Declaration of Conformity and affixes the CE marking to their own product. Manufacturer then must do several things:

1. Decide whether the product needs to have a CE marking and if the product applies to more than one directive it needs to comply with all of them.
2. Choose the conformity assessment procedure from the modules called out by the directive for the product. There are several modules available for the Conformity Assessment Procedures as listed below:
   Module A – Internal production control.
   Module B – EC type-examination.
   Module C – Conformity to type.
   Module D – Production quality assurance.
   Module E – Product quality assurance.
   Module F – Product verification.
   Module G – Unit verification.
   Module H – Full quality assurance.

These will often ask questions about the product to classify the level of risk and then refer to the "Conformity Assessment Procedures" chart. This shows all the acceptable options available to a manufacturer to certify the product and affix the CE marking.

Anywhere, the products with CE label made offside EU don´t need complete the **Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work** and of course not the European Environmental and Seveso Directives

CE Products made offside EU don´t need complete the Council Directive 89/391/EEC

Health and safety at work – general rules

The European Union (EU) establishes a set of base rules in order to protect the health and safety of workers. To this end, this Directive establishes obligations for employers and workers, in particular to limit accidents at work and occupational diseases.

This Directive should also improve the training, information and consultation of workers:

➢The measures aim to eliminate the risk factors for occupational diseases and accidents.

➢Employers are obliged to ensure the health and safety of workers to establish means and measures for protecting workers, including:

- Activities of prevention, information and training of workers
- Avoid risks or manage those risks that cannot be avoided
- Give appropriate instructions to workers by promoting common protective measures
- Adapt working conditions, equipment and working methods by taking into account developments in techniques
- Activities of **first aid, fire-fighting and the evacuation** of workers in danger
- Establish **protective and preventative services** in their company or establishment
- **Monitoring the health** of workers. Each worker requests regular health checks
- Consult workers and their representatives concerning all related to health and safety

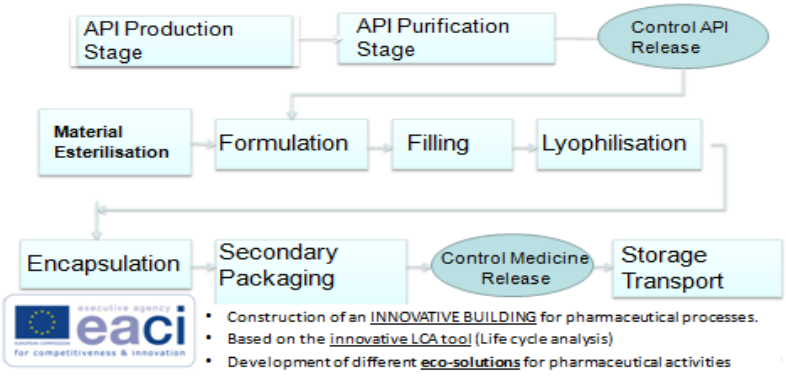
➢Each worker must take care of their own health and security and that of persons affected by their acts or by their omissions at work, in particular: use equipments, PPE, tools and substances connected to their activity of work and inform the employer of any work situation which represents a serious and immediate danger.

Grupo Praxis

PRAXIS EXPERIENCES

Ecopharmabuilding

SUSTAINABILITY OF EFFICIENT PRODUCTION PROCESSES OF NANOBIOMEDICINES of the Praxis Group



eaci executive agency for competitiveness & innovation

- Construction of an INNOVATIVE BUILDING for pharmaceutical processes.
- Based on the innovative LCA tool (Life cycle analysis)
- Development of different eco-solutions for pharmaceutical activities

Grupo Praxis

Sustainability Projects of Praxis group

Reduction of clean rooms volumes	50-60%
Reduction of energy consumption	30%

Reduction of resource consumption and wastes: 40 %

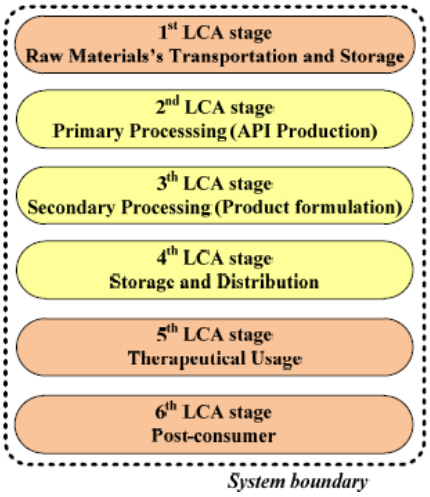
Investments reduction in the building: up 30%

Top Level Research Objective: GS Green-Safe Products and Production

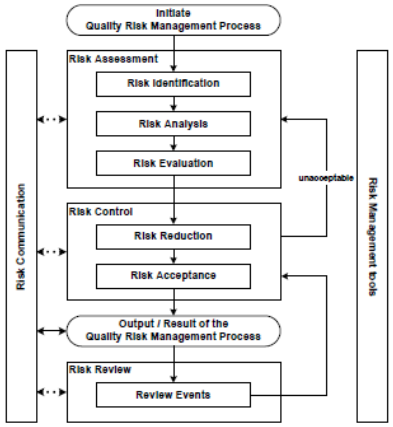
- Green Jobs/ Sustainable production:
  - To redesign working environments & processes to consider environmental and safety regulations as well as the "design for all" paradigm, when designing new tools, equipments & machines
  - Guidelines for workplaces that are friendly to ageing/disabled staff
  - New workplaces designed, tested & scored as "more safety and comfortable" (by a significant number of test population)
- Value chain and interdependencies :
  - Procedures & tools to fully manage environmental and safety regulations
  - Development of a holistic sustainability and safety management systems (LCA, ERP, MRP,...) for the assessment & management
  - To develop procedures & tools facilitating sustainable management
- Green-Safety :
  - Procedures & tools to fully manage environmental and safety regulations.
  - To define new business models based on new technologies to include these changes in a profitable way to future products and production systems.
  - Development of a family of standards for sustainability and safety management including standards to measure & assess new products, production & services

Grupo Praxis

LCA and Risks Assessment: Principal tools



Overview of a typical quality risk management process



Grupo Praxis

Indicative Level of Risks Evaluation-Matrix and the impacts in the Life Cycle of Products

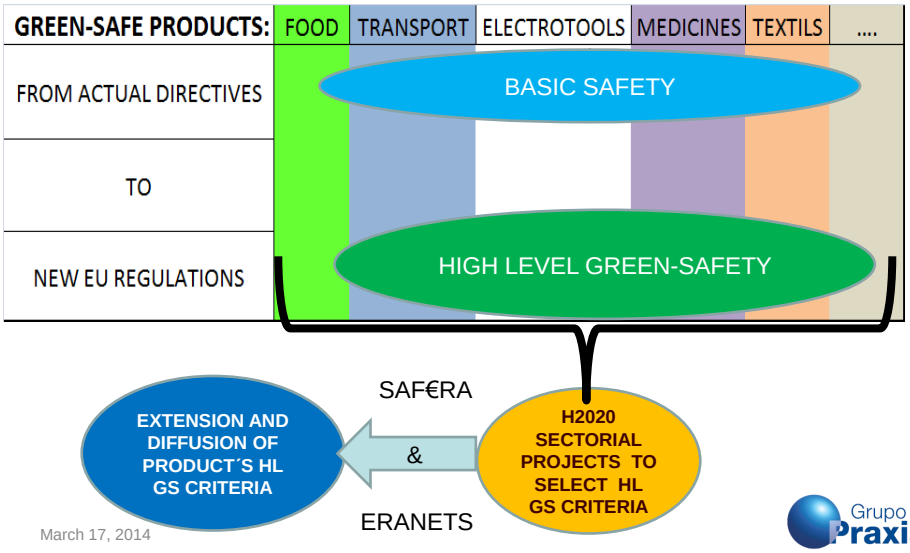
AREA	Impacts to include in the Analysis	Life Cycle of products: Production of RM	Transport and Stock of RM	Manufacturing	Stockand Distribution	Therapy application	End of life
ECOLOGIC	Soil contamination						
	Water contamination						
	Air pollution						
	Trophic chain affections						
	Consume of natural resources						
ECO-SOCIAL	Physic, Chemical and Biologic Risks for workers						
	Physic, Chemical and Biologic Risks for Public						
	Physic, Chemical and Biologic Risks for consumers						
ECONOMIC	Costs						
	Impact on the market						
	Add Valor						
	Quality looses						

3 H IMPACT
2 M IMPACT
1 L IMPACT

LCA-Sustainable, Risk Analysis and Risk Assessment tool for the Analysis of sustainability of Products and their Processes in the Life Cycle (Economical, ecological and social aspects included)

Grupo Praxis

EUROPE GREEN-SAFETY: European Regulations Ideas for "EUR-GS" Label



March 17, 2014

Grupo Praxis

http://www.grupo-praxis.com

Dr. Eusebio Gainza
Praxis Research Manager
egainza@praxisph.com

Grupo Praxis