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PLATFORM: Safe-by-design framework for the development of new pilot lines for the manufacture of carbon nanotube-based nano-enabled products for automotive and aeronautics

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- **PLATFORM** was born in 2016 with the goal of demonstrate the overall **feasibility and competitiveness** of the **new products (carbon nanotube-based nano-enabled products) and production technologies** closer to the market (**TRL6**).
- However the project's impact goes beyond, and PLATFORM also developed a **business platform** to **MANUFACTURE and COMMERCIALIZE** these products in the European market from 2020 onwards (**TRL9**).

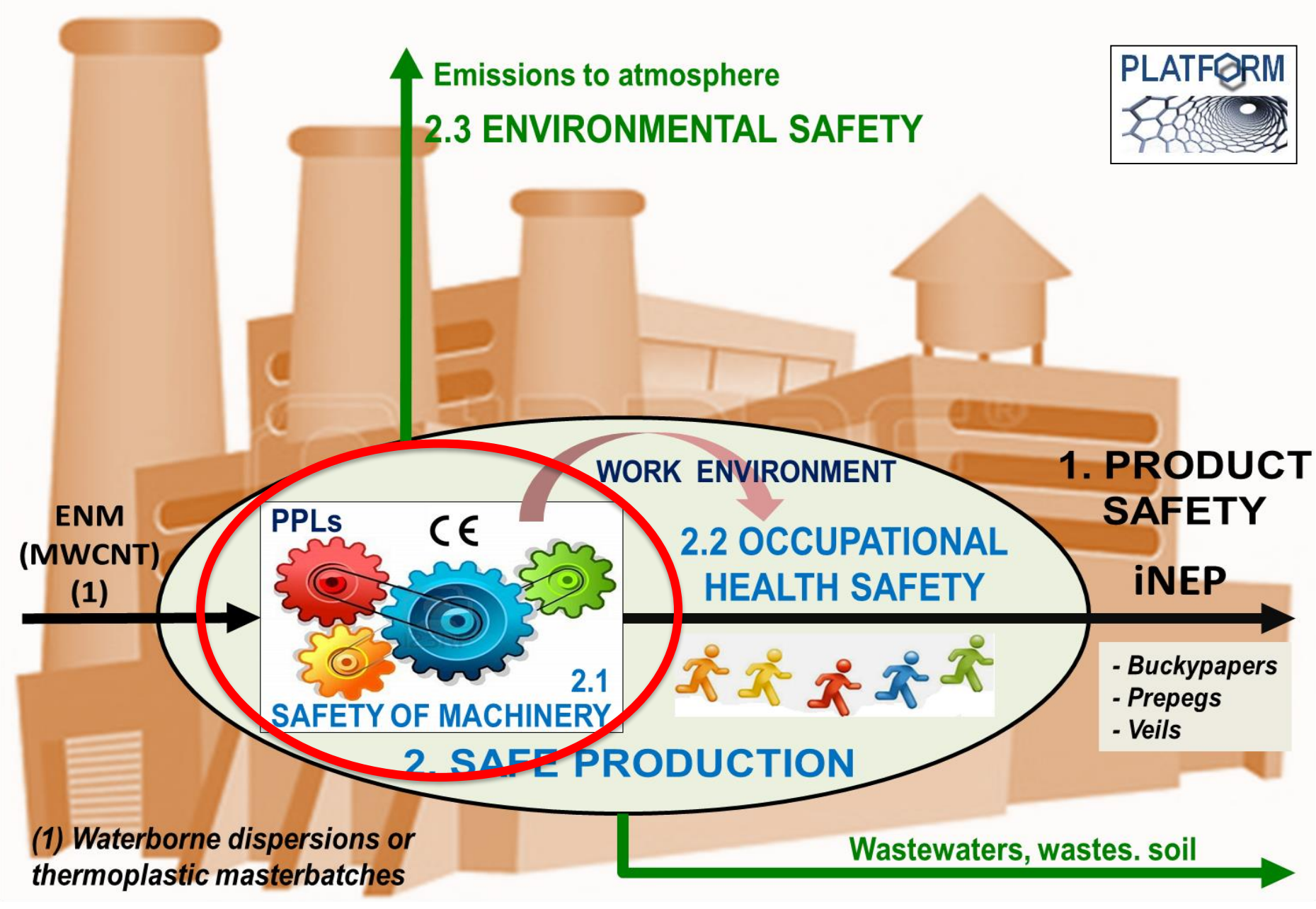
The beginning of the story: the challenge

	THE THREE TYPES OF PLATFORM PILOT LINES (PPLs)		
	▪ Input materials will be CNT-based formulated products such as waterborne dispersions or thermoplastic masterbatches. ▪ Output products will be CNT-based NEPs, such as buckypapers, CNT treated prepregs and CNT doped non-woven veils. ▪ PPLs can include wet or dry process steps as well as thermal stages (e.g. extrusion, drying).		
	1. Buckypapers PPL	**2. CNT-doped prepregs PPL**	**3. CNT-doped veils PPL**
CNT-based NEP manufactured			
	Buckypapers are self-supporting sheets comprised of entangled CNTs.	CNT-doped prepregs are conventional carbon fiber prepregs doped with CNTs.	CNT-doped veils are non-woven thermoplastic textile materials containing CNTs.
Production capacity	2,000 m^2/year	120,000 m^2/year	9,000 m^2/year

What kind of CNT-based NEPs and PPLs?

- **Free movement of goods**
- Common rules across EU
- Clear legal framework for business
- If manufacturers follow these rules, their products can be sold freely in the market
- Safety as one of the key building blocks
- Safety - products marketed in the EU have to meet high safety and environment protection requirements (regulations)

EU Single market and building blocks



PLATFORM Framework for SbD

- The **Machinery Directive 2006/42/EC (MD) – transposed into national legislations** - is the European regulatory framework for the design and construction of **new machinery** - as the PPLs.
- PPLs are not required to comply with the provisions of Directive 2006/42/EC **until they are put into service (expected in 2020).**
- **But in 2020, all requirements of the MD will be mandatory for PPLs.**

EU regulatory framework: The Machinery Directive 2006/42/EC (MD)

Prevention through Design (PtD), **Safe-by-Design (SbD)** or Safety Integration (SI) are similar concepts that refer to **design out hazards or minimize risks early in the design process (1989)**

1. Eliminate or reduce risks as far as possible (**inherently safe machinery design** and construction),

2. Take the necessary **protective measures** in relation to **risks that cannot be eliminated**,

3. **Inform users of the residual risks** due to any shortcomings of the protective measures adopted, indicating whether any particular **training** is required and specify any need to provide **personal protective equipment (PPEs)**.

Principles of Safety Integration (SbD) (MD)

Essential Health and Safety Requirements vs. Harmonized Standards

	EHSRs - Emissions of hazardous materials a
1	Machinery must be designed and constructed in such a way that *ris* *the skin, eyes and mucous membranes and penetration throug* substances which it produces can be avoided.
2	Where a hazard cannot be eliminated, the machinery must be so substances can be *contained, evacuated, precipitated by water s* *equally effective method.*
3	Where the process is not totally enclosed during normal operat containment and/or evacuation must be situated in such a way as to

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 14123-1

Safety of machinery - Reduction of risks to health resulting from hazardous substances emitted by machinery - Part 1: Principles and specifications for machinery manufacturers
(ISO 14123-1:2015)

CEN

CNTs are chemical agents for a

EHSR for emissions of HM&S (such as MWCNTs)

		Exposure potential band			ISO 12901-2:2014
Hazard band		**EB 1**	**EB 2**	**EB 3**	**EB 4**
	A	CB 1	CB 1	CB 1	CB 2
	B	CB 1	CB 1	CB 2	CB 3
	C	CB 2	CB 3	CB 3	CB 4
	D	CB 3	CB 4	CB 4	CB 5
	E	CB 4	CB 5	CB 5	CB 5

Control band matrix as a result of hazard band and exposure potential band

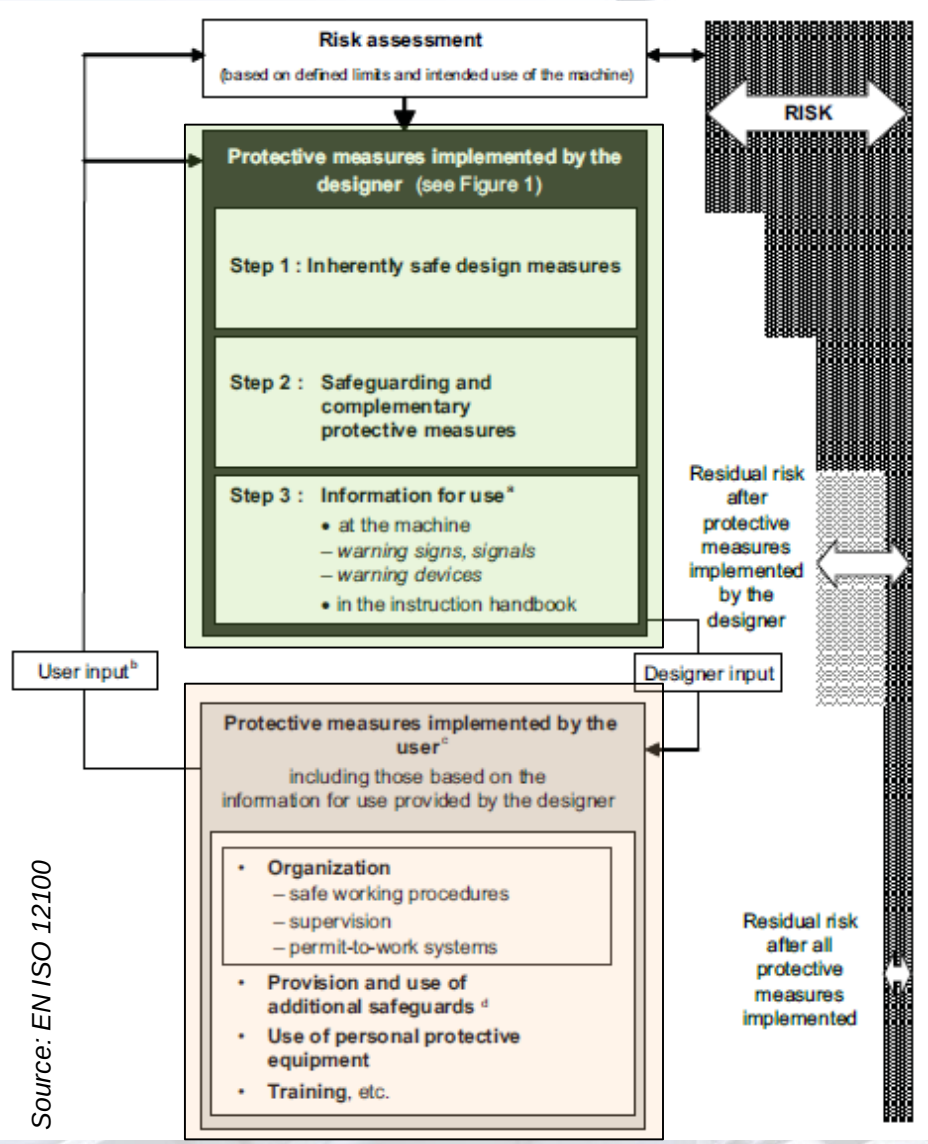
- CB 1: Natural or mechanical general ventilation;
- CB 2: Local ventilation: extractor hood, slot hood, arm hood, table hood, etc.;
- CB 3: Enclosed ventilation: ventilated booth, fume hood, closed reactor with regular opening;
- CB 4: Full containment: glove box/bags, continuously closed systems;
- CB 5: Full containment and review by a specialist: seek expert advice.

Contradictory information about the hazardousness of MWCNTs vs. ALARP

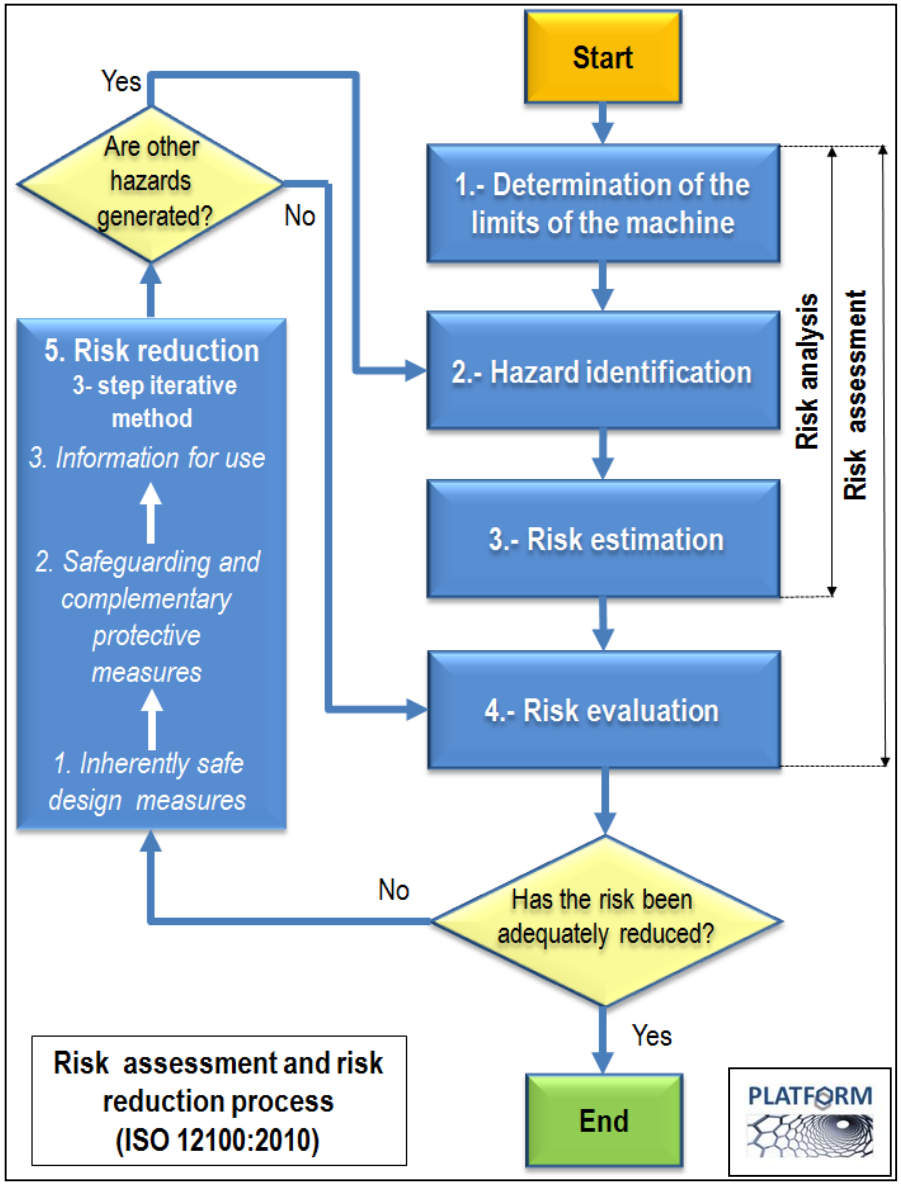
How to design (SbD), construct and put into service three safe PPLs for manufacturing CNT-based NEPs?

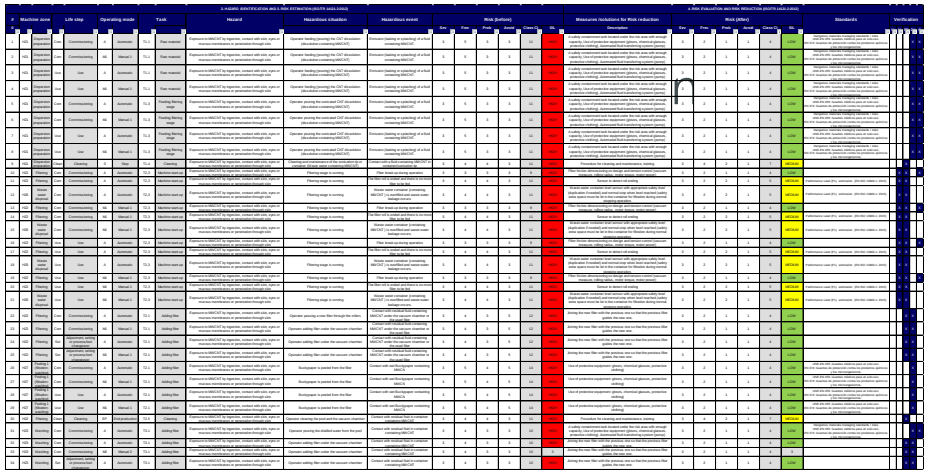
- **Nano-enabled** products (No ENMs)¡
- **Contradictory** information about CNTs¡
- No specific mandatory **EHSRs** (MD) for nanosafety¡
- No specific **harmonized standards**¡

PLATFORM Starting point for SbD



PPLs design and construction taking the results of the risk assessment into account. Obviously this process involves design aspects that go beyond specific aspects of nanosafety.





- **Machine zone**
- **Relevant phases of life cycle**,
- **Expected uses** (IU/EFM)
- **Operation modes**
- **Hazards, hazardous situations, hazardous events**
- **Risk before/after Mesures por risk reduction**
- **Standards**
- **Verification (VI, M, FT, DV, C)**

Main steps in the process of PPLs risk assessment and risk reduction, according to EN ISO 12000 /EN ISO 14123-2

1. Use the **generic SbD approach** of the **Machinery Directive** to conduce the design of PPLs (**Do not invent¡)**
2. Use relevant **generic standards** to **guide** the risk assessment and the design of preventive and protective measures (**EN ISO 12100 and EN ISO 14123-1/2).**
3. Integrate in the design the information from **relevant nanosafety guidelines and standards,** on **the best available practices** to prevent, assess, control and manage CNT emissions and workers exposures.
4. Use **small scale models** to simulate the final manufacturing modules and **refine the design**
5. **Use our best knowledge and engineering practices**

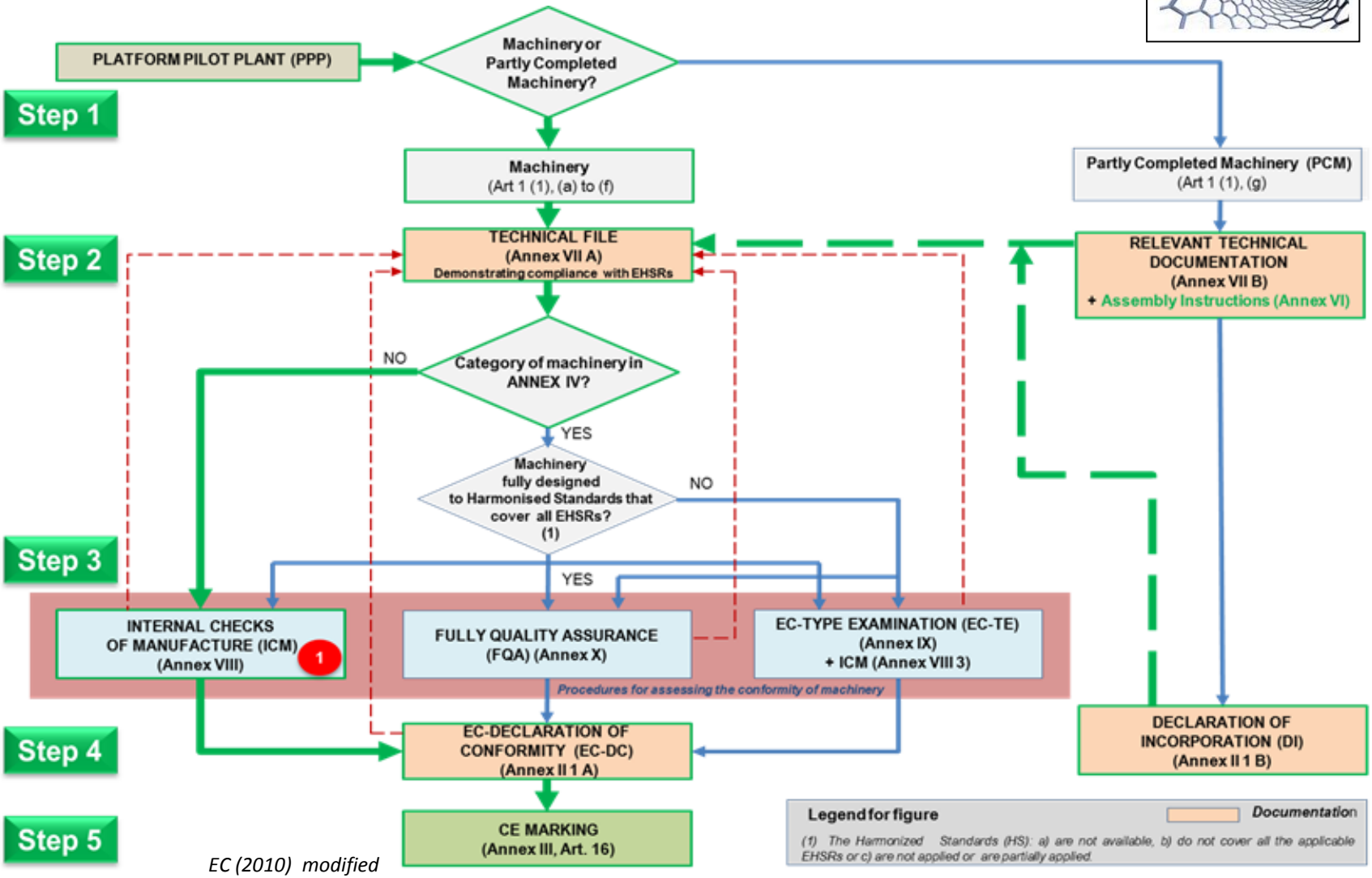
Summarizing the SbD strategy of PPLs

1. **Specific measures** to protect the H&S of potential exposed workers were taken in accordance with the national legislations and the best available practices (DR+WP+PPE).
2. **Verification of safety requirements and measure**s for risk reduction by 1) Visual inspection, 2) Measurement, 3) Functional testing, 4) Design validation or 5) Calculation.
3. Special attention to the **verification by measuring of potential airborne CNT emissions and exposures**.

Summarizing the strategy for PPLs –Commissioning (Testing, validation)

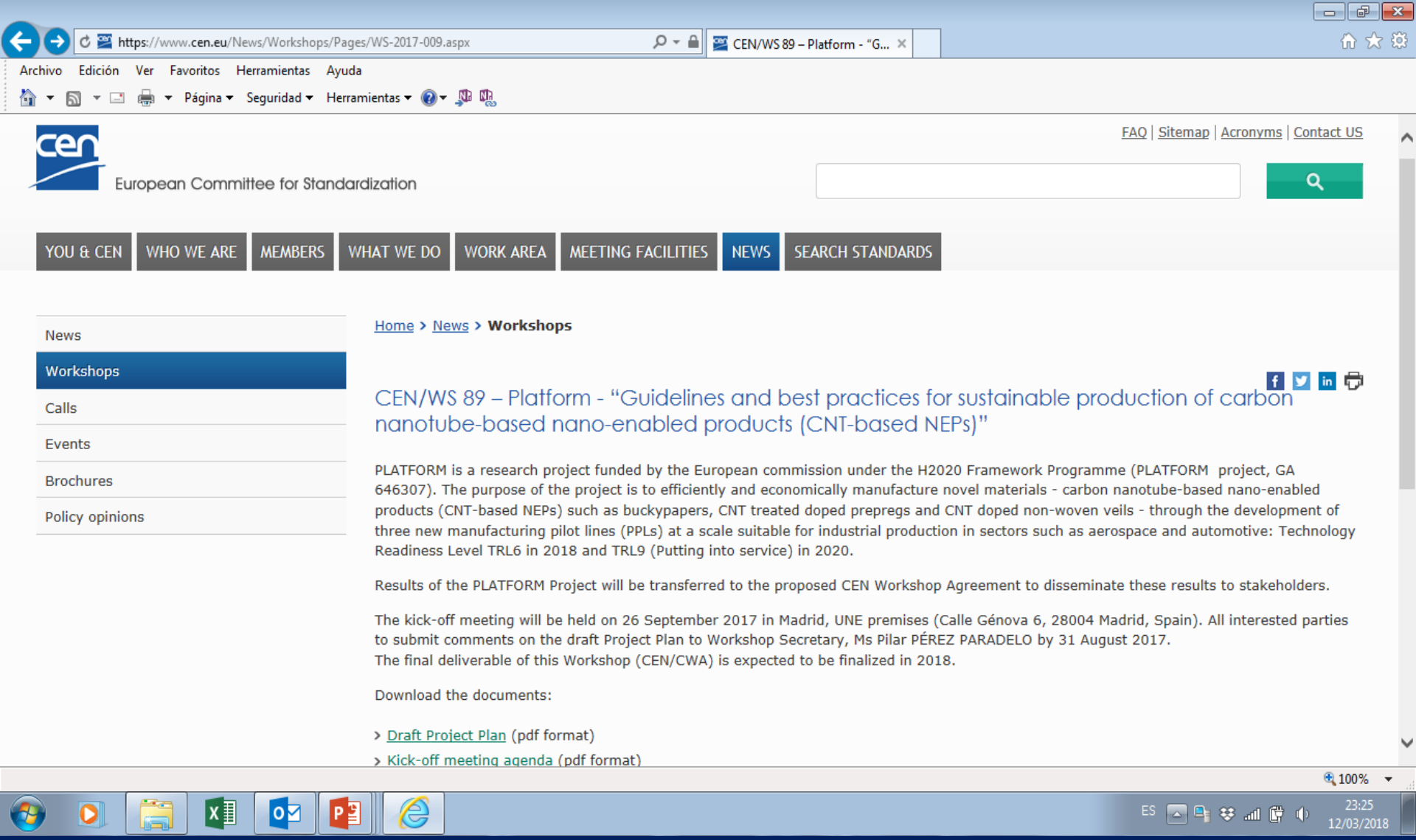
- **Strategy 1: Measuring airborne emissions (Sources)**
  - ✓ According to EN 1093-1 /11 (Field tests)
- **Strategy 2: Measuring exposures**
  - ✓ If previous strategy is **unfeasible (EN ISO 14123-1)**
  - ✓ An **indirect technique**, by measuring the **occupational exposure (**EN 17058)
- **Instrumentation and methods**
  - ✓ DRIs + Sampler at source +Personal samplers + Off site analysis (EC NIOSH 5040 + CNT structures counting ISO 14966)

Strategies for the verification of protective measures by measurement (EN ISO 14123-1): emissions / exposures

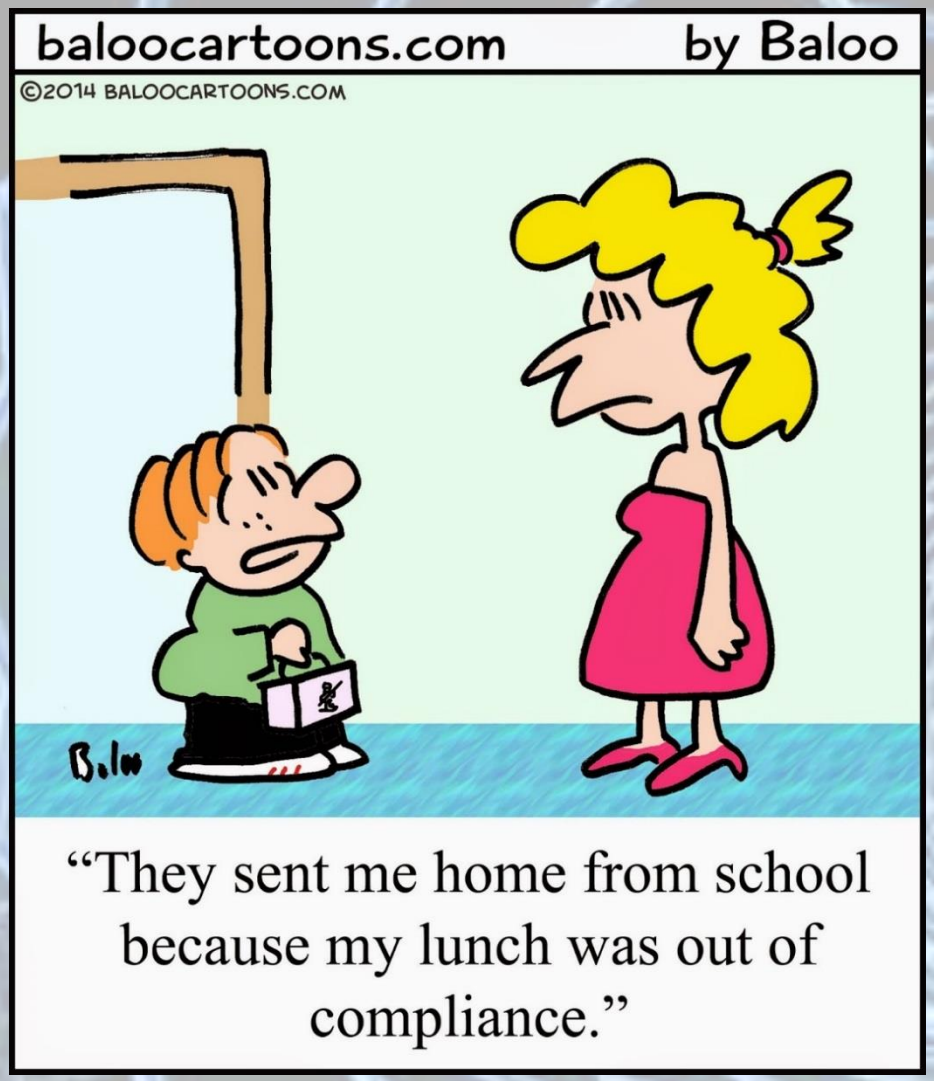


EC (2010) modified

From here till 2020



Encapsulating the know-how of PLATFORM on SbD (CWA)



"Safe by Design" simply means Common Sense

Thank you very much for your attention!

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PLATFORM I.NANO EUSKO JAURLARITZA GOBIERNO VASCO

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