

# Impact of regulations on industry

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# ***NIA: the voice of nanotechnology industries***

**NIA supports the development of nanotech innovations** that improve the lives of consumers, preserve our environment and advance our world

- Support for development of a robust regulatory framework
- Business and scientific networking and promotion for Members
- Working with the EC to build the nanotechnology ecosystem

**Brussels  
Head  
Office**

Team in Belgium,  
UK, France,  
Netherlands,  
Sweden/Portugal

Skills in  
regulatory  
development,  
project delivery,  
advocacy and  
communications



# *Aim of presentation*

- To look at nanotechnology applications from the market perspective
- Understand how regulations affect industrial development and sectors

# Nano from the market end

- The invention is the start of the game
- Not a product until somebody pays you for it
- Many years after the invention and patent
- Market and consumer: Is your nano-enabled product:
  - Better and/or Cheaper and/or Sexy?
- Nano has a tough ride to market:
  - Hard to replicate characterisation – open to challenge
  - Complex, changing regulations, high cost to meet regulatory requirements (33% of dev cost)
  - Not necessarily the USP of your product
  - Many markets do not have the margins for higher cost
  - Food vs medical devices vs cancer therapies
  - Business planning **MUST** plan for regulatory cost and impact



# *What is a regulation?*

*a rule or directive made and maintained by  
an authority*

- To ensure safe and effective products
- Regulatory authorities at national and EU level
- To reach market, must achieve regulatory approval
- Requires submission of data for scrutiny
- Not the same as a standard



# *The impact of regulation on market development*

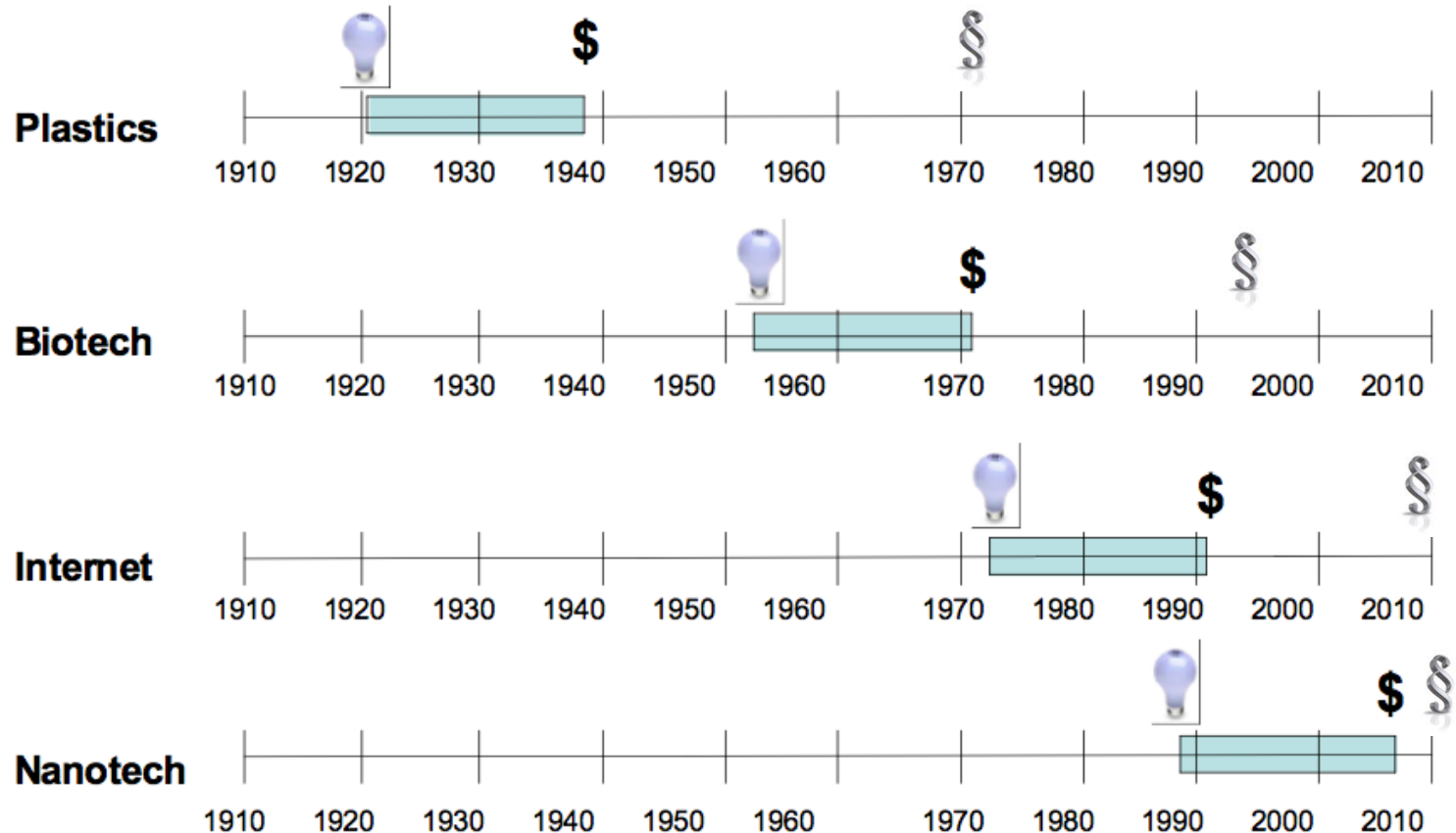
- Regulation is an economic driver
  - For companies creating products
  - For service providers supporting product development
  - For investors seeking a return
  - *All three critical for a successful sector*
- Does not mean it is designed to drive innovation
- Creates certainty & de-risks return on investment



# How regulation shapes the nano industry

- Definition
- \*\*\*\*Regulatory updates\*\*\*\*\*
- Increased certainty for development pipeline
- Innovators can present more convincing business plans
- More companies can start or expand
- Service sector will invest and expand (mature sector)
- Characterisation and reg dossier data faster and cheaper
- Route to market access faster and cheaper
- More market applications as cost reduces
- Nano accelerates as a commercial enabler

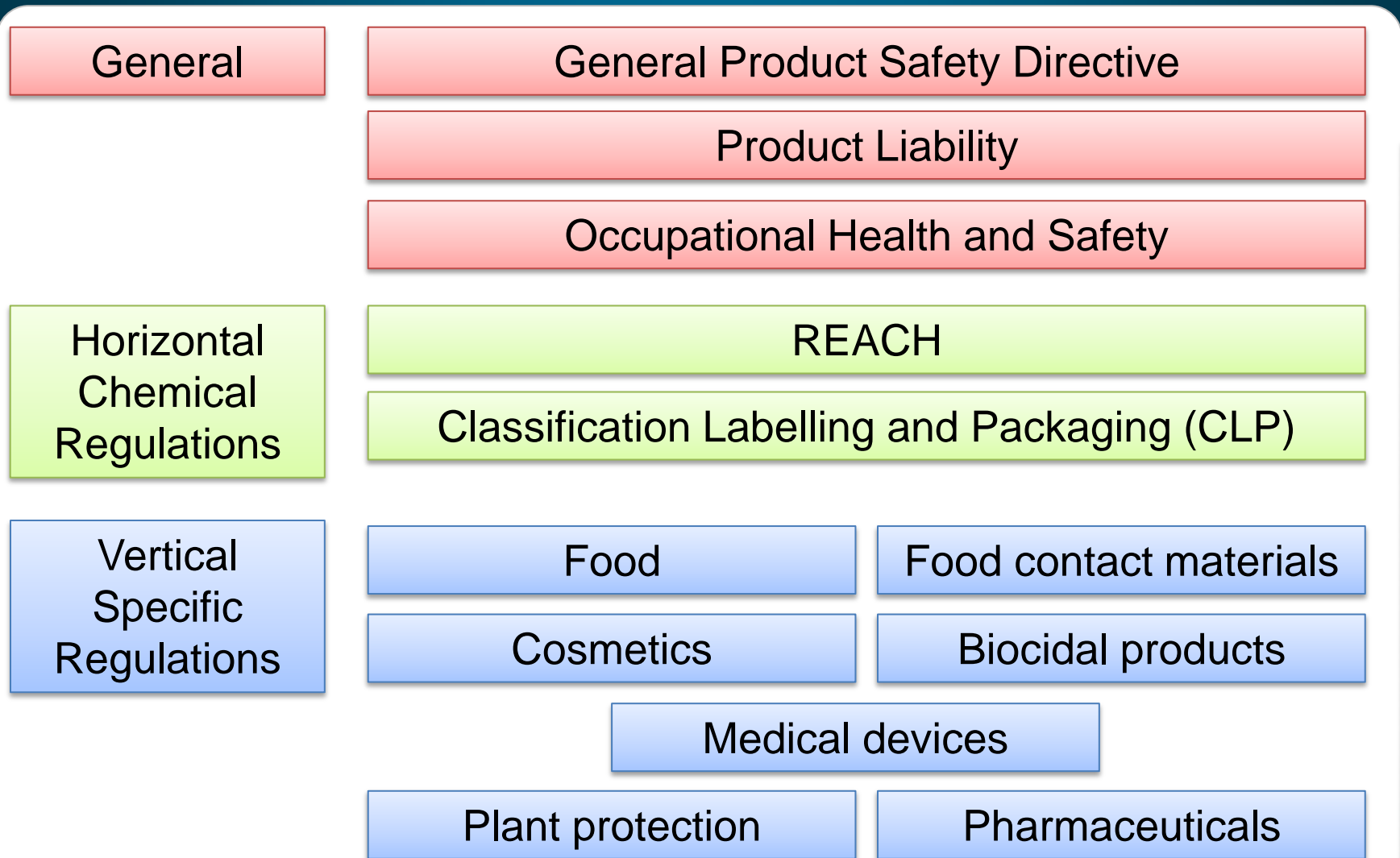
# Commercialisation patterns and regulations



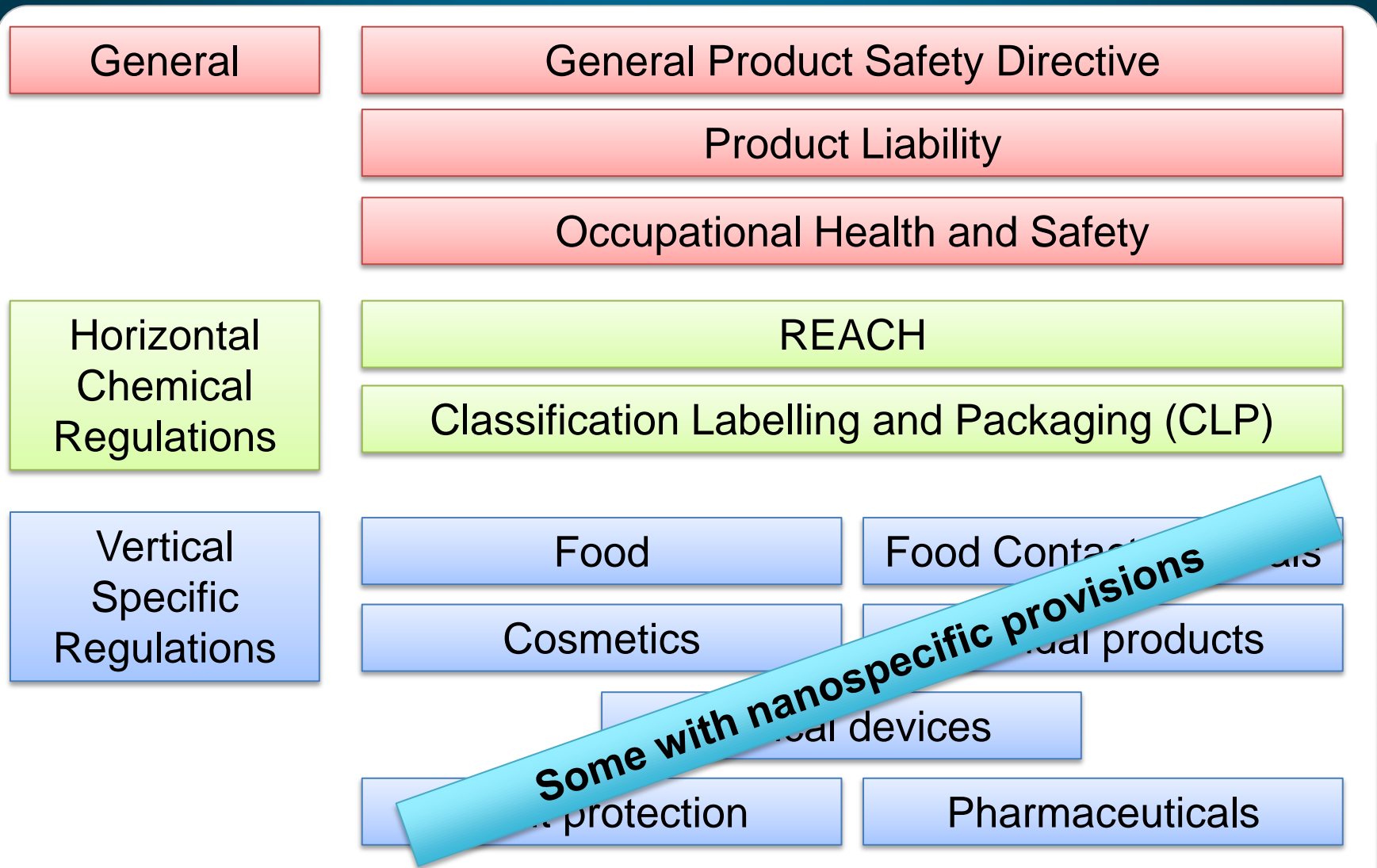
[Modified from Lux Research Inc., Murday et al Nanomedicine NBM, 2009, Vol.5(3),251-273]



# The European regulatory landscape

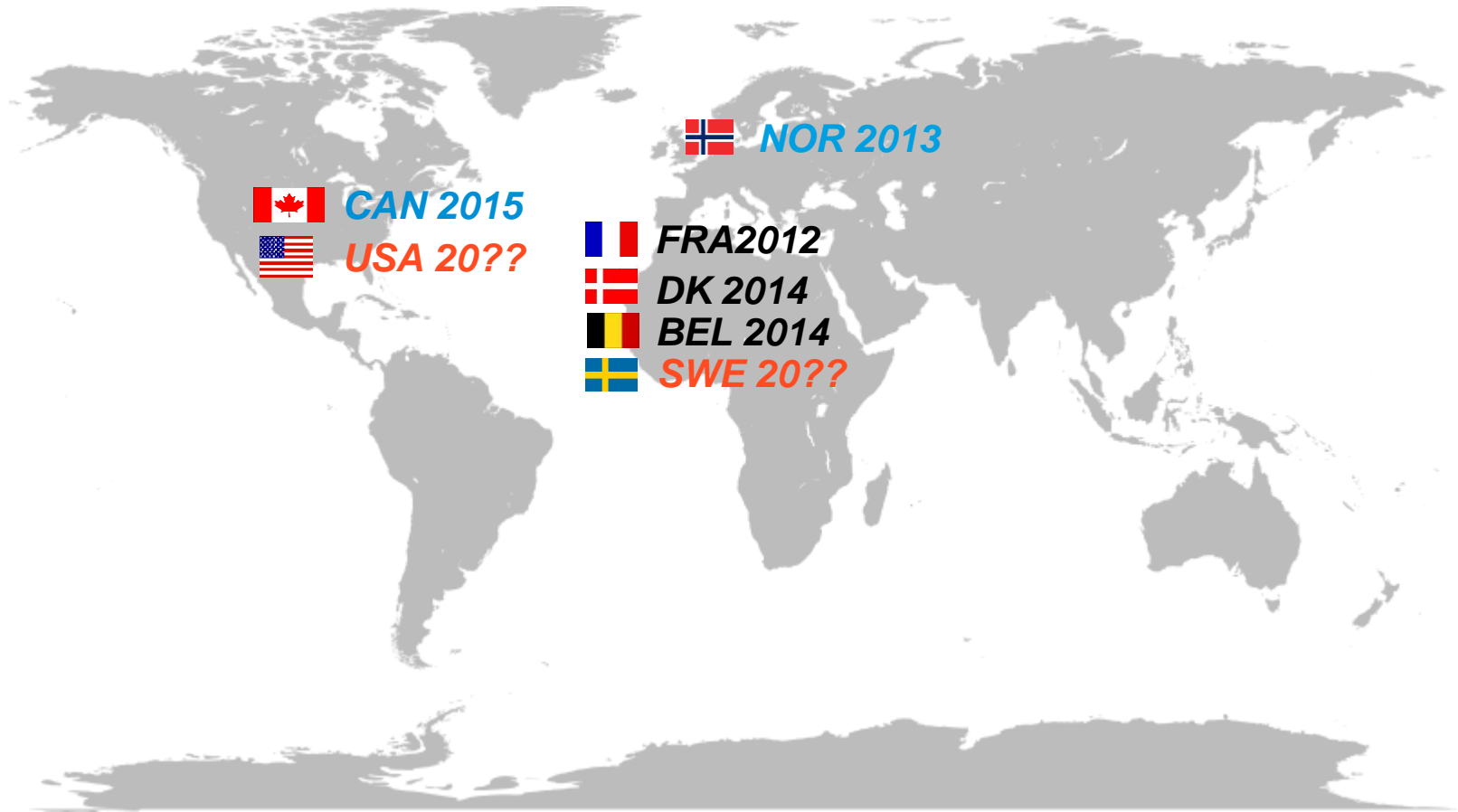


# The European regulatory landscape



# National Nanomaterial Registries

- In this section:



Countries with mandatory reporting schemes for nanomaterials

# *What does 2017 bring in the EU?*

- Nanomaterial definition awaiting final publication for consultation and then adoption – process underway for many years
- Once adopted, it will be implemented into regulations across sectors
- Challenges remain from industry in extent of testing and read across between nanoforms
- Also challenges between sectors e.g. food debating soft vs hard nanomaterials

# *In summary*

- Regulations drive sector development
- Balance between ensuring safe products and enabling innovation to reach market
- Europe is cautious, stung by GM crop experience
- Nano is a rapidly moving target and regulations will always lag behind science of innovation and characterisation
- Potential for significant commercial sector once regulations mature creating a de-risked pathway
- For long term commercial sustainability, need to think beyond current regulations – graphene spray today but probably not tomorrow

*Thank you*

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