



# International perspectives in risk-based regulatory delivery Contrasted approaches and results

Case study presentation - 2018 CFR Regulatory Conference

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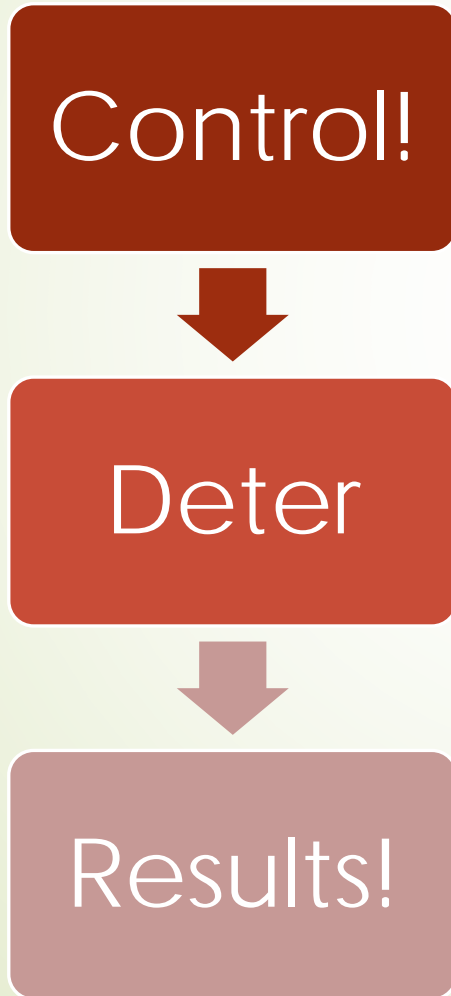
# Overview: contrasted approaches in regard to risk – contrasted outcomes too?

- “Risk-based” is not universal – and not as uncontroversial as it seems
- It is not only about “innovative” approaches, or about inspections (be they pre- or post-market) it can apply (or not) to the entire set of regulatory procedures and instruments (permits, approvals etc.)
- Main argument to resist risk-based approaches = protection – is it a valid argument?
- How about the applications of risk-based approach we might not “spot” because we are too familiar with the existing system?
- What interesting comparisons can international practice offer, both on application of risk-based approaches, and on outcomes?



# Case 1: Occupational Safety in Britain, Germany and France - FACTS

## Traditional view of enforcement



## Findings from case study

- No link between many inspections and good results
- No link between frequent sanctions and good results
- Targeting, differentiation, engagement, prevention seem to give results
- Better results for the "flexible" approach, "as far as reasonably practicable"
- "Deterrence" model not validated
- "Risk-based" is not just "risk-focused deterrence" – it means "focused on preventing risks"

# Case 1: Occupational Safety in Britain, Germany and France - LESSONS





Health and Safety  
Executive

# The absolutely essential health and safety toolkit for the smaller construction contractor

## 2 Provision of welfare facilities at transient construction sites CIS46

### Working at height

- Have you planned the work properly and identified suitable precautions to make sure work can be carried out safely?
- Have you thought about whether you can avoid working at height by using different equipment or a different work method?
- Can you use equipment that will prevent a fall from happening, such as scaffolding or a mobile elevating work platform?



# Risk-focus during inspections

1. Select the areas you will focus on for this inspection
2. For each area, look at
  - ....**physical** controls
  - ...and **management** controls.
3. Make a judgement for each area sampled about how well (or not) the business is managing risks in this area
4. Consider what action you will take



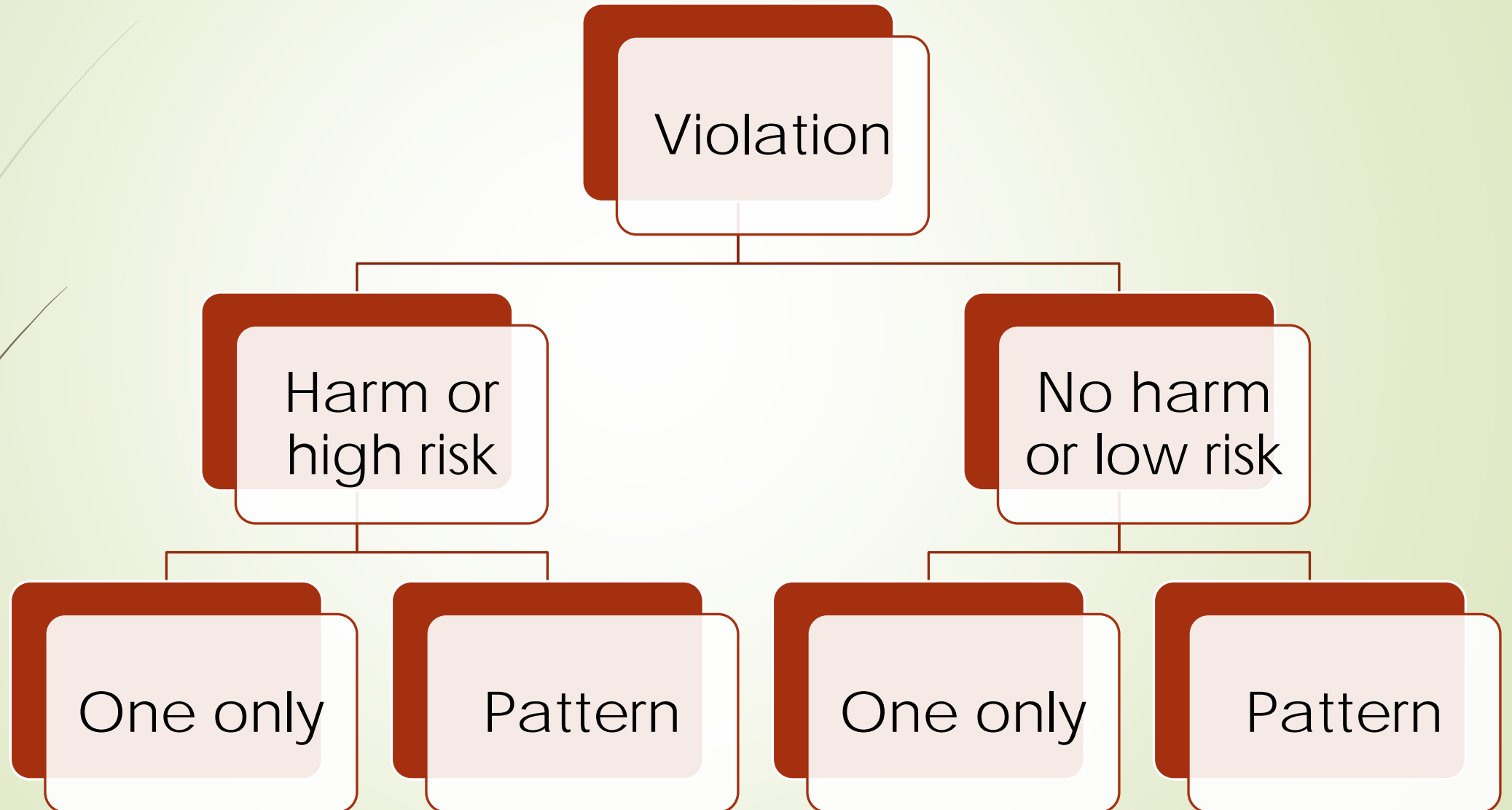
Is the set up, equipment safe?

Does anyone check? Regularly?

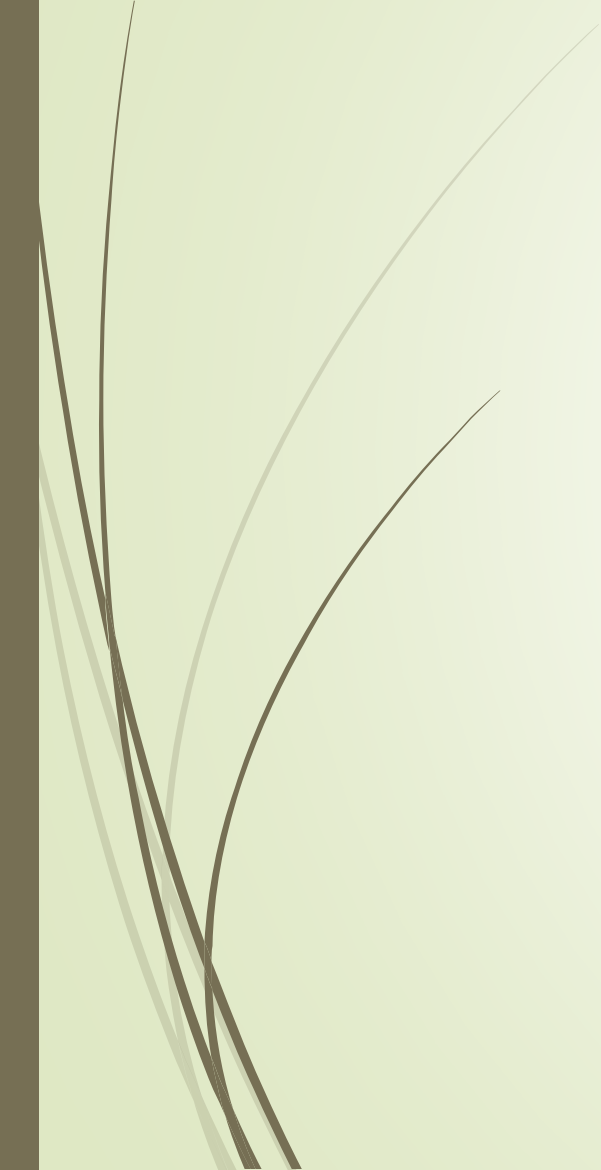


*(HSE material – with kind permission)*

# Enforcement-Management Model







# Case 2: Permitting of economic activities in Greece, Italy and France

- Greece pre-reform: everything needs a permit/license, and not just one, but several – and requirements are not aligned
- Italy ongoing reform: initially similar situation – permits/licenses replaced by self-certification – but requirements not reformed
- France: qualification requirements for professionals, but few licenses/permits, outside of high-risk establishments (and then one consolidated permit as most frequent case)
- Permitting is a regulatory delivery choice – the general requirements in many spheres are EU-harmonized, but control (*ex ante* and *ex post*) are not
- Major impact on competitiveness, growth – how about effectiveness?
- Rapid growth in reformed sectors in Greece since mid-2017...



# Case 3: Non-Food Products Safety in the EU, Canada, Australia and the US

- Different approaches in spite of similar level of economic and market development, and parallel safety expectations
- US: very strict (incl. certification) for toys/children – is this really where most risks are? What is the definition of risk?
- Canada: flexibility but “big stick” in reserve (CCPSA) / strict certification for electrical appliances. Rationale for difference?
- Australia: somewhat similar to Canada – complaints about system being “too lax”. Multiple regulators.
- EU: roughly “hazard-based” / “risk-based” requirements for conformity assessment – reliance on third-parties for testing and certification – liability for producers and third-parties
- Data on differences in outcomes? Unfortunately not much...



# “Risk-based” is not just about targeting – comprehensive approach

- Targeting is important – and it requires information sharing, “intelligence” (see HSE “Find It”)
- Risk-focus *during inspection* and for *enforcement decision* (HSE Enforcement Management Model)
- Differentiating approaches for different types of risks and different target groups – emphasize prevention, upstream work
- Risk-based approach also important to decide which activities should require a license/permit or not – benchmarking can help get a fresh view
- Risk-based approach in product safety: what is really high risk? differentiate conformity assessment approach based on risk?
- More evaluation/comparison of outcomes is needed!