



**WORLD BANK GROUP**  
Trade & Competitiveness

# Reforming Regulatory Inspections for Manufacturing

## International Experience and Application to Greece

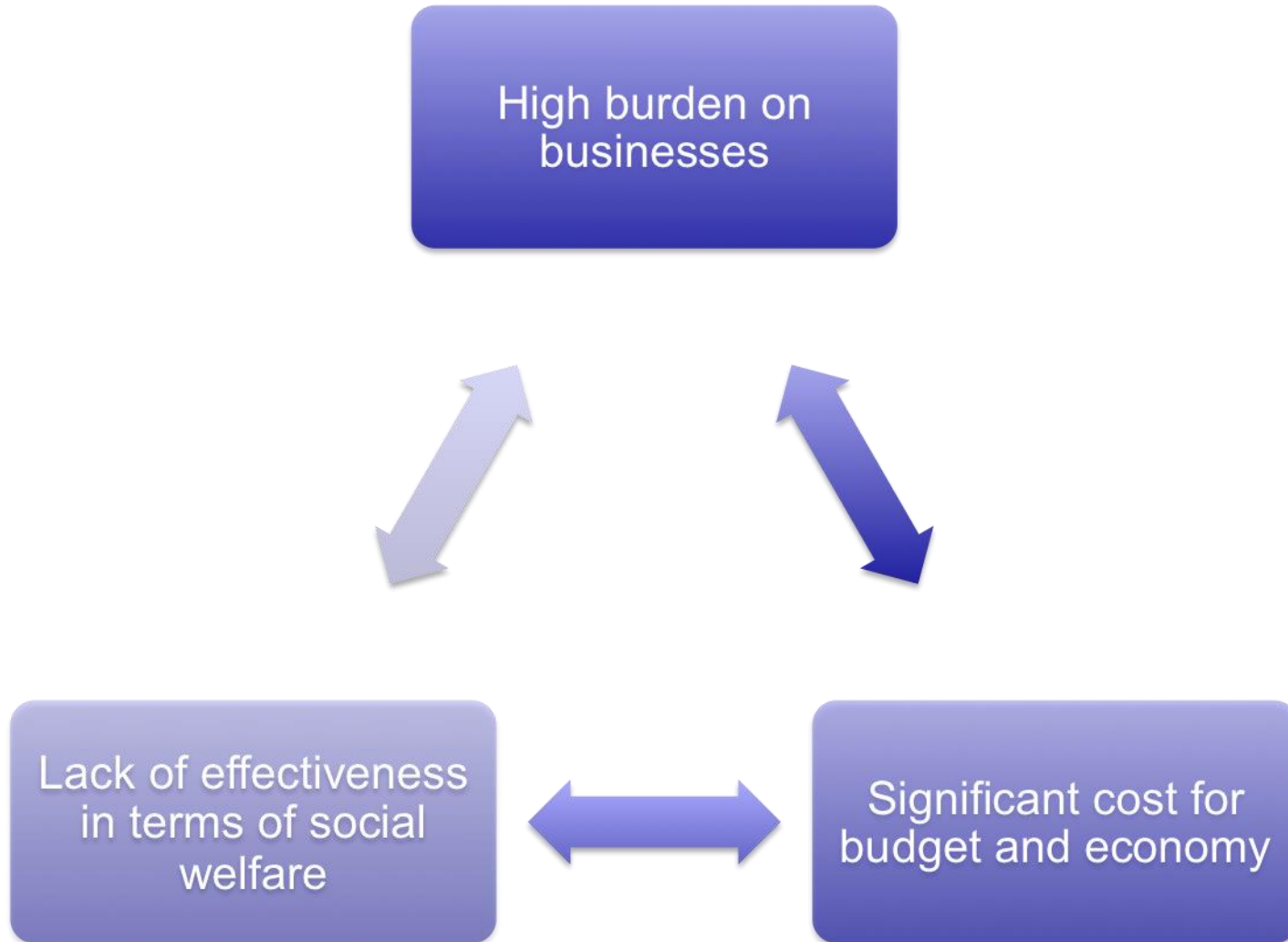
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## WHY REFORM INSPECTIONS?

- In most countries around the world (OECD, developing, transition etc.), to varying levels and extent:
  - Many inspections creating significant costs for the state, and burden for businesses
  - Insufficiently clear requirements, uncertainty, discretion etc. lead to additional barriers to growth
- Impact can be disappointing, or hard to measure, in terms of:
  - Protecting populations (citizens, consumers, workers) from preventable hazards [or securing other public goods]
  - Cost/effectiveness of enforcement and inspections
- Increasing efforts by governments, international organizations (WB, OECD etc.) to improve the situation

# INEFFECTIVE AND BURDENSOME INSPECTIONS – INTERCONNECTED PROBLEMS LEADING TO REFORM



# A VISION OF REFORM



# PURPOSE OF INSPECTIONS REFORM

## *Overall reform goal:*

Combine public welfare and growth, prosperity and protection

## *Specific objectives:*

1. Improve outcomes in terms of public welfare (safety, health, environmental protection) – or at least maintain them
2. Make it easier to create/grow businesses – in a way that is credible and trusted, and has real results in terms of investment and jobs
3. Improve overall trust and confidence – for businesses, consumers, civil society, regulators – as well as foreign trade partners etc.
4. Reduce costs and/or optimize the use of resources for both the public and private sectors

# INSTRUMENTS AND AREAS OF REFORM

## *Instruments:*

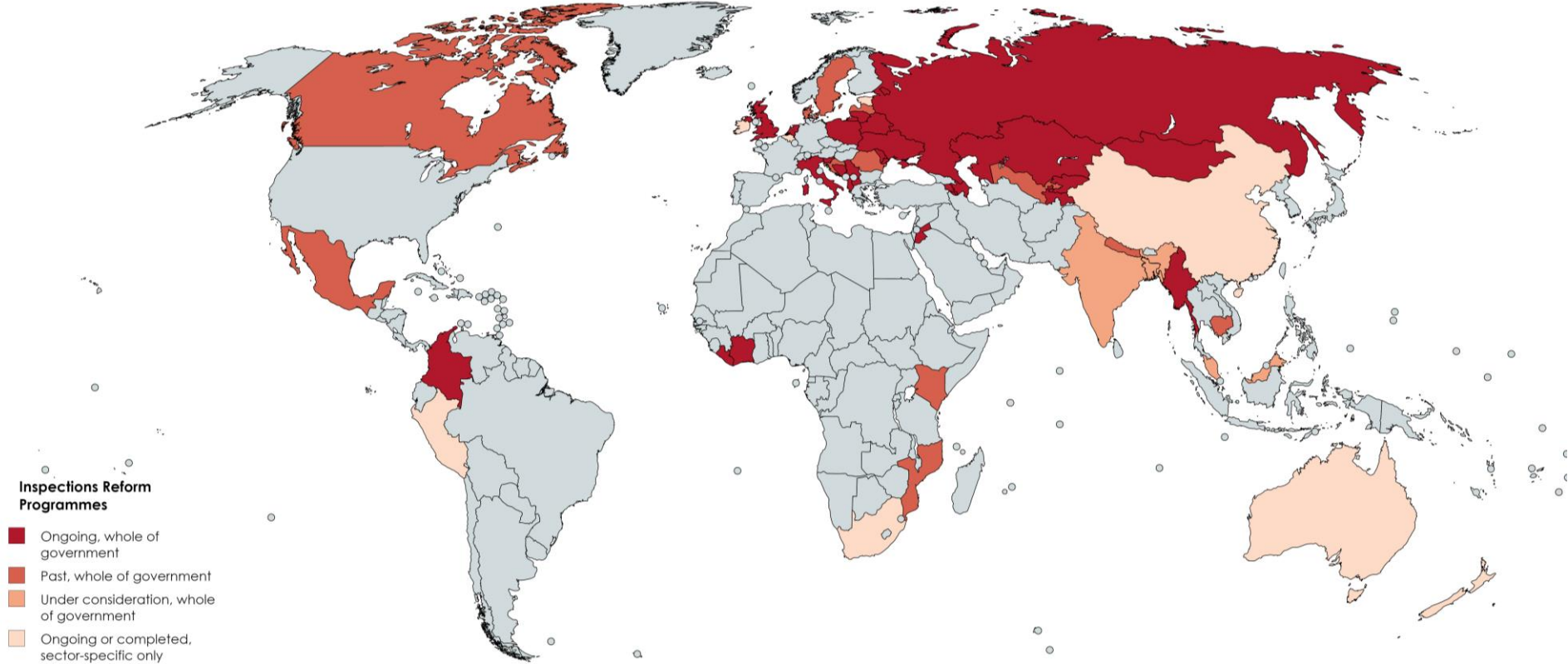
Legislation (framework law, implementing secondary legislation)

Development of practical tools, training etc.

## *Areas:*

1. Rights, obligations, powers
2. Processes and procedures
3. Risk analysis, targeting, planning
4. Inspection methods, skills, investigations
5. Compliance promotion, information, guidance
6. Risk-proportional enforcement
7. Performance management, governance, transparency...

# A GLOBAL TREND



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# CURRENT SITUATION - FINDINGS

## *Sources:*

Focus group and individual discussions, expert opinions, reports etc.

## *Key findings:*

1. Difficulty in conducting proactive inspections – many licensing, complaints related inspections
2. Many violations related to licensing docs. etc. but not necessarily many that carry significant risks for the public etc.
3. Lack of data and IT tools, resources, sometimes of adequate enforcement measures
4. Difficulties in establishing legitimacy of requirements, trust etc.
5. Much non-compliance appears related to knowledge, capacity pbs.



# RISK-BASED REGULATION AND INSPECTIONS

- **Risk = probability x hazard** (*seriousness x magnitude*)
- Regulatory requirements, procedures proportional to risk
- Frequency and depth of inspections proportional to risk – as well as enforcement decisions, measures
- Criteria: type of activity/process/products, scope/size, location etc. - and compliance history of the business/establishment
- Break away from “risk averse” approach (‘everything is risky, everything needs to be controlled’)
- Have realistic approach to regulation, inspections: they are not a “magic wand”, cannot solve everything

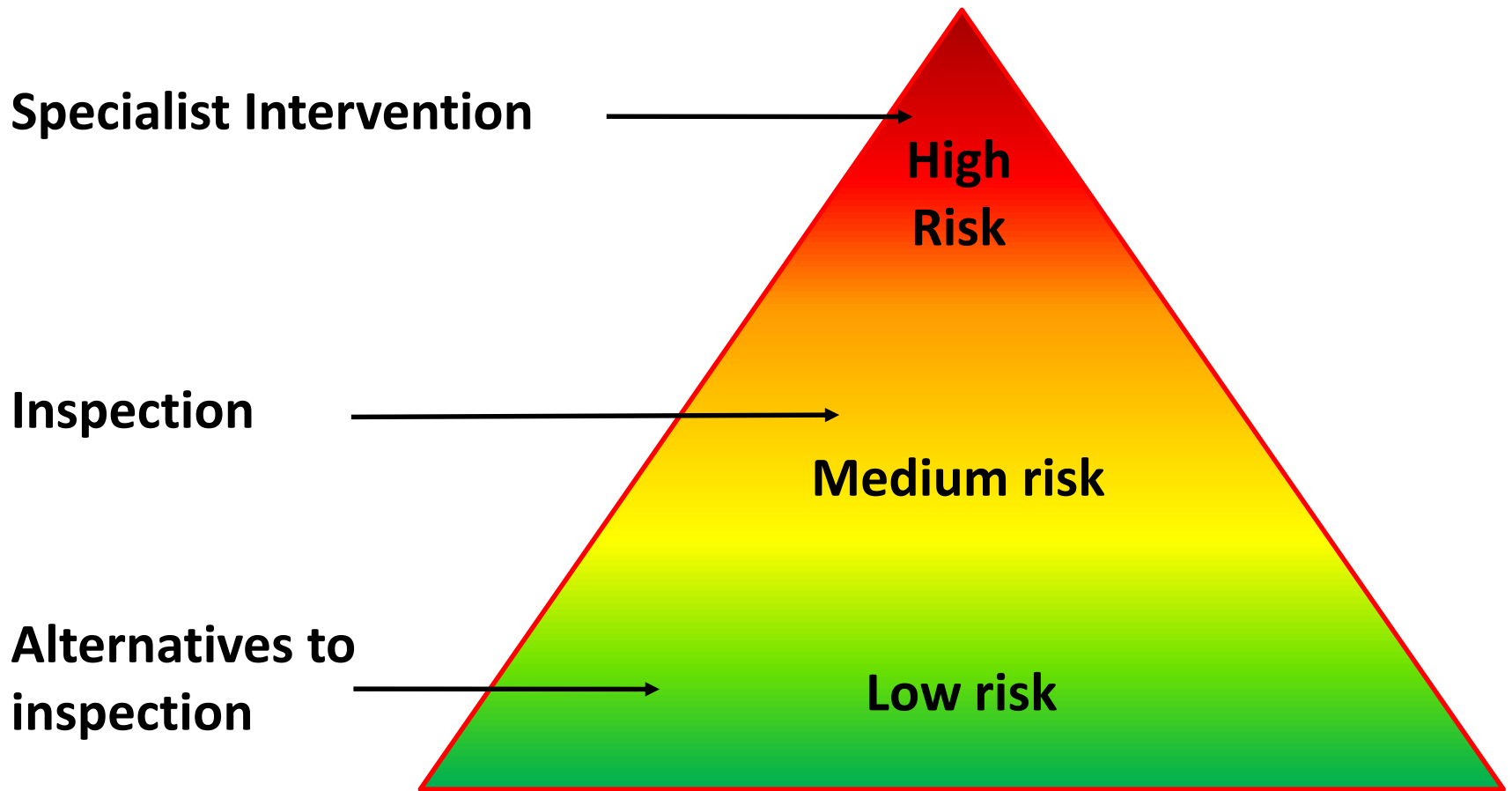
# BUILDING A RISK MATRIX

## Likelihood of non-compliance

	Very low	Low	Medium	High	Very high
High	Lower Medium	Upper Medium	Upper Medium	High	High
Upper medium	Lower Medium	Lower Medium	Upper Medium	Upper Medium	High
Lower medium	Low	Lower Medium	Lower Medium	Upper Medium	Upper Medium
Low	Low	Low	Lower Medium	Lower Medium	Upper Medium

# SELECTING THE RIGHT INTERVENTION

## Profile of businesses



# 4 STEPS TO INTELLIGENT, RISK-BASED INSPECTION...

1. Select the areas you will focus on for this inspection – aim for around 3 key areas
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

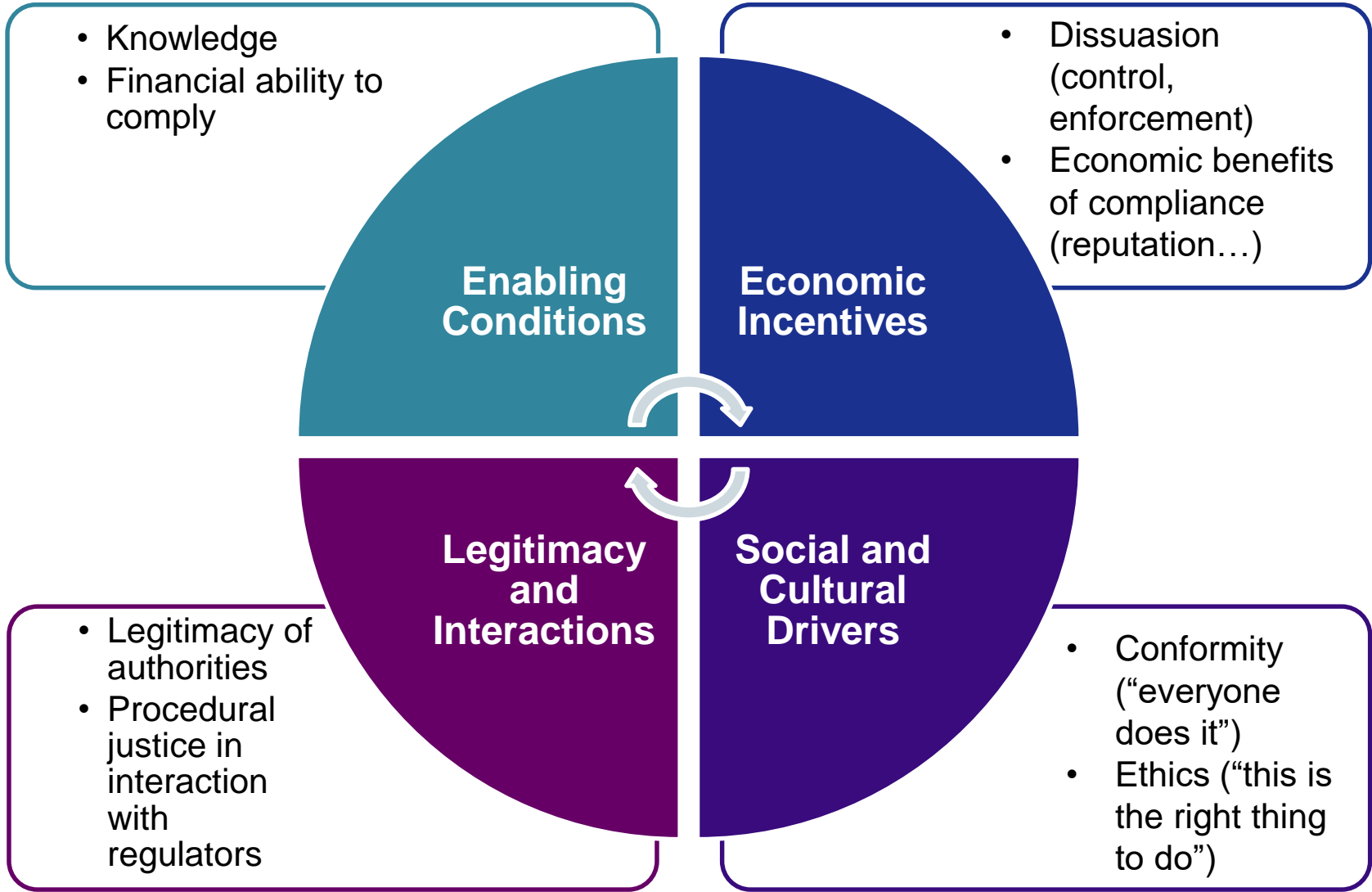


Is the machine guarded?

Does anyone check?



# USING COMPLEMENTARY COMPLIANCE DRIVERS



*Tension: excessive dissuasion efforts reduce voluntary compliance (decrease legitimacy, weaken social conformity, increase costs). Approaches based primarily on heavy dissuasion are not effective.*

# “SAFER FOOD, BETTER BUSINESS” – SELF CONTROL, EXPLAINED

## Safety point

Staff should always wash their hands before preparing food. (See the ‘Clear and clean as you go’ method in the Cleaning section.)

All staff should wear clean clothes when working with food. Ideally, they should change into clean work clothes before starting work and not wear these clothes outside food preparation areas.

Ideally, work clothes should be long-sleeved and light-coloured (to show the dirt) with no external pockets.

## Why?

Handwashing is one of the best ways to prevent harmful bacteria from spreading.

Clothes can bring dirt and bacteria into food preparation areas. Wearing clean clothes helps to prevent this.

This prevents skin from touching food and helps to stop hairs, fibres and the contents of pockets (which can carry bacteria) getting into food.

## How do you do this?

Are all staff trained to wash their hands before preparing food?

Yes  No

Do your staff wear clean work clothes?

Yes  No


Do your staff change clothes before starting work?

Yes  No

Describe your staff's work clothes here:



# “SAFER FOOD, BETTER BUSINESS” – COMPLEX REGULATION, MADE SIMPLE

Safety point	Why?	How do you do this?
<p><b>Preparation</b></p> <p>Prepare raw meat/poultry and other foods in different areas. If this is not possible, separate by preparing them at different times and clean thoroughly between tasks.</p> <p>Never use the same chopping board or knives for preparing raw meat/poultry and for ready-to-eat food (unless they have been thoroughly cleaned and disinfected in between).</p>	<p>This helps to prevent harmful bacteria spreading from one food to another.</p> <p>Harmful bacteria from raw meat/poultry can spread from chopping boards and knives to other foods.</p> 	<p>How do you separate raw meat/poultry and other foods during preparation?</p>

- A small food business operator in the areas covered by the SFBB Toolkit will never need to try and understand the long and complex EU “Hygiene Package” – nor does it need a HACCP consultant or certification
- ***The regulator is providing business with a real tool to achieve safety***

# “ASSURED GUIDANCE” – HOW “PRIMARY AUTHORITY” GIVES CONFIDENCE AND CLARITY TO US BUSINESSES

- Problem: how to give businesses with premises/outlets/facilities in several regions confidence that inspections/enforcement will be consistent?
- Answer = “Primary Authority” – one local authority audits internal procedures of business, discusses/validates them, issues inspections and enforcement guidelines for all others
- Applicability: even in a centralized system, there are issues of variability between inspectors etc. – and of potential conflicts on interpretation of rules, between inspectors’ instructions and central management of the business (internal guidelines of a company etc.)
  - *Auditing internal procedures and validating them at the central level gives confidence and is far more effective*
  - *Transparency and stability promote investment and growth + effectiveness is higher (better compliance)*



# PROMOTING COMPLIANCE – THE ENFORCEMENT PYRAMID



Source: Ayres and Braithwaite, *Responsive Regulation*, 1992

# IMPROVING POLICIES, INSTITUTIONS AND PRACTICES – OECD PRINCIPLES

- Policies:
  - Evidence- and measurement-based enforcement/inspections
  - Selectivity - use enforcement/inspections only where strictly necessary
  - Risk-based and proportionate enforcement
  - “Responsive Regulation” approach
- Institutions:
  - Long-term vision & stable institutional mechanism for improvements
  - Consolidation/coordination of inspection functions
  - Transparent governance + HR policies geared towards professionalism, outcomes
- Tools:
  - Information integration, ICTs to ensure risk focus, coordination
  - Clear and fair process, rules
  - Compliance promotion through toolkits, check-lists etc.
  - Professionalism, inspectors’ training

## APPLICATION TO GREECE

- Framework law on inspections: principles (including “growth duty”, risk, proportionality, responsiveness), procedures, IT system, coordination, requirements to develop guidance, check-lists etc.
- Development and roll-out of unified IT system for licensing and inspections
- Risk-based planning – develop methodologies, rate facilities, use the system
- Risk-focused visits, risk-proportionate enforcement – check-lists, methodologies and training needed
- Major efforts to change attitudes, relationships, culture
- Coordination, allocation of resources – institutional issues have to be resolved (coordinate, or consolidate, but overcome fragmentation)



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**Thank You for Listening!**

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## *1 - Evidence based enforcement*

- Do not inspect and actively enforce “everything that is regulated”
- Rather, evaluate the risk level posed by different types of regulations and regulated areas
- Allocate resources and efforts proportionally to potential outcomes
- Evaluate and adjust based on results

### *3 – Risk focus and proportionality*

- Frequency of inspections should be proportionate to risk level
- Severity of sanctions and burden of enforcement should be proportionate to actual hazard/damage
- Risk = probability x magnitude (scope x severity) of hazard

## 4 – “Responsive Regulation”

- Enforcement modulated based on behaviour of regulated entities
- “Honest mistakes” and one-off violations treated differently from systematic, criminal misconduct
- Aim: promote compliance and positive outcomes

*5 – Long term vision, clear objectives and stable institutional mechanism*

- Official policy, clear objectives for continued improvements in enforcement – long-term perspective
- Institutional set-up gathering all relevant ministries, institutions, stakeholders
- Strong policy leadership



## *6 – Co-ordination and consolidation of inspection functions*

- Less duplication and overlaps – reduced costs and burden
- Greater coherence, better information flow – more effectiveness
- Core list of inspection/enforcement functions to match rational analysis of types of risks – not “historical” list of institutions

## 8 – *Information integration*

- Interconnect databases and systems used by different inspectorates / whenever possible set up single/joint systems
- Data sharing and shared planning mean less duplication, more efficiency – but also better outcomes because key information is shared effectively, risks are better identified
- Initial investment can deliver considerable benefits and efficiencies

## *10 – Compliance promotion and transparency*

- Ensure that regulated subjects know what is expected from them
- Enforcement to be consistent and predictable
- Compliance promotion achieves better outcomes at lower costs
- Tools adapted to different types and profiles of establishments (checklists, guidance, etc.)

## *11 – Professionalism and training*

- The whole training, management, incentives need to be aligned with objectives and principles of “better enforcement”
- Inspectors’ training needs to incorporate risk-management, compliance-promotion, and a whole set of “competencies” related specifically to enforcement
- Aim to increase consistency, quality – reach better outcomes