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# Changing paradigms in regulatory control over food safety - a case for risk-based regulation

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# Presentation Outline

- This presentation is made from the perspective of the regulator based on experiences of what has worked, what is working and what needs to be changed to ensure improving the overall objective of safe food.
- I will focus on:
  - the concept of “quality” regulation;
  - the concept of co-regulation;
  - the concept of risk-based regulation;
  - Experiences of the veterinary regulator;
  - Towards a more effective model of control.

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# 'Quality' Regulation

- A concept introduced in 1994 by the OECD.
- OECD – to promote policies that will improve the economic and social well-being of people around the world.
- The central idea behind 'quality' regulation:
  - Simply regulations;
  - Easy to understand;
  - De-regulate where necessary; and
  - Support business development.

# ‘Quality’ Regulation in the UK

- Tony Blair’s administration advocated improving business development and growth between 1997-2007 – OECD ideals.
- Embraced quality regulation via:
  - Cutting red tape;
  - De-regulation; and
  - Focus on the how the regulator regulated and what it regulated.
- Good case studies may be seen in the work of the HSE, FSA and EA from a PH view.

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# Food safety control in the 1990's

- Early 1990's food safety control not effective
  - Food safety “crises” – e.g.s USA, UK, Australia, Japan.
  - Local and international (exports) pressure on the regulator.
- Food safety crises and scares necessitated review of control strategies, at least public pressure did.
- Co-regulation emerged – given HACCP research.
- Shift in responsibility of ensuring control from the state to private businesses.

# The adoption of co-regulation in food safety control

- Within co-regulation:
  - Government regulated broad standards - Codex Alimentarius Commission;
  - Industry used best practices to comply.
- HACCP-based systems were regulated.
- Industry compliance:
  - Plan – do –check – Act (Deming’s PDCA cycle);
  - Keep records to demonstrate control.
- Government control:
  - Inspection to auditing systems;
  - Verify compliance- effectiveness of the system.

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# The adoption of co-regulation in food safety control

- Problems emerged within co-regulation.
- Literature suggests that:
  - Industry expertise and resources were lacking amongst smaller businesses;
  - HACCP suggested as not suited for certain supply segments e.g. farming;
  - System Standards – one size doesn't fit all; and
  - Government resources constrained.
- This necessitated further review of co-regulation in its implementation.

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# Lessons learned by 2000

- Command and control approaches did not work.
- Regulation process and infrastructure standards does not assure safe food – need management systems.
- The regulator cannot assure safe food, responsibility must be placed at the producer, distributor, retailer levels.
- Co-regulation an attractive approach to control, but had problems.
- Over-regulation kills economic development – quality regulation via risked-based regulation from a public health standpoint.
- The need to strike a balance with business and public health objectives.



# Strengthening control via risk-based regulation

- Literature refers to the concept of 'risk-based regulation' as far back as the 1980's.
- 'Quality regulation' was advocated by the OECD:
  - to facilitate growth of economies of member states.
  - regulating private sector to minimize red tape and support growth and development of businesses.
- Risk-based regulation is an element of quality regulation to achieve the ideals of quality regulation.
- So what is risk-based regulation?


# Strengthening control via risk-based regulation

- Risk-based regulation in a food safety context:
  - Businesses are profiled in terms of risk – indicators;
  - Risk assessment methodology used by the state;
  - Low risk businesses are audited less often;
  - High risk businesses audited more often;
  - Targeted monitoring.
- Government provides advice and guidelines to facilitate compliance.
- Government targets to outcomes – e.g. from number of visits to changing profiles of businesses.
- Better use of state resources.

# Changing paradigms

- Co-regulation tempered with risk-based regulation and supported by well established sanction system. *What about incentives?*
- The task entails various state actors pooling resources and expertise to bear on the plethora of regulations that influence industry in the various industry sectors including food safety.
- Food safety control does not exist in a vacuum but along side those departments (Dti, NPISA) whose ideals are to facilitate business development and growth.

# What model of control?

- Co-regulation tempered with risk-based regulation.
- A suitable model that encompasses the roles of all state actors is beyond the scope of this presentation.
- From a public health viewpoint and more specifically food safety control:
  - Regulations – risk-based approach to food safety management by operators;
  - Positive obligation combined with various options of sanctions;
  - State co-ordination and competence
  - Risk-based regulatory control
  - Consumer awareness of food safe 
  - Brandings/state endorsement/certification by state?

# State competence and management systems in relation to CR and RBR

- Competence management systems – ISO 17000 series-
  - Certification of systems – ISO 17021;
  - Inspection body competence – ISO 17020;
  - Laboratory competence – ISO 17025;
  - Product certification – ISO 17065;
  - Personnel certification – ISO 17024.
- Competency management systems critical to manage state competence in regulatory efforts to control – Procedures must be tempered with current research, research must be supported by the state.
- Management systems critical to ensure standards are followed consistently over time by state departments.

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# Where is South Africa i.t.o these emerging approaches to control?

- Challenges – fragmented laws and state departments controlling them.
- Co-regulation?
- Quality Regulation?
- Risk-based regulation?
- State competence?
- Some insights in veterinary control over meat safety in South Africa

# Meat safety control

- Department of Agriculture – farms and abattoirs
- Dep. Of Health (DoH) – transport, retail, distribution
- DoA
  - No formal control system for farms;
  - Co-regulation - abattoir level in the form of HAS and HMS;
  - Competency of inspections – ISO 17020 accredited by SANAS for ‘farms’ and abattoirs;
  - RBR – No, procedures are target based not outcomes, research not integrated.
- DoH – HACCP Regulation R 908 not extended to meat transport, retail and distribution at present.

# Challenges with CR and RBR in Veterinary Services

- Co-regulatory Control on farms – none
- A questionnaire survey of all VPH officials in Gauteng:
- Co-regulation :
  - Officials required more training in auditing;
  - HAS v HMS and HAS is more important – further training;
  - Don't always apply the rule of no advice/guidelines.
- Risk-based Regulation:
  - High throughput is more compliant than low throughput – conflict with research on TBCs recently done;
  - increase inspection frequency at 'problem' abattoirs;
- Labs – 17025 – not all accredited.
- Incentivizing compliance – branding – Nama ePhepa Awards
  - Additional requirements e.g. veterinary drug testing



# Conclusion

- Since the Stein Commission recommendations in 1978 to decide the fate of meat safety, it doesn't seem likely that control will ever be brought under one Agency.
- Fragmented laws add to the problem of control and its coordination.
- (Re)designing laws to support co-regulation is only part of the challenge, RBR requires not only management systems but competency management by state actors.
- Co-ordination within a system of fragmented laws governed by two separate departments remains the biggest challenge.
- Need to consider risk-based regulation within enforcement strategies – maximize state resources.

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# Thank you



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