INDR
Conference on Engagement by Regulators

Wolfson College, Oxford, 20th November 2023

Summary

This paper summarises the presentations at the INDR Conference held at Wolfson College, Oxford, 20th November 2023. The core theme was: Engagement by Regulators in the context of Outcome-Based Collaborative Regulation (OBCR).

This report contains a wealth of information about aspects of contemporary good practice in regulatory delivery. Examples include:
-   A number of contrasting mechanisms of engagement, including the Primary Authority scheme, and OPSS' highly successful Business Reference Panel meetings.
-   The role of *standards and private accreditation* in 'regulation'.
-   The success of a *self-regulatory* model, combining industry expertise and collaboration, with independent regulatory decisions, exemplified by the ASA.
-   The value of *complaints* as feedback indicating things that organisations need to be aware of to improve; and the need to have a culture that listens and responds.
-   How focus on the subjects and beneficiaries of regulation inevitably leads to concerns over individuals' *vulnerabilities*, be they consumers or part of the regulated population, and means of engagement here.
-   The challenges of engagement with stakeholders around regulating new and innovative technologies, and some learning on how to approach this.

It also contains multiple reports on a sequence of projects that have been adopting OBCR principles, confirmed a range of situations in which the model has been applied and notable successes. Core features of the model noted in the case studies are:
(a) A governing Stakeholder Council that establishes trust, outcomes, rules, and monitors performance – Food in Queensland; Grangemouth's regulatory hub.
(b) Collaborative co-creation – multiple examples, including industry secondment to MHRA (challenging traditional concerns over 'capture'); the Democratic Republic of Congo and Zambia Kasumbalesa Border Collaborative Risk Management project.
(c) Trust as the key enabler for engagement, and for reducing duplication and increasing efficiency and outcomes – The FSA's Achieving Business Compliance Programme; MedTech industry and regulators; trust as the driving factor in the UK Digital Identity framework, and consecutive stages of stakeholder involvement; Ontario's circular economy approach.
(d) The advantage of setting hugely ambitious goals (net zero, just transition, healthy eating for all) under which multiple more detailed goals (reducing environmental pollution, increasing regulatory compliance generally) would be delivered inherently – as opposed to approaching multiple goals in a granular fashion but without generating enthusiasm and motivation for achieving the bigger picture. Eat Right India (creating a mass movement through multiple mass communication strategies and channels around *excite, engage, enable*); Grangemouth,

Contents:

GENERAL ISSUES AROUND ENGAGEMENT

Why engagement is important for regulators
Graham Russell MBE, CEO, Office for Product Safety and Security (OPSS)

The Regulatory Delivery Model[1] suggests that regulators need to engage with three categories: the beneficiaries of regulation (consumers, users, people who may benefit or be protected from harm), those who are subject to regulation (businesses, charities, public bodies); and sponsors (governments, ministries representing wider society.

Why is engagement important for regulators? There are positive and negative aspects to this.

The negative drivers are that while any organisation has to listen to improve, for a regulator, there is a particular challenge. Without any 'sales' data, as an organisation that is not commercially selling a product, so how do you hear what matters to your customers? This applies to any public service organisation, but more so to a regulator who exercises the coercive power of the state. Very few regulated entities will call a regulator's complaints hotline. While it may be controversial to call those you regulate 'customers', it can be helpful to see them in this way. Similarly beneficiaries need to be heard to keep you on course but generally expect regulators to function and fulfil their mandate. In both cases regulators have to build capacity.

The positive driver is that if regulators engage well, then we move towards a outcome based cooperative approach in which stakeholders begin to share a level of ownership. As each party takes responsibility and owns a shared mission there is a releasing of shared effort and more positive approach to shared solutions. The challenge for any regulator is to adopt a learning culture which embraces the power of shared endeavour through an intentional approach to accountability.

As an example of the benefits of engagement, it helps to think about the beneficiaries of regulation. Former UK Cabinet Minister, Lord Eric Pickles referred to an 'army of armchair auditors' - thousands of consumers who 'inspect' daily but might not be empowered. How can the voice, knowledge and views of this population be accessed, so as to be able to benefit from the inherent force, data and commitment? A number of mechanisms are available.

The Outcome-Focussed Collaboration Model
Prof Chris Hodges OBE

This paper records a growing series of case studies in which the elements of OBCR are being used. The range of example is considerable, and the results speak for themselves.

Many recent policy papers cite the need for regulation to be outcome-focused.[2] Some also talk about collaboration. But they rarely expand on *how* these aspects are to be achieved.

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[1] G Russell and C Hodges (eds), *Regulatory Delivery* (Hart, 2019).

[2] Some examples are:
- "UK regulation should be: Proportionate; Forward-looking; Outcome-focussed; Collaborative; Experimental; and Responsive": I Duncan Smith, T Villers and G Freeman, *Taskforce on Innovation, Growth and Regulatory Reform* (June 2021).
- "regulation should be based on outcomes rather than assessing mechanistic "tick-box" compliance with rules": *Reforming the Framework for Better Regulation A consultation* (BEIS, July 2021), para 3.1.15.
- "Several publications highlight the importance of taking an outcome focused approach with an emphasis on avoiding prescriptive regulation, where appropriate and the usefulness of non-legislative measures such as standards.": *'Closing the Gap'. Getting from Principles to Practices for Innovation Friendly Regulation* (Regulatory Horizons Council, June 2022).
- Dame Angela McLean's *Pro-Innovation Regulation of Technologies Review: Cross Cutting and Growth Duty Recommendations* (HM Government, November 2023) refers to the need to 'ensure that regulators

The Outcome-Based Collaboration Model (OBC) and the Outcome-Based Collaborative Regulation Model (OBCR) provide a vision and a framework for how to define and achieve outcomes and, at the same time, how to do so through collaboration – on the basis that a vast amount of scientific evidence supports the propositions that these are the most effective ways by which humans can achieve their multiple shared goals. The framework of OBCR provides a mechanism but does not provide the solutions: the whole point is that relevant stakeholders need to work together to define and agree their shared outcomes, how they will achieve them, how they will define and measure the pathways and mechanisms to achieve them, and how to collaborate to achieve all this.

The key elements of OBC are, therefore:[3]
    A. Agree shared purposes, aims and outcomes.
    B. Collaborate (in such discussions, in monitoring and achieving the desired outcomes) on the basis that all stakeholders are trustworthy, based on objective evaluation of transparent evidence that they can be trusted.

Governing legislation of nearly all regulators typically specifies duties and powers – but omits the outcomes that they are supposed to achieve, and how they should be defined and measured. The typical regulatory model is legalistic: make rules, identify breaches; impose sanctions. This model is based on authoritarian enforcement and fails to promote collaboration between regulators and regulatees (or any other stakeholders).

The OBCR model is based on scientific evidence that this is how humans work best. It is not intended to apply to those who break rules deliberately, or to the extent to which people or organisations cannot be trusted. The regulatory imperative of protecting and sustaining society, markets, states and the environment, usually requires use of traditional enforcement tools. But the evidence is that use oif such tools on those who are well0intentioned will destroy sharing of information, learning and improved performance and certainly of collaboration.

Case studies on OBC show that it is easier to implement in some situations and sectors than others. The existence of some barriers exist in existing and traditional practice (such as globally dispersed actors, and economic incentives (whether criminal or inducing stress) distort the ability to sustain trust. Since the goals of protection and prosperity are typically in conflict, there is an inherent tension between these goals and outcomes, but that does not mean that co-they cannot be achieved at the same time.

Collaborative co-creation requires new ways of working and fresh institutions. Key tools are a governing stakeholder council (striking examples below are from Queensland and Grangemouth), the observation of a common set of values (an ethical code also appears in examples below), and the agreement of detailed implementation plans and metrics to identify performance and the achievement of outcomes. These new approaches constitute a new form of regulation that can be illustrated horizontally as a collaboration between respected equals (albeit respecting the distinct roles of each actor or group), as opposed to a vertical exercise of power by institutions of state (whilst retaining the need fo oversight by such bodies, but also be fresh mechanisms).

Established Frameworks for OPSS' Engagement with Business
*Sarah Smith OBE, Deputy Chief Executive, OPSS*

OPSS is the UK product regulator, established in 2018, responsible for the regulation of most consumer goods, and we are the national regulator for construction products. It is part of the Department for

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prioritise principles-based and outcomes-based regulation' and that they should 'adopt collaborative approaches to overcome fragmentation of regulatory remits'.

[3] C Hodges, *Outcome-Based Cooperation: in Communities, Organisations, Regulation and Dispute Resolution* (Hart, 2022).

Business and Trade (DBT), which has business at its core, helping businesses grow and export. We are about protecting people and places. OPSS holds policy responsibility for product safety, legal metrology (weights and measures), standards and accreditation, hallmarking, and Primary Authority. It enforces regulations across the product lifecycle from design, manufacture and assessment through to supply, end use and safe disposal. OPSS has a leading role in regulatory practice, and was the originator of the Regulatory Delivery Model:

Regulatory Delivery Model
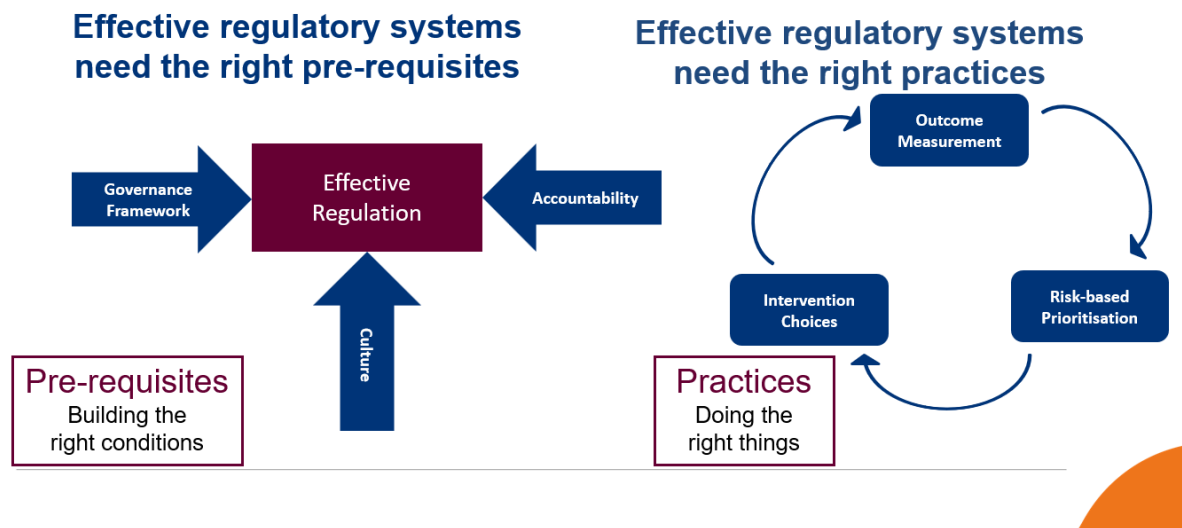
One of the six elements of the Regulatory Delivery Model is accountability, and this element is the focus of this presentation. OPSS has operated two major examples.

OPSS' Business Reference Panel was established over 15 years ago. We created a safe space and environment for businesses to have a dialogue with us, perhaps about more philosophical conversations, identifying things that are on the horizon. It provides an opportunity to talk early, and think about possible impacts. This
- Ensures the voice of business is at the heart of the regulatory agenda
- Provides the opportunity to discuss current and emerging issues
- Explores business thinking and works to identify potential solutions
- Enables members to scrutinise the work of OPSS, share concerns and inform future direction
- Meets four times a year with agendas shaped around the issues of greatest regulatory concern for members
- Consists of regulatory leads across multiple sectors types that represent over 200 different trade associations, representative bodies and individual businesses
- Micro and start-ups, as well as large multi-national corporations make up our membership base providing a voice to over 1 million businesses across the UK
- **Members provide us with the insights we need to better understand the views of the business community and how their individual experiences of regulation impacts upon them – we invite all to share their experiences and provide honest feedback**

The Business Reference Panel has grown from 20 people to over 100 business organisations (large and small) representing around 1 million businesses. It has proved to be really powerful. Other parts of government come and present ideas here. It provides an opportunity to crate cooperation and collaboration in a safe space.

<u>The Primary Authority Scheme</u>. This was initiated in 2009. It is a gateway to simpler, fairer and more successful local regulation, based on developing open relationships between local authorities and businesses. It defines a legally recognised partnership between a business or co-Ordinator and a single local authority, the "Primary" authority. The statutory basis is the Regulatory Enforcement and Sanctions Act 2008 (RESA), as amended.

Dialogue occurs in a trusted structure framed by a set of rules. the structure creates conditions for engagement, dialogue, how we are accountable to business. OPSS holds the rules of Primary Authority; the register of partnerships, preventing regulatory capture; focus on compliance but on how businesses are complying. We also determine any disputes.

Over 146,000 businesses are now involved, giving the regulatory members understanding of business models, enabling the getting and giving of advice, and sharing methods of compliance. The scheme affords genuine collaboration. Primary Authority delivers benefits for all stakeholders:
- The Business - Reliable regulatory advice from a trusted source & and single point of contact.
- Local authorities – Better Informed, more effective regulation, improved targeting of resources
- Both - Information and intelligence sharing & improved compliance
- Public confidence and protection.

Standards in the regulatory space
Daniel Mansfield, Head of Policy Engagement, BSI

BSI is the National Standards Body. It exemplifies how an independent body can support business, innovation and regulation. BSI has a duty to include stakeholders, to achieve consensus, and address how meet the needs of the future. Standards are a mechanism for developing international consensus.
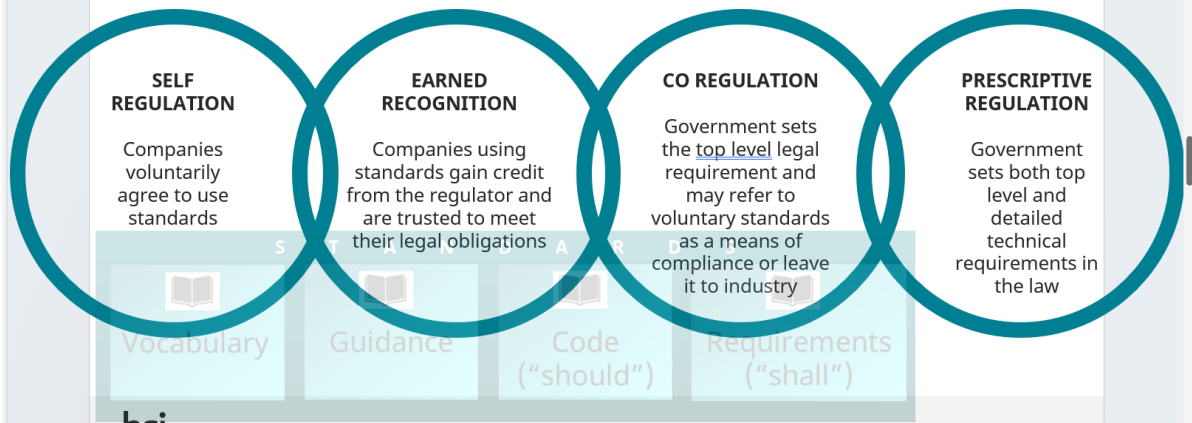
By 'standards', BSI means: stakeholder-led solutions to respond to defined needs. Legitimacy is based on consensus and consultation: BSI does not "decide" or "set" but coordinates. Standards are an agreed way of doing something or what "good" looks like. They can cover anything. Standards are voluntary (BSI is not a regulator, is not government), but can underpin regulation and give confidence to markets and to governments. Standards also remove trade barriers, allow fair competition, manage consumer aspects, innovation, risk management, Net Zero, digital transformation, and so on… Standards are also subject to periodic review.

BSI, the National Physical Laboratory and the UK Accreditation Service (UKAS) together deliver the National Quality Infrastructure. This is a national framework, public and private, that builds trust and confidence in markets and supports innovation and smarter regulation. It enables expected levels of quality, safety, performance and fitness for purpose. It can cover products, services, processes, or business operations. This can also support market-surveillance activities.

The diagram below illustrates how all these elements fit together:

A spectrum of policy possibilities

SELF REGULATION
Companies voluntarily agree to use standards

EARNED RECOGNITION
Companies using standards gain credit from the regulator and are trusted to meet their legal obligations

CO REGULATION
Government sets the top level legal requirement and may refer to voluntary standards as a means of compliance or leave it to industry

PRESCRIPTIVE REGULATION
Government sets both top level and detailed technical requirements in the law

Vocabulary | Guidance | Code ("should") | Requirements ("shall")

bsi

Standards are in the middle of all these models, providing consensus agreement around 'what good looks like'. Examples of the role played by standards in the four models are:

1. **Self-regulation:**
   Government promotes good behaviour:
   - PAS 7100 code of practice for better product recalls
   - PAS 7050 for putting safer products on the market
   - PAS 7055 specification for button and coin batteries

   Government and public bodies model good behaviour:
   - Welsh Senedd adoption of BS 30416 *Menstruation, menstrual health and menopause in the workplace – Guide*

2. **Earned recognition:**
   ESOS (Energy Savings Opportunities Scheme)
   - Qualifying organizations must carry out an assessment every four years
   - But this requirement is relaxed if they have an accredited certification to ISO 50001 (Energy management)
   - The environmental regulators across the UK recognize the value of the standard and accredited certification as evidence and give "credit"
   - Efficient and effective regulation

3. **Co-regulation:**
   Designated standards in the UK and harmonized standards cited in the Official Journal of the EU
   - Some 3500-4000 standards recognized to give "presumption of conformity" to essential requirements of regulation
   - Covering product safety and performance
   - Facilitates trade
   - Drives up compliance without compromising the regulation

4. **Formal regulation:**
   Direct reference to standards in regulations
   - BS 1363 for 13 amp fused plugs and switched and unswitched socket–outlets, referenced in The Plugs and Sockets etc. (Safety) Regulations 1994
   - Incorporation by reference quite commonplace in some jurisdictions
   - Can reduce flexibility and cause issues over revisions

Other policy dimensions are also relevant beyond regulations: meeting stakeholder needs, such as innovation, trade, and international influence
Conclusions:

- Consensus-based stakeholder standards are a valuable asset for government, for supporting regulation and for helping set strategic priorities.
- Regulators should urgently consider how to get the most out of their standards bodies and use standards as a strategic tool domestically and internationally.
- Working with your standards body does not tie your hands as a regulator, but it can and does open doors.
- The Quality Infrastructure is the hidden infrastructure that means that things just work: use it!
- In the UK in BSI and the NQI we see the importance of policy watch and maintaining a view of developments (UK, EU and global) and of continued dialogue and partnership with government at all levels.
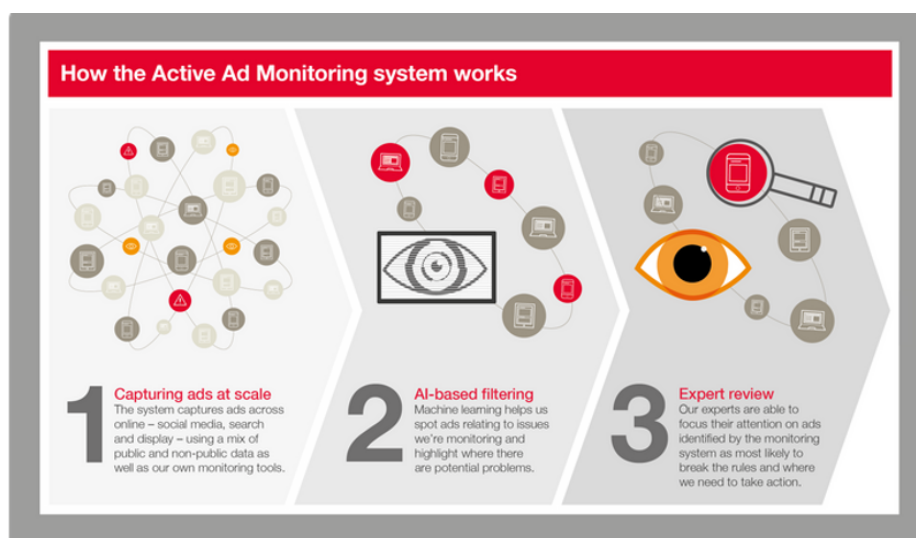
Comments from conference attendees: The Payment Services Regulator operates with panels, but limits membership to 20 people.

The ASA's Self-Regulatory Model
Guy Parker, CEO, Advertising Standards Authority (ASA)

The ASA operates on a self-regulatory model. The rules are contained in the UK advertising codes, written by the Committees of Advertising Practice (CAP) which are two industry committees: the *Committee of Advertising Practice* writes the rules for all non-broadcast media, including social media online, and the *Broadcast Committee of Advertising Practice* writes the advertising rules for all broadcast media. The ASA was set up by the ad industry in 1972. It regulates some media formally with Ofcom. 80% of ad spend is now online.

Our mission is to ensure that ads are responsible (legal, decent, honest, truthful). By focusing on responsibility, we focus on protection, trusting ads, ads to be deserving of their trust. If they are, they will work better. We act independently in administering the codes, reflecting society. We put people first, protecting them from irresponsible ads. We use technology including AI to enhance our effectiveness and efficiency. We have traditionally been seen as being a reactive regulator but we now invest more in preventative activities. The ASA's use of AI can be illustrated like this:

How the Active Ad Monitoring system works

1 Capturing ads at scale The system captures ads across online – social media, search and display – using a mix of public and non-public data as well as our own monitoring tools.

2 AI-based filtering Machine learning helps us spot ads relating to issues we're monitoring and highlight where there are potential problems.

3 Expert review Our experts are able to focus their attention on ads identified by the monitoring system as most likely to break the rules and where we need to take action.

AI has had a considerable impact. The ASA now processes more than 350k pieces of content a month through our Active Ad Monitoring system, overwhelmingly from members of the public. This is projected to rise to processing c3m in 2023. In H1 2023, Data Science supported c70% of total ads amended or withdrawn by our Compliance team. We published 11 formal rulings relating to ads sourced via Data Science in Q1-Q3 (around 5% of the total). Rulings show where the ASA is drawing the line of an issue, often a nuanced or difficult issue.

We want to ensure that industry uses trust and plays by the same rules. Coupled by robust and independent decision-making. Independent of industry, government, special interest groups; much collaborative working with independent regulators (Ofcom, CMA, FCA, ICO, and sectoral ones like the Gambling Commission), businesses (advice and training, much online). We call the model 'collective ad regulation' in preference the term to 'self-regulation'.

In 2022 over 1.5m pieces of advice and training were delivered. The goal is to help businesses to get their ads right before they run them. 3,500 cases were resolved informally; the ASA sometimes asks for an assurance, in other words an issue is privately resolved. Agreement to amend/withdraw occurs in around 1000 ads a year. Machine learning is proving to be v helpful and efficient.

Engagement is built into our structure – CAP and ASBOF boards. It is voluntary for businesses to pay, the SAS itself does not know who does or not. Industry funds the ASA but on a basis that is as arm's length as possible. We will talk to people first, then impose sanctions. Misleadingness is 75% of our work. Ofcom approves any changes to the Broadcast Code. There are regular website consultations. The *Evidence-based policymaking* document sets out what would impress for a change in the code. There is an Experts Panel, the AAC, and 3 practitioner panels, affording high quality expertise, giving advice on industry practice.

A current example of co-creation is a pilot being run in 2022-23, involving 10 platforms applying 6 principles. The pilot has proved to be a success, and the evaluating report concludes that the approach should develop to version 2. This voluntarily generated model will be ready to slot into anticipated future legislation.

The ASA has a commitment to the Principles of good regulation practice: transparent, proportionate, targeted, consistent, accountable, and evidence-based. The IPP puts commitments on advertisers. Consumers are central. A formal intelligence gathering analysis provides a picture of what's going on, and what the public are concerned by, and where we should concentrate. Studies by other regulators. Monitoring is fundamental and permanent. Challenges include accessing identification of some ads, eg influencers.

The place of complaints in the regulatory space
Mick King, formerly Local Government and Social Care Ombudsman

The philosopher Mary Midgley said that to understand any system, imagine you are peering into a dimly lit aquarium. The point is that one can only understand the system by collating as many windows as possible into the fish tank. Complaints are just one of the windows, but very valuable. There are some distortions (sometimes complainers are a self-selecting group, with serial complainers) but also valuable.

The value is that they are one of the only bottom-up sources of information. They can illuminate the unknowns. They happen in real time. They are free.

How do we maximise the value of this data source? The value of complaints is dependent on the culture of how people respond to them. One can identify four approaches (in the public sector especially):
1. A culture of avoidance. Complaints are inconvenient or dismissed. This is a red flag for the wider health and corporate governance of the organisation. An example was Northamptonshire County Council, which failed to respond to complaints or to implement recommendations, and went into bankruptcy.
2. A transactional approach to complaints. This routinizes complaints into the system, eg delay-repay schemes on railways. It pays off the problem, change is not made, and it excuses failure.
3. Judicialization of complaints. A good system will resolve complaints early, but a failing system will be escalated to courts or tribunals. The NHS is sued every 40 minutes, costing £2.6bn pa,

or 2.4% of the annual NHS budget, a quarter of which goes to lawyers rather than patients. This approach has a chilling effect on any learning culture.

4. A culture of learning. This treats complaints as a key corporate metric, driving learning and improvement. The emphasis is not so much on individual redress (which should be automatic) but on extracting the learning. Devon CC used the LGSCO report as training and to transform social care system.

One can make three practical suggestions:

- Regulators should pay far greater attention to complaints as part of their metrics, whether or not they are part of the formal requirements. The data is a valuable source of trust, performance and risk. It should be a core part of regulatory scrutiny.
- Greater sharing of data intelligence. Information is locked up in antiquated systems. It's a goldmine. The LGSCO aggregated complaints across a sector to identify key learnings of the systemic issues and indicators. A planning authority completely changed its approach from the data contained in one of our reports. We put all of our complaints data in a public online mapping system, which drove identification for benchmarking – 95% said they had used that data to drive improvement.
- Regulators need to look at their own position on complaints. The position of power can deter people from speaking truth to power. Regulators need to work hard to create safe space. It may be difficult to do, but is gold dust!

Whether complaint numbers are going up or down is entirely misleading, and drives wrong responses. It does *not* indicate what is good or bad.
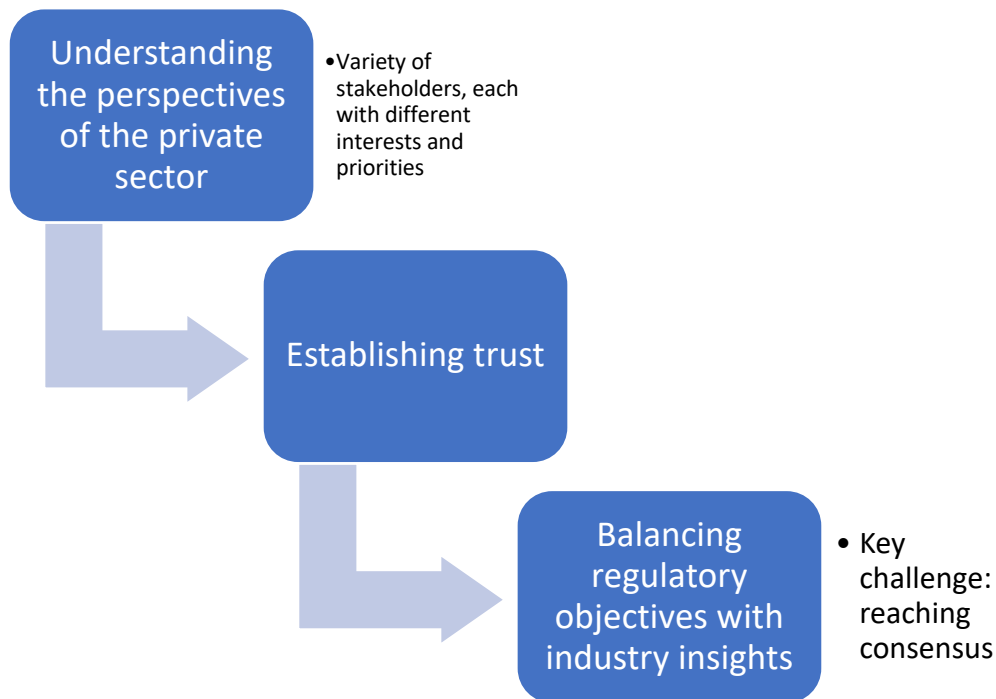
An International View on Regulatory Engagement
Florentin Blanc, Head of Regulatory Delivery Programme, Regulatory Policy Division, OECD

There are extreme variations in how complaints are handled in different countries. In some countries, they trigger an inspection, as opposed to instigating analysis or a discussion. Some countries make complaining as difficult as possible, as opposing to aggregating complaints to identify what is actually happening.

The major engagement issues are: transparency; accountability; trust between regulators, businesses and the public. The rationale for engagement is:

- Changing purposes of engagement: purposes are evolving from compliance to collaborative problem-solving.
- New means of engagement (vital for responsive regulation in a rapidly changing world):
    - Technological advancement
    - Global interconnectivity.

Engagement with the private sector (there are many parts of 'the private sector') can be illustrated like this:

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┌─────────────────────┐
│   Understanding     │   •Variety of
│ the perspectives    │    stakeholders, each
│  of the private     │    with different
│     sector          │    interests and
└─────────────────────┘    priorities
         │
         └──────────►┌─────────────────────┐
                     │                     │
                     │ Establishing trust  │
                     │                     │
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                              │
                              └──────────►┌─────────────────────┐   • Key
                                          │    Balancing        │     challenge:
                                          │   regulatory        │     reaching
                                          │ objectives with     │     consensus
                                          │ industry insights   │
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Non-political interference requires:
> **Regulatory independence:** essential for unbiased and effective decision-making
> **Decision autonomy:** undue political influence

Effective public engagement involves communicating not just challenges but also successes and opportunities. Italy has strong publicity of prosecutions, violations and crime; this gives the public the impression that food is unsafe. Building visibility and credibility can foster trust.

The Netherlands has recently worked with OECD on a Project Strengthening Renewable Energy Permitting. The goal is to speed things up. A barrier was identified around the speed of energy transition being the slow rate of permitting in renewable energy projects. The reasons were, first, a risk-based approach needs more emphasis and, second, stakeholder consultation should be more effective (especially citizen participation). The project identified the necessity of a supportive policy framework, clear guidance and training for permitting authorities, avoiding tunnel vision. Stakeholder consultation should be more effective.

Fostering effective stakeholder and public participation involves:
➢ Integrated public participation: Importance of involving the public not only at the project level but also policy formulation.
➢ Incentivising positive outcomes: Possibility: co-ownership of energy projects.
➢ Clear and effective communication: Between regulators and citizens to build trust.

Future directions are anticipated to involve:
➢ Emerging trends: Digital engagement, and Stakeholder-centric approaches
➢ Adaptation to change: Need to remain adaptive to emerging trends to be effective.
➢ Effective regulatory engagement: Informed, balanced, and transparent.

Medical Technology – an Industry View on Collaboration
Richard Phillips, Strategy Director, ABHI

The Association of HealthTech Industries (ABHI) is the medical technology trade association for the medical devices, diagnostics and digital health technology sectors in the UK. ABHI has 400 members,

which cover over 80% of the value of the businesses in the sectors in the UK, even though the sector has another 4000 mainly small companies. The sector is very diverse. But all businesses have a single customer: the NHS/government. This provides the potential for unique exploitation of data and coordination in research, access, and monitoring. Set against this, the NHS is regarded as a complex, often hostile market, especially for small companies. In regulation, the traditional approach has been worldwide to try to impose medicine-focused solutions on us, inappropriately.

The industry has a heritage of collaboration between innovators, technicians and healthcare. The typical situation involves innovation brought about through technology transfer and serendipity. Hence, peer to peer networks form an essential means of communication. This had its origins right at the start of medical technology in 1958 in Minnesota. Surgeons there had pioneered cardiac surgery, but terrible storms stopped the electricity supply, so technologist Earl Bakken created a device that would operate without mains electricity, based on a transistor. The company that he formed Medical Electronics, is now known under the shorter name of Medtronic.

The latest UK legislative framework, the Medicines and Medical Devices Act 2021, includes Secretary of State being required to take into account of how good regulation is for industry:

"In considering whether regulations under subsection (1) would contribute to this objective, the Secretary of State must have regard to—
(a) the safety of medical devices;
(b) the availability of medical devices;
(c) the likelihood of the United Kingdom being seen as a favourable place in which to—
(i) carry out research relating to medical devices,
(ii) develop medical devices, or
(iii) manufacture or supply medical devices."

The Life Sciences Vision (tomorrow UPDATE) prioritises trust and support through growth between the regulator MHRA and industry. Key statements are that the publication should:

"Build genuine trust between the NHS and the sector about what can be achieved by working together"
"Create an outstanding business for life sciences companies"

Furthermore the regulator has stated that "The Life Sciences Vision remains the roadmap by which MHRA is prioritising its activities and resources".

Current regulatory initiatives include specific instances of collaboration and consultation. First, a Government response to public consultation on revisions to the regulatory framework was published in 2022. Second, the overall strategic approach is also informed by the work of the Life Sciences Council Advisory Group comprising industry/government/regulator membership (including DHSC, Office for Life Sciences, MHRA, ABHI) from which clear priorities have emerged around innovation, capacity, international recognition. Third, the McLean Pro-innovation and Regulation Review includes recommending secondments into MHRA from industry and academia to supplement its expertise.

International recognition is also under discussion: the UK adopted unilateral acceptance of CE marking post-Brexit, and are working on accepting USA FDA recognition. Switzerland provides a lesson in how not to do it, losing thousands of products because of requiring a Swiss representative. Recent UK involvement (both MHRA and industry) in the International Medical Devices Regulators Forum (IMDRF) is a welcome development, enabling UK access to shaping the global framework.

A recent survey showed that Europe has a problem in attracting innovation, and that most companies prioritise USA because the FDA are more pro-innovation. One area where UK is holding its own is collaboration between the health system and industry.
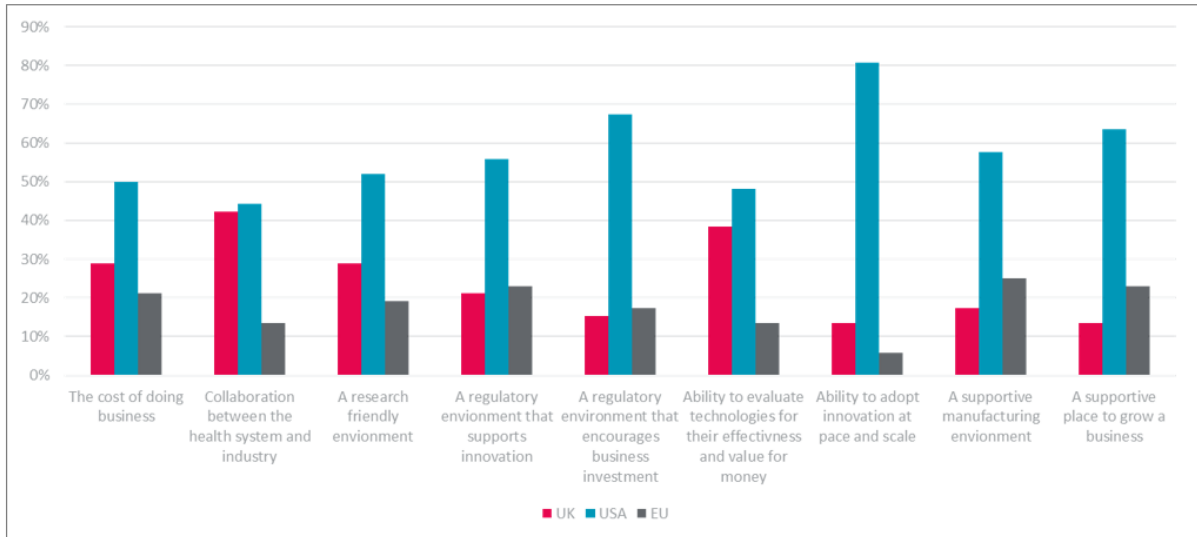
Engaging with vulnerability
Wendy Middleton, Chief Scientific Officer, OPSS

'Vulnerable' is a state not a 'trait'. It can be influenced by various factors:
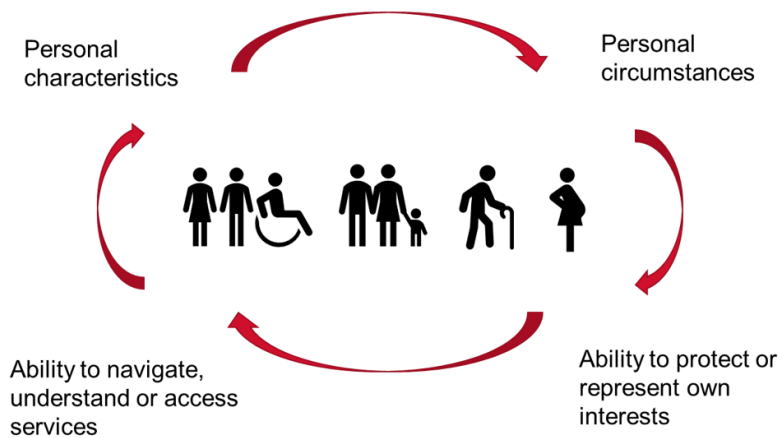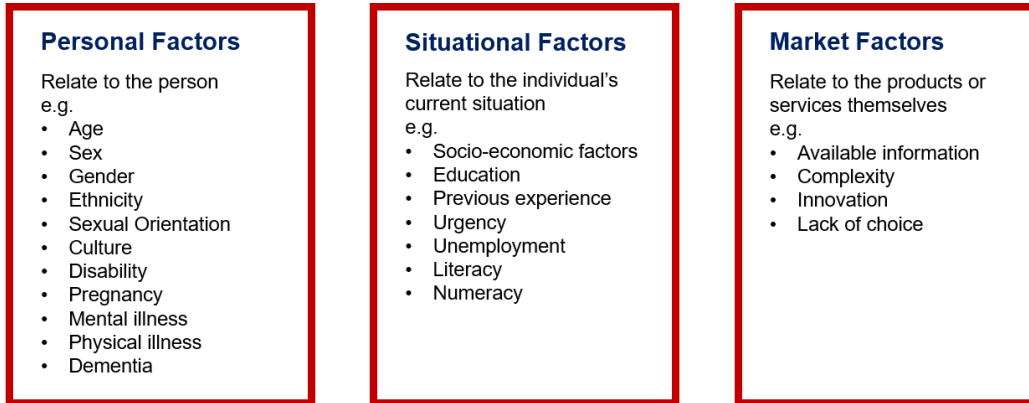

Credit: Community Research (2019)

The linguistic derivation of 'vulnerable' is from the Latin meaning 'wounded'. We can all be vulnerable at points in our lives.

Vulnerability - definitions

The conditions determined by physical, social, economic and environmental factors or processes which increase the susceptibility of an individual, a community, assets or systems to the impacts of hazards

United Nations

Personal Factors	**Situational Factors**	**Market Factors**
Relate to the person e.g. • Age • Sex • Gender • Ethnicity • Sexual Orientation • Culture • Disability • Pregnancy • Mental illness • Physical illness • Dementia	Relate to the individual's current situation e.g. • Socio-economic factors • Education • Previous experience • Urgency • Unemployment • Literacy • Numeracy	Relate to the products or services themselves e.g. • Available information • Complexity • Innovation • Lack of choice

Why engage with vulnerability?

UK House of Lords Science and Technology Committee Report 'Behaviour Change' (2011) said:

"The aim of much government policy is to bring about **changes in people's behaviour** and so a government's success will often depend on their ability to implement effective behaviour change interventions whilst, at the same time, avoiding significant harmful side effects."

Engaging with vulnerability helps ensure behavioural change interventions take the needs of everyone into account, not only avoiding significant harmful side effects but promoting positive fairer and more equitable outcomes for everyone in society.

When thinking about engaging with vulnerability through delivery of regulation, it can be helpful to consider how you do so through the domains of the:

- *Regulation*, for example rationale, approach, legislative framework, role of standard etc;
- *Regulator*, for example culture, outcome measurement, intervention choices, risk-based prioritisation etc; and
- *Regulated*, for example their corporate governance, demographic features, culture, outcome measurement etc

Remainder of talk considered examples of how OPSS, the UKs National Product regulator, engages with vulnerability through each of these domains.

Regulation

Current legislation places a Public Sector Equality Duty on all public bodies, under the Equality Act 2010, public authorities like OPSS have an obligation to consider to *positively promote equality*, and not merely to avoid discrimination, *when exercising our functions*. The decision-maker needs consider this *before the policy is implemented* and needs to weigh potential impacts on equality against other factors. The legislation specifies 9 *protected characteristics* that should be considered e.g. age, gender, sexual orientation, faith. This is also a *continuing duty*, which means the duty applies even after the implementation of a policy / service / function. It leads to better policy making & better outcomes for stakeholders / the public. However, the requirements present a challenge for regulators. It's our duty to do this. it is about equality, and creating spaces to deliver this.

Regulator

OPSS's mission is about protecting people and places so vulnerability is inherent. The Regulatory Delivery Model suggests that we can engage with vulnerability through the behaviour of the regulator by a number of means, including:

- Education - Access to relevant L&D
- Tools - Creation of a 'Vulnerabilities toolkit' & Consumer Plan
- Outcome Measurement - Monitoring compliance with the Public Sector Equality Duty
- Culture - Value placed on D&I
- Risk-based Prioritisation – Allows consideration of vulnerability

As an example, OPSS has developed a Product Safety RISk Methodology (PRISM), which engages with vulnerabilities in risk assessment. It specifies:

1. Identification of a non-compliant product.
2. Risk triage.
3. Risk assessment.
4. Risk evaluation.
5. Quality assurance and reporting/recording.
6. Risk management.

The last 3 elements in particular enable us to engage with vulnerabilities in our risk assessment. Addressing physical harms is relatively straightforward, but it is more challenging when one considers psychological or brain harms. Engaging with vulnerabilities in risk assessment requires looking at:

- Subjects at risk
- Potential for physiological/ psychological harm
- Prevalence forecast
- Level of uncertainty
- Risk presented by comparable products
- Potential for multiple casualties
- Risk differential
- People at increased risk
- Action taking place elsewhere

Regulated

Engaging with vulnerability in our regulated populations has included:

- *Considering business types*. A recent survey found:[4] 45% of UK businesses agree that regulation is a blocker to success. Businesses that said length of time taken to comply with regulation is a burden were more likely to agree that regulation is an obstacle to their success. Small businesses with 10-49 employees (66%) & businesses in the Agriculture/ Mining/ Energy sector, Finance sector, Manufacturing sector & Retail/ Distribution sector were most likely to feel that the time taken to go through the whole process of complying is a burden. Innovative businesses were more likely to say a range of issues presented a challenges to their business compared with other non-innovative businesses (e.g. access to finance 21% vs. 9%, level of regulation and time to compliance 49% vs 44%).
- *Perceptions of regulators*. Survey evidence finds a healthy response that regulators provide advice and guidance that helps businesses comply.[5] An example of an engaged approach arose following low rates of compliance in food businesses in West of England. After it was seen that many people involved were Somalis, and that language was a barrier, the local TSs offered training courses in English to them, which transformed ability to comply with food regulations.

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[4] https://www.gov.uk/government/publications/business-regulation-business-perceptions-survey-2022
[5] https://www.gov.uk/government/publications/business-regulation-business-perceptions-survey-2022

- *Supporting businesses to think about vulnerability*. Consideration of age in the context of consumer products is an interesting example of the complexity of the issue. Research clearly demonstrates that older people can be vulnerable, and be made to feel vulnerable, by products that are not designed to be as easy to use for older age consumers who are experiencing decline (such as mobility, eyesight, dexterity).[6] However, consumer research also shows that older people are more likely to be 'safer consumers', in that they are more likely to consider safety when purchasing a product, to register a product and act on a recall[7]. Therefore, with some products, that have no design failures, older people may be less vulnerable as a result of their consumer behaviour.
- Other topical examples include additional harms presented to women by products such as body armour, PPE and wearable immersive devices that have not taken their metrics into account. To respond to this, OPSS sponsored BSI to produce a PAS FLEX on the role of data and data analysis in the development of inclusive standards.[8]

In summary, vulnerability should be considered as a 'state' rather than a 'trait' that varies depending on personal, situational & market factors. When considering how best to engage with vulnerability through the delivery of regulation, it can be useful to consider both how compliance impacts vulnerability and how vulnerability might impact compliance. This can be done through consideration of vulnerability through policy formulation and the development of the *regulations*, how it is embedded through the behaviour of the *regulator* and consideration of vulnerability in both the *regulated* population itself and the population their activity impacts. Noted that need more empirical studies and case studies to support and share best practice.

Engagement challenges with new and innovative technologies
Dr Andy Greenfield,
Honorary Research Fellow, Nuffield Department of Women's & Reproductive Health, University of Oxford[9]

A number of case studies illustrate real-world perspectives in regulation and engagement.

<u>HFEA: mitochondrial donation regulation</u>. The Human Fertilisation & Embryology Authority (HFEA) is the UK's independent regulator of fertility treatment and research using human embryos. It licences, monitors and inspects fertility clinics and research labs. It is an arms-length body of the DHSC, and was created by the Human Fertilisation and Embryology Act (1990). The Board includes patients, lay people, clinical leads and other professionals. The inclusion of sector professionals on the board (which has a lay majority) is an immediate indicator of the willingness to routinely engage with the sector.

Mitochondrial donation (MD) is the effective removal (or reduction) of disease-causing mitochondria from a fertilised human egg by transferring pronuclei to an enucleated donor zygote – the procedure can also be performed prior to fertilisation. MD can completely transform the health of any child born – mitochondrial diseases can be devastating - but to some it involves having 'three parents' – with all the attendant social and ethical issues this implies. How could the HFEA decide how to proceed?

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[6] https://www.gov.uk/government/publications/ageing-society-product-design-for-older-people
[7] https://www.gov.uk/government/publications/opss-product-safety-and-consumers-wave-1
[8] https://knowledge.bsigroup.com/products/enabling-the-development-of-inclusive-standards-understanding-the-role-of-data-and-data-analysis-guide-1?version=standard
[9] Member of Human Fertilisation & Embryology Authority (HFEA) Board, 2009-2018; Member of Human Tissue Authority (HTA) Board, 2022-; Member of FSA's Advisory Committee on Novel Foods & Processes (ACNFP), 2022-; Chair of its Products of Genetic Technology (PGT) subcommittee; Council Member, Regulatory Horizons Council, 2020-.

The HFEA commissioned several expert panels that assessed safety and efficacy of MD. But it also had to reach out to the wider public and other professionals. It conducted a *public dialogue exercise* to explore the *ethical aspects* and related issues involved in MD; and it engaged professional bodies to understand the *practical implications* of allowing such techniques within regulation. One comment from the public engagement exercise was 'Maintaining public confidence requires regulation'. MD might well have been ideal for a sandbox approach. An introductory briefing note was produced to inform Parliamentary debate, recommending a regulatory framework involving a licensing process with the following features:

➢ Safety and efficacy considerations (independent scientific advice)
➢ Licence: clinic competence (the greatest source of expertise is the applicant)
➢ Approval on a case-by-case basis – patient suitability
➢ Donor anonymity.

Legislation was then introduced that has worked reasonably well: Mitochondrial Donation Regulations 2015. In respect of the wider question of how to regulate emerging technologies, the HFEA are currently consulting on updating the Act.

HFEA: Multiple births policy. Multiple births represent the single biggest risk to health and wellbeing of mother and children born following IVF. The multiple birth rate was around 28% in 1990s (natural twinning rate is around 1-2%). Clinics' economic model was built on guaranteeing success, and they accepted multiple births. Addressed through collaboration. The '*One at a Time*' report was published in 2006, and resulted in One at a Time campaign (HFEA soft powers to regulate). HFEA actively engaged with professional bodies. The challenges were to maintain live birth rates following single embryo transfer *and* engaging with patient groups.

The collaborative strategy was judged to have been a success. Jane Denton, Director of Multiple Births Foundation (MBF), said:

> "*I have no doubt that the collaboration between the HFEA, professional bodies and organisations, and most essentially the patient representatives, was the main factor in achieving our goal.* Workshops were held with staff from HFEA licensed centres, in which they shared their multiple births minimisation strategies, their difficulties and successes."

In 2019, multiple birth rate in UK following IVF was 6% (and falling). Of course, not everyone is happy. The HFEA operates in a litigious environment. One objection was that the HFEA should not intervene between the patient and their clinician – it is a matter of clinical judgment. Related difficulties have arisen in HFEA work on clinic 'add-ons' ons', where the HFEA has collaborated with the CMA. HFEA work continues with recommendations for amendments to the Act, including sensitive areas of policy such as the 14-day rule, embryo models, genome editing of human embryos etc.

Neurotechnologies. These scientific interventions can make people walk, see, hear when they could not. But there are concerns over safety, efficacy, accessibility, and so on. The Royal Society's public dialogue on neurotech identified the following areas for future public engagement:

• **Equity of access:** How does society create an environment in which the ultimate goal is that everyone who suffers from a debilitating medical condition or injury has access to neurotechnologies to restore or improve their quality of life?
• **Control, transparency and choice:** How can we make sure neurotechnologies develop in such a way that people have the opportunity to opt-in pro-actively to the use of the technology based on factual information about the pros and cons and who has access/owns the data generated by their devices?
• **Regulation:** How do we arrive at a regulatory framework that is sufficiently flexible to enable science and medicine to progress whilst making sure it covers the elements participants in this study identified as essential: the publication of open standards, transparency of information, data protection assurances, safety of the devices and clarity about the purposes neurotechnologies can be developed for?

- **Managing health in a neurotechnology-enabled society**: How is society going to redefine the current health and social care system to meet the needs of growing numbers of independent older people whilst ensuring equity of access to neurotechnology?
- **Managing productivity and efficiency in a neurotechnology enabled society:** What needs to be in place in a society that might have to balance a lower demand for labour due to automation and an increased efficiency of neurotechnology equipped workers within a growing workforce as a result of a more widespread use of medical NIs?

The Regulatory Horizons Council issued a Report on *Neurotechnology Regulation* in November 2022. It adopted a technique of interviewing all stakeholders before reaching its own independent conclusions. An issue identified was:

> "4.1.1 *Unclear and difficult-to-navigate regulatory pathways to market, and insufficient pre-submission advice and guidance.*
> Researchers and manufacturers clearly expressed a desire for more tailored advice and dialogue, on a case-by-case basis, on top of the generic guidance documents and services currently available and described above. This is especially important in a complex area such as neurotechnology, where general guidance may be insufficient due to the lack of previous case studies and the number of borderline cases."

The RHC's primary recommendation was to build a routine enhanced culture of dialogue and early engagement between regulators and innovators. Experimental approaches could also be used, such as sandboxes, testbeds and so on. It also recommended that HMG set our senior accountability for neurotech, in order to promote discussion of wider governance issues, nationally and internationally.

The FSA and genetic technologies in food production. Since the 90s, there has been a history of heated debate over whether "GM" products are safe and ethically acceptable. The Food Standards Agency (FSA) has consulted widely, including a recent *Consumer perceptions of genome edited food* survey. The Advisory Committee on Novel Foods and Processes (ACNFP), whose Products of Genetic Technologies (PGT) Subcommittee, has been responsible for recommending a risk assessment framework for foods derived from precision bred organisms. The public engagement was part of a process that led to passing the Genetic Technology (Precision Breeding) Act 2023. There is ongoing detailed interaction, taking account of sensitivities around food safety and security, use of genetic tech in farmed animals, and the wider imperative to innovate.

(Tentative) conclusions from these case studies and experience would be:
- One size does not fit all!
- How 'controversial' is the sector/technology use-case? Public engagement key.
- What is the level of compliance in the sector?
- What are relations like between the regulator and the regulated? Mature? (Public versus private interactions).
- Might the regulator be accused of capture? Or of not being 'good value' or 'a burden'?
- Regulators should limit 'tick box' activities – but public tends to be supportive of such 'watchdog' functions.
- Collaboration between regulated and regulator requires 'give and take'.

CASE STUDIES ON OBCR AND NEW FORMS OF ENGAGEMENT

The Outcome-Focused, Collaborative Approach to Food Regulation in Queensland
Brian Witherspoon. Safe Food Queensland.

Safe Food Queensland (SFQ) is a statutory body, operating under the Food Production (Safety) Act 2000. It has around 35 FTE staff and Board of Directors. It reports to the Queensland Minister for Agriculture, and regulates the meat, dairy, eggs, seafood and (now) horticulture sectors, using a through-chain approach, science and risk-based framework, and cost recovery business model. The shared goal operates as:
-   Regulated business are responsible for producing safe and suitable food
-   SFQ regulates food businesses' food safety controls.
-   Together, the parties protect the health of consumers by reducing food safety risks.

SFQ has been working towards transformation. Being a good regulator requires understanding different perspectives. The agency established 20 years ago, merging two authorities, and covers 5.5m people (the same number as New Zealand), in a huge geographical area. About 15 years ago we realised that our regulated businesses did not fully understand their role and our role within the food system, so we needed to engage differently. The key has been working out how can we verify compliance in different ways.

The traditional regulatory toolkit includes: accreditation, verification studies/surveillance, food safety programs, audit (incl. third party), investigations & enforcement, and inspection. In our transformation, we have developed our regulatory toolkit more towards using a different set of tools, such as:
-   Preferred Supplier Arrangements (PSAs), such as with dairy. We no longer do routine audits: they do. They share data with us and we work together if concerns arise
-   Food safety notifications; business identifies an issue and tells us, then we work with them, on the basis of 'Let's problem solve this together'. This has worked well, and has built up a lot of trust.
-   Food safety assessment (Compliance Assessment System) rather than audits. This involves a commitment to manage those risks, effectively a culture management approach.
-   Online accreditation register for transparency and to help businesses and consumers verify what businesses are accredited
-   Food safety management statements: short sharp documented system, as opposed to detailed, complex food safety programs
-   Co-created baselines: with industry. SFQ did poultry first, for all activities in the supply chain (see illustration below). Questions were: Does this reflect your operation? How do you see yourself in this, making it work? This helped SFQ understand what *they* do. What control points apply? Stability of the system. Industry agreed all the targets (not in legislation). We worked out the baselines. Sequence of best practice in stages baselines (see figure below), compliance just falls into place.
-   Data sharing (Central Information Management System). Data is already being collected – we want to use this, not just get people just to collect data for us. We are continually improving the system, and this involves more and closer engagement. The businesses are sharing more information amongst themselves, recognising that this is in their best interests.

An Industry Best Practice Approach: the QLD Poultry Industry:
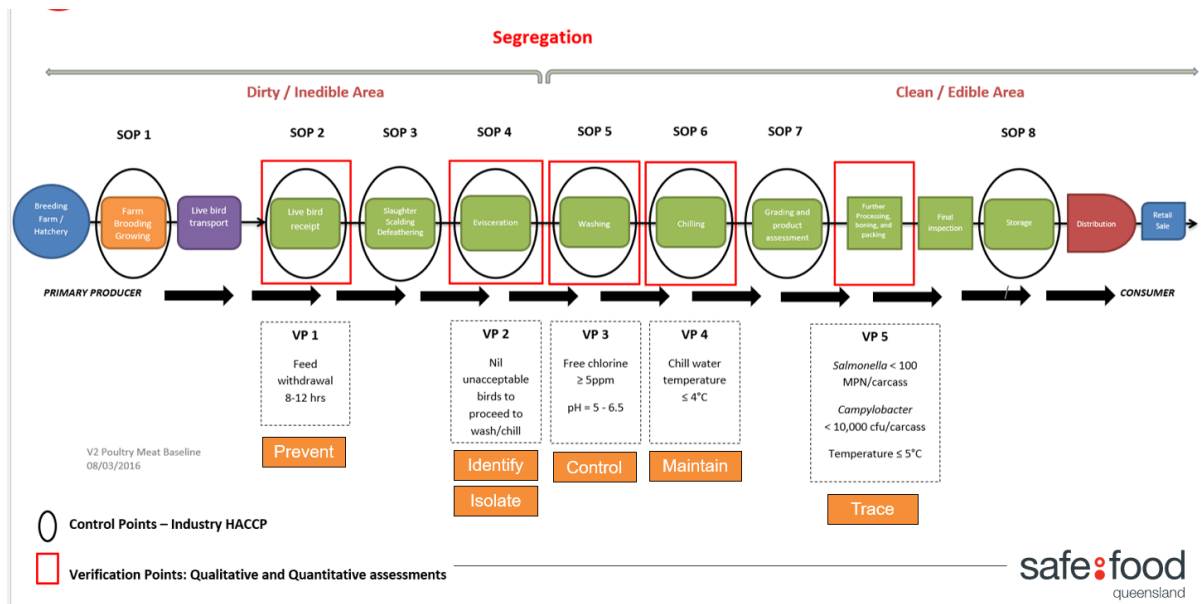
Baselines:
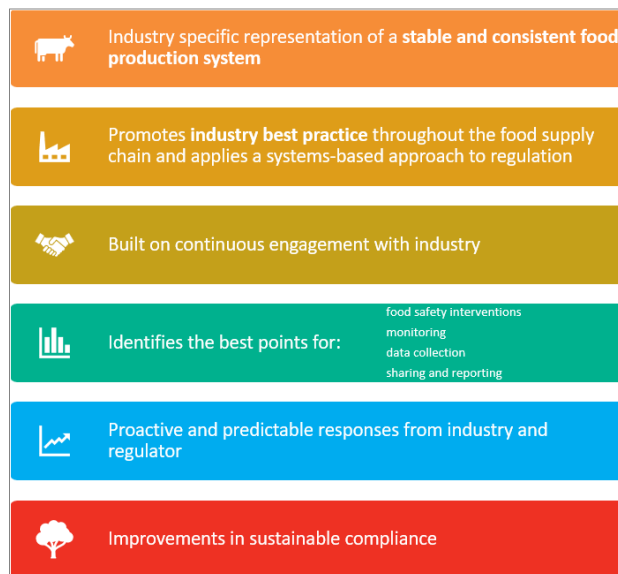
A number of regulatory and organisational challenges have existed: diverse and demanding consumers; innovative and dynamic food sectors; stubbornly high foodborne illness rates; increased supply chain disruptions; resource constraints; legislation limitations; 'traditional' reactive monitoring tools; What does success look like??; "One size fits all", no it doesn't – so how do we prioritise?; financially viability (significant, cost of audits in our business model, if we move away from audits, how do we change to best practice model?); systems that don't speak to each other (IT and regulatory). There are also changes in supply chains, and the arrival of new technologies.

SFQ has undertaken a Digital Transformation Programme based on the strategic priorities of: expanding its positive influence & impact; leading the way in regulation innovation; transforming its corporate capabilities; and strengthening its scientific contribution. The components of the DTP have been: a new regulatory delivery framework, a new operating model, a workforce Strategy, and a digital platform.

The new regulatory delivery framework (and evolution of the pre-existing approach) was created to harness digital technology; recognise the importance of genuine collaboration and engagement with all

food supply chain participants; proactively manage risk ; and recognise that food safety is critical, but only one element in Queensland's broader food system. It is illustrated as a circular, joined up system, and includes SDGs.

Related bi-national developments have also occurred in Australia and New Zealand, on jurisdictional consistency. The *Bi-National Priority* was *Maintaining a strong, robust and agile Food Regulation System*:[10]

- Facilitating Jurisdictional Consistency Project (Safe Food led)
- Explored contemporary regulatory models that could facilitate greater jurisdictional consistency.
- Reports prepared by Prism Institute to inform work.
- Adjusted the perspective of how to modernize the system.

The introduction of three New National Horticulture Food Safety Standards is now proceeding on the new basis:

- 30-month implementation period (February 2025).
- Combination of regulatory and non-regulatory measures needed to effectively .manage food safety risks in the three sectors.
- Responsibility of each jurisdiction i.e. the States and Territories.

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[10] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/Modernisation-of-the-food-regulation-system

Implementation was based on a PRISM Report & workshop - *Future Visioning Safe Food's Regulatory Delivery Model*,[11] providing an opportunity to work with the horticulture industry to apply bi-national learnings, using the RDM to guide co-design process, which will act as a 'pilot' for all regulated sectors. The co-design process has commenced, starting with a co-designed code on collaborative environment with the horticulture industry. The Goal is stated to be:

"To build a collaborative regulatory environment in which:
- all participants understand their roles and responsibilities in ensuring our food is safe, and
- work together to problem solve and overcome the challenges we face now and into the future."

A Queensland Horticulture Regulatory Delivery Steering Committee has been created to design a regulatory framework that:
- drives best practice through the whole supply chain within Queensland;
- aligns with national decisions regarding the implementation of the standards;
- aligns with the Queensland Government's Regulator Performance Framework;
- incorporates key indicators to measure the framework's effectiveness.

There are two supporting groups: an Industry Advisory Technical Group looks at 'how' through recognition of industry certification systems, and a Cross-Agency Reference Group looks at 'how' on the government side.

The stages in design and implementation have been:
1. Preparation (the groundwork)
2. Framework co-design (the theory)
3. Framework development (the practice)
4. Pre-commencement engagement (the promotion)
5. Roll out of standards (the implementation).

At end 2023, stage 3 has been reached, and the intention is to reach stage 5 by 2025.[12]

Eat Right India
Pawan Agarwal

India has a population of 1.4 billion, and 5.1 million licensed or registered food businesses, but also a large unorganised food sector. The annual economic burden of food borne diseases is significant: $15bn, and number of cases expected to rise to 159-177 million by 2030. To address foo regulation, two tracks were adopted:

Track 1: Traditional regulatory approach for the formal sector (engagement largely with businesses in the formal sector).

Track 2: Outcome-based cooperative approach for the informal sector (engagement largely with businesses in the informal sector and mass movement on food safety awareness for consumers).

The principles were: a systems approach; mass mobilisation; standardisation; capacity building and partnerships; and recognition and rewards.

1. **Systems Approach**. Integrating: People eat safe food, healthy and sustainable diets; understanding the complex system.

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[11] https://www.safefood.qld.gov.au/wp-content/uploads/2022/08/Future-Visioning-Safe-Food-Production-Queenslands-Regulatory-Delivery-Model-PRISM-Institute-Report.pdf

[12] Further information: Safe Food Production Queensland www.safefood.qld.gov.au; Australia and New Zealand Food Regulation www.foodregulation.gov.au; Food Standards Australian New Zealand (FSANZ) www.foodstandards.gov.au.

An integrated approach was adopted called 'Eat Right India'. The elements were: safe, healthy, sustainable.
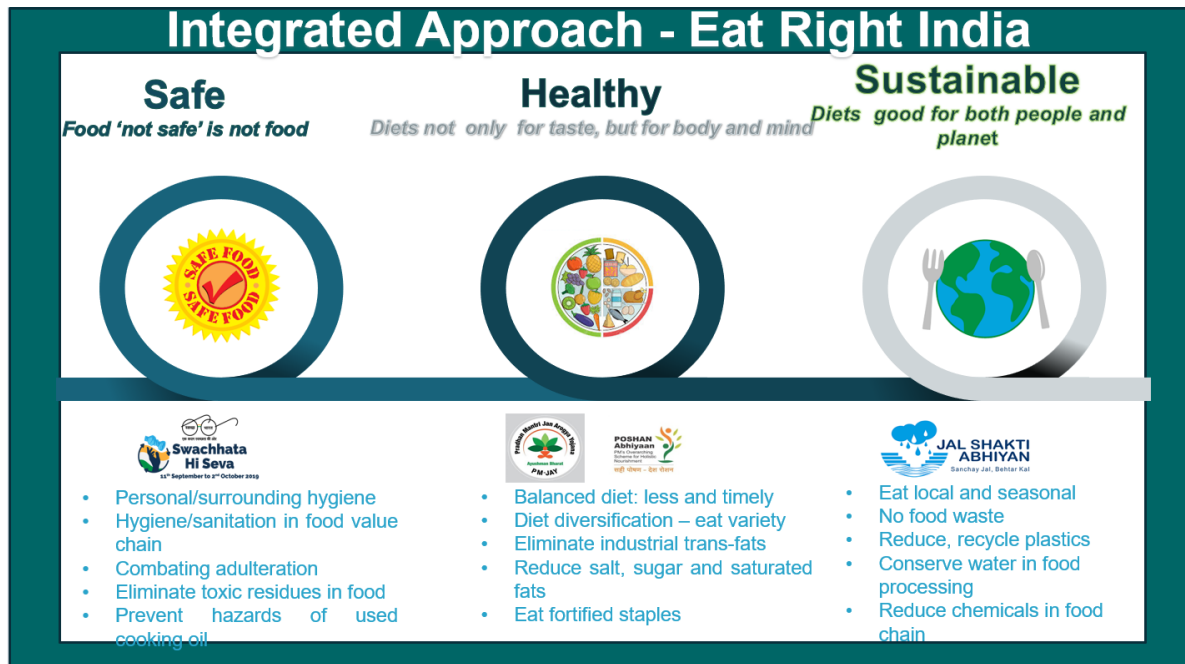
Designed interventions – home, school, small and larger workplaces. Excite, engage, enable.
It included both community and Individual aspects:

- Community – coalition building and advocacy.
- Individual – learning, trust building.

2. **Mass Movement**: Create Excitement; Focus on the informal sector.
This adopted social and behavioural change.
At the Government-level

- Eat Right Challenge for Districts : **260 participating districts**
- Eat Smart Cities Challenge: **109 Smart Cities**

At the Society-level
- Challenges and contests
  - ✓ Indi-genius Millets Recipes
  - ✓ Eat Right Creativity Challenge
  - ✓ Plan Protein Breakfast Recipes
  - ✓ Nature's Sweetness in every bite (healthy dessert recipes without use of sugar or artificial sweeteners)
  - ✓ Fat Free Cooking Challenge

Eat Right Walkathons & Eat Right Mela Fair in 122 Cities
- Focus on local/ seasonal food; Balanced Diet and Millets
- Door to door engagement via Food Safety of Wheels (Mobile Food Testing Vans)

Influencers were signed up to deliver messages. Techniques involved social media, radio, community radios , WhatsApp messages/videos, posters at prominent places, LED Screens, Melas/ Fairs.

3. Standardisation.
Program SoPs, Branding, Content Creation, Build ecosystem; Essential for Scale
5-year achievement (2017-2022):
- **Eat Right Campus** covering workplaces, hospitals, educational institutions, Jails, Tea Estates and Police Stations. Campuses certified till date: **1639.**
- **Eat Right School:** A powerful tool to create an environment of safe food and healthy eating across all schools in India through training of food handlers and audit of canteens. No of School Registered: **1,00,321.**
- **Hygiene Rating:** Covering food service establishments; restaurants and hotels; sweet shops, bakeries and meat shops. No of HR certified establishments: **27,922.**

Rich content was produced. A video library on various topics for consumer awareness is available on ERI website under Resources tab including:
- TVC Campaigns
- Short videos on food safety, hygiene and nutrition for Citizens to understand the concept of Eating Right
- Books and Guidance Documents
- Posters and Creatives
- Social Media for engaging consumers

4. Capacity Building and Partnerships. A shared responsibility.
- Over 1 million Food Safety Supervisors trained (small businesses form the largest proportion).
- Over 25,000 teachers.
- Population coverage: Entire country of 1.4 billion people(Focus 200 million). 75 Eat Right Districts and 11 Eat Smart Cities.

5. Recognition and Rewards. Understanding motivations and drivers; Stay on Course.
Awards, prizes, State Food Safety Index.

Lessons learned.
- A fragmented system of regulates needed a fresh integrated approach:
  - o A complex interplay of a range of factors
  - o Linkages between food safety with nutrition and sustainability
- For a cultural change – create excitement through mass mobilization
- Require standardization and multi-stakeholder engagement to scale
- Build capacity and develop partnerships for mutually reinforcing process of change
- To stay on course – have rewards, recognition, and branding

Conclusion by Steve M Jaffe, former Lead Agriculture Economist World Bank, email dated 3 Dec 2022:

"This is really a distinctive approach. In most other places we see technical siloes (rather than linkages between nutrition, food safety, and the environment). And, on the food safety side, there is lots of emphasis on inspections, testing, and administering punishments to violators!

In Vietnam, they are very proud to announce how many companies have been fined, as presumably that results in safer food."

Stakeholder engagement and resource recovery regulation
Noah Gitterman, Ontario Resource Productivity & Recovery Authority

The Resource Productivity and Recovery Authority (RPRA) is a regulatory body created by the Government of Ontario to administer a new regulatory framework for recycling and waste diversion in the province. This involves a transition from an older system involving centralized program operation and no strict performance targets, to a newer system that puts individual performance obligations on the businesses (producers) that sell the products that end up as waste in the province, overseen by regulator that can enforce performance. RPRA is an independent regulator. We were created as a new "administrative authority" with the power to enforce circular economy laws and collect fees from registrants to fund our programs. We are not part of government, but have accountability and reporting obligations to the provincial Minister of the Environment.

The legacy waste diversion system in Ontario had the following features:
- **Centralized system**: Statutory monopolies created to run recycling programs for different materials across the province. These entities typically ran all the recycling operations – collection, hauling, and resource recovery.
- **No business choice**: Most businesses had little to no say in how recycling programs were run. Producers were required to register and pay fees to the monopoly entity; service providers who did collection, hauling, and resource recovery only dealt with the monopoly purchaser.
- **No enforcement**: Monopoly programs had aspirational recycling performance targets to meet. Limited consequences for failure to meet targets.

A new circular economy framework was introduced in 2107:
- **Individual responsibility**: Producers are individually obligated to meet minimum annual performance targets for material required to be recovered at end of life (among other obligations).
- **Producer choice**: Producers have market choice for how they want to fulfill their obligations to collect and recover products at end of life.
- **Enforcement**: A regulator (RPRA) is given the power to enforce obligations to register, report data, and achieve performance targets.

The Producer Responsibility Framework has these features:

Producer responsibility framework

- Producer choice

- Competitive markets for recycling services

- Mandatory performance targets

- Accurate data

- Verification and independently audited

- Common standards and definition set by RPRA

- Level playing field

- Empowered regulator

- Enforcement mandate and tools

RPRA's role – what we don't do:
- **Not government:** RPRA **does not** determine policy or write regulations.
- **Not a service provider:** RPRA **does not** arrange for collection or recycling.
- **Not a market regulator**: RPRA **does not** regulate commercial arrangements:
    - RPRA doesn't set contract terms, decide if prices or offers are "fair," or enforce the terms of service provider contracts.
    - However, RPRA does enforce participation in the market, e.g., capture free riders.

Materials have been designated sequentially under the new regulatory framework: tires (2019), batteries (2020), electronics (2021), hazardous and special products (2021), lighting (2023), blue box (2023-25).

Engaging business: goals, tactics, successes, learnings
We tried to meet producers where they were. Data is used to drive performance.

Key players in Ontario's producer responsibility regulatory framework

Ontario Government

Develops, approves and makes amendments to legislation (e.g., acts, regulations)

Issues Minister's directions

RPRA

Implements and enforces regulations

Primary enforcement approach is effective communication

Has power to:
- Conduct inspections and audits
- Conduct Investigations
- Issue compliance orders
- Issue Administrative penalty orders
- Undertake Prosecutions

Producers

Responsible for establishing collection and management systems to ensure their products and packaging are properly managed and recycled after consumers have finished using them

Producers have the choice to operate their own system or work with a PRO(s) to meet those requirements on their behalf
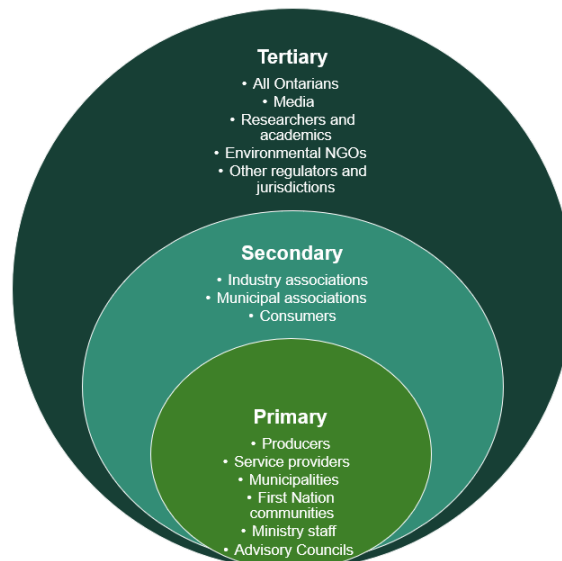
Service Providers

Provide collection and management services for producers

Includes:
- Producer responsibility organizations (PROs)
- Haulers/Transporters
- Reuse/Refurbishers
- Processors
- Disposal Facilities
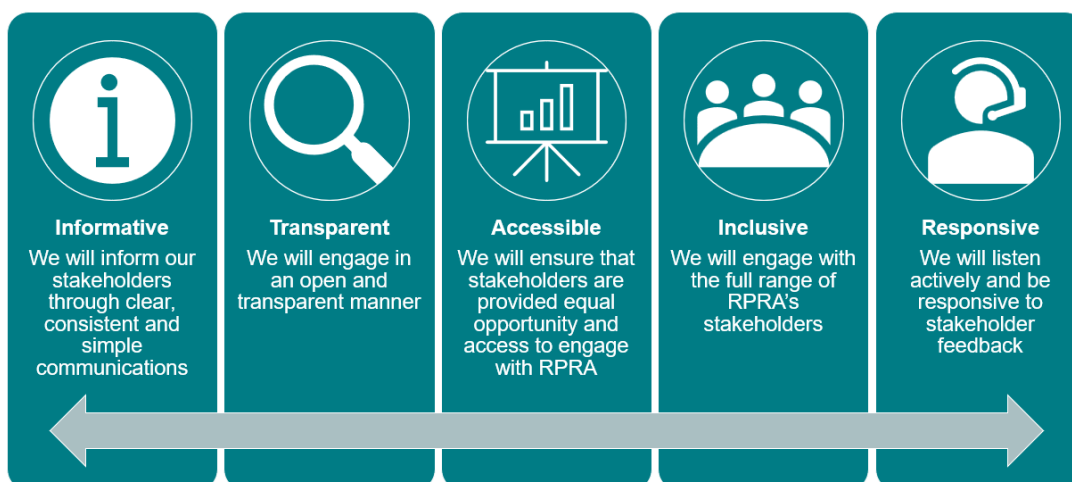
Broader stakeholder map

Tertiary
- All Ontarians
- Media
- Researchers and academics
- Environmental NGOs
- Other regulators and jurisdictions

Secondary
- Industry associations
- Municipal associations
- Consumers

Primary
- Producers
- Service providers
- Municipalities
- First Nation communities
- Ministry staff
- Advisory Councils

Engagement goals

As a new regulator with a new mandate, our goals included:
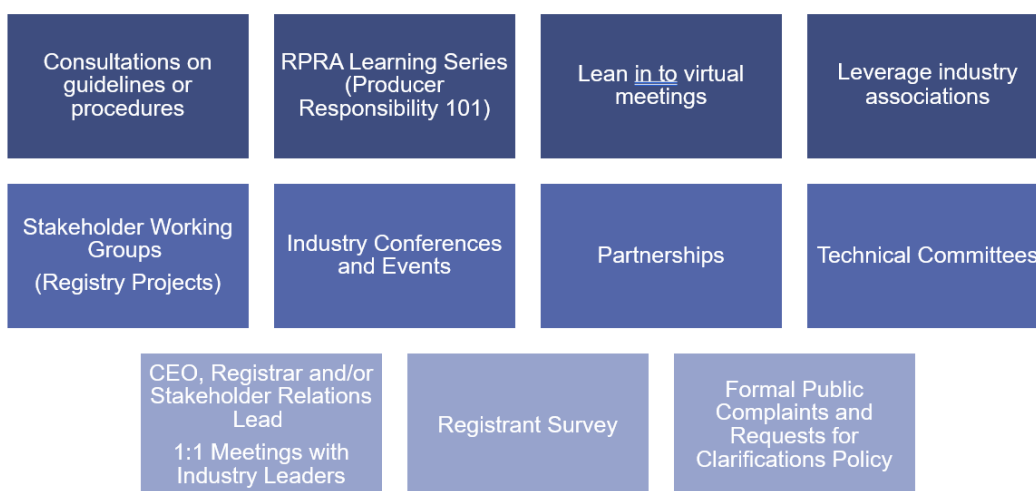
- Inform and educate: There was a clear need to engage with stakeholders early and often to be clear about who RPRA is, what we do, what producers' obligations are, and how the regulations 'work'.
- Communicate first: Traditional enforcement tools would be too cumbersome on a wide scale for an entirely new program – compliance would require high levels of communication and engagement to ensure producers took the right steps in the market to achieve the performance outcomes the framework required.
- Focus on risk: Resource constraints meant that compliance and communications tools should be targeted to areas where impact and need were highest.
- Build trust: Trust, with a basis in transparency, would be needed to ensure that the regulated community listened to and believed in RPRA's approach.
- 'No surprises': Communicate proactively about expectations for producer reporting and performance, and what they can expect from RPRA in response.

Engagement approach: values and commitment

Informative	Transparent	Accessible	Inclusive	Responsive
We will inform our stakeholders through clear, consistent and simple communications	We will engage in an open and transparent manner	We will ensure that stakeholders are provided equal opportunity and access to engage with RPRA	We will engage with the full range of RPRA's stakeholders	We will listen actively and be responsive to stakeholder feedback

Key tactics

RPRA deploys a range of stakeholder engagement tactics based on best practices and stakeholder preferences.

Consultations on guidelines or procedures	RPRA Learning Series (Producer Responsibility 101)	Lean in to virtual meetings	Leverage industry associations
Stakeholder Working Groups (Registry Projects)	Industry Conferences and Events	Partnerships	Technical Committees
CEO, Registrar and/or Stakeholder Relations Lead 1:1 Meetings with Industry Leaders	Registrant Survey	Formal Public Complaints and Requests for Clarifications Policy	

Engagement successes

Substantial compliance to date without enforcement tools:
- Compliance with registration and reporting obligations often over 80%
- Only one group of orders issued; no penalties issued.
- Focus on achievement of outcomes and not heavy-handed enforcement.

Broad buy-in from producers, service providers, and their associations:
- Productive and helpful consultations on guidance and procedures.
- Most producers and service providers can be convinced to 'do the right thing'.
- Some producers went over and above obligations, without enforcement from RPRA.

Key learnings:
- **Businesses need to be sold on it**: Even though the framework seems business-friendly on its face, apart from some sophisticated entities, many did not see value in producer choice; instead, it seemed like extra burden on them. More effort than expected was needed to explain 'why' the framework is set up this way and what the benefits are to producers and the public (rather than just describing obligations). There was no explicit economic incentive, other than automatic prospect of reducing business cost.

- **Businesses need help to adapt**: Change is hard, and it's easy to underestimate how hard it is. Businesses looked repeatedly to RPRA to tell them how to achieve their obligations under the new framework. More focus on 'soft law' upfront – guidelines and procedures – may have made this easier.
- **Look to other jurisdictions**: Many regulated businesses operate nationally or internationally. In figuring out how to comply, they look to practices elsewhere. Early outreach to other jurisdictions to help compare and contrast systems, definitions and requirements; line up expectations where possible; and identify where Ontario is different may have helped at the start.
- **Give them even more transparency**: Along with a communications-first approach, businesses demanded fairness. The regulated community wanted to know they were being told the same thing, treated the same way, and not doing more or less than their competitors. This led to demands from RPRA for more transparency about our activities and communications than we had initially planned to provide.
- **Change takes time**: Long reporting cycles for producers and ability to phase in some performance obligations allowed RPRA some time to get it right. Perfect performance was not needed out of the gate. Also, the data repository takes time to assess – collecting a lot of data from different entities cannot be relied on right away.
- **Slippage/complacency:** There is a need to continue to engage to ensure producers remain vigilant and performance doesn't slip. Some complacency with the communications-first approach can lead to misaligned expectations later on.

Establishing a new framework of standards, governance and legislation for Digital Identity – based explicitly on collaboration and trust.
Eleanor Curry, Department for Science, Innovation & Technology (DSIT)

HMG is working to enable the use of trusted digital identities in the UK. Digital identities give people another way to prove things about themselves, such as their age, address or qualifications, without the need for physical documents. In order to build the trust that is required to realise the potential benefits of digital identities, the Department for Science, Innovation and Technology is committed to creating a framework of standards, governance and legislation, so that businesses and users know what a good digital identity looks like.

DSIT is focussing on doing what only the government can do: enabling the growth of trust in digital identities while leaving space for the market to develop solutions, in accordance with the response to the Digital Identity Call for Evidence. The government is committed to enabling a digital identity system without introducing ID cards or mandating the use of digital identity.

The methodology for creating this framework that was adopted by DSIT has been through an open collaborative approach based on stakeholder engagement. Following the Call for Evidence, the Government committed to:
- Creating a *framework of rules* that show what 'good' digital identities look like to underpin *trustworthy, interoperable* products.
- Establishing a *governance and oversight* function to own these rules, keep them up to date, and make sure they are followed
- Developing *legislative proposals* to create a secure register of trusted providers, enable trust mark issuance, and permit sharing of trusted government-held attribute
...all while focusing on *privacy, inclusion and international interoperability.*

Stakeholder engagement was pursued in the following stages:
- *Ongoing engagement*: Industry engagement sessions, with cross-government engagement, (approx. every six weeks) to update stakeholders and gather feedback on policy as it develops.
- *Beta testing*: Dedicated engagement in adoption sprints and sandbox testing to test whether the beta version of the trust framework is effective for all users
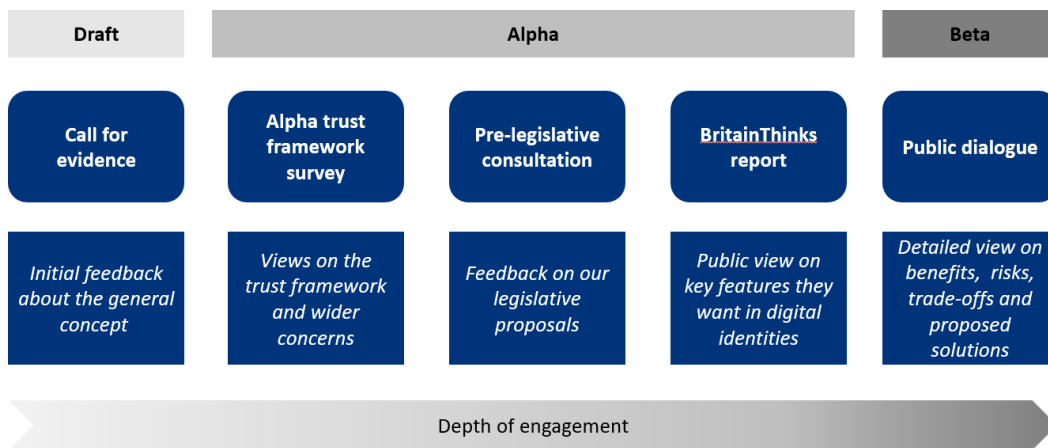
- *Public trust*: Engagement to capture public perspectives through public dialogue and public attitudes research.

DSIT has published three published versions of a trust framework. The trust framework has been developed in an open and iterative way, with all interested parties invited to provide feedback throughout the process.

The adoption sprints were a series of six in-person events bringing together organisations from across the digital identity ecosystem. This included digital identity service providers, relying parties, regulators, policy officials, academics and civil society groups. The events took place between January and March 2023. The aims of the adoption sprints were to *build market confidence*, gather *feedback on specific areas of the trust framework* and to *surface - and identify possible mitigations for - the barriers to adoption* in five priority sectors. The first five sprints (in financial services, employment, property services, travel, retail/age assurance, plus one cross-cutting sprint) each focused on a *specific sector* and the final adoption sprint focused on cross-cutting policy issues, including *inclusion, governance, and strategic communications*.
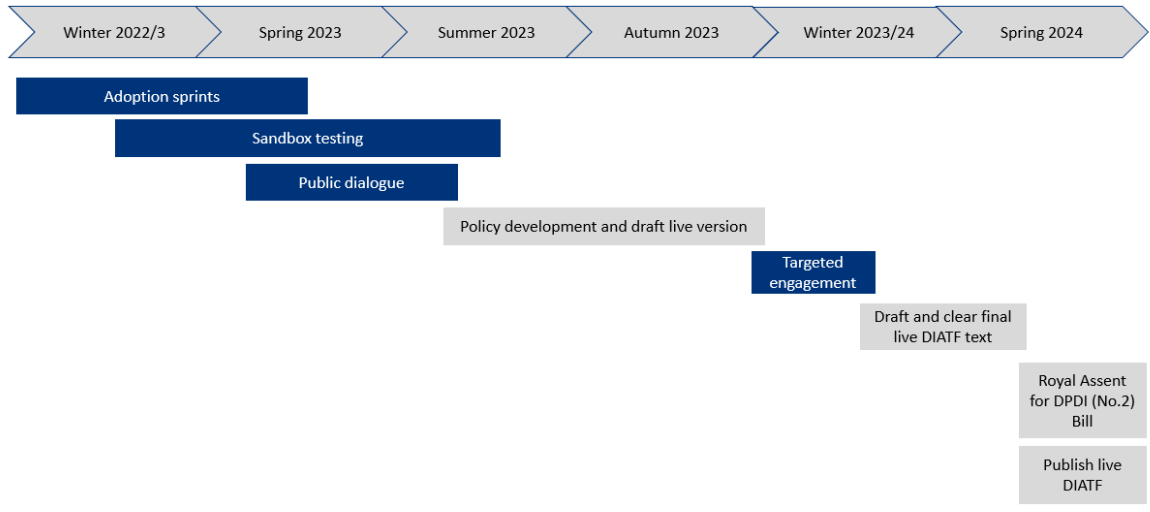
Following the updates to the alpha version 2 of the trust framework, DSIT committed to testing the effectiveness and proportionality of the new requirements in the beta version. The adoption sprints focused on testing 4 of these policy areas. Issues discussed were: relying party flow down terms; fraud; user agreement; and biometrics. The discussions were run on the basis of: sector-specific scenarios; a DSIT facilitator and note-taker; specific questions and planned prompt; and mixed participants across the market.

DIST also engaged with members of the public. Many respondents are people who tend to feel strongly about a subject, sometimes based on misconceptions. The selected public engagement techniques can be represented like this:

Draft	Alpha			Beta
Call for evidence	**Alpha trust framework survey**	**Pre-legislative consultation**	**BritainThinks report**	**Public dialogue**
Initial feedback about the general concept	*Views on the trust framework and wider concerns*	*Feedback on our legislative proposals*	*Public view on key features they want in digital identities*	*Detailed view on benefits, risks, trade-offs and proposed solutions*

Depth of engagement

The public dialogue allowed DSIT to gather in-depth insights from a demographically representative sample of the UK population. Around 100 people engaged in around 20 hours of dialogue, with independent evaluation, independent oversight, and stakeholder involvement. This dialogue impacted: the rules in the UK digital identities and attributes trust framework; the development of functions of OfDIA and how it interacts with the public; and planning for strategic communications work.

The timeline for development of the trust framework is this:

| Winter 2022/3 | Spring 2023 | Summer 2023 | Autumn 2023 | Winter 2023/24 | Spring 2024 |

Adoption sprints

Sandbox testing

Public dialogue

Policy development and draft live version

Targeted engagement

Draft and clear final live DIATF text

Royal Assent for DPDI (No.2) Bill

Publish live DIATF

The trust framework is intended to be a live document that will be continually updated.

The Grangemouth Outcome-Based Cooperative Regulation Project.
Dr Alison Auld, Scottish Environmental Protection Authority (SEPA)

Grangemouth is an area that produces 6% of Scotland's greenhouse gas emissions. It houses chemicals manufacturing, Scotland's largest container port, petrochemical manufacturing, sites of scientific interest, and housing.
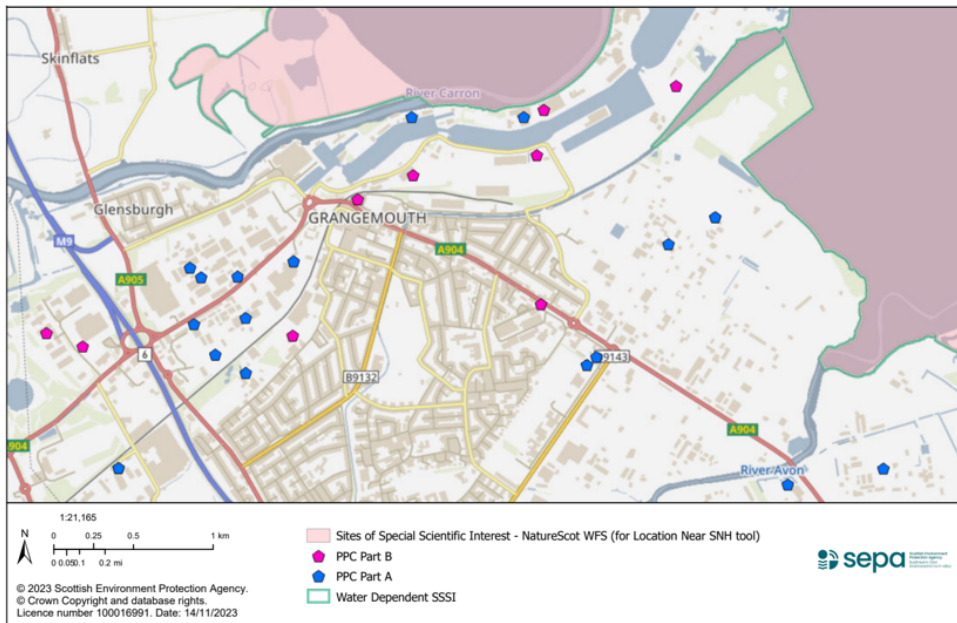
SEPA has had previous successful experience with a collaborative project at The Leven area, which led to a community of stakeholders agreeing an area plan that included the objectives of delivering a just transition as more polluting businesses were replaced by greener ones. In March 2023, SEPA held workshops with stakeholders at the more challenging Grangemouth area at which Prof Hodges explained the OBCR methodology. The feedback was:

- All felt that the ideas and concepts where the right way to go - but as you would expect at this stage there was no clear way to take them forward.
- Desire to focus on the key issues – i.e. those that have the greatest local or global impacts. But also, a need for sustainable growth.
- Request for case studies for a business in the private sector as some felt that it might be different for a public sector organisation.
- Clear messages that communication and collaboration were key.
- Keen to work with us.

In November 2022, BEIS awarded SEPA a grant of £990k from the Regulators' Pioneer Fund to deliver outcome-based regulation. The RPF is a grant-based fund to enable UK regulators and local authorities to help create a UK regulatory environment that encourages business innovation and investment. The current £12m round is being delivered by the DSIT. SEPA's project will pilot an outcome based collaborative regulatory approach in the Grangemouth area. The project will a focus on supporting the achievement of net zero with partners in the HSE and Falkirk Council.

A significant range and number of stakeholders are involved:
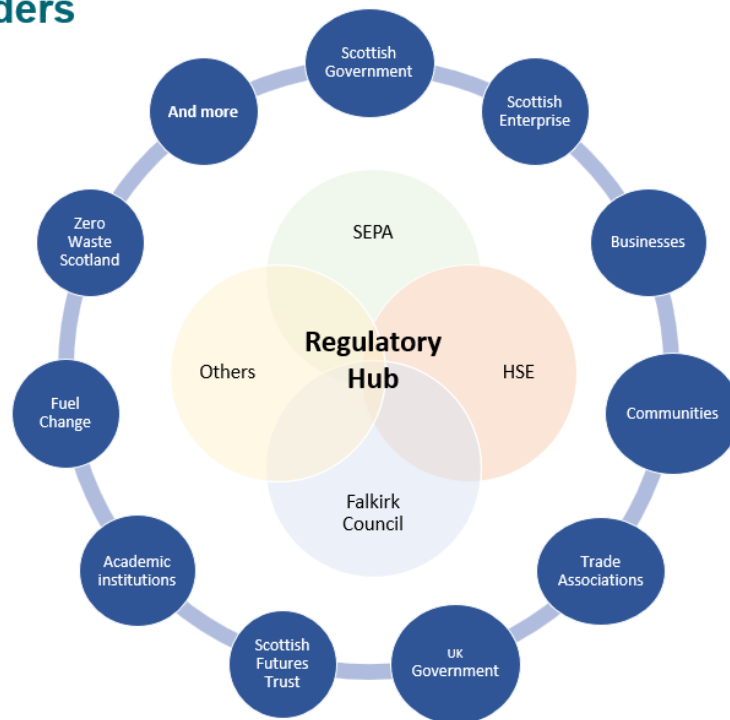
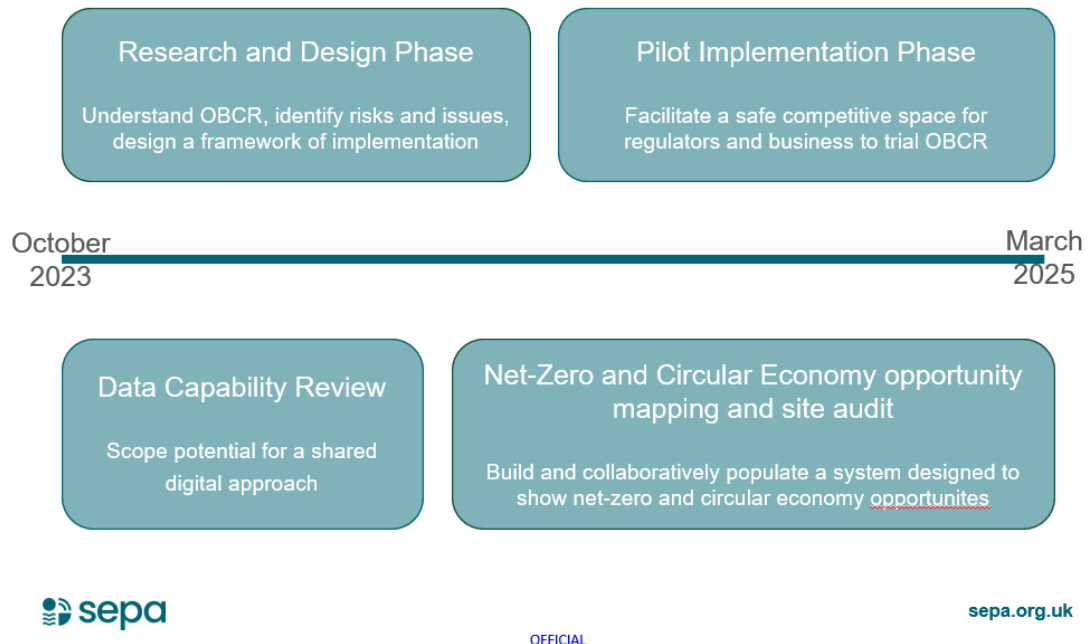We created a regulatory hub for the project.

Challenges
Businesses have told us regulation is:
- Too slow
- Too prescriptive
- Too costly

And it
- Doesn't support innovation
- Doesn't deliver the best environmental outcome from business investment
- Doesn't consider business competitiveness
- Can be a barrier in their transition to net zero

Project structure

Next steps:
Short Term
- Currently getting resource in place & starting detailed scoping
- Discussion paper on OBCR – starting point for working to clarifying what OBCR approach might looking for our regulations
- Compiling list of Grangemouth sites and shortlist for OBCR pilots

Longer Term
- Develop communications strategy
- Desktop study to identify any existing case studies & learn from them
- Stakeholder workshops
- Identify two or three projects to pilot approach(es)

There are elements of our existing regulation that are about outcomes, but we are reviewing all of our permits to pull out anything that is prescriptive.

OTHER EXAMPLES OF OBCR NOT COVERED SPECIFICALLY IN THE CONFERENCE

Case studies involving **Aviation Safety** and **Economic Regulation of Water in Scotland** have been written about elsewhere. The former involved collaboration across all public and private actors who need to contribute to achieving aviation safety, in a culture of psychological safety, sharing all relevant information about their systems and data, in an 'open and just culture'. The setting of water prices in the most recent round in Scotland notably involved stakeholder agreement on objectives and outcomes, open sharing of all relevant data, and transparent discussion to reach agreement.

Facilitating Small Scale Trade through Collaborative Risk Management – Democratic Republic of Congo and Zambia (Kasumbalesa Border)
Srikanth Mangalam, PRISM Institute

The inhabitants of the Congolese provinces of Haut-Katanga, Lualaba, Haut-Lomami and Tanganyika (formerly Katanga) receive their supplies of goods mostly from the neighboring country Zambia.

Kasumbalesa is one of three border posts where these goods cross into the Democratic Republic of Congo (DRC). More than two million traders who earn their living from mostly informal trade in food and other products use this border post. At least 650 commercial trucks also pass through the border crossing every day in both directions.

Goods that cross the border post from Zambia to DRC and vice-versa come in consignments of varying sizes and pose different types of risk to the consumers in DRC including risks from fraud, smuggling and/or accidental importation of diseases and other health and safety threats, it is important for DR Congo border control agencies to monitor the movement of these goods in a manner that protects the consumers in DRC from not only health and safety threats but also provides economic protection and impetus.

Prism Institute, contracted by GIZ, worked on a project between 2019 and 2020 with stakeholders at the Kasumbalesa border with the objective of improving conditions for accelerated and more transparent border release and clearance of goods and services at the Kasumbalesa border-crossing for small scale trade by:
- ❑ Establishing an integrated risk management framework (IRM) for the border agencies for protecting public safety and health while facilitating trade
- ❑ Enhancing the coordination and cooperation amongst various border agencies in DRC and Zambia and its stakeholders.

Kasumbalesa (Democratic Republic of Congo) Informal Trade
- • Straddles international border between Zambia and DRC with approximately 40,000 people
- • Main exit point for exports of copper and cobalt
- • Conflict ridden region, 40,000 children work in mines
- • Large transient population of traders (informal trade)
- • Informal trade import value has risen from $81.02 million in 2019 to $206 million in 2021

The risks and challenges to safe and seamless cross-border trade were identified to be multi-dimensional including:
- • Governance (political, regulatory, institutional)
- • Extreme poverty (national poverty rate is around 75%)
- • Socio-economic (informal labour, gender inequity, limited market access)
- • Public health and physical safety include gender- based violence
- • Extreme weather
- • Cash based economy
- • Poor infrastructure including basic amenities

More specifically, regulatory barriers posed further challenges to the traders including:
- ❑ Lack of an efficient transparent border release and clearance of goods and services for small scale trade
- ❑ Limited capacity to manage risks to public safety and health while facilitating trade
- ❑ Lack of coordination and collaboration (Limited to no trust) amongst agencies, businesses and various stakeholders

A collaborative and coordinated approach to management of risks and facilitating trade was proposed for the following reasons:
- ❑ Improving cross-border small trade dependent on several contributing factors
  - ❑ regulations, infrastructure, logistics, physical conditions etc.
- ❑ Risks associated with contributing factors are interconnected and can cause multiple consequences
  - ❑ e.g., Poor physical conditions and lack of adequate infrastructure can lead to increased wait times, public health outbreaks
- ❑ Achieving desired objectives requires an integrated, structured and disciplined approach

The approach that was taken to build a collaborative framework is illustrated below:
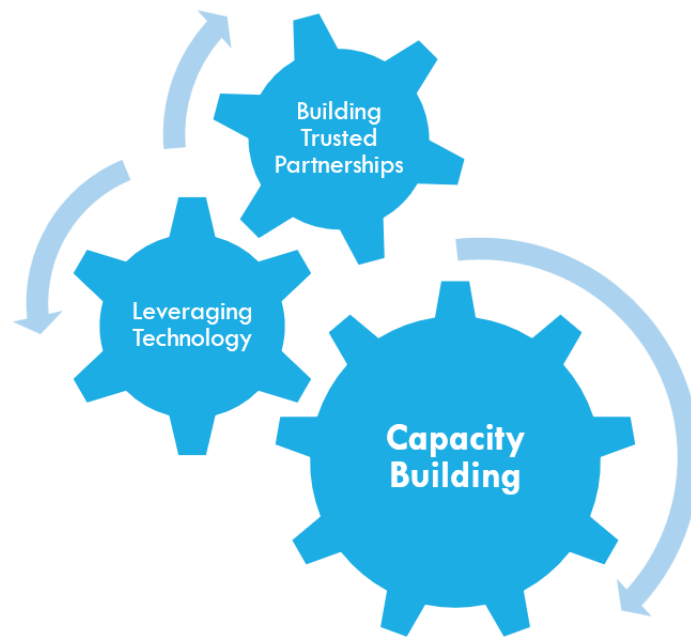
Source: Prism Institute.

Key activities and outcomes of the project included**:**
1. Co-creating recommendations including a range of policy, regulatory and technical solutions that would address risks at the border and improve trade facilitation
2. Development of a phased implementation plan for the identified solutions and interventions
3. Establishment of a multi-stakeholder working grop to coordinate and monitor the progress of the implementation plan.

The project at Kasumbalesa resulted in several positives obtained through independent observation and through feedback from the participating stakeholders. These include:
1. Collaborative and co-creative approach to integrated risk management

Using a collaborative and co-creative approach to developing an integrated risk management framework helps:
- ❑ increase the level of trust between the government, business, and civil society,
- ❑ empower the stakeholders to take ownership of the problems,
- ❑ enable the creation of localized interventions as opposed to force fitting external interventions that may not be applicable or relevant.

2. Standardized, transferrable framework.

The use of an integrated risk management approach used in this project and based on international best practices and involving a collaborative approach as described above also helps:
- ❑ Realise the benefits of a structured and disciplined approach to analyzing and prioritizing risks including understanding the role of data and evidence, analytical thinking and prioritizing choices and interventions.
- ❑ Establish a framework that can be transferred and applied at other border locations in DRC and elsewhere.
- ❑ Ensure consistency in application of risk management principles irrespective of the border or the sector of application.
- ❑ Benchmark the maturity levels of various programs to create competitive advantages and increase growth opportunities.

3. Resilience to Adverse Events

The second phase of the project began after the onset of the Covid-19 pandemic creating significant challenges including the inability to physically travel to the border. However, this resulted in adapting to alternative approaches including the use of technologies that would help in any future scenarios. Examples of such alternative innovations included:

❑ Increasing familiarity and use of virtual platforms to conduct workshops.
❑ Familiarity and use of electronic survey tools like SurveyMonkey to gather feedback and inputs into issues and solutions.
❑ Increased communications amongst stakeholders using tools like email and social media platforms like WhatsApp.
❑ Efficient use of time and resources due to limitations with virtual technologies and electronic tools

In addition to the positives, there were several lessons learned through the project including:

❑ The need to be more realistic in designing the scope and expected outcomes of projects when operating in a virtual environment.
❑ Better understanding the challenges and disparities in the state of technology and infrastructure when organizing virtual programs
❑ Be aware and cognizant of workshop fatigue amongst stakeholders especially as most participants are looking to move forward with actual implementations on the ground.
❑ Be aware and cognizant of the levels of trust between the various stakeholders especially due to reduced physical interactions.
❑ The need to focus on obtaining some form of consensus with respect to prioritization of risks but more importantly when making recommendations for interventions.
❑ Plan the long-term sustainability of such projects in advance especially when the outcomes may lead to strong expectations from the stakeholders for future interventions.

The FSA' Achieving Business Compliance Programme

The UK Food Standards Agency (FSA) is running a project called Achieving Business Compliance (ABC). This has a number of elements. One is Enterprise Level Regulation, developing engagement with large supermarkets at enterprise level (described as 'aligned with an outcome-based collaborative regulation model') aimed at building trust that systems, compliance, performance and outcomes around safe food can be achieved through more integrated means, leading to reduced reliance on inspections and duplication of effort and data.[13] This involves closer integration between the public regulatory system and private control and accreditation systems.

As at December 2023, the FSA summarised progress on the project like this: "So far the access to the business level data, and the increased dialogue with the retailers has exposed a number of opportunities which could be explored further in future:

• the ability to see business-wide impacts of policy changes, which could enable us to forecast where risk may materialise in future. For example, where we know a business has introduced new cleaning contracts, we can see in the data a short-term variation in standards, followed by improvement and subsequent maintenance. In future we could use this insight to set leading indicators and target controls;
• increased understanding of the wider food system. We are starting to comprehend the supply chain links and the industry controls in place to identify and manage risks. If the trial is successful we would seek to explore a similar approach with other sectors, like manufacture, to further increase our understanding and investigate where greater value can be added, and share good practice;

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[13] http://www.food.gov.uk/about-us/achieving-business-compliance-abc-programme

- the potential to reduce local authority planned inspection numbers if the model is proven successful. During the twelve month trial there will have been up to 3000 planned food hygiene inspections(footnote) for the five participating retailers' premises in England." [14]

Another element of the ABC programme involves working with local authorities in modernising delivery of food standards. The new approach "fundamentally changes the way that local authorities consider the levels of risk and compliance associated with food businesses and how this informs the subsequent intervention frequency, including more intensive intervention for the most non-compliant businesses and less frequent controls for those that are less risky. It also embeds the use of intelligence to inform official controls, so the system is agile enough to respond to the changing food system."[15] All the 147 Local Authorities who deliver food standards controls are transitioning to the new model between 2023 and March 2025.

In a related initiative, the FSA has worked on a joint project with online food aggregators Deliveroo, Just Eat, and Uber Eats testing a charter designed by the aggregators. The charter commits the aggregators to:
- ensuring that all food businesses registered on our (aggregator) platforms are registered as a Food Business Operator (FBO) with their local authority.
- setting (aggregator) minimum standards of Food Hygiene Rating Scheme (FHRS) ratings and introducing FHRS rating filters for consumers. (UberEats and Deliveroo have a minimum of 2, JustEat has a minimum of 3).
- working with the FSA to use our (aggregator) distribution channels to share any FSA information to support couriers and restaurant partners in meeting appropriate food safety and hygiene practices.
- working with restaurant partners and third-party groups to support those with food hypersensitivities.

Through joint work, a number of tangible changes have been made to the aggregators' operating models to help promote food safety, including:
- Training Aide Memoire for Aggregator Onboarding Teams, a jointly developed FSA product that directly addresses local authority concerns about registration of small businesses, and helps to ensure FBOs trading on their platforms are complying with food safety requirements. Direct feedback from local authorities is that there has been a reduced number of registration queries since this product was launched.
- FHRS Supplementary Information Sheets, a jointly developed FSA product that addresses local authority queries in relation to aggregator use of FHRS on their platforms.
- Dossier of aggregator policies, processes and future product plans in relation to hypersensitive consumers. The FSA can now directly input into the development of policies and product changes, with the ability to reach thousands of food businesses on this critical subject.
- promotion of FSA/FSS guidance and training. Through the aggregators, the FSA now has indirect access to a larger number of food business operators (over 100k), predominantly SMEs. It is intended to use this route to deliver allergen training, which will now reach a greater percentage of higher risk businesses, enhancing the consumer safety and supporting FBOs.

[14] FSA Board paper, *Achieving Business Compliance Programme*. 5 December 2023, at
http://www.food.gov.uk/board-papers/achieving-business-compliance-programme-0
[15] Ibid.