Q and A on "Regulated Private Assurance" (RPA)

Through the Regulating Our Future (ROF) Programme we have been consulting and working with consumers, food businesses, local and national government, and food regulators in other countries, to develop our future approach to food regulation in England, Wales and Northern Ireland.

Many businesses invest heavily in internal processes that provide them with the assurance that they are managing their food safety and standards related risks; they do this because of their duty to produce and provide safe and authentic food. Its an underpinning ROF principle for the future operating model that regulators should take into account all available sources of information – one vehicle for this will be Regulated Private Assurance (RPA)

This Q&A explores and seeks to clarify RPA questions relevant to those who are involved in official and private sector activities aimed at assessing food business controls – it assumes some knowledge of that world.

Q 1. In a nutshell - What does "Regulated Private Assurance" mean?

A 1. RPA is an umbrella term, coined by the FSA, for industry assurance being used by regulators to inform the nature, frequency or intensity of official controls. The industry assurance in these cases will need to meet, and be used in accordance with, the relevant FSA standards.

Put another way, RPA is a controlled subset of all private assurance that industry generates and it's the regulatory oversight that makes the private (industry) assurance 'Regulated Private Assurance'.

Q 2. Why does the FSA want to progress RPA?

A 2. The underpinning ROF principle that all available data in the future model should be taken into account was discussed and accepted by the FSA Board some time ago and we are committed to realising that for the supply of assurance data. The detailed rules of how that will be done have not been decided yet and we are applying the established ROF approach of discovery, then development with stakeholders towards a solution.

The food industry generates wider "industry assurance" from assurance activities that take the form of food businesses' own checks (1st party assurance) or checks on food and feed safety controls carried out by others at the business (2nd and 3rd parties). As described above, the ROF team are currently exploring with stakeholders which of those industry assurance routes could provide RPA into the new delivery model. Robust forms of industry assurance could be used to reduce the burden on regulators and businesses that arises from current, and at times duplicated, verification of food business controls.

We don't have a pre-prepared set of RPA rules that we will roll out, they will be developed incrementally, and in consultation with stakeholders, as we proceed with RPA discovery work.

Q 3. What sources of industry assurance are being considered for RPA?

A 3. We know that food businesses use a variety of methods and go to different lengths to assure themselves and their customers that the food they produce is safe and what it says it is. For example, some businesses use internal audits, audits carried out by customers, or independent 3rd party bodies; these audits reference different standards and call for different levels of auditor competency. We want to harness the elements of these various methods, that can reliably contribute to informing official controls; we're taking an open approach to define and challenge the evidence base and using studies and pilots to test how RPA could be used.

Beneath the umbrella of RPA we're considering a number of strands; these strands will change over time to take account of developments in technology, industry and regulation. The main strands include:

a) Primary Authority (PA) National Inspection Strategies – where a PA, working to the FSA Standard, will make use of their partner business' assurance data and use this to inform the frequency of official controls. See https://www.food.gov.uk/sites/default/files/media/document/nis-feasibility-study%20%281%29.pdf

b) 3rd party certification schemes – we conducted a study with BRC Global Standards, local authority officers and businesses – it can be seen at: https://www.food.gov.uk/sites/default/files/media/document/fsa-brc-report-oct17.pdf

   We are now working to consider the recommendations both at a global level and as part of the Review of Cutting Plants and Cold Stores. https://www.food.gov.uk/news-alerts/news/review-of-cutting-plants-and-cold-stores

c) 1st party assurance data – we conducted a study with Cambridge City Council and CheckIt to consider how digital information could contribute to monitoring food business activity. See report at https://www.food.gov.uk/sites/default/files/media/document/checkitfeasibilitystudyreport.pdf

d) Certified Regulatory Auditor (CRA) - we undertook extensive and open stakeholder exploration and engagement to assess the potential for a private sector CRA to supply RPA into the future model. In December 2017, the FSA Board considered the evidence and decided development of the CRA route for RPA was not a priority (see question 6).

Q 4. Is there a clear legal basis and support for introducing RPA?

A 4. Yes. Directly applicable EU legislation has facilitated the use of RPA for some years and a number of EU countries make use of it, in particular The Netherlands, France and Belgium plus the UK in respect of animal feed and primary production of milk, take into account assurance information from industry.

Recital13 of Regulation EU 882/2004 says that “The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or Quality Assurance Programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules”;

882/2004 also lays down requirements for competent authorities, in order to ensure official controls are carried out in a harmonised and consistent manner throughout the EU. In particular, programming of official controls should be risk based, as stated in article 3. This programming should take into account criteria such as “identified hazards with the products” or the “operators' past record as regards compliance with […] food law”, but also “the reliability of any own checks that have already been carried out”. Own checks could include 1st, 2nd and 3rd party assessments.

A European working group is actively considering the use of private assurance schemes to inform official controls and in the international arena CODEX is drafting worldwide guidance for regulators on the use of 3rd party private assurance to inform the delivery of official controls.

Nearer to home, the Cabinet Office Regulatory Futures Review[1] concluded that there is considerable scope to extend the use of RPA across the many regulatory regimes and it usefully draws the distinction between “self-assurance” by businesses which we will not allow, and **regulated** business assurance.

Q 5. Don’t the recent food safety related incidents in businesses that have assurance schemes in place indicate that RPA can’t be trusted?

A 5. In the future model food business operators remain fully responsible for producing food that is safe and what it says it is, but where they can offer robust and useable assurance information it will be taken into account to influence the nature, frequency or intensity of official controls. Currently, a small number of assurance schemes are recognised by the FSA, they are in the areas of primary production of food and also for animal feed production. To create an environment where we can confidently take in assurance from other schemes we will establish assessment criteria to ensure that scheme standards map to legislative requirements and that scheme controls are robust and remain robust – creating Regulated Private Assurance. The schemes associated with businesses involved in the recent food safety incidents were not subject to such FSA requirements, in this context it is wrong to suggest that the assurance schemes involved in the recent incidents reflect the RPA arrangements that the FSA will introduce in the future delivery model.

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1 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/582283/Regulatory_Futures_Review.pdf

Q 6. Can you say what industry assurance will be included in RPA in the future delivery model?

A 6. There is much development work on private assurance taking place across the world in the private sector and the regulatory community and we can't say at this stage of exploration and development what the final RPA arrangements will include. We need to maintain the flexibility to take appropriate future developments on board that benefit businesses, regulators and consumers. The rules and standards for RPA will allow for future innovations in this area while ensuring that consumers are protected.

We are currently working on the application of RPA through existing 3rd party assurance schemes and through development of Primary Authority National Inspection Strategies which we aim to have in place for food safety before EU exit.

We also explored the concept of delivering RPA through private sector Certified Regulatory Auditors (CRAs) seen in other international regulatory regimes. We carried out extensive research and engagement to test the concept with local authorities, other UK and international regulatory bodies, industry and consumers. This showed that whilst CRA type roles did operate effectively in other regulatory regimes, confidence in CRAs operating in the England, Wales and NI delivery model would be contingent on the FSA building and maintaining an extensive control infrastructure. The FSA Board considered the evidence in open forum at its Board meeting in December 2017; balancing the potential benefits against the resource investment required, FSA board members concluded that development of the CRA role in the future model was not a priority relative to the pursuit of other RPA opportunities and wider considerations for the future delivery model. See relevant FSA Board report here

Q 7. The widened scope of RPA seems to be pushing the boundaries and it feels a bit uncomfortable – are we going to be out of step with other countries?

A 7. As mentioned above, the legal basis for using RPA has been around for some time and is included in legislation for official controls – it just hasn't been used to any great extent so far, but other countries are now becoming interested. The inefficiency of ignoring private assurance data has been recognised and there are European and CODEX working groups focused on looking at how private assurance can be used to inform official controls. Specific countries around the world are making advances in introducing recognition of private assurance and as an example a scheme in the USA now fast tracks imports through official checks where product is subject to certain private assurance scheme controls.

The ROF programme presents us with an opportunity to get ahead of the curve and establish RPA standards that can be referenced by others. In developing those standards we will take account of, and actively influence, worldwide developments on the use of private assurance.

Q 8. Until RPA is accepted worldwide won't we end up with a two-tier system where RPA is used in the home market but not accepted by international trading partners?

A 8. Any RPA that is used in the future delivery model, by definition, will be **Regulated** Private Assurance that is formally part of our national programme of food and feed safety controls routinely applied to product destined for both home

and export markets. Given the discussions and developments on the use of RPA worldwide we anticipate that international trading partners will recognise and accept our controls, including the RPA element. However, individual trading countries may impose their own additional control requirements for food and feed that they import over and above our own controls. If they should choose to import only product produced under controls that exclude RPA, this would be a country specific requirement over and above our accepted controls for the production of safe food and feed. As mentioned earlier, it's not unusual for specific importing countries to impose additional requirements in excess of our accepted controls for safe food – but this in itself does not create an across the board two-tier domestic, versus export, control system.

Q 9. How will the FSA and food and feed regulators make use of RPA evidence and data?

A 9. RPA that has been recognised by the FSA will be considered within the delivery model in different ways. For example, where a new business has RPA in place this may inform the priority ranking for the first inspection to be carried out and for existing businesses that have demonstrated compliance (a pre-requisite for being eligible to avail of RPA) it may become a determining factor throughout the life of the business in the new approach to risk-based segmentation. The information from RPA will therefore inform the frequency of official controls. It is also envisaged that the information from RPA will be taken into account by regulators to inform the nature and intensity of the official control that needs to be conducted when an intervention is due, thereby facilitating better targeting of resources and avoiding duplication of effort. Primary Authority National Inspection Strategies are another form of RPA and where these are put in place the Primary Authority will analyse the RPA information provided by the business to verify compliance across the business's establishments; this will inform the official control interventions that are required.

The FSA digital infrastructure for handling business risk data is under development but we anticipate that it will interface with the management information systems of individual regulators; this will mean that RPA could be recognised through input at the FSA level or at the level of each individual regulator following an intervention.

Q 10. How will food businesses benefit from supplying RPA?

A 10. We anticipate that the RPA supplied into the system will vary according to the business type and the nature of the interface with the regulatory community, but in all cases the RPA supplied may influence the nature, frequency and intensity of official controls – influencing some or all of these according to clear FSA guidance. The recognition that businesses may receive will need to be tailored to the level of assurance gained and the assurance route - for example the type of recognition and the route for assurance will be different for a business involved in a Primary Authority National Inspection Strategy compared to a business that offers RPA through membership of a recognised 3rd party assurance scheme. We are aware that accessing RPA in a controlled and bespoke manner will introduce a level of complexity into the delivery model; we aim to address this by developing overarching FSA criteria for RPA with sub-sets of rules that will apply to different RPA routes. The potential RPA benefit for regulators is a resourcing efficiency arising from improved risk based targeting of official

intervention that will release resource to tackle the least compliant businesses. For compliant businesses the benefit will be reduced costs in a charging regime for official controls, where our assumption is that costs will be 'no more than they need to be'.

Q 11. How will the use of RPA sit with the Food Hygiene Rating Scheme?

A 11. Current FHRS arrangements rely on a flow of information on business compliance from official interventions. Since the routes to RPA are actively under development through the ROF programme we can't describe at this stage how they will contribute to an FHRS rating. However, this will be a key consideration for the future delivery arrangements and we need to consider how the flow of assurance information from RPA could be used by local authorities. We will be involving relevant stakeholders including local authorities in that development discussion, and we will also take account of the different status and underpinning requirements for FHRS across England, Wales and Northern Ireland.

Q 12. When will RPA become a reality in the regulatory model?

A 12. There will be no big bang approach, development and implementation will be evolutionary and incremental, taking account of business and regulatory environments and private assurance developments nationally and globally. The first RPA that we envisage operating in the model will be Primary Authority National Inspection Strategies by late 2018. We will identify new RPA opportunities as they arise and then research, develop and test them before implementation. Existing RPA arrangements will be reviewed to ensure they remain fit for purpose and meet the RPA standards that we are developing, ROF is founded on a principle that the future delivery model will be able to adapt to future needs.

Q 13. How can regulators, officials and wider stakeholders become involved in the introduction of RPA?

A 13. Throughout the ROF Programme we have been listening to the views and comments of stakeholders, we value your input and ask you to continue engaging with us as we develop a delivery model for the future.

In developing RPA the FSA will be mindful of any risks and ensure that they are effectively managed. As we move from exploration to development and eventually implementation of RPA we will seek your views through the most appropriate channels at each stage. We need your enthusiastic and expert input if we are to develop robust, efficient and controlled use of RPA.

If you would like to engage with us to help shape RPA please email us at: FutureDelivery@food.gov.uk

Here is the link to our monthly newsletter and podcast: https://www.food.gov.uk/about-us/regulating-our-future-newsletter where you can also sign up to received regular updates and communication on the ROF programme.