

FSA APPROACH TO REGULATORY ENFORCEMENT AND SANCTIONS

Report by Chris Harvey, Head of Better Regulation and Chris McGarvey, Head of Legal Services,

For further information contact Chris Harvey on 020 7276 8308 /
chris.harvey@food.gov.uk

1. Summary

1.1 To provide the FSA Board with an update on the current FSA position in relation to regulatory enforcement and sanctions (legal powers and penalties to address non-compliance with the legislation) and seek its agreement to the future approach.

1.2 The Board is asked to:

- Note the issues identified by this paper and the proposed approaches outlined in the conclusion section.
- Provide their views on the matters discussed.

2. Responsibilities under Food and Feed Law

2.1 Food businesses are responsible for producing food that is safe and what it says it is. Consumers have a right to information to help them make informed choices about the food they buy. Consumers should also have confidence that those businesses that don't meet their obligations are identified and dealt with effectively. Likewise, businesses also have the right to expect that businesses that fail to comply with the legislation, those that have the potential to jeopardise confidence in the whole sector, are dealt with effectively. This should create a level playing field which benefits both consumers and business alike.

2.2 The FSA is the Central Competent Authority (CCA) for food and feed in the UK. It is responsible for ensuring that proportionate but effective sanctions, that

serve as an effective deterrent, in food and feed law under its policy remit are available to competent authorities (e.g. the FSA and Local Authorities(LAs)) and consistently applied to address non-compliance with legislation.

3. Wider Government Context

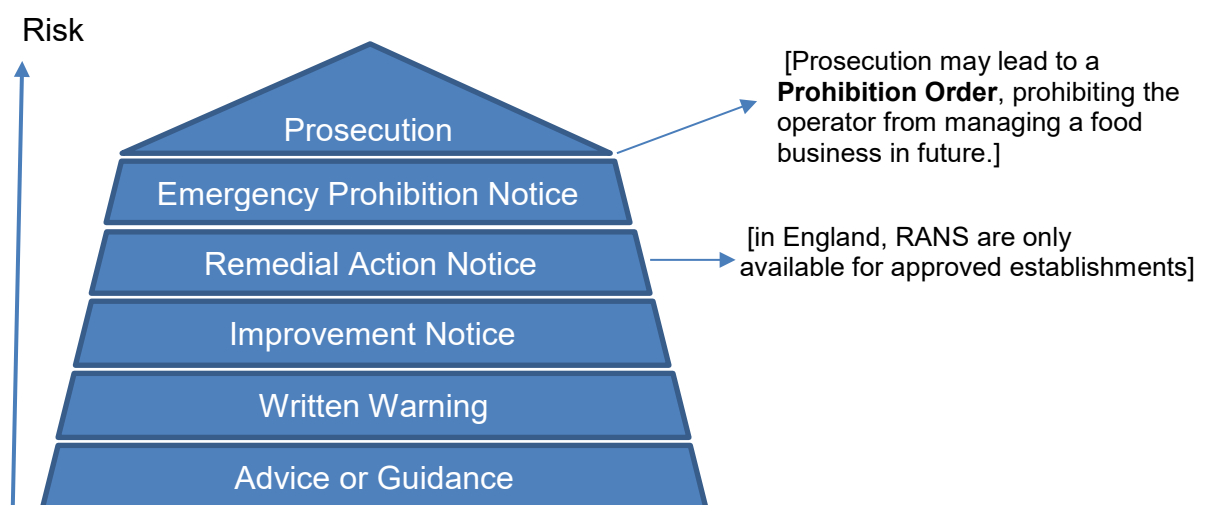
- 3.1 The UK Government has long stated its concern about the creation of new criminal offences, due to pressure imposed on prisons and courts and the added complexity to the already extensive body of criminal law.
- 3.2 Criminal offences are based in criminal law, prosecuted through criminal courts (e.g. Magistrates' and Crown Courts) with sentences passed down by Magistrates and Judges. Food law convictions in England, Wales and Northern Ireland largely consists of sentences of a fine, but also custodial sentences of no more than 2 years. Criminal convictions also result in a criminal record and can result in an order to prohibit a food business operator or proprietor from running a food business.
- 3.3 The FSA has committed, to Ministers in England, to reduce reliance on criminal offences and sanctions for feed and food law in England through greater use of civil powers (e.g. improvement notices and stop notices) and sanctions (e.g. fixed penalty fines and pursuing larger fines through civil law action). Further detail about the evolution of UK Government policy in relation to criminal sanctions and the FSA commitment to reduce reliance on criminal sanctions in England is provided in **Annex A**.

4. The FSA Approach to Regulatory Enforcement and Sanctions

- 4.1 We believe that prevention of non-compliance is better than cure. To that end we work proactively with business to help them understand and to comply with the rules in the first place. The reforms we are introducing under our Regulating Our Future (ROF) programme are designed to free up capacity within LAs to support new businesses, shape their behaviour and establish compliance from the outset. There will, however, always be a need for

enforcement action where businesses don't meet their responsibilities. Under ROF the FSA has pledged to be firm and quick in dealing with irresponsible businesses, whether their non-compliance relates to food safety, authenticity, or any other requirement within our area of responsibility.

- 4.2 This paper attempts to describe the complex topic of food and feed law enforcement in straightforward terms. It does not attempt to identify all areas of divergence or different terminology. For context however, we note that food law has generally evolved under three distinct policy areas: Food Hygiene and Safety, Food Standards, and Feed.
- 4.3 Though there has been some divergence in recent years, most notably the introductions of Remedial Action Notices (RANs) in 2012 for registered establishments in Scotland, Wales and Northern Ireland, the legislative approach to enforcement and range of sanctions available is largely consistent across the UK.
- 4.4 When taking enforcement action, authorised officers are required to follow a hierarchy of enforcement that details how and when to use different enforcement tools. Though the terminology and approach may vary slightly across policy areas and between approved and registered establishments the principles of enforcement are the same.



A simplified diagram of the steps the enforcement hierarchy (similar to that used for enforcement training)

- 4.5 Often, compliance is gained simply through educating food businesses on the risks associated with certain activity and providing information on how best to manage those risks. Where more leverage is needed, compliance/improvement notices or stop notices are usually an effective means of securing compliance and changing a food businesses behaviour. Powers to sample, detain and/or seize food are also essential food law enforcement tools. [Enforcement data provided in **Annex B**]
- 4.6 Alternative approaches to secure compliance with regulatory requirements, such as the mandatory Food Hygiene Rating Scheme (FHRS) in Wales and Northern Ireland have also proven very effective at driving businesses compliance and providing consumers with information to enable them to make informed choices about where they choose to eat¹. A recent study has also shown a link to public health and uplift linked to mandatory display².
- 4.7 In England, FHRS remains a voluntary scheme, providing a strong alternative to regulation but its full potential is constrained by a lack of regulatory underpinning. Mandatory display in England would likely raise FHRS levels, which will improve public health. Other alternatives to regulation, such as publishing survey result of campylobacter levels in retail chicken, have also proven very effective in driving changes in business behaviour without the need for regulatory enforcement or sanctions. These approaches are generally beyond the scope of this paper however, which is focused on regulatory enforcement and sanctions.
- 4.8 From the outset, ROF identified that additional sanctions could complement the existing enforcement tools, encouraging a quick return to the right behaviour by businesses. For example, using civil sanctions such as fixed penalty notices to incentivise the right behaviour, and reduce the burden on regulatory authorities and the legal system. In particular, the availability of fixed monetary penalties

¹ <https://www.food.gov.uk/sites/default/files/media/document/Chief-Scientific-Adviser-report-on-FHRS.pdf>

² <https://doi.org/10.1016/j.foodcont.2018.08.034>

for failing to register a food business is considered necessary to help ensure business comply with the rules in the first place.

- 4.9 Historically the regulations through which feed and food law in England, Wales and NI is enforced have ultimately relied on criminal sanctions. The use of criminal sanctions is an action of last resort and is most appropriate when addressing persistent non-compliance, or where the severity of the offence is so great that the risk to public health demands more immediate and punitive action. Criminal sanctions have broadly proven to be an effective means of securing compliance when absolutely necessary. Frequently however, in relation to some lower level failures of compliance, criminal sanctions present a disproportionate and overly burdensome response that undermines effectiveness.
- 4.10 Prosecuting offences under criminal sanctions present a significant burden on LAs due to the level of resource and expertise required, and the burden of proof that must be demonstrated to successfully achieve a criminal conviction. Using such sanctions can present challenges, for both larger and smaller LAs, depending on the resources that can be made available to undertake prosecutions and the level of experience within the LA. Broader access to civil enforcement tools, particularly fixed penalty fines, stop notices and improvement notices should therefore reduce the pressure on LAs. It is important however, to ensure that the sanctions, when used appropriately, will be effective in securing compliance and drive the right behaviour by the food or feed business operator. Not simply factored in to the day-to-day running costs by business (e.g. cheaper to pay the fine than to fix the problem).
- 4.11 To help prevent fixed penalty fines simply becoming a routine cost for business, it is essential to ensure that more punitive sanctions are able to be applied. Currently the FSA relies on backstop criminal offences and, based on limited available evidence, view these as being necessary to ultimately ensure compliance for food safety breaches. Replacing criminal backstop offences with civil law action (i.e. through County or High Courts) would not reduce the

burden on LAs. Though the burden of proof is lower for civil action, the costs are higher (i.e. there is no charge for LAs taking criminal prosecutions), the procedures are understood to be more rigid and recovering fines and other costs is left to the responsibility of the LA.

4.12 The FSA routinely reviews regulatory sanctions when developing new legislation, including under the Government's Red Tape Challenge exercise in England that commenced in 2011. The review resulted in a number of changes including replacing a number of criminal sanctions with new civil sanctions (e.g. improvement notices) for non-food safety related breaches, whilst retaining a backstop criminal penalty for non-compliance with the civil sanctions.

4.13 The FSA also introduced new provisions enabling authorised officers to issue Improvement and Compliance Notices³, and in England the FSA introduced fixed monetary penalties, stop notices and improvement notices in the Novel Foods (England) Regulations 2018. Their introduction provides access to broader civil enforcement tools, filling an enforcement gap in those areas of legislation that were not served by the Improvement Notice that can be used to address non-compliance with food safety and hygiene offences.

4.14 These recent changes, as well as recent divergence in access to enforcement tools across England, Wales and Northern Ireland (i.e. the extension to RANs, in Wales and Northern Ireland, for use in registered food establishments) has led to some inconsistency across the body of food law.

5. Remedial Action Notices (RANs)

5.1 RANs have proved an effective enforcement tool (in practice a stop notice that requires the business to take remedial action before resuming stated activities) in approved establishments for many years. They are particularly well suited to establishments under constant supervision, such as approved red meat

³ under the Food Information Regulations and the Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations in England Wales and Northern Ireland.

slaughterhouses, as they provide a means of rapidly responding to identified non-compliance and can be just as rapidly lifted by authorised officers once required remedial action is taken (a typical example would be requiring a food business to stop using a certain piece of equipment until it has been appropriately cleaned) [Further details on RANs and when they are used is provided in **Annex C**].

- 5.2 Many believe that RANs could also be usefully deployed in registered establishments in England, in line with the approach taken in Wales and Northern Ireland. In particular, LAs in England are keen to have access to RANs for registered establishments. Access to RANs for registered establishments in England should also help to reduce reliance on criminal sanctions. Previous attempts by the FSA, however, to extend the use of RANs to registered establishments in England were not supported by the UK Government or business.
- 5.3 It remains unclear whether a new proposal by the FSA to extend RANs to registered establishments would now be supported by the UK Government and whether business concerns have subsided in light of the experience of the use of RANs in Scotland Wales and Northern Ireland. The political landscape has changed considerably since the FSA's last proposed to introduce RANs for registered establishments in England. [Further detail on the use of RANs in registered establishments is provided in **Annex C**].

6. Discussion

- 6.1 Regulatory enforcement and sanctions for food and feed law must be, and be seen to be, effective in order to maintain confidence in the regulatory system.
- 6.2 There is an identified evidence gap on the effectiveness of civil sanctions without criminal offence backstops currently considered necessary for food safety related breaches. The need to establish necessary systems and structures to support any move towards greater use of civil action must also be recognised. This would include providing advice, guidance and training for

enforcement officers and, significantly, establishing new appeal mechanisms for civil sanctions. These mechanisms are likely to involve the use of the Tribunal system, use for which the FSA would be expected to make adequate funding available.

- 6.3 There is also an evidence gap in relation to consumer and business views and attitudes towards regulatory enforcement and sanctions for feed and food law offences. Data available from routine FSA attitude trackers is far too broad to derive substantive conclusions or robust evidence.

7. Conclusions

- 7.1 Sanctions are an important part of the regulatory toolkit. As part of our goal to be an excellent, accountable, modern regulator we need to make sure we are using them in the most effective way. We want to establish best practice and continue to have a regulatory regime that provides the optimum means of protecting consumers.

- 7.2 While continuing to address issues as they arise in relation to Statutory Instruments (SIs) in England, we will undertake a thorough review of our approach to enforcement and sanctions, including:

- Commissioning new research to support the FSA's understanding of the effectiveness of regulatory sanctions and provide evidence to support the FSA approach going forward. Research should include:
 - Evidence on business and consumer attitudes to sanctions.
 - Further analysis of the effectiveness of RANs in registered businesses, including a review of the FSA enforcement policy and safeguards in relation to RANs.
 - Evidence on the effectiveness of civil sanctions for safety related offences, including a review of supporting material and processes in place.

- Undertaking a broader review of all enforcement and sanctions in feed and food law that the FSA has responsibility for in England. [The relevance/priority of such an approach to be considered separately by the FSA in Wales and Northern Ireland]. The review would map the entirety of all current sanctions and develop a unified view on the approach that should be taken to sanctions and identify proposals to deliver against the Government expectations and strengthen effectiveness of sanctions. The approach requires significant FSA resource commitment and will need to be taken forward as a priority.
- Depending on the outcomes of the above, we may proceed to undertake an ambitious simplification and rationalisation exercise to create a single sanctions instrument across feed and food law that the FSA has responsibility for in England. [The relevance/priority of this approach would need to be considered separately by the FSA in Wales and Northern Ireland]. The approach would involve developing a new single enforcement policy/framework and would require significantly more FSA resource to undertake and implement. It would satisfy UK Ministers' expectations and remove future uncertainty as well as significantly reducing FSA resource requirements in the longer term and speed up the clearance process for future SIs.

8. Recommendation

8.1 The Board is asked to:

- Note the issues identified by this paper and the proposed approaches outlined in the conclusion section.
- Provide their views on the matters discussed.

Annex A

Wider Government Context

1. In 2015, the UK Government discontinued the criminal offences gateway⁴ [the gateway was established several years earlier by the MoJ to prevent the proliferation of unnecessary new criminal offences] and decided instead to increase the scrutiny on the appropriateness and associated costs of new and amended offences through the Home Affairs Committee write round process.
2. In February 2018, the government published updated Transposition Guidance⁵, [guidance for government policy-makers and lawyers on how to transpose EU Directives into UK law]. The Guidance makes clear that, although focused on the transposition of Directives (the majority of EU food law is directly applicable and does not require transposing into UK law), the Guiding Principles reflect good practice, which should be applied to the enforcement of all types of EU legislation, where practicable.
3. The Transposition Guidance notes that the creation of a new criminal offence (including the creation of a new offence, the amendment or repeal and re-enactment of an existing one, or the creation of a power in primary legislation to create or extend a criminal offence in subordinate legislation) should happen only rarely, and must be explicitly approved by the relevant Cabinet Committee.
4. In January 2018, as part of the new clearance process for new and amended offences, the FSA was asked to provide assurance that we are delivering against the UK Government's objectives and reducing our reliance on criminal sanctions. The FSA was advised by the MoJ to look to examples of new civil sanctions introduced by other departments that provide for significant financial

⁴ <https://www.justice.gov.uk/downloads/legislation/criminal-offences-gateway-guidance.pdf>

⁵

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/682752/eu-transposition-guidance.pdf

penalties (e.g. civil powers available to LAs to impose on landlords and powers to issue administrative fines of up to 4% of annual global turnover or €20 million for offences under the General Data Protection Regulations GDPR).

5. Comparisons with other departments' activities and other policy areas is not always straightforward, however. For instance, in the case of the GDPR, enforcement was largely secured by way of primary legislation (under the Data Protection Act 2018). This allowed Parliament to create whatever sanctions it saw fit, and engaged its unlimited law making power to create – in this case – very significant civil fines. The FSA is largely confined to inviting ministers to make secondary legislation under regulation 2(2) of the European Communities to enforce directly applicable EU law. The powers of ministers under regulation 2(2), though wide, are unlikely to be sufficient to apply sanctions of the weight and gravity that is possible using primary legislation.

6. To address the issues raised by UK Government Ministers, the FSA undertook an interim review of regulatory sanctions across the breadth of food law in England. A number of commitments were made in relation to future updates to food law in England. This included identification of regulations where, subject to consultation, the introduction of new civil sanctions could supplement existing criminal sanctions. And others where existing criminal sanctions could be replaced with new civil sanctions to ensure the full range of enforcement tools are consistently available to address non-compliance. UK Government Ministers welcomed the FSA commitment and Cabinet Committee clearance was given based on the commitment.

ANNEX B

Enforcement Data

1. The tables below show the number of establishments subject to LA enforcement action⁶ reported in the FSA Annual Report on Local Authority Food Law Enforcement⁷ for England, Wales and Northern Ireland 2017/18.

Number of establishments subject to food hygiene enforcement actions in 2017/18

	ENGLAND	NORTHERN IRELAND	WALES	TOTALS
VOLUNTARY CLOSURE	912	13	94	1,019
SEIZURE, DETENTION & SURRENDER OF FOOD	289	31	32	352
SUSPENSION/REVOCATION OF APPROVAL OR LICENCE	13	0	1	14
HYGIENE EMERGENCY PROHIBITION NOTICE	240	1	7	248
HYGIENE PROHIBITION ORDER	66	1	4	71
SIMPLE CAUTION	222	2	11	235
HYGIENE IMPROVEMENT NOTICES	2,720	14	207	2,941
REMEDIAL ACTION AND DETENTION NOTICE ¹	96	7	72	175
PROSECUTIONS CONCLUDED	251	3	13	267
TOTAL FORMAL ENFORCEMENT ACTIONS	4,809	72	441	5,322
WRITTEN WARNINGS	130,707	6,367	13,465	150,539
TOTALS	135,516	6,439	13,906	155,861

¹ Remedial action notices (RANs) only apply to a small percentage of establishments in England, i.e. those approved under EC Regulation 853/2004, whereas amendments to the domestic hygiene legislation in Wales and Northern Ireland extended the scope of RANs into premises that are registered under Regulation 852/2004.

⁶ LAEMS records the number of establishments subject to each type of enforcement action. The total number of enforcement actions taken by LAs is likely to be higher.

⁷ <https://signin.riams.org/connect/revision/msy26/Environmental-Health/LAEMS-Annual-report-2017-2018>

NUMBER OF ESTABLISHMENTS SUBJECT TO FOOD STANDARDS ENFORCEMENT ACTIONS in 2017/18

	ENGLAND	NORTHERN IRELAND	WALES	TOTALS
SEIZURE, DETENTION & SURRENDER OF FOOD	44	2	4	50
SIMPLE CAUTION	43	2	8	53
PROSECUTIONS CONCLUDED	42	2	9	53
STANDARDS IMPROVEMENT NOTICE	240	0	15	255
TOTAL FORMAL ENFORCEMENT ACTIONS	369	6	36	411
WRITTEN WARNINGS	15,780	2,280	2,423	20,483
TOTALS	16,149	2,286	2,459	20,894

2. The tables below show the number of enforcement actions taken in FSA approved establishments in England and Wales and those in Northern Ireland⁸

England and Wales: formal and informal enforcement action taken during 2017/18

Formal action	Number of notices 1 April 2016 to 31 March 2017	Number of notices 1 April 2017 to 31 March 2018
Hygiene Emergency Prohibition Notice,	Nil	Nil
Hygiene Improvement Notice	198	152
Remedial Action Notice	166	245

Informal action	Number of warnings 1 April 2016 to 31 March 2017	Number of notices 1 April 2017 to 31 March 2018
Written warning	2,567	2,433

Northern Ireland: formal and informal enforcement action taken during 2017/18

Formal action	Number of notices 1 April 2016 to 31 March 2017	Number of notices 1 April 2017 to 31 March 2018
Hygiene Emergency Prohibition Notice,	Nil	Nil
Hygiene Improvement Notice	7	8
Remedial Action Notice	2	3

Informal action	Number of warnings 1 April 2016 to 31 March 2017	Number of notices 1 April 2017 to 31 March 2018
Written warning	24	61

⁸ <https://www.food.gov.uk/sites/default/files/media/document/fsa-annual-report-accounts-2017-18-westminster.pdf>

3. In 2017/18, the FSA Criminal Investigation Branch accepted 100 referrals from Operations Directorate for investigation with a view to prosecution. The timescales for prosecutions mean that it is rare for a case to progress from referral to a final court hearing within the same reporting year. Therefore, many of the cases referred for investigation in 2017/18 have yet to be concluded. During 2017/18, eleven cases investigated by the FSA were concluded at court with convictions secured against eleven defendants. A further 7 cases are currently being prosecuted.

There were 97 recorded investigation referrals in England and Wales during 2016/17. The outcomes or status of those referrals are as follows:

Outcomes/current status	Number of referrals
Convictions	10
Warning letters issued	17
Ongoing prosecutions in Court	10
Acquittals	1
Withdrawn prosecutions	2
No prosecution taken	57

ANNEX C

Remedial Action Notices (RANs)

[Extract from the Food Law Code of Practice England]

1. Powers to issue Remedial Action Notices and Detention Notices in respect of establishments subject to approval under Regulation 853/2004 are provided by regulation 9 and 10 of the Food Safety and Hygiene (England) Regulations 2013.
2. Regulation 9 provides for authorised officers to serve a Remedial Action Notice if any of the requirements of the “Hygiene Regulations”, as defined by regulation 2 of the Food Safety and Hygiene (England) Regulations 2013, are being breached or an inspection under the “Hygiene Regulations” is being hampered. More specifically, this provision provides, through the service of a Remedial Action Notice, for the prohibition of the use of any equipment or any part of the establishment, the imposition of conditions upon, or prohibiting, any process and also allows for the rate of an operation to be reduced or, stopped completely. Regulation 10 additionally makes provision for the detention of any food, including the taking of samples for the purposes of examination, by the service of a Detention Notice.
3. Authorised officers must seek to remedy non-compliance in establishments subject to approval under Regulation 853/2004 by a graduated approach to enforcement (see Section 7.1.1). When necessary, the Hygiene Improvement Notice provisions in regulation 6 must be considered (see Section 7.2.1). Authorised officers must consider these options before commencing any other enforcement action. However, Remedial Action Notices and/or Detention Notices as provided for by regulation 9 and 10 of these Regulations can be used, when appropriate.

When to use RANs

4. Circumstances which may lead to the issue of a Remedial Action Notice in respect of an establishment include:
 - the failure of any equipment or part of an establishment to comply with the

requirements of the “Hygiene Regulations” as defined by regulation 2 of the Food Safety and Hygiene (England) Regulations 2013

- the need to impose conditions upon or the prohibition of the carrying on of any process breaching the requirements of the Regulations or hampering adequate health inspection in accordance with the Regulations; and
 - where the rate of operation of the business is detrimental to its ability to comply with the Regulations.
5. Circumstances which could lead to the issue of a Detention Notice include where there are indications or suspicions that food at an establishment is unsafe and therefore examination is necessary, including the taking of samples.
 6. Such action must be proportionate to the risk to public health and used only where immediate action is required to ensure food safety. A Remedial Action Notice can be used if a continuing offence requires urgent action owing to a risk to food safety or when corrective measures have been ignored by the food business operator and there is a risk to public health.
 7. As soon as the authorised officer who served the Remedial Action Notice is satisfied that the action specified in the notice has been taken, the notice must be withdrawn by means of a further notice in writing. Similarly, in respect of a Food Detention Notice, if the authorised officer is satisfied that the food need no longer be detained, the relevant notice must also be withdrawn by means of a further notice in writing.
 8. If an authorised officer considers it necessary to serve a Remedial Action Notice owing to the conditions or practices found on the inspection of an establishment subject to approval under Regulation 853/2004, the officer must also consider whether food at the establishment must be detained for the purposes of examination by means of a Detention Notice under regulation 10.

Annex D

Introduction of Remedial Action Notices (RANs) In Registered Establishments

1. At the start of 2012, RANs were introduced in Scotland, Wales and Northern Ireland for use in registered establishments. Prior to the introduction across the rest of the UK, the FSA attempted to introduce legislation providing for the use of RANs in registered establishments in England. The proposals were part of a package of measures taken forward by the FSA ahead of the 2012 Olympics to support Local Authority (LA) enforcement and strengthen consumer protection. The proposals were met with vocal resistance by some in industry, concerned that the move would prove a disproportionate response, and the FSA was unable obtain support for the proposals in England from the UK Government at the time.
2. A post implementation study of the introduction of RANs in Scotland, Wales and Northern Ireland⁹ was published by the FSA in 2015. The study was ultimately inconclusive as to the effectiveness of RANs, it found that RANs had been increasingly used, but that only half of the LAs in the devolved nations had served any RAN to a registered food business for the period 2013/14. [This is not necessarily surprising as the RAN is only one of a series of enforcement tools available to LA authorised officers, towards the top of the hierarchy of enforcement. It would, perhaps, be more surprising therefore if the study found all LAs had found cause to use a RAN]. The study largely attributes the inconsistency to confidence of officers in using the tool at the time and lack of training in this area.
3. Importantly, the study found extensive evidence that RANs were being used in conjunction with other tools, both informal and formal. Conducting revisits and providing advice and education were often undertaken before and/or after a RAN was served.

⁹ <https://old.food.gov.uk/science/research/choiceandstandardsresearch/enf-research/fs514108>

4. The study recorded wide spread support for RANs by all the LAs visited as part of the study, including those that had not yet served any RANs, or very few. LA views were consistent that RANs provided a welcome addition to the toolkit of enforcement officers, one that filled a gap – though views differed on the extent of this gap. Overwhelmingly, those interviewed for the study, reported RANs to be effective, chiefly because of the immediacy of the tool, that it seemed to drive compliance and that it did not appear to alienate business and offered a more business friendly response to non-compliance than Hygiene Emergency Prohibition Notices.

 5. The study also identified a striking degree of inconsistency across LAs and between authorised officers on when RANs could be served and when they could not.

 6. A further study of RANs in registered establishments, now that the tool is less novel and more data is available, is required to better understand and evidence the effectiveness and value of this tool. This correlates with the recommendations identified by the study.
-