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1   Management of food incidents by Australian food regulators

2

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1 **Author contributions**

2 All authors contributed to and reviewed the final manuscript. AW collected the data and managed the

3 project. JC, JH, PW, SM and TW were involved in the design of the project. DM and TW assisted

4 with participant recruitment.

5

17

18 **Conflicts of Interest**

19 Dean McCullum is employed by SA Health and Trevor Webb is employed by Food Standards

20 Australia New Zealand. Both of these organisations funded the project in part.

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1   **Abstract**

2   *Aim*

3   This paper explores how food regulators respond to food incidents and the barriers and enablers

4   associated with doing so.

5

6   *Methods*

7   Twenty-six semi-structured interviews lasting between 30 and 60 minutes were undertaken with

8   Australian food regulators. Regulators worked across food policy development, implementation,

9   enforcement and standards setting. These interviews ascertained food regulators' views on food safety

10   and responses to real and hypothetical food incidents. Data were analysed using thematic analysis.

11

12   *Results*

13   Food regulators reported that working together with other food regulators is an important part of

14   effective food regulation and response to food incidents. Strategies for working together included

15   clarifying expectations and developing formal documents such as a memorandum of understanding.

16   However, challenges in working together were reported, including different risk thresholds, different

17   political agendas and a lack of clarity on regulators' roles.

18

19   *Conclusions*

20   A focus on partnerships and good communication between food regulators is likely to facilitate

21   effective management of food incidents, and maximise the chances that food incidents do not lead to

22   increased consumer morbidity and mortality as a result of a poor response to a food incident.

23   **Key words:** Food regulator, food incident, Australia, food safety, morbidity, mortality, diet,

24   relationships

1   **Introduction**

2   Food incidents are defined as 'any situation within the food supply chain where there is a risk or

3   potential risk of illness or confirmed illness or injury associated with the consumption of a food or

4   foods'. [1] Food incidents have been demonstrated to have a number of impacts across multiple

5   systems, often with economic consequences. For example, milk sales declined following

6   contamination of fresh milk in Hawaii[2] and a food recall of a specific brand of peanut butter had a

7   negative impact on the demand for that specific brand.[3]   Food incidents are also a cause of morbidity

8   and mortality[4], and may also affect consumer dietary intake. For example, during 2010, it was

9   estimated that 4.1 million cases of foodborne gastroenteritis occurred annually in Australia, with an

10   estimated 31 920 hospitalisations and 86 deaths due to foodborne illness.[4] Dietary intake is affected

11   by a number of factors beyond the physiological, including those that are environmental, social,

12   cultural and political; for example cost, time, safety, knowledge, accessibility, convenience and social

13   trends. [5] Understanding what influences dietary intake is important because diet is a major risk factor

14   for serious health issues including diabetes, cardiovascular disease, obesity and cancer. [6] Food

15   incidents (primarily those that are long-term) have also been shown to affect dietary intake and diet

16   when high profile food issues are reported in the media.[7] For example, the concern over bovine

17   spongiform encephalopathy (BSE) in beef in the UK led to a decrease in consumption of beef and

18   beef products and this reduction was shown to result in decreased intakes of iron and zinc.[7] Therefore

19   effective management of food incidents is important to, firstly, minimise large scale changes in

20   individual dietary intake and nutritional status, secondly, minimise impact on consumer morbidity and

21   mortality, and lastly, mitigate economic and reputational effects on food companies.

22

23   Food regulators are defined as the major public health workforce charged with ensuring food safety to

24   protect the health and wellbeing of the population.[8] Food regulators mostly work in policy

25   development, standards setting, regulation, implementation and inspection and enforcement. In

26   Australia, Food Standards Australia New Zealand (FSANZ) sets food standards at a national level,

27   each state and territory has its own laws to implement and enforce these standards.[9] Local government

28   is usually involved in the monitoring and enforcement of food standards.[9] Thus food regulation

1   involves multiple parties at national, state and local government levels, in Australia and New

2   Zealand.[9]

3

4   In Australia, food regulators play a key role in managing and responding to food incidents and may

5   work for local or state Governments or at national organisations like FSANZ or the Department of

6   Health. Previous evidence in the United Kingdom and Europe has suggested that food authorities and

7   government expert messages are not always trusted by consumers. [10, 11] Poor food safety surveillance

8   and inadequate enforcement have previously been identified as contributors to food incidents.[12]

9   Furthermore, negative media coverage of food incidents have been shown to lead to greater public

10   awareness than positive coverage.[2] And, when a large amount of negative information has been

11   supplied by the media, the messages of government officials to provide assurance to consumers about

12   food safety have been shown to be ineffective in restoring consumer confidence in times of food

13   incidents.[2] It has been proposed that consumer trust in food regulatory institutions and the

14   professionals within them affects general consumer confidence in the ways in which food is made and

15   kept safe. Damage to consumer trust may have a number of behavioural consequences including

16   product substitution and reduced consumption.[13] , which might have poor health outcomes. Therefore,

17   it is vital to ensure that regulation is optimal in order to avoid and minimise the risks of food

18   incidents, and to ensure that consumer trust in the messages of food regulators is maintained.

19

20   There is a lack of information about the role that food regulators play in managing food incidents and

21   strategies they use, and there has been minimal investigation which directly assesses the culture and

22   behaviour of individuals within food regulatory bodies.[12] This paper reports research that explored

23   regulators' views on how they work together to manage food incidents. The purpose of the research

24   was to explore how food regulators respond to food incidents and the barriers and enablers associated

25   with doing so. This paper aims to identify how food regulators can facilitate an effective and efficient

26   response to food incidents to ensure that consumer trust in food is maintained so that food intake,

27   diets and, ultimately, nutrient intake are not adversely affected. This is of relevance because areas of

1 strength can be highlighted and continued, while areas of challenge can be addressed for potential

2 improvement and ultimately better management of food incidents.

3

4 **Methods**

5 This study was part of a larger study looking at trust in the food system across three countries –

6 Australia, the United Kingdom (UK) and New Zealand (NZ) – which has been described in a protocol

7 paper published elsewhere.[14] In the present paper, we focus on the perspectives of food regulators

8 from Australia. The protocol for the research received ethics approval from the relevant University

9 Social and Behavioural Research Ethics Committee. The research confirms to the provision of the

10 Declaration of Helsinki.

11

12 *Recruitment*

13 Individuals working in the food regulation setting were recruited via purposive sampling, which

14 enabled participation of individuals who were information rich[15] and had relevant experiences to

15 share.[16] Potential participants and contacts were identified based on their experience and position in

16 the regulatory system. Two members of the research team who worked in the food regulation setting

17 helped to identify further participants.

18

19 Potential participants and organisations were contacted by email by the researcher (AW). If a response

20 was not received, a follow-up email was sent and this was followed up with a phone call. The purpose

21 of the study was explained to participants, they were given a participant information sheet and letter

22 of introduction and were invited to participate in an interview. A sampling strategy was developed to

23 ensure recruitment of food regulators working at both national and local levels in different areas

24 including policy development, standards setting, regulation, implementation and inspection and

25 enforcement. This sampling strategy did not seek to obtain equal numbers of food regulators working

26 in different areas, but rather representation from each area. In this paper we use the term 'regulator'

27 to refer broadly to all those included in these groups.

28

1   *Data collection*

2   Data were collected using semi-structured interviews, using the interview schedule provided (Table

3   1). The interview schedule was piloted before use to check for usability. Minor changes based on

4   feedback were made to increase flow of the interview. The interview schedule was used as a guide for

5   discussion during interviews and as data collection progressed, minor alterations were made as new

6   themes emerged. The interview schedule was designed to discuss food regulators' ideas about food

7   safety, responses to food incidents in general, and in the context of a specific, hypothetical scenario

8   (Table 2). The hypothetical scenario was based on real events and designed to start conversation with

9   participants about food incidents.

10

11   Interviews were conducted face to face or over the telephone at a time and location convenient for the

12   participant. Phone interviews were necessary when participants were based at a geographical distance

13   from the interviewer. Interviews ranged from 30-60 minutes. Written informed consent was obtained

14   from all participants. Interviews were conducted between July and November 2013 until theoretical

15   saturation of themes was reached.[17] Interviews were digitally recorded using a voice recorder after

16   consent had been obtained.

17

18   *Data analysis*

19   Digital voice files were deidentified and transcribed verbatim by a professional transcriber. Interview

20   transcripts were checked by the interviewer for accuracy by reading through and listening to the

21   interviews. Interviewees were given pseudonyms. Deidentified transcripts were imported into NVivo

22   10.0 (QSR International, Doncaster). Transcripts were coded by one researcher (AW) using a start list

23   of codes developed by the research team, following six stages of thematic analysis: familiarising

24   yourself with the data, generating initial codes, searching for themes, reviewing themes, defining and

25   naming themes and producing the report [18]. The start list of codes was developed from the research

26   objectives and included: response to real food scares, response to the hypothetical scenario, role of

27   interviewees in food regulation, enablers and barriers to managing food incidents, stakeholders, use of

28   social media and consumer trust in food. As coding progressed, further themes and sub-themes were

1 added based on the objectives of the research and information in the data. Coding was checked and

2 agreed upon by team members at fortnightly team meetings and at two larger data analysis

3 workshops. Other members of the research team reviewed up to five transcripts each to confirm the

4 themes arising from the primary researcher's analysis.

5

6 **Results**

7 Twenty-six food regulators from 13 different organisations participated in an interview, including 13

8 from inspection and enforcement, two from implementation, eight from standards setting and three

9 from policy development. Regulators talked about three main themes, including the importance of

10 relationships and trust when working together, strategies they use to develop these relationships and

11 trust, and challenges posed by working together.

12

13 *Relationships and trust*

14 Regulators agreed that working together with other regulators is important to manage food incidents.

15 In particular, relationships were cited as a way of ensuring that different elements of the food

16 regulatory system work effectively together:

17   I think the food regulatory system, the way that it is established, …[ ]… forces a level of

18   interaction that means that we have to develop good relationships in order for us to get stuff

19   done. So I'd say that …[ ] …. our food regulatory system is separated in terms of its food

20   policy function, its standard development function and its enforcement function so they all sit

21   at three different levels with three different bodies but without them all working together the

22   system doesn't work. But underpinning that is the need to develop relationships regardless of

23   whether there's an incident or not but that is obviously enhanced during incidents. (Jennifer)

24

25 Following on from the importance of relationships, trust between regulators, and also other

26 stakeholders more widely, was cited as vital to effective food regulation, and the management of food

27 incidents:

1   It [trust] would be one of the most important things that we have. It underlays all of our

2   activities, the fact that we can share information freely and know that it won't be shared

3   further. Trust is essential otherwise things would go; things would be very difficult to

4   manage. (Jennifer)

5

6 The need for trust between food regulators was also explained in the context of needing to trust that

7 other food regulators are competent and able to do their job:

8   ….sometimes if there's a national incident you'll be basically acting on the advice or

9   information supplied by another state government department. So you've got to have faith

10   and trust, I guess, that they're competent, capable and telling you everything …[ ] … because

11   ultimately you can be caught out if that information isn't there. (Roger)

12

13 Similarly, trusting that there are systems in place to adequately manage food incidents in other

14 locations where regulators relied on actions of colleagues was a consistent theme between regulators:

15   Over a period of time we've developed a relationship based on trust but that's one aspect of it,

16   working with co-regulators, and we have an understanding and we have systems in place as to

17   how we deal with these particular events (Michael).

18

19 *Strategies used to develop relationships and trust*

20 Following on from the importance of trust and relationships, regulators reported strategies that they

21 use to develop this trust and relationships, and ultimately work together to manage food incidents. For

22 example, relationships were often formed by discussing expectations and ensuring there is mutual

23 benefit in a relationship:

24   ….it's critical for us that we have really good relationships….[ ] … and it needs to be very

25   clear about the expectations that we have of them [other regulators] and the expectations they

26   have of us. I think we've tried quite hard in recent years to be very responsive to any concerns

27   that they've had and we do make changes to address their concerns. (Anna)

28

Strategies such as formal meetings and signed memoranda of understanding (MOUs) were also cited as ways to establish and maintain good relationships, as well as good communication between food regulators when managing food incidents:

> Well we have existing processes in place to do that, so we have informal and formal meetings, so it depends really what's happening. (Catherine)

Similarly, another participant, Michael, said:

> So for example we might have an agreement or an MOU with the environment protection authority here in [state] and we might also have a separate agreement to regulate the food industry with the Local Government Association of [state] and the Department of Health so that we can clarify roles and responsibilities, so we do that to ensure that where there's one business there's one licence.

The need to work together towards a common goal while managing a food incident seemed to be an incentive for regulators to put other challenges aside and develop relationships in order to progress with the job:

> ….in this group …[ ] … often around the table we can be arguing like crazy…[ ] ..Put them around the table on incident response around a teleconference, I just find totally – it's a totally different environment, that it really is constructive as far as 'let's forget about it. Let's not personalise anything, let's just move forward and try and find solutions about it'. And I think that's part of working together over a number of years, being in the thick of these things where it just gets to a case of 'you've got to respond because all of us are being scrutinised, the minister's office is scrutinising us, the public is scrutinising us' you know. (Lauren)

Challenges in working together

In contrast to the strategies participants mentioned that assisted them to form trust and relationships and ultimately work together, three main challenges to working together were also reported. These included different risk thresholds, different political agendas and a lack of clarity in regulators' roles.

1 Participants discussed how different understandings of risk and political agendas can make working

2 together difficult. These issues were reported as leading to conflict which made it difficult to work

3 together. For example:

4   There are certain organisations and jurisdictions that have different risk thresholds to

5   [organisation] and we would believe that a certain level of risk required action and other

6   jurisdictions or other organisations may not and that can cause conflict, both within the state

7   and nationally. (Naomi)

8

9 The influence of politics on food regulation was further described by a participant. Food law is

10 determined by the State Food Acts which are unique in each state. However, , to achieve some level

11 of consistency, they are based on the Model Food Act. Furthermore, food standards are enforced by

12 the states and territories, usually health or human service departments, or in some cases, by local

13 government. This complexity can result in different priorities of the states which can make a

14 consistent approach, and therefore working together, more difficult because "there is constant conflict,

15 within the state and nationally" (Naomi):

16   I don't know of anybody in any of the states who hasn't got competent people working there.

17   Different states have different political agendas at different times and one state's agenda

18   might not line up with others, particularly when it comes to, well, standards development.

19   One state might have one way that they want the outcomes of a standard to look like and

20   other states might want it a different way so there can be, at times, a little bit of conflict. But I

21   think all states, from where I sit, still seem to have an overarching desire to ensure that we're

22   maintaining food safety standards, which is the really important bit I think. (Jake)

23

24 The notion of the Australian states and territories working separately was further elaborated on by the

25 same participant who said that while regulators across Australia strive for consistency in their

26 approach, the differences between states and territories makes this consistency difficult to achieve:

27   .... the system's a bit funny because it's relying on the voluntary contributions of all of the

28   states to make it work and we're trying to have consistent, uniform standards that are applied

1   equally in all states, but we all work under our own legislation. Even though it comes from

2   the Model Food Act, to get it through seven parliaments in Australia, and you've got different

3   power factions, different political persuasions in place in each state, you'll never get the

4   regulation exactly the same, or the focus being exactly the same. (Jake)

5

6   A lack of clarity in regulators' roles, especially in relation to who is responsible for what, was also

7   highlighted. Participants consistently said that the large number of regulators working to respond to a

8   food incident, across multiple jurisdictional levels, could lead to uncertainty about exactly who was

9   responsible for a certain action when responding to a food scare and confuse the response:

10   The problem you get in these sorts of situations is somebody quite senior in the Health

11   Department will start asking questions of the people, the policy people that we deal with.

12   Then you'll get the Ministers come in over the top of that and everybody gets really excited

13   because everybody wants instant answers and it was a point that several of us came to after –

14   we had a final sort of debriefing on what went wrong with [food incident] basically – and the

15   thing that was obvious was that far too many people that didn't know what they were doing.

16   [This was] putting too much pressure on the one or two people that really did know what they

17   were doing and as a result of that too much time was diverted from fixing the problem into

18   answering questions. (Gregory)

19

20   Other participants, working at a less senior level, talked about the challenges of not finding out about

21   important information, which made it difficult to respond to situations:

22   ....a lot of things are dealt with before it gets to our level. I suppose for want of a better word

23   we're the last people to find out but that's not a bad thing, it's because it's being dealt with at

24   a higher level so, yeah, we're just the working bees in the hive. (Jack)

25

26   The lack of understanding about each other's roles that sometimes exists, due to the complexity of the

27   system, was described by one regulator:

I think that's a little piece that we're missing, how all the pieces fit together, and that's the

work that's currently been identified as being an issue; that's actually been identified from

our last few big recent recalls. It's just […] you know, that communication and that, to me is

the issue, just better communication between all of us rather than a failure in the system. It's

not that we're lacking the process, we're not lacking the access, we're not lacking the

expertise. I think it's the communication about all of that, that needs to be improved. It's not

the communication per se, it's just our general communication of understanding what we all

do and what our roles are. (Lauren)

Due to this complexity, including the number of players in the food regulatory system across both

state and national levels, including local government, participants stressed the importance of all food

regulators understanding their role and the role of others. As well, it was considered to be important

to make the effort to align expectations in relation to who, and which organisation, is responsible for

what.

Discussion

Effective management of food incidents by food regulators and ensuring consumer confidence in the

messages of food regulators is important in order to minimise the impacts of food incidents.[4] This

paper reports on the views of Australian food regulators about how they work together to effectively

manage food incidents. Food regulators in this study reported that working together is an important

part of being effective in responding to food incidents. Forming trust and relationships, using a variety

of formal and informal strategies, was identified in this study as an important way to do this.

However, in addition to the positive elements of relationships between regulators, challenges exist in

working together, including different political agendas, different risk thresholds, different priorities in

different organisations, the complexity of the system, the number of people involved in responding to

food incidents and a lack of understanding of each other's roles and responsibilities.

1   Food regulators saw the benefits of working together to manage food incidents and reported ways in

2   which they foster relationships and trust with others. There is agreement in the literature about the

3   need for food regulators to work in partnership. Our data supplement and support effective strategies

4   reported elsewhere that strengthen relationships between regulators, including joint decision making,

5   information sharing, ongoing dialogue, agreed, realistic goals, an agreed agenda and trust.[19] Good

6   communication has been reported as an element of an effective work culture as was peer group

7   support, good staff communication and consultation and recognising that all staff have a role to play.[12]

8   Therefore, organisations can use the findings of this research as strategies to encourage their food

9   regulators to develop trust and relationships.

10

11 Factors which regulators cited as challenges to working together in this study included the

12 involvement of multiple organisations responsible for food regulation, different risk thresholds and

13 different political agendas. Regulators in this study said that multiple levels, leading to a fragmented

14 system, makes communication and hence the management of food incidents, more difficult. Similar

15 challenges have previously been reported, for example, it has been acknowledged that "enforcement

16 may also be especially difficult in a system where there is a division between centralised policy

17 making, a highly fragmented and dispersed system of local enforcement and the presence of

18 conflicting organizational cultures in local government that may demand the adoption of market-

19 based principles to service delivery".[20, p. 16] However, despite the challenges with fragmented systems

20 where there are multiple organisations responsible for food regulation at the state, local and national

21 level, it has previously been identified that "the merging of responsibilities under unitary systems does

22 not necessarily overcome the potential for conflict between professional actors".[20, p. 12] Therefore how

23 best to address the issue of fragmentation requires further research.

24

25 More effective partnerships between regulators has previously been cited as a benefit to organisations.

26 For example, a report looking at the relationships between the UK Food Standards Authority (FSA)

27 and its stakeholder organisations identified that change within the FSA could be the establishment of a

28 common understanding of the identification of the need for and the nature of partnerships.[19] It was

suggested that this could be achieved by clearer lines of communication and a more stable structure. This paper provides empirical data to support this suggestion. Clarity in relation to food regulators' roles – who is responsible for what, and how different stakeholders communicate – was identified as a challenge to effective food incident management and is therefore an area for development amongst organisations.

Identified challenges, both in this research and research elsewhere, indicate areas for development for food regulators seeking to facilitate effective management of food incidents. Ideally, good management of food incidents will minimise unnecessary loss of consumer trust and unnecessary changes in dietary habits and nutritional status, that may have implications for public health. Similarly, good management of food incidents is important to avoid unnecessary economic effects previously reported as outcomes of food incidents.[3, 21] It is clear that fostering trust and the development of relationships between food regulators, using the strategies identified in this research, will facilitate effective management of food incidents. Providing clarity of the roles of food regulators, both within and between organisations, is also important to facilitate effective food incident management. Development of strategies for working together effectively and ensuring consistency despite different jurisdictions and different organisational/ state agendas is an area for future development.

In conclusion, a focus on partnerships and good communication between food regulators is likely to facilitate effective management of food incidents., Effective food incident management can reduce unnecessary loss of consumer trust in food and large changes in dietary habits and nutritional status that could impact on the public's health..

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1

2 **Tables**

3 Table 1: Interview schedule used in interviews with food regulators

Section of the interview	Example questions
Hypothetical scenario	• To what extent is this situation likely to be a realistic scenario? • To what extent is this situation likely to be a significant issue for the company concerned? o If so, what features are salient? • Would issues of public trust or confidence in the food supply are considered in dealing with this issue? Why/ why not/ how?
Real food incidents	• Are you willing to give an example of a real food scare your company has been involved in and how you responded?
Trust	• What is the food regulator's role in trust building (with consumers about food), trust maintenance and trust repair • Who are the key stakeholders that you work with around food? • Does the food regulatory system have a role in development of consumer trust in the food system? If yes what is this role, if no why not? • What strategies do you use to build trust with consumers when they do not trust the food system? If trust already exists, what strategies do you use to maintain it? • In your view, how could industry and regulators work together to have more practical outcomes when building consumer trust in food?

4

5

6

1

2   Table 2: Hypothetical scenario used in interviews with food regulators

Scenario	Elements
	• Large food manufacturer has identified contaminated soy protein isolate during routine testing of raw ingredients • Source of contaminated soy protein isolate is an Asian country • Soy protein isolate is used extensively in the food industry to increase the protein content of a wide variety of foods and drinks that are consumed across all age and social groups • Soy protein isolates are also used in infant formulas • Subsequent testing has identified the contaminated soy protein isolate in leading brands of infant formula, breakfast cereal, bread and other products that are currently on sale • The contaminated product is potentially hepatotoxic, containing a toxin that causes acute liver disease • Literature suggests that the toxin can be fatal in vulnerable groups such as children, pregnant women and older people

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