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Abbey Court
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26th April 2016

Re: Review of Official Control System in Ireland and Opportunities for Change

Dear Pamela,

I am writing to you in follow up to your letter of the 29th January 2016 concerning the above and our subsequent meeting on the 8th of February to discuss the related report and recommendations.

We welcome the energy for collaboration toward maintaining and developing a world class official control system that you have brought to your role. A positive outcome from our meeting on the 8th February was our agreement in principle to the establishment of a cross agency steering group to progress strategic issues on a partnership basis. We look forward to working with you on this group.

You have asked me to provide you with a written response to two related FSAI reports, which you intend to publish, along with the formal responses from other official agencies.

At our recent meeting on the 8th February last, I and colleagues reiterated our concerns about the limited opportunity for input by Official Agencies in the official control review process and as a result of this, we highlighted a number of issues in relation to the subsequent reports and some of the recommendations.

Three important observations are relevant here.

Firstly, the Scientific Committee did not appear to adhere to its own Terms of Reference (ToR). Appendix 1 of the Scientific Committee Report sets out the ToR which state on page 4, "The draft report (of the Steering Committee) should be provided to the official agencies for observations and comments before it is sent to the Scientific Committee." The HSE have not seen the Steering Group report referred to in the ToR and were not afforded any opportunity to comment on any drafts of the ICF report. The Scientific Committee of the FSAI was therefore furnished with two reports, the original consultant's report and the Steering Committee report, neither of which were given to Official Agencies for comment or review, prior to finalisation.

These reports cannot be seen to reflect the input or views of the wider food safety community in Ireland and this is unfortunate and a significant missed opportunity. This is especially so when the report attempts to set out issues that would benefit from a collaborative cross-agency approach to resolution and others requiring an individual agency approach. Clearly the need for multiple levels of formal and informal collaboration on a national exercise of this nature is essential to realising its objectives.

Secondly, without access to all of the evidence considered by the Scientific Committee it is difficult for my team to link the findings of the Scientific Committee report findings and recommendations to the evidence underpinning same. While it is our view that the recommendations, in the main, provide very useful reference points for cross-agency discussion, the quality, strength objectivity and balance of the evidence is impossible to assess and seems to rely heavily on the ICF consultants report.

Thirdly, in general the reports do not consider the synergistic benefits of the existing governance and service contract arrangements from a national perspective. For example, from a health service perspective, the availability of HSE expertise in disease surveillance and outbreak management to support FSAI in food borne outbreaks and the efficiencies being delivered with consequent reduction in the burden on businesses by concurrent inspections for Food Safety and Tobacco Control. There will be many other examples across all of the Official Agencies. These types of synergies underpin the current statutory arrangements and any discussion on revised funding or governance arrangements would require careful consideration of these broader issues. The formal input of all stakeholders and critically of the Department of Health and other Government Departments prior to the development of recommendations would be imperative.

More specific observations include:

- The direct input from the HSE EHS into the review process was limited to one meeting with ICF consultants in December 2013. ICF concentrated on a narrow range of topics which ICF advised had been predetermined by the FSAI, including a unified food safety agency and a single food safety system for all official control staff. The HSE sought to broaden the discussion and provide context to the points raised by ICF. Following the meeting the HSE made a written submission outlining the views and context provided by the HSE on the day.
- The final ICF report does not reflect the limited direct input afforded to the HSE in the review process e.g. that data requirements are agreed within the FSAI/HSE service contract and reviewed via the liaison process; and also the importance of validation and interpretation of raw data to avoid misrepresentation and duplication. The latter points are acknowledged in the current FSAI/HSE service contract (Schedule 4, para 4, p 46). Instead the ICF report draws unwarranted conclusions (ICF, p 23, para 1) from selected findings from their survey of and interviews with official control staff e.g. implying an organizational culture within the HSE not to share detailed data (in their raw state) with the FSAI (based on what seems to be a very small and not representative sample of EHS staff) (ICF, p. 25, para 3).

- As a consequence of the limited opportunity for input and particularly the absence of any consultation on the draft reports, the ICF report contains a range of significant omissions and inaccuracies that were pointed out and acknowledged at our meeting e.g.
 - Section 5.7.1 which deals with 'Public release of data to encourage compliance' makes no reference to Article 13 of S.I. 117/2010 which effectively prohibits same.
 - Sections ES 1.6.1 & 6.4.1 refer to 'establishment of an internal audit function as required by EU law'. This point is carried through to Recommendation 7 of the Scientific Committee report which relates to Official Agency Internal Audit Systems, the commentary beneath which states; "*Agencies have a legal obligation to audit their own activities.*" Yet the legal requirement concerned is Article 4(6) of EC Regulation 882/2004 which states: "Competent authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner." As such the internal audit function is optional and not a mandatory requirement. It is not clear from the report what internal audit arrangements the FSAI has as a competent authority under EC Reg 882/2004.
 - Section 4.3.3.1 (ICF para 3, p. 26) incorrectly states that the HSE report the average number of establishments and inspections per inspector. The FSAI may generate such indicators from data provided by the HSE. However, as advised to ICF because most EHOs deal with a range of official food controls e.g. food sampling, investigation of complaints etc. and many food safety inspections are done concurrently with inspections under tobacco & cosmetics legislation for efficiency, which is in keeping with better regulation principles, the average number of food safety inspections per inspector is a crude indicator that can be and has been misunderstood and misrepresented in the past.
 - The ICF report comments extensively on the concept of tracking changes in the 'stock of risk' without defining what is meant by the term and how it would be measured. This concept is contained in recommendation 8 of the Scientific Committee report. At our meeting on the 8th no one present could explain the concept or how the recommendation could be implemented.

Given the foregoing and in particular the fact that the Scientific Committee appears not to have followed its own terms of reference the report misrepresents the level of consultation that actually occurred with the Official Agencies. As a consequence the Scientific Committee report should not be presented or construed as reflecting the input of the HSE on these matters.

In addition, the Scientific Committee report presents an historic perspective which reflects an unduly negative ICF report (2013/2014). It is my belief that the ICF report and the process underpinning its production did not reflect the breadth of positive national and local partnerships and professional working relationships that have characterised an improved food safety culture and practices over the last ten years in Ireland. Neither report acknowledges the significant ongoing work between the FSAI and the Official Agencies including the agreement of new service contracts in 2015 that address many of the report's recommendations. As suggested and agreed at our meeting, it will be important for the FSAI to set out a context to these reports and detail the many advancements and progress made in recent times on many of the recommendations and areas set out in the reports.

The HSE welcomes the FSAI commitment to a collaborative and partnership approach and the agreement to establish a cross agency steering group to consider and progress the strategic issues arising from the Scientific Committee report. In our formal submission to ICF consultants, we recommended that the Official Control review should clarify / document the respective statutory roles and responsibilities of the FSAI and the Official Agencies under the service contract model established by the FSAI Act. An early priority for the high level cross agency group should be to formally examine, delineate and document the respective statutory roles of the FSAI and the Official Agencies and in the process of doing so demonstrate the leadership, collaboration, effective use of resources expected of all public/civil service organisations.

On the basis of the renewed energy clearly visible over the last year and a half to lead, build trust and use the State's investment in food safety activities in the most efficient way possible, the future looks very bright. While these reports and the process underpinning them do not represent this way of working in our view, and reflect a different culture and way of doing business, we commit to working steadfastly with the FSAI to ensure Ireland is seen as a leading light in implementing efficient, world-class Official Control Systems underpinned by trusted cross-sector collaborations. We look forward to joining a cross-agency collaboration, led of the FSAI, to deliver this.

If you have any queries in relation to this correspondence please do not hesitate to contact me by email healthandwellbeing@hse.ie.

Yours sincerely,



Dr. Stephanie O'Keeffe
National Director
Health and Wellbeing

CC: Dave Molloy, AND, Environmental Health Service, Health and Wellbeing Division, HSE