Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed (Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirement of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[(1)], and in particular Article 55 thereof,

Whereas:

(1) Article 55 of Regulation (EC) No 178/2002 provides that the Commission is to draw up in close collaboration with the European Food Safety Authority ('EFSA') and the Member States, a general plan for crisis management in the field of safety of food and feed, ('the general plan'). Accordingly, Commission Decision 2004/478/EC[(2)] set out the general plan.

(2) Since the adoption of the Commission Decision 2004/478/EC, further experience in crisis management coordination at Union level has been gained during a number of food- and feed-borne incidents.

(3) The experience gained over the years, as analysed in the REFIT evaluation of Regulation (EC) No 178/2002 (Fitness Check of the General Food Law)[(3)], has demonstrated that there is a need to re-evaluate the management of food and feed crises at Union and national level. The findings showed a need for a stronger focus on crisis preparedness, alongside crisis management, in order to avoid or minimise the public health impact of a food or feed crisis. Such focus could substantially reduce the economic impact (such as trade restrictions) of a food or feed crisis and thereby contribute to the achievement of the objective of the Commission on jobs, growth and investment. In addition, there is a need for a greater role of the Commission in communication and general coordination of Member States in this area. The Fitness Check of the General Food Law contains a number of recommendations to enhance the efficiency of the general plan.

(4) EFSA is responsible for providing the opinions serving as the scientific basis for the adoption of Union measures and has the task to provide scientific and technical

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assistance in the crisis management procedures in the field of food and feed. The role of EFSA in the general plan should be fine-tuned and strengthened in view of the experience gained.

(5) While respecting each agency's competence, EFSA should coordinate with other relevant Union scientific agencies, such as the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Medicines Agency (EMA) and the group of experts appointed by the Scientific and Technical Committee referred to in Article 31 of the Euratom Treaty[(4)], when input or action is needed within their respective competence. In addition, the general plan needs to ensure coordination with the ECDC crisis preparedness and response systems related to human cases so that health authorities and stakeholders are alerted on a possible food-, or feed-borne crisis with a potential human health impact.

(6) Decision 1082/2013/EU of the European Parliament and of the Council[(5)] lays down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, including preparedness and response planning related to those activities, for threats of biological, chemical, environmental and unknown origin and the establishment of the Early Warning and Response System (EWRS). Given the potential links with crisis preparedness and crisis management in the area of the food chain, the relevant arrangements set out in Decision 1082/2013/EU should also be considered in the general plan.

(7) The Union general plan should be revised to include procedures to facilitate coordination with national contingency plans for food and feed to be drawn up in accordance with Article 115 of Regulation (EU) 2017/625[(6)] of the European Parliament and of the Council on official controls.

(8) The main objective of this Decision is to protect public health in the Union. Therefore, the general plan should be limited to situations with a direct or indirect risk to public health in accordance with Article 55 of Regulation (EC) No 178/2002. The risks to public health may be of biological, chemical and physical nature. These cover allergenic and radioactive hazards. The approach, principles and practical procedures of the general plan could however also be considered as guidelines for the management of other food-borne incidents without such public health risk.

(9) In 2017, the Commission carried out an internal audit on ‘DG SANTE's food safety crisis preparedness’, which identified some weaknesses in the existing general plan that need to be addressed.

(10) A number of conclusions were made at the Ministerial Conference of 26 September 2017 on the follow-up of the fipronil incident[(7)]. Although focusing on this incident and fraud, a number of conclusions are relevant for crisis management in food and feed in general, including the creation of one single contact point in each Member State for the coordination of such crisis management in respect of each national administrative organisation.

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(11) Decision 2004/478/EC should therefore be repealed and replaced by a new Decision setting out an updated general plan in order to take into account experience gained since the adoption of Commission Decision 2004/478/EC and to adapt to new developments.

(12) This Decision should lay down a stepwise approach to which types of situations should be dealt with as a crisis, including the related criteria. Not all situations that may fall within the scope of Article 55 would necessarily require the setting-up of a crisis unit in accordance with Article 56 of Regulation (EC) No 178/2002, but they may still benefit from enhanced Union coordination. These criteria should include the seriousness and extent of the incident in terms of public health impact, the relevant consumer perception and political sensitivity, especially where the source is still uncertain, whether the incident was intentional (e.g. bioterrorism or side effect of fraud) aiming at creating a crisis (e.g. bioterrorism) and the repetition of previous incidents attributed to the possible lack of sufficient action.

(13) Coordination between the different authorities at the Union and national level, alert and information systems and laboratories is necessary to share information and take measures to manage a crisis. In that respect, an interlink between the Early Warning and Response System and other alerts and information systems at Union level such as the Rapid Alert System for Food and Feed would enhance the 'One Health' approach, e.g. coordinating the activities of food safety and public health authorities on the same incident, by granting food safety authorities access to information distributed on human cases by public authorities.

(14) Effective crisis management of the food and feed chain requires that practical procedures for preparedness to enhanced coordination at Union level should already be in place before an incident occurs.

(15) The practical procedures for the situations referred to in Article 55 of Regulation (EC) No 178/2002 should be clearly defined in order to ensure a smooth and rapid response to such situations. The role, composition and practical operation of the crisis unit should be laid down for the same reasons.

(16) Evidence-based, real-time communication to the public and to trade partners is essential to contribute to protecting public health by avoiding further spread of risks and to restoring confidence in the safety of food or feed not affected by an incident. The development of principles of transparency and a communication strategy are therefore essential parts of crisis management.

(17) This general plan has been the subject of consultations with EFSA and has been discussed with Member States in the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

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CHAPTER I

General provisions

Article 1

Subject matter

1 This Decision establishes the general plan for crisis management in the field of the safety of food and feed in accordance with Article 55 of Regulation (EC) No 178/2002.

2 The plan covers the following two types of situations:

a Situations requiring enhanced Union coordination; and

b Situations requiring the setting up of a crisis unit bringing together the Commission as well as relevant Member States and Union agencies.

3 The plan also sets out the practical procedures necessary for enhanced preparedness and for the management of incidents at Union level, including a communication strategy in accordance with the principle of transparency.

Article 2

Scope

The general plan shall apply to situations involving direct or indirect risks to public health deriving from food and feed, in particular in relation to any hazard in food and feed of biological, chemical and physical nature, which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of application of emergency measures in accordance with Article 53 or 54 of Regulation (EC) No 178/2002.

Article 3

Objectives

The objectives of this Decision are to minimise the extent and impact of food- or feed-borne incidents on public health, by ensuring enhanced preparedness and effective management.

Article 4

Definitions

For the purposes of this Decision, the following definitions shall apply:

(1) ‘Incident’ means the detection of a biological, chemical or physical hazard in food, feed or humans which might result in or indicate a possible public health risk with the exposure of more than one person to the same hazard, or a situation in which the number of human cases or detections of a hazard exceed the expected number and where cases are linked or probably linked, to the same food or feed source;

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(2) 'foodborne outbreak' as defined in Article 2(2)(d) of Directive 2003/99/EC of the European Parliament and of the Council[8];

(3) 'crisis coordinator' means a person and his/her alternate from the European institutes and from competent authorities of Member States who acts as one single contact point to ensure effective exchange of information between all partners involved in the coordination of the general plan and efficient decision making and implementation of actions within the competence of his/her organisation.

CHAPTER II

Structures and procedures of preparedness

Article 5

Crisis coordinators

Each Member State, EFSA and the Commission shall designate one crisis coordinator and his/her alternate to carry out the tasks set out in Annex I. The Commission shall keep up-to-date the names and contact details of the designated 'crisis coordinators' and their alternates. The crisis coordinators shall hold regular meetings, at least yearly, organised by the Commission with the purpose to present initiatives at the Union level, share national contingency plans and provide follow-up and evaluate the management of recent crises in accordance with Article 22.

Article 6

Alerts and information systems

The Commission shall interlink the Early Warning and Response System (EWRS) with other Union-level alerts and information systems, including the Rapid Alert System for Food and Feed (RASFF). Data submission through the alert networks shall be further harmonised.

Article 7

Laboratories

The Commission and the Member States shall ensure the maintenance of a network of European and national reference laboratories, and other official laboratories, in accordance with Regulation (EU) 2017/625, ready to provide swift and high-quality analytical support as required for most significant food- and feed-borne hazards.

Article 8

Training, exercises and state-of-the-art tools

The Commission shall offer advanced training modules on foodborne crisis preparedness, foodborne outbreak investigation and other incident management within