

Note to the Management Board

Renewal of the List of Competent Organisations (Article 36 List)

Summary

The Management Board is **informed** about the work in renewing the List of Competent Organisations designated by Member States and its result. In close collaboration with Member States, EFSA streamlined procedures for managing the List, supported by a new tool. Member States have checked compliance of their countries' organisations and have consequently newly designated or withdrawn organisations from the List. The project on the list renewal (timeline depicted in Annex 2) was presented to the Management Board in December 2016 and December 2018 and meets Strategic Objective 3 of EFSA's Strategy 2020¹.

The **renewed List of Competent Organisations** is presented to the Management Board **for adoption**.

Background

Article 36 of the Regulation (EC) No 178/2002 foresees the drawing-up and updating of a **List of Competent Organisations** designated by Member States, which may support EFSA with its mission. These organisations may be tasked by EFSA for, *inter alia*, undertaking preparatory work for scientific opinions² and preparing scientific opinions to be peer-reviewed by the Scientific Panels before they adopt them³. **Criteria** have been defined by the legislator to ensure that the competent organisations work within EFSA's remit, have a high level of expertise, act in the interest of the public, and have rules in place to ensure independence and integrity.

The procedures⁴ of managing the List have been **streamlined** in close collaboration with Member States, avoiding duplication of work between Member States and EFSA, and reducing administrative burden. The new procedures further support a more **aligned** assessment at Member State level and **strengthen** the role of Member States, facilitated by Focal Points, to: 1) collect information and check whether the organisations comply with the criteria of Commission Regulation (EC) No 2230/2004, taking into account the national law, and 2) facilitate the decision in Member States, which organisations to designate as competent organisations for the List.

List Renewal

As a result of extensive training and support to Focal Points by EFSA, and their substantial commitment, the **List** has been reviewed and is proposed for approval to the Management Board, at its meeting on the 18th of December 2019. Following the Management Board's decision on renewing

¹ "build the EU's scientific assessment capacity and knowledge community" <https://www.efsa.europa.eu/sites/default/files/151008.pdf>

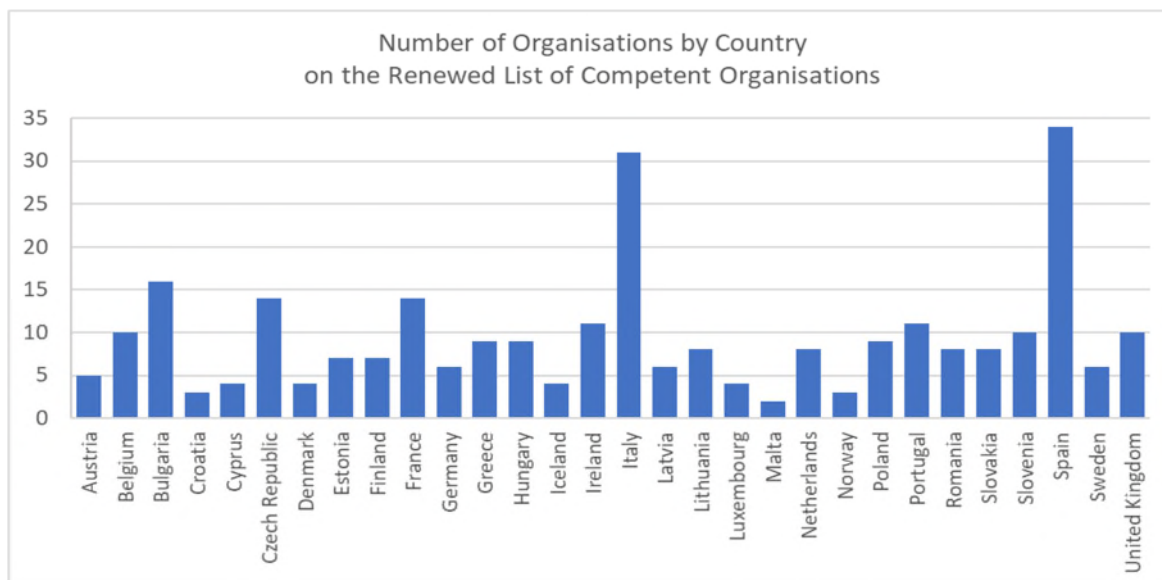
² Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission.

³ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance.)

⁴ See Annex 1 for high-level process

the List, it will supersede the current one. The List will be accessible via EFSA's website, being automatically sourced from the new tool, and notified in the EU Official Journal.

The proposed renewed List includes **281** organisations from **30** Member States⁵. Each entry on the List is at **legal entity level** (one of the legal criteria for inclusion). Information provided includes the competent organisations' **contact details** and their **competences** in EFSA's field of work (i.e. 13 high-level competencies as EFSA's Panels). Further information about the renewed List, i.e. the distribution of competences of organisations and the number of contact persons for organisations' competences (in total 1.8K), is presented in Annex 3.



Next Steps

The roles of various actors in the process of updating the List of Competent Organisations will remain the same in future:

- **Member States** assess whether their countries' organisations on the List still comply with the criteria (supported by Focal Points) and decide whether to confirm or withdraw the designation of these organisations; they also assess the completeness of the List, checking whether new organisations, complying with the criteria, should be designated newly for inclusion on the List (supported by Advisory Forum members);
- **EFSA** ensures that organisations comply with the criteria, supports Member States and manages the List updates;
- EFSA's **Management Board** updates the List regularly, on the basis of proposals from EFSA's Executive Director, taking account of any substantial changes to organisations on the List (i.e. changes related to the criteria for inclusion, e.g. splits or mergers) and designations of new organisations by Member States;
- EFSA's **Executive Director** updates the List regularly, as per Management Board Decision⁶, taking account of technical changes (i.e. changes which do not directly affect the compliance with the criteria, e.g. simple name changes of organisations (re-branding)).

⁵ 28 EU Member States, Iceland and Norway

⁶ Decision of the Management Board of the 18 December 2008 concerning the delegation given by the Management Board to the EFSA's Executive Director to adapt the list of competent organisations designated by the Member States which may assist the Authority (Article 36 List) in case of technical changes submitted by a Member State on one of the existing entities on the list (Decision of the Management Board on the "technical changes to the list of competent organisations designated by the Member States which may assist the Authority", Annex 3 of the Management Board document: mb 18 12 08 item 8 doc 6b - Update on Art. 36 list of organisations.)

Annex 1: High-level process of updating the List of Competent Organisations

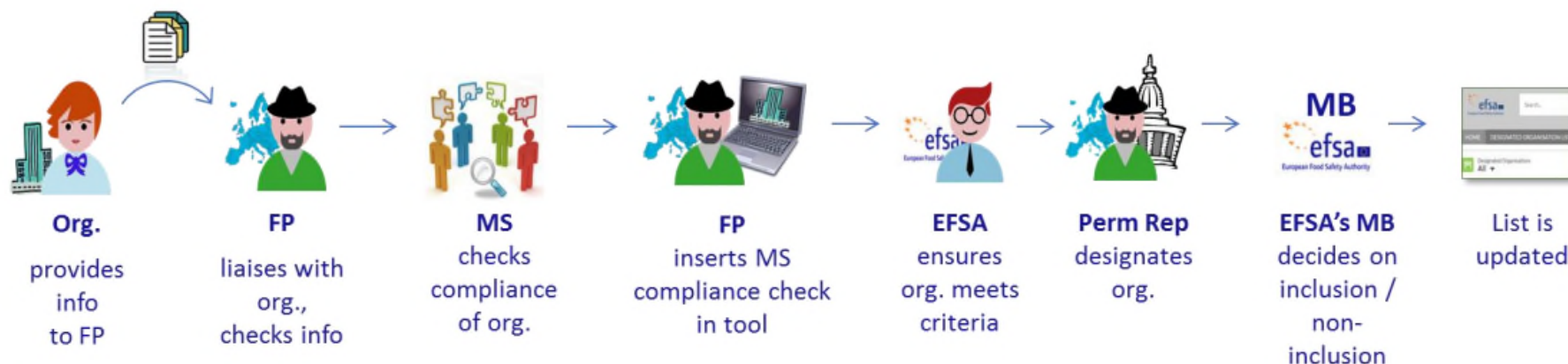


Figure 1: Depiction of high-level process for updating the List of Competent Organisations designated by Member States (Org. – organisation; FP – Focal Point; MS – Member State; Perm Rep – Permanent Representation / Mission to the EU in Brussels; MB – Management Board)

The Focal Point liaises with the organisations and other relevant players at national level to collect and store information (steps 1 and 2), so the Member State can assess if organisations meet the criteria for the List of Competent Organisations (step 3), i.e.:

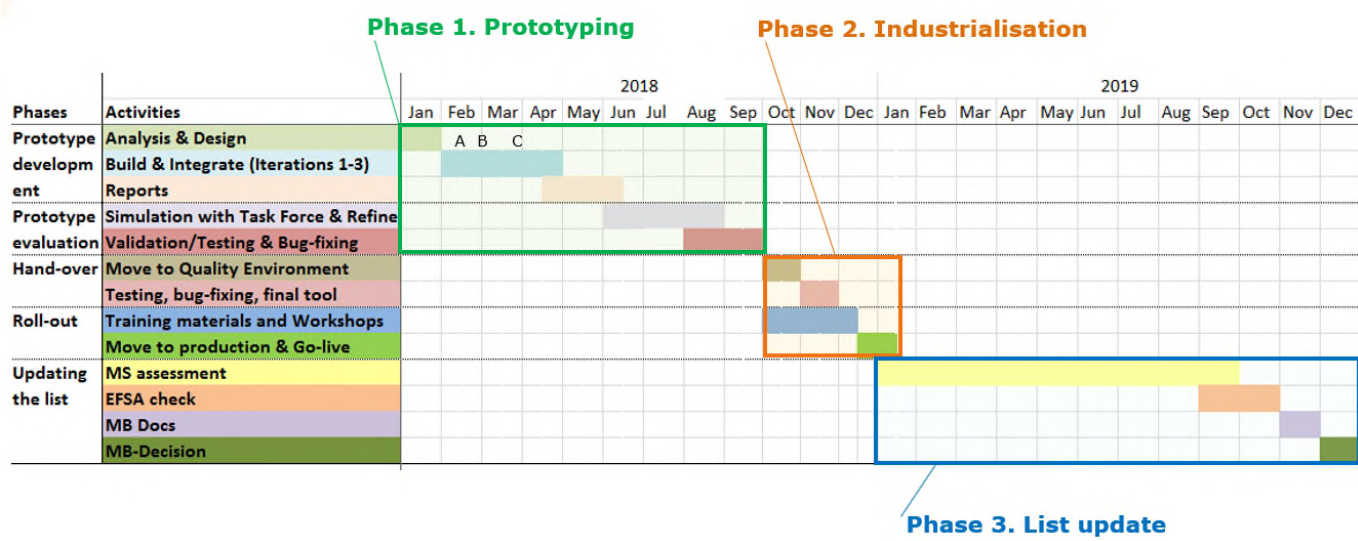
1. The Organisation provides information and supporting documents to the Focal Point;
2. The Focal Point checks the information's completeness, if necessary, requests further information/documents, and stores them;
3. When all information is available, the Focal Point facilitates the compliance check of the organisation at national level and records the conclusions.

After the Member State has assessed an organisation and concluded that it complies with the criteria:

4. the Focal Point inserts the summary of the compliance check in the tool (Competent Organisations Database).
5. EFSA reviews the evidence of compliance provided by the Focal Point to ensure that the organisations meet the criteria and, if necessary, requests further evidence.
6. Upon positive review by EFSA, the Member State can designate the organisations via its Permanent Representation / Mission to the EU in Brussels.
7. EFSA's Management Board, acting on a proposal from EFSA's Executive Director, decides on inclusion/non-inclusion of organisations on the List,
8. leading to an automated update of the List using the new tool (<https://efsa.force.com/competentorganisations>).



Annex 2: Project Timeline



Annex 3: Results of renewing the List of Competent Organisations

The List of Competent Organisations has been consolidated by all 30 Member States, from 363 entries on the current List to 281 organisations on the renewed one. In this process they ensured that:

1. they had the necessary up-to-date information to assess whether organisations (still) complied with the regulatory criteria and, if this was not the case, withdrew the organisations (until they show compliance, upon which they can be re-designated in future);
2. the organisations are listed at the legal entity level (one of the criteria), removing parts of organisations as entries from the list;
3. any organisations which have merged or no longer exist were removed; and
4. any organisations no longer interested in being included on the List were withdrawn.

Figure 2 shows the number and percentage of organisations on the current List for which designation was confirmed or withdrawn, and of newly designated organisations. It further indicates the reasons for withdrawal of organisations, as indicated by the Member States.

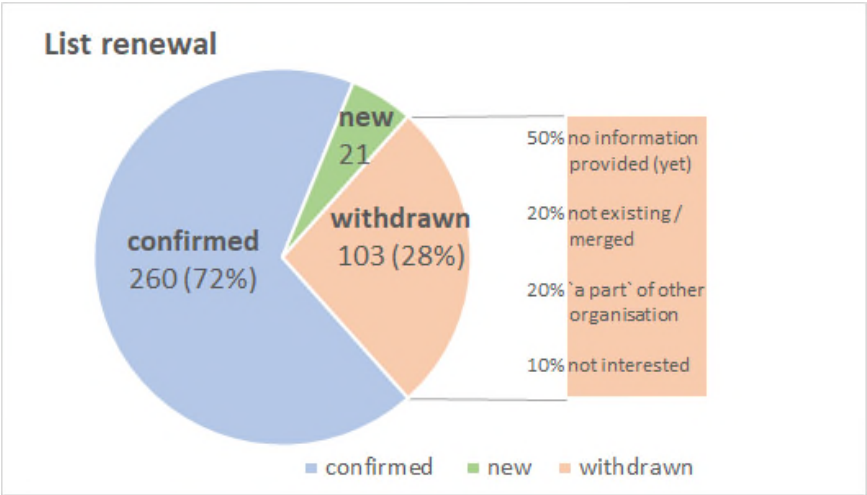


Figure 2: Results of Member States’ assessment of organisations and designations for the List renewal

Figure 3 shows the number of organisations for which designation was confirmed or withdrawn and the number of new organisations designated by each country.

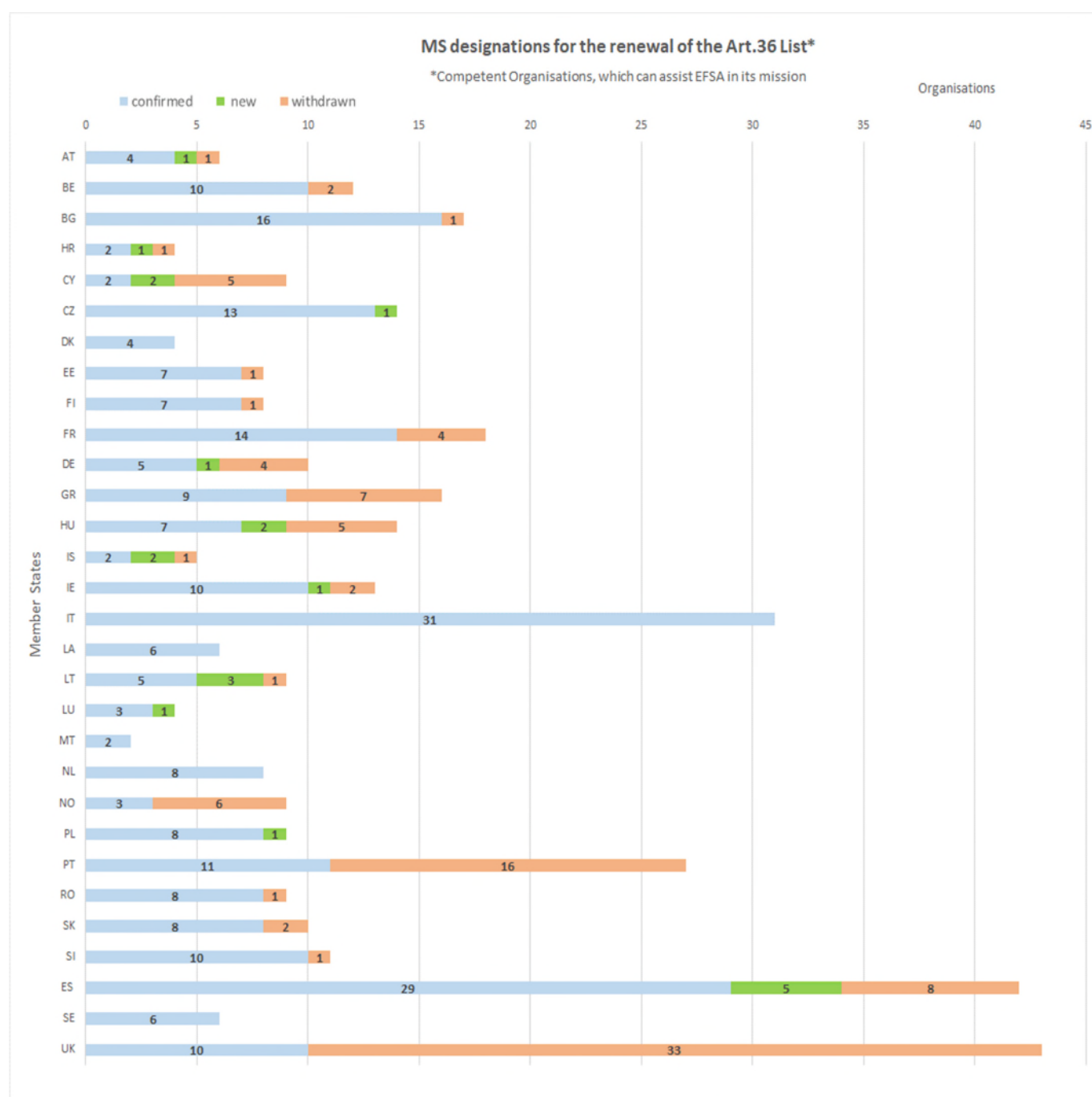


Figure 3: List renewal by country

The following two figures present the distribution of competencies of the organisations and the number of contact persons per competence on the renewed List:

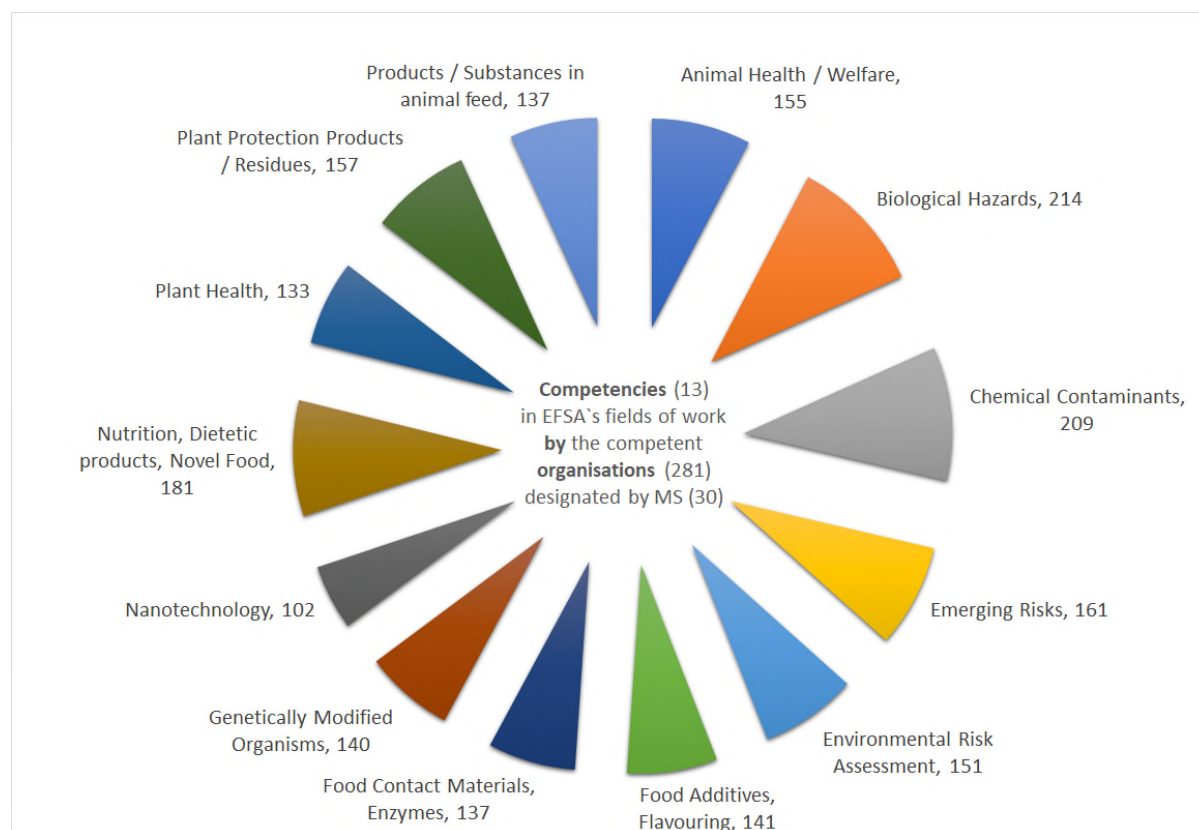


Figure 4: Number of organisations with certain competences on the renewed List

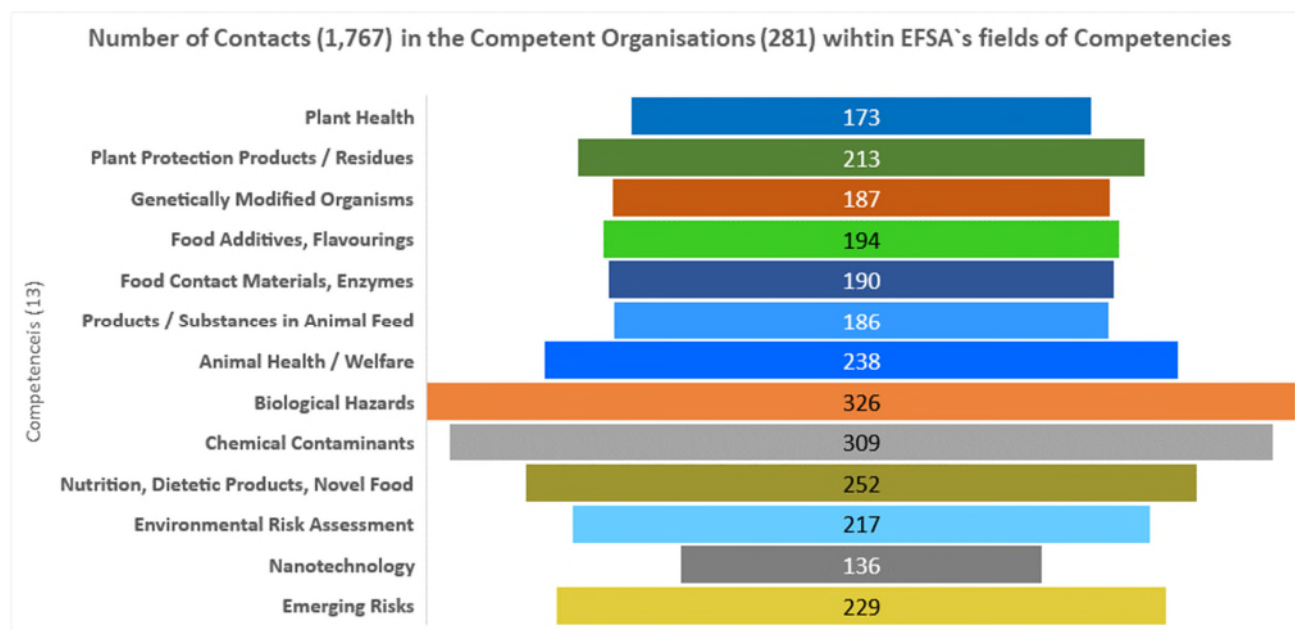


Figure 5: Number of contact persons for organisations on the renewed List, per competences