Study on compliance documentation on food contact materials (FCMs) in the supply chain

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Executive summary

DG SANTE undertook three surveys in 2017 to assess the quality and exchange of compliance documentation in the food contact materials (FCMs) supply chain, targeting respectively business operators (BOs), trade business associations and public authorities. It focused on whether Article 15 on Declaration of Compliance (DoC) and Article 16 on Supporting Documentation (SD) of Commission Regulation (EU) No 10/2011 function as they should. The aim was to evaluate how the compliance of FCMs is verified, and whether the exchange of information across the supply chain is sufficient, including for official controls.

In total, 227 business operators, 59 trade and business associations and 230 public authorities from EU and non-EU countries participated. In addition, the Commission collected and analysed 123 documents provided separately by business operators, including DoCs and SD.

The survey shows the documentary system based on a DoC backed by SD has become common practice within the FCM sectors, with the use of DoCs even for non-harmonised materials (FCMs for which no specific EU measures exist). However, some gaps exists in the flow of information along the supply chain and in enforcement by control authorities, compromising effectiveness of this system in ensuring compliance and safety of FCMs.

Business operators report that they usually receive DoCs from their suppliers but that obtaining adequate supporting information is more difficult, mentioning confidentiality issues and a lack of knowledge among business operators, and in particular, SMEs and actors based at both ends of the supply chain. Checks are mainly limited to visual identity checks, with only 11% of BOs analytically checking SMLs/OMLs and the authorisation status of substances. Still, most are confident they can ensure the safety of their products.

The analysis of DoCs provided shows that most contain basic information and mention compliance with Regulation (EC) 1935/2004 and Regulation (EU) 10/2011. The main shortcomings were in referencing Regulation (EC) 2023/2006 on good manufacturing practice (GMP), clear identification of substances used, on dual use additives, functional barriers and specifications on the adequate use. Few provided the identity of upstream suppliers. Overall, most DoCs were incorrectly filled-in and incomplete.

Trade business associations represent an important channel for information, providing industry guidelines and information and advice on compliance work and legislation to their members. Most mentioned issues in the functioning of information in the supply chain, frequently mentioning the lack of a common structure for DoCs, lack of capacity of SMEs, lack of clarity of responsibilities and varying degrees of knowledge on FCMs along the supply chain.

Regarding competent authorities, most understand the purpose of compliance documentation but often lack the necessary expertise and resources to actually obtain information and assess compliance. Testing costs are high and adequate analytical methods lacking. This is in line with the low number of tests conducted, focused on the few EU-regulated substances, despite a majority considering compliance with migration limits as more important than other aspects.

Among those performing analytical testing, almost half consider they do not conduct sufficient testing to ensure the safety of FCMs.

The outcome of these surveys supports the need for further harmonisation, to simplify and clarify rules, reinforce the quality and exchange of information along the supply chain and improve the enforcement system.

List of abbreviations

BO: Business Operator(s)

BTSF: Better Training for Safer Food

DoC: Declaration of Compliance

EFSA: European Food Safety Agency

EU: European Union

EURL: European Union Reference Laboratory

FCM: Food Contact Material(s)

GMP: Good Manufacturing Practice

MS: Member State

NRL: National Reference Laboratory

OML: Overall Migration Limit

QA: Quality Assurance

QC: Quality Control

SCM: Standard Cost Model

SD: Supporting Documentation

SML: Specific migration limit(s)

TBA: Trade and Business Association

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Introduction

Between January and February of 2017, DG SANTE conducted surveys on the presence and quality of compliance documentation required in the food contact materials (FCMs) supply chain. The aim of the work was to assess and identify potential problems with the exchange of such documentation, including the information delivered to competent authorities during official controls. In particular, the Commission was interested in assessing the functioning of Articles 15 and 16 of Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food concerning, respectively, Declarations of Compliance (DoC) and Supporting Documentation (SD).

Therefore, the survey focused on the verification of compliance of FCMs on the market, paying particular attention to the documentary evidence. The Commission undertook three types of surveys targeting three groups of participants: business operators (BO), trade and business associations (TBA) and public authorities from Member States (MS). This document is divided into three parts, dedicated to the results of each survey.

Articles 15 and 16 of Commission Regulation (EU) No 10/2011:

Article 15 – Declaration of compliance

1. At the marketing stages other than at the retail stage, a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 shall be available for plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles.
2. The written declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex IV.
3. The written declaration shall permit an easy identification of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued. It shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available.

Article 16 – Supporting documents

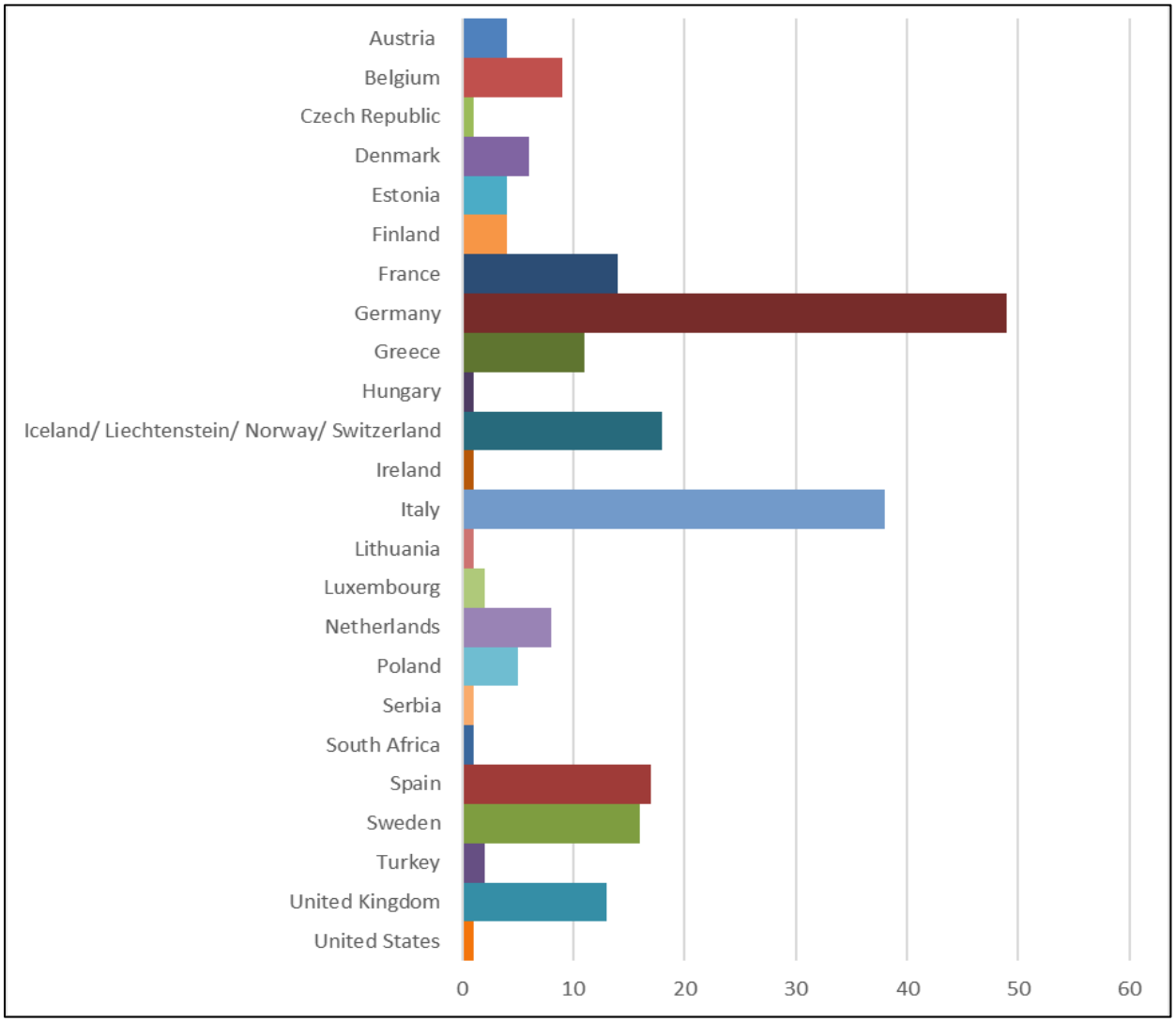
1. Appropriate documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Regulation shall be made available by the business operator to the national competent authorities on request.
2. That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance. Rules for experimental demonstration of compliance are set out in Chapter V.

1. Business operators' survey

1.1. Participants overview

Overall, 227 business operators from 23 different countries responded to the survey (figure 1). Most are based in the EU; with the highest number of replies from Germany (49) and Italy (38), but a few replies came from operators in the US, South Africa, Turkey or Serbia.

Figure 1: Geographical distribution of respondents

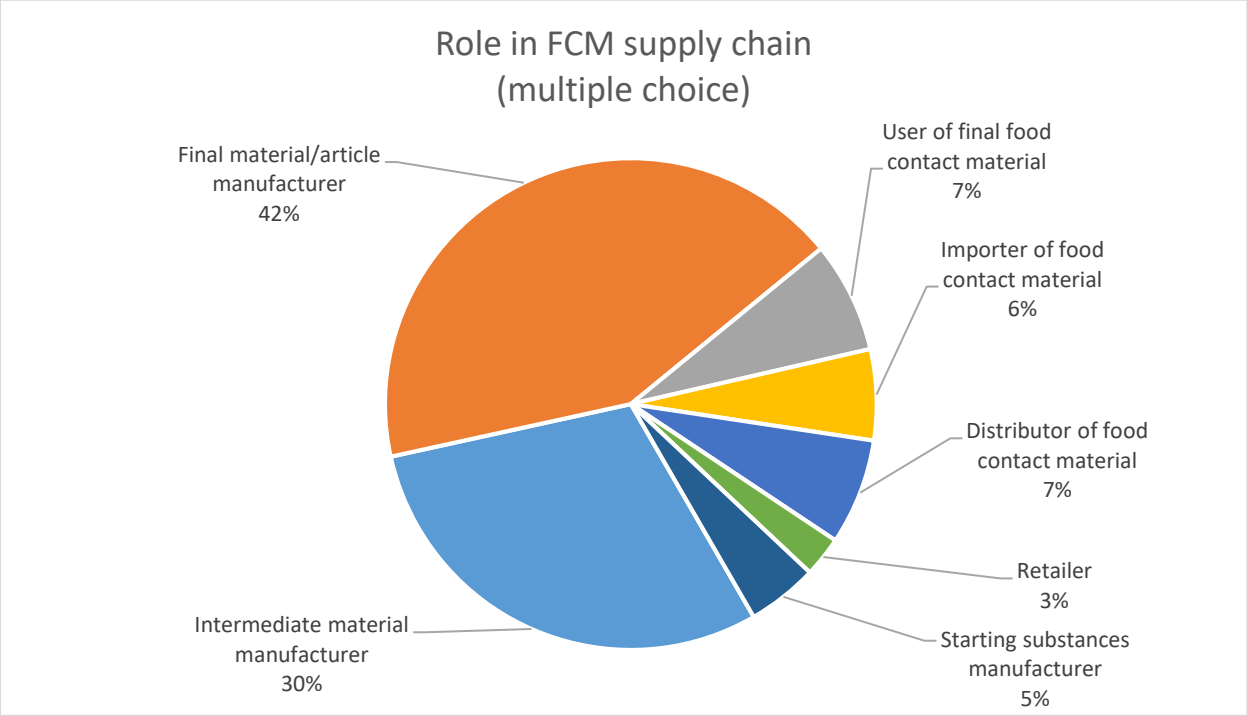


Nearly half of the respondents (42%) were manufacturers of final articles, whereas about a third were intermediate material manufacturers (30%) (figure 2). This may derive from the structure of the supply chain where raw materials are not specifically manufactured for FCMs, whereas users are less concerned with compliance work and FCMs overall. Despite this survey's focus on Articles 15 and 16 of Regulation (EU) 10/2011, around 50% of respondents who replied do not work with plastic FCMs. Nearly half of the respondents work with multi-material multi-layer

FCMs, including those replying as "other". This reflects that material distinction may not be as relevant, as most manufacturers and BOs deal with multiple-materials, partly because FCMs are made of multiple materials. The remaining work with single materials, and out of them, half work with plastics.

Interestingly, 30% of respondents work exclusively with "non-harmonised" materials (mainly metals and alloys, paper and board and printing inks), for which there are no EU requirements for DoCs or SDs[1]. Among those, 66% actually receive some form of DoC from their suppliers, which shows that DoCs are becoming common practice, whether provided voluntarily or due to national legislation.

Figure 2: Roles of the survey participants in the FCM supply chain



1.2 Declaration of Compliance (DoC)

Responses suggest that whilst DoCs are provided by suppliers in most cases and BOs do perform checks, checks are not systematic and rarely go beyond verifying visually that the DoC corresponds to the supplied article or material. When the DoC is not adequate, the business operators generally contact the supplier asking for more information.

- 79% of respondents declared that a DoC, provided mostly by e-mail, accompanied articles and materials they received from suppliers.
- Three quarters state they often check the DoC, but only half of those do so systematically.

[1] « Other » has been excluded as most respondents are either food businesses where the material of the FCM is not specified or manufacturers working with flexible and multi-material.

- Checks are mainly limited to visual identity checks (61% of business operators).
- Only 28% do further checks using other ways of verification, e.g. checking the material description.
- Only 11% of the business operators perform analytical tests.

Some 70% of BOs import FCMs, reflecting the global nature of supply chains. Among those:

- 80% reported receiving DoCs accompanying the imported materials or goods.
- In 25% of the cases, DoCs were considered of lower quality compared to equivalent documentation from EU.

This is corroborated by an overall agreement that information from EU suppliers tends to be better than from non-EU suppliers. This is because DoCs from non-EU business operators do not always provide information on applicable migration limits or substance restrictions, materials used by suppliers, impurities or NIAS and corresponding testing results as SD. According to respondents, this is mainly due to a lack of understanding of non-EU suppliers of EU legislation and requirements, e.g. regarding information required in DoCs, applicable legislation, migration testing methods and limits. Indeed, DoCs provided by non-EU suppliers may sometimes instead refer to US Food Drug Administration's requirements or EU Member States' national legislation. This leads importers to occasionally ask whether, for example, the DoC can be adapted to meet EU standards, or to perform additional testing as the articles were tested against different standards (e.g. Japanese legislation). However, none of the examples of DoCs received were from non-EU operators, hence a concrete comparison was not possible within this study.

1.3 Compliance Work

As a part of their compliance works and risk assessments, 62% of business operators combine different methods to check compliance of their articles and materials. Still some 37% only rely on one method, with half of them checking against the specific migration limits (SMLs) and the overall migration limit (OML).

In order of frequency, BOs mentioned using:

- Verification of the compliance of SML and OML through screening or verification (68%).
- Verification of the authorisation status of intentionally added substances (56%).
- Identification of NIAS (40%).
- Verify purity criteria of intentionally added substances (30%).
- Other analyses such as migration modelling or consider documentary verification with applicable legislation (15%).

When performing analytical testing, only 11% are able to rely on an in-house laboratory whereas the majority use externally contracted laboratories. Most use food simulants rather than food when conducting migration testing. A number of respondents also confirmed complementing migration testing with screening approaches according to point 2.2 in Annex V Commission Regulation (EU) No 10/2011.

Most respondents explained that usually, information received from suppliers is sufficient for their own compliance work (65% confirming information as usually or always sufficient), including on the composition (e.g. migrating substances) and/or permitted conditions of use of the substances/materials supplied. Around half of the respondents state that the DoC is insufficient in itself and requires additional adequate information via supporting documentation. Most also explain that the lack of information is rarely due to business confidentiality. Still, some 40% of BOs report usually or always keeping some confidential information. Replies suggest the use of non-disclosure agreements (NDA) in such cases: 40% usually or always doing so. This suggests that proprietary information is not really an issue for compliance work. Information received is generally easy to understand (80% reporting as usually or always easy), though there are differences in the format of the documents (with over 60% reporting it to be never or only sometimes similar).

Of potential concern is that about half of the respondents report that suppliers put disclaimers to waive or reduce responsibility regarding information provided.

Overall, 94% of BOs are confident of the safety of their products following their compliance work, with 90% stating applicable rules and information available enables them ensuring so. This is in line with 90% confirming that their customers are satisfied with the compliance information provided. However, EU and national legislation and EU guidance on the supply chain could be improved, with only half of the respondents considering such documents sufficiently clear. The burden of compliance work is perceived as acceptable by 60% of respondents.

1.4 Supporting documentation (SD)

As a demonstration of compliance, BOs mentioned different kinds of supporting documentation (SD) they keep and are able to provide if asked:

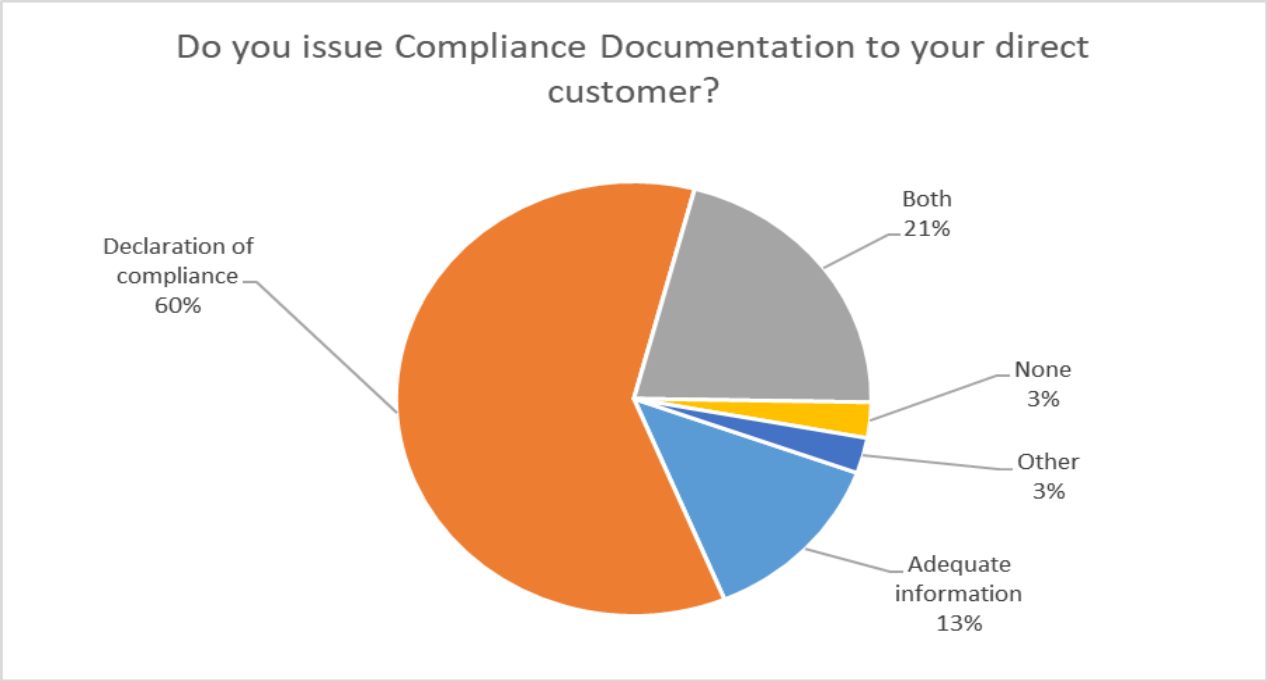
- 84% keep results of migration testing or migration modelling
- 80% keep the DoCs received by suppliers
- 66% keep quality control documentation
- 63% keep information on formulation/composition
- 33% keep relevant information on the process undergone by the material
- 31% keep toxicological information on a substance

Almost 50% of the respondents have their SD compiled and ready for inspection, but all are able to compile them if asked by a competent authority. SD is kept according to the EU legislation (57%), own company's instructions (23%), national legislation (10%) and association's guidelines (10%). If required, 46% of the business operators can provide their documentation immediately, 45% can provide it within 10 working days whereas only 9% of the respondents would need more than 10 working days.

As shown in figure 3, 60% only issue the DoC to their direct customer, 13% only issue adequate information whereas 21% provide both Doc and SD, and the remaining only if required by the customer. Some 27% of respondents update Compliance Documentation regularly. Around 65%

update it after changes in material composition and/or changes in legislation and/or upon customers' request. Only 4% replied updating DoCs only when asked by customers suggesting that business operators do actively update DoCs.

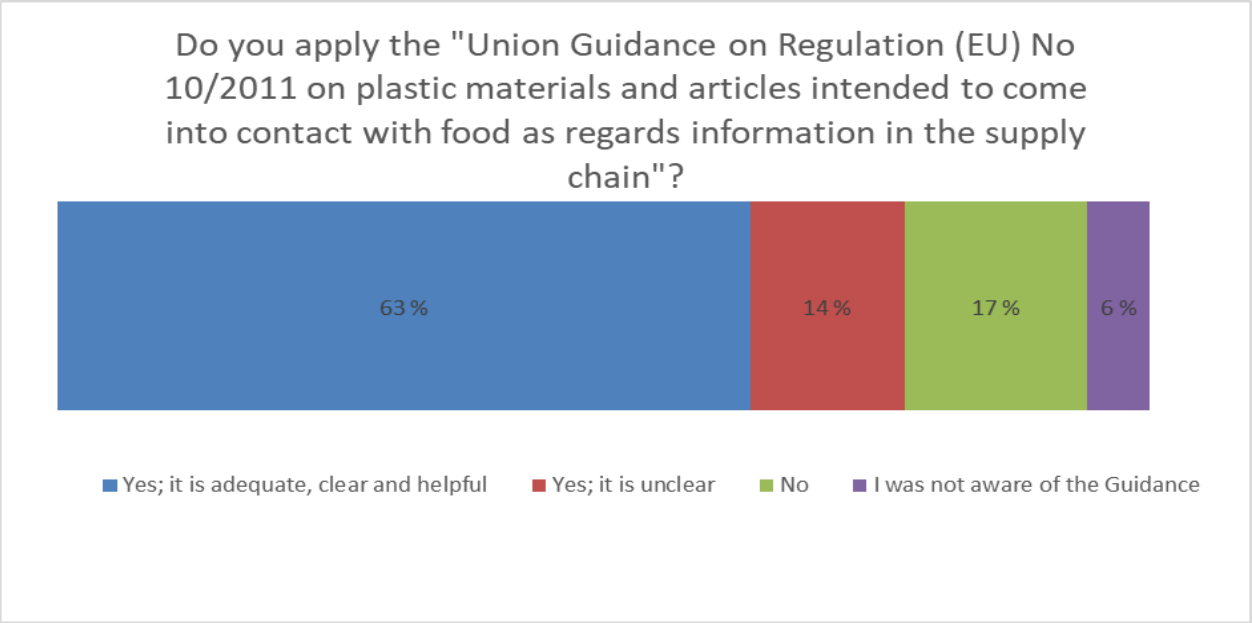
Figure 3: Respondents' replies about issuing Compliance Documentation



The "Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain" is published on the EC website[2]. As figure 4 shows, only 63% of respondents are aware of the guidance and actually find it clear and useful. 14% do not find it useful, while 6% are not aware of it at all and 17% do not use the guidance but the reason was not asked in the survey. This is in line with most respondents finding the Union guidance useful in addressing issues related to the supply chain (45% always/usually and 30% sometimes).

[2] https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en

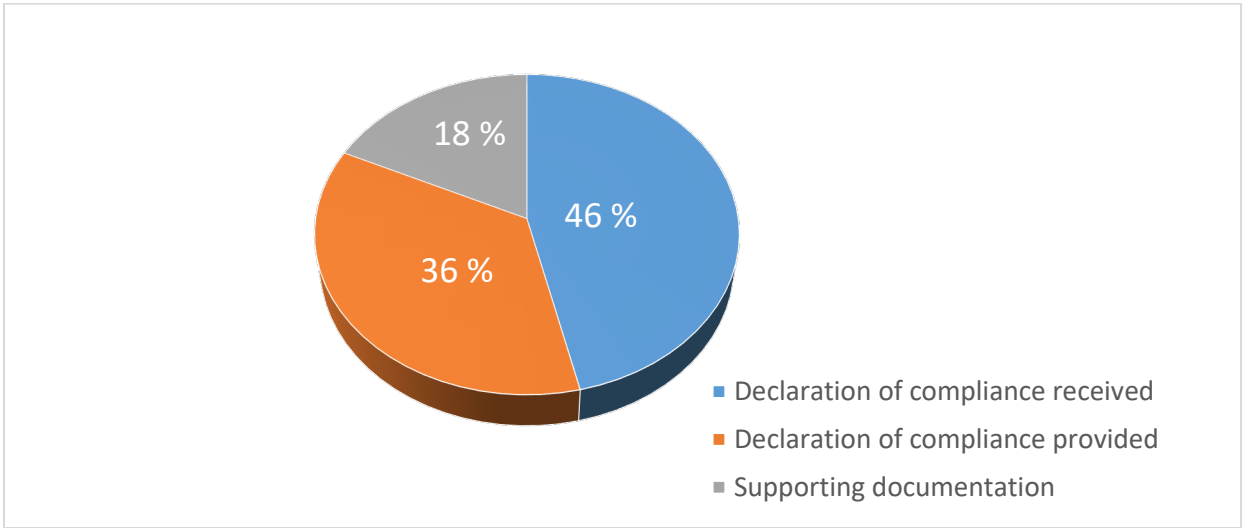
Figure 4: Respondents' application of the Union Guidance



1.5 Examples of compliance documentation

As part of the survey, respondents were able to provide some examples of DoCs and/or SD[3]. In total, 123 documents from 16 different countries were provided, with the majority coming from Germany, Belgium, Greece, Italy and the United Kingdom. As shown in figure 5, 46% were DoCs received from suppliers and 36% were DoCs provided by business operators directly to customers. Only 18% of respondents also included SD.

Figure 5: DoCs and SD sent to the Commission by survey respondents



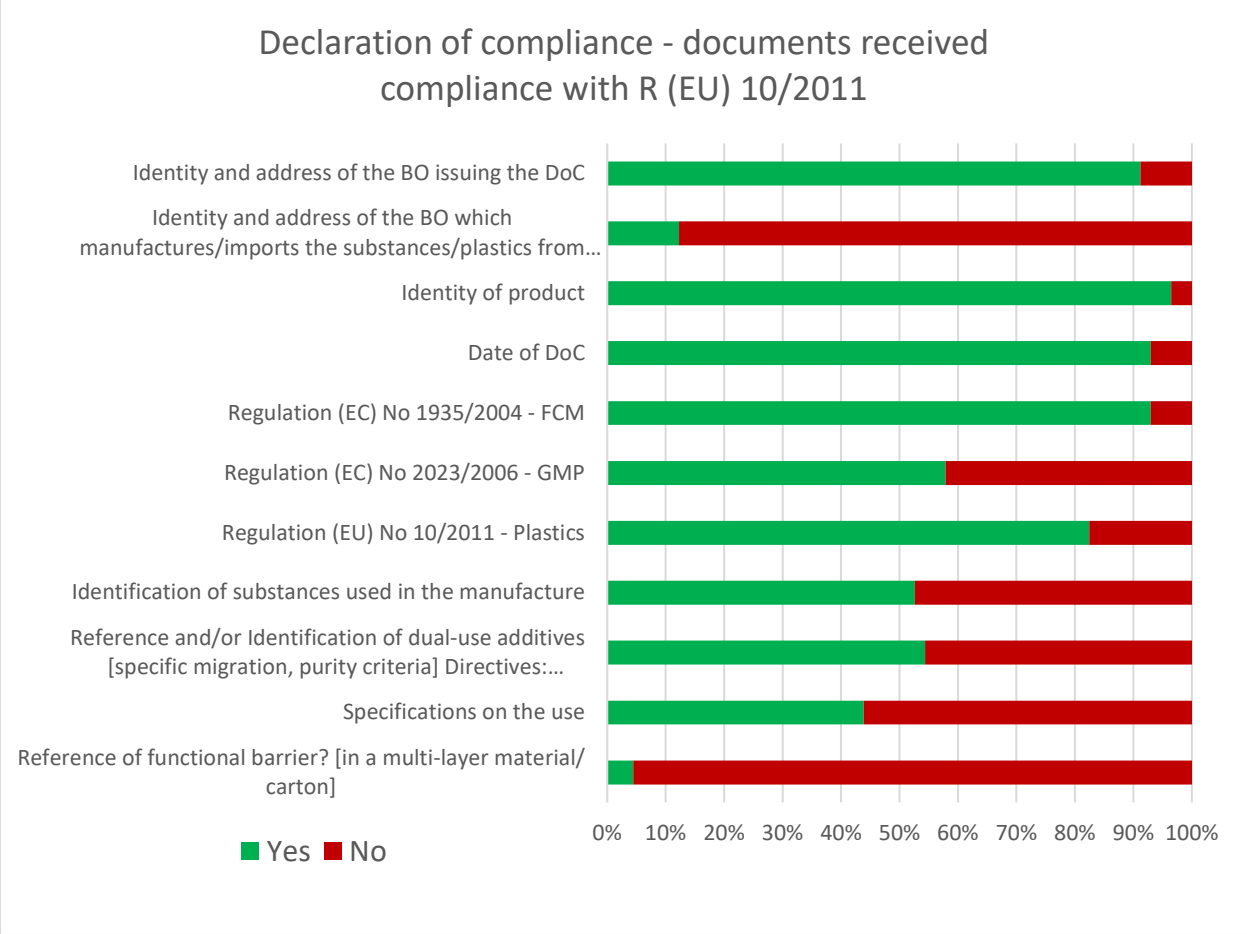
[3] The sample DoCs and SD were provided to the Commission for this study on the condition that they were kept confidential. As such, the samples were destroyed after the analysis was completed.

1.5.1 DoCs received by respondents from their suppliers

57 DoCs received by respondents from their suppliers were assessed. Figure 6 shows the information included in the DoCs. Overall, most of the DoCs report the date, the identity and address of the issuing BO, and mention compliance with Regulation (EC) No 1935/2004 for FCMs in general and Regulation (EU) No 10/2011 for plastic FCMs. On the other hand, only half of the DoCs mention compliance with Good Manufacture Practice (GMP) set under Regulation (EC) No 2023/2006. Only half of the DoCs identify the substances used in the manufacture or identify dual-use additives. Even less (around 40%) include specifications on the use of the article or material. Finally, only a small percentage (10%) of the documents included the identity and address of the operators that manufactured or imported the substance from intermediate stages and almost none of them reference to functional barriers.

The quality and information included in the DoCs hardly differ across the different types of BOs, although DoCs received by final article manufactures seem to mention compliance to Regulation (EC) No 2023/2006 on GMP (70%) more often compared to DoCs received by intermediate material manufacturers (40%).

Figure 6: Compliance with the EU legislation of DoCs received by respondents from their suppliers

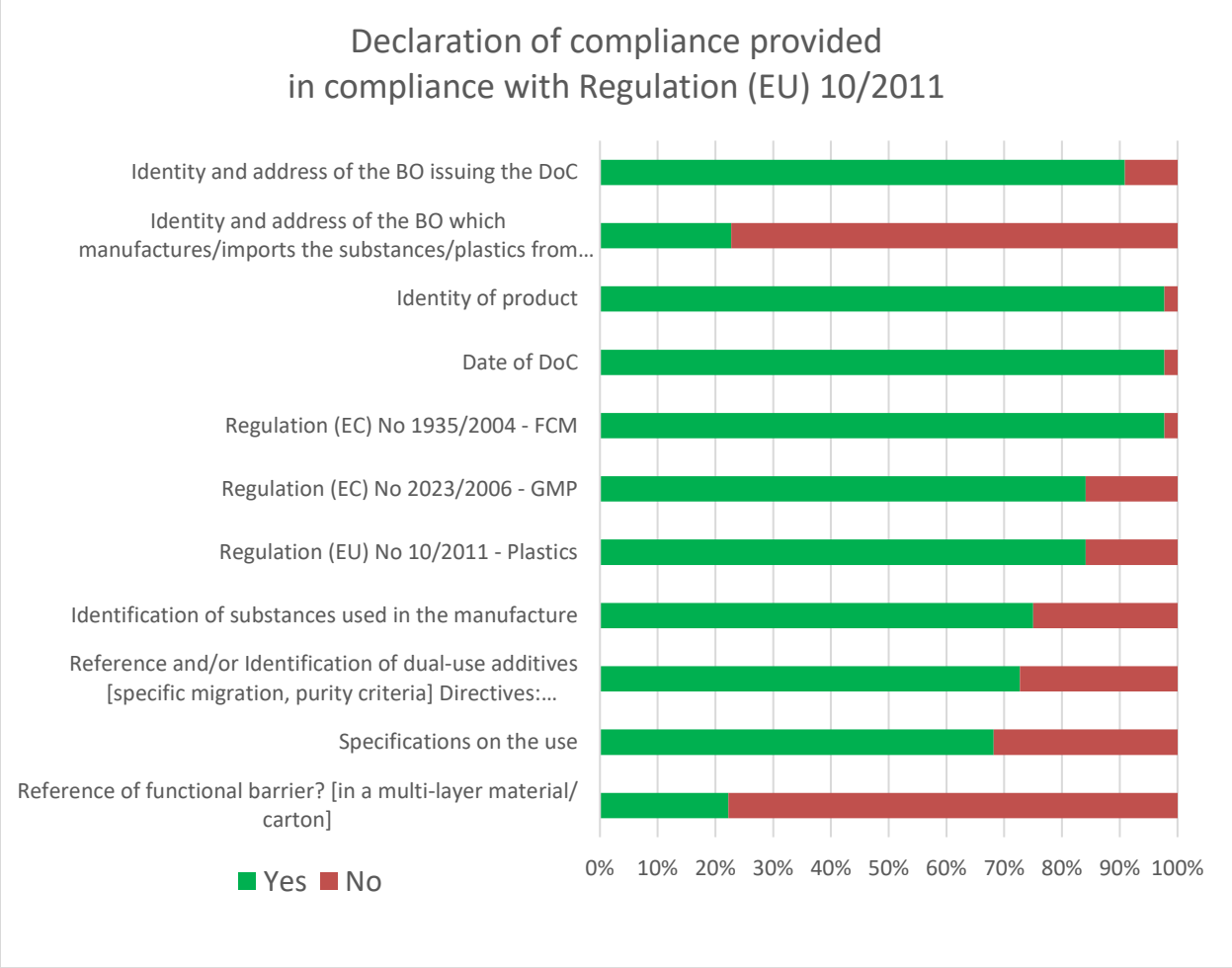


1.5.2 DoCs sent by respondents to their customers

44 examples of DoCs sent by respondents to their customers were assessed. Figure 7 illustrates the main findings. Similar to the DoCs respondents received from their suppliers, most of the DoCs they in turn provided report the identity and address of the business operators, the identity of the product and the date. Moreover, almost 100% of the DoCs mention compliance with Regulation No 1935/2004 and around 85% mention compliance with Regulations (EC) No 2023/2006 and (EU) No 10/2011. In comparison, DoCs prepared by the respondents tend to include more often the identification of substances used, the identification or reference to dual-use additives, specifications on the use and references to functional barriers.

Similar to the DoCs respondents received from their suppliers, there are not consistent differences in the DoCs respondents provided to their customers, but this depends on their position in the supply chain. DoCs from final manufacturers tend to identify substances used less often (70% of DoCs) compared to those from intermediate manufacturers (95% of DoCs). On the other hand, DoCs provided by final manufacturers mention compliance with EU legislation more often.

Figure 7: Compliance with the EU legislation of DoCs to customers received by respondents



1.5.3 Examples of incomplete DoCs

Most DoCs received suffered from one or several issues, such as being incompletely or incorrectly filled, being unclear because it contained other irrelevant information, providing a blank statement regarding compliance without any supporting evidence or explanation, containing disclaimers waiving responsibility or blatant incompliance with actual requirements and legislation.

The following figure is an example of a DoC included with a product that was found not compliant with Regulation (EU) No 10/2011 (identities protected):

Declaration of Conformity

Identity and address of the Importer:

[redacted]

Identity and address of the bamboo fibre factory:
Name of the supplier:
[redacted]
Address : [redacted]

Description of the articles : bamboo fibre Plate / Bowl / Tumbler
with the following designs : [redacted]

Date of the Declaration: 03.12.2018

We declare our goods' food contact is following article 15 and 16 + Annex IV of EU regulation n°10/2011 from 14th Jan2011.

[redacted]

2. Trade and business association survey

2.1 Participants overview

In total, there was a good representation (58) of trade and business associations (TBAs) with the remaining nine replies coming from consultancies and private laboratories. Around half of trade and business associations (31) only operated at a national level. The remaining (26) operated at European level to a lesser or greater extent, including EFTA and neighbouring countries. A couple operated worldwide.

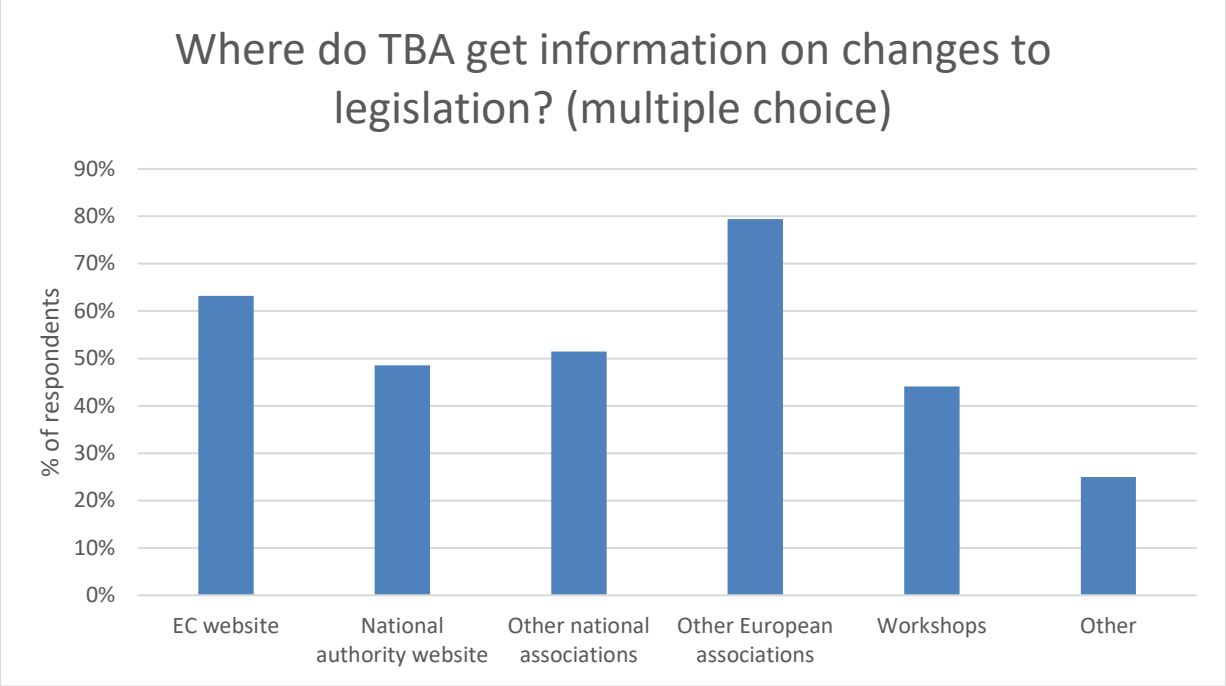
Around 85% of respondents represented different FCM sectors (materials in Annex I of Regulation (EC) 1935/2004). The remaining 15% who replied as "other" for the materials covered were mainly associations representing food business operators.

The profiles of respondents show that the flexible packaging industry works across the broad range of materials as listed in Annex I of Regulation (EC) 1935/2004 with coatings, printing inks and varnishes represented jointly. For paper and board, some trade and business associations represent both paper and wood, or also waxes and coatings used on, for example, cardboard.

2.2 Survey results

Figure 8 shows how the trade and business associations are informed about changes in the FCM legislation. The majority of them inform themselves through other European associations or the European Commission website. Around half also keep informed through other national associations, notably during workshops or from the national competent authority's website.

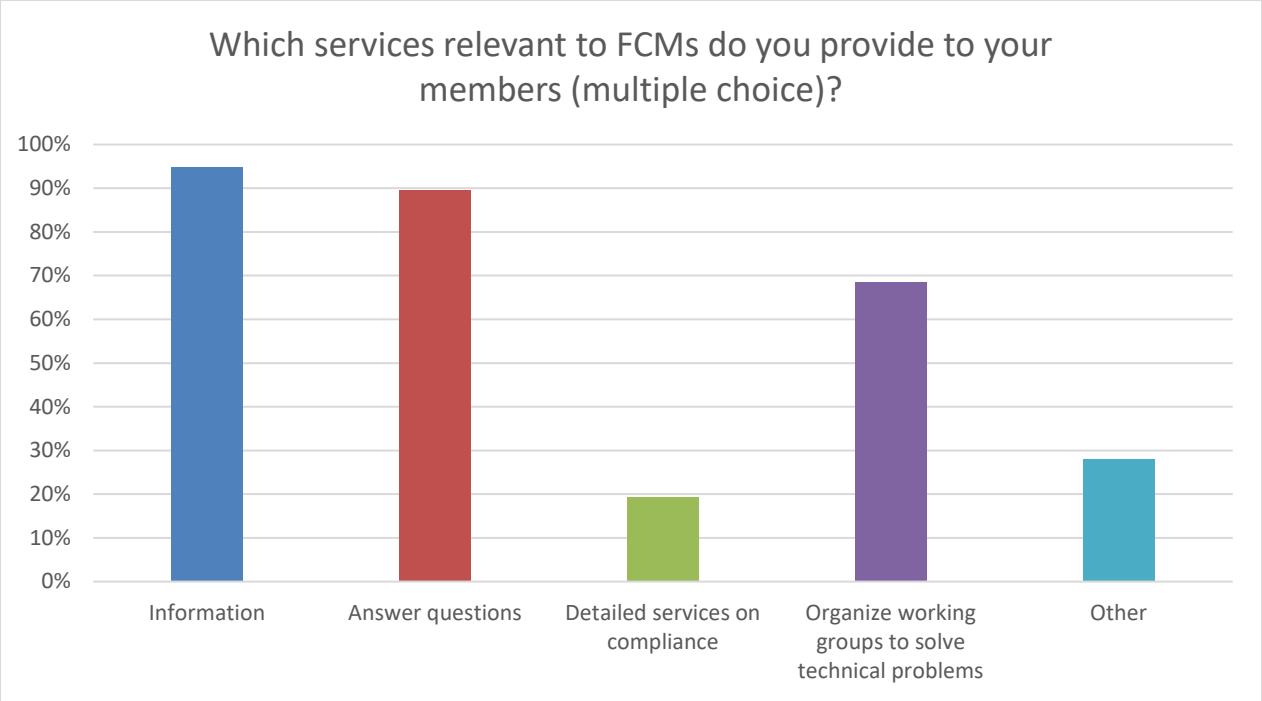
Figure 8: Survey answers on how the trade and business associations receive information on changes to the legislation



More than half (63%) of the trade and business associations provide guidelines on FCM compliance documentation to their members, although only three oblige members to comply with them.

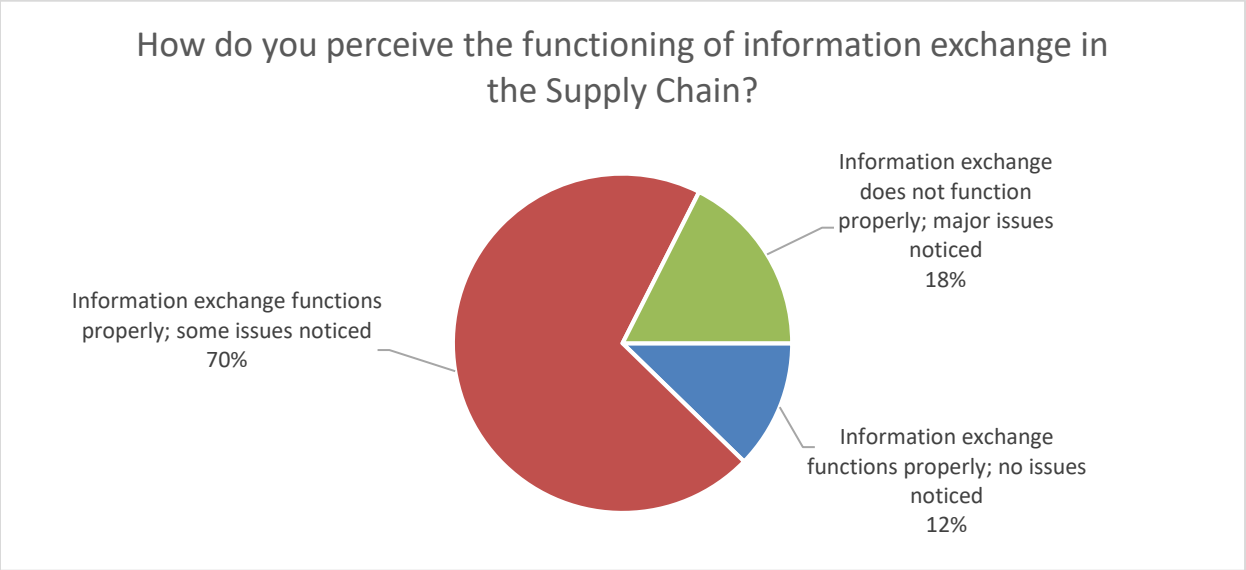
Almost all of the trade and business associations provide information to their members and answer their questions (figure 9). 68% of them organise working groups to solve technical issues while only a limited number, less than 20%, offer detailed services on compliance. Other services offered include training courses, translation of national legislation, audits of self-controls, conference meetings and guidance documents.

Figure 9: Services provided by trade and business associations to their members



The vast majority of respondents perceive that some issues exist in the exchange of information along the supply chain, with 18% stating information flow does not function at all (figure 10). Only 12% feel that information flow along the supply chain functions properly.

Figure 10: Respondents' opinion on the information flow along the supply chain



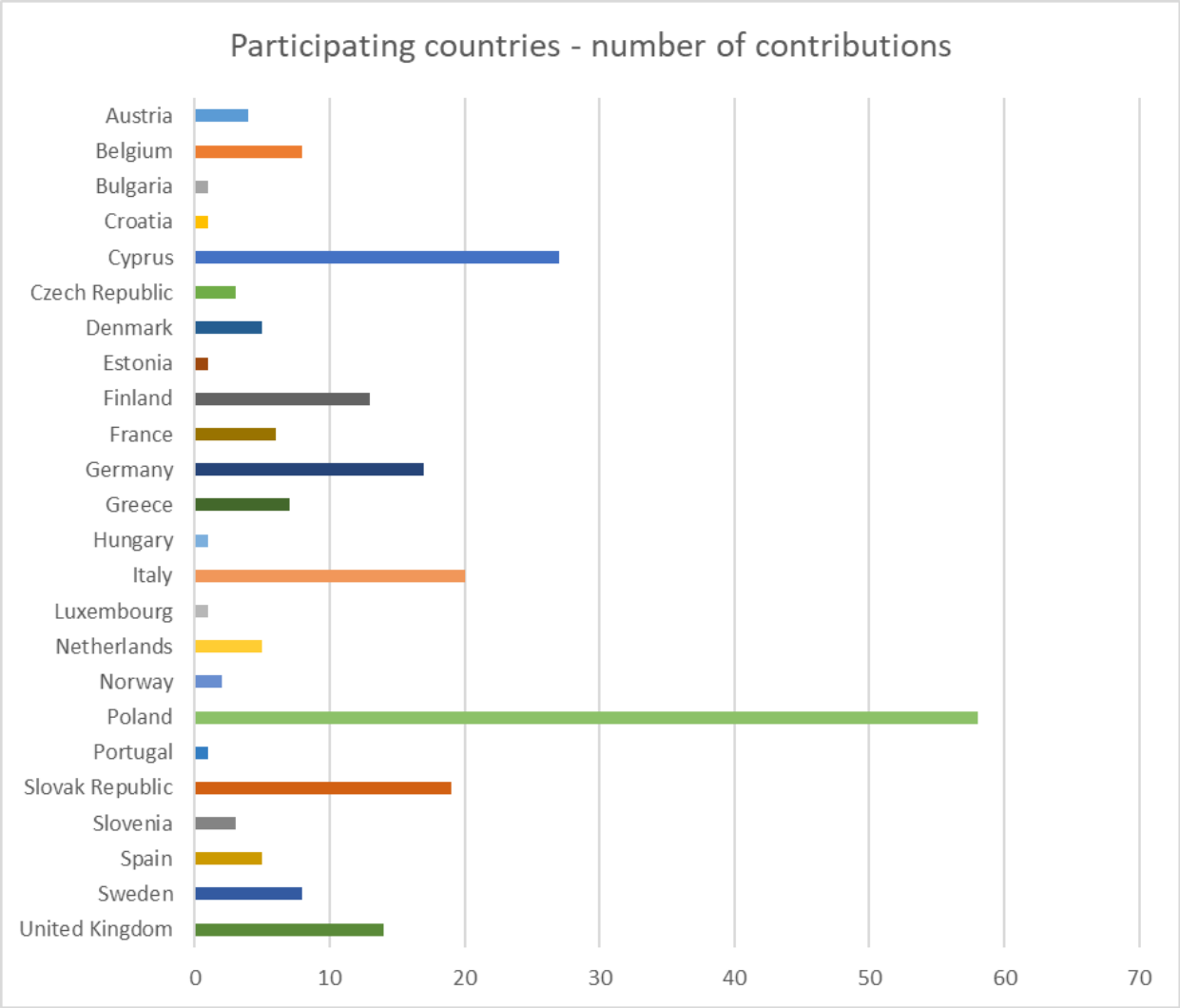
Only 20 respondents provided motivated replies. The most frequent issues mentioned were the lack of a common structure for DoCs, lack of capacity of SMEs to provide or obtain adequate information, lack of clarity of responsibilities and varying degrees of knowledge on FCMs along the supply chain at both ends as well as, in particular, business confidentiality. For the latter, a few respondents mentioned that non-disclosure agreements were very time consuming.

3. Public authorities survey

3.1 Participants overview

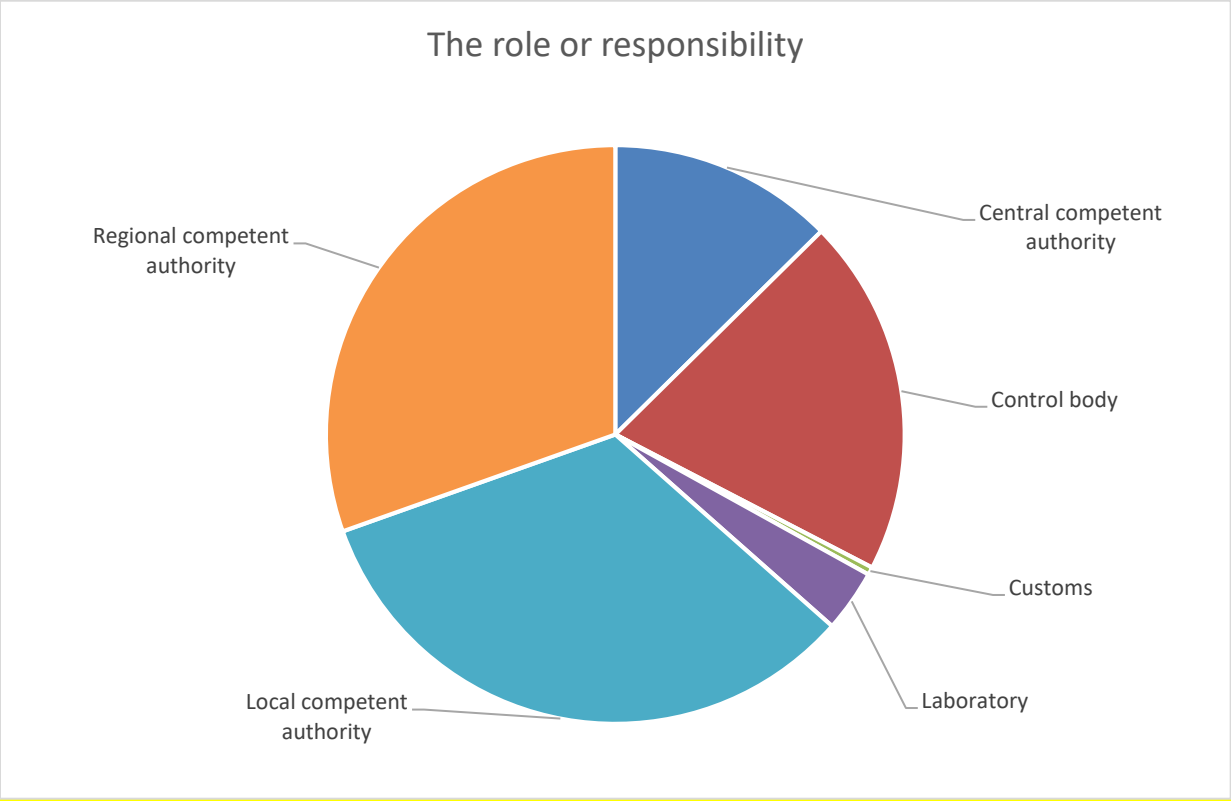
Overall, 230 public authorities from 24 EU and non-EU countries participated in the survey with a relatively substantial number of contributions from Poland, Cyprus and Slovakia (figure 11).

Figure 11: Number of public authorities per country participating in the survey



Regarding the role of the respondents, the majority of respondents are either local competent authorities (33%) or regional competent authorities (30%), whereas only 13% are central competent authorities. The remaining respondents were control bodies (20%), laboratories (3%) or customs authorities (1%) (figure 12).

Figure 12: Roles/responsibilities of the public authorities participating in the survey



The majority of the respondents (86%) have received some kind of training on FCMs. 56% of them declared to have attended national training courses on FCMs and 45% have participated in EU training courses such as those provided under the Better Training for Safer Food Initiative (BTSF). 4% indicated that they have not received any training. Many respondents (69%) supported further BTSF training and in particularly on plastic FCMs, DoCs and current legislation. This may reflect specific topics respondents feel they would like better knowledge and expertise on to support their control work.

Less than 10% of respondents mention working mainly or fully on FCMs. For the vast majority it is a small part or even occasional part of their work. For over 95% of respondents, FCMs make up only a marginal part of the control work with nearly 60% spending less than 5% on market controls (figure 13). The figure is worse for import controls, reaching close to 80% (figure 14). In fact, only one respondent out 230 replied working full time on FCMs. Such shortcomings seem to stem from a number of reasons: the complexity of the FCM legislation, but also as a technical field, the lack of resources and lack of perception of FCMs as an immediate priority have all been mentioned by MS competent authorities at various occasions, such as BTSF trainings and MS expert working groups.

There were no significant differences on the time spent between local, regional and central competent authorities.

Figure 13: Percentages of working time spent on FCM market controls of public authorities participating in the survey

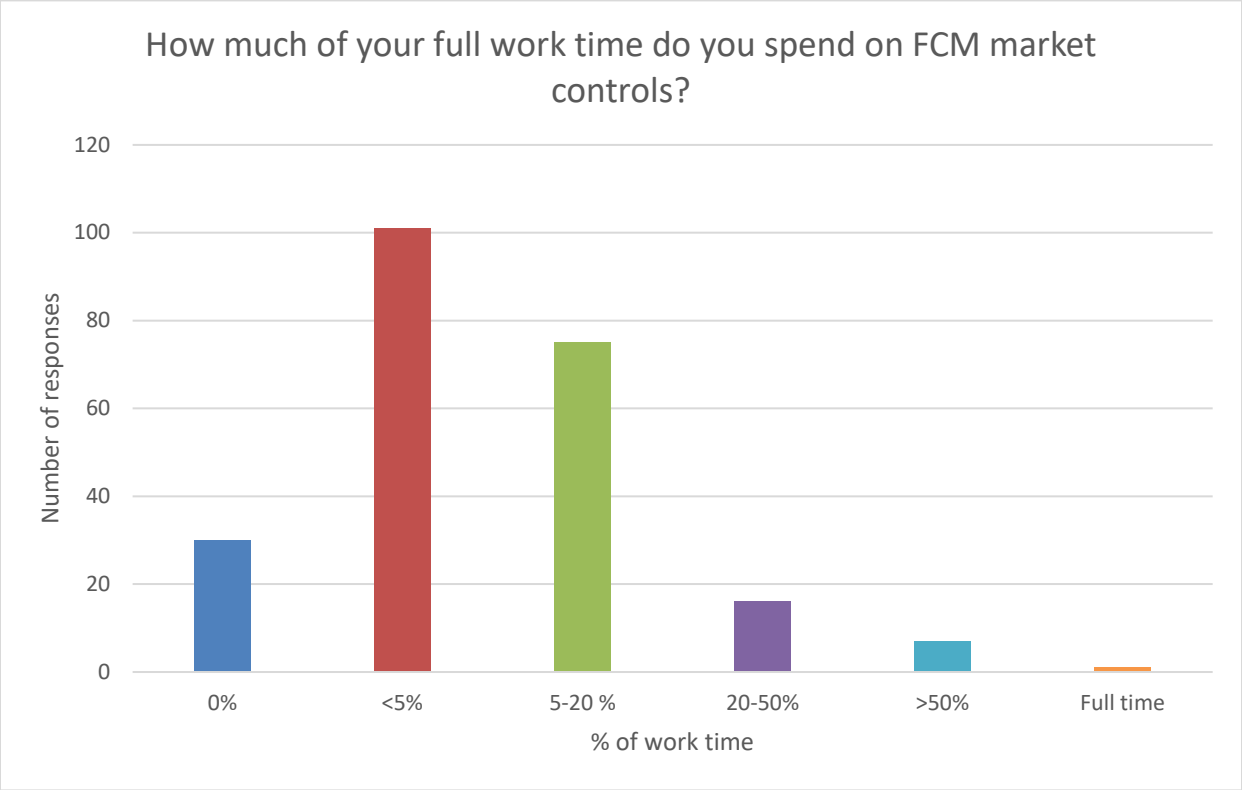
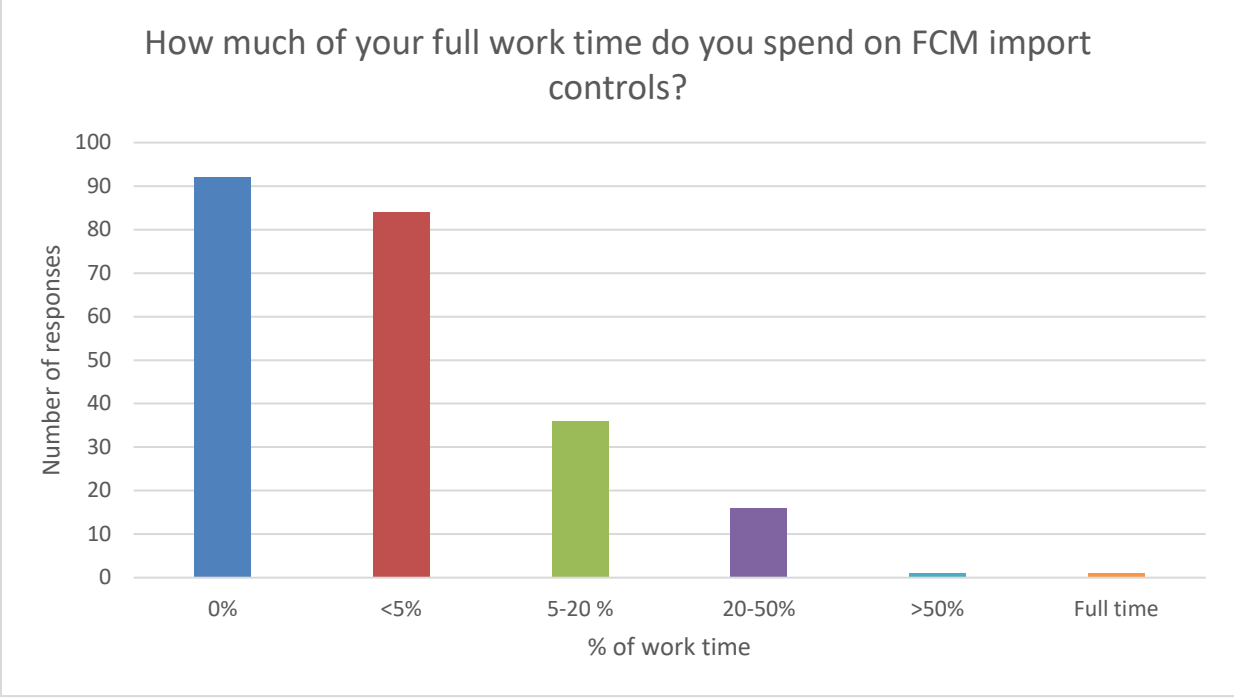


Figure 14: Percentages of working time spent on FCM import controls of public authorities participating in the survey

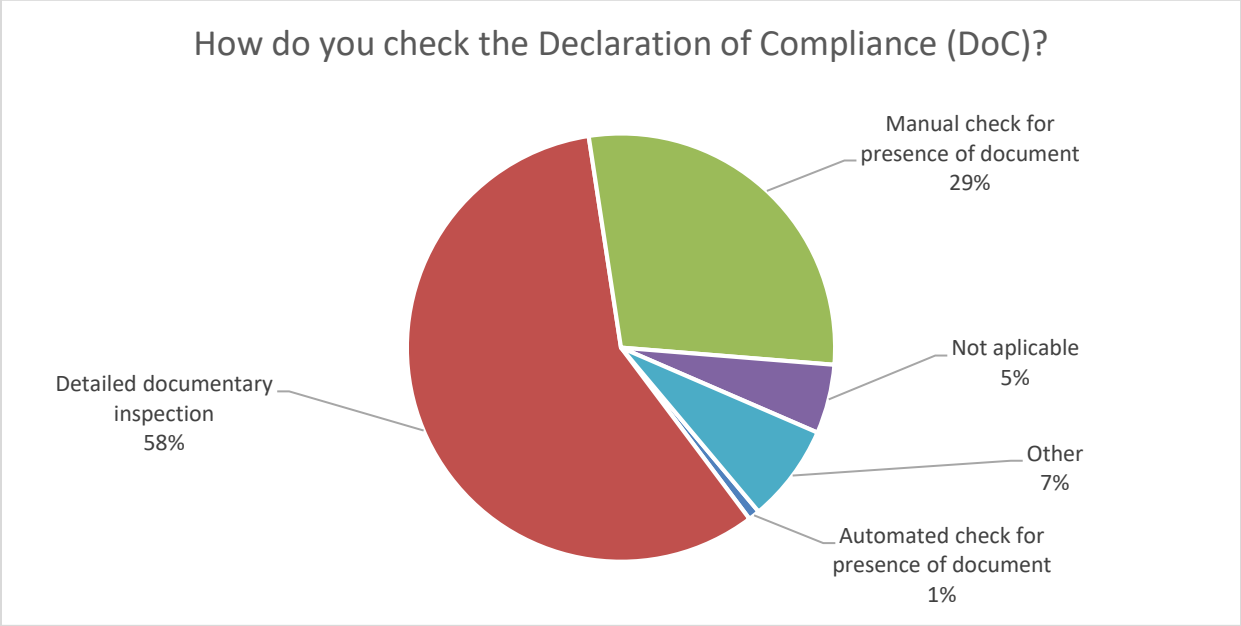


3.2 Checking of Declarations of Compliance

Slightly over half of the respondents state that they perform a detailed documentary inspection when assessing DoCs (figure 15), meaning that for a third of control checks, only the documentation is present. A handful perform automated checks or use other methods, e.g. inspection. Regarding the EU's rapid alert system for food and feed (RASFF), 30% of respondents replied checking it only occasionally.

The procedure to perform checks appears to differ according to the role of the competent authority, with regional authorities relying more on manual checks for the presence of documents (47%), while control bodies, local and central authorities perform detailed documentary inspection more often (around 65%).

Figure 15: Inspection method for DoC of public authorities participating in the survey



If the DoC received is incomplete or insufficient, the competent authorities usually ask for additional information or SD to complement information. Some of the most mentioned actions are:

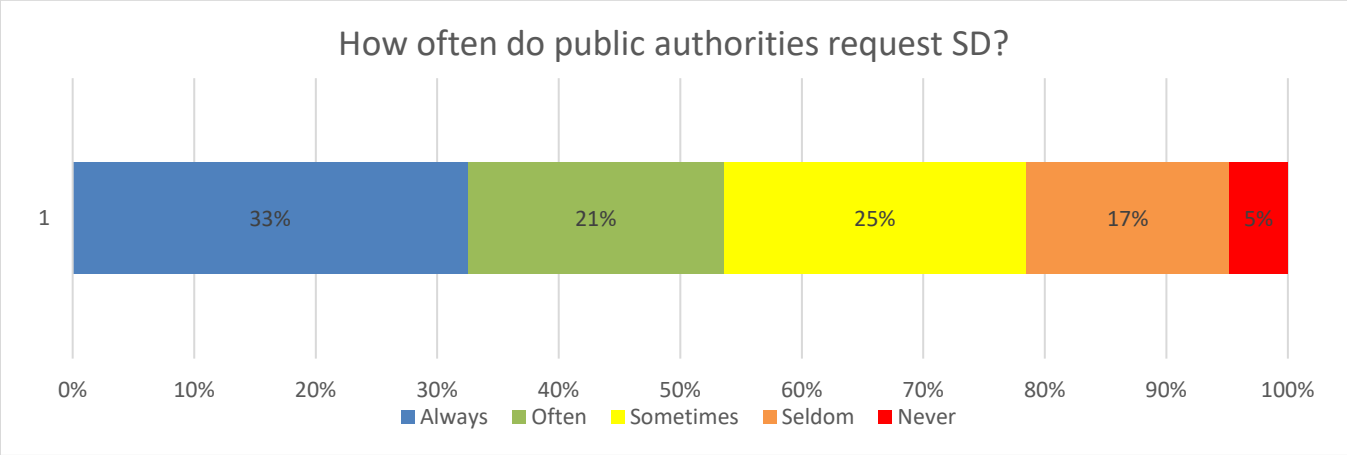
- Ask for a supporting document/additional documentation;
- Issue an official warning or fine (if reiterated) to the company issuing the DoC;
- Ask for an amendment of the document within a specific deadline;
- Conduct an administrative procedure;
- Take precautionary measure (e.g. product detention, stop distribution) until the DoC is updated.

3.3 Checking of Supporting Documents

Nearly half of the respondents usually do not request supporting documentation (SD), with a small percentage (5%) never asking for SD at all (figure 16). More concerning is that nearly 40%

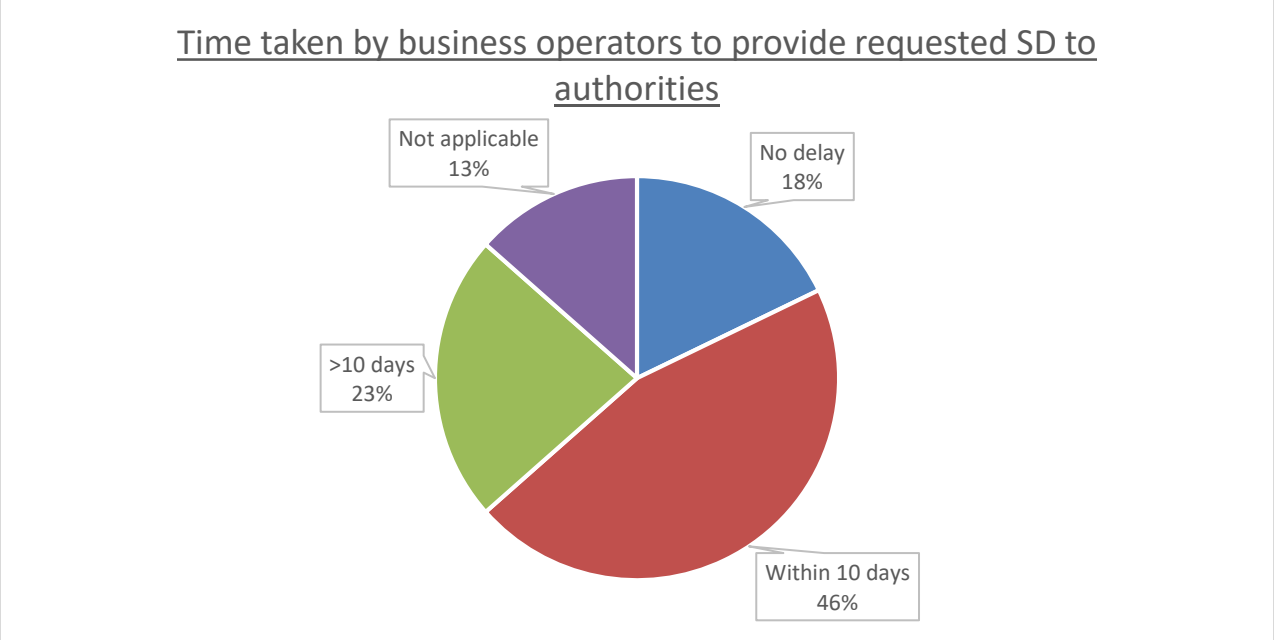
of respondents do not usually receive any SD back when requesting it. As the survey from BOs suggests, information flow is an issue in the supply chain, with BOs not always being aware of their obligations or able to collect adequate information.

Figure 16: Percentages of public authorities participating in the survey that request supporting documentation



However, replies suggest that when BOs do provide the requested SD, they are able to do so either immediately or within 10 days (Figure 17).

Figure 17: Time taken by business operators to provide requested SD to authorities[4]



Competent authorities mentioned the following aspects to be most relevant when assessing a SD (multiple-choice answer):

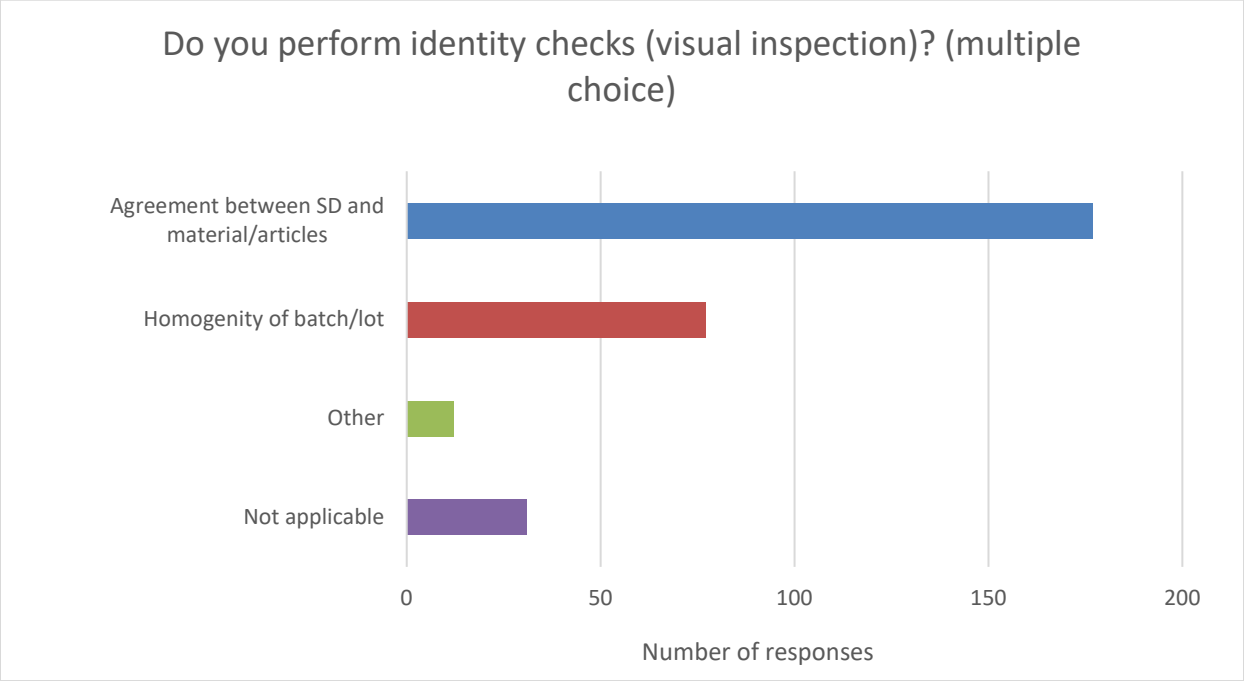
[4] This figure only takes into account cases where requested SD is received by MS Competent Authority.

- 85% check results of migration testing or migration modelling;
- 46% check information on formulation/composition;
- 35% check quality control documentation;
- 30% check relevant information on the process undergone by the material;
- 30% check toxicological information on a substance.

If the SD is considered insufficient, competent authorities usually ask for additional information or for an amendment of the documentation. In some cases, additional measures may be taken, such as laboratory tests, issuing warnings or detaining products.

In most cases, competent authorities check whether there is an agreement between SD and articles, with about half also checking the homogeneity of the batch or lot, i.e. that it contains the same articles produced as a single batch or lot (figure 18).

Figure 18: Execution of identity checks of FCMs by public authorities participating in the survey

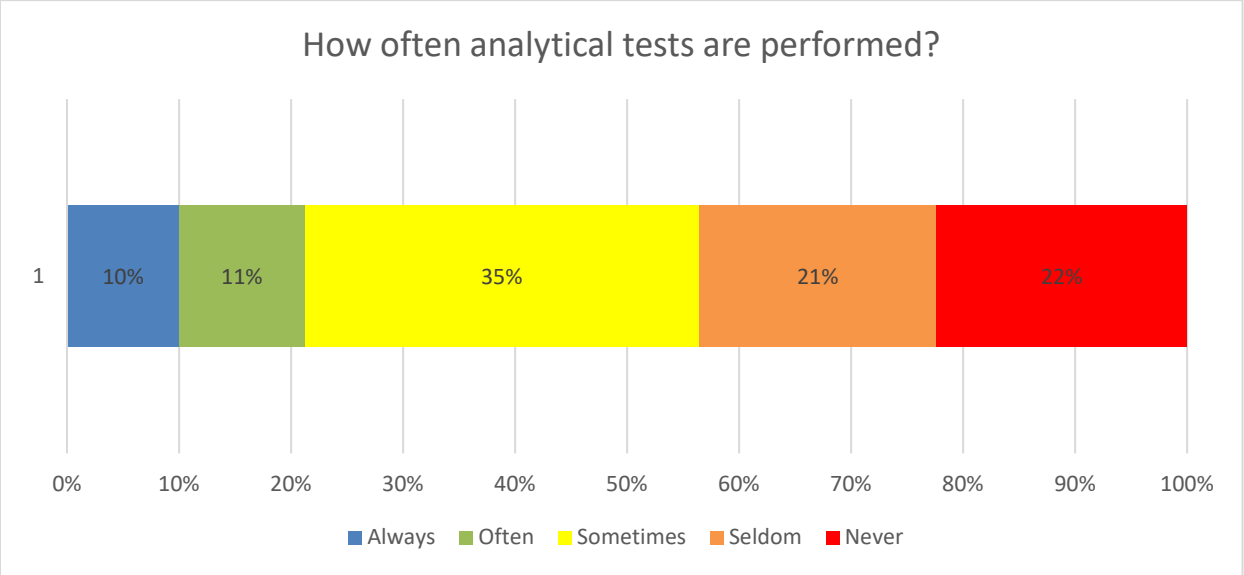


3.4 Analytical tests

Nearly 80% of respondents only perform analytical tests occasionally, with 50% never or very rarely doing so. Only 10% of the competent authorities always perform an analytical test (figure 19). Some of the issues mentioned for analytical testing were related to the cost of testing, lack of resources and staff, low capacity and lack of analytical methods and uniform rules. This is in line with information obtained in BTSF trainings on controls, audits, MS expert groups and work done in the context of the evaluation of the FCM legislation, reporting the high complexity of analytical work in FCMs and overall lack of resources and expertise. Of those conducting analytical tests, testing seems focused on a simple identification of the material (25%), control of

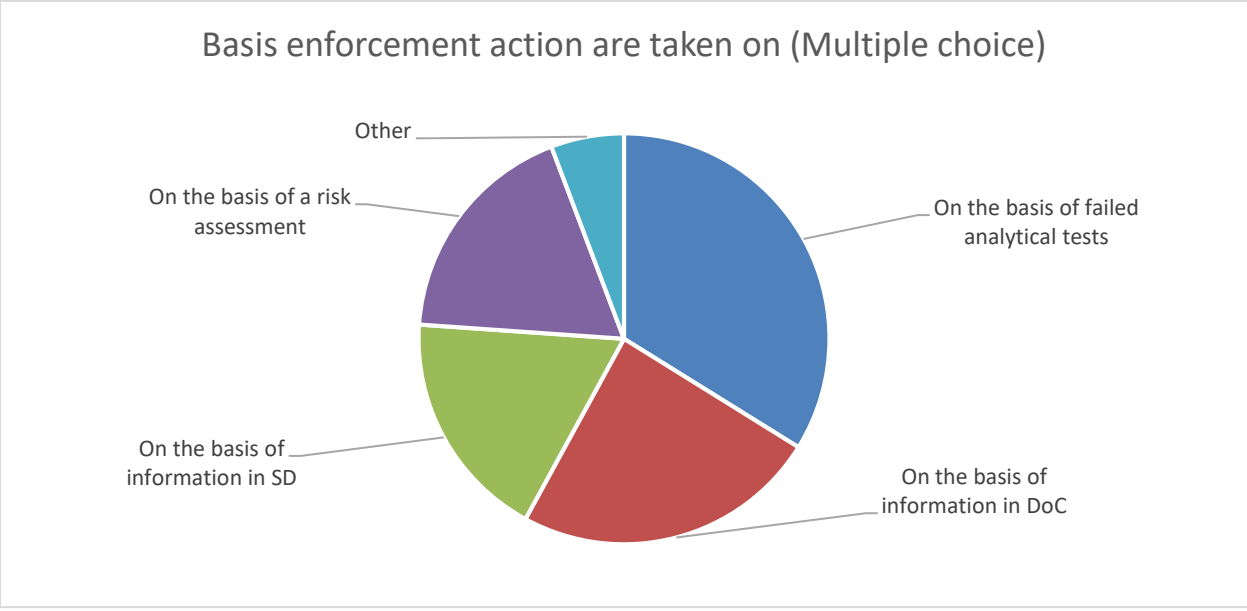
"bamboo" imports under Regulation (EU) 284/2011[5] (24%) and specific migration limits (24%) and overall migration limit (23%) set under EU legislation (mostly under the plastics' Regulation (EU) 10/2011)).

Figure 19: Execution of analytical tests by public authorities participating in the survey



Enforcement action is undertaken based on failed analytical tests (34%), information provided by DoC (24%), information provided in SD (18%) or risk assessment (18%) (Figure 20).

Figure 20: Basis for enforcements actions by public authorities participating in the survey



[5] Commission Regulation (EU) No 284/2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China

3.5 Public authorities views

In the last part of the survey, public authorities were invited to share their opinion on several aspects related to FCM compliance documentation and analytical testing (Figure 21, Figure 22).

Figure 21: Opinions on FCM compliance documentation by public authorities participating in the survey

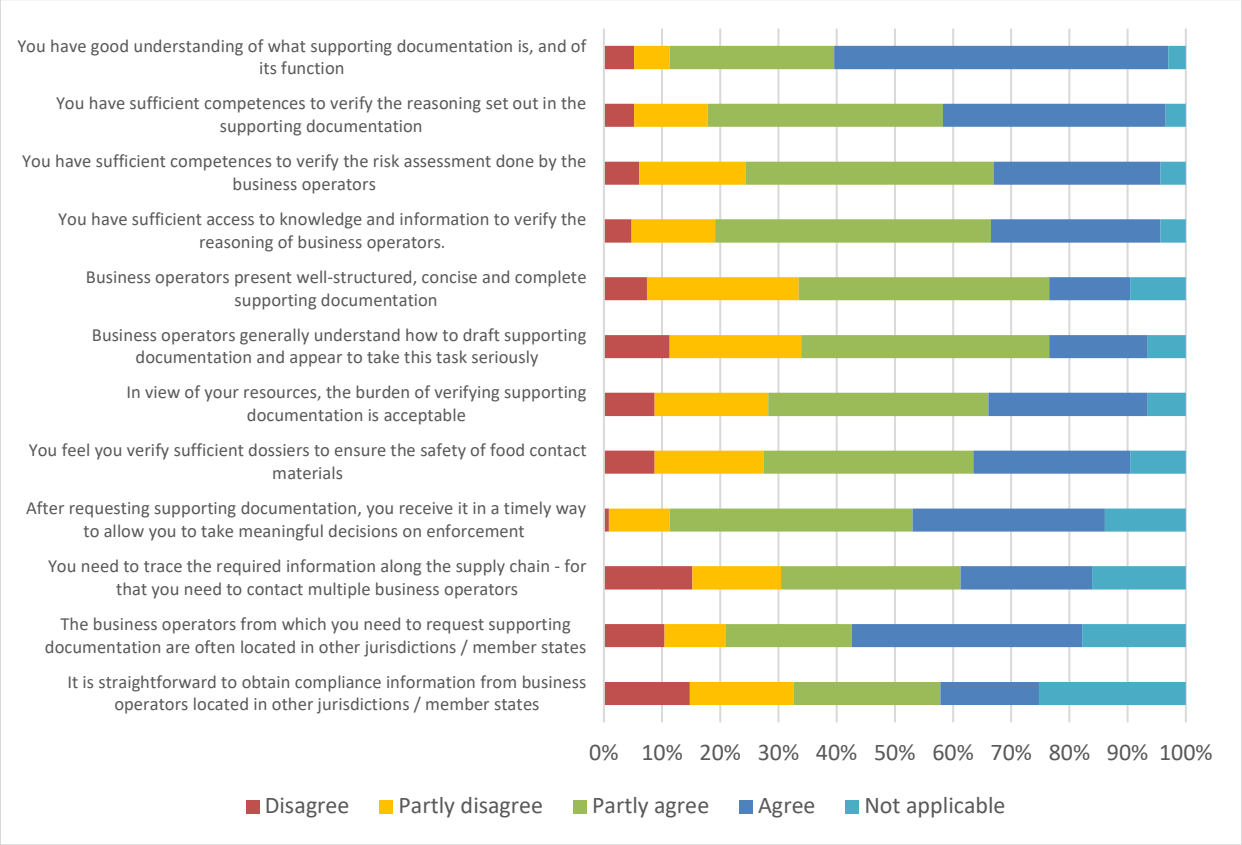
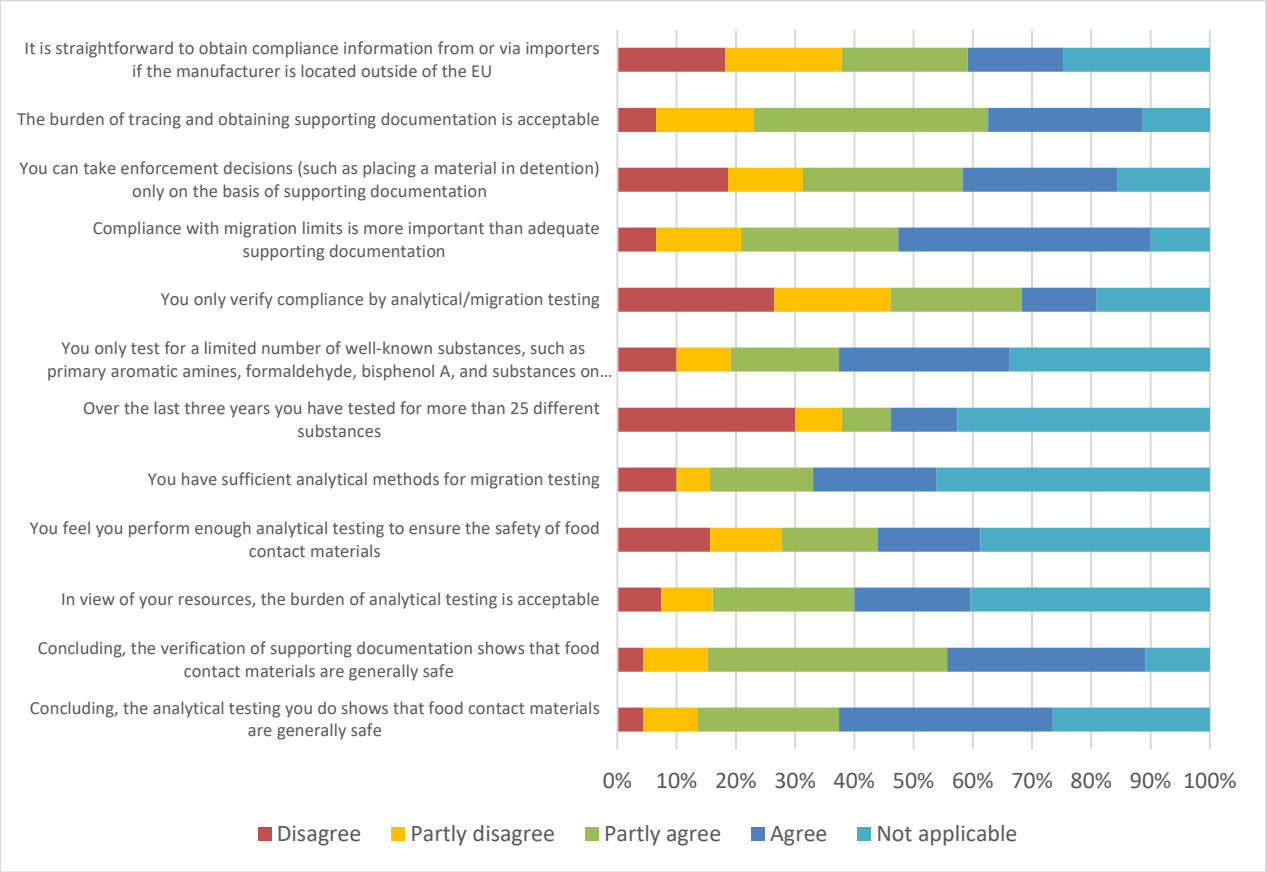


Figure 22: Opinions on FCM compliance documentation by public authorities participating in the survey



Overall, most competent authorities seem to understand the purpose of SD but fewer are confident that they have the necessary knowledge to understand the reasoning provided by BOs on the compliance of their product and risk assessment work conducted to assess and check compliance.

Respondents point rather to the difficulty of obtaining adequate information from BOs, with over 80% finding information provided incomplete and unstructured and perceive BOs lack either the understanding or the importance of such SD.

The majority of public authorities have to contact multiple business operators along the supply chain, which are often located in different jurisdictions or Member States, but obtaining compliance information from BOs whether EU or non-EU is more challenging. About a quarter of respondents find the burden of tracing and obtaining information as acceptable. However, for most, it is not a straightforward process.

Most competent authorities (65%) find the burden of verifying SD as acceptable, although a higher proportion of local (40%) and central (35%) authorities feel the burden as high compared to regional authorities (18%) or control bodies (25%).

A high proportion of respondents combine different ways to check compliance and do not rely only on analytical testing. This is in line with the overall low number of tests conducted and low number of substances tested. Indeed, those that conduct analytical testing tend to focus more on the few substances regulated at EU level, such as Bisphenol A or primary aromatic amines.

However, close to 70% consider compliance with migration limits more important than other methods to assess compliance. Worryingly, among those performing analytical testing, almost half consider they do not conduct sufficient testing to ensure the safety of FCMs.

Information from the survey but also other sources (FCM evaluation, audits, BTSF trainings, MS working groups) point towards a lack of expertise on FCMs and ways to assess compliance other than through testing, lack of adequate information, and overall a lack of capacity to conduct such testing as important issues.

When compliance documentation is checked and analytical tests are conducted, around half of the respondents agree that results confirm the safety of the FCMs with the other half being less affirmative that this is the case.

Finally, around 80% of respondents consider information requirements for DoC (as defined in Annex IV of Regulation (EU) No 10/2011) as adequate and 65% perceive the guidance on information in the supply chain as useful. Of concern is that some 10% were not aware of the existence of such guidance.

4. Conclusions

The documentary system based on declarations of compliance (DoC) backed by supporting documentation has become common practice within the FCM sectors, with the use of DoCs even for non-harmonised materials, where no EU-specific requirements for such compliance documentation exist. However, when it comes to the effectiveness of this system to ensure the compliance and safety of FCMs, some gaps exists in the flow of information along the supply chain and in enforcement by control authorities.

Business operators report that they usually receive DoCs from their suppliers but that obtaining adequate supporting information is more difficult. This is partly due to confidentiality issues and partly due to a lack of knowledge and capacity of business operators, in particular, SMEs and actors based at the start (raw materials) and end (retailers/end users) of the chain. Checks are mainly limited to verifying that there is a DoC and that the DoC and material or article correspond. Few assess the completeness and correctness of DoCs, with only 11% of BOs checking compliance analytically, focused mainly on SMLs/OMLs and the authorisation status of substances. Still, most are confident they can ensure the safety of their products on the basis of applicable rules and information available.

The analysis of DoCs provided shows that most contain basic information and mention compliance with Regulation No 1935/2004 and Commission Regulation (EU) No 10/2011. Main shortcomings were in referencing Regulation (EC) No 2023/2006, clear identification of substances used, dual use additives, functional barriers and specifications on the adequate use. Few provided the identity of upstream suppliers. Overall, most DoCs were incorrectly filled-in and incomplete.

Trade business associations represent an important channel for information. They often provide industry guidelines and other useful services such as information and advice on compliance work and legislation to their members. Most mentioned that there are issues in the functioning of information exchange in the supply chain, most frequently mentioning the lack of a common structure for DoCs, lack of capacity of SMEs, lack of clarity of responsibilities and varying degrees of knowledge on FCMs along the supply chain.

Regarding competent authorities, most understand the purpose of compliance documentation but often lack the necessary expertise and resources to actually obtain information and assess compliance. Testing costs are deemed high and adequate analytical methods are lacking. This is in line with the low number of tests conducted, focused on the few EU-regulated substances, despite a majority considering compliance with migration limits as more important than other aspects. Worryingly, among those performing analytical testing, almost half consider that they do not conduct sufficient testing to ensure the safety of FCMs.

The outcome of these surveys supports the need for further harmonisation, to simplify and clarify rules, reinforce the quality and exchange of information along the supply chain and improve the enforcement system.