Participation in European agencies: Keeping promises in institutional practice
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The establishment of dedicated participatory forums that collaborate with the agencies in general matters (which do not relate to a specific decision-making procedure) is understood to have originated in the need to build trust in agencies’ operation, and to ensure their credibility on a more horizontal level. This form of participation is considered particularly relevant in the case of European agencies that deal with sensitive affairs, such as public health and safety, which are of increasing concern to the general public. The present chapter delves into two participatory forums belonging to this category of participation: the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform. As will be intimated below, these advisory groups fulfil important roles as participatory spaces for the presentation of interested parties’ concerns, and for the communication of emerging risks.

5.1 ACCESS: SETTING UP A PLATFORM FOR A GENERAL DISCOURSE

Given that the EFSA and the EMA primarily deal with the protection of public health, a highly sensitive field of operation, it would seem indispensable that the respective agencies secure their credibility towards those affected by interacting with them and responding to their concerns. Such “general” collaboration is furthered through the creation of permanent participatory structures, including representatives of affected interests, which offer advice regarding the impact of agencies’ operation on stakeholders, on the agencies’ communication with interested parties, and which alert the agencies of any possible risk. Thus, it is assumed that such interaction with interested parties is intended to fulfil promises that would promote the agencies’ long-term credibility. In the pages below the envisaged promises of participation in general matters will be elucidated, and their fulfilment will be examined and discussed on the basis of the composition of the participatory forums, the selection of the participants, and their representativeness.1

5.1.1 Creation, Mandates and Primary Promises

The relevance of the EMA and the EFSA interaction with interested parties is emphasised in their respective founding regulations. The EMA is mandated to introduce appropriate means of contact between the agency and the representatives of patients and consumers, as well as healthcare professionals,2 while the EFSA is required to “establish effective contacts” with consumer and producer representatives and any other interested parties.3 Admittedly, these provisions could provide a general basis for the set up of any form of communication with interested parties (i.e. in regard to any aspect of the agencies’ operation), which could carry forward various, case specific (sets of) promises. One instance where the involvement of interested parties in the remit of the EMA and the EFSA is promoted can be seen in the creation of permanent participatory groups

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1 See Chapter 2, Sections 2.3.1 and 2.4.
2 Art. 78(1) of Regulation (EC) No 726/2004, as subsequently amended.
that assist the agencies in *general matters* concerning interested parties. In both contexts, formal decisions regarding interaction with interested parties and/or the establishment of participatory forums are a responsibility of the agencies’ management boards.

In the case of the EMA, the formalisation of interaction with patients and consumers is envisaged in the Framework on the Interaction between the EMA and Patients’ and Consumers’ Organisations, which the agency’s management board endorsed in 2005. In particular, this Framework indicates the need to create a dedicated forum of organised interests – the EMA Patients’ and Consumers’ Working Party – which would provide advice to the EMA and its scientific committees on issues of direct and indirect interest to patients and consumers in relation to medicines. The EMA Patients’ and Consumers’ Working Party was officially set up in 2006. As further clarified by an EMA official,

> We did not feel any pressure from outside the agency to introduce this [forum for the participation of interested parties]; we felt there is a need on the patients’ and consumers’ part and on our part as well. Progressively we saw that there would be an added value for us to involve them in our activities. And I think that this is the main feature of the success of the interaction we have had with the patients’ and consumers’ representatives. (Respondent #5)

This shows that the EMA was interested in creating such a participatory forum because it perceived that it might benefit from interactions with interested parties. Since its creation the Patients’ and Consumers’ Working Party has made “good progress in involving patients and consumers in the work of the agency on a wider scale” (Respondent #25). According to the primary sources, the focus of the EMA working party has expanded quite a bit over the years. Although the core activities of the Patients’ and Consumers’ Working Party still pertain to the questions of transparency, exchange of information and communication regarding medicinal products, the working party now also focuses on other questions pertaining to the safety of medicines and aims to bring a “real-life perspective” into the regulatory area. In this respect, a member of the Patients’ and Consumers’ Working Party highlighted the following *promises* of this form of participation:

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5 Ibid. See also EMA website, <http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000708.jsp&mid=WC0b01ac05809e2d8c>.

6 Initially, the Patients’ and Consumers’ Working Party was concerned with contributing to the implementation of the recommendations stemming from its informal predecessor, especially in the field of transparency and dissemination of information, product information, pharmacovigilance, and interaction with the EMA scientific committees and patients’ organisations. See, European Medicines Agency (2013a), ‘Mandate, Objectives and Rules of Procedure for the European Medicines Agency Human Scientific Committees’ Working Party with Patients' and Consumers' Organisations (PCWP)’, EMA/369907/2010 Rev. 2, 30.5.2013, p. 1.

7 *Inter alia*, the EMA Patients’ and Consumers’ Working Party may perform the following tasks: “implement and monitor the proposals within the Framework of interaction between EMA and patients’ and consumers’ organisations”, “contribute to the provision of information adapted to patients and consumers needs”, “contribute to the development of appropriate communication tools”, “contribute to increase awareness of patients in relation to the use of medicines”, “contribute to promote a rational use of medicines”, “contribute to the development and the training of a network of patients’ and consumers’ organisations”, “provide advice in relation to product specific matters, at the request of the EMA Human Scientific Committees”, and “liaise with interested parties (health-care professionals’ organisations, learned societies, academia, pharmaceutical industry)”. See, European Medicines Agency (2013a), p. 2.

Our task is to make sure that the EMA is more open to people, so that people can understand what it does. Transparency [of the EMA activities] is one thing, but what we also wanted to make sure is that the language that is used in all [agency] texts becomes much more understandable. That was a simplification process, as it was called. [...] And above all, we want to make sure that the agency, and even the regulators, does not decide without us. (Respondent #29)

In the case of the EFSA, the management board agreed to establish a permanent forum for discussion with interested parties in the food chain “following on the demands of many interest groups for more structured and transparent forms” of interaction.⁹ The EFSA Stakeholder Consultative Platform was created in 2005, in order to advise the agency on general matters related to its work, and in particular, on the impact of its operation on stakeholders.¹⁰ An EFSA official further clarified the reasons motivating the creation of the Platform,

We work in this very sensitive area; do not forget the serious food crisis [i.e. food safety controversies, such as the “mad cow disease”, and subsequent loss of public confidence in food regulation] that occurred in the past. So we need to engage with stakeholders. [...] And one way to ensure that was to create the Platform. (Respondent #20)

It appears that the establishment of the EFSA Platform is aimed at increasing trust and avoiding possible public dissatisfaction with the agency’s operation. It may also be argued that this in turn promotes the agency’s credibility with regard to food and feed safety at the European level, which was identified as one of the core motivations for the creation of the EFSA.¹¹ As in the case of the EMA, the tasks of the EFSA participatory group have developed and expanded over the years. In the words of the same EFSA official,

Lately, [the EFSA Stakeholder Consultative Platform] has become more than just a group of stakeholders who are expressing their views, interests, and presenting their reports to the executive director of EFSA. [...] In comparison to the initial, more general interaction, we are getting much more into an exchange of raw data, and in terms of topics, [the members’] contributions actually have a much bigger impact on the shaping of [the EFSA’s] work. (Respondent #20)

The EFSA Platform members themselves recognise the relevance of having such a group and of being involved in its activities. As one respondent from the EFSA Platform explained,

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¹⁰ The EFSA Stakeholder Consultative Platform offers advice to the agency’s executive director. According to the Terms of Procedure, the platform may: "a) comment on EFSA’s work program and annual management plan; b) comment on the EFSA’s stakeholders annual work plan; c) provide EFSA with feedback on the effectiveness of its policies in responding to stakeholders’ concerns; d) alert EFSA to key issues of current or emerging stakeholders’ concern, as well as concerns on possible emerging and existing risks; e) advise on risk assessment methodologies, including the topics for consultation and the best way to organize such consultations; f) provide information and cooperation at the technical level; g) set up objectives to be achieved by the Platform during its mandate; [and] h) advise on communication to different target groups." See, European Food Safety Authority (2010), ‘Stakeholder Consultative Platform. Terms of Reference’, mb 17 06 10 item 4 doc 3, 17.6.2010, p. 1.

¹¹ See Chapter 1, Section 1.1.2.
I think it is important to have a Stakeholder Platform, because it opens up a debate, and you get good debates with the agency and all other stakeholders in [the food] chain. You get the divergent views in all their nakedness. And you do not get that normally in other groups. (Respondent #23)

As the EMA and the EFSA participatory groups are purely advisory, their contributions are not binding on the respective agencies. In essence, they provide general assistance and can only indirectly influence final outcomes in terms of the operation of the agency. Judging from the above-mentioned rationales for the creation of the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform, we can deduce that the promises of participation in such advisory groups are quite similar. Prima facie, such interactions with interested parties are first and foremost aimed at increasing transparency and building trust in the more sensitive areas in which the agencies operate (both agencies deal with issues pertaining to public health). In particular, they make the EMA and the EFSA more open to interested parties, so that they can better understand the activities of the agencies, which may in turn increase public confidence in food and medicines regulation at the European level. Considering that both participatory groups appear to be relatively open to diverse interests in the food and medicines sectors, it can also be argued that this form of participation is intended to promote inclusiveness of potentially affected parties. In addition, according to the primary sources both advisory groups are expected to play visible roles in advising the respective agencies on their interaction with interested parties, and in monitoring the progress of this interaction. Given that there is a regular flow of information between the agencies and the advisory forums, as well as between the members of such forums, it might be suggested that this contributes to more informed and effective agency operation on a general level (i.e. improve the correctness and the overall quality of agency operation).

The rationales underpinning the creation of the EMA and the EFSA advisory groups, their mandates and tasks, and the subsequent identification of the intended promises, however, offer little indication of how participation in relation to general matters is actually implemented in terms of access. To assess whether the primary promises are actually fulfilled, it is also necessary to consider which interests are formally given access to such participatory groups, and how their members are selected. Furthermore, it is important to explore whether such participatory forums are indeed inclusive and adequately representative of the sectoral interests they are said to represent. These considerations are important as structural or practical barriers to access could potentially impair the accomplishment of the intended promises of participation. Given that the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform were established in the absence of an immediate legal obligation, it is necessary to rely on the agencies’ documents and interview data to shed light on this matter.

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14 See Chapter 2, Section 2.4.
5.1.2 Composition and Eligibility Criteria: Who is in?

In terms of composition, it is up to the respective agencies to determine the structure of these two participatory groups. The manner in which the EMA and the EFSA have approached this matter is a decisive variable in an assessment of the eventual impact of such arrangements on the fulfilment of the identified promises of participation in general matters. After all, the level of transparency, inclusiveness and more informed outcomes necessarily correlates with the actual openness and comprehensiveness of participation.

According to the Rules of Procedure of the EMA Patients’ and Consumers’ Working Party, the group consists of a maximum of 20 members representing patient and consumer organisations, five members from the EMA scientific committees (i.e. the Committee for Medicinal Products for Human Use, the Paediatric Committee, the Committee on Herbal Medicinal Products, the Committee for Orphan Medicinal Products, and the Committee for Advanced Therapies), and one representative from the agency. Observers from the Healthcare Professionals’ Working Party, the EMA management board, and the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) may also participate with the consent of the two chairpersons of the group. The overall composition of the EMA advisory group must be measured against its responsibilities. As observed before, the Patients’ and Consumers’ Working Party advises the EMA and its scientific committees on all matters of direct and indirect concern to patients and consumers in relation to medicinal products (e.g. by providing advice on product specific matters and promoting the rational use of medicines). The inclusion of representatives from the EMA scientific committee and from the agency as members of the group can be seen as a means of encouraging interaction and communication with the agency. In comparison, the EFSA Stakeholder Consultative Platform is composed entirely of “EU-wide stakeholder organisations operating in the food chain and active within the mandate of EFSA, covering in particular food and feed safety, nutrition, animal health and welfare, [and] plant health.” In order to promote “active participation and effective discussions”, the total number of member organisations should not exceed 24 members.

In both cases, organisations representing interested parties that wish to participate in the EMA or the EFSA participatory group need to fulfil detailed eligibility criteria determined by the agencies’ management boards. It can be assumed that such eligibility criteria are intended to support the primary promises of this form of participation, especially inclusiveness and provision of relevant information, and to reduce the potential risk of capture (i.e. the possible adverse effects of participation). In the case of the EFSA Platform, in order to be considered eligible for membership, organisations need to represent one of the following stakeholder interests: (i) “consumer associations and NGOs representing consumer interests”, (ii) “farmers and primary processors including feed processors”, (iii) “food industry including raw material processors”.

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15 European Food Safety Authority (2010), pp. 1-2; European Medicines Agency (2013a), pp. 3-4.
17 Ibid, p. 3.
19 Ibid. p. 2.
(iv) “trade and catering (wholesale, retail, hotel, restaurants, etc.)”, and (v) NGOs involved in health protection, animal welfare [and] environment”.20 In addition, they need to be “an EU wide stakeholder organisation”, in existence for at least five years, “having legitimate and general interests covered and represented by the EFSA’s remit”, as well as a “major organisation in [their] field of competence, representing relevant areas within EFSA’s remit, playing a crucial role for the area represented, and securing significant expertise in the fields covered by the EFSA’s remit”.21

Since seats in the EFSA Platform are capped at a maximum number of members, the prescribed eligibility criteria aim to ensure an all-encompassing and balanced representation of the five categories of stakeholder interests, while avoiding the participation of organisations covering the same or overlapping areas.22 It appears, formally at least, that such arrangements are intended to promote the openness and inclusiveness of various, possibly conflicting interests.

Like the EFSA, the EMA has also developed detailed criteria, which need to be fulfilled by patient and consumer organisations involved in the EMA participatory group.23 According to these criteria, patient organisations must be non-profit, patient-focused organisations, where patients or carers represent a majority of members in the governing bodies.24 Such organisations can be either “general umbrella organisations” (e.g. representing European, disease specific organisations and/or national umbrella organisations), or “European disease specific organisations” (i.e. representing national organisations or individual patients on acute and chronic diseases).25 In the same vein, consumer organisations need to be non-profit organisations that defend and promote “the general interests of European consumers – citizens as purchasers or users of goods and services.”26 To be considered eligible, both patient and consumer organisations have to be established in the EU and need to prove their legitimacy,27 have clearly defined missions and objectives, have a specific and documented (e.g. through a report) interest in medicinal products, be representative of patients and consumers throughout the EU, have adequate structures (i.e. have governing bodies which are elected by their members, who are patients, their carers, or their elected representatives),28 as well as accountability and consultation modalities,29 and operate in a transparent way.30 For

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22 Ibid, p. 2.
23 In fact, these EMA “eligibility criteria” apply to all patient and consumer organisations that wish to interact with the EMA, not only in the Patients’ and Consumers’ Working Party, but in all other agency activities, such as those related to scientific committees, and the review of EMA information. These criteria, however, do not apply to EMA external consultations. See, European Medicines Agency (2014c), ‘Criteria to be Fulfilled by Patients’ and Consumers’ Organisations Involved in European Medicines Agency (EMA) Activities’, EMA/24913/2005 - rev. 2, 12.6.2014.
25 Ibid.
26 Ibid.
27 According to the criteria, the organisation needs to have statutes registered in one of the EU/EEA Member States. If it is an international organisation not registered in an EU/EEA Member State, additional information needs to be provided demonstrating its EU focus and activities. See, European Medicines Agency (2014c), p. 2.
29 According to the criteria, statements and opinions of the organisation should reflect the views and opinions of its members, and adequate consultation procedures with those members should be in place. In particular, the organisation should ensure that the appropriate flow of information is in place to allow dialogue both ways: from and towards its members. See, European Medicines Agency (2014c), p. 2.
30 The organisation needs to disclose to the EMA its sources of funding, both public and private, by providing the name of the bodies and their individual financial contributions, both in absolute terms and in terms of overall percentage of the organisation budget. Any relationship with corporate sponsorship should be clear and transparent. This information needs to be communicated to the EMA on an annual basis. Also, in the case of umbrella organisations, the list of member associations needs to be available to the EMA. See, European Medicines Agency (2014c), p. 2.
transparency reasons, the EMA has set up a public registry, listing all eligible patient and consumer organisations.\textsuperscript{31} While the EMA eligibility criteria for access are even more exhaustive than those of the EFSA, one may argue that the goal of these criteria is the same in both cases: to ensure a wide and accurate representation of concerned interests in the participatory groups. In particular, in both cases, such agency rules appear to promote a broad representativeness of different interests (i.e. by seeking to include different shades of opinions and concerns on the European level), and to ensure the general competence of the members of the advisory groups (i.e. by stressing the relevance of the subject or interest related knowledge). However, the question of whether such criteria are respected in practice also arises. As the eligibility criteria should be observed in the selection procedure, this issue will be addressed in more detail in the following sub-section.

5.1.3. Selection Procedure and \textit{De Facto} Representativeness

The Terms of Reference of the EFSA Stakeholder Consultative Platform envisage that the decision on which organisations will be represented in the Platform is a responsibility of the agency’s management board.\textsuperscript{32} According to these self-imposed rules, when reviewing the membership of the Platform, the management board needs to adhere to the principles of transparency, openness and equal treatment.\textsuperscript{33} Arguably, this illustrates the EFSA’s commitment to promoting the fulfilment of the identified promises of participation. In order to ensure a “maximum level of transparency”, the renewal of the Platform membership needs to be organised through a public call for expression of interests.\textsuperscript{34} The formal determination of the selection procedure only goes this far. Questions thus arise as to how often the membership is reviewed (in order to establish a fresh opportunity for access and enable accurate representation in a group limited to a maximum number of members), and above all, of how the EFSA decides between competing applications for membership (i.e. different stakeholder organisations) and whether the representativeness of the concerned (eligible) interests is in fact ensured.

The EFSA Evaluation Report on the Renewal of the Stakeholder Consultative Platform of 2012\textsuperscript{35} presents a thorough explanation of the selection procedure. In particular, it reveals that the mandate of the Platform is renewed every three years and that the selection procedure is organised in a manner that guarantees that new appointments are made before the expiration of the mandate of the previous ones. On the one hand, this arguably ensures a rotation of various eligible interests (i.e. openness to new members) and, on the other hand, a continuity in the group’s operation. According to the Evaluation Report, the selection procedure is carried out as follows. After an open call for expressions of interest, the management board receives applications from organisations that wish to participate in the EFSA Stakeholder Consultative Platform. These

\textsuperscript{32} European Food Safety Authority (2010), p. 2.
\textsuperscript{33} Ibid.
\textsuperscript{34} Ibid.
applications are then assessed in the light of the above-mentioned eligibility criteria. According to the Evaluation Report, when renewing the mandate of the Stakeholder Consultative Platform in 2012,\(^{36}\) the EFSA received 57 applications, of which a total number of 41 were considered eligible. Based on the evaluation of all available documentation, 24 stakeholder organisations (not individuals) were recommended for appointment as members of the EFSA Platform. As reported, when making these decisions, the management board strives for a balanced representation of eligible interests. An EFSA official described how the agency actually decides between several eligible organisations operating in the same field. In her own words,

> We need to ensure that for every single aspect of the food chain there is a representative in the Platform. So imagine: if we have three producers of enzymes, we will definitely choose the one which is the biggest and the most representative at the European level. (Respondent #20)

The fact that preference is given to umbrella stakeholder organisations could be understood as an additional guarantee of representativeness on a broader scale. It is in their very nature that umbrella organisations tend to cover and coordinate a wide range of organisations, for instance sector-specific national associations, pursuing a common purpose (i.e. shared interests). Also the Evaluation Report explains the concrete choices in much detail and, \(\textit{prima facie}\), indicates that great emphasis is given to weighing between the different interests to be included and ensuring that the selected stakeholder organisations are indeed representative of the affected interests.

Under the EFSA rules, once appointed, “representatives of members’ organisations attending the Platform meetings represent their organisations and are not attending the Platform in their individual capacity.”\(^{37}\) Indeed, the members of the EFSA Platform are the selected stakeholder organisations and their representatives are not appointed \textit{ad personam}, which effectively means that “members’ organisations” could assign a different representative for every Platform meeting to participate on their behalf. Practically, however, this would not make much sense and, generally, the EFSA Platform respondents confirmed that it is usually one or two assigned representatives from a stakeholder organisation that take turns attending the meetings (Respondents #20, #23, #30). According to the respondents this also ensures familiarity with the topics discussed and continuity of debates within the group.

The question is then whether the EFSA Stakeholder Consultative Platform is \textit{de facto} representative of the before mentioned five categories of “eligible interests” (i.e. consumer interests, interests pertaining to food safety, farmers and primary producers, food industry, and trade and catering). This issue is of specific relevance, given that the degree to which the promises of this form of participation (i.e. transparency, inclusiveness, and more informed outcomes) are advanced depends on the actual breadth and the adequacy of representation of the different interests included in the group. The Evaluation Report on the Renewal of the Stakeholder Consultative Platform reveals that the Platform comprises two organisations representing consumer interests in the food chain, five NGOs with an interest in the various aspects of the food chain, seven organisations covering

\(^{36}\) The last renewal of the EFSA Stakeholders Consultative Platform is applicable for the time period 2012-2015.

the interests of farmers and primary producers, six organisations covering the interests of industry in the various stages of food processing at the EU level, and four organisations representing the interests of the food trade and catering sector along the whole food chain. This means that out of the 24 “member’s organisations” only seven organisations explicitly represent “public interests” in the food chain, whereas the rest are predominantly representing various interests of the food industry. In no respect can such representation in the EFSA Platform be considered a “balanced representation” of different interests. This also casts serious doubt on the credibility of the selection procedure as a whole. The empirical data however, reveals that the EFSA is only partially, if at all, to blame for such “unbalanced” representation of “public” versus “industry” interests. The main responsibility rests with the limited financial resources of the organisations that voluntarily represent public interests. According to a representative of public interests in the EFSA Platform:

There have been concerns that the Platform is over-represented by the food industry in comparison to public health and consumers, but it is rather obvious why that happens. Public organisations, like ours, have had significant cutbacks, we are in a recession and it is difficult to get the money to have a representative there for the interests of public health which are vague and one is wondering about the actual outcomes of such [participation]. Of course, you are defending the interests of the public, but it is not as hard-core as food industry which is trying to get a place on the Platform to get a health claim that will immediately affect the price of whatever commodity they are selling. [...] For us it is very much a voluntary role on top of many other things [that we are doing], and the industry has much more money, so for them it is easier [to participate]. (Respondent #23)

Participation in the EFSA Stakeholder Consultative Platform is voluntary and the costs of participation in the meetings are borne by each individual organisation. Exceptionally, the EFSA “may contribute to financing the costs of those organisations that could not otherwise afford to participate in meetings of the Platform.” If awarded however, such contributions barely cover the transport and accommodation costs for the meetings, let alone the work and time spent in preparation for the meetings (Respondent #23, #30). In terms of financial resources, the organisations representing the interests of the industry are obviously in a better position compared to those representing public interests. Arguably, this could be the reason why, in the first place,

38 As of 2014, the EFSA Stakeholder Consultative Platform comprises the following 24 organisations: two consumer organisations - Bureau Européen des Unions de Consommateurs (BEUC), and European Community of Consumer Co-operatives (EUROCOOP); five NGOs - European Public Health Alliance (EPHA), European Environmental Bureau (EEB), Friends of the Earth (FoEE), European Federation of the Associations of Dieticians (EFAD), and Greenpeace; seven farmer and primary producer organisations - COPA-COGECA, European Crop Protection Association (ECPA), EU Association of Speciality Feed Ingredients and their Mixtures (FEFANA), European Feed Manufacturers Federation (FEFAC), Euroseeds, EuropaBIO, and International Federation of Animal Health Europe (IFAH); six organisations representing the food industry - Food Drink Europe, Primary Food Processors in the EU (PFP), European Chemical Industry Council (CEFIC), Association of Manufacturers and Formulators of Enzyme Products (AMFEP), Association of the European Self-Medication Industry (AESGP), and Federation of European Speciality Food Ingredients Industries (ELC); four trade and catering organisations - European Liaison Committee for Agricultural and Agri-Food Trade (CELCAA), Union européenne de l’artisanat et des petites moyennes entreprises (UEAMPE), EuroCommerce, and European Fresh Produce Association (Freshfel Europe). See, European Food Safety Authority (2012), pp. 4-5.

39 European Food Safety Authority (2010), p. 3.

40 Ibid. However, financial contributions can only be awarded to organisations which are non-governmental, non-profit making, independent form industry, commercial or business, and which have as their primary objectives and activities the promotion and protection of the health and safety of consumers.
fewer organisations representing public interests apply for the membership in the EFSA Platform. The statistics of the 2012 selection procedure seem to support this observation: out of a total of 57 applications only 15 were submitted by consumer organisations and NGOs - 5 of these were considered non-eligible by the EFSA, and 7 were appointed as members of the Platform.41

Attempts by the EFSA to ensure balanced representation in its advisory group are also evident in the Terms of Reference of the Stakeholder Consultative Platform. These rules foresee that if any of the five categories of stakeholder interests is underrepresented, the agency may permit the organisations belonging to that category to be represented by more than one delegate.42 However, in light of the financial concerns described above, the impact of this “remedial measure” appears rather limited.43

On a critical note, the gap between the reported commitment of the EFSA to strive for balanced representation, and the actual membership of the Platform is still rather striking. As the input provided by the EFSA Stakeholder Consultative Platform and the quality of its operation depend on the representativeness of its members, it might be time for the EFSA and its management board to re-evaluate the rules and practices guiding its selection procedure, and to ensure inclusive representation in the participatory forum they set up. One solution could be to cover the expenses of participation. However, as I will elaborate below, this could result in a “professionalization” of the group, which would be problematic in terms of the identified promises of this form of interaction with interested parties, and might affect the main value of having such a participatory group.

In the case of the EMA Patients’ and Consumers’ Working Party, the determination of which “eligible” organisations will be represented in the group is made by the agency.44 The organisations are selected “on the basis of their appropriateness to the subjects covered within the scope of the working party’s mandate”, and according to the Patients’ and Consumers’ Working Party’s Rules of Procedure, the following areas must be covered within the group: general patient and consumer organisations and “organisations with specific interest in the mandatory scope of the centralised procedure (orphan drugs, HIV/AIDS, cancer, diabetes, neurodegenerative disorders or other autoimmune diseases and other immune dysfunctions).”45 If several organisations are eligible from the same subject area, the EMA may select only one or some of them, given that the number of seats for patient and consumer organisations is limited to a maximum of 20.46 Nothing further is specified regarding the selection of the members of the Patients’ and Consumers’ Working Party, and therefore attempts to formulate the selection procedure for the EMA advisory group’s members prove difficult. At this point empirical research becomes necessary to elucidate the matter. One EMA official explained the procedure as follows:

42 European Food Safety Authority (2010), p. 2.
43 The minutes of the EFSA Stakeholder Consultative Platform reveal that only one “public organisation” – the European Consumer Organisation (BEUC) is occasionally represented by more than one delegate, but so are some organisations that cover the interests of the industry, even though their category is not underrepresented. See for example, <http://www.efsa.europa.eu/sites/default/files/event/140326-m.pdf>.
46 Ibid, p. 3.
We identify the organisations to be represented in the Patients’ and Consumers’ Working Party through a call for expression of interest, so we receive applications for being part of this working party, and then we select [the members] because, of course, we cannot accept all that apply. [...] So we have this grid with essential requirements [i.e. the eligibility criteria] and in case we have to select between different organisations that all meet these criteria, then we tend to guarantee equal representation to different therapeutic areas, so not to have three patients’ organisations on pathology diseases and nobody on neurodegenerative diseases. We tend to have a balance between organisations: if we have two applications, one coming from a cardiopathic disease organisation and the other coming from, for example, Alzheimer disease, and we already have a neurodegenerative disease association in the group, but nobody from the cardiological area, then we give privilege the cardiological one, because Alzheimer is already covered by neurodegenerative diseases. (Respondent #1)

This means that when several eligible organisations that are active in the same area apply, the EMA purportedly selects those that are most representative in a given field. As of 2015, the EMA website lists 36 patient and consumer organisations eligible to work with EMA,47 19 of which are members of the Patients’ and Consumers’ Working Party.48 All the above-mentioned areas are indeed covered; for example, various general patient and consumer organisations are included (e.g. European Consumers’ Organisation - BEUC, European Patients’ Forum, European Public Health Alliance, International Alliance of Patients’ Organizations, etc.), as well as organisations interested in the therapeutic areas where medicines need to be evaluated by the EMA, such as orphan drugs (European Organisation for Rare Diseases), AIDS (European AIDS Treatment Group), cancer (European Cancer Patient Coalition, European Prostate Cancer Coalition), diabetes (International Diabetes Federation European Region), neurodegenerative disorders (Alzheimer Europe), neurological diseases (European Federation of Neurological Associations, European Multiple Sclerosis Platform), and immune dysfunctions (International Patient Organisation for Primary Immunodeficiencies).49

Upon a request from the EMA, the selected organisations nominate one representative as a member of the Patients’ and Consumers’ Working Party for a term of three years.50 In this respect the EMA gives clear instructions: representatives are required to “liaise with their organisations as necessary in order to provide the position of the organisation on the topics to be addressed.”51 Hence, such members are nominated as representatives or “agents” of the patient and consumer organisations they affiliate with.

48 AGE Platform Europe (AGE), Alzheimer Europe (AE), European AIDS Treatment Group (EATG), European Cancer Patient Coalition (ECPC), European Consumers’ Organisation (BEUC), European Federation of Allergy and Airways Diseases Patients’ Associations (EFA), European Federation of Neurological Associations (EFNA), European Heart Network (EHN), European Institute of Women’s Health (EIWH), European Multiple Sclerosis Platform (EMSP), European Organisation for Rare Diseases (EURODIS), European Patients’ Forum (EPF), European Prostate Cancer Coalition (EUomo), European Public Health Alliance (EPHA), Health Action International Europe (HAI), International Alliance of Patients’ Organizations (IAPO), International Diabetes Federation European Region (IDF Europe), International Patient Organisation for Primary Immunodeficiencies (IPOPI), and Patients Network for Medical Research and Health (EGAN). See EMA website, <http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CHMPPeople_list,img_000017.jsp&mid=WC0b01ac0580028d52>.
49 See also, I. Moulon and N. Dedes (2010), pp. 191-192.
50 European Medicines Agency (2013a), p. 3.
51 Ibid.
On the whole, judging from the information presented above (such as the members’ appropriateness to the subject matter and the broadness of their interests) the selection procedure seems to ensure that all relevant patient and consumer interests are properly covered in the EMA Patients’ and Consumers’ Working Party and that an accurate and balanced representation is in fact guaranteed. In other words, it appears that the EMA participatory group is relatively open to various interested parties and that everyone that matters for the fulfilment of the promises of transparency, inclusiveness and informed outcomes is actually included. However, the considerations expressed above in relation to financial resources available to the organisations representing public interests in the case of the EFSA Stakeholder Consultative Platform, also apply in the case of the EMA advisory group. Representatives of patient and consumer organisations in the Patients’ and Consumers’ Working Party participate on a voluntary basis and do not receive any financial compensation from the EMA and often not even from their “background” organisations. This could potentially influence their decision on whether or not to participate in such a structure, or at least could make participation rather difficult. As observed by one former member of the EMA Patients’ and Consumers’ Working Party:

It is a battle. I would love to continue with this work, but economically speaking it does not sum up. I have not yet retired, so I have to earn my salary somewhere. [...] You could do a part time job, but still you would need days off to travel to the EMA and to prepare [for the meetings]... What kind of job is it where you can have this? You have to be retired, or you need to have a partner who is incredibly rich, who can support you. So it goes back to the ancient days when rich ladies did charity work, and they would sit in their committees and show all the diamonds on their rings. It is that kind of notion and it makes me upset. (Respondent #14)

Once again, this is illustrative of how financial resources (or the lack thereof) can have a serious impact on the participation of interested parties, and consequently, on the representativeness of agencies’ advisory groups. The origin of this problem seems to lie with the participating organisations rather than the agencies. However, paid placements and subsequent (almost certain) professionalization of such groups is not a viable solution and could in fact diminish the primary quality of such groups – i.e. interaction with interested parties. In other words, being paid by the agency could be interpreted as working for the agency, and in such cases interest representation could become a secondary concern, which would clearly hinder the identified promises of this form of interaction (i.e. enhancing transparency and building trust, ensuring inclusiveness of various possibly conflicting interests, and garnering a wide range of relevant information). Thus, there are limits to what agencies can formally do in this regard. Nevertheless, this issue can be identified as a clear deficiency in relation to participation in general matters, and could lead to situations where, contrary to the envisaged aims, certain interests might be able to create a more influential role for themselves.
Overall, it seems that the EFSA and the EMA have developed thorough rules regarding the creation and composition of their stakeholder advisory groups. As nothing in the accumulated empirical evidence would testify to the contrary, it can be submitted that in terms of access to participation the two agencies are committed to respecting their own rules to the extent that this is practically feasible and within their immediate control. However, given certain shortcomings (e.g. financial resources) of stakeholder organisations, in particular of those concerned with public interests, concerns remain that the spectrum of interests represented in the EFSA and the EMA advisory groups could fall short of what is envisaged in the agencies’ rules.

5.2 Quality of Deliberation: A Matter of Established Practices

The overall quality of deliberation, comprising three interrelated and mutually enforcing facets – provision of information, debate and recognition, determines the actual influence of participation. It is assumed that particular arrangements pertaining to each of the facets are put in place to ensure the fulfilment of the intended promises of participation in general matters: enhancing transparency of agencies’ operation and building trust, promoting inclusiveness (balancing of different, possibly conflicting views) and facilitating the provision of advice with regard to stakeholder concerns which, in turn, may improve the quality of agencies’ outcomes. The analysis below will be structured by reference to the particular elements of the quality of deliberation and will attempt to ascertain whether and in what manner the envisaged promises are de facto accomplished.

5.2.1 Provision of Information: Regular Communication

Access to information and the subsequent interested parties’ preparation for the execution of the responsibilities they are entrusted with establish an essential element for the subsequent stages of participation, namely the debate and the participatory groups’ contributions. In the case of participation regarding general matters, this means that the respective agencies need to present the type of information which would advance interactions with the concerned interests and further the fulfilment of the identified promises. Relying on the empirical evidence at hand, the following pages will shed light on the relevant “informing” arrangements and assess whether they are adequate in terms of the underlying promises.

As observed above, the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform were established outside specific legal requirements (i.e. agencies’ founding regulations) in order to promote the collaboration of interested parties in general matters, which

52 See Chapter 2, Sections 2.3.2 and 2.4.
are not restricted to a particular decision-making procedure. Given the more informal character of the said participatory groups, in neither of the cases is the provision of information regulated in much detail. Thus, to first establish the nature of information that would be deemed relevant, it is necessary to consider the particular tasks that interested parties are entrusted with.

The rules of procedure of the EFSA Platform state that this group offers advice to the EFSA’s executive director on general issues regarding the work of the agency and, especially, the impact of its work on stakeholders. In particular, the Platform may comment on the EFSA’s work programme and annual management plan, as well as the agency’s plans for interaction with stakeholders, provide the agency with feedback on the effectiveness of its policies in response to stakeholders’ concerns, and alert the EFSA of any emerging stakeholders’ concerns and possible risks. This means that the type of information would need to include various documents pertaining to the work of the agency (i.e. work, management and interaction plans) and communication of risks. The minutes of the EFSA Platform further show that in the meetings, the participants are also regularly informed – either by the executive director or by the EFSA staff, on the agency’s progress, performance of risk assessments, as well as planned public consultations, and that such information is shared with the Platform members beforehand via the group’s extranet space.

An analysis of the EMA documents reveals that the provision of information to the Patients’ and Consumers’ Working Party is organised in a more “targeted” manner. According to the rules of procedure of the Patients’ and Consumers’ Working Party, this advisory group prepares an annual work programme which identifies topics for consideration. The main issues that the group focuses on include activities of the EMA scientific committees and working parties, activities related to information and communication with interested parties, pharmacovigilance and risk management, research, and clinical trials. This means that the EMA would need to present specific information supporting the focus of the group. Apart from stating that the meeting documentation needs to be submitted to the participants, the rules of procedure of the EMA advisory group do not reveal anything further. However, the minutes of the Patients’ and Consumers’ Working Party disclose that, in the meetings of the group, the EMA staff should systematically give presentations on various issues listed above.

54 Ibid.
56 European Medicines Agency (2013a), p. 5.
57 See, European Medicines Agency (2015a), pp. 2-5.
58 European Medicines Agency (2013a), p. 3.
Table 5.1 Overview of the Promises of General Participation/Type of Information/Deadline

<table>
<thead>
<tr>
<th>Envisaged Promises</th>
<th>Participation in General Matters</th>
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</table>
| - Regular exchange of information between the agencies and advisory forums, as well as between the members of these forums.  
- Inclusiveness.  
- Transparency.  
- Increased confidence and trust in agency operation. | EMA Patients’ and Consumers’ Working Party  
| Information/Documents (Examples) | EFSA Stakeholder Consultative Platform |
| - Activities of the EMA scientific committees and working parties, activities related to information and communication with interested parties, pharmacovigilance and risk management, research, clinical and emerging issues on medicines during their life-cycle. | - Draft work programme, annual management plan, the EFSA’s stakeholders annual work plan, agency’s progress, performed risk assessments, and planned consultations. |
| Deadlines | - Not specified.  
| Deadlines | - Not specified. |

A further issue is whether the type and the nature of information that the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform actually receive is capable of ensuring quality of participation in a manner that would enable the fulfilment of the envisaged promises (See Table 5.1 above). Considering the participatory groups’ responsibilities, the information provided should, *inter alia*, include a broad range of documents and presentations pertaining to the mission of the EMA and the EFSA and its impact on stakeholders, information on emerging stakeholder risks and potential concerns, as well as agencies’ plans for any other communication with stakeholders (e.g. the envisaged public consultations).

Generally, the respondents from the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform reported that, in terms of the type of information and substance, they are sufficiently informed by the respective agencies. In their view, they receive plentiful information on all pertinent issues both before and during the meetings. There are, however, no rules as to when the relevant documents need to be submitted to the two participatory groups. Nevertheless, in both cases, the respondents confirmed that the respective agencies make sure that information is provided to the groups in a timely manner. This hints at the agencies’ dedication to promoting the overall quality of deliberation and living up to the primary promises of participation. In the words of the EFSA stakeholder relation officer,

> There is a regular flow of communication. For example, the Platform has an extranet, a virtual platform for the exchange of information, and all documents are placed there. [...] The members receive agendas [...] for the meetings two months in advance and the rest of the documents two weeks before [the meetings], and since I started working with the Platform, I try to stick to these deadlines. (Respondent #20)
This was also confirmed by the EFSA Platform members, who felt that the agency is keeping their part of the deal by equipping them with timely and adequate information (Respondent #23, #30).

Similar observations were made with respect to the EMA, where the respondents from the Patients’ and Consumers’ Working Party generally reported that the agency’s secretariat is “very good” at providing sufficient and timely information (Respondent #25, #27, #29). One of the members of the EMA advisory group described the situation as follows:

[We receive] a lot of documents. It is always quite sizeable. For every agenda item in the EMA, in all working groups, there is always a document given in advance. That would be two weeks in advance, and you would always have this package updated if there are changes or if there is an addition. So you receive an e-mail notification to download the latest version, and there is always a post-meeting communication with the final documents which were used [in the meetings]. Some presentations are given on the spot and then a few days later, in the follow-up, the whole material that was discussed is provided. [...] Also, do not forget that the topics in the EMA do not come and go within weeks; they usually take months or years. So these documents do not just come out of the blue and disappear; they take time to review and to reflect upon. (Respondent #29)

Moreover, the respondents form the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform generally felt that, with the information received, they can adequately prepare for the groups’ meetings. The members of the two participatory groups are supposed to represent the interests of their background organisations. In this connection, the respondents also confirmed that they were sufficiently connected to their background organisations, and were therefore appropriately briefed about the interested parties’ concerns before the groups’ meetings (Respondent #14, #23, #27, #29, #30).

These are cases where even in the absence of a legal obligation to provide adequate and timely information, positive working practices, which motivate the fulfilment of the promises of participation in general matters, have developed. It can be understood therefore, that the agencies actually adhere to the self-imposed principles of behaviour in regard to the participatory forums they have voluntary created. On the whole, it seems that the EMA and the EFSA have the utmost interest in ensuring the credibility of this form of participation for the promises established above.
5.2.2 Debate, Input and Recognition: Keeping Up With the Promises?

The interaction between the respective agencies and interested parties in general matters however, goes beyond the timely and adequate access to information. The actual fulfilment of the promises of this form of participation also depends on the second essential facet of the overall quality of deliberation, namely the debate.⁶⁰ The deliberation of different issues, the exchange of views and the provision of advice on the various matters that may concern stakeholders, normally takes place in the participatory groups’ meetings.

In terms of the organisational aspects of the debate and commenting, the respondents from the EMA and the EFSA participatory forums generally felt that adequate time was devoted to every topic on the groups’ agenda. For example, a member of the EMA Patients’ and Consumers’ Working Party remarked that there is “absolutely enough time to converse about specific issues and it does not seem that one is not given the chance of being heard in the meetings” (Respondent #29). In a similar vein, one respondent from the EFSA Stakeholder Consultative Platform stressed: “I think there is enough time and we are never rushed” (Respondent #23). Considering that most of the actual “work” (i.e. reporting to interested parties and communication of information and advice) is done in the participatory groups’ meetings, this is clearly an important observation in terms of the intended promises. After all, having sufficient time dedicated to discussions likely ensures that different stakeholder views and concerns are put forward, and thus supports the quality of the debate.

The question of the level of the participants’ engagement in the groups’ discussions also arises. Once again the respondents from both participatory groups generally reported their satisfaction with the quality of communication in the meetings. For example, one of the EFSA Stakeholder Consultative Platform members explained that “usually nearly everybody is interested and actively engages in discussions” (Respondent #23). Another respondent added, “like any other member of the Platform, I pay attention and make sure that I am actively involved in whatever [issue discussed] that would affect the [interests] of my organisation” (Respondent #30). Similar observations were also made with respect to the EMA Patients’ and Consumers’ Working Party, where one of the respondents perceived that “the cooperation between the members has always been good and it is really beneficial to discuss issues across different diseases” (Respondent #29). However, the same respondent also remarked, “throughout the years, we had some people that are much better read and prepared; but it also takes many years of learning and preparation to become an optimal participant in discussions.” Or as observed by another EMA working group member, “most people are very engaged, but the newcomers are not because they do not know enough about how things are run around here” (Respondent #14). In fact, the respondent added that the EMA Patients’ and Consumers’ Working Party regularly organises trainings for newcomers, and “every new member of the group gets a mentor. Then the mentor meets with the disciple and works on simple texts, and that is a way of introducing them to the work of the group and to make them feel prepared to participate. And this is to make people more comfortable, because for a lot of new members it is a daunting, daring experience to come to the EMA.”

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⁶⁰ See Chapter 2, Sections 2.3.2 and 2.4.
Overall, this is yet again illustrative of practices in relation to participation that promote the accomplishment of the envisaged promises. In particular, it shows that in terms of the actual arrangement of the debate there are no deficiencies which could impede the involvement of interested parties in general matters and undermine the credibility of the input of the EMA and the EFSA advisory groups.

Let us now have a look at the actual output of the EMA and the EFSA participatory groups, and the agencies’ recognition of this output. This represents the third and last facet of the quality of deliberation and its consideration is a decisive part of the final judgement on the fulfilment of the promises of participation in general matters.

A common feature of the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform is that their role is purely advisory and not tied or limited to a particular decision-making procedure. Therefore the contributions of the EMA and the EFSA participatory groups are necessarily more general; the two forums provide advice on various issues that are of direct and indirect concern to interested parties.

Normally, the views of the interest representatives are presented to the agencies in the advisory groups’ meetings, and during such sessions the members may flag any issues that the respective agencies should take into consideration. As was noted above, the agencies’ representatives (e.g. executive director, members of the scientific committees, observers from the management board, and the staff of the agencies) are expected to regularly attend the meetings of the EMA and EFSA advisory groups. In both cases, the contributions of the participants are compiled in the minutes of the advisory group’s meetings, which are published on the agencies’ websites.61 In addition, the EMA also prepares an annual report on the interaction with patient and consumer organisations, which provides a detailed account of all instances of collaboration with such interested parties.62 For a better visualisation, the table below presents the results of the input of the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform.

### Table 5.2 Results of the EMA and the EFSA Advisory Groups’ Input

<table>
<thead>
<tr>
<th>Participation in General Matters</th>
<th>EFSA Stakeholder Consultative Platform</th>
<th>EMA Patients’ and Consumers’ Working Party</th>
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<tbody>
<tr>
<td></td>
<td>- Publication of the meeting minutes on the EFSA website.</td>
<td>- Publication of the meeting minutes on the EMA website.</td>
</tr>
<tr>
<td></td>
<td>- Exchange of views with the executive director and the EFSA representatives in the meetings.</td>
<td>- Annual report on the interaction with patients’ and consumers’ organisations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Exchange of views with the representatives of the EMA scientific committees and the EMA representatives in the meetings.</td>
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</tbody>
</table>

Furthermore, the respondents from both groups provided concrete examples of their contributions. For example, a member of the EMA Patients’ and Consumers’ Working Party provided the following insight,


Our demand was to make sure that the EMA is more open to the patients and consumers, so that people are aware of what the agency does. We have achieved that the agendas of the various EMA working parties are now going to become public. Also, we wanted to make sure that the wording of all agency texts is simplified. And the other is, of course, to make sure that the opinion of expert patients [who participate in the EMA scientific committees] is incorporated in all decisions that the EMA takes, so that the benefits and risks of the medicines are not evaluated by the scientific committees for us without us. (Respondent #29)

In this connection, another member of the EMA advisory group reflected,

We have achieved that the EMA has become more transparent. We have initiated the so called EPAR summaries [European public assessment reports for human medicines that the EMA publishes for every medicine granted a central marketing authorisation by the Commission]. The authorisations of medicines are very large and technical documents, and not very patient friendly. So we came up with this proposal for a three page simplified version, where you have a set of questions of what is this medicine, what is it for, what are the side effects, and how you take it. (Respondent #27)

In the case of the EFSA Stakeholder Consultative Platform, the respondents reported that they could provide interested parties’ insight on a wide range of issues pertaining to the agency’s operation and its impact on stakeholders (Respondent #23, #30). In this respect, a member of the EFSA advisory group observed,

I think that it is very useful for the agency to have such a platform, to which it can present the issues that are bubbling, and where we [the interested parties] can present our insights. [...] I actually think that the EFSA holds [the Stakeholder Consultative Platform] in high regard, there is a great kind of responsiveness from their side. They did not set us as a lame duck, so when we present our views, the agency listens and faithfully reflects to that; it is a touchstone that we receive a response from EFSA. (Respondent #23)

All in all, the empirical data shows that the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform indeed play an important role in advising the respective agencies on different issues pertaining to interaction with interested parties (e.g. how to increase transparency and how to further involve interested parties). One of the possible reasons for this is that both groups were established on the respective agencies’ own motion, as a consequence of emerging needs for interested parties’ input on any possible concern they might have. Another reason for the effective functioning of these participatory groups could be the very nature of participation in general matters. The mandates of these two groups are clearly different from the mandate of other “advisory” groups, such as the EASA Advisory Board63: the input that the former provide is more general and is not pinned-down to a specific decision-making procedure (e.g. managerial). In the case of the EMA Patients’ and Consumers’ Working Party one may also argue that the composition is more uniform than in the EASA Advisory Board, and that there is

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63 See Chapter 4 for comparison.
a greater possibility that the EMA participatory groups’ members will have common (or at least more similar) missions. We have not identified any specific deficiencies regarding the provision of documents to the EMA and the EFSA advisory groups and the level and quality of the debate. Therefore, in terms of the promises of participation, it may be concluded that this more general form of participation actually ensures that there is a regular flow of information between the agencies and interested parties, as well as between different interests represented in the groups. In particular, the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform provide relevant feedback on the effectiveness of the respective agencies’ policies in response to interested parties’ concerns. To the extent that the agencies equip the participants with all relevant information and respond to their concerns, it can also be argued that this in fact increases transparency of the agencies’ operation, which as a consequence enhances the trust and confidence of the participants, in turn furthering the credibility of the EMA’s and the EFSA’s operation.

5.3. CONCLUSIONS

This chapter has confirmed that participation in general matters satisfies a particular functional role: it is primarily intended to increase the credibility of the EMA and the EFSA in sensitive fields of operation from the perspective of interested parties. On the basis of inquiry into the primary sources and the underlying empirical evidence, it can be argued that this form of participation actually promotes interactions with potentially affected interested parties and ensures a regular exchange of information between the agencies and the advisory forums, as well as between the members of such forums (i.e. across different interests), with regard to any horizontal issues that might be of concern to stakeholders (e.g. establishing further interactions with interested parties and discussing the impact of agencies’ operation on stakeholders). Furthermore, general participation may also be seen as a means of increasing transparency and building trust in the work of the EMA and EFSA. The fact that agencies interact with interested parties so they can better understand their activities may diminish public dissatisfaction with the agencies’ affairs (for example with regard to medicines or food and feed safety).

On the whole, it has been shown that in the cases of the EMA and the EFSA, participation in general matters works rather well in practice. This could be attributed to the fact that the establishment of permanent forums of concerned parties was voluntary. The two advisory groups emerged following the respective agencies’ and the interested parties’ need for more focused collaboration on various horizontal issues. Generally, it can be argued that mechanisms ensuring the openness of access and representation of different interests concerned are in place. Indeed, the EMA Patients’ and Consumers’ Working Party and the EFSA Stakeholder Consultative Platform comprise a wide range of interested parties with different backgrounds and claims. On the basis of the empirical inquiry, it has also been suggested that the actual influence of general participation (i.e. the eventual difference) de facto corresponds with the envisaged promises. The members of the participatory groups are frequently and sufficiently informed, they engage in exchanges of views and in debate with the respective agencies on a variety of issues, and
their input is adequately acknowledged, which furthers the envisaged promises (i.e. transparency, inclusiveness and more informed outcomes). These findings tie in with the earlier observation of Borrás et al., who maintained that such interactions with interested parties “indicate that instead of isolating itself from the wider scientific and societal context [an agency] is actively seeking input and comments by stakeholders in a structured and transparent way.”

On a more critical note, the empirical investigation pinpointed one flaw in the practice of general participation. In the cases of the EMA Patients’ and Consumers’ Working Party and the EASA Stakeholder Consultative Platform, it was observed that (the lack of) financial resources might have a defining impact on the actual opportunity of interested parties to participate (in particular those representing societal interests), and consequently may cause de facto asymmetries in the representativeness of different interests in such participatory groups. In particular, it was demonstrated that problems with financial resources could potentially lead to situations where, contrary to the intended purposes, certain interests can create a better position for themselves in the participatory groups. In terms of the primary promises of participation, this situation could be seen as problematic for actual inclusiveness (balancing of different interests) and may also negatively affect (i.e. reduce) the spectrum of relevant information that would be available to the agencies. These deficiencies, however, do not occur due to the agencies’ misconduct, but can be attributed to the shortcomings of stakeholder organisations that are eligible to participate. This example was illustrative of the limits to what agencies can formally do to tackle this type of shortcomings. As argued, paid placements and potential professionalization of advisory groups would not be an appropriate solution, as it could diminish the fundamental value of such groups, namely collaboration with interested parties and the furthering of agencies’ credibility towards those concerned.