Scientific Committees

1) State of play de jure and in practice

The constituent acts of five agencies\(^1\) foresee the establishment of one Scientific Committee, while ECHA has two independent Scientific Committees\(^2\) and one Scientific Committee, where independence from the Member States is not required\(^3\); furthermore EMA has six Scientific Committees\(^4\). In addition to that, EFSA has ten Scientific Panels\(^5\), while ECDC has set up seven scientific panels\(^6\) and four technical advisory bodies\(^7\).

CEPOL does not have a Scientific Committee in the strict and simple sense. Instead, matters of ‘Research & Science’ in regard to the agency’s overarching objectives are mainly tackled by a permanent ‘Research and Science Working Group’ (RSWG), which is assigned to a ‘Training and Research Committee’ (TRC). The TRC in turn makes proposals and recommendations to the Governing Board in regard to any matters of research strategy.\(^8\)

Tasks of the Scientific Committees

Some Scientific Committees assist the Management Board and the Director by providing technical and scientific advice and delivering professional opinions on scientific orientations in the areas of work undertaken by the agency. In other agencies, like in the case of EFSA, the scientific committees adopt the scientific opinions of the agency.\(^9\) As regards EMA, the main

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1. EEA, EFSA, EMCDDA, FRA, GSA
2. Committee for Risk Assessment and Committee for Socio-economic Analysis
3. Member States Committee
4. Committee for Medicinal Products for Human Use (CHMP), Committee for Medicinal Products for Veterinary Use (CVMP), Committee on Orphan Medicinal Products (COMP), Committee on Herbal Medicinal Products (HMPC), Committee for Advanced Therapies (CAT) and Paediatric Committee (PDCO).
5. Panel on food additives and nutrient sources added to food, Panel on additives and products or substances used in animal feed, Panel on plant protection products and their residues, Panel on genetically modified organisms, Panel on dietetic products, nutrition and allergies, Panel on biological hazards, Panel on contaminants in the food chain, Panel on animal health and welfare, Panel on plant health, Panel on food contact materials, enzymes, flavourings, and processing aids.
6. Scientific panel on Influenza in reply to eight questions concerning avian influenza, Scientific panel on Vaccines and Immunisation, Expert advisory groups on human influenza H5N1 vaccines, Scientific panel on Human Papillomavirus Vaccination, Scientific panel on Childhood Immunization Schedule, Scientific panel on Rotavirus Vaccination, Scientific panel on Childhood Pneumococcal Vaccination.
7. Advisory group on producing guidance for prevention and control of Methicillin-resistant Staphylococcus aureus, Working Group for the project: “The bacterial challenge - time to react, A call to narrow the gap between multirug-resistant bacteria in the EU and the development of new antibacterial agents”, Expert group to help with definitions for multirug-resistant (MDR), extensively drug-resistant (XDr) and pandrug-resistant (PDR) bacteria (other than Tuberculosus), Expert group on guidance on healthcare-associated infection (HAI) prevention and control.
8. In addition, a network of “National Research and Science Correspondents” (RSC) for each Member State has been established recently. The RSCs, working through their ‘National Contact Points’ (NCP), are supposed to facilitate channels of communication exchange and establish closer cooperation between scientists and researchers on the one side and CEPOL trainers, lecturers and course organizers on the other.
9. In the case of EFSA, both the Scientific Committee and the Scientific Panels provide for scientific opinions, each within their own sphere of competence. In particular, the Scientific Committee is responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure and for providing
scientific committees adopt the scientific opinion which forms the basis for the EU-wide marketing authorisations granted by the Commission (in the form of Commission decisions).

In five cases (EFSA, EEA, EMCDDA, ECHA, EMA), the opinions of the scientific committees shall be published, while in four cases (FRA, ECDC, GSA, CEPOL), regulation n° 1049/2001 on access of documents applies.

Composition and designation of the Scientific Committees

The number and origin of the Scientific Committees' members differ between agencies.

In the case of six agencies, members of the Scientific Committees are appointed by the Management Board. Instead, concerning EMA, all Scientific Committees' members are appointed by the Member States, and for the main scientific committees (CHMP and CVMP), members are appointed by the Member States following consultation of the Management Board. The members of the Scientific Committees shall be independent, except for the Member States Committee of ECHA.

Additional information on scientific committees of individual agencies follows.

The two Scientific Committees of ECHA are composed of at least one member but not more than two from the nominees of each Member State and up to five members chosen by the Committee on the basis of their specific competence. The Management Board appoints the members based upon a list of nominees established by the Executive Director. In January 2010, the Committee for Risk Assessment consisted of 39 members while the Committee for Socio-economic Analysis consists of 34 members. The Member States Committee of ECHA consists of one representative directly appointed by each Member State.

The Scientific Committee of the EEA is composed of up to 20 scientists from the Member States, appointed through an open selection process.

The EFSA's Scientific Committee is composed of the Chairs of the abovementioned Scientific Panels and six independent scientific experts. The EFSA's Scientific Panels are composed of independent scientific experts.

The Scientific Committee of the EMCDDA consists of up to 15 well-known scientists appointed in view of their scientific excellence and their independence by the Management Board.

The EMA's main Scientific Committees - CHMP and CVMP - consist of one member and an alternate from 27 EU Member States, one member and an alternate from Iceland and Norway (Liechtenstein has never appointed any member in the scientific committees), and up to 5 co-opted members, chosen among experts to gain additional expertise in a particular scientific area. Some of the other EMA's Scientific Committees (PDCO and COMP) have in addition also civil society representatives as members.

opinions on multi-sector issues falling within the competence of more than one Scientific Panel and on issues which do not fall within the competence of any of the Scientific Panels.

10 ECHA, EEA, EFSA, EMCDDA, GSA, FRA

11 The Committees appoint one of its members to act as (co)-rapporteur to draft the assessment report. The (co)-rapporteur sets up Assessment Teams including experts chosen from the European expert list available at the EMA and uses the scientific evaluation and resources made available by the national competent authorities and the EMA.
The Scientific Committee of GSA consists of members appointed by the Management Board from among acknowledged experts from Member States and the Commission.

The Scientific Committee of FRA is composed of eleven independent persons, highly qualified in the field of fundamental rights, appointed by the Management Board.

The chairperson and, where appropriate, vice-chairperson of agencies' Scientific Committees are elected from amongst the Scientific Committee's members.

The term of office of the Scientific Committees' members varies between agencies from 3 up to 5 years.

2) **Critical analysis of the issue at hand**

Work carried out by scientific committees

When looking at the functioning of agencies' scientific committees, no overall lesson can be actually drawn at agency system level, as the assessment varies from one agency to another, depending on the specificities of each of them. An analysis of the work carried out by scientific committees of individual agencies follows.

An example of well performing scientific committee is the one of EFSA. Indeed, this scientific committee, together with the Scientific Panels, has a proven capacity to timely deliver scientific opinions of high scientific quality. This is also due to a number of horizontal tools and procedures put in place,\(^\text{12}\) which contributed to improve work planning, increase the quality of the opinions and cooperate with external experts. On the other hand, one of the main challenges is the fact that EFSA's Committee/Panels are composed of independent experts who are not remunerated, as they just receive allowances for their work. The high workload implies that these experts have to devote much time to EFSA, which is not always easy considering that they are employed by national scientific bodies (academia, research public bodies, national scientific agencies). Appointing members to the scientific committees of an agency should be seen as a means to build a structured and fruitful relationship between the various actors involved, leading to benefits also for the appointed person and the institution he/she is coming from\(^\text{13}\). With this in mind, appropriate support to the experts, good planning procedures and priority settings are essential in this specific context, and initiatives have been taken in this respect.

It is also recognised that the scientific opinions of the EMA are of very high scientific quality, as indicated in the recent Evaluation of the EMA by Ernst&Young. The EMA model has been considered a success story where the EMA secretariat coordinates the scientific resources put at its disposal by the Member States (network). However, having each Member State represented in each Committee as a prerequisite is sometimes not optimal with the aim of having the best expertise and for the most efficient organisation. Another issue to be considered relates to the funding of EMA-related activities by the Member States' rapporteurs and co-rapporteurs. While in the majority of cases, the rapporteur/co-rapporteurs are

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\(^{12}\) The Commission and EFSA developed common cooperation tools to ensure adequate and continuous coordination of the respective work programmes. EFSA developed procedures ensuring that preparatory work for the development of scientific opinions is planned in advance and carried out in the most efficient ways including by externalising it (contracts) or by entrusting national scientific bodies with specific preparatory tasks (grants). EFSA established several working groups of the Panels involving external experts. This is necessary to ensure that adequate and sufficient expertise is mobilised; it is also a tool to train and identify future members of the Panels (need to enlarge the pool of expertise).

\(^{13}\) E.g. recognising the professionalism of the person and increasing the reputation of the institution he/she is coming from.
remunerated (receiving 50% of the fees paid by industry to the EMA), there are some activities for which no fee or a reduced fee is foreseen in the legislation, such as paediatric activities. This could create difficulties to find rapporteurs and co-rapporteurs. It should also be noted that several Member States have been reluctant to submit data on their costs for carrying out EMA-related activities (despite repeated requests by the Commission following recommendations by the Court of Auditors), and there is an on-going costing exercise in order to address this issue.

In the case of EEA, its scientific committee seems to be somehow under-utilised and to play a relatively marginal role in influencing or contributing to EEA products. One aspect to be stressed is that often the members of the committee lack full understanding of policy processes that would allow them to provide reliable input without fairly strong guidance.

An external evaluation carried out in 2008 underlined that the ECDC Advisory Forum should focus more on the scientific policy issues rather than management problems.

The Commission is not invited to participate in the meetings of the Scientific Committee of EMCDDA. Communication and coordination with the Scientific Committee could be improved.

In other cases (FRA and ECHA), the work of the scientific committees has just started; thus there are not yet enough elements to draw a critical analysis.

Finally, the scientific committee of GSA, which is foreseen in its founding regulation, was never constituted.

**Transparency of selection procedures**

By providing scientific and technical advice, scientific committees play an important role, especially within those agencies where these committees are responsible for delivering the scientific opinions of the agency. Therefore, it is necessary to ensure that the selection procedures in place guarantee the level of expertise and independence needed. This may be easier to achieve in those agencies whose founding regulations provide for clear rules on selection procedures, although good results have been achieved also in cases where the founding regulation does not itself set out detailed rules for the appointment of members. As seen above, selection procedures differ. The assessment of their functioning is mixed and changes from one agency to another.

In the case of EFSA, it seems that the current rules have ensured an independent functioning of the Scientific Committee and Panels; the quality and independence of EFSA's scientific opinions are recognised. The experts are selected following an open call of interest and appointed by the Management Board (itself composed of 14 independent persons plus one representative of the Commission). In addition, stringent rules apply in terms of declaration of interests.

As regards EMA, the members of the main opinion-issuing scientific committees are appointed by the Member States following consultation of the Management Board. In addition, the Member States transmit to the Agency the names of national experts who would be available to serve on the working parties or scientific advisory groups of these committees. In addition, the EMA can also appoint experts. The independence of the members of the main scientific committees is provided for in Article 61 point 6 of Regulation No 726/2004 (regulation establishing the EMA), which stipulates that Member States are to refrain from giving committee members and experts any instruction which is incompatible with their own
individual tasks or with the tasks and responsibilities of the Agency. As regards transparency and the independence of the members of scientific committees and experts, it may be noted that the EMA is currently reviewing its policy.

In the case of ECDC, an external evaluation carried out in 2008 highlighted that there was not enough transparency on the selection of experts for the advisory bodies and scientific panels of the agency. The capacity in which some members act in the advisory bodies (as individuals or on behalf of the Member State) was referred as not completely clear.

The current Scientific Committee of the EMCDDA was appointed in 2008 on the basis of a new procedure whereby the members are selected on personal merit/scientific excellence as opposed to geographical balance. Its mandate can be renewed after a three year period. The mandate of the current Scientific Committee was recently renewed from 2011 to 2013 on the basis of a decision by the Management Board. However, it was decided that the process for renewal should be reviewed in 2012, as a number of members of the Management Board, including Commission representatives, took the view that there is a need to allow for rotation of members of the Scientific Committee.

Although the EEA’s founding regulation does not itself set out detailed rules for the appointment of members, the rules of procedure do provide for a transparent process based on an open call for interest and ensure fair recruitment. The issue of scientific excellence versus other factors such as geographical or gender balance has arisen in recent appointments, and although a satisfactory solution was found, some clarification of the rules may be helpful.

FRA’s founding Regulation provides for a selection procedure which aims at guaranteeing transparency and independence. The process, although somewhat cumbersome, was unanimously considered as best practice in terms of transparency.