Health Policy 121 (2017) 594–603

Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

The Directorate-General for Health and Consumers 1999–2014: An assessment of its functional capacities☆

Timo Clemens[a,*], Kristine Sørensen[a], Nicole Rosenkötter[b], Kai Michelsen[a], Helmut Brand[a]

[a] Department of International Health, CAPHRI School for Public Health and Primary Care, Maastricht University, The Netherlands
[b] Department of Health Data, Analysis and Health Services, NRW Centre for Health, Bielefeld, Germany

ARTICLE INFO

Article history:
Received 23 July 2014
Received in revised form 27 March 2017
Accepted 29 March 2017

Keywords:
DG SANCO
DG SANTE
European union
Health policy making
Capacity assessment

ABSTRACT

Capacity assessment has become a popular measure in the health sector to assess the ability of various stakeholders to pursue agreed activities. The European Commission (EC) is increasingly dealing with a variety of health issues to coordinate and complement national health policies. This study analyses the functional capacity of the Directorate-General for Health and Consumers (DG SANCO) between 1999 and 2004. It applies the UNDP Capacity Assessment Framework and uses a literature review, a document review of EU policy documents and expert interviews to assess the capacity of DG SANCO to fulfill its mandate for public health and health systems. Our results suggest that DG SANCO has established capacities to engage with stakeholders; to assess various health issues, to define issue-specific health policies and to collect information for evaluative purposes. In contrast, capacities tend to be less established for defining a clear strategy for the overall sector, for setting priorities and for budgeting, managing and implementing policies. We conclude that improvements to the effectiveness of DG SANTE's (the successor of DG SANCO) policies can be made within the existing mandate. A priority setting exercise may be conducted to limit the number of pursued actions to those with the greatest European added value within DG SANTE's responsibilities.

1. Introduction

The improvement of capacities for public policy in general [1–3] and for health systems in particular [4–6] has become a key approach for effective (health) policy making. By capacity we understand broadly the ability to pursue a certain action in accordance with defined goals or choices [3]. The performance of public policies is deemed to be improved by strengthened capacities because they are regarded as necessary conditions to develop, implement and evaluate policy actions effectively [1,5]. Capacity entails not only the institutional strengths and competences of a government but also the strategies and skills used to pursue policies [3,7]. Since the mid-1990s, multiple examples of capacity assessments have been conducted in the health sector using different conceptual models with varying geographical coverage and focal areas of interest [8].

☆ This article has been made Open Access through funding by the European Observatory on Health Systems and Policies as part of its Health Systems and Policy Monitor (www.hspm.org), an innovative platform that provides a detailed description of health systems and provides up to date information on reforms and changes that are particularly policy relevant.

* Corresponding author at: Maastricht University, CAPHRI Care and Public Health Research Institute, Department of International Health, Duboisdomein 30, NL– 6229 GT Maastricht, The Netherlands.
E-mail address: timo.clemens@maastrichtuniversity.nl (T. Clemens).

http://dx.doi.org/10.1016/j.healthpol.2017.03.018

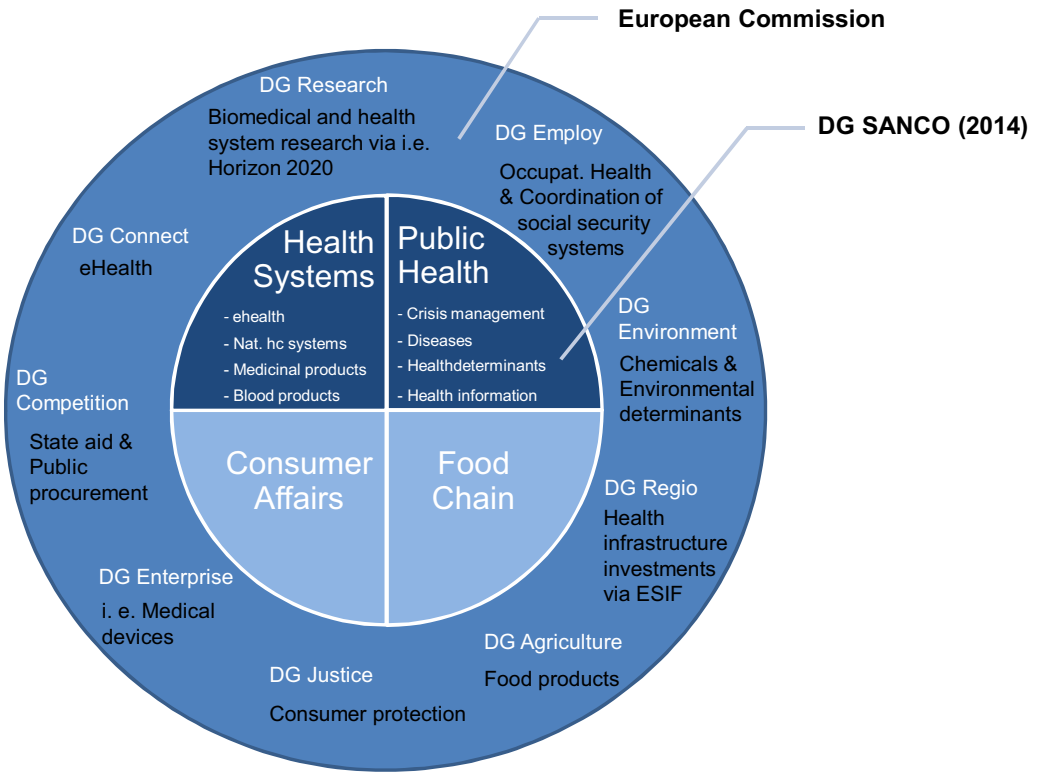

Fig. 1. Responsibilities for health within the European Commission (2014).
Abbreviations: ESIF: European Structural and Investment Funds; Nat. hc: National healthcare.
Sources: Greer SL, Fahy N, Elliot HA, Wismar M, Jarman H & Palm W. Everything you always wanted to know about European Union health policies but were afraid to ask (2014) Copenhagen, WHO Europe on behalf of the European Observatory on Health Systems and Policies; DG SANCO Organizational Chart 01/09/2013.

The European Union (EU) has established a mandate for health. As enshrined in Article 168(2) of the Treaty on the Functioning of the EU, the major form of European action in public health is to foster cooperation between Member States (MS) and to support national activities. However, over the last two decades, the EU has increased the applicability of its legal principles to national laws regulating health [9–11]. This has been explained by a series of developments including responses to international public health crises, spill-over effects from internal market law to healthcare as well as a strategic coordination led by the European Commission (EC) [12]. In contrast to the wide scholarly attention that the development of EU competences has received [11,13], capacities are not frequently discussed at EU level in terms of the Commission services pursuing health policies effectively. The analysis on the effects of EU health policy making on national policies remains incomplete so far [14]. To bridge the gap, the aim of the study is to assess the functional capacities of the Directorate–General for Health and Consumers (DG SANCO) for policy making regarding its mandate for public health and health systems (see Fig. 1) between 1999 and 2014 by critically reviewing literature including EU official documents and interview data. On the basis hereof, we draw conclusions on potential avenues for more effective EU health policy making.

2. Methods

2.1. Framework for analysis

We assess the functional capacities of DG SANCO with the help of the United Nations Development Programme (UNDP) Capacity Assessment Framework [15]. The UNDP framework has so far been applied at national and subnational levels in low to middle income countries. Although the EU combines functions of a state and of an international organisation in health policy and represents upper-middle-income to high-income countries, the UNDP framework is beneficial to study the EC's capacities for health policy making. It identifies a number of functional capacity dimensions necessary to 'get things done', these comprise the capacities to:

a ***engage stakeholders*** (mobilising stakeholders, creating partnerships, open dialogue, managing different interests)
b ***assess a situation and define a vision*** (gathering and analysing data and information, specifying capacity assets and needs, defining a vision)
c ***formulate policies and strategies*** (setting objectives, managing priority setting, devising (inter) sectoral policies)

Table 1
Changing health responsibilities within DG SANCO and the European Commission 1999–2014.

Year	Developments
Until 2014	Barrosso II Commission: DG SANCO Health and Consumers • Directorate B Consumer Affairs • Directorate C Public Health (Programme management & Diseases, Health threats, Health information, Health determinants) • Directorate D Health Systems & Products (Strategy & International, Healthcare systems, Medicinal products, Products of human origin, ehealth & Health technology Assessment) • Directorate E, F & G Food Chain (safety of the food chain, food and veterinary affairs) Changes (in 2010) • Health technology and pharmaceutical policy (incl. responsibility for EMA) moves from DG Enterprise to DG SANCO • Biotechnology, Pesticides and Health moves from DG Environment to DG SANCO • Consumer Contract and Marketing Law moves from DG SANCO to DG Justice Responsible for • Consumers, Health and Food Executive Agency (CHAFEA, est. 2005) • The Community Plant Variety Office (CPVO, est. 1995) • The European Centre for Disease Prevention and Control (ECDC, est. 2005) • The European Food Safety Authority (EFSA, est. 2002) • The European Medicine Agency (EMA, est. 1995)
1999	Prodi Commission: DG XXIV Consumer Protection renamed to DG Health and Consumers (DG SANCO) Changes/Merging responsibilities of • DG XXIV on Consumer Protection • Feed and animal policies move from DG Agriculture to DG SANCO • Food policies move from DG Enterprise to DG SANCO • Public Health policies move from DG Employment to DG SANCO [12]
Before	DG III Industrial policy responsible for pharmaceutical and foodstuff policies DG V Employment & Social Affairs responsible for Health Protection and Occupational health and safety DG VI Agriculture for feed and animal policy DG XI Environment on consumer protection (later DG XXIV) and environmental health determinants

Sources: European Commission (2009), President Barroso unveils his new team, Press Release 27 Nov 2009 (IP/09/1837) http://europa.eu/rapid/press-release_IP-09-1837_en.htm?locale=fr by DG SANCO Organizational Chart 01/09/2013.
est.: established.

d ***budget, manage and implement projects and programmes*** (managing projects and programmes, setting indicators of monitoring)
e ***evaluate*** (collecting feedback, establishing lessons learned)

These functional capacities are embedded in a wider framework [15] covering broader institutional and societal arrangements which are described in the background section (see Section 3.1).

2.2. Data collection and analysis

This assessment of capacities uses a qualitative design for the analysis of EU policies based on three data sources: a literature review, an analysis of EU policy documents, and interview data. First, to map the functional capacities, a literature search in Medline via PubMed was performed using the MeSH term combination of 'Capacity Building' OR 'Health Resources' OR 'Health Policy' OR 'Legislation' OR 'Health Planning' AND 'European Union'. The search was limited to English publications and human subjects. From a total of 889 retrieved sources, 100 publications have been considered for full text analysis after the screening of titles and abstracts and 28 sources have been used in this review. Publications were included if functional capacities according to the UNDP framework at EU level were assessed, described or commented on. Retrieved research articles, viewpoints and editorials were also screened for additional publications and relevant EU documents in their bibliographies.

The second source, EU official documents, including internal and external evaluations, reports, communications, and strategy documents discussing health policy outputs at European level were analysed. In addition to the hand searching of bibliographies, a pool of EU documents were taken from an earlier study [14] in which experts identified them as potential policy outputs. The selected documents either commented on capacities as in the case of evaluation reports or were regarded as the output of a certain level of capacities like strategy documents.

The third data source comprised of twenty semi-structured interviews on the successes, failures and missed opportunities of EU health policy among twenty key informants [14]. Themes identified included perceptions on functional capacities within the EU health sector linked to specific policy areas and the policy process in general. A direct content analysis [16,17] was used to extract relevant information on DG SANCO and to group information to the predefined capacity dimensions according to the UNDP framework described above. Triangulation of different data

sources allowed for cross-checking of findings and helped to ensure credibility [18,19].

3. Results

3.1. Background

Overall, the capacities at EU level for policy making on health systems and public health are scattered. First, regulative power is predominantly with MSs on the basis of Article 168 of the Lisbon Treaty [20]. Article 168(7) grants that the responsibilities for the organisation and financing of healthcare systems rest with MSs. The EU is supposed to complement and coordinate MS actions by establishing guidelines, exchanging best practices, funding research and supporting health monitoring and surveillance (Article 168(1–2)). Only in a limited number of public health domains, such as cross-border threats, substances of human origin, veterinary and phytosanitary measures, medicinal products and medical devices the EU has legislative power (Article 168(4)). The implementation and application of EU legislation in the above described areas remains with MSs like in social policy in general [21].

Second, EU policies for health have developed in other policy areas such as social policy, consumer protection, occupational health protection or environmental policies. Moreover, other non-health policy domains of the EU affect health systems and determinants of health as well, such as internal market policies, competition law or fiscal surveillance of national government budgets [22]. Hence, policy capacities for health at the EC exist also in other Directorate Generals (DGs). An overview of various DGs working on health or related policies is given in Fig. 1.

Third, the DG SANCO was only established in 1999 by augmenting the existing DG on consumer protection. The responsibility for certain health policies were added including food policy, feed and animal health and public health issues from other DGs. On these specific health dossiers DG SANCO is the leading policy actor within the EC. However, DG SANCO's responsibilities have changed over the years – most remarkably the pharmaceutical dossier including the relations with the European Medicines Agency have been added in 2010–and changed again after the time of writing when the new Juncker Commission took office. From end of 2014 onwards DG SANCO has been renamed and reorganised to the Directorate General for Health and Food Safety (DG SANTE). A summary over the historic developments regarding the composition of DG SANCO's remit between 1999 and 2014 is provided in Table 1.

Fourth, capacities for health at EU level do not only rest within the EC but in other EU bodies as well. Three institutions are occupied with the law making at the EU level in general. The EC is the executive body. Its role involves, firstly, policy making by laws subject to subsequent MS implementation then. Secondly the EC has the right to initiative – the legislative process of the EU usually starts by a proposal from the Commission. Thirdly, the EC is tasked to safeguard the compliance with EU legislation in MSs.

The European Parliament, representing EU citizens, and the Council of Ministers, representing national governments, hold jointly the legislative powers in the EU policy making process. More specifically, the Parliament's Committee for Environment, Public Health and Food Safety (ENVI) is tasked to prepare a report (and suggestions for changes) on the Commission's proposal in the area of health. With the Council, the MS holding the Council Presidency has an important role in setting the agenda and facilitating compromises within the legislative process. The Council can issues also non-binding Recommendations which can be nevertheless influential because they portrait the joint view of all MS. Moreover, the European Union uses agencies to delegate technical tasks such as scientific assessments outside the Commission spheres [22,23].

These institutional arrangements and their main developments have been well described in the literature [9–13,24–26]. In contrast, this assessment will focus on the functional capacities of DG SANCO on public health and health systems from an organisational perspective, because pursuing healthy policy at EU level effectively is regarded as key given the existing scattered responsibilities described above [14,27].

3.2. DG SANCO: a capacity assessment

In line with the matrix of the UNDP framework, this section provides an analysis of the functional capacities of DG SANCO for policy making regarding its mandate for public health and health systems. By means of a literature and document review augmented by interview data the capacities for policy making regarding DG SANCO's public health and health system dossier have been assessed. An overview of the main findings is provided in Table 2.

3.2.1. Capacities to engage stakeholders

> *Decision makers are obviously facing [. . .] better worked out set of opinions, because there is DG SANCO and because it has networks and because there's people around it. (Interview 19)*

In order to engage stakeholders and create partnerships and networks among various interested parties, DG SANCO uses first and foremost a set of formal structures to engage public and private actors in the policy process. Among these are communications and green papers inviting stakeholders to comment on initial positions, problem framing or questions. Secondly, there are initiatives such as the EU Health Forum, the Inter-service Group on Public Health or the Working Party on Public Health at Senior Level which bring together various actors relevant to health at EU level. Moreover, issue-specific structures to create dialogue with interested parties include inter alia the EU Platform for Action on Diet, Physical Activity and Health or the EU Alcohol and Health Forum. DG SANCO also has a reputation to finance – via the Action Programmes – professional and stakeholder networks to pro-actively engage them in agenda setting and problem definition processes at an early stage [12].

While the organisational capacities in many areas seem to be in place based on the established structures, the extent to which some of them are effective is debated in the literature – the retrieved sources do not touch upon all

Table 2
Main findings of the capacity assessment by data source.

	Data sources/Main findings		
UNDP framework	Document analysis	Literature review	Interviews
Engage stake-holders	Various fora for engagement of actors have been established	Mixed view on the effectiveness of consultations	Multi-stakeholder approach of DG SANCO is welcomed Confirmation of mixed views regarding its effectiveness
Assess situation	Improvement/widened scope of data collection activities	Challenges of meaningful comparative data analysis	Data relevant for benchmarking purposes A number of blank spots have been identified where comparable data on EU level is still lacking
Define vision	Strategy document White Paper "Together for Health"	Move from vertical to horizontal approach has been welcomed Need for a clearer framework for action	White Paper is regarded as important policy output Strategic vision is still lacking
Formulate policies	EU policies using hard and soft law regarding the included policy dossiers of DG SANCO	Structural problems of the EU health mandate and scattered health policy responsibilities have been raised Priority setting is lacking	Priority setting is lacking Clearer division of tasks between EU and MS needed
Manage projects	Criticism on the management of EU action programmes for health	Lack of implementation Only effective in raising awareness	Importance to devise hard law for effective policy making
Evaluate	Mechanisms to receive feedback are in place Adjustment of policies using the received feedback is less clear		n.a.

structures. On the one hand, specific networks have been instrumental to put certain topics prominent on the health agenda in Europe such as cancer [28], health literacy [29], or infectious diseases [30]. On the other hand, the limited scope of the EU Health Policy Forum excluding health responses to EU trade or previously pharmaceutical policy has been regarded as a drawback [31]. Moreover, the capacity to collect opinions could be detrimental to health because of larger industry investments into lobbying [32]. This has also been documented with respect to conducting EU impact assessments with '*less well-resourced* [public health] *stakeholders [. . .] either unaware of or unable to fully participate in the consultation processes*' [33,p 482].

The interview data addressed the collaboration between MS as a general theme where the EU is held to be an arena for knowledge sharing, for facilitating research consortia and for collaborative work on specific topics such as rare diseases, infectious diseases or cancer. Moreover, DG SANCO is complimented for its multi-stakeholder approach in general (Interview 6, 8, 9, 23, 26). However, engagement of stakeholders from outside the public health sector (Interview 9) has not been without problems. Some interviewees mentioned examples were engagement has improved (WHO, EIP AHA) (Interview 6, 9) while others corroborated the failure of the system by which engagement options are used much more by the industry than by public health advocates (Interview 2, 9, 22).

3.2.2. Capacities to assess a situation

So, policy makers, the fact they now have a peer group of 27 other countries and that the data is now being collected by Eurostat or the OECD or anyone else, that's a powerful mechanism for change. (Interview 32)

The capacities to gather data and information have gradually increased over time. First, the collection of public health statistics have been formalised by a regulatory framework in 2008 [34] formally requesting MS to deliver some of the relevant health data on a regular basis. Second, the EC is a partner of the European Observatory on Health Systems and Policies which provides in-depth analyses of health systems and their reforms to support evidence informed policy making in MS and at an EU level [35,36]. Third, data on specific topics is collected via project funding for example on maternal health, health literacy or via grants to other bodies such as the International Agency for Research on Cancer or the OECD [37,38]. While continuous grants to other bodies ensure to some extent sustainability in data collection and assessment capacities, project-based data collections only provide a one-time assessment [39]. Fourth, a relatively new form of providing advice to the EC is the Expert Panel on effective ways of investing in health [40] and the reflection processes on chronic diseases and resilient health care systems in which MS cooperate to compile evidence and experiences with certain health system tools or interventions [41,42]. Fifth, more data on specific health areas is collected within the mandate of several health agencies such as the European Centre for Disease Prevention and Control (ECDC), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) or the European Agency for Safety and Health at Work (EU-OSHA). In doing so, the EC is committed to synthesise data in a comparative manner and to strengthen national data collection infrastructures in these areas.

Despite the upgrade of capacities for data collection over the last two decades, the EC acknowledged that the '*[g]athering [of] information on the comparative effectiveness of health systems is still at an early stage*' [43,p 4]. Meaningful data for policy making is produced for certain areas

regarding health systems but does not cover all areas systematically [44]. Certain areas such as rare diseases [45] or health system performance assessment – despite the efforts and investments by inter alia DG SANCO – still lack comprehensive and comparative data sets due to lacking or incomparable data at MS level [44].

Overall, the interview partners reflect the mixed discussion on assessment capacities. On the one hand, the ability to compile data at a central level and perform benchmarks – albeit on a limited scale – is regarded to be in place and to be a catalyst for change and mutual learning in some areas (Interview 3, 6, 32). On the other hand, interviewees mentioned several areas where data is still missing or not comparable such as morbidity data, behavioural risk factors (Interview 6), performance indicators for obesity and tobacco policy (Interview 30) or health care quality indicators (Interview 3).

3.2.3. Define an overall strategy for the public health field

European health policy has never been the object of an overall master plan or strategy. Health policy is located within many different Commission Directorates with differencing priorities and tasks, with health often not being the central one [46,p 143]

The major EU document as an output of the DG SANCO's capacity to contour an overall strategy for its actions is the 2007 White Paper "Together for Health" which outlined a new overall vision for the health sector for the period 2008–2013 [47]. The White Paper embraced four underlying principles: I) Shared health values, II) Health is the greatest wealth, III) Health in all Policies and IV) EU's voice in global health. In order to implement the principles and objectives laid out in the Strategy, the Commission established the Second Programme of Community Action in the Field of Health 2008–2013. At the time of writing (December 2014) it remains unclear how the expired EU Health Strategy will be followed up.

The White Paper has been prepared by an extensive consultation process over several years. At the start, a communication on a health strategy has been launched in 2000 [48]. This has been followed by a reflection process on enabling good health for all initiated in 2004 by Commissioner Byrne [49]. Finally a discussion document was launched in 2006 to retrieve comments for the plans of an overall health strategy [50]. The White Paper has devised actions for public health that go beyond the remit of DG SANCO as such (and thereby the scope of this analysis) by including strategies to address wider determinants of health by seeking collaboration with other sectors and partners inside and outside the EC.

According to the literature, the inclusion of the principles of 'Health in all Policies' and 'Health is wealth' by DG SANCO has been welcomed in the White Paper as an attempt towards more inter-sectoral strategies and collaboration. However, given the limited resources linked to its implementation by means of the Action programmes administered by DG SANCO with the help of the Executive Agency, doubts have been raised on whether the strategy would be designed to accomplish the aligning of health policies at EU level across other policy streams [51]. Moreover, the White Paper has been assessed as very broad in nature and not able to address areas of action where EU level coordination could bring added value. In fact, the Mid-term evaluation of the 2nd Action programme suggested that a *'clearer framework for action'* is needed [52,p 207f].

The White Paper [47] has been rated as important policy output by a majority of the interview partners [14]. Moreover, a few interview partners share the perception that a common vision is lacking (Interview 12, 25, 29). One interviewee relates this to a current absence of individual visionary leaders within DG SANCO compared to the 1990s and early 2000s (Interview 25).

3.2.4. Capacities to formulate policies and strategies

Europe works best on public health when it gets a specific point and a specific network of people that it can mobilise. That Europe works best when the data is meaningful (Interview 09)

DG SANCO has proven its capacities to develop sectoral policies and strategies on some specific issues of health policy. Next to the few policy areas where DG SANCO has been leading to come to hard law output namely on blood safety, tobacco, cross-border health care, or infectious diseases, in many other areas DG SANCO pursues soft law measures due to the limited scope for legislation in the Treaty. An array of 'new governance' tools is used such as recommendations, conclusions, communications, action plans, programmes, green and white papers, platforms or coordination tools. The policy areas subject to new governance tools applied by DG SANCO that are discussed in the retrieved literature and interviews include ehealth [53,54], organ donation [55], alcohol [56,57], mental health [58,59], rare diseases [45], cancer [28], patient safety [60,61] and quality of care [62]. However, EU policies affecting considerably public health and health systems are made by other DG's as well (see Section 3.1 and Fig. 1). Examples include the regulation of cancer causing agents led by DG Environment, licensing of health professionals by DG Markt or the safety regulations of medical devise by DG Enterprise.

The capacities to formulate cross-sectoral public health and health system policies are less positively rated in the literature and by interview partners. Issues like health promotion, health inequalities, or Health in all Policies are seen as less effective because of the interference with other EU priorities and policy sectors on dossiers such as alcohol or nutrition [63,64]. The interview data adds that the respective EU infrastructure – the set-up and mandate of DG SANCO – is not designed to support the cross-sectoral nature of these policies (Interview 29). In addition, it is acknowledged that these policies on average need more time to evolve (Interview 01).

. . .if one looks what is happing currently at EU level in the area of health. There is nothing which is not dealt with. [. . .] albeit in many areas European action is unnecessary. In this respect, this is a suggestion to reduce and focus on concrete things (Interview 12, own translation)

The capacity to formulate policy entails the element of priority setting [65] – the ability to determine which policies and its respective goals should be focused on by DG

SANCO. Within its portfolio, firstly, DG SANCO has moved from managing specific vertical programmes to set out wider public health topics of health promotion, health protection, health inequalities and health in all policies in its action programmes [66–68]. Secondly, DG SANCO is adding health care systems challenges to its portfolio such as cross-border care, quality of care, patient safety or performance of health systems since the start of the millennium. However, critics have been raised regarding the mismatch between the abundance of objectives and resources in the 1st Action Programme [69] and the EU Health Strategy [64].

3.2.5. Capacities to budget, manage and implement

The health programme has never seriously got traction and we have been fighting, since it was created, in 2002 people have been saying it's underfunded. And you know what we haven't money to increase it, in fact it's even less than it was. (Interview 32)

The main implementing tool of DG SANCO's health policies is the Action Programme for Health which provides finances and more explicit and practical formulation of established policies. The Action Programme has been administered by the Executive Agency for Health and Consumers (EAHC) (now Consumers Health and Food Executive Agency – CHAFEA) since 2005. Nevertheless, the capacities to budget, manage and implement health policies are perceived as weak so far.

First, DG SANCO's budget is rated to be very small with respect to three issues. The budget is only a small fraction compared to what MS spend on health [44]. Moreover, the budget operated is small in terms of what other DGs spend on health such as for example DG Research and Innovation (RTD). Additionally, the budget is limited when taking into consideration the large number of topics it is expected to support (see section above on priority setting).

Second, while there has been severe criticism on the management and implementation of the 1st Action Programme [70,71], the situation may have improved as regards the 2nd Action Programme due to the establishment of the Executive Agency providing opportunities for enhanced guidance for beneficiaries on selection and management procedures. However, the mid-term evaluation calls for improved support and guidance during the design and dissemination phase by CHAFEA but at the same time raises concerns about the feasibility of such enhanced support as the work load of project officers was estimated to be already high [72]. Moreover, difficulties in disseminating projects' results have not only been a concern for the Action Programme's projects but also for health related projects funded under the EU FP5 and FP7 too [73–75]. Meanwhile to support dissemination, CHAFEA has started to organise Regional conferences and Media Cluster meetings on specific issues such as rare diseases, HIV/AIDS, patient safety and quality of care results or transplantation and blood diffusion. Results of multiple projects funded by the Action Programme in the dedicated areas are presented for information and exchange to public health experts, journalists, national public authorities and policy makers [74].

Third, the assessment regarding the capacities for implementation varies. On the one hand, the reliance on project structure for financing actions seems to be counter-effective for implementation which often needs sustained commitment to be successful as has been pointed out for cancer [76] or health monitoring [77]. Since the majority of health policy areas are implemented via soft law measures, DG SANCO is largely reliant on MS action to translate its policy goals into concrete actions [78]. As a potential solution to implementation difficulties, DG SANCO is increasingly reliant on Joint Action financing. Joint Actions focus on sustained implementation by involving national competent authorities as partners, and ensuring commitment by higher percentages of co-financing by the MS [72].

Interview data on the theme of implementation stresses the relevance of the ability to enact hard law for effective policy making (Interview 6, 8, 15, 18) despite the limited scope of the health mandate. Several interviewees acknowledged that soft law tools for implementation have impacts but they are less obvious (Interview 2, 32). Others corroborated that the capacity to implement is constrained by a lack of priorities (Interview 12). In this regard, according to an interview partner, the fragmented application of the Health Strategy is exacerbating the lack of capacities for implementation (Interview 3). Finally, concerns by McHale [58] with regard to EU mental health policy might be valid for other policy initiatives in so far that *'the EU initiatives [.] may have helped to raise awareness but there is the risk that many of these initiatives simply work at a rhetorical level' [p 618].*

3.2.6. Capacities to evaluate

DG SANCO has achieved mechanisms and procedures to receive feedback on the progress of its health policies. Examples include mid- and end-term evaluations of policy actions, status, progress and implementation reports or (Eurobarometer) surveys after defined time periods laid down in policy documents. Often, data collection and the measuring of results are tendered to external providers, commissioned and financed through the Action Programmes. Alternatively, reports may be based on data provided by MS to DG SANCO and produced by DG SANCO staff itself. In addition, the various platforms, fora, expert or working groups in the specific areas of health policy are a potential source of feedback to the EU [79]. All these sources for feedback could serve as the foundation of evaluation.

The degree to which DG SANCO is capable of codifying the feedback into lessons learned – into the adjustment of policies – remains less clear from the examples in this review. On the one hand, severe criticism on the management of the 1st Action Programme [71] has led to the development of the Executive Agency. Moreover, evaluations of previous Action Programmes have informed the design and management of the new 3rd Action Programme. On the other hand, when it comes to health policies it seems that recommendations are sometimes not taken into account in the development of follow-up policies. In fact, a number of cases, strategies or action plans come to an end without a (immediate) successor (Health Strategy, mental health pact). There are also instances when reports conclude it would be too early for a sound analy-

sis and recommend another moment of review eventually procrastinating actions to be taken up from the evaluation.

4. Discussion

Previous work has strongly focussed on the development of competences for EU health policy making elucidating the drivers for increased relevance and scope of EU activities in the field of health [12,24]. In this study, the UNDP Capacity Assessment Framework has been applied to analyse the current state-of-the-art concerning different functional capacities of DG SANCO regarding its mandate for public health and health systems that may be used to better understand its policy making. This capacity assessment of DG SANCO has been based on a review of literature and EU policy documents, complemented and advanced by an interview study with European health experts.

Overall, the DG SANCO has gradually improved its capacities for public health and health systems policies linked to additional institutional capacities. From an organisational perspective, DG SANCO has: (1) established capacities to engage with stakeholders; (2) developed different capacities to assess various health issues of which some still lack a sustainable basis; (3) not defined a clear strategy providing direction for its actions; (4) demonstrated the capacity to formulate polices and strategies in some areas of its policy making; (5) needs to improve priority setting capabilities, (6) established limited capacity to budget, manage and implement policies and (7) capacities to collect information potentially useful for evaluating its own progress. In light of the policy cycle process, results suggest that DG SANCO's capacities to assess a situation, set the agenda and decide on a concrete policy are to some extent established, whereas, the capacities for implementation and evaluation are perceived as less developed.

In light of these findings, two observations are worth mentioning. First, difficulties in the setting of priorities and defining inter-sectoral actions are also common in national political arenas. Various forms of priority setting activities for example establishing principle frameworks for priority-setting [80] or health targets [81], despite being institutionalised in selected European countries, had meagre influence on the practice of national health policy making. Similarly, inter-sectoral policy making for health at national level had little success because of 'administrative silos' [82,p 336]. DG SANCO has committed to clearer priorities for its action in the design of the new 3rd EU Health programme which is claimed to be more targeted and with clearer indicators towards its priorities [83]. However, results need to be awaited because the political realties may require taking on new responsibilities and the impact of new financing mechanism such as Joint Actions on the level of implementation in MSs are not clear yet.

Second, limited implementation capacities of DG SANCO need to be balanced against the institutional constraints at EU level described above in Section 3.1. The Treaty mandate in Article 168 gives only delineated legislative powers to the EC. Moreover,DG SANCO is supposed to pursue coordination among MS by means of soft-laws and incentive measures, while the EC in general predominantly pursues regulatory policies [21,84]. DG REGIO's cohesion policy is an exception here because the structural fund's direct health sector investments have co-funded considerably health infrastructures in various central European countries [85]. This implies that DG SANCO's policies in the area of public health and health systems are largely contingent to the discretion of MSs for implementation and application at national level [78] in the multi-level governance structure of the EU [86].

Despite these constraints, our findings propose that improvements in the effectiveness of DG SANCO's (now DG SANTE) policies can be achieved in the existing institutional framework. Prioritising a set of specific policies – within DG SANTE remit – with the greatest EU added value is likely to yield concrete results. The use of limited EU resources has shown to be capable of redirecting existing national infrastructures, funding and policies to be in line with, for example, EU social policy goals [87], cancer [28] or infectious diseases policy [30]. This might ultimately halt the ongoing addition of new topics to the Commission's health policy portfolio which are not reflected in its resource allocation. The EU health policy field has been so far an uncompleted area with 'blank spots' where the EU's added value is marginal [24]. And a 'patch work' of responsibilities exists at the EC with other DGs leading on certain health policies [10]. The reputation of DG SANTE should not be defined by the number of health topics that they are dealing with but whether they can make a difference to existing national activities on selected health issues.

This research provides an initial assessment of DG SANCO's functional capacities rather than an in-depth analysis to devise a comprehensive capacity development response. In order to be able to develop needed capacities, future work would have to collect information from inside DG SANTE to better understand the processes and structure in place to produce certain outcomes. Moreover, a follow-up analysis could cover other institutions with capacities for health policy making at EU level taking into account the spreading of health responsibilities across EU institutions and additional capacities at other international organisations. This would help to understand better how institutions can match each other's resources, responsibilities and expertise in potential future co-operations as called for above.

5. Conclusions

Since the inclusion of the health mandate in the Maastricht Treaty, much attention has been devoted to how the mandate can be enlarge, concretise and empowered. Notwithstanding a strong health mandate is crucial for the development of capacities, in the current Euro-sceptic mood this seems not very likely [75]. This study has focused on a number of functional capacities within DG SANCO. Results suggest that some capacities seem to be rather well established while others need to be strengthened. Our results indicate that improvements are possible in the given institutional arrangements; more concentration should be devoted to develop capacities at EU level for more effective policy making for health. This is a point of attention for DG SANTE to continue to work on, not only in

light of the EC's 'Better Regulation' agenda but as well to contribute to a healthier place for European citizens.

References

[1] Polidano C. Measuring Public Sector Capacity, 28. World Development; 2000. p. 805–22, http://dx.doi.org/10.1016/S0305-750X(99)00158-8.

[2] Parsons W. Not just steering but weaving: relevant knowledge and the craft of building policy capacity and coherence. Australian Journal of Public Administration 2004;63:43–57, http://dx.doi.org/10.1111/j.1467-8500.2004.00358.x.

[3] Davis G. Policy capacity and the future of governance. In: Davis G, Keating M, editors. The Future of Governance. St Leonards, New South Wales: Allen & Unwin; 2000. p. 230–42.

[4] LaFond AK, Brown L, Macintyre K. Mapping capacity in the health sector: a conceptual framework. International Journal of Health Policy and Management 2002;17:3–22, http://dx.doi.org/10.1002/hpm.649.

[5] Goodman RM, Speers MA, Mcleroy K, Fawcett S, Kegler M, Parker E, et al. Identifying and defining the dimensions of community capacity to provide a basis for measurement. Health Education & Behavior 1998;25:258–78, http://dx.doi.org/10.1177/109019819802500303.

[6] Hawe P, Noort M, King L, Jordens C. Multiplying health gains: the critical role of capacity-building within health promotion programs. Health Policy 1997;39:29–42, http://dx.doi.org/10.1016/S0168-8510(96)00847-0.

[7] Jänicke M. The political system's capacity for environmental policy. In: Jänicke M, Weidner H, editors. National Environmental Policies A Comparative Study of Capacity-Building. Berlin: Springer; 1997.

[8] Aluttis C, van den Broucke S, Chiotan C, Costongs C, Michelsen K, Brand H. Public health and health promotion capacity at national and regional level: a review of conceptual frameworks. Journal of Public Health Research 2014;3, http://dx.doi.org/10.4081/jphr.2014.199.

[9] Hervey TK, McHale JV. Health Law and the European Union. Cambridge: Cambridge University Press; 2004.

[10] Mossialos E, Permanand G, Baeten R, Hervey TK. Health Systems Governance in Europe – The Role of European Union Law and Policy. Cambridge: Cambridge University Press; 2010.

[11] Steffen M. Health Governance in Europe – Issues, challenges and theories. New York: Routledge; 2005.

[12] Lamping W, Steffen M. European Union and health policy: the chaordic dynamics of integration. Social Science Quarterly 2009;90:1361–79, http://dx.doi.org/10.1111/j.1540-6237.2009.00659.x.

[13] Greer SL. Uninvited Europeanization neofunctionalism and the EU in health policy. Journal of European Public Policy 2006;13:134–52, http://dx.doi.org/10.1080/13501760500380783.

[14] Rosenkötter N, Clemens T, Sørensen K, Brand H. Twentieth anniversary of the European Union health mandate: taking stock of perceived achievements, failures, and missed opportunities –a qualitative study. British Medical Centre Public Health 2013;1:3, http://dx.doi.org/10.1186/1471-2458-13-1074.

[15] UNDP. Capacity Assessment Practice Note. New York: United Nations Development Programme; 2008.

[16] Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. Qualitative Health Research 2005;15:1277–88, http://dx.doi.org/10.1177/1049732305276687.

[17] Mayring P. Qualitative Content Analysis. Forum: Qualitative Social Research; 2000. p. 1.

[18] Denzin NK. The Research Act in Sociology. Chicago: Aldine; 1970.

[19] Webb EJ, Campbell DT, Schwartz RD, Sechrest L. Unobtrusive measures: Nonreactive Measures in the Social Sciences. Chicago: Rand McNally; 1966.

[20] European Union treaty of Lisbon 2010/C83/01. Luxembourg: Official Journal of the European Union 2010.

[21] McKee M, Hervey T, Gilmore AB. Public health policies. In: Mossialos E, Permanand G, Baeten R, Hervey T, editors. Health Systems Governance in Europe- The Role of European Union Law and Policy. Cambridge: Cambridge University Press; 2010. p. 231–81.

[22] Greer SL, et al. Everything you always wanted to know about the European Union health policies but were afraid to ask. Copenhagen: WHO Europe on behalf of the European Observatory on Health Systems and Policies; 2014.

[23] European Union. Website, About the EU; 2016. Last accessed on January 5, 2017 from https://europa.eu/european-union/about-eu_en.

[24] Greer SL. The Politics Of European Union Health Politics. Maidenhead: Open University Press; 2009.

[25] Domoulin M. The European Commission 1958–72 - History and Memories of an Institution. Luxembourg: European Union; 2014.

[26] Bussiere E, Dujardin V, Dumoulin M, Ludlow P, Brouwer JW, Tilly P, editors. The European Commission 1973-86 History and Memories of an Institution. Luxembourg: European Union; 2014.

[27] Greer SL. Glass half empty: the Eurozone and internal market overshadow the health effects of Maastricht. The European Journal of Public Health 2013;23:907–8, http://dx.doi.org/10.1093/eurpub/ckt163.

[28] Trubek L, Nance M, Hervey TK. The construction of healthier Europe: lessons from the fight against cancer. Wisconsin International Law Journal 2009;26:804–43.

[29] Sørensen K. Health literacy: the neglected European public health disparity. Maastricht: Department of International Health. Maastricht University; 2013.

[30] Greer SL. The european centre for disease prevention and control: hub or hollow core? Journal of Health Politics, Policy and Law 2012;37:1001–30, http://dx.doi.org/10.1215/03616878-1813817.

[31] The Lancet. What does the EU do for its citizens' health? (Editorial), 365. The Lancet; 2005. p. 189–90.

[32] Koivusalo MT. The future of European health policies. International Journal of Health Services 2005;35:325–42, http://dx.doi.org/10.2190/X120-PJFG-V1AN-E2J7.

[33] Smith KE, Fooks G, Collin J, Weishaar H, Gilmore AB. Is the increasing policy use of Impact Assessment in Europe likely to undermine efforts to achieve healthy public policy? Journal of Epidemiology and Community Health 2010;64:478–87, http://dx.doi.org/10.1136/jech.2009.094300.

[34] European Parliament and Council of the European Union. Regulation (EC) No 1338/ on Community statistics on public health and health and safety at work; 2008. p. 2008. Brussels : O.J. L354/70.

[35] European Observatory on Health Systems and Policies; 2014. Webpage.

[36] Langel SJ. An essential resource in European health policy. Health Affairs (Millwood) 2013;32:743, http://dx.doi.org/10.1377/hlthaff.2013.0222.

[37] OECD. Health at a Glance: Europe 2012. OECD Publishing; 2012.

[38] OECD. Health at a Glance: Europe 2012. OECD Publishing; 2010.

[39] Verschuuren M, Gissler M, Kilpeläinen K, Tuomi-Nikula A, Sihvonen A-P, Thelen J, et al. Public health indicators for the EU: the joint action for ECHIM (European Community Health Indicators & Monitoring). Archives of Public Health 2013;71(1):12-.

[40] European Commission. Commission Decision 2012/C 198/06 of 5 July 2012 on setting up a multisectoral and independent expert panel to provide advice on effective ways of investing in health. Official Journal of the European Union 2012;C198/7.

[41] Council of the European Union. Council Conclusions: Towards modern, responsive and sustainable health systems. Luxembourg: Council of the European Union; 2011.

[42] Council of the European Union. Council Conclusions: Innovative approaches for chronic diseases in public health and healthcare systems. Brussels: Council of the European Union; 2010.

[43] European Commission. Communication from the Commission on effective, accessible and resilient health systems. Brussels: European Commission; 2014.

[44] McCarthy M. Targets for health in Europe: the debate continues. The European Journal of Public Health 2012;22:455–6, http://dx.doi.org/10.1093/eurpub/cks082.

[45] Taruscio D, Trama A, Stefanov R. Tackling rare diseases at European level: why do we need a harmonized framework? Folia Medica (Plovdiv) 2007;49:59–67.

[46] Graham I. European health policy: working within a paradox. Journal of Allied Health 2004;33:139–43.

[47] Commission of the European Communities. White Paper. Together for Health: A Strategic Approach for the EU 2008–2013. Brussels: Commission of the European Communities; 2007.

[48] European Commission. Communication from the Commission on the health strategy for the European Community (COM(2000) 285final). Brussels: European Commission; 2000.

[49] Byrne D. Enabling Good Health for all –A reflection process for a new EU health Strategy. Brussels: European Commission, DG Health and Consumer Protection; 2004.

[50] European Commission. Health in Europe: A Strategic Approach - Discussion Document for a Health Strategy. European Commission, DG Health and Consumer Protection: Brussels; 2006.

[51] McCarthy M. The European health strategy—so what next? The European Journal of Public Health 2008;18:554–6, http://dx.doi.org/10.1093/eurpub/ckn117.

[52] Public Health Evaluation and Impact Assessment Consortium. Mid-Term Evaluation of the EU Health Strategy 2008–2013 - Final Report. Bologna: Public Health Evaluation and Impact Assessment Consortium; 2011.

[53] Iakovidis I, Purcarea O. eHealth in Europe: from Vision to Reality. Studies in Health Technology and Informatics 2008;134:163–8.

[54] Olsson S, Lymberis A, Whitehouse D. European Commission activities in eHealth. International Journal of Circumpolar Health 2004;63:310–6.

[55] Farrell AM. Adding value? EU governance of organ donation and transplantation. European Journal of Health Law 2010;17:51–79, http://dx.doi.org/10.1163/157180909X12604572349683.

[56] Gordon R, Anderson P. Science and alcohol policy: a case study of the EU Strategy on Alcohol. Addiction 2011;106(Suppl. 1):55–66, http://dx.doi.org/10.1111/j.1360-0443.2010.03324.x.

[57] McKee M. A European alcohol strategy. Will the opportunity be missed? British Medical Journal 2006;333:871–2, http://dx.doi.org/10.1136/2Fbmj.39003.629606.BE.

[58] McHale JV. Mental health law and the EU: the next new regulatory frontier? Medical Law Review 2011;19:606–35, http://dx.doi.org/10.1093/medlaw/fwr030.

[59] Kelly BD. The emerging mental health strategy of the European Union: a multi-level work-in-progress. Health Policy 2008;85:60–70, http://dx.doi.org/10.1016/j.healthpol.2007.06.005.

[60] Watson R. European Commission urges governments to reduce hospital acquired infections. Britsh Medical Journal 2008;337:a3059, http://dx.doi.org/10.1136/bmj.a3059.

[61] McHale JV. Patient safety and professional practice across European borders. British Journal of Nursing 2010;19:520–1.

[62] Vollaard H, van de Bovenkamp HM, Vrangbæk K. The emerging EU quality of care policy: from sharing information to enforcement. Health Policy 2013;111:226–33, http://dx.doi.org/10.1016/j.healthpol.2013.05.004.

[63] Rayner M. European Union policy and health. British Medical Journal 1995;311:1180–1.

[64] Birt C. Response to 'The European health strategy—so what next?'. The European Journal of Public Health 2008;18:556–7, http://dx.doi.org/10.1093/eurpub/ckn118.

[65] Forest L, Mulcahy S. First Things First – A handbook of Priority Setting in Extension. Madison, WI: University of Wisconsin- Extension, Division and Staff Development; 1976.

[66] Ståhl T, Wismar M, Ollila E, Lahtinen E, Leppo K, editors. Health in All Policies: Prospects and potentials. Helsinki: Finish Ministry of Social Affairs and Health; 2006.

[67] Menke R, Streich W, Rössler G, Brand H. Report on Socio-Economic Differences in Health Indicators in Europe – Health inequalities in Europe and the situation of disadvantaged groups. Bielefeld, Germany: Institute of Public Health, NRW; 2003.

[68] European Commission. The health status of the European Union - Narrowing the health gap. Luxembourg: European Communities; 2003.

[69] Bosch X. Europe streamlines approach to public-health research. Lancet 2003;361:1191, http://dx.doi.org/10.1016/S0140-6736(03)12971-6.

[70] RANDC orporation. Interim Evaluation of the Public Health Programme 2003–2008. Cambridge: RAND EUROPE; 2007.

[71] European Court of Auditors. The European Union's Public Health Programme (2003–2007): An effective way to improve health? Special Report No 2//2009. Luxembourg: European Court of Auditors; 2009.

[72] Public Health Evaluation and Impact Assessment Consortium. Mid-Term Evaluation Health Programme (2008–2013) - Final Report. Bologna: Public Health Evaluation and Impact Assessment Consortium; 2011.

[73] Charlesworth K, Galsworthy MJ, Ernst K, Irwin R, Wismar M, McKee M. Health research in the European Union: over-controlled but under-funded? European Journal of Public Health 2009;21:404–6, http://dx.doi.org/10.1093/eurpub/ckp212.

[74] Consumers Health and Food Executive Agency (CHAFEA). Health Programme Events; 2014. Website, Last accessed on December 22, 2014 from http://ec.europa.eu/chafea/health/events_en.html.

[75] Brand H. A new agenda for health in Europe. European Journal of Public Health 2014;23:904–5, http://dx.doi.org/10.1093/eurpub/ckt192.

[76] Illman J. Funding cuts for public health projects in europe may affect international cancer effort. Journal of the National Cancer Institute 2004;96:428–9, http://dx.doi.org/10.1093/jnci/96.6.428.

[77] Achterberg PW, Kramers PG, van Oers HA. European community health monitoring: the EUPHIX-model. Scandinavian Journal of Public Health 2008;36:676–84, http://dx.doi.org/10.1177/1403494808096182.

[78] Clemens T, Michelsen K, Brand H. Supporting health systems in Europe: added value of EU actions? Health Economics, Policy and Law 2014;9:49–69, http://dx.doi.org/10.1017/S1744133113000273.

[79] Senden L. Soft law, self-regulation and co-regulation in European law: where do they meet? Electronic Journal of Comparative Law 2005:9.

[80] Sabik L, Lie R. Priority setting in health care: lessons from the experiences of eight countries. International Journal for Equity in Health 2008;7:4, http://dx.doi.org/10.1186/1475-9276-7-4.

[81] Van Herten LM, De Water HPAV. Health policies on target? Review on health target setting in 18 European countries. The European Journal of Public Health 2000;10:11–6.

[82] Leppo K, Ollila E, Pena S, Wismar M, Cook S. Lessons for policy makers. In: Leppo K, Ollila E, Pena S, Wismar M, Cook S, editors. Health in All Policies Seizing opportunities, implementing policies. Helsinki, Finland: Ministry of Social Affairs and Health; 2013. p. 325–38.

[83] European Parliament and the Council of the European Union. Regulation (EU) No 282/2014 on the establishment of a third Programme for the Union's action in the field of health (2014–2020). Official Journal of the European Union 2014;L 86/1.

[84] Majone G. Regulating Europe. New York: Routledge; 1996.

[85] Watson J. Health and Structural Funds in 2007–2013: Country and regional assessment. Summary Report. European Commission, DG Health & Consumers; 2017. Last accessed on January 5 2017 from http://euregio3. eu/pages/existing-knowledge-learning-using-sf-health-investments/publications-policy-documents/.

[86] Marks G, Hooghe L. European integration from the 1980: state-centric v. multi-level governance. Journal of Common Market Studies 1996;34, 341-337.

[87] Verschraegen G, Vanhercke B, Verpoorten R. The european social fund and domestic activation policies: europeanization mechanisms. Journal of European Social Policy 2011;21:55–72, http://dx.doi.org/10.1177/0958928710385733.