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European Chemicals Agency and Good Governance

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Abstract

Today, the European Union deals with complex issues other than political, demanding issues call for a more technocratic approach. One major problem clearly affecting human health and the environment is the use of chemical substances. For that reason, Regulation No. 1907/2006 (REACH Regulation) was adopted and the European Chemicals Agency was established. The aim of this paper is to make an overview of the REACH Regulation, a really complex piece of legislation and make its major parts clear. Plus, the contribution of the Agency to the ultimate EU target of Good Governance is briefly examined.

Keywords: European Chemicals Agency (ECHA), REACH Directive, Good Governance, European Legislation

1. Introduction

More than ever, nowadays, the European Union becomes more than a political organization. The integration process reaches specific issues; the Union deals with complicated issues that cover all scientific fields and is obliged to formulate a policy that contributes to what it is called "good governance". This is a major political target for the European Union and is explicitly cited in the White Paper for European Governance¹ published by the Commission concerning all fundamental changes needed for achieving the above mentioned target.

The aim of the good governance is based on the development of five principles that will promote a more democratic way of governance; openness, participation, accountability, effectiveness and coherence. The EU institutions shall act in a more open way taking into consideration all possible actors. Furthermore, the policies adopted shall be decided and implemented in a more effective way; the EU institutions shall clarify their roles and competences within the Union system for the avoidance of confusions. The actions taken on behalf of all EU and national institutions must be clear and consistent. Most of the times,

¹ European Governance White Paper Brussels, 25-7-2001 COM (2001) 428 final.

decisions need to be taken in complex issues where all participating institutions shall ensure coherence.

As it is stated in the White Paper "effective decision-making also requires the combination of different policy instruments to meet Treaty objectives. In making full use of the Treaty, the Commission could also make proposals to take the Union's objectives forward through enhanced co-operation". The Commission White Paper emphasizes in one key word: co-operation. That practically means that the formal EU institutions, especially those that have the major decision making competence, shall co-operate with all possible partners. In that sense, the co-operation shall be broad; not only with the traditional partners, like the Member States, but also other bodies more specialized in scientific and technical issues shall be included.

Scientific and technical experts shall play an important role in advising the Commission in the field of their expertise. As a result, bodies of experts were established for assisting the Commission in relevant issues; those bodies are widely known as "agencies". This paper will focus on the one of the newest and most complicated agencies, the European Chemical Agency. The aim and objectives, the structure and the organization, the scope and practical impact to the EU policy will be underlined. As it is a new-established agency (Regulation No. 1907/2006), useful results can be drawn about its contribution to the "good governance" target.

2. Agencies in general

At that point it will be useful to refer to the concept of European agencies in general, their distinctions and their role in the whole European Union system. It is difficult to be defined what an agency is; it consists of experts, specialists in technical and scientific matters that deal with usual and most of the times, complicated issues that arise and hence, they contribute to the accomplishment of the best possible result. Therefore, an organizational level must be secured, to a certain extent, for the achievement of co-operation between the member of the agencies themselves and between the agency and the European institutions.

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Another fundamental issue for a body to be characterised as an agency is the independence that it enjoys in a certain degree.² Most of the agencies have legal personalities and legal representatives so they can act in a more efficient way. That is the major difference among the agencies and other types of committees; the role of the agencies to assist the EU institutions in scientific and technical matters gives them the capability to take actions that are not directly legally supervised by the EU institutions. Nevertheless agencies are not totally independent. As they are not recognized as official EU institutions, agencies have the powers that the official institutions allow them to have. In that sense, agencies depends the field of their competence on the formal EU institutions.

The establishment of all European agencies is based on EC legislation. This piece of legislation is based on the EC Treaty; hence there is a strong connection between the Community institutions and the agencies in the sense that if the establishment of an agency is not relied on a Community statute, it cannot be characterised as Community agency. Nevertheless there is no specific provision concerning agencies in either EU or EC Treaty. As a result the general Article 308 of the Treaty establishing the European Community (TEC) which is related to the power of the Council to take the appropriate measures for the promotion of the common market policy if those powers have not been provided by the Treaty. Besides Article 308 TEC, the establishment of agencies can be based on other provisions³ more relevant to their concept.

Although agencies are established by secondary EU legislation and the powers that they have are also mentioned in that piece of legislation according to a Treaty provision, the European Court of Justice (ECJ) stated in the *Meroni* judgment⁴ that the delegation of power is not permitted in the situations that the delegatee can make actual policy choices instead of the delegating authority. However, the decision-making powers of the regulatory agencies are not interpreted by the Commission⁵ and scholars⁶ as being policy making. In that sense the

² R. van Ooik, "The Growing Importance of Agencies in the EU: Shifting Governance and the Institutional Balance", in D. M. Curtin and R. A. Wessel (eds.), *Good Governance and the European Union. Reflections on Concepts, Institutions and Substance* (Intersentia 2005), pp. 125-152.

³ Both the European Network and Information Security Agency and the European Chemical Agency are based on article 95 TEC.

⁴ Case 9/56, *Meroni & Co., Industrie Metallurgische, S.p.A. vs. High Authority of the ECSC*, [1957-58] ECR 133 and Case 10/56, *Meroni & Co., Industrie Metallurgische, S.p.A. vs. High Authority of the ECSC*, [1957-58] ECR 157.

⁵ European Governance White Paper Brussels, 25-7-2001 COM (2001) 428 final, at p. 24.

⁶ D. M. Curtin, "European Legal Integration: Paradise Lost?", in D. M. Curtin, J. M. Smits, A. Klip, J. McCahery (eds.), *European Integration and Law* (Intersentia 2006) at p. 18.

delegation of powers to the agencies by the EU institutions is in practice in conformity with ECJ judgement in *Meroni*.

3. Division⁷ of the agencies

According to their function, the European agencies can be distinguished in categories. This categorisation of the agencies is not always possible due to complex issues that arise with regard to their role and their position in the European Union system. Example of this complexity is that on one hand the Commission subcategorises agencies in executive and regulatory agencies. Executive agencies are established by Council Regulation 58/2003 and are responsible for the management of certain Community programmes under the control of the Commission. Regulatory agencies can take individual decision in specific areas; they have decision-making power that is given by the Treaty.⁸ Regulatory agencies are autonomous but their actions are limited by the legislature. On the other hand, according to their position in the European Union system, the Commission distinguishes the agencies to Community agencies, Common Foreign and Security Policy agencies, police and judicial co-operation in criminal matters agencies and EURATOM agencies.⁹

Following the division made by the Commission the European Chemicals Agency can be categorized as a regulatory Community agency.

4. The European Chemicals Agency (ECHA)

4.1 Legal Basis

⁷ In academic papers different division can be found; R. van Ooik, "The Growing Importance of Agencies in the EU: Shifting Governance and the Institutional Balance", *supra* note 2, M. Everson, G. Malone, L. Metcalfe, A Schoutatanag, "The Role of Specialised Agencies in Decentralising EU Governance" (Report Presented to the Commission, 2001), D. Geradin, "The Development of European Regulatory Agencies: what the EU should learn from American experience", 11 *Columbia Journal of European Law* (2004).

⁸ European Governance White Paper Brussels, 25-7-2001 COM (2001) 428 final, at page 24.

⁹ Europa, "Agencies of the EU", available on the internet at <u>http://europa.eu/agencies/index_en.htm</u>.

The legal basis for the Regulation No. 1907/2006 (hereinafter REACH Regulation) is Article 95 TEC. As it is explicitly mentioned in the preamble of the REACH Regulation the establishment of the European Chemicals Agency is legally based on Article 95 TEC following the procedure laid down in Article 251 TEC. Article 95 is chosen as the ECHA by applying the REACH policy will promote the EC objectives set out in Article 14 TEC as part of the general internal market policy. In particular, paragraph 3 of Article 95 applies to that case because of the nature of the ECHA which concerns health, safety, environmental and consuming protection.

4.2 Aim and objectives

The fundamental aim of this new-adopted chemical strategy is, as it is cited on Article 1 (1) of the REACH Regulation, the assurance of a high level protection of human health and the environment from the risks that arise from the use of chemical substances. Furthermore, the other basic is related to the internal market policy of the EU; through the REACH policy the chemical industry of will be enhanced.

To be more specific the objectives¹⁰ can be set as follow:

- Protection of human health and the environment
- Maintenance and enhancement of the competitiveness of the EU chemicals industry
- Prevention of fragmentation of the internal market
- Increased transparency
- Integration with international efforts
- Promotion of non-animal testing
- Conformity with EU international obligations under WTO

Those objectives must always be in conformity with the overall framework of sustainable development; this general EC objective is referred to Article 2 TEC

"The Community shall have as its task...to promote throughout the Community a harmonious, balanced and sustainable development of economic activities..."

¹⁰ European Commission Environment Directorate General, *REACH in brief*, October 2007.

The objectives mentioned above not only include the basic aims of the REACH policy but also promote the activities of the Community described in Article 3 (1) TEC concerning the contribution to health and environmental protection, the internal market and the strengthening of the competitiveness of the chemical industry.

For the achievement of those aims and objectives the ECHA was established. In that sense the general mission of the agency is to manage and co-ordinate the whole REACH policy. The ECHA is responsible for providing scientific and technical support to the Community institutions, the Member States and industries by guiding and advising them in issues that are related to chemical substances. As it is described in the official website¹¹ the mission of the Agency is:

- Manage and carry out technical, scientific and administrative aspects of REACH
- Ensure consistency at Community level in relation to these aspects
- Provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall under REACH
- Manage IT based guidance documents, tools and data bases
- Support national helpdesk and run a helpdesk for registrants
- Make information on chemicals publicly accessible

To sum up, ECHA plays a very significant role in the achievement of the REACH objectives. Not only as a scientific body but also as an institution with decision-making power, the ECHA is responsible for the consistency needed for the best possible result. Therefore, the high amount of money that is invested on this agency (estimated that the overall cost fails in the range of 71.635.588 million euro for 2009)¹² is totally presumable taking into consideration the role of the ECHA in a very sensitive area of interest as the human health and environment protection.

4.3 Organisation of the Agency

¹¹ The official website of the European Chemical Agency <u>http://echa.europe.eu</u>

¹² ECHA, "Budget 2009 and Establishment plan 2009", available on the internet at <u>http://echa.europa.eu/doc/about/organisation/mb/mb_68_2008_budget_establishment_plan_2009.pdf</u>

In this part the way that the Agency is organized will be examined with a brief analysis of the role of each body. According to Article 76 of the REACH Regulation the Agency consists of the following elements:

- A Management Board
- An Executive Director
- 3 Committees (a Committee on risk assessment, a Committee on socio-economic analysis and a Member State Committee)
- A Forum for exchange of information on enforcement activities
- A Secretariat
- A Board of Appeal

The Management Board is comprised of 27 members chosen by the Member States, 6 members maximum in total are selected by the European Commission (up to 3 of those members may come from interested organizations without voting rights) and 2 independent members that are appointed by the European Parliament. It is the basic body of the Agency, responsible for the adoption of the financial plan and the work programme for the actions of the Agency as well as of the annual report and other administrative documents.

The Executive Director is the legal representative of the Agency. He has the general management responsibility of the Agency with the obligation to report to the Management Board.

The Committee on risk assessment is responsible for assessing the danger of a chemical substance for human health and the environment, estimating if the restrictive measures suggested by the Member States or the Agency are sufficient for the abatement of the risk for human health and estimating proposal of the Member States for the classification of chemical substances as toxic. The members of this Committee are appointed by the Management Board after nominations by the Member States.

The Committee on socio-economic analysis is responsible for assessing the technical issues of the alternatives associated with a chemical substance from a socio-economic perspective. Plus the Committee is competent on evaluating the restrictions suggested by the Member States and the Agency in relation to the social and economic field. The process for the selection of the member is the same as in the Committee on risk assessment.

The Member States Committee consists of members selected by the Member States with each Member State to appoint one member to the Committee. It can be characterized as the more "political" Committee of the Agency comparing to the other two because of the role to decide in case of differences of opinion on draft decisions proposed by the Agency or the Member States concerning identification of substances of very high concern.

The Forum for exchange of information on enforcement activities coordinates a network of competent authorities of the Member States for the enforcement of the REACH Regulation. It is a body of high political importance as it proposes plans and projects for the better harmonization in the REACH policy and also develops working methods for the implementation in practice. Plus, the Forum is the bridge between the Agency and the industrial factors. The members of the Forum are appointed by the Member States as in the Member State Committee.

The Secretariat is responsible for the bureaucratic part of the Agency by working on the registration and evaluation process. Plus it is responsible for supporting the Committees and the Forum and ensuring the appropriate coordination between them. It works under the leadership of the Executive Director.

The Board of Appeal is the competent body to decide on appeals against decisions taken by the Agency. Despite being a body of the Agency, the Board must decide independently; both natural and legal persons have the right to appeal before the Board. It consists of a Chairman and 2 members that are appointed by the Management Board after the proposal of the Commission. The decisions of the Board can be appealed before the Court of First Instance.

By analyzing briefly the bodies of the Agency it is clear that there is a balance of power between the Commission and the Member States in the structure of the bodies. Although the agencies are generally independent, they may receive influence from both EU institutions (Commission) and Member States according to their interests. The Committees (especially the Member State Committee) and the Forum of the Agency are more influenced by the Member States as they are in charge for the selection of the members. The Commission pre selects the members of the Board of Appeals for achieving the most objective result possible.

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5. The REACH Regime

Regulation (EC) No 1907/2006 of the European Parliament and of the Council does not only establish the European Chemicals Agency but also the legal framework which the ECHA is supposed to administer. This legal framework concerns the registration, evaluation, authorization and restriction of chemicals within the Community and it is abbreviated REACH.

5.1 Why a new Community chemical regime?

The reason for the Community to adopt new chemical regime was basically to improve research and innovation and make the internal market more competitive and improve safety for human health and environment (Article 1 REACH Regulation). The old regime was based on division between so-called "existing" substances and "new" substances, where the old or "existing" substances were exempt from tests before they were placed on the marked while the "new" substances had to be tested. That lead to a barrier to innovation of new substances and favored the development and use of "existing" substances over new ones¹³.

The biggest change with the new chemical regime (REACH) is that no longer will there be made distinction between "existing" substances and "new" substances. There is however a transitional phases for the REACH Regulation and it will not be fully implemented until 2018 (Title XV)¹⁴. The biggest innovation with REACH is that all substances fall under the Regulation unless explicitly exempted (Article 2), other important innovation under REACH is that the public authorities are not longer responsible for risk assessment but the enterprises themselves under the administration of the ECHA according to procedure lay down in the REACH Regulation.

5.2 How does the REACH regime work?

5.2.1 Scope of REACH

¹³ European Commission Environment Directorate General, *REACH in brief, supra* note 10, at p. 3.

¹⁴ HSE, "REACH", available on the internet at <u>http://www.hse.gov.uk/reach/timeline.htm</u>.

The REACH regime has a wide scope. According to Article 1 and 2 of the Regulation all substances are covered by the REACH whether manufactured, imported, used as intermediates or placed on the market , either on their own, in preparations or in articles, unless they are explicitly exempted. The substances which are exempted are mainly those substances where other equivalent legislation applies, for example medicinal products (Article 2 (5)), food additive and flavoring in foodstuff (Article 2 (5)(b)(i) and (ii)), but also radioactive substances (Article 2 (1)(a)), substances which are stationed in the Community for transit or re-exportation (Article 2 (1)(b)), non-isolated intermediates (Article 2 (1)(c)), waste (Article 2 (2)) and substances used for the interest of defence (Article 2 (3)). Furthermore substances that generally present very low risk, like some minerals and water and substances of that kind are exempted (see for example Article 2(7)).

5.2.2 Registration

Registration of substances at the ECHA is one of the most important functions of the REACH regime. Article 5 states:

"Subject to Article 6, 7 and 23, substances on their own, in preparation or in articles shall not be manufactured in the Community or placed on the marked unless they have been registered....."

That is, the general rule is that substances which fall under the scope of the REACH regime which have not been registered at the ECHA are unlawfully placed on the market. According to Article 6 and 7 of the REACH Regulation the duty to register applies to all manufacturer or importer of a substance, either on its own or in preparations, in quantities of 1 ton or more per year. The above mentioned natural or legal persons shall register the substances at the ECHA. The registration involves handing in technical dossier and chemical safety report for the substances (Article 10 and 14). After the manufacturer or importer has submitted that information to the ECHA it will checks and evaluates if the registration is in conformity with the REACH Regulation (Article 20 and 41), but it must be emphasized that though the ECHA has given the substances the green light for registration is does not imply any form of approval of the assessment or use of the substance¹⁵. Evaluation of the ECHA of a substance which is being

¹⁵ European Commission Environment Directorate General, *REACH in brief, supra* note 10 at p. 9.

registered can lead to authorization or restriction process under REACH (see below). In the end it should also be mentioned that it is possible to get exemptions because of R&D purposes (Article 9) and there are rules in place under the REACH Regulation for data sharing for registering purposes in order to avoid unnecessary animal testing (Title III).

5.2.3 Authorization

The main rule is that substances in Annex XIV of the REACH Regulation are considered to be of high risk and manufacturer, importer or downstream user¹⁶ can not place them on the market without authorization (Article 55-56). The Annex is not an exhausted list and it is under constant review via comitology by the Member State Committee of the ECHA (Article 59). If a manufacturer, importer or downstream user wants to place a substance which is in the Annex on the marked it needs authorization from the Commission (Article 60). Before the Commission takes a decision The Committees for Risk assessment and Socio-economic Analysis of the ECHA provides expert opinions on the application (Article 64).

5.2.4 Restriction

Substances which fall under Annex XVII of the REACH Regulation may not be placed on the market within the Community unless it's used for R&D purposes (Article 67). Where there is an unacceptable risk to human health or the environment arising from a substance which is going to be placed on the market and the substance does not fall under the Annex, the Commission can take a decision to amend the Annex and in effect restrict the substance from the internal market, after having received opinion from the Committee for Risk assessment and Committee for Socio-economic Analyses of the ECHA (Article 68-73).

6. Review of the decisions of the ECHA

The main decision making power of the ECHA which are binding on legal and natural persons concerns the registration process in the REAH Regulation.

¹⁶ A natural or a legal person established within the Community who uses a substance, either on its own or in a preparation, in the course of his industrial of professional activities, cf. Article 3 (13) REACH Regulation.

6.1 Administrative review

Article 89 of the REACH Regulation establishes a Board of Appeal within the ECHA. The members of the Board are appointed by the Management Board on the basis of a list of candidates proposed by the Commission. According to Article 89 (3) the members shall be appointed on the basis of "the relevant experience and expertise in the field of chemical safety, natural science or regulatory and judicial procedures..". Further qualification requirements are taken by the Commission by decision based on Article 133 (3). The term of office is five years and they shall be independent and not bound by any instructions (Article 90 (1) and (2)), they shall not perform any other duties in the ECHA (Article 90 (3)).

According to Article 92 any natural or legal person may appeal against a decisions addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former, however only certain decisions of the ECHA can be appealed to the Board of Appeal. The following decisions are subject to appeal to the Board of Appeal (Article 90):

- decisions concerning exemptions from the general obligation to register, for the purpose of R&D (Article 9);
- 2. decisions concerning rejection of registration, because of lack of information or failure to complete registration within deadline (Article 20).
- 3. decisions concerning enforcement proceedings by the ECHA because of non compliant with the procedure in Article 27 and 30 regarding sharing of data between registrants for the purpose of avoiding unnecessary testing, for example on animals, and
- decisions concerning substance evaluation according to Article 51.
 An appeal lodged in accordance with Article 91 has suspensive effect.

6.2 Judicial review

According to Article 94 (1) of the REACH Regulation an action may be brought before the Court of First instance or the Court of Justice (ECJ) in accordance with Article 230 TEC, contesting a decision taken by the Board of Appeal. Also according to Article 94 (1) an action may be

brought against the Court of First Instance or the ECJ in accordance with Article 230 TEC contesting a decision of the ECHA where there is no right of appeal to the Board of Appeal. Furthermore according to Article 94 (2) an action may be brought against the ECHA for failure to act in accordance with Article 232 TEC.

The ECHA has a legal personality (Article 100) and the ECJ has jurisdiction in any dispute relating to compensations derived from contractual liability (Article 101). Furthermore the ECJ has jurisdiction in any dispute relating to compensation derived from non-contractual liability (Article 101) and that means that in a case where the European Courts annuls an ECHA decision or a Board of Appeal decision, a demand for may be brought before the ECJ for damages which the annulled decision has caused.

7. Enforcing the REACH regime

According to Article 121-127 of the REACH Regulation it is up to the competent authority of the Member States to enforce the REACH regime. The ECHA does not directly enforce the REACH regime however the ECHA has a Forum for Exchange of Information on Enforcement (The Forum) which works closely with the competent authority of the Member States in enforcing the regime. The Forum for example shall under Article 77 (4) coordinate and evaluate harmonized enforcement projects and joint inspections, coordinate exchange of inspectors, identify enforcement strategies as well as best practice in enforcement, develop working methods and tools of use to local inspectors, developing an electronic information exchange procedure etc.. The competent authorities have access to ECHA databases which they can use to monitor the compliance of manufacturers, importers and downstream-users with the REACH regime, for example if manufacturers or importers have registered their substances at the ECHA (Article 20 (4)) and if substances have been authorized or restricted within the Community.

8. Good governance and the ECHA

As mentioned before in this paper the Commission published a White paper on European governance in 2001¹⁷. The aim of the paper was to enhance good governance within the EU. The paper distinguishes between five principles underpinning good governance which according to the White paper will reform governance within the Institutions of the EU. Those principles are openness, participation, accountability, effectiveness and coherence. This part of the paper will examine if the ECHA fulfills those principles. However because the REACH Regulation established a new chemical regime with a transitional period that won't end before 2018 it will not be possible to examine the principles of effectiveness and coherence simply because there is not enough experience on the impact of the new REACH regime and the action of the ECHA. For the above mentioned reasons only the principles of openness, participation and accountability will be examined in this paper.

8.1 **Openness**

It is difficult to assess if this principle applies to the ECHA for the same reasons as the principle of effectiveness and coherence because little experience has been with the activity of the ECHA. But by scrutinizing the provisions of the REACH Regulation it is possible to formally test the ECHA conformity with the principle of openness.

Article 109 states:

"To ensure transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in preparations or in articles which is not of a confidential nature"

Furthermore Article 118 states that Regulation (EC) No 1049/2001 of the European Parliament (EP) and the Council regarding public access to EP, Council and Commission document shall apply to the ECHA, and Article 119 states that certain information held by the ECHA shall be made publicly available over the Internet.

8.2 Participation

¹⁷ European Governance White Paper Brussels, 25-7-2001 COM (2001) 428 final.

After analysing the structure of the ECHA it is clear that the principle of participation is reinforced. Both EU institutions and the Member States in co-operation with individual experts participate in that agency. The Member States are more involved into the committees and the Forum while the Commission in co-operation with the Member States is responsible for the creation of the Management Board where the European Parliament also participates. Therefore, this wide participation makes the agency more effective and more convincing for its function.

8.3 Accountability

For simplification the examination of the accountability of the ECHA in this paper will be divided between on the one hand, internal accountability or those instruments that hold the ECHA accountable on a day to day basis and on the other hand, external accountability or those instruments that hold the decisions, budget or the workings of the ECHA accountable.

8.3.1 Internal accountability

According to Article 78 REACH Regulation the Management Board plays a big role in the internal accountability of the ECHA. It adopts each year a general report, working program, the final budget according to Article 96 and internal rules and procedures of the ECHA. The Management Board exercises disciplinary authority over the Executive Director. Furthermore the Board adopts financial rules after having consulted the Commission (Article 99). Finally the ECHA is under obligation to state the reasons for all decisions it makes according to Article 130.

8.3.2 External accountability

Concerning the judicial and administrative review of the ECHA decisions and its liability, they are cited in Chapter 2 where these issues are dealt with. But the external accountability of the ECHA does not stop there. The budget is under supervision of the Commission, EP, the Council and the Court of Auditors and the budget has to be approved by the EP according to Article 96-97 REACH Regulation. The Regulation (EC) No 1073/1999 of the EP and the Council concerning investigations conducted by the European Anti-Fraud Office applies to the ECHA (Article 98). Every five years the ECHA has to submit to the Commission a report on the

operation of the REACH Regulation and every three years it has to submit to the Commission a report on the status of implementation and the use of non-animal testing (Article 117). Finally the Commission has a strict review of the ECHA regarding the transitional period of the REACH Regulation under Article 137.

9. Conclusions

Although the establishment of the agencies is based on Treaty provision, there is no official recognition of the agencies on the Treaty. The articles that constitute the legal basis of the agencies are interpreted in such a way that gives to the official EU institutions the opportunity to overrule de facto the *Meroni* case, especially in the case of regulatory agencies which have decision-making power. A possible solution could be given in the Treaty of Lisbon with the recognition of the agencies or the inclusion of provisions related to the delegation of power to agencies. The agencies are not recognized as an official EU institution in the Treaty of Lisbon and there are no special provisions concerning the delegation of powers to bodies like the agencies.

Nevertheless, agencies are mentioned in articles in the Treaty of Lisbon and their contribution to good governance is emphasized. In Article 9, 15, 16, 21 of the consolidated version of the Treaty on the European Union (TEU) and article 298 of the consolidated version of the Treaty on the functioning of the European Union (TFEU), the agencies are presented as an inextricable part in the Union system that is necessary for the achievement of good governance. It is arguable if this change is sufficient as the judgement of the *Meroni* case is still active. More strong decisions shall have been taken; the recognition of institutions of such importance like the agencies and the extent that they can have power shall have been explicitly mentioned in the Treaty of Lisbon.

Before making final remarks about if the Agency fulfills the good governance's criteria as they lay down in the Commissions White paper on European governance it must be emphasised again that the ECHA has only be examined by the principle of openness, participation and accountability for the reasons stated in Chapter 8. It must also be emphasized that the Agency is new and there is no conclusive experience on how the ECHA works in practice. However by

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analyzing the provisions in the REACH Regulation which concern those above mentioned principles it must be concluded that at least in theory the Agency fulfills the criteria's laid down in the Commissions White paper. The REACH Regulation provides open administration, participation of the Member States in the administration and decision making process. Furthermore the decisions of the ECHA are secured administrative and judicial review under the REACH Regulation and finally the ECHA has in place instruments that should guarantee the general accountability of the Agency.

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