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ADMINISTRATIVE LAW OF THE EUROPEAN UNION

ADJUDICATION

CO-REPORTERS ON ADJUDICATION

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How to read this report

This report concerns administrative adjudicatory procedures in the European Union.[1] The executive summary briefly presents our overall findings. Part I discusses our three most significant findings: adjudicatory procedure differs in each of the six sectors studied; Commission procedures are inquisitorial rather than adversarial; and a strong trend has emerged in favor of requiring Commission decisionmakers to provide procedural protections for private parties. Part II presents a brief summary of procedures in the six sectors. A detailed summary of procedures in those six sectors (approximately 120 pages in length) is available from the co-reporters. The full sectoral reports (about 400 pages in length) are also available from the co-reporters.

Executive Summary

This report concerns adjudicatory procedures of the European Commission and other executive agencies of the European Union. (Sometimes adjudicatory procedures are referred to as "decision-making" procedures and we will use these terms interchangeably). The report does not consider adjudicatory procedures at the Member State level nor judicial review issues. It concerns decisions of specific rather than general applicability. The report describes adjudicatory procedures in six sectors: competition, trade remedies, trademarks, food safety, pharmaceutical licensing, and state aids.

Part I. of the report discusses three overall themes. First, there is no single adjudicatory procedure. The procedures differ in numerous respects in the six sectors. Thus EU adjudicatory procedures are quite different from those employed in the US or the UK where there are procedural templates that describe most administrative adjudicatory procedures. (Part I.A.)

Second, EU adjudicatory procedure is inquisitorial rather than adversarial. In this respect it differs sharply from most administrative procedures employed in the US and UK A notable feature of inquisitorial systems is that hearings are considered part of the investigation, rather than a phase that occurs after investigation is completed. As a result, there is no separation of functions between staff members engaged in investigation and staff members who provide hearings. Hearings are conducted by the same personnel who are responsible for the investigation (competition cases are an exception). Rights usually associated with administrative hearings in common law systems (such as cross-examination) are not present. The purpose of the hearing is to provide a forum for the presentation of additional information or analysis, rather than a process resulting in a decision. (Part I.B.)

Third, an evolving body of case law from the European Court of Justice (ECJ) and the Court of First Instance (CFI) provides substance to the rights of defense and of good administration. These procedural rights are comparable in many respects to US procedural due process or UK natural justice. Indeed, there has been a marked convergence between US and UK procedures, on the one hand, and EU procedures on the other. Thus private litigants enjoy the rights to receive notice of the Commission's position, to inspect the Commission's file, to lodge objections (often in an oral hearing), to receive a decision within a reasonable time, and to receive a statement of reasons for the Commission's action. (Part I.C.)

Finally, Part II. consists of a brief summary of the procedures in the six sectors.

[1] We are grateful for the research assistance of Gabe Grossman and for the editorial assistance of Nancy Landreville and Eleanor Fox.

Table of Contents

I. ADJUDICATION IN THE EUROPEAN COMMUNITY: GENERAL THEMES

Introductory note: This report concerns adjudicatory decisions taken at the European Commission level, not those taken at the Member State level. The report is intended as a practical rather than a theoretical account of EU administrative procedure. Its target audience is lawyers who represent clients in disputes before the Commission, particularly lawyers from outside the European Union.

The great majority of regulatory schemes involving private companies are administered by Member States (in many cases pursuant to legislation adopted at the Community level). This report considers the relatively few regulatory schemes administered at the Commission level.

For this purpose, the term "Commission" includes not only the Commission itself but also European "agencies" empowered by the Council to play key roles in making individualized decisions. Agencies include the Office for the Harmonization in the Internal Market (OHIM) which administers the trademark law; European Agency for the Evaluation of Medical Products (EMEA) which plays a key advisory role in pharmaceutical licensing; and European Food Safety Authority (EFSA) which carries out important functions in food safety regulation.[2]

The report considers the procedures at the administrative level, not issues relating to judicial review by Community courts. The emphasis is on procedural protections available to private parties in connection with these proceedings.

The report concerns decisions of *specific* applicability (that is, adjudication) rather than decisions of *general* applicability (that is, rulemaking), although in some cases the Commission's final decision takes the form of a rule rather than an individualized decision. It does not consider the impact of the European Constitution since it is uncertain at this time whether the Constitution will be ratified and enter into force. If the Constitution does become effective, its provision on administrative justice will broaden and constitutionalize procedural rights already recognized in various regulations and court decisions.[3]

Part I of this report consists of a discussion of three general themes that emerge from the sectoral reports we have received as well as our own research about European administrative law.

- Commission-level adjudication has no common procedure. The procedure is different in each of the six sectors we have studied (Part I. A.) Part II summarizes the key features of the procedures employed in each of the six sectors.

[2] See Geradin 2005.

[3] Art. 41(2) of the Charter of Fundamental Rights of the European Union (2000), which would be embodied in the EU Constitution, provides a right to "good administration." Good administration means that every person has a right to have his or her affairs handled impartially, fairly, and within a reasonable time; every person has a right to be heard before any measure which would adversely affect him or her is taken; every person has a right of access to his or her file, while respecting the legitimate interests of confidentiality and professional and business secrecy; and the administration is obligated to give reasons for its decision. See Chiti 2004, 43-44. While the right to "good administration already exists as a principle of Community law, see Nehl 1999, 13-39, the Constitution would probably extend administrative hearing rights to certain sectors in which they are not yet fully recognized.

- Commission-level adjudication is inquisitorial in nature rather than adversarial. (Part I. B.)

- While administrative procedure is guided by general principles of Community law (such as the right to defense, the right of good administration, and the duty to state reasons), a trend has emerged in the decisions of Community courts in favor of providing additional procedural protections for private parties engaged in Commission-level adjudication. (Part I. C.)

A. EC adjudicatory procedures in the six sectors differ from each other.

This sub-section points out the wide differences between the adjudicatory procedures in the six sectors we studied: competition, trade remedies, trademarks, food safety, pharmaceutical licensing, and state aids. Part II of this report briefly summarizes what we have learned about the adjudicatory procedures in the six sectors we have studied.[4]

The administrative procedure that is provided in each of the six sectors has little in common with the others. Each has its own foundation in the Treaty or in statutes, each is administered by a separate bureaucratic structure, each has its own procedural regulations, each has its own historical development, each has a different relationship with decisionmaking processes in the Member States.

In this respect, Commission adjudicatory procedure is quite different from US or British procedure because in those countries there is a broadly applicable template for administrative adjudication. In the US, most administrative adjudication consists of a trial-type hearing conducted by a hearing officer (often an administrative law judge) who writes a proposed decision; the final decision at the agency level is rendered by the agency head or heads.[5] In the UK, a multi-member tribunal performs most administrative adjudication. But EC administrative procedure does not fit any pre-established template. It must be studied sector-by-sector. There is no Administrative Procedure Act (as in the US), no Tribunals and Inquiries Act (as in the UK).

Adjudicatory procedures vary depending on whether they are triggered by an initial application for a benefit (merger applications, trademark applications, food licensing, pharmaceutical licensing, state aids) or whether they are triggered by administrative action that could lead to a sanction or deprivation of an existing status (competition, trade remedies, trademark oppositions, changed circumstances or sanctions in pharmaceutical cases). In two areas (state aids, food licensing), the decisional process is more political rather than adjudicatory in nature.

[4] A detailed summary of procedures in those six sectors (approximately 120 pages in length) is available from the co-reporters. Similarly, the much lengthier full sectoral reports (about 400 pages in length) are available from the co-reporters.

[5] Obviously, American adjudicatory procedures vary greatly, particularly the many adjudications that are not covered by federal or state APAs. Nevertheless, most of them cluster around the norm described in the text. Many such proceedings do not employ trial-type procedures such as oral testimony and cross-examination; instead the parties engage in written presentations followed by oral argument.

Each sector follows its own investigative procedure which enables the relevant directorate of the Commission to inform itself about the facts and circumstances of a dispute.[6] In competition cases, the Directorate General for Competition (DG COMP) conducts an intrusive investigation that can include unannounced site visits and inspections of non-business premises including residences.[7] In other cases, such as trade remedies, food safety, state aids, and pharmaceutical licensing, the Commission or independent agencies such as EFSA conduct an active investigation based primarily upon documents furnished by the parties or by experts in the field. In the trademark area, OHIM conducts an initial trademark search and thereafter relies on complaining parties or Member States to provide the necessary data. In the area of state aids, the Commission's investigation consists primarily of requesting information from Member States.

In some areas, such as competition and trademarks, the parties to a dispute have broad access to all documents in the Commission's file, other than material protected by confidentiality (such as informers or business secrets) or internal Commission documents.[8] However, non-parties (such as complainants) have more limited access to files. In other areas, the parties have access only to non-confidential versions of the documents in the files (trade remedies). In state aids, neither Member States nor private parties have access to the Commission's file.

Oral hearings are routinely allowed upon request in some areas (competition, trade remedies, pharmaceutical licensing), occur rarely in some areas (trademarks), and are never held in other areas (food safety,[9] state aids).[10] In many cases, a written, rather than an oral exchange,

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[6] Generally in American administrative law, an agency has broad and unconstrained powers to subpoena documents as part of an investigation. While subpoenas must be judicially enforced, the agency needs only to show that the documents in question are relevant to a subject the agency is authorized to investigate. See American Bar Association 2003 pp. 47-57.

[7] In American administrative law, an agency generally must secure a warrant to inspect business premises, but the requirements for obtaining such warrants are much less demanding than in criminal cases. Marshall v. Barlow's Inc., 436 US 307 (1978).

[8] In American administrative law, neither the APA nor due process requires agencies to provide discovery of documents in their files. See American Bar Association 2003, ¶4.03. However, many agencies have adopted rules permitting parties to discover material in the agency's files. Alternatively, such information is available on demand to anyone (including third parties) under the Freedom of Information Act (FOIA). However, under FOIA exceptions, an agency is not required to disclose pre-decisional intra- or inter-agency memoranda. 5 USCA §552(b)(5); See NLRB v. Sears, Roebuck & Co., 421 US 132 (1975). In addition, an agency is not required to disclose various documents compiled for law enforcement purposes, such as those that might disclose the identity of a confidential source. Id. §552(b)(7).

[9] In the area of genetically engineered foods and novel foods, applications are filed at the Member State level and it would be necessary to survey Member State procedures to ascertain whether any hearings are granted. We have not undertaken such a survey.

[10] By comparison, US administrative adjudication normally calls for oral presentation of testimony by witnesses followed by cross-examination. See Administrative Procedure Act, 5 USCA 556(d) which provides: "A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts." Nevertheless, relying on the last clause of the provision just quoted, the courts allow agencies to dispense with cross-examination when credibility is not at stake, such as in cases involving only differences of expert testimony. See American Bar Association 2003, ¶5.08. An oral hearing can be denied

furnishes all the process a party receives. In state aids, there is an opportunity for interested parties to submit written comments (to which Member States can reply)[11] and to engage in informal meetings with the staff, but there is no oral hearing.

Generally oral hearings are conducted by the team of case handlers who are investigating the application or sanction. [12] The exception is in competition cases, where the hearing officer specializes in conducting hearings (and dealing with data requests and confidentiality issues), but who does not conduct investigations. Hearings officers in competition cases are responsible to the Commissioner, not to DG COMP. In general, the case handlers who conduct hearings do not write proposed decisions. In competition cases, however, the hearing officer files a report on whether the procedural rules have been observed. This report may also contain substantive observations on the Commission's internal draft decision.

The ultimate Commission decision generally takes for the form of an individualized decision addressed to the parties. However, in some cases (trade remedies and most food safety cases) the decision takes the form of a broadly applicable rule.[13] An individualized decision must state reasons that are sufficient to allow for judicial review and must contain discussion of both law and facts, but the necessary detail of the statement of reasons varies with the circumstances of the case.[14]

Generally there is no opportunity for administrative reconsideration. However, in trade remedy cases, after one year parties may apply for an interim review of the definitive measures imposed by the Commission. In trademark cases, OHIM provides is a board of appeals to reconsider the agency's initial decisions.

The relationship between decisions at the Community level (Commission-level adjudication and judicial review in Community courts) and decisions at the Member State level (Member State administrative agencies and courts) varies as between the six sectors. In each

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entirely if there are no disputed issues of fact. See, e.g., Weinberger v. Hynson, Westcott & Dunning, Inc., 412 US 609 (1973) (upholding summary judgment procedure at Food & Drug Administration). An oral hearing can also be denied in cases involving claims for money or benefits or initial licensing when "a party will not be prejudiced thereby." APA §556(d), last sentence. .

[11] Reg. 659/1999, Arts. 6(1), 20(1).

[12] As discussed below, in American practice, adjudicatory hearings are generally subject to separation of functions, so that the hearing officer (generally referred to as an administrative judge or AJ) has not played any adversary role in respect to the pending case. In cases covered by the APA, the hearing officer (referred to as an administrative law judge or ALJ) engages exclusively in hearing cases and never conducts investigations. ALJs cannot receive ex parte communications from other agency staff members with respect to "facts in issue." ALJs work for the agencies for which they decide cases but cannot be supervised by staff members who engage in adversary functions. See American Bar Association 2003, ¶¶10.05, 10.10.

[13] In American practice, adjudicatory disputes are resolved by a decisional document produced by the agency heads or heads. The decision is individualized and addressed to the parties. APA §556(b).

[14] In American practice, the APA requires a statement of findings of fact, conclusions of law, and reasons for discretionary decisions. APA §557(c); American Bar Association 2003, ¶6.021. So- called post-hoc rationalizations (reasons supplied by the agency at the judicial review stage are not allowed). Due process also requires a statement of reasons even though the APA does not apply. Id. ¶6.021 n.7.

case, the comitology process provides input opportunities for Member States even if they are not engaged in the formal decisional process. Thus in the competition area, enforcement is divided between the Commission and competition authorities and courts in the Member States, although Member States must follow the law established at the EU level. In pharmaceutical licensing, under the centralized process, licensing occurs at the Commission level but under the decentralized process, it occurs at the Member State level. In trademarks, licensing of community trade marks occurs at the Commission level but Member States license trademarks enforceable within that State. A large amount of trademark litigation occurs in courts of the Member States. In the case of food safety, most regulation is at the Commission level. In the case of novel foods, applications are lodged in a Member State which performs the initial assessment, though the final decision occurs at the Commission level. In the areas of trade remedies and state aids, decisionmaking is lodged exclusively at the Community level.

B. Commission procedures are inquisitorial rather than adversarial.

In EU adjudicatory procedure, a hearing is often provided, but the nature of the hearing is quite different from those that typically occur in the US or UK The procedures are also quite different from *droit administratif* countries (such as France, Germany, or Italy). In the latter countries, the law provides for relatively little formal procedure at the administrative level, but specialized administrative courts furnish in depth review of the administrative action.[15]

In the US model, the investigative stage and the adjudicative stage *are separate*. First, the agency staff conducts an investigation and decides to issue a complaint (in the case of violations of law) or to reject an application (in cases that have been triggered by an application for some benefit or status). Then the target of the complaint (or the rejected applicant) is furnished a *hearing before an impartial and previously uninvolved administrative judge* (hereinafter referred to as an "AJ"),[16] followed by a final decision made by the agency head or heads.[17] Judicial review on the administrative record is almost always available but the reviewing court's powers are constrained. The administrative hearing is *adversarial in nature* and it is similar to a judicial trial.[18] In the UK, an tribunal (the members of which were not previously involved in the case)

[15] Bignami 2005, 260, 266-69. The administrative courts generally receive new evidence and entertain new objections to the administrative decision. Nevertheless, the administrative courts tend to be quite deferential to the administration.

[16] In cases covered by the federal Administrative Procedure Act, the AJ is an administrative law judge (ALJ). An ALJ works for the agency for which the ALJ decides cases but is hired according to a strictly defined procedure. ALJs enjoy a series of procedural protections for their independence provided by statute. See American Bar Association 2003, ch. 10.

[17] See APA §557(b); American Bar Association 2003, ¶6.03.

[18] Some extremely large systems of administrative adjudication in the US do not fit the adversary model. In Social Security Administration adjudication (which mostly concerns applications for disability benefits), the SSA is not represented by counsel. The ALJ is responsible for representing the agency, safeguarding the interests of the applicant (especially if the latter is not represented by counsel), and then deciding the case. This inquisitorial approach was approved by the US Supreme Court in Richardson v. Perales, 402 US 389 (1971). Similarly, the Court upheld a provision prohibiting the payment of more than $10 to an attorney for a claimant for veterans' benefits, stating that Congress was not required to follow adversarial procedures, at least in cases of benefit determinations. Walters v. Ntl. Ass'n of Radiation Survivors, 473 US 305 (1984). In addition, administrative adjudication is often much less adversarial than civil or criminal litigation. For example, AJs are not supposed to sit back and serve as umpires while the lawyers

provides the hearing at which a party can challenge an administrative determination. The tribunal is independent of the agency that made the adverse decision; judicial review is on the record and judicial power is constrained.

The US model generally provides for a *separation of functions*, meaning that persons who have been adversaries (prosecutors, investigators, or advocates) are not permitted to serve as decisionmakers (either AJ or agency head).[19] In addition, neither outsiders nor adversary staff members are permitted to engage in ex parte communications either with the AJ or the agency heads. Separation of functions is not complete since, in most cases, the AJ is an employee of the agency that has conducted the investigation. However, AJs are organizationally separated from adversaries and generally have considerable de facto independence.

EU administrative adjudication does not follow this adversarial model. Instead the model resembles that of the inquisitorial or civil-law criminal justice system.[20] Inquisitorial criminal law systems vary greatly among the civil law countries, but generally a magistrate judge supervises the investigation by the police and prosecutors and assembles a dossier. The magistrate can dismiss the case at any time. If a criminal case is not dismissed, a judge conducts a trial. The trial is based primarily on the written materials contained in the dossier. There may be oral testimony by witnesses and by the accused, but the judge controls the proceedings and the lawyers who have relatively little to do. *The trial is viewed as the end point of the investigation, not as a separate phase from the investigation*.

EU administrative procedure resembles the inquisitorial criminal law model. The specialized staff members of the relevant directorate of the Commission conduct an investigation of a proposed enforcement action or of an application for a benefit. The investigation concludes with a notice to the target or applicant setting forth the Commission's tentative findings.

At some point in the investigation, a hearing may take place. The same case handlers who conducted the investigation also conduct the hearing. The hearing is viewed as an opportunity for the investigated party to state its side of the case. There is no cross-examination or confrontation of adverse witnesses. The single important exception occurs in competition cases. In competition cases, the hearing is conducted by an independent officer who specializes in presiding at hearings and who has not been involved in the investigation. The case handlers in competition cases are present; they answer questions (and sometimes ask them). The hearing officer in competition cases does not render a substantive decision (although the officer is allowed to make observations on substantive issues). The hearing officer's job in competition cases is to make sure the target's procedural rights are respected.

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run the hearing. Instead, AJs are expected to play an active role in structuring issues and questioning witnesses, or assisting unrepresented parties, whereas such actions are quite problematic for trial judges.

[19] APA §554(d). Note, however, that the APA does not require separation of functions in initial licensing. APA §554(d)(A). In practice, however, agencies frequently separate functions in initial licensing. Many federal adjudicatory schemes are not covered by the APA but the general rules of separation of functions are observed in practice in non-APA adjudication. Due process may require separation of functions in some instances, but the case law is sketchy. See American Bar Association 2003, ¶7.061 n. 76.

[20] See Damaŝka 1986 for a thorough discussion of inquisitorial systems and a comparison to adversarial systems.

The one exception to the generally inquisitorial mode of decision-making occurs in trademark opposition cases; here the responsible agency (OHIM) functions as an impartial arbiter in a dispute between an applicant for a Community trademark and the holder of an existing mark that alleges the new mark would be infringing.[21] Most of the investigation in these cases is left to the parties and the Office resolves the dispute based on the submissions of the opposing party.

C. The trend in favor of providing procedural protections for private parties in EU administrative adjudication.

1. **Overview.** There has been a steady accretion of procedural protections for private litigants engaged in administrative adjudication before the European Commission. These rights concern investigative protections, access to Commission files, adequate notice, the right to some kind of hearing (oral or written), the right to a decision within a reasonable time, and a statement of reasons. These rights are derived from several different sources: i) provisions in the Treaty, ii) regulations applicable to specific sectors, and iii) an evolving body of ECJ and CFI case law that draws on principles of law in Member States.[22] The case law seems similar to the case-by-case evolution of the standards of US procedural due process[23] and of UK natural justice.[24] As a result, there has been a convergence between procedural norms governing adjudication in the US and UK, on the one hand, and the EU on the other.

2. **Early procedural protections and UK accession**. The "right of defense" for parties who are targets of administrative action is a concept that has long been recognized in the law of Member States, particularly France. The right of defense was traditionally also recognized in Community law. However, in earlier years, the rights of defense were rather sketchy by the standards of US or UK law. For example, in competition cases, a target company had a right to notification of the Commission's objections; received a summary of the contents of the Commission's file; had an opportunity to make known its views and provide exculpatory evidence; and had a right to statement of reasons sufficient for the parties and reviewing courts to understand whether a decision was lawful.[25]

These rights have evolved over time, largely through judicial consideration of competition cases. Some commentators believe this was a natural evolution.[26] Others argue that the judicial decisions are, in part, attributable to the UK's accession to the EU treaty in 1973. British commentators criticized Community procedures in competition cases because they fell short of satisfying UK standards of "natural justice." Natural justice is the British analogue to due process and is well established in case law; it includes an unbiased decisionmaker as well as the

[21] Trademark cases also include a form of separation of functions in that officials who participated in one phase of the trademark process (such as an opposition) cannot be the same officials who worked on the earlier application. Members of the Board of Appeals cannot have participated in any prior proceedings.

[22] Schwarze 2004, 969-76; Lenaerts & Vanhamme 1997; Nehl 1999.

[23] See American Bar Association 2003, ch. 2.

[24] See Wade & Forsyth 2004, ch. 12-14.-

[25] Bignami 2005, 259-65.

[26] See generally Nehl 1999.

right to notice, right to know the government's case, and an appropriate, usually oral, hearing.[27] To deal with these objections, the EU changed its procedures and expanded the target's rights, more along the lines of a natural justice model. These changes were reflected first in critical reports by an EU Advocate General (who was British); by critical repots of a Select Committee of the House of Lords; and then in a series of ECJ decisions.[28]

3. **Development of the right of defense through competition cases: *Transocean and Hoffman-La Roche.*** In the *Transocean* case,[29] the ECJ considered the complaint of an association of marine paint manufacturers that had earlier received a five-year exemption under Article 85(3) of the Treaty for various anti-competitive practices embodied in its agreement. The Commission renewed the exemption but inserted a new condition requiring the members to report any common managers or directors between the members and non-member paint companies. The association objected to this condition. It also objected to the fact that the Commission had imposed it without giving the association notice and an opportunity to be heard.

The Commission had notified the association that it would impose conditions on the renewal, including required disclosure of "any change in the participatory relationships of the members," but the association argued that they could not infer from this statement that the Commission intended to impose the actual disclosure requirement, to which they would have strongly objected if they had been so notified.

The Court decided that the failure to give notice of the precise condition violated the requirements of notice and hearing in the competition regulations. "It is clear, however, both from the nature and objective of the procedure for hearings...that this Regulation...applies the general rule that a person whose interests are perceptibly affected by a decision taken by a public authority must be given the opportunity to make his point of view known. This rule requires that an undertaking be clearly informed, in good time, of the essence of conditions to which the Commission intends to subject an exemption and it must have the opportunity to submit its observations to the Commission..."[30] Thus *Transocean* construed the regulations implementing the competition law broadly to assure that a party who is subject to some kind of adverse action is entitled both to adequate notice and to some opportunity to make its objections known.

Transocean might be viewed as based on an interpretation of the regulations. However, in *Hoffmann-La Roche*, the ECJ generalized the requirements of procedural fairness articulated in *Transocean* into broad principles of Community law, at least in cases involving a sanction.[31] In sweeping dictum, the Court declared: "Observance of the right to be heard is in all proceedings in which sanctions, in particular fines or penalty payments, may be imposed, a fundamental principle of Community law which must be respected even if the proceedings in question are

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[27] Bignami 2005, 269-72. See generally Wade & Forsyth 2004, chapters 12-14.

[28] Bignami 2005, 272-79, observing that there was concern in the EU that UK national courts might not enforce Community decisions that failed to meet the standards of natural justice.

[29] Transocean Marine Paint Assoc. v. Commission, Case 17/74, 1974 ECR 1063.

[30] Id. at 1079-80. The Advocate General in *Transocean* was English and had strongly argued that the principles of natural justice applied before European courts.

[31] Hoffmann-La Roche & Co. v. Commission, Case 85-76, 1979-1 ECR 461.

administrative proceedings...The undertakings concerned must have been afforded the opportunity during the administrative procedure to make known their views on the truth and relevance of the facts and circumstances alleged and on the documents used by the Commission to support its claim that there has been an infringement of Article 86 of the Treaty."[32] However, the Court found there had been no breach of this obligation since the target company had seen and inspected all of the documents on which the Commission relied.[33]

4. **Subsequent competition cases—the right to inspect the file.** Later decisions by European courts vindicate the right of the parties in competition cases to inspect all non-confidential documents in the file.[34] Clearly, the right to inspect the file is an essential aspect of the right of defense, particularly given the inquisitorial, document-based approach taken in EU cases.

For example in *Hercules*,[35] the target complained that only selected documents in the Commission's file had been disclosed prior to the hearing. The Court of First Instance said that the Commission was bound by its own regulations to disclose all of the information in the file (other than business secrets or internal commission documents or information disclosed to Commission under a promise of confidentiality). However, the failure to disclose the responses of other targets to the statement of objections was not prejudicial since disclosure could not have led to a different result.[36]

Similarly, in the *Soda Ash* cases,[37] the CFI used the phrase "equality of arms" to describe the target's need for broad access to possibly exculpatory documents in the file.[38] "It is sufficient for it to be established that the non-disclosure of the documents in question might have influenced the course of the procedure and the content of the decision to the applicant's detriment...if the documents in question might...have had a significance which ought not to have been disregarded."[39] "It cannot be for the Commission alone to decide which documents are of use for the defense. Where, as in the present case, difficult and complex economic appraisals are to be

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[32] Id. at 511-12.

[33] A recent application of the right of defense in a competition case occurred in the case of a merger. The Commission breached the right of defense of one of the merger partners (which still exists as a separate entity) by failing to permit it to defend itself. The Commission allowed the merged entity to submit observations but was obliged to allow the constituent company to submit objections also. Thyssenkrupp Stainless GmbH v. Commission, Cases C-65/02P and &-73/02P, [2005] CMLR 16.

[34] For detailed discussion of cases involving access to Commission files, see Lenaerts & Vanhamme 541-49.

[35] S.A. Hercules Chemicals N.V. v. Commission, Case T-7/89, [1991] II-1711, 1739-40, ¶¶53-54. Cases with II before the page number are decisions of the Court of First Instance (CFI), whereas cases with I- before the page number are decisions of the European Court of Justice (ECJ).

[36] Id. at 1740, ¶56.

[37] Solvay SA v. Commission, Case T-30/91, 1995 II-1775.

[38] Id. at 1802, ¶59, quoting *Hoffmann-La Roche*.

[39] Id. at 1806 ¶68.

made, the Commission must give the advisers of the undertaking concerned the opportunity to examine documents which may be relevant so that their probative value for the defense can be assessed."[40] "Having regard to the general principle of equality of arms, which presupposes that in a competition case the knowledge which the undertaking concerned has of the file used in the proceeding is the same as that of the Commission, the Commission's view cannot be upheld in such a situation, [that is, the Commission decides what documents are exculpatory] the rights of defense which the applicant enjoys during the administrative procedure would be excessively restricted in relation to the powers of the Commission, which would then act as both the authority notifying the objections and the deciding authority, which having more detailed knowledge of the case-file than the defense."[41]

Of course, the right of access to the file must be balanced against the obligation to maintain the confidentiality of the business secrets of other undertakings, a right protected by the Treaty. This requires a delicate balancing of the right of defense against the right of confidentiality.[42]

The most recent iteration of the competition regulation builds on the above court decisions. The regulation provides that the Commission shall base its decision only on objections on which the parties concerned have been able to comment.[43] "The rights of defense of the parties concerned shall be fully respected...They shall be entitled to have access to the Commission's file." However, access rights are subject to protection of business secrets, confidential information, internal documents of the Commission and correspondence between the Commission and Member States.[44]

5. **Expansion of the right of defense in competition cases to other sectors**

Subsequent decisions by European courts have expanded the rights of defense to areas other than competition cases.

a. **Trade remedies.** In *NTN Toyo Bearing Co.*,[45] the Advocate General (who was British) urged that the principles of disclosure of files developed in competition law should apply in the area of trade remedies as well, regardless of the absence of regulations that required such disclosure. Although the Court decided the case on other grounds, the anti-dumping regulations

[40] Id. at 1811-12 ¶81.

[41] Id. at 1812, ¶83.

[42] Id. ¶88, allowing access to documents with narrow deletions to preserve confidentiality. See Lenaerts & Vanhamme 541-49 for discussion of balancing access to documents against confidentiality. See also Sison v. Council of the European Union Cases T-110/03, T150-03, T405/03, [2005] 2 CMLR 29 (CFI) (individual whose assets were frozen as part of the fight against terrorism did not have right of access to his file nor to names of states that furnished information about him).

[43] Reg. 1/2003, Art. 27, ¶1.

[44] Id. ¶2.1

[45] Case 113-77, NTN Toyo Bearing Co. v. Council, 1979 ECR 1185. See report of the Advocate General at 1261-65.

were shortly amended, giving the right to all parties on the foreign and domestic sides of trade regulation disputes the right to inspect all the information in the non-confidential files.[46]

In *Al-Jubail Fertilizer,*[47] the views of the Advocate General were endorsed by the Court and became Community law. In that case, the ECJ overturned an anti-dumping duty because of a failure to disclose critical information to a target exporter, including information on European costs of production and prices of fertilizer, which had served as the basis for concluding that the domestic industry had been injured. Although the regulations only required disclosure of information relevant to the defense of the exporters' interests or that the Commission in the investigation uses that, the Court declared that "fundamental rights form an integral part of the general principles of law, whose observance is ensured by the Court. Consequently, it is necessary when interpreting... the regulation to take account in particular of the requirements stemming from the right to a fair hearing, a principle whose fundamental character has been stressed on numerous occasions in the case-law of this court...Those requirements must be observed not only [in penalty cases] but also in investigative proceedings prior to the adoption of anti-dumping regulations which, despite their general scope, may directly and individually affect the undertakings concerned and entail adverse consequences for them."[48]

b. **State Aids.** The Treaty provides for a notice and comment procedure in the area of state aids which is open not only to Member States but to beneficiaries of the aid and to competitors of the aided industry.[49] That provision has been supplemented by regulations that require the Commission to provide an opportunity for comments in doubtful cases.[50]

In the *Netherlands* case,[51] the statement of objections to a state-aid scheme was not sufficiently specific. In addition, the Netherlands was not given an opportunity to make known its position on the consultations the Commission had conducted with organizations of persons that competed with the aided company. As a result, the Member State's right of defense was infringed.[52] Similarly, PTT, the direct beneficiary of the aid in question, was also entitled to be

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[46] Bignami 2005, 284-86.

[47] Al-Jubail Fertilizer Co. v. Council, Case C-49-88, 1991 ECR I-3187.

[48] Id. at I-3241. This decision again reflected the views of the Advocate General that Hoffmann-La Roche applied to anti-dumping cases. Id. at I-3221-22.

[49] Art. 88(2): "If, after giving notice to the parties concerned to submit their comments, the Commission finds that aid granted by a State or through State resources is not compatible with the common market..." The ECJ held that this provision must be followed in all cases in which the Commission finds that a state-aid scheme presents difficulties of deciding whether it is compatible with the common market. As the result, the Court annulled a Commission decision that declined to challenge an aid scheme because a competitor of the aided industry was not invited to submit comments. Cook v. Commission, Case C198/91, 1993 ECR I-2487, 2529-31.

[50] Reg. 659/1999, Art. 6(1).

[51] Kingdom of the Netherlands v. Commission, Joined Cases C-48/90 and C-66/90, 1992 ECR I-565, I-638-40.

[52] Id. ¶¶44-49

heard by the Commission since the contested decision related directly to it and the economic consequences directly affected it. It was entitled to receive a specific statement of objections and a right to be heard.[53] In addition, competitors of an aided entity have a right to a statement of reasons for the Commission's determination that no state aid exists.[54]

c. **Customs duties.** The provision for customs duties is administered by both Member States and the Commission. In the *Technische Universität München* decision,[55] the Court determined that in making such determinations, the competent institutions have a duty to examine carefully and impartially the relevant aspects of the individual case, and the person concerned has a right to make his views known and to have an adequately reasoned decision. In that case, all three of these obligations were infringed.

The issue was whether an electron microscope similar to that which the University wanted to import from Japan was manufactured within the Community. If not, the instrument could be imported duty-free from Japan. A committee of experts that was not shown to be qualified made the decision. "The right to be heard in such an administrative procedure requires that the person concerned should be able, during the actual procedure before the Commission, to put his own case and properly make his views known on the relevant circumstances and, where necessary, on the documents taken into account by the Community institution."[56] In a 2005 case, *Suproco,* CFI annulled a customs decision because the Commission's reasoning was not spelled out in a way that permitted it to be judicially reviewed.[57] Despite the *Technische Universität München* and *Suproco* decisions, the contours of required procedure in customs cases remain uncertain.

6. **Other procedural rights: Attorney-client privilege, confidentiality, decision within a reasonable time, and statement of reasons.**

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[53] Id. ¶¶50-53.

[54] Commission v. Chambre Syndicale Nationale des Enterprises de Transport de Fonds et Valeurs (Sytraval and Brink's France), Case C-367/95 P, 1998 ECR I-1719, ¶¶58-59, 64. In Union Francais de l'Express (UFEX) v. Commission, Case T-613/97, [2006] ECR --, Celex No. 697A0613(01), CFI set aside a Commission decision in a state aid case because of an inadequate statement of reasons. The issue was whether assistance given by the French Post Office to SFMI was state aid and this turned on whether the price charged SFMI covered variable costs and was an adequate contribution to fixed costs. The Commission failed to explain how various approximations of variable cost were made and it required a general summary of the analytical accounting calculations.

[55] Hauptzollamt München-Mitte v. Technische Universität München, Case C-269/90, 1991 ECR 5495. See Schwarze, 2004b at 94-96.

[56] Id. at 5501. See Bignami 2005, 288-89, for discussion of additional cases providing for rights of defense in customs cases.

[57] Suproco NV v. Commission, Case T-101/03, 2005 ECR --, Celex No. 603A0101. In *Suproco,* the CFI annulled a customs decision because of an inadequate statement of reasons. In this case, the court was unable to ascertain how the Commission had made its decision because the various calculations were not spelled out in the record. For example, the Commission found that the figure given by the applicant for the transport cost of Guyana sugar was excessive ($37.20 per ton rather than $85 per ton) but there was no indication how this figure was determined.

a. **Attorney-client privilege.** The Court recognized that a limited form of attorney-client privilege applies to investigations undertaken by the Commission.[58] The privilege applies to written communications between lawyer and client but with two important conditions: i) the communications are made for the purposes and in the interests of the client's right of defense;[59] and ii) they emanate from independent lawyers registered with an EU bar (that is, lawyers who are not bound to the client by a relationship of employment).[60] Whether attorney-client privilege should extend to employed lawyers is the subject of a pending case before the CFI.[61]

b. **Confidentiality.** Article 287 of the Treaty provides that Community personnel "shall be required...not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components." The right to confidentiality often calls for a delicate balance between the rights of the target to examine documents in the file and the confidentiality rights of those who have submitted information to the Commission.[62]

In the *Adams* case,[63] the ECJ held that this obligation runs to individuals as well as to undertakings and applies to information supplied voluntarily by an informant to the Commission under a request for confidentiality. The Commission probably breached the duty by supplying photocopies of redacted documents to the target company from which it was able to deduce the identity of the informant who had supplied the Commission with the documents, although that issue was not decided. The Court held that the Commission breached its duty by failing to warn the informant that he was in serious danger of prosecution by the Swiss authorities for business espionage if he returned from Italy to Switzerland.

The *Akzo* procedure[64] applies in cases where the Commission proposes to disclose information and the company that provided it wants such information to be treated as confidential. The Commission must inform the company of its intention and the reasons for it. If the company objects to disclosure, but the Commission finds that the information is not protected and may be disclosed, that finding shall be stated in a reasoned decision. The company concerned must be notified of the decision and has an opportunity to challenge the decision in the CFI. The information may not be disclosed prior to one week after the decision has been notified.

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[58] Australian Mining & Smelting Europe Ltd. v. Commission, Case 155/79, 1982 ECR 1575, 1611 ¶21-28.

[59] This means that privilege applies to "all written communications exchanged after the initiation of the administrative procedure" though it may be extended to "earlier written communications which have a relationship to the subject matter of that procedure." *AM&S* ¶23.

[60] See Gippini-Fournier 2005 for an extensive discussion of attorney-client privilege in Community law.

[61] Commission v. Akzo Nobel Chemicals Ltd., Case C-7/04 P(R).

[62] See Lenaerts & Vanhamme 541-49.

[63] Adams v. Commission, Case 145/83, 1985 ECR 3539, 3585-91. See Schwarze, 2004b at 96.

[64] See Akzo Chemie BV and Akzo Chemie UK Ltd. v. Commission (1986) ECR p., 1965, ¶29; Art. 9, Commission Decision, May 23, 2001, OJ L 162, 19.6.2001, p. 21).

c. **Decision within a reasonable time.** Both the investigatory phase and the administrative decision phase must be completed within a reasonable time.[65] The reasonableness of a particular delay is appraised in light of the circumstances specific to each case and, in particular the importance of the case for the person concerned, its complexity and the conduct of the applicant and of the competent authorities.[66]

d. **Statement of reasons.** Art. 253 of the Treaty establishes the right to a statement of reasons.[67] "It is settled law that the statement of reasons required by Art. [253] of the Treaty must be appropriate to the nature of the measure in question. It must show clearly and unequivocally the reasoning of the Community authority which adopted the measure so as to inform the persons concerned of the justification for the measure adopted and to enable the Court to exercise its powers of review."[68] The reasons for a decision that follows a well-established line of decisions may be given in summary fashion by reference to those decisions, but the authority must give an explicit account of its reasoning if the decision goes appreciably further than the previous decisions.[69]

The Commission is not required to furnish all the details of the factual and legal aspects of every decision. Whether a statement of reasons meets the requirements of Art. 253 depends not only on its wording but also on its context and on all the legal rules governing the matter in question. The degree of precision of the statement of reasons must be weighed against the practical realities and the time and technical facilities available for making the decision. Thus the Commission was not required to explain the details for setting a subsidy level for butter, which are adjusted every two weeks, especially since the industry is quite familiar with the process for setting the price.[70]

"The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the

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[65] See Lenaerts & Vanhamme 567.

[66] Limburgse Vinyl Maatschappij NV v. Commission, Joined Cases C-238-99 etc., 2002 ECR I-8375, 8685 ¶193-94. In that case, the court held that the period of the investigation of four years and 10 months was not excessive, given the complexity of the case, the amount of documents that had to be considered, and the large number of parties. In addition, the ten-month period of adjudication could not be considered excessive.

[67] "Regulations, directives and decisions adopted jointly by the European Parliament and the Council, and such acts adopted by the Council or the Commission, shall state the reasons on which they are based and shall refer to any proposals or opinions which were required to be obtained pursuant to this Treaty." See Lenaerts & Vanhamme 562-66.

[68] Windpark Groothusen GmbH & Co. Betriebs KG v. Commission, Case C-48/96 P, [1998] ECR I-2873, 2909 ¶34. See also Société Française des Biscuits Delacre v. Commission, Case C-350/88, 1990 ECR 395, 422 ¶15.

[69] Delacre, ¶17-19.

[70] Delacre ¶¶

reasons given, and the need for information of those to whom the measure is addressed or of other parties to whom it is of direct and individual concern..."[71]

7. **Procedural protections in application cases**

The law relating to the procedural rights of persons who have applied for a benefit is less well developed than in cases of parties who are subject to some kind of sanction or other loss of status. *Technische Universität München,* discussed above, involved an application to import a scientific instrument into the Community without payment of duty. The ECJ held that the applicant had procedural rights, including a right to make its objections known to the Committee, which made the decision. In the trademark area, rejected applicants are entitled under the regulations to a right to file observations (and in unusual cases to an oral hearing) even when no opposition has been filed.[72] In the area of pharmaceutical licensing, there is a right to submit written observations and to an oral hearing before the CHMP members processing an application. There is also a right to have the CHMP opinion reviewed by the Commission.

In *Windpark,*[73] the applicant applied for financial aid to construct a wind park under a program whereby various recipients of energy projects could receive aid. There were about 700 proposals. The applicant was not selected to receive support but was placed on the reserve list. Later, in response to a letter, the Commission stated that available funds had been exhausted. In this situation, there is no right to a detailed statement of reasons for the decision rejecting the application for financial support, including comparative information on the competing projects that were selected, since the applicant's legal position remains unchanged in the event of rejection. Its sole entitlement is to an objective examination of the application.[74]

In *Windpark,* the court also decided that the rejected applicant is not entitled to a hearing, because that right arises only where the Commission contemplates the imposition of a penalty or adoption of a measure likely to have an adverse effect on that person's legal position. In addition, the fact that there were hundreds of applicants militates against giving any of them a hearing. However, this decision would not resolve the issue of whether there is a right to hearing in connection with the rejection of an application for a license or permission to market a food or drug or reject a trademark application (as opposed to an application for funding where only some of the applicants can be funded).

II. SUMMARY OF ADMINISTRATIVE PROCEDURE IN THE SIX SECTORS

The following brief summary of the adjudicatory practice in the six sectors of EU administration is based upon the detailed reports contributed by our sectoral reporters. These reports total about 400 pages in length and contain a wealth of detail, documentation, and footnotes. We have prepared a summary of the reports (about 135 pages in length). Both the full sectoral reports and our detailed summary thereof are available on request from the adjudication

[71] Windpark, ¶34-35.

[72] Reg. 40/94, Art. [check #s, is it 56(1), 37(2), 38(3)]

[73] Windpark Groothusen GmbH & Co. Betriebs KG v. Commission, Case C-48/96 P [1998] ECR I-2873 (affirming Case T-109/94, 1995 ECR II-3007 (CFI))

[74] Id. I-2909-10, ¶¶ 34-39.

reporters or the sectoral reporters (email addresses can be found on the title page of this report). Ultimately both the full sectoral reports and the detailed summary thereof will be published but the exact mode of publication (whether in hard copy or on the internet) has not yet been determined).

A. *Competition*.

Article 81(1) of the Treaty prohibits various anti-competitive practices that are incompatible with the common market. Broadly speaking, this provision parallels section 1 of the US Sherman Act. Article 81(3) provides that the prohibition of Article 81(1) may be declared inapplicable to certain restrictive practices that are found to be economically beneficial and justified.

Under regulation 1/2003, which went into effect in 2004, the Commission no longer has a monopoly on granting such exemptions; they can now be granted by Member States. Courts of the Member States can adjudicate cases arising out of both public and private enforcement of the competition articles of the Treaty. The prior practice of requiring parties to notify the Commission of anti-competitive practices has been abolished (although it still exists in some Member States). Article 82 of the Treaty prohibits abuse of a dominant position and thus roughly parallels the monopolization provision of Section 2 of the US Sherman Act. Finally, the Commission regulates mergers that have a Community dimension.

The Directorate General for Competition (DG COMP) may initiate an investigation of a possible violation of Articles 81 and 82 in response to a complaint, or on its own initiative (often having been informed by an application for leniency) or by a referral from a Member State. A team headed by a DG COMP case manager and consisting of several case handlers conducts the investigation. The investigation usually includes an on-the-spot inspection. The investigators may seek additional information informally or through a formal decision requiring information to be furnished. In some cases, non-business premises can be searched.

If DG COMP decides to proceed further (with the approval of Legal Services and the Competition Commissioner and, in some cases, approval of an advisory committee of competition authorities from Member States), it issues a "statement of objections" (SO) consisting of a factual description of the conduct involved and a legal assessment. If a compromise is reached, however, the Commission issues a "preliminary assessment" which contains commitments by the companies involved.

In merger cases, the process is initiated by prior notification to the Commission of a proposed merger in order to obtain clearance of the merger. Generally pre-notification contacts occur between the applicants and Commission staff. The Commission conducts a Phase I investigation of the proposed merger and may grant clearance at that stage. If it concludes that the proposed concentration raises serious doubts as to its compatibility with the Common Market, it initiates a Phase II investigation and issues an SO. "State of play" meetings occur during Phase II to facilitate exchange of information.

The SO (in both antitrust and merger cases) informs the target companies of the charges against them (or the Commission's doubts about a proposed merger) and sets a time limit within which they can inform the Commission of their views. They can file written objections and attach relevant documents or can request a hearing. The Commission must provide full access to all documents in its file to the target companies, other than business secrets or other confidential information or internal Commission documents. Complainants (as opposed to targets) have access only to the non-confidential version of these documents.

While the right to be heard is primarily exercised through filing written materials, the Commission must provide an oral hearing on request in antitrust and merger cases. At the hearing, the targets (or merger applicants) have the right to make their views known about the facts and circumstances alleged against them and to support their claim that they have not infringed the Treaty. The hearing follows a detailed order of presentation and may include both the testimony of live witnesses and experts. There is no right of cross-examination or confrontation, but the Commission officials may question any witness who appears. If the SO is significantly amended, an additional hearing must be provided. Complainants may also be heard but this is discretionary with the Commission.

The hearing officer is a high-ranking Commission officials who has not previously been involved in the investigation. Hearing officers report to the Competition Commissioner and organizationally are not part of DG COMP. The hearing officer conducts hearings and manages access to documents and resolves claims of confidentiality. The role of the hearing officer is to make sure the parties' rights of defense are respected. The hearing officer reports to DG COMP on the procedural issues in the case and whether the right to be heard was respected. In addition, the hearing officer can make observations on the further progress of the proceedings. After the draft decision is prepared, the hearing officer prepares a final report on the procedural aspects of the case and whether due account has been taken in the draft decision of all relevant facts. This final report is delivered with the decision to the addressees of the decision.

The case handlers draft a preliminary decision. The preliminary decision is reviewed by Legal Services and presented for consultation to the Advisory Committee (consisting of Member State representatives). The final decision is made by the College of Commissioners. The hearing officer does not make a substantive (as opposed to a procedural) decision. However, the hearing officer may comment on the draft decision. Such comments are not made available to the parties.

The final decision must contain a sufficient statement of reasons so that a reviewing court may exercise its supervisory function and the parties can ascertain whether the decision is well founded. The statement of reasons must include both factual and legal grounds on which the decision is based, including comment on the evidence. It must be more fully reasoned if it states a new legal interpretation. The Commission's final decision is published.

Decisions are judicially reviewed on the basis of whether relevant procedural rules were observed, an adequate statement of reasons was supplied, and whether there was any manifest error of assessment or a misuse of powers. Reviewing courts have greater powers in respect to fines. As to remedies the Commission has the power to bring the infringing conduct to a halt through an injunction, to grant structural relief, and to punish the perpetrator (including imposition of fines). It can approve a merger based on commitments made by the merging parties or disapprove a merger or dissolve one (or take other interim measures) if the merger has already been implemented, or impose fines.

B. *Trade remedies.*

Under the law of trade remedies, the Commission can protect Community industry from dumping (that is, unfairly low priced goods imported into the Community) and from governmental subsidies that give foreign competitors an unfair advantage.[75] In dumping and

[75] The basic anti-dumping regulation is Council Reg. 384/96 (22 Dec. 1995), as last amended by Council Reg. 461/2004, 8 Mar. 2004. The basic anti-subsidy regulation is Council Reg. 2026/97, 6 Oct. 1997, as last amended by Council Reg. 1973/2002, 2 Nov. 2002.

subsidy cases, the complained-of conduct must cause material injury. Anti-dumping and anti-subsidy cases can result in imposition of additional duties on foreign goods. In addition, the EU can take "safeguard" measures that protect Community industry with temporary relief against foreign competition that causes serious injury. Safeguard cases, which are quite rare, usually result in quantitative restrictions on imports from all countries.[76]

Provisional dumping and subsidy measures are imposed by a Commission regulation (approved by simple majority of the College of Commissioners). Only the Council of the EU imposes definitive measures. Safeguard measures can be taken by a vote of the Commissioners, but if a Member State objects, it can refer the matter to the Council for approval by qualified majority.

Anti-dumping and subsidy cases usually begin with a written complaint on behalf of Community industry. Safeguard cases usually begin with a complaint by a Member State (which has been prompted by complaints of affected industry). [The following material applies only to dumping and subsidy cases, not safeguard cases, in light of the rarity of safeguard cases]. Before lodging a complaint, companies usually consult informally with DG TRADE.

During a 45-day period, the Commission evaluates the complaint and the representativeness of the complainants. Thereafter, it publishes a relatively brief notice of initiation of investigation and invites interested parties to come forward (within 10 days) and submit information and request a hearing (within 40 days). The Commission advises particular importers and exporters (and associations thereof) that it knows to be concerned of the initiation of the investigation. If the Commission rejects the complaint, there is no public announcement of the decision.

Separate teams of case-handlers evaluate the existence of dumping or subsidization and of material injury. A Head of Section supervises each team of case handlers. The overall timing of the investigation is short and inflexible: 9 months for provisional remedies, 15 months for dumping and 13 months for subsidy. An advisory committee, consisting of Member State representatives, is consulted at each critical stage. Consultation with other DGs is also routine.

The investigation consists of sending detailed questionnaires to the Community industry, foreign exporters and governments. On-site verification visits generally follow. Furnishing information is voluntary, but companies generally provide it because otherwise the Commission can proceed on the basis of the "best information available" in the case of "non-cooperation." Non-confidential versions of all written submissions to the Commission are available to other parties. Oral statements made to case-handlers during on-site verifications can be quite significant; if they are "relied on," a non-confidential summary must be provided to other parties.

Complainants, importers, exporters, and their representative associations, as well as users and consumer organizations, have a right to inspect all information made available by any party to an investigation. The general public has no inspection rights. All written submissions and questionnaire replies must be accompanied by a non-confidential version. The non-confidential version is placed in the file for inspection. There is no disclosure of confidential information or of the Commission's internal memoranda and mission reports. Lawyers generally stay in contact with the Commission officials to find out if a file has been updated,.

[76] The basic safeguard rules for WTO members are contained in Council Reg. 3285/94 (22 Dec 1994), as last amended by Council Reg. 2474/2000 (11 Nov. 2000); for non WTO members, Council Reg. 519/94 (7 Mar. 1994), as last amended by Council Reg. 427/2003 (3 Mar. 2003).

The Commission summarizes its conclusions in a "provisional disclosure letter" which is provided to the parties at the same time as a regulation imposing provisional measures is adopted. Other interested persons can request a copy. The provisional disclosure letter discloses the facts and considerations on the basis of which provisional measures were imposed. The provisional disclosure letter also contains a part addressed only to individual companies that analyzes confidential information. A final disclosure letter precedes definitive duties and the parties have at least ten days to comment.

Dumping and subsidy investigations can be "settled" after the issuance of the provisional determination if the company or government involved agrees to an "undertaking." An undertaking in a dumping case would usually be a promise from the exporter to charge at least a certain amount for the product in the future. In a subsidy case, the government might promise to cease subsidization or particular companies would agree to discontinue exports or charge at least a certain price. After undertakings have been accepted, the EU usually proceeds to adopt a definitive regulation and impose a definitive duty, which would apply to companies that did not conclude an undertaking or which may apply if the undertaking is breached.

Prior to adoption of the provisional regulation, an oral hearing is provided to a target company as a matter of right. Sometimes the officials handling the case exercise discretion to provide additional hearings. These hearings furnish an opportunity for companies to make their views known on the circumstances alleged against them and on the evidence relied on by the Commission. In addition, other interested parties generally are entitled to a hearing on request. After a hearing, a party will often submit a written copy of its presentation in both confidential and non-confidential versions. The officials handling the case may, in their discretion, provide an additional hearing after adoption of the provisional regulation.

Essentially the interested party determines what happens at the hearing. The officials are there to listen but usually will not enter into a dialogue. There is no "hearing officer" as such. The case handlers and their immediate superiors attend the hearing and sometimes ask questions of the company representatives. The hearing is considered part of the information gathering process and thus is inquisitorial rather than adversarial in nature. The hearings are informal and unstructured, but they provide an opportunity to make case-handlers aware of specific facts, circumstances, or arguments. Parties can bring witnesses, but the witnesses are subject to being questioned by the officials and a refusal to answer questions would be viewed negatively. No transcript is made; instead, the officials take notes. A party may provide a written copy of its presentation in confidential and non-confidential form. The regulations contain a provision for a confrontational hearing but these are exceedingly rare.

The hearing is not followed by issuance of a proposed decision. The first decision is the Commission's provisional regulation, which is adopted not later than 9 months after initiation of the procedure. Later the Council imposes the definitive anti-dumping or countervailing duty. The decisions must state reasons and make findings on all relevant issues including the question of whether imposition of duties is against the Community's interest. The decisions must disclose "the details underlying the essential facts and considerations" on the basis of which duties were imposed. Provisional and final decisions are published. The final decisions are in the form of regulations of general application but these regulations contain individualized as well as generalized measures. Decisions are reviewable on the basis of unreasonable exercise of discretion or lack of proportionality.

One year after definitive measures are imposed, interested parties may apply for an interim review in which the Commission examines the need for continued imposition of measures or whether the measures ought to be increased. There is also provision for a newcomer review on

behalf of a company that was not exporting the product during the investigation period. Definitive anti-dumping and anti-subsidy measures expire after 5 years unless it is determined in an expiry review that they should be continued. The procedures that apply to investigations also apply to these various forms of post-adoption review. There is also provision for reviews on the part of Community industry in the event that the exporters have "absorbed" the additional duties or "circumvented" the measures previously imposed.

C. *Trademarks*

A Community trademark (CTM) provides Community-wide protection for distinctive signs used to distinguish a product or service from those of competitors. [77]A CTM must be registered with the Office (Office for the Harmonization in the Internal Market or OHIM) in Alicante, Spain. OHIM is an agency outside the European Commission that is responsible for enforcing Community trademark law. Private parties can challenge a CTM by means of an "opposition" filed by an earlier trademark owner complaining of a likelihood of confusion as well as by an application for "invalidity" or for "revocation" (in the event of nonuse or that the mark has become generic). Member States also register trademarks which provide protection in that state only. Litigation about the validity of trademarks can be conducted both before Community courts and courts in Member States.

An application for a CTM is filed with OHIM either in writing or on line. European lawyers must represent non-European based applicants. The application must contain a list of the goods or services in respect of which registration is requested using the classification system in the Nice Agreement. A CTM application must be filed in any of the official languages of the Community and a second language must also be specified; the choice of languages can be used as a strategic tool. After filing, OHIM considers whether the application meets all requirements and whether any grounds for refusal are present. It is possible to conduct informal meetings with the examiner to discuss a CTM application. OHIM then conducts a Community search to discover earlier identical marks that may be invoked as grounds for refusal to register the mark in an opposition proceeding. After the search report is communicated to the applicant, the general public is informed of the application through publication in the Community Trademarks Bulletin.

OHIM has no investigatory powers other than those already mentioned. Further investigation is left to private parties who may choose to file a "notice of opposition" within 3 months after the application has been published. Opponents can also file an application to hold a CTM invalid or file a counterclaim in Member-State infringement proceedings. A 2-month cooling-off period applies after an opposition petition is filed. Thereafter the opponent files arguments and documents within the times set by OHIM and the applicant files responding documents. The files arising out of an application or an opposition are open to inspection. However, some material may be made unavailable either because it is confidential or because it is an internal OHIM document. Settlements of trademark disputes are possible during the cooling off period or after proceedings have begun. Examiners sometimes suggest settlements.

Proceedings before OHIM are mainly written. Oral hearings are uncommon (other than the informal meetings held during the application process as mentioned above). Oral hearings may occur if OHIM feels one is necessary or if a party requests a hearing and OHIM deems it expedient. If a hearing is held, the hearing officers are the same officials who are working on the underlying application or opposition proceeding. The hearing is an informal conference; it provides an opportunity for a party to convey its arguments or highlight the evidence it has

[77] The basic regulation concerning trademarks is Reg 40/94.

submitted to OHIM. The OHIM officials can ask questions of the parties or witnesses. An agenda will set forth the points to be discussed.

If OHIM decides that an oral hearing is needed, it selects the witnesses and frames the issues and issues a summons for the attendance of the witnesses. If a party requested the hearing, it selects the witnesses and frames the issues and OHIM will issue a summons to those witnesses. The officials working on a trademark case or an appeal may not have any personal interest in the matter and may be disqualified for partiality. Ex parte contacts are not allowed.

Trademark proceedings contain a form of separation of functions: officials working on an opposition cannot have also worked on the application; members of the cancellation division cannot have participated in application or opposition proceedings; and members of the Boards of Appeal cannot have participated in any prior proceedings. The primary record is contained in minutes that must be approved by the witnesses (but a recording of the hearing is also made). There is no specific time limit on making a trademark decision; it depends on the complexity of the case and the workload of the responsible officials.

Parties may appeal decisions of the Office to a Board of Appeals within two months after notification of the decision complained of. The Board will invite the parties to file observations and is empowered to take any action OHIM could have taken originally or it can remit the matter to OHIM. Board of Appeal decisions can be further appealed to CFI and ECJ. After an appeal is filed, the OHIM division that took the original decision can "revise" it.

The decision of the Office or the Board of Appeal must provide the legal interpretations and reasoning on which the decision is based. The statement of reasons must be detailed and respond to all arguments submitted by the parties (though if one or more of these arguments are sufficient to justify the decision the opinion need not consider all other arguments). The decisions are reviewed for unreasonableness or lack of proportionality as well as for manifest error. The decision is first notified to the parties and then published in the Community Trademarks Bulletin. A CTM is recorded in the Register of Community trademarks.

There is no duty of care imposed on OHIM since discovery of relevant facts and their presentation is up to the parties rather than to OHIM. Principles of res judicata apply so that invalidity or opposition cannot be invoked a second time. As in all other cases, complaints of maladministration can be filed with the ombudsman.

D. *Food safety*

Food safety decisionmaking is triggered by an individual application for approval of a new food product. [78] The outcome is the promulgation of a regulation that allows any manufacturer that meets the standards to import the food item into the Community.[79] The exceptions are novel foods and genetically modified foods,[80] which result in an individualized decision covering only the particular applicant. Regardless of whether the process results in a rule or an individualized decision, the process used is more appropriate to rulemaking than

[78] See generally Reg. 178/2002.

[79] An important consequence of treating the decisions on food applications as rulemaking is to diminish the opportunity for judicial review (for example the rules cannot be challenged in the CFI and there are strict rules about standing to seek review).

[80] See Reg. 258/97 (novel foods) and Reg. 1829/2003 (genetically modified food).

adjudication. Generally the decisions regarding specific applications for approval are made through the comitology process.

Depending on the particular type of product, an application to introduce food products is filed with a Member State (in the case of novel foods) or with the European Food Safety Agency (EFSA) (in case of other food products). This application triggers an extensive scientific assessment process by EFSA. In the case of novel foods, Member State officials conduct an initial assessment which is forwarded to Member States for comment; further investigation is carried out by EFSA. The assessment process can take between one and five years.

There is no opportunity for an adjudicatory hearing or other procedural protections in cases involving applications to introduce foods into the Community, even if the ultimate decision will be individualized or have an individualized impact.[81] A recent ECJ case (which involved procedures whereby a food supplement could be approved for sale in the Community) contains dictum that might, in the future, be the basis for a judicial decision (or for procedural regulations) that provide such protections. The Court suggested that EFSA procedures must meet the requirements of good administration. There must be provision for an applicant to make its views known and for a reasoned decision provided within a reasonable time.[82]

The procedure used to approve an application to introduce a new food product begins with adoption of general legislation under EC Treaty Art. 251. For example, the responsible Commission service (DG SANCO) might initiate a legislative text dealing with a broad subject such as "obesity." After ad hoc consultations, consultations with advisory groups from Member States, and inter-service consultations, the draft text is submitted to the College of Commissioners for approval.

The second stage is the adoption of rules through the comitology process that include the approval of new food products. Once the products are approved, other manufacturers can then introduce identical products without securing approval. The Commission submits its decision to approve the product to SCFCAH (Standing Committee on Food Chain and Animal Health), which consists of food safety officials from Member States. The process of approval here is highly politicized and ex parte contacts and political pressures are common. Generally the Commission submits draft proposals to SCFCAH to see whether there will be problems and it attempts to work out the problems in advance. If a proposal receives a qualified majority in SCFCAH, it must be adopted by the Commission; if it fails to achieve a qualified majority, the decision is made by the Council. There are relatively limited opportunities for input by the applicant or by other interested parties and the process is not transparent. The process of food safety regulation is described in greater detail in the report on rulemaking.

E. *State aids*

[81] Some recently adopted regulations provide for an undefined appellate process to the Commission from any act or omission by EFSA. However, this process as yet unused and its impact cannot be assessed. There are serious uncertainties surrounding the procedure. See Food Contact Material Regulations 1935/2004, Art. 14.

[82] *The Queen on the Application of Alliance for Natural Health v. Secretary of State for Health*, Joined cases C-154/04 and C-155/05 ¶¶72, 73, 82 (July 12, 2005).

Under Articles 87 to 89 of the Treaty, Member States may not grant subsidies or other advantage to entities within their states unless first authorized to do so by the Commission.[83] Such subsidies have the potential to distort competition in the internal market and thus should be viewed as complementary to the regulation of private competition and monopoly discussed above.

Thus states must notify the Commission of schemes of new aid. If a State has granted state aid without prior authorization, the state must recover it from the beneficiaries. The Commission may authorize various forms of aid if compatible with the common market (such as aid to make good the damage caused by natural disasters or aid to promote economic development of underdeveloped areas).[84]

State aid proceedings are bilateral—between the Commission and the Member State that grants the aid—and neither beneficiaries of the aid nor competitors of the beneficiary are parties to the proceedings. The Commission initiates a Phase I investigation when it receives a notification or receives information from a complainant that state aid will be or has been granted. Phase I lasts a maximum of two months following receipt of a complete notification. If the measure raises doubts about whether the aid is compatible with the common market, the Commission then initiates a Phase II investigation. It notifies the concerned Member State of the decision to go to Phase II and publishes it in the Official Journal. The decision must summarize the relevant issues of fact and law and contain a preliminary assessment of the measures and set out the Commission's doubts about compatibility with the common market.

Phase II investigations generally take at least a year and often more than 18 months. The Commission's investigation runs to Member States, not to private enterprises. If the State does not reply to a request for information, its notification is deemed withdrawn. In practice, the Member State usually consents to the Commission's questioning the beneficiary of the aid, though the Member State controls the process. The one area in which the Commission takes investigative action directly against private parties involves compliance monitoring. The Commission does not give Member States access to its file but will inform the states of relevant information in its file. Private parties have no access to the file though the Commission will usually discuss issues with the beneficiary of the aid.

During Phase II, the Member State concerned and any other interested parties can submit comments. The Member State can respond to any third-party comments. There is no oral hearing but there are informal meetings between Commission staff, Member State representatives, and other interested parties.

The proceeding closes with a Commission decision stating one of three possible outcomes: the measure does not constitute state aid, the measure is authorized, or the measure is not authorized. A final decision is taken by a majority of the Commissioners. The decision consists of the reasons for the Commission's conclusions. The Commission need not enter into a dialogue by addressing every issue of fact or law raised by any party, but it is required to consider

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[83] Save as otherwise provided in this Treaty, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favoring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the common market." Treaty Art. 87(1). The details of state-aid regulation are set forth in Reg. 659/1999.

[84] Art. 87(2).

all submissions. Decisions closing a Phase 2 investigation are published in full in the Official Journal. The Council may, by unanimous vote, authorize state aid in exceptional circumstances.

F. *Pharmaceutical licensing.*

A manufacturer wishing to introduce a pharmaceutical product into EU markets must obtain a marketing authorization to do so. Licensing of new medicines requires a delicate balance between the benefits of the medicine and its risks. Approval of new medicines is heavily regulated because medicines play a key role in public health care and there must be adequate guarantees for their quality, safety and efficacy. Regulation extends not only to the decision about whether a new medicine can be introduced but regulates the product in detail, including, among others, the composition, therapeutic indications, prescription status, persons involved in the manufacturing process, method of packaging and package sizes, the wording of the package leaflet, labeling on the containers, and prescribing information for physicians.

The pharmaceutical licensing systems distinguish between centrally and decentrally approved products. The centralized procedure is administered at the Commission level and applies to biotechnology medicines and other innovative products. The decentralized procedure is administered at the Member State level and applies to other medicinal products. In the decentralized procedure, the decision on marketing authorization is prepared by the Reference Member State and the Concerned Member States as a rule follow the decision. A Coordination Group mediates disagreements between Member States under the decentralized procedure. In the event of further disagreement, the Committee for Medical Products for Human Use (CHMP) renders an arbitral opinion, which is the basis of a Commission decision that is binding on the involved Member States.

In the centralized procedure, the Commission makes decisions with the assistance of the European Medical Agency (EMEA) and, in particular, the CHMP which is a division of the EMEA. The CHMP brings together scientific and regulatory expertise from the Member States and provides scientific assessment of medicines for human use on which Commission decisions are based. The Commission can vary, suspend or withdraw a marketing authorization if new scientific evidence alters the risk-benefit assessment. In the future, it will be able to impose a range of financial sanctions in cases of infringement of certain legal obligations related to centrally approved products. EMEA and Member States engage in pharmacovigilance with respect to approved medicines. In general, proceedings in pharmaceutical cases are inquisitorial in nature rather than adversarial. The Standing Committee on Medicinal Products for Human Use represents Member States and is consulted by the Commission as part of the comitology process in the decision-making procedure.

Applications for approval under the centralized procedure contain a great deal of data, particularly concerning clinical trials of the medicine. Applications are filed with EMEA in London. EMEA requests a six-month pre-filing announcement and applicants generally engage in a pre-submission meeting with EMEA to obtain procedural and regulatory advice. A project manager is appointed during the pre-filing period.

In general, the process within the CHMP should be completed within 210 days after an application is validated, but there are various clock-stops that extend the process. After validation, the CHMP appoints a rapporteur and a co-rapporteur to evaluate safety, efficacy, and quality and provide a preliminary assessment to the CHMP. Scientific advisory committees are often employed during this process. The CHMP ordinarily sends a list of questions and a positive or negative recommendation to the applicant who has up to six months to answer the questions and provide additional information.

Based on the applicant's response, the rapporteurs provide their joint assessment to the CHMP (a copy is provided to the applicant). The CHMP may request further oral responses. If not, it will provide its final report, based on its scientific consensus. If the report is negative (in part or in total), the applicant may request reassessment. The CHMP then drafts a final opinion, which is provided to the applicant and the Commission.

Applicants for marketing authorization and targets of regulatory review action have an opportunity to furnish written or oral explanations to the CHMP. These hearings are part of the investigation process and are conducted together with scientific evaluation of a medicine or the investigation in alleged infringements of marketing authorization obligations. The applicant can bring in experts or other witnesses to further explain its position. Third parties (such as scientists who oppose licensing a medicine) have in principle no right to participate in these hearings, or more generally, in the licensing procedures as such, but their views may be taken into account. No hearing officer is appointed. The CHMP then provides its detailed and reasoned opinion to the Commission along with extensive documentation. The Commission makes the final decision, which must contain a detailed statement of reasons. It involves the Standing Committee in the decision-making process. In the event the Commission disagrees with the Standing Committee, the Council makes the final decision. In cases of such disagreement, the Commission often refers the case back to the CHMP. All such decisions are posted on the Commission's web site. Similar procedural rights are provided for in the draft Penalties Regulation.

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