The Precautionary Principle: New Developments in the Case Law of the Court of First Instance

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[1] The *Pfizer* and *Alpharma* judgments(1) , both delivered by the Court of First Instance (hereinafter "the Court") on 11 September 2002, provide us with interesting precisions on the interpretation and scope, within the European Communities' legal order, of the much discussed precautionary principle(2) . In particular, they attest to the Court's willingness to leave the Community institutions a certain margin of appreciation in this field, while ensuring that the judicial review of such decisions is thorough enough to prevent abusive reliance on the precautionary principle.

A. Factual background

[2] On 17 December 1998, the Council adopted, on a Commission proposal, Regulation 2821/98(3) by which it withdrew the authorization, granted pursuant to Directive 70/524(4) , to use as additives in animal feedingstuffs four antibiotics, among which virginiamycin and bacitracin zinc. These antibiotics had one common characteristic: besides being used as additives in feedingstuffs as animal growth promoters, they were also used to treat human infections. By banning them, the Commission and the Council in substance took the view that this dual use entailed the risk of reducing their effectiveness as human medicinal product: animals could develop a resistance to them, and this resistance could in turn be transferred to humans. Given that neither the reality of this risk nor its seriousness could be scientifically established, the Council relied on the precautionary principle to justify its decision(5) .

[3] The withdrawal of the authorization previously granted to virginiamycin (an antibiotic belonging to the streptogramin's class) was adopted following an application for adjustments submitted by Sweden(6) and a decision of Denmark, taken on the basis of the safeguard clause provided by Directive 70/524(7) , banning on its territory the use of this antibiotic in feedingstuffs. Denmark based its decision primarily on a report of the Danish Veterinary Laboratory warning that the use of virginiamycin as a growth promoter could result in the development by some bacteria of resistance to virginiamycin and to other antibiotics of the streptogramin class (cross resistance). The report stressed that such a resistance could be transferred from animals to human beings, thus imperilling the use of streptogramins for the treatment of human infections in Denmark. Although the report acknowledged that streptogramins were not yet used in Denmark to treat human infections and that, *"(t)herefore, an acute threat to public health* (did) *not exist"* , it emphasized that this could change and that, in such a case, *"the use of virginiamycin as a growth promoter will increase that risk of adverse resistance development"* (8) ..

[4] Following the communication of the Danish decision, the Commission asked the Scientific Committee for Animal Nutrition (hereinafter "SCAN")(9) to give its opinion on the risk posed by the use of virginiamycin as a growth promoter to the value of streptogramins in human medicine. In its opinion, published on 10 July 1998, SCAN concluded that *"the use of virginiamycin as a growth promoter* (did) *not constitute an immediate risk to public health in Denmark"* (10) . SCAN held that the data provided by the Danish authorities did not justify the ban and, while expressing its sympathy to Denmark's concern, stated that *"a full risk assessment* (could not) *be made until quantitative evidence of the extent of transfer of antimicrobial resistance from livestock sources* (was) *obtained"* (11) . On 16 and 17 July 1998, Danish authorities submitted a new scientific study to the Standing Committee for Feeding-stuffs(12) . This study (hereinafter "the study on live rats") provided new evidence of the transfer of resistance to streptogramins from animals to human beings. Consulted on this study, SCAN merely stated that it "(did) *not bring new information to the subject"* (13) .

[5] The withdrawal of the authorization granted to bacitracin zinc under Directive 70/524 was for its part taken following Sweden's abovementioned application for adjustments which, in addition to virginimaycin, also mentioned bacitracin zinc as a potential threat to human health. Sweden's request was discussed by the Standing Committee and SCAN; the Scientific Steering Committee(14) set up a working group to examine the problem of antibiotic resistance and to submit a report on the subject towards the middle of 1999.

[6] When Regulation 2821/98 was adopted, Pfizer was the only producer in the world of virginiamycin and Alpharma was the only manufacturer and the largest supplier of bacitracin zinc in the European Economic Area. They both decided to seek annulment of the Regulation 2821/98 on the basis of Article 230 para. 4 EC. They notably claimed that the Council had erred in assessing the risks posed to human health by the use of virginyamicin and bacitracin zinc as additives in animal feedingstuffs.

B. Risk assessment

[7] In both judgments, the Court begins by recalling its earlier case-law on the precautionary principle's scope of application and stresses that it applies with regard to decisions aiming at the protection of human health taken within the common agricultural policy(15) . Hence, the Council could validly purport to rely on the precautionary principle when it adopted the contested Regulation.

[8] The Court then proceeds on to determine if the Council had correctly assessed the risks entailed by the use of virginiamycin and bacitracin zinc as growth promoters. In this regard, the Court specifies that, on one hand, *"a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality"* (16) , but that, on the other hand, *"a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified"* (17) . The precautionary principle can thus only be relied upon following a risk assessment whose purpose is *"to assess the degree of probability of a certain product or procedure having adverse effects on human health and the seriousness of any such adverse effect"* (18) . The Court's subsequent analysis of the risk assessment conducted by the Commission and the Council allows us to distinguish a formal aspect of the precautionary principle [1] from a substantial one [2].

I. "Formal" precaution: scientific risk assessment

[9] At the outset, the Court recalls the Community institutions' obligation to carry out, in complex matters such as those relating to the use of additives in feedingstuffs, a scientific risk assessment before taking any preventive measures(19) . This assessment must be entrusted to experts, and their *"advice on matters relating to consumer health must* (…) *be based on the principles of excellence, independence and transparency"* (20) . However, the Court acknowledges that when the precautionary principle is relied upon, it may be impossible to carry out a full risk assessment because of the insufficiency of scientific data(21) . In such a case, and *"(n)othwitsanding the existing scientific uncertainty, the scientific risk assessment must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society"* (22) . Consequently, Community institutions are not required to prove the reality or the seriousness of the risk at stake, but merely to show that the decision was adopted after as thorough a scientific assessment as possible, providing sufficient scientific indications to conclude that the use of virginiamycin and bacitracin zinc constituted a risk to human health.

[10] Pfizer criticized the risk assessment carried out by the Council to the extent, notably, that its conclusions diverged from those reached by SCAN. The Court refutes this argument, and stresses that SCAN is an advisory body and that its role is accordingly limited *"to providing a reasoned analysis of the relevant facts of the case (…) in order to provide the institution with the factual knowledge which will enable it to take an informed decision"* (23) . The Court feels however obliged to add that in adopting the contested Regulation, the Council did not ignore SCAN's opinion, and on the contrary *"relied primarily on certain matters analysed in the opinion"* (24) . Furthermore, it stresses that when Community institutions decide to disregard a scientific opinion, "(they) *must provide specific reasons for* (their) *findings by comparison with those made in the opinion, and* (their) *statement of reasons must explain why* (they are) *disregarding the latter. The statement of reasons must be of a scientific level at least commensurate with that of the opinion in question"* (25)

[11] The Court is obviously concerned about the potential for abuses entailed by its acknowledgment of the non binding character of SCAN's opinion. Its approach seems indeed well founded: it ensures that, whether or not Community institutions decide to follow the opinion given by the scientific committees assisting them, their decision will always be grounded on ascertainable scientific data. This approach guarantees that, while the necessary distinction between scientific advice and political decision-making is preserved and the former remains subordinated to the latter, decisions founded upon the precautionary principle remain, albeit to a limited extent, amenable to judicial review.

[12] The same approach is also applied by the Court when dealing with Pfizer's plea concerning the absence of any SCAN consultation after Denmark submitted the study on live rats to the Standing Committee. The Court first notes that Directive 70/524 allows the Community institutions to withdraw authorization without consulting SCAN(26) , but it immediately recalls the obligation for the Council to base its risk assessment on an expert scientific advice meeting the requirements of excellence, independence and transparency and states that *"it is only in exceptional circumstances and where there are adequate guarantees of scientific objectivity that the Community institutions may, when – as here – they are required to assess particularly complex facts of a technical or scientific nature, adopt a preventive measure withdrawing authorisation from an additive without obtaining an opinion from the scientific committee set up for that purpose at Community level on the relevant scientific material"* (27) .

[13] Applying this approach *in casu* , the Court then judges that SCAN's statement - according to which the study on

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live rats "(did) *not bring new information to the subject"* (28) - did not amount to a scientific opinion since it was not adopted under SCAN's rules of procedure and since SCAN did not provide any statement of reasons enabling the Community institutions to determine their position(29) . Neither did the Standing Committee's study on live rats (as the Council and the Commission argued): according to the Court such an analysis cannot be qualified as a scientific advice based on the principles of excellence, transparency and independence, given that the Standing Committee is not an independent scientific committee and that its analysis of scientific material is not published(30) . Accordingly, only exceptional circumstances could have justified the absence of any consultation of SCAN on the study on live rats. Fortunately for the Council, the Court found that such exceptional circumstances indeed existed, basing itself on the fact that, thanks to the previous SCAN opinion, to the scientific data submitted by Denmark and to Pfizer's comments, the Community institutions *"were sufficiently well informed to take the study into account in their risk assessment"* (31) .

[14] The Court thus ensures that the Community institutions abide by their duty to carry out a scientific risk assessment, but stops short of imposing them unduly burdensome obligations. This "leniency" is also present in the *Alpharma* judgment: although the Commission failed to consult SCAN when it analysed the risk entailed by the use of bacitracin zinc as a growth promoter, the Court refused to consider as invalid the Community institutions' risk assessment. In the Court's view, the Commission and the Council could validly rely, on one hand, on the information contained in the SCAN opinions relating to the other antibiotics whose authorization was withdrawn and, on the other hand, on reliable reports of international, Community and national bodies(32) dealing with the issue of resistance to antibiotics in general and with the possible implications of their use as additives in feedingstuffs.

[15] It is apparent that, in the Court's view, the scientific risk assessment must be carried out primarily by the scientific committees set at the European Community's level. It is only under exceptional circumstances, i.e. when they already possess sufficient scientific data on the risk at stake, that they are allowed to rely on the conclusions of other bodies.

II. "Substantial" precaution: political risk assessment

[16] After having held that the Community institutions were entitled to rely on the scientific material mentioned in Regulation 2821/98, the Court had to determine whether they had erred in concluding that the use of virginiamycin and bacitracin zinc as additives in animal feedingstuffs constituted a risk to human health.

[17] In that respect, Pfizer and Alpharma maintained that, even if a transfer of resistance to certain antibiotics could take place owing to the use of virginiamycin and bacitracin zinc as growth promoters, this would not have any adverse effects on human health. More specifically, Pfizer argued that, in Denmark, infections caused by enterococci and staphylococci had been dealt with successfully. The Court rebuts this argument, stressing that resistance to antibiotics had been observed worldwide(33) , that the Community institutions' risk assessment had to be carried out at Community (and not only at national) level(34) and that *"anti-microbial resistance has significant long-term effects on public health in that it is a virtually irreversible phenomenon"* (35) . Accordingly, the Court finds that the Commission and the Council could *"adopt a cautious approach and pursue the objective of preserving the effectiveness of products used in human medicine even though (…) they were little used in that sphere"* (36) . The Court similarly refuses to endorse the applicant's submission that, even if streptogramin resistance were to be observed, it could be treated with new antibiotics. It notes the *"great importance in human medicine of the possibility of using several antibiotics"* , and holds that the Community institutions could therefore decide to preserve the largest possible number of antibiotics(37) . Lastly, the Court is unsuprisingly not convinced by Pfizer's argument that streptogramin-resistant bacteria cause infections only in patients having a defective immune system, and states that the preservation of the effectiveness of medicinal products used for the treatment of patients needing a particularly high level of protection is a valid objective(38) . The Court also rebuts Alpharma's contentions relating to the absence of serious consequences for human health entailed by the possible reduction of effectiveness in bacitracin zinc, stressing notably that *"it is for the competent public authority to determine the level of risk which it deems appropriate for society and that, in the performance of that duty, the Community institutions have a broad discretion"* (39) .

[18] Similarly, the Court finds that, contrary to Pfizer and Alpharma's submissions, the Commission and the Council were apt to prove that a link could exist between the use of virginiamycin and bacitracin zinc as growth promoters and the development of resistance to these products in humans. In *Pfizer*, the Court cites three scientific studies(40) on which the Community institutions relied on to establish that link(41) . With regard to the alleged lack of appropriateness of these studies, in that they did not provide a definitive answer to the issue, the Court affirms that the Community institutions were not required to postpone their decision until additional scientific research had been carried out. In particular, the Court emphasizes that such an approach is based on an incorrect interpretation of the precautionary principle(42) and states that *"when the precautionary principle is applied, the fact that there is scientific uncertainty and that it is impossible to carry out a full risk assessment in the time available does not prevent the competent public authority from taking preventive protective measures if such measures appear essential, regard being had to the level of risk to human health which the public authority has decided is the critical threshold above*

which it is necessary to take preventive measures" (43) . Accordingly, the institutions could not be required to wait until the adverse effects materialised, otherwise *"the precautionary principle, the aim of which is to prevent the occurrence of any such adverse effect, would be rendered devoid of purpose"* (44) . *In casu* , the Court concluded that, having regard to the seriousness of the repercussion should the risk materialise and to the results of the scientific research, the Commission and the Council did not make any manifest error of assessment(45) .

C. Conclusion

[19] The Court repeatedly stresses in both judgments that the Commission and the Council enjoyed a broad discretion when they adopted Regulation 2821/98 and that judicial review must accordingly be limited(46) . However, the Court does not leave the Community institutions with a virtually absolute discretion to invoke the precautionary principle.

[20] Hence, the Court lays down a formal *encadrement* of the scientific risk assessment which has to be carried out prior to the decision's adoption, requiring that this assessment be entrusted to the European Community's scientific committees. It is only under *"exceptional circumstances"* that the Community institutions can decide to rely on other scientific material. In that case, this alternative assessment must be *"based on the principles of excellence, independence and transparency"* . The Court's aim is simply to ensure that decisions founded on the precautionary principle are based on the best scientific data available. This approach enables it to review the adequacy of the scientific assessment used by the institutions, but also allows the institutions, provided that the scientific material they rely on meets the abovementioned criteria, to reach different conclusions than those reached by EC's scientific committees. It also constitutes a valuable safeguard against potential abuses, since "(a) *scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures"* (47) .

[21] Once these "formal" conditions are met, the Court leaves a wider discretion to the Community institutions. Provided that they do not manifestly err in drawing conclusions from the scientific material, their decision will be upheld by the Court since "(i) *t is not for the Court to assess the merits of either of the scientific points of view argued before it and to substitute its assessment for that of the Community institutions"* (48) .

[22] It is submitted that the Court's approach is correct: when there is scientific uncertainty as to the reality of a risk, it is precisely not for scientists to decide whether or not that risk is acceptable for society. This evaluation can only be entrusted to political bodies, and the Court is thus right to distinguish clearly scientific expertise from political responsibility: "(w) *hilst the Commission's exercise of public authority is rendered legitimate pursuant to Article 211 EC, by the European Parliament's political control, the members of SCAN, although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. Scientific legitimacy is not a sufficient basis for the exercise of public authority"* (49) .

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(1) Cases T-13/99 *Pfizer* and T-70/99 *Alpharma* (nyp in the ECR, both judgments are available at http://curia.eu.int).

(2) Given the limited scope of this study, we will focus on these judgments' contribution to the European Court of Justice and Court of First Instance's case-law on the precautionary principle. It should however be noted that there are other points of interest in these judgments, particularly with regard to admissibility and to the application of the proportionality principle.

(3) Regulation amending, as regards withdrawal of the authorization of certain antibiotics, Directive 70/524 (OJ 1998 L 351, p. 4).

(4) OJ, English Special Edition 1970 (III), p. 840. This directive lays down Community rules concerning the authorization of additives for incorporation in feeding-stuffs, and is founded on Article 37 EC.

(5) *"(T)he prohibition on the use of (…) bacitracin zinc* (and) *virginiamycin* (…) *ought to be perceived as an interim protective measure taken as a precaution, which could be reconsidered in the light of the investigations which will have been carried out* (…)" (Recital 29 of Regulation 2821/98).

(6) Until 31 December 1998, Sweden was authorized, under Annex XV, Title VII, point E1(4) of its Act of Accession, to maintain its pre-accession legislation concerning the use of antibiotics as additives in feedingstuffs. Before that date, *"a decision (had to be) taken in accordance with* (…) *Directive 70/524 on requests for adaptation presented by*

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the Kingdom of Sweden".

(7) Article 11 : *" 1. Where a Member State, as a result of new information or of a reassessment of existing information made since the provisions in question were adopted, has detailed grounds for establishing that the use of one of the additives listed in Annex I or its use in conditions which may be specified constitutes a danger to animal or human health or the environment although it complies with the provisions of this Directive, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving reasons for its decision.*
2. The Commission shall, as soon as possible, examine the grounds cited by the Member State concerned and consult the Member States within the Standing Committee for Feedingstuffs; it shall then deliver its opinion without delay and take the appropriate measures.
3. Should the Commission consider that amendments to the Directive are necessary in order to mitigate the difficulties mentioned in paragraph 1 and to ensure the protection of human or animal health or the environment, it shall initiate the procedure laid down in Article 24 with a view to adopting these amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments enter into force".

(8) *Pfizer* at 44.

(9) SCAN was created by Decision 76/791 of 24 September 1976 (OJ 1976 L 279, p. 35), replaced by Commission Decision 97/579 of 23 July 1997 (OJ 1997 L 237, p. 18). According to article 8(1) of Directive 70/524 (as amended by Directive 96/51), its task is to *"assist the Commission, at (its) request, on all scientific questions relating to the use of additives in animal nutrition"* .

(10) *Pfizer* at 53.

(11) *Ibid.*

(12) Established by Council Decision 70/372 of 20 July 1970 (OJ, English Special Edition 1970 (II), p. 534). This Committee, set up under Article 202 EC, is chaired by a representative of the Commission and consisting of representatives of the Member States. Articles 11 and 24 of Directive 70/524 provide that it must be consulted by the Commission both at the stage of risk assessment and of risk management.

(13) *Pfizer* at 57.

(14) Established by Commission Decision 97/404 of 10 June 1997 (OJ 1997 L 169, p. 85). Its task is notably to assist the Commission to obtain scientific advice in the field of consumer health.

(15) *Pfizer* at 114, *Alpharma* at 135. The CFI referred to its judgments in Cases C-180/96 *United Kingdom v. Commission* [1998] ECR I-2265 and C-157/96 *National Farmers' Union* [1998] ECR I-2211.

(16) *Pfizer* at 142, *Alpharma* at 155.

(17) *Pfizer* at 143, *Alpharma* at 156.

(18) *Pfizer* at 148, *Alpharma* at 161.

(19) *Pfizer* at 154 and 155, *Alpharma* at 167 and 168.

(20) *Pfizer* at 159, *Alpharma* at 172. These principles were already mentioned in the Commission's Communications on the Precautionary Principle (COM/2000/01final) and on Consumer Health and Food Safety (COM/97/183 final).

(21) *Pfizer* at 160, *Alpharma* pt. 173.

(22) *Pfizer* at 162, *Alpharma* pt. 175.

(23) *Pfizer* at 196 and 197.

(24) *Pfizer* at 194.

(25) *Pfizer* at 199.

(26) *Pfizer* at 265.

(27) *Pfizer* at 270, *Alpharma* at 213.

(28) See *supra* .

(29) *Pfizer* at 274 and 275. See also *Alpharma* at 234 to 236.

(30) *Pfizer* at 285 to 287, *Alpharma* at 234 to 236.

(31) *Pfizer* at 298.

(32) *Inter alia* conclusions of the Berlin World Health Organization conference (October 1997), the Economic and Social Committee of the European Union (9 September 1998, OJ 1998 C 407, p. 7), the Copenhagen conference on antibiotic resistance (September 1998), as well as reports of national specialist bodies from Sweden, Netherlands and the United Kingdom.

(33) *Pfizer* at 327.

(34) *Pfizer* at 329.

(35) *Pfizer* at 334.

(36) *Pfizer* at 335.

(37) *Pfizer* at 338.

(38) *Pfizer* at 340.

(39) *Pfizer* at 265.

(40) *Pfizer* at 365-368.

(41) See also *Alpharma* at 296-302.

(42) *Pfizer* at 381.

(43) *Pfizer* at 382.

(44) *Pfizer* at 386.

(45) *Pfizer* at 387.

(46) *Pfizer* at 166-170, *Alpharma* at 177-181.

(47) *Pfizer* at 172, *Alpharma* at 183.

(48) *Pfizer* at 393.

(49) *Pfizer* at 201.