II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 21 May 1997

on the proposal of Austria to award aid to the Hoffmann-La Roche company for the development of the drug 'Orlistat', designed for the treatment of pathological obesity

(Only the German text is authentic)

(Text with EEA relevance)

(98/251/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular the first subparagraph of Article 93(2) thereof,

Having regard to the Agreement establishing the European Economic Area, and in particular Article 61(1) thereof,

Having given the parties concerned the opportunity to submit their comments, in accordance with the abovementioned Articles,

Whereas:

I. DESCRIPTION OF THE FACTS

A. Antecedents

By letter dated 2 October 1995, Austria, pursuant to Article 93(3) of the EC Treaty, notified proposed State aid to Hoffmann-La Roche (hereinafter 'HLR') for the development of the drug 'Orlistat', designed for the treatment of pathological obesity.

By letter dated 5 March 1996, the Commission informed the Austrian authorities of the opening of the procedure provided for in Article 93(2) the EC Treaty.

The multinational company HLR began the development of the anti-obesity drug Orlistat in 1986. A cooperation contract between HLR and Chemie Linz (hereinafter 'CL'), a chemical company owned by the Austrian State, was finalised in October and November 1992 to produce an intermediate compound essential for the production of the drug Orlistat.

This contract involved the construction in Linz of a plant to produce hydroxy-beta-lactone, a key intermediate in the production of Orlistat. The implementation of the contract entails several phases going from the basic engineering work (which began in August 1992, before signature of the contract) and construction of the plant, to start-up and production (planned for 1998 and for a 10-year duration). The whole production output of the intermediate product is to be exported to Switzerland, where Orlistat will be manufactured.

The State aid proposal for the Orlistat project can be divided in two parts: one subsidy of ATS 300 million for research and development, and the other a grant of ATS 78 million for environmental protection. The aid is to be granted in principle by the federal, regional and local authorities. Austria considers the aid intensity to be 5,3 %, since the total amount of the project (including investment and research) is about ATS 7 124,9 million.

The Commission decided to initiate the procedure provided for in Article 93(2) of the Treaty for the following reasons:

— a previous aid proposal, first notified on 18 October 1994 and for the same amount of aid as the present proposal, was presented as investment aid, although

the CL plant was located in an area not eligible for regional aid. The aid proposal was withdrawn by Austria when it appeared inevitable that the Commission would decide to open the procedure within the meaning of Article 93(2) of the EC Treaty, and would probably adopt a negative decision,

— with regard to the proposed aid for research and development, the Commission expressed doubts as to whether the aid conformed to the criteria given in the Community framework on State aid for research and development ([1]). In particular, the research and development activities were described in broad terms, without a structured technical approach and lacking in specific technical targets and milestones. Moreover, neither the 'incentive' effect nor the necessity for the aid were convincingly demonstrated,

— with regard to the aid for environmental protection, a technical description of the measures envisaged were described in general terms, without detailed information as to the eligible costs and the relationship between the aid and the improvement of environmental protection due the aided investments,

— as regards the aid of ATS 5 million to CL for the retraining of CL employees, the Commission requested legislative and regulatory information confirming that the granting of this type of subsidy was open to all undertakings established in Austria on an objective and non-discretionary basis,

— finally, given the loss-making situation of CL, the Commission raised the question whether the proposal of Austria to grant aid to HLR for the establishment of HLR in Linz might constitute an indirect means of providing a State subsidy for CL.

Austria's observations to the opening of the Article 93(2) procedure were submitted to the Commission by letter registered on 26 April 1996. A meeting between the Austrian authorities and the Commission took place on 19 September 1996, and further information was received by letters registered on 31 October and 20 November 1996.

The other Member States and interested parties were informed of the Commission's decision to initiate proceedings and were invited to submit their observations, by publication of a notice on 12 June 1996 in the *Official Journal of the European Communities* ([2]). No observations were received either from other Member States or from third parties.

([1]) OJ C 45, 17. 2. 1996, p. 5.
([2]) OJ C 168, 12. 6. 1996, p. 2.

B. **The company**

HLR is a leading international pharmaceutical corporation, founded in 1896. The company, which comprises four divisions, pharmaceuticals, vitamins and fine chemicals, diagnostics and fragrances and flavours, researches, develops, manufactures and markets high-quality products and services in the field of health care. The pharmaceuticals division is the largest, making up 63 % of Group sales in 1995.

The HLR group has some 50 000 employees of whom about 50 % are located in Europe and 30 % in North America. Turnover amounted to ECU 8 500 million in 1995 (increasing to ECU 9 400 million in 1996), with net income increasing by over three times from ECU 555 million in 1990 to ECU 2 000 million in 1995. Sales by region in 1995 were 37 % in Europe, 37 % in North America, 14 % in Asia, and 3 % in Africa, Australia and the Pacific.

HLR's record of innovation derives primarily from its heavy investment in research and development, with expenditure of about ECU 1 340 million on R & D in 1995, or about 16 % of sales. In the pharmaceutical division, R & D expenditure was above 20 % of pharmaceutical sales. According to company information, it currently takes about 10 years and ECU 260 million to bring a new drug onto the market. HLR invests a major part of the profits from product sales in research and development and hence in the future of the company.

Company literature states that HLR addresses safety and environmental issues as thoroughly and responsibly as questions relating to improving product quality and productivity, and hence considers these issues to be an integral part of its business activities. Risk analysis has emerged as the main tool for identifying possible hazards, whereas environmental protection efforts are focused on pollution prevention. Total expenditure on safety and environmental protection was ECU 300 million in 1995, equivalent to nearly 4 % of sales.

C. **Potential to distort trade between Member States**

(a) *Trends in the development of anti-obesity drugs*

The treatment of obesity, the reduction of real or perceived excess body weight, can in principle be achieved by the pharmacological manipulation of any one of the several biochemical pathways involved in regulating body weight, and involving many different parts of the body including the brain, fat tissue, muscle fibres and the cells lining the gut. The manipulation of any single pathway is expected by most in the field to provide sufficient clinical benefit to give rise to a commercially feasible product.

Several pathways have been studied for many years including inhibition in the gut of fat-digesting enzymes (termed lipases), which modulate the digestion of dietary fat, as well as means to stimulate the oxidation of fat in the body (thermogenesis). In the last four years, there has been a rapid increase in the understanding of the molecular biology of obesity, driven by the discovery of genes linked to obesity. Some of the most recent anti-obesity drug developments are summarised below.

Sibutramine, an anti-obesity treatment from Knoll Pharmaceuticals (a company arising from the takeover of Boots Pharmaceuticals by BASF in 1995), has been approved for marketing by the US Food and Drug Administration. Sibutramine works by increasing the levels of the hormones serotonin and noradrenaline, both of which are involved in appetite control, in the brain. The drug works by enhancing a feeling of fullness, thereby reducing appetite. It is also thought to increase energy expenditure. Sibutramine was developed at Knoll's Nottingham UK site and it will be produced at Nottingham and also at Cramlington. The company is currently pursuing approval of the drug in Europe. In early 1996, the Food and Drug Administration approved the anti-obesity drug Isomeride (dexfenfluramine) developed by the French laboratory Servier. The drug, which reduces hunger by raising the levels of serotonin in the brain, is to be produced by Interneuron Pharmaceuticals under the name Redux.

The UK company Alizyme is working on several drugs (termed lipase inhibitors) to block the action of fat-digesting enzymes in the gut, thereby reducing the intake of fats into the body. HLR pioneered this approach, and the company has filed a New Drug Application on the lipase inhibitor Orlistat.

Germany's Boehringer Ingelheim and the Danish firm Novo Nordisk have entered into a multiyear agreement on research into drug treatment for obesity. The focus of the agreement will be the discovery of new drugs which influence receptors on cells in the brain or in fat cells, thereby regulating food intake, energy expenditure or the number of fat cells, and thus decreasing fat accumulation in obese people.

Ciba-Geigy (Basle, Switzerland) and Synaptic Pharmaceutical (Paramus, New Jersey, USA) have found a new Neuropeptide Y (NPY) receptor, (Y5). The peptide is produced in the brain and is important in regulating appetite, being the most potent appetite stimulant yet described. New treatments to fight obesity will be targeted at the receptor for NPY. Synaptic and Ciba-Geigy are engaged in preclinical research on various small-molecule compounds specific for the Y5 receptor. The first drug targeting Neuropeptide Y (NPY1), developed in a collaboration between Neurogen and Pfizer, has begun first-phase clinical trials on humans.

In the United States alone, customers paid as much as ECU 43 billion for weight-loss products such as special diets and over-the-counter medications, even though the results are short-term effects in most cases. Indeed, Redux, the first anti-obesity drug to be approved by the Food and Drug Administration in May 1996 is expected by some market analysts to generate peak annual sales of about ECU 430 million. Given the enormous market potential of anti-obesity drugs, it is not surprising that several companies are working in this highly competitive area, targeting a broad range of pharmacological pathways.

(b) *Development of Orlistat*

The development of the anti-obesity drug Orlistat has followed the usual development path for pharmaceuticals:

Preclinical testing:

a company conducts laboratory and animal studies to show biological activity of the compound against the targeted ailment, and the compound is evaluated for safety. This phase may take from two to four years.

Clinical trials, phase I:

these tests involve about 20 to 80 normal, healthy volunteers and focus on drug safety and dosage, including studies of drug absorption, distribution in the body and drug metabolism.

Clinical trials, phase II:

studies with 100 to 300 volunteer patients to test the drug's effectiveness.

Clinical trials, phase III:

studies with 1 000 to 3 000 patients, usually in clinics and hospitals to determine drug efficacy and identify adverse reactions.

The clinical trials (phases I, II, III) may last from five to seven years.

New drug application (NDA):

the company files an NDA with the Food and Drug Administration if the data successfully demonstrate safety and effectiveness. Approval may take up to two years.

Approval:

once the drug is approved, it becomes available on the market.

On average, only 5 in 5 000 compounds pass on from the preclinical testing phase to clinical trials, and only one of these five is finally approved. From preclinical testing to approval may take in excess of 10 years, and the cost may be over ECU 450 million to get a drug from the laboratory to the market place.

According to information provided by Austria, laboratory work on Orlistat apparently began in 1986. The drug, to be marketed under the name Xenical in the United States, is a potent inhibitor of intestinal lipases and blocks the absorption of approximately 30 % of dietary fat.

In early 1992, it appears that phase II clinical trials on 400 overweight individuals were completed, and phase III trials were due to begin. By 1993, it appeared that phase III trials were under way. In December 1996, HLR filed a new drug application with the Food and Drug Administration.

The company views Xenical as one of its most important products, and advertising will be aimed at the medical profession, managed-care organisations and consumers. Some analysts forecast that peak annual sales could reach up to about ECU 450 million.

D. **Proceedings following opening of the Article 93(2) procedure**

As mentioned above, and in accordance with the Article 93(2) procedure, the Commission invited the Austrian Government to submit its observations. The other Member States and interested parties were informed of the Commission's decision to initiate proceedings and were invited to submit their observations. No third party comments were received.

The Austrian Government's reply

The observations submitted by the Austrian authorities in arguing that the aid should be allowed may be summarised as follows.

(a) Aid for research and development

— pharmaceutical research has specific characteristics which are not taken into consideration by the Community framework of aid for research-development. Indeed, pharmaceutical research can be divided into three stages which stretch over at least 10 years: the research concept phase, preclinical tests and clinical trials. The last-named stage can be subdivided in three phases, of which only the third involves tests on a significant number of persons (several thousand);

— the research corresponds to 'industrial research' and 'precompetitive development activity' according to the definitions given in the 1996 State aid guidelines, since at the time of the notification the drug Orlistat was still several years away from the market.

Furthermore, the research concept phase, preclinical tests and the first two stages of the clinical trials constitute 'industrial research' not only because the drug is several years from the market, but also because of the still substantial risk that the drug will not pass the final stages of clinical testing. Also, the third stage of the clinical tests are to be regarded as 'precompetitive development activity',

— other pharmaceutical companies carry out research on anti-obesity drugs, but their procedure is different from that of Orlistat,

— the 'incentive' effect is clear since HLR would not have carried out the production of 'hydoxy-beta-lactone' at CL without the prospect of receiving State aid,

— finally, as regards the necessity of the aid, the Austrian authorities consider that the aid is necessary because of the high development costs, the substantial risk that the drug will not be approved for marketing, as well as the particularly innovative character of Orlistat.

(b) Aid for environmental protection

— according to the Austrian authorities, the measures of environmental protection to be implemented by HLR at the CL plant go beyond the standards required by Austrian legislation,

— Austria provided further information on the eligible costs and on the economic advantages for the company arising from the implementation of the environmental measures.

(c) As regards aid for CL personnel retraining, this subsidy constitutes a general measure, not limited to any region, sector or individual company.

(d) Finally, as to possible indirect aid for CL, Austria considers the aid for research and development and for environmental protection to be compatible with the EC Treaty; therefore the issue as to whether the aid intended for HLR actually benefits CL is not relevant.

II. LEGAL ASSESSMENT

A. **Compatibility of the aid with the common market**

Article 92(1) lays down the principle that, except where otherwise provided, aid which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods is, in so far as it affects trade among Member States, incompatible with the common market. However, Article 92(2) and (3) set out the circumstances in which such aid is, or may be, allowed.

In this case, Article 92(2) is inapplicable, owing to the character, purpose and location of the aid in question. Article 92(3) further provides that other aid may be compatible with the common market. Compatibility must be determined within the context of the Community and not of a single Member State.

In this case, the aid cannot benefit from the derogations under points (a), (b) and (d) of Article 92(3) because the area where the investment will be realised is not an assisted area, the project is not an important project of common European interest, nor does it aim to remedy a serious disturbance in the economy of a Member State, nor is it intended to promote culture and heritage conservation.

Furthermore, the Commission has for research and development and environmental measures adopted Community guidelines setting out the criteria for assessing the compatibility with the common market of State aid in this area, thereby limiting the discretionary margin under point (c) of Article 92(3).

The Commission has therefore to consider the compatibility of the proposed aid with the assessment criteria described in the research and development guidelines and environmental aid guidelines ([1]).

B. **Compatibility of the research and development aid with the common market**

The R & D programme goes from the research concept phase to clinical trials (phase III), and aid is proposed of ATS 300 million. The company considers the total costs for the development of the drug to be ATS 4 354 million.

(a) *Need for the aid*

Although the project is stated to have begun in 1986, the proposal for State aid was only notified by the Austrian authorities in October 1995, by which time phase II clinical trials which demonstrated the effectiveness of Orlistat as an anti-obesity drug had been concluded (in 1992), and phase III clinical trials with a large number of obese individuals were well under way.

At present, phase III clinical trials have been completed and approval of the drug (for sale) is expected by 1999. Since the drug development project has come to a successful end, the granting of aid to Hoffmann-La Roche at the present time for an already terminated R & D project constitutes *a priori* an operating aid to that company.

Even in October 1995 when the aid was notified, phase III clinical trials had begun and the drug development project was more than half-complete in terms both of duration and of expenditure. In these circumstances, it is evident that Hoffmann La Roche began the project at is own risk and without the prospect of receiving aid. Indeed, the Commission calls on Member States to demonstrate that the aid is necessary as an incentive and is on no account operational aid (point 6.3, Community framework for research and develpment, 1996). In this case, the Commission considers that Austria has not demonstrated the need for the aid.

(b) *Nature of the research and development*

A categorisation of a research project according to the definition of types of research activities (fundamental research, industrial research, precompetitive development activity) is meant to serve as an indicator as to how close to the market the aid proposal is, and thereby to help in defining the maximum allowable aid intensity. Fundamental research and industrial research may qualify for higher levels of aid than precompetitive development activities which are closer to the market and which could therefore have a greater potential to distort competition and trade. However, this is not to say that companies, particularly those in R & D-intensive sectors do not need to carry out all the different categories of research and development research as part of their normal activity, either to remain competitive or to secure future competitive advantage.

Even in the pharmaceutical ssector where product development times are long, categorising a research project as fundamental research, industrial research or precompetitive development activity is open to a wide range of interpretation. Particular account needs to be taken as regards the existing state-of-the-art technology and technology trends.

Nevertheless, the boundary conditions of the types of research and development that may benefit from State funding are clearly defined, and may be used to determine whether the R & D aid is compatible with the common market.

To qualify as 'fundamental research' (and eligible for up to 100 % funding) the work should not be linked to any industrial or commercial objective of any particular enterprise, and a wide dissemination of the results of the research must be guaranteed (in a time frame such that the whole industrial sector may benefit). The definition of 'precompetitive development activity' encompasses research activities (eligible for up to 25 % funding) up to

([1]) OJ C 72, 10. 3. 1994, p. 3.

and including the creation of an initial prototype, initial demonstration projects or pilot projects which cannot be converted or used for industrial applications or commerial exploitation; explicitly excluded are routine or periodic changes made to products, production lines, manufacturing processes, existing services and other operations in progress, even if such changes may represent improvements.

It has already been indicated above that the development of Orlistat is typical of drug development in the pharmaceutical industry, and therefore constituted normal operations in progress for the company at the time the project began, being the consequence of a strategic business decision to develop anti-obesity drugs. Indeed, developing an anti-obesity drug has long been an objective of Hoffman-La Roche, which previously had five other drugs in development which were discontinued for a variety of reasons. Furthermore, the pharmaceuticals division of HLR itself considers 'preclinical research' and 'drug development' to be fundamentally different tasks which have as a consequence been split into different departments (La Roche annual report 1995). According to company information, development functions ranging from clinical trials of new drugs to drug regulatory affairs were reorganised with the aim of streamlining and refining business processes and to pursue process optimisation as an ongoing task. The project as notified when phase III clinical trials were well under way, and it would appear that the company itself considers this phase to be part of the normal business process rather than research.

On the basis of the above, the Commission cannot agree with Austria's claim that the work is eligible for funding as 'industrial research' and 'precompetitive development activity' within the meaning of the State aid guidelines of 1996. Neither is the work eligible for funding as 'applied research and development' withtin the meaning of the State aid guidelines of 1996.

(c) *Incentive effect of the aid*

The 'incentive' effect of the proposed aid, an inducement for the company to carry out research which it would not otherwise have pursued as part of its normal R & D activities, was examined, back to the time when the project was notified in October 1995. This incentive effect is clearly expressed in both the 1986 [1] and 1996 research and development guidelines, both placing emphasis on the need to ensure that such aid does not become the equivalent of operating aid.

As indicated above, the development programme of the anti-obesity drug 'Orlistat' was one typical for the pharmaceutical sector, which, furthermore, was well advanced at the time of the notification. Given the market prospects, it would have been perfectly normal for any pharmaceutical company to carry out the research on anti-obesity drugs. As shown above, other anti-obesity drugs are currently on the market, and there has been a rapid increase in research on obesity in the last few years, driven by the discovery of genes linked to obesity.

On the basis of the above, the Commission does not agree the Austrian authorities' argument that in 1995 the project as described was especially ambitious, involving expenditure and risks well above the normal for this type of drug development, and that the project demanded extraordinary efforts outside the scope of the company's normal R & D activity. Indeed, the conjectural effect of granting aid to the company in October 1995 would simply have been to reduce the normal risk of commercial failure in the development of an anti-obesity drug by providing a State subsidy for a project which would anyhow have had to have been carried out in order for the company either to remain competitive, or to gain future competitive advantage.

Any 'incentive' achieved through granting the proposed aid was highly unlikely at the time the project was notified to the Commission in October 1995 and at the present time is clearly non-existent. The Commission considers then, that Austria has not demonstrated the existence of an incentive effect of the aid.

Therefore, given that the proposed aid for research and development does not fulfil the criteria set out in the State aid guidelines on research and development, it is not compatible with the common market.

C. **Compatibility of the aid environmental protection**

(a) *The measures*

HLR has offered to implement additional measures which, according to the Austrian authorities, go considerably beyond the level of environmental protection required in Austria and the standards normally promoted by HLR itself. The mandatory environmental standards applicable to chemical plants such as the project in Linz have their legal basis in federal law which applies to the whole of Austria.

The offer by HLR to go beyond legislative requirements was made on the assumption that the aid promised by the Austrian authorities would actually be granted. Accordingly, these environmental measures must be considered additional measures that HLR would not implement without State aid.

Three series of environmental measures are concerned: five measures to reduce the risk of environmental accidents, three measures to prevent water pollution, and seven measures to combat air pollution.

The specific measures and the aid proposed are as follows (figures in ATS million):

[1] OJ C 83, 11. 4. 1986, p. 2.

Description	Extra investment	Aid amount	Aid intensity (gross %)
Five measures to reduce the risk of accidents			
1.1. Production building as containment	30,1	9,03	30
1.2. Blow down container	4,95	1,485	30
1.3. Pressure resistant apparatus	47,5	12,6	26,53
1.4. Fully automatic control	51,5	15	29,13
1.5. Separate storage facility for butyllithium	7,1	1,5	21,13
Three measures to prevent water pollution			
2.1. Collecting tanks for production platforms	4,7	1,41	30
2.2. Stripping of waste water	28,4	5,67	19,96
2.3. Chemical treatment of waste water	14,9	3,3	22,15
Seven measures to combat air pollution			
3.1. Discharged air	65,6	16,2	24,70
3.2. Solvent recovery	110	0	0
3.3. Heat recovery for heating and cooling	4	0	0
3.4. Prevention of diffuse emissions	13	3,9	30
3.5. Glove boxes	15,8	4,5	28,48
3.6. Low-emission sampling	1,692	0,507	30
3.7. Vacuum pumps fitted with a magnet	0,96	0,289	30

Measures 3.2 and 3.3 are not eligible for aid because of the high operational savings involved in their implementation.

For each of the additional measures, the Austrian authorities have submitted a detailed description of the standard legal requirements, the investment needed to achieve the standard requirements, the nature of the additional measures, the investment related to the additional measures, and the aid element expressed in monetary terms and as a percentage of the eligible costs.

(b) *Measures to reduce the risk of accidents*

The first series of measures are presented by Austria as concerning the reduction in risk of 'environmental' accidents. In opening the procedure, the Commission had already stated that '... when it assesses new investments with environmental aspects, it has to take a strict approach in order to prevent firms from receiving aid towards supposed environmental expenditure that serves to finance investments which they would have carried out in any event'.

The Commission continued '... new plants will inevitably be built to the highest level of safety available on the market, it is consequently difficult to accept that State aid should be granted to help the firm to reach this level'. Finally, the Commission added that 'aid towards measures to improve the protection of workers or health or to improve the firm's efficiency or reduce its costs cannot be declared compatible with the common market, as those measures would have had to be taken in any event'.

Contrary to the other measures for which the Austrian authorities notified environmental aid, the alleged justification of this first series of measures is not to reduce the release into the environment of polluting substances emanating from normal production activities, but they are clearly described as targeted towards reducing the risk of explosion as well as the release of harmful substances in case of operating plant malfunction. The main purpose of these measures is to prevent catastrophic occurrences, minimising harm to humans (for example, employees, adjacent residents, etc.), and not primarily aimed at reducing environmental damage.

Even if the proposed measures go beyond the prevailing mandatory standards in Austria, aid necessity cannot be justified because the prevention of accidents constitute an obligation for the company, which in case of accident would bear liability for it. The Commission is of the view that State aid should not be granted to cover the companies' obligations.

Austria has provided no justification as to why it considers these measures to be primarily 'environmental' and therefore eligible to benefit from State aid, particularly since it is supposed that the best available safety technology is used in the construction of new chemical plants.

As already mentioned, the Commission is of the view that the highest level of safety would have to be implemented in the interest of the company itself. Public opinion is such that firms are fully expected to carry out risk analysis and implement the appropriate safety measures in order to prevent accidents. Safety and the prevention of damage are clearly a key concern for chemical companies, since any accident would likely involve high liability as well as a loss of public image and a reduction in sales.

The high priority placed on safety is confirmed by HLR company literature. In the foreword of the 'Safety and environment protection at Roche: group report 1995', the Chairman of the Board of Directors states that 'Continuous study of possible damage scenarios, however, logically led to a change in attitude. Instead of waiting passively for damage to occur, players shifted their attention to measures designated to prevent damage. Risk analysis emerged as the main tool for identifying possible hazards. Now performed in all processes and plants, risk analysis enables chemists and engineers to assess the impact of possible process deviations and to reduce the risk to an acceptable level by suitable technical, organisational and personnel measures'.

Furthermore, the Chairman added that '... we do not consider safety and environmental protection solely as an obligation towards government and the public but also as an integral part of our business activities'. The fact that safety matters are of vital concern to the chemical industry in general and for HLR in particular is confirmed in the same report, which states that HLR wants '... to present our data in a way that would satisfy a demanding specialist readership, but we would also like to reach out to a wider audience of employees, customers, shareholders and others, givin them the background information that will help them see the broader picture and make it easier to assess the Roche data'.

Given that safety measures are aimed at reducing the risk of accidents and that they are a key part of the business activities of HLR, the necessity of the aid in favour of such measures has been not demonstrated. Hence, aid for the safety measures foreseen (1.1 to 1.5 in the above table) is to be considered as general investment within the meaning of the Community guidelines on State aid for environmental protection, and therefore excluded from its scope. On this basis, the Commission considers that the aid proposal for the planned safety measures is not compatible with the common market.

(c) *Measures to combat water and air pollution*

The measures aimed at preventing water pollution are intended to significantly reduce emissions into the Danube. For example, the new measures will enable emission of solvents and residual substances such as phenylethylamine to be stopped, although this is still permitted under existing environmental regulations. In addition, levels of organic halogen compounds (AOX) in wastewater will be reduced by more than 75 %.

The measures to combat air pollution are claimed to reduce to zero the emissions into the atmosphere of hydrocarbons, heat-transfer oils, and dangerous dust and solvents, although these emissions are still permitted under the existing environmental regulations. Other measures will reduce the uncontrolled release of gases into the environment. Here too, the existing standards will be exceeded.

Aid for investment that allows significantly higher levels of environmental protection to be attained than those required by mandatory standards may be authorised up to a maximum of 30 % gross of the eligible costs. The level of aid actually granted in order to exceed mandatory standards must be in proportion to the environmental improvement to be achieved and to the extra investment necessary for achieving the improvement.

Due account must be taken of any costs savings or other advantages obtained by the investor on the back of the investment. These elements should be deducted from the nominal extra investment costs to achieve the eligible costs. *Mutatis mutandis,* operational costs should be added to the investment in order to obtain the eligible costs.

Taking into account the arithmetical error committed by the Austrian authorities in subtracting the operational savings from the aid amount and not from the extra investment, the amount of aid allowable under the abovementioned guidelines are the following (figures in million ATS):

Description	Extra investment	Eligible cost	Aid amount (30 % gross intensity)
2.1. Collecting tanks for production platforms	4,7	4,7	1,41
2.2. Stripping of waste water	28,4	25,2	7,56
2.3. Chemical treatment of waste water	14,9	14,9	4,47
3.1. Discharged air	65,6	65,2	19,56
3.2. Solvent recovery	110	11	0
3.3. Heat recovery for heating and cooling	4	4	0
3.4. Prevention of diffuse emissions	13	13	3,9
3.5. Glove boxes	15,8	17	5,1
3.6. Low-emission sampling	1,692	1,692	0,507
3.7. Vacuum pumps fitted with a magnet	0,96	0,96	0,289
Total	259,05	157,65	42,796

The grant of aid up to ATS 42 796 000 for additional measures to prevent water and air pollution is in conformity with the Community guidelines on State aid for environmental protection, and is compatible with the common market in accordance with the derogation in Article 92(3)(c) of the EC Treaty.

D. **The aid for personnel training to Chemie Linz**

In the opening of the proceedings, the Commission requested the Austrian authorities to confirm that the training aid given to the firm Chemie Linz (CL) was a general measure.

The measure is based on the Order on aid to general industrial training measures (implementing the Labour-Market Aid Act, part B/IV/C). Its legal basis was extensively modified in 1994 and it is now Article 33, read in conjunction with Article 34(2), points 2 and 4, of the Labour Market Service.

The aim of the measure is to train people previously placed in a firm by the Labour Market Service, the body in charge of reallocating unemployed people in the labour market. The objective is to raise the level of an individual's qualifications and to increase individual professional mobility. The measure, according to the Austrian authorities, is not restricted to any particular region, sector or firm.

However, a discretionary decision must be taken by this body in order to allow the training aid. The criteria taken into account when assessing an application are the risk of job-loss in a company, whether the former unemployed person now hired by the company needs training, whether the training obtained is of use to more than one firm, and a long-term commitment by the company to the training programme.

Therefore, as the subsidy is not granted under objective and automatic criteria it must be considered State aid in the meaning of Article 92(1) of the EC Treaty, because it relieves firms of some of the financial costs arising from their normal economic activities.

According to Article 172(5) of the Act of Accession of Austria, Finland and Sweden to the European Union, '... all decisions taken by the EFTA Surveillance Authority before the date of accession pursuant to Article 61 of the EEA Agreement and which fall under Article 92 of the EC Treaty as a result of accession shall, on accession, remain valid with respect to Article 92 of the EC Treaty unless the Commission decides otherwise pursuant to Article 93 of the EC Treaty'.

Consequently, as a major modification took place in 1994 to the legal basis of the training aid scheme in question, it should have been notified to the EFTA Surveillance Authority (ESA) pursuant to Article 1(3) of Protocol 3 to the Surveillance and Court Agreement [1]. As the Austrian authorities have not complied with this notification obligation, the scheme has to be considered a new aid and not an existing aid. It is, moreover, illegal for having been put into force before the ESA (and later the Commission) could state its view as to its conformity with State aid rules.

The assessment of the Commission will therefore be limited to the individual aid of ATS 5 million to CL towards the retraining of its employees enabling them to operate the chemical plant for the production of hydroxy-beta-lactone, and is without any prejudice to the position of the Commission on the scheme itself.

The amount of the aid is small, ATS 5 million (ECU 360 000) as compared to the cost of the training

[1] OJ L 231, 3. 9. 1994, p. 1.

programme which is ATS 150 million for the first four years and covers at least 150 people. The aid intensity is therefore about 3 % gross.

The training obtained through the individual aid is of use to more than one firm and is by no means specific to the firm's operations. The aid should thus be considered a measure in favour of workers, even if a company benefits indirectly from it. Besides that, it is clear that owing to the financial and economic difficulties suffered by CL and the potential risk of job losses, employees of this company who benefit from the training aid have a better chance in finding other qualified jobs in case they lose their present jobs.

The position of the Commission on measures such as those to promote training and the acquisition of new skills is expressed in the Guidelines on aid to employment [1] which states that '... where such measures fall within the scope of Article 92(1) of the EC Treaty, the Commission usually gives them sympathetic consideration'.

Given these considerations, the Commission considers the proposal to grant the planned individual training aid to be compatible with the common market in accordance with the derogation provided for in Article 92(3)(c) of the EC Treaty.

E. **Possible indirect restructuring aid to Chemie Linz**

In its decision to initiate proceedings in this case, the Commission also considered that, were it to find that the aid measures were not compatible with the Treaty under the rules on aid for the environment or for research, the alternative question would then have to be asked whether it had to be regarded as aid to Chemie Linz, a company in financial difficulties.

As far as the notified aid for R & D and environmental protection is concerned, the Commission has found that part of it is compatible, on its own merits, with the common market and that part of it is incompatible. Accordingly, as the incompatible aid cannot be granted to HLR, it could not constitute an indirect aid to CL and the examination of this aspect no longer has any relevance,

HAS ADOPTED THIS DECISION:

Article 1

Research and development aid of ATS 300 million which Austria plans to grant to Hoffmann La Roche for the development of the anti-obesity drug Orlistat is not compatible with the common market within the meaning of Article 92(2) and (3). The proposed aid shall, therefore, not be paid.

Article 2

The aid of ATS 39 615 million which Austria proposes to grant to Hoffmann La Roche for additional measures to reduce the risk of accidents in the operation of the plant for hydroxy-beta-lactone in Linz, is not compatible with the common market within the meaning of Article 92(2) and (3). The proposed aid shall, therefore, not be paid.

Article 3

Environmental aid of ATS of 42 796 million to Hoffmann-La Roche for additional measures to prevent water pollution and combat air pollution, in the operation of the plant mentioned in Article 2 is compatible with the common market within the meaning of Article 92(2) and (3).

Article 4

The individual aid of ATS 5 million granted to Chemie Linz towards the retraining of its employees so as to enable them to operate the chemical plant for the production of hydroxy-beta-lactone is illegal on the ground that the scheme under which it was granted was not notified to the EFTA Surveillance Authority, as required by Article 172(5) of the Act of Accession of Austria, Finland and Sweden to the European Union.

Without prejudice to the position of the Commission on the scheme itself, the individual aid to Chemie Linz can be considered compatible with the common market within the meaning of Article 92(2) and (3).

Article 5

The Republic of Austria shall inform the Commission of the measures it has taken to comply with this Decision within two months of the date of its notification.

Article 6

This Decision is addressed to the Republic of Austria.

Done at Brussels, 21 May 1997.

For the Commission

Karel VAN MIERT

Member of the Commission

[1] OJ C 334, 12. 12. 1995, p. 4.