EFTA SURVEILLANCE AUTHORITY

Invitation to submit comments pursuant to Article 1(2) in Part I of Protocol 3 to the Surveillance and Court Agreement concerning aid measure — State guarantee in favour of deCODE Genetics in relation to the establishment of a drug development department (SAM 030.02.006 — Iceland)

(2003/C 308/09)

By means of Decision 139/03/COL of 16 July 2003, reproduced in the authentic language on the pages following this summary, the EFTA Surveillance Authority initiated proceedings pursuant to Article 1(2) of Protocol 3 of the Surveillance and Court Agreement concerning the above mentioned aid measure. The Icelandic Government has been informed by means of a copy of the decision.

The EFTA Surveillance Authority hereby gives the EFTA States, EU Member States and interested parties notice to submit their comments on the measure in question within one month from the publication of this notice to:

EFTA Surveillance Authority
Rue de Trèves/Trierstraat 74
B-1040 Brussels

The comments will be communicated to the Government of Iceland. Confidential treatment of the identity of the interested party submitting the comments may be requested in writing, stating the reasons for the request.

SUMMARY

Procedure

By letter dated 27 May 2002, the Icelandic Government notified, pursuant to Article 1(3) of Protocol 3 to the Surveillance and Court Agreement, a proposal to provide a guarantee to deCODE Genetics Inc. (US) in connection with a research and development project which the company intends to undertake in the field of biotechnology in Iceland.

In the course of the investigation, the Icelandic Government submitted an expert report on the estimation of the net grant equivalent of the planned aid and informed the Authority that the Icelandic Government had decided to request deCODE Genetics Inc. (US) to pay an annual guarantee fee amounting to [. . .] (*) % of the nominal value of the bonds.

In September 2002, the Authority received a complaint against the proposed State aid in favour of deCODE Genetics. The complainant argued that the proposed State guarantee constituted incompatible State aid. The complainant argued, in particular, that the project would have to be qualified as 'pre-competitive development'. As such, the proposed aid granted for the notified project would exceed the permissible aid ceiling of 25 % of eligible costs. The complainant *inter alia* also claimed that due to recent development within the company, it was unlikely that the proposed State aid would contribute to the European industry's competitiveness.

In December 2002, the Authority awarded a contract to an external expert, concerning the evaluation of the notified R & D project under the R & D Guidelines. The external expert delivered his final report on 10 April 2003.

In a letter dated 9 May 2003, the Authority informed the Icelandic Government of its doubts concerning the compatibility of the notified aid for R & D projects which had not been clearly identified. It also informed the Icelandic Government that, due to the lack of sufficiently precise information regarding the individual R & D projects, the Authority was not in a position to verify that the proposed State aid would be in compliance with Article 61(3)(c) of the EEA Agreement, in combination with the R & D Guidelines.

(*) Business secret — deleted figures.

Description of the aid measure — State guarantee

In May 2002, the Icelandic Parliament authorised the Ministry of Finance to issue a guarantee to deCODE Genetics Inc. (US) in relation to a bond amounting to USD 200 million. DeCODE is a population genetics company working to identify the genetic causes of common human diseases and to apply this knowledge to discover novel means of treating, diagnosing and preventing disease. DeCODE also provides drug discovery services to third parties, typically major pharmaceutical or biotechnology companies. The proceeds of the bond would be passed down to deCODE's wholly owned subsidiary, deCODE erfðagreining ehf., located in Reykjavik and then be utilised to establish a new department for developing bio-pharmaceutical products in Iceland.

The Icelandic authorities informed the Authority about the main characteristics of the bond and the State guarantee. However, the terms of the bond, as well as the terms under which the State guarantee would be issued, would only be finally fixed after the Authority had approved the aid. The Icelandic authorities informed the Authority that contrary to what was initially notified, the bond would have a duration of five years (instead of the initially foreseen seven years). The bond could be converted into deCODE stock in the event that the price of the shares would exceed USD 18. In addition, deCODE would have the right to reduce the conversion price. If the bonds were converted into stocks, they would be regarded as paid up and the State guarantee would lapse.

At the time the proposed guarantee was notified to the Authority, the price of the company's stocks was in the range of USD 5 per share. Since then, the share price havs fallen to below USD 2 per share and they are currently traded at around USD 3.5 per share.

The R & D project, the financing of which should be secured through the notified State guarantee, consists of the establishment of a new drug development department based on research carried out by deCODE in population genomics and genealogy-based genetic research.

DeCODE uses population genomics to discover how genetic factors contribute to the cause of diseases. DeCODE's access to an extensive genealogical database and associated bioinformatics is the core of DeCODE's approach to identifying human disease genes and associated drug targets. deCODE hopes that working with the Icelandic population puts it in a position to accelerate the discovery and development of new proprietary diagnostic and therapeutic products.

According to the information submitted, deCODE has successfully isolated genes related to specific diseases [. . .]. For certain drug targets, deCODE has concluded collaborative agreements with pharmaceutical companies in relation to several of the disease genes discovered. DeCODE now wishes to develop a portfolio of drug targets for in-house drug development based on the results from its genetic research.

The R & D activities covered by the notified State support consist of 'target validation' and 'drug development'. The Icelandic authorities explained that after a drug target for a specific disease has been identified, the fundamental research under the current project would start. Once deCODE succeeded in identifying a disease gene it would conduct fundamental research within the scope of the proposed project to define molecular pathways in which the disease gene plays a role. In the next phase of the project, drug development really begins. During this phase, research is carried out to identify the drug leads (i.e. work on the initial chemicals which have been identified during the screening assays phase and which showed positive results in acting against the drug target).

Appreciation of the aid

According to an evaluation carried out by the expert in July 2002 on behalf of the Icelandic State, the State guarantee would allow deCODE to borrow money on the market at conditions more favourable than without the proposed State guarantee. The Authority considers that it is reasonable to assume that the State guarantee would give deCODE a financial benefit and strengthen deCODE's position in relation to its competitors within the EEA. Consequently, the proposed State guarantee is liable to distort competition and affect trade between the Contracting Parties within the meaning of Article 61(1) EEA Agreement.

According to the Icelandic Government, the proposed State guarantee would be compatible under Article 61(3)(b) of the EEA Agreement, according to which 'aid to promote the execution of an important project of common European interest' may be considered to be compatible with the functioning of the EEA Agreement. According to relevant practice of the European Commission, this derogation may apply particularly to 'transnational projects of major qualitative and, in principle, quantitative significance'. Since the proposed State aid would benefit only the establishment of a drug development department by deCODE, the Authority has doubts as to whether the notified aid can be regarded as compatible with Article 61(3)(b) of the EEA Agreement.

The Authority has then assessed the aid according to Article 61(3)(c) of the EEA Agreement in conjunction with Chapter 14 of the Authority's State Aid Guidelines. In line with point 14.2.1(1), 14.5.1 and 14.7 the Authority needs to assess the scope and nature of the research activity, the aid intensity and the incentive effect of the aid.

Proposed State aid for specific R & D projects

The Authority has doubts as regards to the exact number of target validation and drug discovery programmes which would be carried out by deCODE under the R & D project for which State support is sought.

According to the information submitted to the Authority, deCODE has not taken a decision on which specific drug targets would be included in the project for which State support is sought. Given the lack of a decision on the part of deCODE as well as the Icelandic authorities on which specific R & D projects would be carried out, the Authority is not in a position to ascertain that the proposed State aid would be used to carry out a specific R & D project. The Authority cannot therefore exclude that the proposed State aid could be used by deCODE to cover running expenses with respect to the establishment of a drug development department. Any such aid not linked to a specific R & D project bears the risk of constituting operating aid.

The Authority has doubts as to whether State aid may be approved with respect to R & D programmes which have not been clearly identified as being included in the project (with explicit reference to disease targets) and which may only later materialise (possibly years after the request for State support was submitted) and then be possibly included in the overall R & D project. In addition, the Authority has doubts as to whether deCODE is willing and capable of carrying out the R & D programmes (as regards both target validation and drug discovery) which have been identified by the Icelandic authorities as being candidates for drug development under the envisaged research project.

As regards target validation, the Icelandic authorities submitted that this can only start after a disease gene has been identified. Disease genes with respect to which target validation work should be carried out, have, however, only been established for a certain number of diseases. The Authority has doubts as to whether target validation could be carried out with respect to diseases for which the disease genes have not yet been identified and whether the costs related to this work can be determined without having identified the disease gene.

As regards the drug discovery programmes, the Authority has doubts as to whether deCODE would actually carry out drug discovery with respect to all drug discovery programmes identified by the Icelandic authorities.

Incentive effect

Based on the information in the Authority's possession, and in light of the evaluation made by the external expert, the Authority currently sees no reason to question the incentive effect of the proposed Sate aid.

Eligible costs

In the absence of more detailed information, the Authority cannot verify whether it is reasonable to expect that the kind of research activity which is described in general terms will actually be carried out with respect to individual disease programmes. The information submitted by the Icelandic authorities rather indicates that the nature and scope of the research activities may differ quite significantly, depending on the disease target in question. Consequently, in the absence of an individualised work plan for a specific programme, the Authority is not in a position to clearly identify the eligible costs.

Permissible aid ceilings

Given the absence of verifiable information concerning the eligible costs for individual R & D programmes, it is not possible for the Authority to ascertain that the proposed State aid respects the permissible aid ceilings. The various concerns expressed above rather indicate that the proposed State aid would exceed the permissible aid intensities.

Conclusions

The aid proposed for the project constitutes aid within the meaning of Article 61(1) of the EEA Agreement. The Authority has doubts as to whether the notified aid may be regarded as compatible with the functioning of the EEA Agreement, and in particular Article 61(3)(c), because the information submitted by the Icelandic authorities does not demonstrate that the conditions set out in Chapter 14 of the Authority's State Aid Guidelines are fulfilled.

Consequently, and in accordance with Chapter 5.2 of the Authority's State Aid Guidelines, the Authority is obliged to open the formal investigation procedure provided for in Article 1(2) of Protocol 3 to the Surveillance and Court Agreement against the proposed State aid in the form of a guarantee in favour of deCODE Genetics Inc.

I. **FACTS**

A. **Procedure**

Notification by the Icelandic Government

By letter from the Ministry of Finance dated 27 May 2002, received and registered by the Authority on 30 May 2002 (Doc. No 02-4055-A), the Icelandic Government notified, pursuant to Article 1(3) of Protocol 3 to the Surveillance and Court Agreement, a proposal to provide a guarantee to deCODE Genetics Inc. (US) in connection with a research and development project which the company intends to undertake in the field of biotechnology in Iceland.

By letter dated 24 July 2002, the Authority acknowledged receipt of the notification and requested additional information to be submitted within one month from receipt of that letter (Doc. No 02-5620-D).

By letter from the Ministry of Finance dated 13 August 2002, received and registered by the Authority on 19 August 2002 (Doc. No 02-6060-A), the Icelandic Government submitted a report on the estimation of the net grant equivalent of the planned aid (hereinafter referred to as the '[. . .] (**) Report') and informed the Authority that the Icelandic Government had decided to request deCODE Genetics Inc. (US) to pay an annual guarantee fee amounting to [. . .] % of the nominal value of the bonds.

The Authority acknowledged receipt of this information by letter dated 22 August 2002 (Doc. No 02-6078-D).

After several requests for an extension of the deadline (cf. letter from the Ministry of Finance dated 6 September 2002, received and registered by the Authority on 10 September 2002 (Doc. No 02-6456-A); letter from the Ministry of Finance dated 4 October 2002, received and registered by the Authority on 7 October 2002 (Doc. No 02-7176-A) and letter from the Ministry of Finance dated 17 October 2002, received and registered by the Authority on 18 October 2002 (Doc. No 02-7574-A)), the Icelandic Government responded to the questions raised in the Authority's letter of 24 July 2002, by letter from the Ministry of Finance dated 30 October 2002, received and registered by the Authority on 31 October 2002 (Doc. No 02-7905-A) and the letter from the Icelandic Mission dated 8 November 2002, received and registered by the Authority on that same day (Doc. No 02-8063-A). In addition, the Authority was informed of certain amendments to the initial notification.

By letter dated 25 November 2002 (Doc. No 02-8459-D), the Authority acknowledged receipt of this information. In this letter, the Authority informed the Icelandic Government that the notification could not be regarded as complete since the final terms for the guarantee, the convertible bonds and the security arrangements, were not then available. The Authority further informed the Icelandic Government that it would engage an external expert in order to assess, inter alia, the qualification of the nature of the project, the suitability of the project's budget, as well as the State aid's incentive effect for the project in question in light of Chapter 14 of the Authority's State Aid Guidelines ('R & D Guidelines').

In December 2002, the Authority awarded a contract to an external expert concerning the evaluation of the notified R & D project under the R & D Guidelines.

In February 2002, the external expert submitted his draft report. The expert's statements revealed the need for further information.

By letter dated 10 February 2003 (Doc. No 03-808-D), the Authority requested the Icelandic Government to submit additional information. The Icelandic Government responded to this request by letter dated 10 March 2003, received and registered by the Authority on that same day (Doc. No 03-1443-A).

The external expert delivered his final report on 10 April 2003.

In a letter dated 9 May 2003 (Doc. No 03-2990-D), the Authority informed the Icelandic Government of its doubts concerning the compatibility of the notified aid for R & D projects which had not been clearly identified. It also informed the Icelandic Government that, due to the lack of sufficiently precise information regarding the individual R & D projects, the Authority was not in a position to verify that the proposed State aid would be in compliance with Article 61(3)(c) of the EEA Agreement, in combination with the R & D Guidelines.

Following this letter, several meetings were held between representatives from the Icelandic Government and the Authority in which the Icelandic authorities presented proposals of how the Authority's concerns could be allayed. The arguments presented by the Icelandic Government were, however, not regarded as dispelling the Authority's doubts.

Complaint

In September 2002, the Authority received a complaint against the proposed State aid in favour of deCODE Genetics. The complainant argued that the proposed State guarantee constituted State aid within the meaning of Article 61(1) of the EEA Agreement. In the complainant's view, the proposed State guarantee was incompatible with the functioning of the EEA Agreement. In this respect, the complainant maintained that the conditions as laid down in Article 61(3)(c) of the EEA Agreement, in combination with the R & D Guidelines were not fulfilled. The complainant argued, in particular, that the project would have to be qualified as 'pre-competitive development'. As such, the proposed aid granted for the notified project would exceed the permissible aid ceiling of 25 % of eligible costs. The complainant also considered that the proposed State aid would not have the required incentive effect.

In a further submission of May 2003, the complainant pointed to, in his view, significant changes in the market which would imply that the value of the State guarantee would have increased significantly. The complainant also claimed that due to recent development within the company, it was unlikely that the proposed State aid would contribute to the European industry's competitiveness.

B. **Description of the aid measure — State guarantee**

In May 2002, the Icelandic Parliament authorised the Ministry of Finance to issue a guarantee to deCODE Genetics Inc. (US) in relation to a bond amounting to USD 200 million. The proceeds of the bond would be passed down to the wholly owned subsidiary, deCODE erfðagreining ehf., located in Reykjavik and then be utilised to establish a new department for developing biopharmaceutical products in Iceland [1].

The Icelandic authorities informed the Authority about the main characteristics of the bond and the State guarantee. However, the terms of the bond, as well as the terms under which the State guarantee would be issued, would only be finally fixed after the Authority would have approved the aid.

[1] Whereas the guarantee is proposed to be granted to deCODE Genetics Inc. (US), proceeds from the State guaranteed bond will go to deCODE ehf. (Iceland). The direct aid recipient and the aid beneficiary are therefore two legally distinct entities. In the following, reference will be made to 'deCODE' without making a distinction between the mother and the daughter company.

The Icelandic authorities informed the Authority that contrary to what was initially notified, the bond would have a duration of five years (instead of the initially foreseen seven years). The bond could be converted into deCODE stock in the event that the price of the shares would exceed USD 18. In addition, deCODE would have the right to reduce the conversion price. If the bonds were converted into stocks, they would be regarded as paid up and the State guarantee would lapse.

At the time the proposed guarantee was notified to the Authority, the price of the company's stocks was in the range of USD 5 per share. Since then, the shares price fell to below USD 2 per share and is currently traded at around USD 3,5 per share ([2]).

According to the Icelandic Government, deCODE would have to pay a guarantee premium. Even though the exact amount had not been finally decided upon, the notification was based on the assumption of a possible guarantee premium of [. . .] %.

The Icelandic Government asked an independent expert [. . .] to evaluate the guarantee. The expert based its assessment of the value of the proposed State guarantee, *inter alia*, on the preliminary terms of the guarantee and the bond (this assessment was based on a duration of the bond of seven years and the payment of a guarantee premium) and the financial information available about deCODE at the time of the assessment. The value of the State guarantee was determined by comparing the estimated cost of capital based on a CAPM ([3]) analysis without the State guarantee, with the estimate cost of debt based on the proposed State guarantee for the USD 200 million bond. The expert came to the conclusion that the value of the State guarantee ('net grant equivalent') would be in the range between USD [. . .] and USD [. . .] (the midpoint of this range being USD [. . .]).

C. **Description of the aid beneficiary**

DeCODE Genetics Inc. was incorporated in Delaware (US) in 1996. Its wholly owned subsidiary, deCODE erfðagreining ehf. has its headquarters in Reykjavik. DeCODE is a population genetics company working to identify the genetic causes of common human diseases and to apply this knowledge to discover novel means of treating, diagnosing and preventing disease. DeCODE also provides drug discovery services to third parties, typically major pharmaceutical or biotechnology companies. In addition to its genetics research and drug discovery services, deCODE commercialises database services and healthcare informatics products. With the acquisition of MediChem Life Sciences Inc. in March 2002, deCODE has access to advanced drug discovery and development capabilities. In addition, in November 2000, deCODE acquired Encode, to launch pharmacogenomics studies in Iceland and to conduct clinical trials for new and existing therapeutics as a Contract research organisation.

The company has, according to the information provided in the notification, around 600 employees worldwide (as of 31 December 2001) ([4]).

According to the Annual Report for 2001, deCODE had an annual turnover amounting to USD 31,5 million, a net loss of USD 47,8 million and a balance sheet total of USD 256,4 million. Operating expenses for R & D development amounted to USD 71,8 million.

D. **Description of the R & D project**

1. *Project description*

(a) General outline and objectives

The R & D project, the financing of which should be secured through the notified State guarantee, consists of the establishment of a new drug development department based on research carried out by deCODE in population genomics and genealogy-based genetic research.

DeCODE uses population genomics to discover how genetic factors contribute to the cause of diseases. DeCODE's access to an extensive genealogical database and associated bioinformatics is the core of deCODE's approach to identifying human disease genes and associated drug targets. DeCODE hopes that working with the Icelandic population puts it in a position to accelerate the discovery and development of new proprietary diagnostic and therapeutic products.

According to the information submitted, deCODE has successfully isolated genes related to specific diseases [. . .]. For certain drug targets, deCODE has concluded collaborative agreements with pharmaceutical companies in relation to several of the disease genes discovered.

DeCODE now wishes to develop a portfolio of drug targets for in-house drug development based on the results from its genetic research. DeCODE will continue its genetic research to identify disease genes responsible for other diseases for which it has already mapped genetic loci. This research is not covered by the proposed State aid.

In the company's view, the development of a portfolio of several drug targets at any given time is necessary in order to be successful in bringing even a few products to the market. Therefore, the scope of the overall R & D project for which State support has been notified, is not limited to the R & D projects for which disease genes have already been identified. The scope of the R & D project for which State support is sought is therefore intended to cover also possible future drug candidates which could be included at a later stage depending on the progress made by deCODE in identifying new disease genes.

The R & D activities covered by the notified State support consist of 'target validation' and 'drug development' (for a more detailed description of these activities, please see below). Clinical research required to put new drugs on the market will not be covered by the notified State support. The envisaged State support project would only cover a period of 5 years up to the filing of an Investigatory New Drug filing with the US Food and Drugs Administration or its equivalent in other jurisdictions.

([2]) Information from http://www.nasdaq.com/ (date 11 July 2003).

([3]) Capital Asset Pricing Model.

([4]) The Authority notes that the actual number of deCODE employees in Iceland is not entirely clear, since the company had to lay off around 200 employees worldwide in the autumn 2002.

Based on the information submitted by the Icelandic authorities, deCODE has identified at present [. . .] target validation and [. . .] drug discovery programmes as being candidates for research (so-called 'initial programmes'). However, the overall R & D project for which State support is sought consists of, in total, [. . .] target validation and [. . .] drug discovery programmes.

(b) 'Target Validation'

The Icelandic authorities explained that after a drug target for a specific disease has been identified, the fundamental research under the current project would start. Once deCODE succeeded in identifying a disease gene it would conduct fundamental research within the scope of the proposed project to define molecular pathways in which the disease gene plays a role [. . .].

(c) 'Drug development'

In the next phase of the project, drug development really begins. During this phase, research is carried out to identify the drug leads (i.e. work on the initial chemicals which have been identified during the screening assays phase and which showed positive results in acting against the drug target).

This phase can be divided into the following phases [. . .].

2. *Eligible costs*

According to the financial schedule submitted by the Icelandic authorities, the project for which State support is sought comprises in total [. . .] R & D programmes ([. . .] target validation programmes and [. . .] drug discovery programmes). The costs to be incurred in the first five years of the project (i.e. the duration of the project covered by the proposed State guarantee) are estimated to amount to ISK 34 billion. Of this amount, ISK 20 billion (approximately USD 200 million, based on a conversion rate of USD 1 = ISK 100) would be raised through the issue of convertible bonds with the proposed State guarantee. The remaining costs of the project shall be financed by deCODE Genetics.

These overall cost estimates are broken down into operating expenses, interest costs and investment costs. Operating costs consist of personnel costs amounting to [. . .], chemicals and consumables amounting to [. . .], contractor services amounting to [. . .], and overhead expenses amounting to [. . .]. Net interest costs were estimated to amount to [. . .] and investments costs [. . .].

For the five-year period, the costs related to 'target validation' (which was regarded by the Icelandic authorities as fundamental research) were estimated to amount to [. . .], and for 'drug development' (which was regarded as industrial research) [. . .].

Whereas personnel costs were in addition allocated to the specific research programmes (i.e. research into a specific disease/drug candidate), and further broken down with respect to the specific activity within either target validation or drug discovery, no such comparable cost allocation was done for other cost items. Other costs were only allocated to what was regarded by the Icelandic authorities to constitute either fundamental or industrial research.

3. *Incentive effect*

According to the Icelandic authorities, the proposed aid has the required incentive effect. In this respect, the Icelandic authorities refer to the risks involved in the project which would exceed those risks faced by other companies engaged in a more conventional approach to drug discovery and development.

In the Icelandic Government's view, the project would be extremely ambitious in scope and its aims. The project would entail the creation of the world's first proprietary drug discovery operation based largely upon fundamental research in human genetics. What makes the project so ambitious is, according to the Icelandic authorities, the aim of bringing a steady stream of the targets isolated and verified through subsequent drug development and into clinical testing and to sustain several projects at any one time at various stages of development over a period of many years. Given the lack of precedent for successful drugs developed from population genetics research, and the large investment in terms of finance and time required to follow through such a project, the Icelandic authorities consider the project to be extremely ambitious.

As regards the comparison between the envisaged project and deCODE's current activities, the Icelandic authorities informed the Authority that the project would only extend to target validation and drug development of disease targets that are not currently a part of deCODE's ordinary business activities (i.e. covering only those drug targets which are not subject to collaborative arrangements with pharmaceutical companies).

Finally, and as regards the quantifiable factors as referred to in point 14.7(2) of Chapter 14 of the Authority's State Aid Guidelines, the Icelandic authorities point to an increase in R & D spending, based on current R & D spending amounting to USD 71,8 million in 2001 and the projected R & D spending over the first five years of the project. Furthermore, and according to the amended notification, deCODE would envisage recruiting up to 350 new employees to undertake fundamental and industrial research (compared to the envisaged 300 additional employees referred to in the initial notification). All the 350 employees would be new staff dedicated solely to the new research and development activity.

II. APPRECIATION

A. State aid within the meaning of Article 61(1) of the EEA Agreement

By virtue of Article 61(1) of the EEA Agreement, '*any aid granted by EC Member States, EFTA States or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between the Contracting Parties, be incompatible with the functioning of this Agreement.*'

According to an evaluation carried out by the expert in July 2002 on behalf of the Icelandic State, the State guarantee would allow deCODE to borrow money on the market at conditions more favourable than without the proposed State guarantee. The expert came to the conclusion that the aid element contained in the proposed State guarantee would amount to approximately [. . .] (the average being [. . .]). Apparently not included in this evaluation, is the guarantee premium of [. . .] % (i.e. approximately [. . .] expressed in net present value terms ([5])). The financial benefit to deCODE after taking into account the payment of a guarantee premium would consequently be reduced to [. . .] (the average being [. . .]).

Without it being necessary at this stage to assess in more detail whether the evaluation which was made in July 2002 would still be valid, the Authority considers that it is reasonable to assume that the State guarantee would give deCODE a financial benefit and strengthen deCODE's position in relation to its competitors within the EEA. Consequently, the proposed State guarantee is liable to distort competition and affect trade between the Contracting Parties.

In light of these considerations, the Authority has concluded that the proposed State guarantee constitutes aid within the meaning of Article 61(1) of the EEA Agreement

B. **Notification requirement and standstill obligation**

Pursuant to Article 1(3) of Protocol 3 to the Surveillance and Court Agreement, *'[t]he EFTA Surveillance Authority shall be informed, in sufficient time to enable it to submit its comments, of any plans to grant or alter aid . . . The State concerned shall not put its proposed measures into effect until the procedure has resulted in a final decision'*.

The Act authorising the Ministry of Finance to issue a guarantee in favour of deCODE does not, in the Authority's understanding, confer any right on deCODE with respect to the guarantee. It is still for the Icelandic Government to take a decision whether or not and, if so, under which conditions to issue a guarantee to deCODE. Since no such decision has been taken, the Authority considers that the proposed State aid has not yet been put into effect.

C. **Compatibility of the aid measures**

1. *Assessment of the aid measure under Article 61(3)(b) of the EEA Agreement*

According to the Icelandic Government, the proposed State guarantee would be compatible under Article 61(3)(b) of the EEA Agreement.

By virtue of Article 61(3)(b) of the EEA Agreement, *'aid to promote the execution of an important project of common European interest'* may be considered to be compatible with the functioning of the EEA Agreement.

As stated in Chapter 14 of the Authority's State Aid Guidelines, this provision has been applied in the field of R & D by the European Commission, only in a limited number of cases. According to relevant Commission practice, this derogation may apply particularly to *'transnational projects of major qualitative and, in principle, quantitative significance'* ([6]). Aid granted for a project the results of which only benefit a single undertaking, without a co-operation with other companies in the EEA and without a dissemination of the results, which would result in the formulation of EEA wide industry standards as referred to in the guidelines, would not seem to be covered by this exemption.

Since the proposed State aid would benefit only the establishment of a drug development department by deCODE, the Authority has doubts as to whether the notified aid can be regarded as compatible with Article 61(3)(b) of the EEA Agreement.

2. *Assessment of the aid measure under Article 61(3)(c) of the EEA Agreement*

The Icelandic Government claimed that the proposed State guarantee was justified under Article 61(3)(c) of the EEA Agreement. It would be in the common interest of the EEA to strengthen the position of Europe in the field of biotechnology. According to the Icelandic Government, the aid would provide a significant boost to the competitiveness of the European biotechnology industry by opening up a completely new way of approaching genetic research. The reason for the project being undertaken in Iceland was because of the unique genetic pool of its inhabitants. This project would lead the way to other companies in the EEA being able to build on this foundation. This would provide the EEA an advantage in the development of novel pharmaceutical products developed from genetic and biotechnological research and would give the European industry a competitive advantage compared to the US.

Article 61(3)(c) of the EEA Agreement regards aid to facilitate the development of certain economic activities, where such aid does not adversely affect trading conditions to an extent contrary to the interests of the Contracting Parties, as compatible with the functioning of the EEA Agreement. Aid granted for R & D activities is assessed under Chapter 14 of the Authority's State Aid Guidelines.

According to point 14.2.1(1) of Chapter 14 of the Authority's State Aid Guidelines, *'The closer the R & D is to the market, the more significant may be the distortive effect of the State aid. In order to determine the proximity to the market of the aided R & D, the EFTA Surveillance Authority makes a distinction between fundamental research, industrial research and precompetitive development activity.'*

([5]) The Authority's calculation of the net present value of the guarantee premium is based on the reference rate of interest which was, as from 1 January 2002, fixed for Iceland at 9,54 %.

([6]) See e.g. State aid case N 692/2001 — Germany.

According to point 14.5.1 of Chapter 14 of the Authority's State Aid Guidelines, *'The allowable intensity of aid will be determined by the EFTA Surveillance Authority on a case-by-case basis. The Authority's assessment in each case will take into consideration the nature of the project or programme, overall policy considerations relating to the competitiveness of European industry, the risk of distortion of competition and the effect on trade between the Contracting Parties. A general evaluation of such risks leads the Authority to consider that fundamental research and industrial research may qualify for higher levels of aid than precompetitive development activities, which are more closely related to the market introduction of R & D results and, if aided, could therefore more easily lead to distortions of competition and trade.'*

According to point 14.7 of Chapter 14 of the Authority's State Aid Guidelines, *'State aid for R & D should serve as an incentive for firms to undertake R & D activities in addition to their normal day-to-day operations. It may also encourage firms not carrying out research and development to undertake such activities. Where this incentive effect is not evident, the EFTA Surveillance Authority may consider such aid less favourably than it usually does.'*

Against this background, the Authority needs to assess the scope and nature of the research activity, the aid intensity and the incentive effect of the aid.

(a) Proposed State aid for specific R & D projects

The Icelandic Government notified the Authority of the intention to grant a State guarantee to deCODE Genetics in relation to a bond amounting to USD 200 million. The proceeds from the bond shall be used to finance deCODE's project of establishing a biopharmaceutical research and development department in Iceland [. . .].

According to the information submitted to the Authority, deCODE has not taken a decision on which specific drug targets would be included in the project for which State support is sought. Given the lack of a decision on the part of deCODE as well as the Icelandic authorities on which specific R & D projects would be carried out, the Authority is not in a position to ascertain that the proposed State aid would be used to carry out a specific R & D project. The Authority cannot, therefore exclude that the proposed State aid could be used by deCODE to cover running expenses with respect to the establishment of a drug development department. Any such aid not linked to a specific R & D project bears the risk of constituting operating aid.

Furthermore, an assessment of the R & D projects benefiting from the proposed State support under the R & D Guidelines is difficult since the Icelandic authorities failed to submit detailed work plans for specific R & D projects (in particular when it comes to determining and evaluating the reasonableness of the proposed R & D budget; see below).

According to the financial schedule submitted by the Icelandic authorities, the overall project deCODE wants to embark upon, consists of [. . .] target validation programmes and [. . .] drug discovery programmes. However, the Authority also notes, that out of the [. . .] target validation programmes and the [. . .] drug discovery programmes, only [. . .] target validation programmes and [. . .] drug discovery programmes have been clearly identified as possible candidates for research to be carried out with the proposed State support. The remaining programmes (i.e. [. . .] target validation programmes and [. . .] drug discovery programmes) would possibly become part of the project at a later stage.

As pointed out above, the Authority has doubts as to whether State aid may be approved with respect to R & D programmes which have not been clearly identified as being included in the project (with explicit reference to disease targets) and which may only later (possibly years after the request for State support was submitted) materialise and be possibly included in the overall R & D project.

In addition, the Authority has doubts as to whether deCODE is willing and capable of carrying out the R & D programmes (as regards both target validation and drug discovery) which have been identified by the Icelandic authorities as being candidates for drug development under the envisaged research project.

Based on the description given by the Icelandic authorities, target validation work can only start after a disease gene has been identified. Disease genes with respect to which target validation work shall be carried out under the project have, however, only been identified for [. . .] diseases [. . .]. As regards other diseases mentioned by the Icelandic authorities in the financial schedule for the project [. . .], the information submitted shows that even though genetic loci have been mapped/candidate genes identified, a disease gene has not been discovered yet. The Authority has, therefore, doubts as to whether target validation could be carried out with respect to diseases for which the disease genes have not yet been identified.

Furthermore, based on the explanations provided by the Icelandic authorities, it is the nature of the disease gene which is determining for the scope and nature of research work. Therefore, the Authority has doubts as to whether the research work to be carried out by deCODE with respect to a specific disease target, and thus the costs related to this work, can be determined without having identified the disease gene.

In addition, the Authority has doubts as to whether deCODE would actually carry out drug discovery with respect to all drug discovery programmes identified by the Icelandic authorities [. . .]. These doubts result from information about deCODE's financial performance in 2002, according to which, drug discovery work for Myocardial Infarct and Hypertension may not be necessary (cf. deCODE Genetics Annual report (SEC form 10-K) presented on 15 April 2003: *'. . . in our drug discovery work on our findings in myocardial infarction and hypertension, we believe we may be able to bypass much of the drug discovery process and enter directly into phase II clinical trials as early as mid-2003.'*).

Against this background, the Authority has doubts as regards to the exact number of target validation and drug discovery programmes which would be carried out by deCODE under the R & D project for which State support is sought. Based on the concerns raised above, eligible research projects might be limited only to [. . .] target validation programmes and [. . .] drug discovery programmes.

(b) Assessment of the type of research

According to the initial notification, the project for which State support is sought consists of elements of fundamental research ('target validation') and industrial research ('drug discovery').

According to the external expert, 'target validation' qualifies as 'fundamental research'. This activity is designed to increase scientific and technical knowledge about the diseases being studied. It is primarily linked to understanding some of the mechanisms involved in disease initiation and progression and is not necessarily leading to the development of new commercial products. According to the external expert, this activity is very much upstream in the R & D process, and there is a significant risk that it may not lead to the identification of drug targets and the development of new products, processes or services. Time-to-market may be greater than 10 years.

As regards 'Drug Development', the external expert considers that phases 1-4 [. . .] could be classified as 'industrial research'. On the other hand, phases 5 and 6 [. . .] would qualify as 'pre-competitive development activity'. In his view, the objective of phases 5 and 6 is to create initial prototypes of drugs that provide a strong basis for patent filing and that will direct the development of new products.

The Authority sees no reason to deviate from this assessment as regards 'target validation' and parts of 'drug development'. However, the Authority has doubts as to whether certain activities forming part of the 'drug development' (i.e. phases 5 and 6) can be qualified as 'industrial research' as claimed by the Icelandic authorities ([7]).

(c) Assessment of the incentive effect of the aid

The external expert agreed that the proposed State aid would have an incentive effect, since a large proportion of deCODE's project corresponds to a new activity (i.e. large-scale drug discovery effort performed by deCODE alone). According to the external expert, the aid would indeed induce deCODE to pursue new R & D activities that imply a considerable increase in R & D spending. The proposed aid would permit deCODE to widely expand the scope of its research to drug discovery and drug development.

In the expert's view, the incentive effect of the aid specifically relied on the fact that the aid would allow deCODE to embark upon a large-size drug development program, in particular to hire a large number of scientists and to secure high financial input. The project exceeded in risk and ambition what is normally done by other companies in the same industry, strictly because of the large number of simultaneous research programs, especially if considering that deCODE would invest heavily and immediately in activities (drug development) for which the company has previously not demonstrated success. On the other hand, the expert pointed out that the risks associated with the individual target validation and drug discovery programs planned by deCODE, do not exceed in nature and intensity those faced by other companies in the same industry. Individual target validation and drug discovery programs comprised in deCODE's project were not 'extremely ambitious' as compared to other programs foreseen or being performed by other companies in the same industry.

Based on the information in the Authority's possession, and in light of the evaluation made by the external expert, the Authority currently sees no reason to question the incentive effect of the proposed Sate aid.

(d) Assessment of the eligible costs

The information submitted by the Icelandic Government does not allow the Authority to determine the exact amount of eligible costs given that the R & D programmes have not been clearly identified by the Icelandic authorities and given that no detailed work plan has been submitted which could have been used as a basis for evaluating the reasonableness of the proposed R & D budget.

The Icelandic authorities have merely described in abstract terms the kind of activities that need to be carried out in the context of target validation and drug discovery, without specifying the kind of activities that will actually be carried out with respect to individual programmes.

It is the kind of activity which will be carried out by deCODE which will determine the eligible costs for a specific R & D programme. In the absence of more detailed information, the Authority cannot verify whether it is reasonable to expect that the kind of research activity which is described in general terms will actually be carried out with respect to individual disease programmes. The information submitted by the Icelandic authorities rather indicates that the nature and scope of the research activities may differ quite significantly, depending on the disease target in question. Consequently, in the absence of an individualised work plan for a specific programme, the Authority is not in a position to clearly identify the eligible costs.

Even though the external expert was able to provide the Authority with average figures concerning the personnel required for target validation and drug discovery activities in general, the Authority cannot, due to the uncertainties referred to above, exclude the possibility that the requirements for individual programmes may differ substantially from these average figures. In this context, the Authority also notes that, according to the external expert, the estimates regarding required personnel as well as other cost items were overstated.

In addition to the lack of detailed information as referred to above, the exact determination of the eligible costs has not been possible because the Icelandic Government has not allocated all cost items to specific R & D programmes (most cost items have only been shared between fundamental research and industrial research without being allocated to individual R & D programmes or activities) and because certain cost items have not been properly justified (in particular building costs).

([7]) According to the external expert, activities related to phases 5 and 6 qualify as 'pre-competitive development'. As such, they could benefit from aid up to 25 % of eligible costs. It would, however, appear that the notified aid should not cover 'pre-competitive development' activities.

The Icelandic authorities have only submitted detailed information as regards personnel costs. Based on the information submitted, it is not possible to allocate other cost items to individual research programmes and activities within each programme.

The Authority also notes that the Icelandic authorities have not provided a satisfactory explanation concerning the extraordinary building expenses which are supposed to be incurred in the first two years of the project [. . .].

(e) Assessment of the permissible aid ceilings

Given the absence of verifiable information concerning the eligible costs for individual R & D programmes, it is not possible for the Authority to ascertain that the proposed State aid respects the permissible aid ceilings. The various concerns expressed above rather indicate that the proposed State aid would exceed the permissible aid intensities.

In this respect, the Authority observes that the project's budget of ISK 34 billion was based on [. . .] target validation programmes (for which a budget of ISK [. . .] was foreseen) and [. . .] drug discovery programmes (for which a budget of ISK [. . .] was foreseen). In the following, the Authority would like to illustrate the effects of a limitation of the scope of the R & D project on the budget and thus the permissible aid. The figures presented are based on average cost figures for target validation and drug development programmes, respectively, and do not necessarily reflect the exact consequences of a limitation of the eligible R & D projects on the budget.

If the R & D projects which can be regarded as sufficiently concrete would be limited to those clearly identified by the Icelandic authorities as being candidates for the project (i.e. [. . .] target validation programmes and [. . .] drug discovery programmes), the budget would be reduced as regards target validation to approximately ISK [. . .] and as regards drug discovery to approximately ISK [. . .]. If in addition, as pointed out above by the Authority, eligible R & D projects would be limited to [. . .] target validation and [. . .] drug discovery programmes, the budget would be reduced as regards target validation to approximately ISK [. . .] and as regards drug discovery to approximately ISK [. . .]. It is also noted that building costs amounting to ISK [. . .] have not been properly justified by the Icelandic authorities. Any such costs would therefore, based on the information currently available, not be included in the eligible costs. Finally, it is noted that, according to the external expert, personnel costs, in particular, were overestimated.

Whereas costs regarding target validation could benefit as fundamental research from 100 % aid intensity, the costs regarding drug discovery were regarded by the external expert, only to a certain extent, as falling within the definition of industrial research, for which the permissible aid intensity is 50 %. The remaining activities which were regarded as pre-competitive development could only benefit from 25 % aid.

Taking all this into account, it appears that the proposed State guarantee, with an estimated aid element amounting to USD [. . .], or on average USD [. . .] (which at a conversion rate of 100 would amount to ISK [. . .]), may exceed substantially what could, based on the information currently available to the Authority, be regarded as permissible.

(f) Assessment of the nature of the project or programme, overall policy considerations relating to the competitiveness of European industry, the risk of distortion of competition and the effect on trade between the Contracting Parties

The Icelandic Government took the view that the proposed aid was unlikely to lead to any significant distortion of competition. In its view, the relevant market was that of biotechnological research. According to the Icelandic Government, the biotechnological research market was 'wide open and not as easily prone to distortion as the pharmaceutical product market', given the extremely high level of risk and lack of investment across the EEA. It is further maintained that the market for biotechnological research was '*a growth market with the bounds for exploitation on the open market in a worldwide context almost limitless*'.

According to the external expert, deCODE's project concerns a large number of common diseases that are targeted by virtually all biotech companies (especially if they are initially genomic companies) and bio-pharmaceutical companies worldwide. Some of deCODE's direct competitors (i.e. genomic firms including Millenium, Celera, HGS, Myriad Genetics, Lexicon genetics and Incyte) have been, or are in the process of, moving into the therapeutic business.

In the external expert's view, the market potentially affected by the proposed aid is that of drugs that will reach clinical phases and will be best positioned to be acquired by big pharmaceutical companies. With the expectation of 200 drugs to be derived from genomic targets and considering not more than 10-20 players in the market which will be able to develop these drugs, the market size would appear to be rather limited, allowing each player to struggle for approximately 10 % of the market. The grant equivalent of the proposed aid as calculated by the expert's report amounting to USD [. . .], would represent, according to the external expert, [. . .] of either the one-year revenues or available cash for most of deCODE's direct competitors. Based on the market size and the aid intensity, the external expert considered the risk for distortive effects of the proposed aid to be significant.

In addition to gaining operational and strategic advantages over its competitors, deCODE would be able to attract investors that might no longer consider investing significantly in other European drug discovery companies, a situation that may last for a significant period of time. Human resources and facilities available to sustain the development of the emerging biomedicine sector in Iceland (basically in the Reykjavik area) were obviously limited. There is a significant number of companies that are emerging in this sector. In particular, there were at least 5 emerging pharmaceutical companies that employ 30-150 people and that develop activities in the field of therapeutics (noticeably production of generics, and design of drug delivery systems). When deCODE is allocated the proposed aid, the emerging biomedicine companies in Iceland may encounter serious difficulties in attracting investors, qualified personnel, and in accessing relevant facilities.

In light of the external expert's comments in this respect, the Authority has doubts as to whether the propose State aid in favour of deCODE would risk distorting competition and trade to an extent contrary to the common interest.

D. **Conclusions**

The aid proposed for the project constitutes aid within the meaning of Article 61(1) of the EEA Agreement. The Authority has doubts as to whether the notified aid may be regarded as compatible with the functioning of the EEA Agreement, and in particular Article 61(3)(c), because the information submitted by the Icelandic authorities does not demonstrate that the conditions set out in Chapter 14 of the Authority's State Aid Guidelines are fulfilled.

Consequently, and in accordance with Chapter 5.2 of the Authority's State Aid Guidelines, the Authority is obliged to open the formal investigation procedure provided for in Article 1(2) of Protocol 3 to the Surveillance and Court Agreement against the proposed State aid in the form of a guarantee in favour of deCODE Genetics Inc.

The Icelandic Government is invited to submit its comments to this decision.

The Icelandic Government is further requested to submit all information necessary to assess the compatibility of the proposed State guarantee with the functioning of the EEA Agreement.

The Icelandic Government is reminded not to put the proposed State aid into effect.

The Icelandic Government is invited to notify without delay the potential aid beneficiary of the initiation of the proceedings.

Finally, the Authority would like to point out that the decision to open the formal investigation procedure is without prejudice to the final decision (cf. point 5.2(2) of Chapter 5 of the Authority's State Aid Guidelines).

HAS ADOPTED THIS DECISION:

1. The Authority opens the formal investigation procedure pursuant to Article 1(2) of Protocol 3 to the Surveillance and Court Agreement against the proposed State guarantee in favour of deCODE Genetics Inc.
2. The Icelandic Government is invited, pursuant to point 5.3.1(1) of Chapter 5 of the Authority's State Aid Guidelines, to submit its comments to the present decision within two months from receipt of the present decision.
3. The Icelandic Government is requested to submit all information necessary to enable the Authority to examine the compatibility of the proposed State aid under Article 61(3)(c) of the EEA Agreement, in combination with Chapter 14 of the Authority's State Aid Guidelines, within two months from receipt of the present decision.
4. The Icelandic Government is invited to notify without delay the potential aid beneficiary of the initiation of the proceedings.
5. Other EFTA States, EC Member States and interested parties shall be informed by the publishing of this decision in the EEA Section of the *Official Journal of the European Union* and the EEA Supplement thereto, inviting them to submit comments within one month from the date of publication.
6. This decision is authentic in the English language.

Done at Brussels, 16 July 2003

For the EFTA Surveillance Authority

Einar M. BULL	Hannes HAFSTEIN
President	*College Member*