Dear Commissioner Dimas,

BASF’s application for the genetically modified starch potato Amflora was voted on in the Regulatory Committee on December 4th, 2006. The potato and the starch derived from it, is intended solely for industrial purposes – such as in the paper, textile and adhesive industry. Application and use of this specialty starch enables optimizing production processes resulting in a lower consumption of energy and resources.

Following the regulatory procedure (Council Decision 1999/488/EC), we understand that the Commission is obliged to submit the draft decision without delay to the Council in order to enable a vote. In no case shall the time from the date of referral by the Commission to the vote in Council exceed three months, therefore we anticipate our application to be on the agenda of the next meeting of the Council on February 20th, 2007.

We appreciate the support you have given to the Amflora dossier during the approval process so far, and for this reason we are surprised to recognize that the regulatory procedure was not followed and the Amflora dossier has not yet been forwarded to the Council.
We assume that the reason for the delay may be the antibiotic resistance marker gene nptII that is present in our product. It is our understanding that a WHO report of 2005 is being used to re-evaluate the previous safety assessment of the antibiotic resistance marker and that this report is put forward to justify a re-examination of the dossier.

After an approval process that has already lasted more than 10 years, we consider a re-examination as an additional and unwarranted delay since the evaluation and confirmation of safety of the nptII gene in Amflora potato was already part of the approval procedure. The safety of the selectable marker gene was fully assessed by the Rapporteur, by the Member States, by EFSA and the assessment process included a public consultation period. Moreover, the use of the nptII gene as a selectable marker gene in Amflora has no implications on the spread of microbial resistance to antibiotics. This is supported by the Commission's funded ENTRANSFOOD study stating that the nptII gene is without any risk of compromising the use of important clinically used antibiotics.

Therefore, we do not see any reason applying the precautionary principle in this case. On the contrary, this would constitute an undue delay.

We are aware of the fact that approval of GMO products in Europe is a politically highly sensitive issue. However, we do not understand your hesitation in forwarding the draft decision to the Council. The safety of Amflora potato has been demonstrated through extensive food, feed and environmental safety studies. Results of these studies have been reviewed by numerous scientific experts who collectively concluded that Amflora potato is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses. Furthermore, Amflora strengthens the Commission's overall policy as well as the numerous policy initiatives such as the Lisbon Strategy, the Biotechnology Strategy, the Strategy on Sustainable Use of Resources, the Environmental Technology Action Plan, the Biomass Action Plan and the EU-Strategy for Biofuels. The product can help increase European competitiveness in global markets, creating new income opportunities for European farmers, and contributing to environmental sustainability.

Therefore, we count on your support to enable a vote in the Environment Council on February 20th, 2007. BASF has committed significant investment and resources to the development and safety assessments of the Amflora potato in order to provide potato growers, processors and the starch industry access to the benefits of this technology.
The schedule of voting in the Environmental Council is absolutely critical. Any further delays to the Regulatory approval process will continue to deny these stakeholders access to this technology and will seriously compromise the commercial cultivation of Amflora in 2007.

Yours sincerely,

Hans Kast

cc.
President José Manuel Barroso
Commissioner Markos Kyprianou
Commissioner Günther Verheugen
Commissioner Janoz Potocnik
Commissioner Mariann Fischer Boel
Commissioner Peter Mandelson
Secretary General Catherine Day
Director General Mogens Peter Carl
Director General Robert Madelin
May 8th 2007

Re: C/SE/96/3501 – Vote in Council of Ministers on the Commission’s decision for Amylopectin potato Amflora

Dear Commissioner Dimas,

As the notifier of the genetically modified Amylopectin potato EH92-527-1, Amflora, we are approaching you with respect to the ongoing authorisation procedure under Directive 2001/18/EC.

On 4th December 2006, in the Regulatory Committee, member states voted with a simple majority in favour of the Amflora potato. Given the timelines set forward by the Commission for the remaining steps of the approval process, we expected the approval in time for the potato planting period in spring 2007.

The discussion about the safety of the use of the nptII gene brought the approval process to a halt. However, on 13th April 2007, EFSA confirmed that the use of the nptII gene as selectable marker in GM plants does not pose a risk to human or animal health or to the environment. EFSA also confirmed its earlier safety assessments of GM plants and derived food/feed products, comprising the nptII gene (e.g. Amflora).

Therefore, from our point of view, all requirements have been met to continue the approval process without any delay. This was also confirmed by DG Environment.
Please may I also remind you that the approval process for Amflora has now been running for more than 10 years and any further delay will have a significant negative economic impact on our product.

Moreover, further delays would contradict the Commission’s overall policy as well as the numerous policy initiatives - such as the Lisbon Strategy, the Biotechnology Strategy, the Strategy on Sustainable Use of Resources, the Environmental Technology Action Plan, the Biomass Action Plan and the EU Strategy for Biofuels – since our product developed in Europe for Europe can create new income opportunities for European farmers, contribute to environmental sustainability and increase European competitiveness in global markets.

Therefore, we kindly ask you to pursue the authorization procedure as quickly as possible and to ensure that a vote is held on Amflora at the next meeting of the appropriate Council of Ministers such as the Environment Council in June 2007.

Yours sincerely,

Hans Kast

cc.
President José Manuel Barroso
Commissioner Markos Kyprianou
Commissioner Günther Verheugen
Commissioner Janez Potocnik
Commissioner Mariann Fischer Boel
Commissioner Peter Mandelson
Secretary General Catherine Day
Director General Robert Madelin
Director General Mogens Peter Carl
Re: C/SE/96/3501 - Adoption of the proposed implementing act concerning the placing on the market of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch

Dear Commissioner Dimas,

We are contacting you in expectation of a final decision regarding the BASF product Amflora, our genetically modified starch potato with enhanced amylopectin content. Since all procedural requirements for the cultivation notification according to Directive 2001/18/EC are fulfilled, we are surprised that the final decision is still pending.

After an approval process lasting more than ten years the Commission’s decision proposal for cultivation of Amflora was voted on in the Council of Agricultural Ministers on 16 July 2007. According to the Commitology procedure 1999/46/EC Art. 5 it is now up to the Commission to adopt the proposed implementing act. Therefore, we would like to ask you to adopt timely the decision.

The fact that the Commission so far did not adopt the proposed implementation act is all the more difficult to understand as the GMO potato Amflora and the starch derived from it are intended solely for industrial purposes – such as for use in the paper, textile and adhesive industry. The potato will be produced in a tightly controlled identity preservation system by farmers who do the planting under a contract agreement with a starch factory. This is important from a business point of view since we have to maintain the unique quality of our amylopectin speciality starch. Furthermore, potato as a crop is easy to cultivate in co-existence with any other potato farming practice, be it conventional or organic.

We are aware of the fact that there have been discussions in the public media about the use of an antibiotic resistance gene nptII as a selection marker conferring resistance against kanamycin and neomycin in our amylopectin potato. However, these concerns are unjustified as you have stated also in your response to the written question P-4070/07 by MEP Mrs. Hiltrud Breyer and as underlined manifold by EFSA, EMEA and the
competent authorities of different European member states. Therefore the use of nptII is also fully in line with all legal requirements resulting from directive 2001/18 (Art. 4) or other legal documents.

We acknowledge that in general approvals of GM products in Europe are a politically highly sensitive issue. But, we wish to emphasize that the safety of Amflora potato has been demonstrated through extensive food, feed and environmental safety studies. The results of these studies have been reviewed by independent scientific experts who collectively concluded that Amflora potato is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses.

Amflora can help to increase the competitiveness of European farmers in global markets, creating new income opportunities, and contributing to environmental sustainability. Any further delays to the Regulatory approval process will continue to deny these stakeholders access to this technology and will seriously compromise the commercial cultivation of Amflora in 2008. Only an adoption and publication of the decision still within 2007 will enable the rapporteur country Sweden to issue the consent prior to February 2008, which allows the farmers to prepare for cultivation in 2008 (e.g. announcement of planting in the national GMO registers, ordering seed potatoes).

We are looking forward to the Commission's adoption of the proposed implementing act concerning Amflora.

Yours sincerely,

Hans Kast

cc.
President José Manuel Barroso
Commissioner Markos Kyprianou
Commissioner Günther Verheugen
Commissioner Janez Potocnik
Commissioner Mariann Fischer Boel
Secretary General Catherine Day
Re: Genetically modified potato “Amflora”

Dear Commissioner Dimas,

Attached is the formal request to the European Commission of BASF SE’s affiliate, BASF Plant Science GmbH (“BPS”), for which I have responsibility in BASF SE’s Board of Managing Directors, to adopt the implementing act regarding the placing on the market of BPS’ genetically modified starch potato “Amflora”.

I would have preferred to hand over this request to you in person, and explain to you in more detail why the growing and marketing of the “Amflora” potato is unobjectionable and safe under environmental, health and all other relevant aspects, that BPS has complied with all legal requirements, and is, therefore, entitled to the requested decision.

Unfortunately and to my regret, my numerous attempts, commencing in January of this year, to arrange an appointment with you had been unsuccessful.
Nevertheless, Dr. Jürgen Hambrecht, the Chairman of BASF SE's Board of Managing Directors and I would still be happy to meet and discuss with you all aspects related to BPS' request. I am confident that we could convince you on the safety of the "Amflora" potato and its benefit for both, the agriculture and the starch industry in Europe. Your proposals for a date and time of a meeting would be highly appreciated.

Neither BASF SE, nor BPS intend to make the attached formal request public at this point in time and I am assuming that the Commission would also make no public announcement until the decision has been made and communicated to BPS.

Yours sincerely,

Attachment

cc.
President José Manuel Barroso
Vice President Günter Verheugen
Commissioner Androulla Vassiliou
Commissioner Peter Mandelson
Commissioner Janz Potocnik
Commissioner Mariann Fischer Boel
Secretary General Catherine Day
BY REGISTERED POST

Notification C/SE/96/3501 – Adoption of the proposed implementing act concerning the placing on the market of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch

Call upon the Commission to act in view of an action for failure to act in accordance with Article 232 (2) of the EC Treaty

Dear Commissioner Dima,

We refer to our letter which we submitted to you on 19 November 2007 and by which we had urged you to take a final decision regarding the BASF product Amflora, BASF's genetically modified starch potato with enhanced amylopectin content.

Since up to date, the Commission has still not adopted a final decision, BASF Plant Science GmbH hereby formally calls upon the European Commission to adopt a decision in accordance with Article 18 (1) of Directive 2001/18/EC and with Article 5 of Council Decision 1999/468/EC,

in relation to the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch.

Should the Commission not define its position within a time limit of two months

starting with reception of this formal request, BASF Plant Science GmbH intends to bring an action for failure to act according to Art. 232 EC before the EC Court of First Instance.
GROUND:

All procedural and substantial requirements for the adoption of the requested decision of the European Commission are fulfilled.

1. All procedural requirements in accordance with Article 18 (1) of Directive 2001/18/EC are fulfilled and the time limit of 120 days has expired.

Article 18 (1) stipulates that "in cases where an objection is raised and maintained by a competent authority or the Commission in accordance with Articles 15, 17 and 20, a decision shall be adopted and published within 120 days in accordance with the procedure laid down in Article 30 (2)." (emphasis added)

After an approval process lasting more than ten years the Commission's decision proposal for cultivation of Amflora was voted on in the Council of Agricultural Ministers on 15 July 2007. The Community procedure as provided for under Article 18 having been opened in early 2005, the period of 120 days has expired, even taking into account the provisions for the calculation of the time period, namely the fact that "any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee (...) shall not be taken into account" and that the period of time that the Council takes to act in accordance with the comitology procedure shall not be taken into account.

The European courts have held repeatedly that where secondary legislation stipulates that the Commission "shall" adopt a specific measure and has exclusive authority to adopt the measure in question, it is obliged to do so. According to Article 18 (1), it falls under the Commission's exclusive authority to adopt a decision and "a decision shall be adopted and published within 120 days". Consequently, the Commission has no discretionary power as regards the question whether or not to adopt a decision.

2. Moreover, in accordance with Article 18 (1), 30 (2) of Directive 2001/18/EC in conjunction with Article 5 (6) subparagraph 3 of Council Decision 1999/468/EC, as the Council has neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures during its vote on 16 July 2007, "the proposed implementing act shall be adopted by the Commission". (emphasis added) The wording of the provision demonstrates clearly that the Commission does not have a discretionary power as to whether or not to adopt the implementing act. Besides, it has to adopt the implementing act as it has been submitted to the Council. This interpretation is in accordance not only with the letter but also with the spirit and purpose of Council Decision 1999/468/EC and more particularly with its regulatory procedure under Article 5.

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1 See Case T-126/98, Lilly-Industries, (1998) ECR II-2571, where the Commission was under an obligation to act on the basis of a regulation in the veterinary sector, Regulation 2377/90, under which the Commission had the exclusive authority to deal with requests made pursuant to the Regulation. The Court held at para. 59: "In this case, the Commission had no discretion to decide whether there is any need to act on the request made by the applicant under Article 8 (2) of Regulation No 2377/90. Rather, it has exclusive authority to act on requests made under that article, it was under an obligation to act on the applicant's request." Similarly, in C-170/02 P, Schlüsselverlag J.S. Meyer GmbH and others v Commission (2003) ECR I-4969, the Court held at para. 16 that the Commission could not decline to take a formal decision on the question whether a particular transaction fell to be considered under Regulation 4546/99 where it was solely responsible to take decisions under that Regulation.

2 The German version of Article 18 (1) stipulates that "In Fällen, in denen ein Eingriff vorgenommen und von einer zuständigen Behörde oder der Kommission gemäß den Artikeln 15, 17 und 20 eingeleitet wird, wird nach dem Verfahren des Artikels 30 Absatz 2 innerhalb von 120 Tagen eine Durchführungserlaubnis und -vermerkerte." The French version of Article 18 (1) stipulates that "Lorsqu'une objection est soulevée et maintenue par une autorité compétente ou la Commission conformément aux articles 15, 17 et 20, une décision est adoptée et publiée dans un délai de cent vingt jours, selon le procédure prévue à l'article 30, paragraphe 2." (emphasis added)

3 The German version of the provision stipulates as follows: "Hat der Rat nach Artikel 30 Absatz 2 innerhalb von 120 Tagen eine Durchführungserlaubnis und -vermerkerte, so wird der Verantwortliche, der die Durchführungserlaubnis von der Kommission erteilt, die Maßnahmen ausgesprochen, so wird der Verantwortliche, der die Durchführungserlaubnis von der Kommission erteilt." The French version stipulates: "Si le Conseil n'a pas adopté les mesures d'application proposées ou s'il n'a pas indiqué qu'il s'opposait à la proposition de mesures d'application, les mesures d'application susmentionnées sont arrêtées par le Conseil." (emphasis added)
3. In addition, all substantial requirements for the adoption of a decision in accordance with Article 18 (1) of Directive 2001/18/EC in relation to the placing on the market of the potato product Solanum tuberosum L. line EH92–527-1 genetically modified for enhanced content of the amylopectin component of the potato starch are fulfilled as no new elements have arisen since the vote of the Council on 16 July 2007 and the Commission's written answer to a Parliamentary question dated 21 September 2007, by which the Commission again dispelled any concerns which had been raised before.

BASF Plant Science GmbH would like to recall, first of all, that the European Food Safety Authority has held in its opinion of 7 December 2005 and repeatedly thereafter that there is no evidence to indicate that the placing on the market of the potato EH92–527-1 intended to be cultivated for industrial starch production is likely to cause adverse effects on human and animal health or the environment.

Secondly, the Commission has already on two occasions prepared a positive proposal for decision regarding the placing on the market of the potato line EH92–527-1. It has stated in this regard in a written answer of 21 September 2007 to the question P–4070/07 by MEP Hilfrud Breyer that it had prepared its proposal for the draft decision to the Council in the light of the positive position adopted by the EFSA. The Commission stated further that it "has established all possible requirements to prevent under the current decision the presence of potatoes in other products and in the feed and food chain." 

The Commission has convened several working group meetings with the relevant national competent authorities, and the majority of Member States concurred with the opinion of EFSA. (...) Moreover, in the light of the information provided by EMEA concerning the use of kanamycin and neomycin in human and veterinary medicine, the EFSA GMO panel published a statement in March 2007, reiterating its earlier conclusions that the use of the nptII gene as selectable marker in GM plants (and derived food or feed) does not pose a risk to human or animal health or to the environment. The GMO Panel also confirmed earlier safety assessments of GM plants and derived food/feed comprising the nptII gene."

(Emphasis added)

Thirdly, it should be noted that the potato product in question and the starch derived from it are intended for industrial purposes, such as for the use in the paper, textile and adhesive industry. The potato will be produced in a tightly controlled identity preservation system by farmers who sell the planting under a contract agreement with a starch factory. The measure requested in the procedure relating to the placing on the market for food/feed use under Regulation 1829/2003 is fully independent from the implementing act requested above. This has been confirmed by the Commission in its answer to written question P–4070/07 by MEP Hilfrud Breyer (at point 2).

4. BASF Plant Science GmbH would like to emphasise that due to the delay caused by the commission's failure to act, a cultivation of Amanita in 2008 is not possible anymore. This has already caused and will further aggravate the economic damage sustained by BASF Plant Science GmbH.

Yours sincerely,

Hans Kaas
President José Manual Barroso
Vice President Günter Verheugen
Commissioner Androulla Vassiliou
Commissioner Peter Mandelson

Ralf-Michael Schmidt
Commissioner Janez Potocnik
Commissioner Marianne Fischer Boel
Secretary General Catherine Day
Dear Commissioner Dimas,

Thank you for taking time to meet us on April 15th to discuss Amflora, BASF’s genetically optimised starch potato.

Amflora is for industrial use – developed in Europe for the European starch industry. The potato produces pure amylopectin, a starch for use in technical processes such as paper making. It is a renewable raw material that helps in saving energy and water.

Leading starch producers confirm that amylopectin potatoes such as Amflora are estimated to create an added value of at least €100 million per year for the European starch industry and farmers. Industry and farmers now want to see Amflora cultivated.

Genetically modified crops are already reality, being grown by 12 million farmers around the world on more than 114 million hectares, although on only 0.1 million hectares in Europe. In the future, the importance of genetically modified crops will further grow. To remain competitive on the world market, European farmers must be granted access to safe, innovative technology now!

EU experts at the European Food Safety Authority (EFSA) have repeatedly stated that Amflora is as safe as conventional potatoes. Their conclusion is based on extensive scientific studies on Amflora. All scientific evidence supports the safety of Amflora. You, Commissioner Dimas, confirmed Amflora’s safety to the European Parliament on September 21, 2007, stating that it does not pose a risk to human or animal health or to the environment.
The arguments you raised yesterday do not include any new evidence that would challenge the previous position. Therefore, we do not understand why the approval of Amflora is further delayed. Amflora is a safe, environmentally friendly product that brings competitive advantages to farmers and industry in Europe.

Amflora was submitted to the EU for approval years ago. BASF has adhered to all EU processes that have been agreed upon between EU countries, and has submitted all required data. We were encouraged to see that you initiated the approval process by recommending the approval of Amflora in your own "positive draft decision" in 2008.

Now, although all political and administrative steps have been taken, the final decision by the EU Commission has been pending since July 2007. We believe that a failure to implement EU legislation questions the credibility of the EU approval processes. In addition, the approval delay has a negative impact on BASF's business and that of our customers. We call once again on you to follow EU processes immediately and allow Amflora to be cultivated commercially in Europe.

Yours sincerely,

Stefan Marcinowski
Board of Executive Directors, BASF SE

Hans Kast
President and CEO, BASF Plant Science GmbH

Cc:
President José Manuel Barroso
Commissioner Androulla Vassiliou
Commissioner Günther Verheugen
Commissioner Janez Potocnik
Commissioner Mariann Fischer Boel
Commissioner Peter Mandelson
Secretary General Catherine Day
Director General Robert Madelin
Director General Peter Mogens Carl
Notification C/SE/96/3501 – Adoption of the proposed implementing act concerning the placing on the market of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch

Dear President Barroso,

On 17 March, 2008, BASF Plant Science has formally called upon the Commission to adopt a decision in accordance with Article 18(1) of Directive 2001/18/EC and with Article 5 of Council Decision 1999/468/EC. Although the approval process for Amflora has been lasting for 12 years, approval has still not been granted. The process was even stopped several times for incomprehensible reasons. And since the final vote in the Council in July 2007 we are waiting for the adoption of the decision by the EU commission.

As a result of the orientation debate on GMOs on 7 May, 2008, the Commission asked EFSA to prepare a consolidated scientific opinion on the safety of antibiotic resistance marker (ARM) genes when used as marker genes in genetically modified (GM) plants. This includes nptII, the ARM gene of Amflora, BASF’s genetically modified starch potato for industrial applications.

However, the question of safety of nptII is not new. Indeed, EFSA has already evaluated Amflora three times including the nptII marker, and EFSA repeatedly stated that the use of nptII as selectable marker gene in plants does not pose a risk to human or animal health or to the environment. Even the Directorate-General Environment clearly expressed (reply of 12 October, 2007) – based on the same scientific rationale that has led to the third EFSA re-evaluation – that the antibiotic resistance marker gene nptII and GM plants that contain the nptII gene are safe.

After the above-mentioned orientation debate, the Commission announced to adopt the approval of Amflora if and when EFSA has confirmed the safety of nptII. However, we do not see the need for this additional process since no new scientific evidence questions the safe use of nptII. All the more we deplore that the deadline for completion of the EFSA re-assessment has been postponed until 15 December, 2008.
Based on all circumstances BASF Plant Science has now decided to bring an action for failure to act according to Art. 232 EC to the EC Court of First Instance. By doing so we aim at ensuring that the approval process will then be completed in a timely manner. Please understand that for us the point of time when an approval is granted is critical, as we might loose another planting season. Only an approval by the Commission in January 2009 will allow us to start commercial cultivation of Amflora in April 2009.

We welcome that the Commission - as stated during its orientation debate - will base its decisions on science and confirmed its confidence in the high standard of scientific advice provided by EFSA. Therefore, we expect that European farmers and the European potato starch industry will finally get access to Amflora which will bring them an added value of more than €100 million per year.

Sincerely yours,

[Signature]

Stefan Marcinowski

cc.  
Vice President Günter Verheugen  
Commissioner Stavros Dimas  
Commissioner Mariann Fischer Boel  
Commissioner Peter Mandelson  
Commissioner Janez Potočnik  
Commissioner Androula Vassiliou  
Secretary General Catherine Day
Approval Process of Amflora

Dear President Barroso,

In Mr. Vale De Almeida’s letter dated October 9, 2008 sent on your behalf you refer to the Commission’s request to the European Food Safety Authority to analyze further scientific evidence on GMO’s, such as Amflora, which contain antibiotic resistance marker genes. In May the Commission asked for EFSA’s opinion by September 30, 2008, nevertheless the deadline has been extended to December 15, 2008.

Since the Amflora dossier has been reviewed intensively by EFSA with the conclusion that it is as safe as any conventional potato and, according to our knowledge there is no new scientific evidence presented, the extended timeline is for us difficult to understand. We expect that EFSA will deliver its opinion latest by December 15 based on science as required by legislation. We advocate the clear commitment of the Commission in the orientation debate that “the Commission will adopt pending decisions if and when EFSA has confirmed the safety of the products”.

Let me point out that any further delays to the regulatory approval process will continue to deny stakeholders access to this technology and will seriously compromise the commercial cultivation of Amflora in 2009. Only an adoption and publication of the decision in January 2009 will enable the rapporteur country Sweden to issue the consent in February 2009, which will allow farmers to prepare for cultivation in 2009.
Dear President Barroso, we believe that, after being in the European approval process for more than 12 years, the decision on our genetically modified potato Amflora with enhanced amylopectin content is more than overdue.

Sincerely yours.

cc.
Vice President Günter Verheugen
Commissioner Stavros Dimas
Commissioner Mariann Fischer Boel
Commissioner Catherine Ashton
Commissioner Janez Potočnik
Commissioner Androula Vassiliou
Secretary General Catherine Day
From Beate von Borcke, BASF Plant Science GmbH, Carl-Bosch Strasse 64, BPS - Li 439, 67117 Limburgerhof, Germany

To Commissioner Androulla Vassiliou

0032 2 298 1098

Dear Commissioner Vassiliou,

please find attached the letter of Dr. Stefan Marcinowski and Dr. Hans Kast from the 15th of June 2009. The original you will receive via TNT tomorrow.

Sincerely,

[Signature]

Beate von Borcke

BASF Plant Science GmbH
Carl-Bosch-Strasse 64
BPS - Li 439
67117 Limburgerhof
Germany
Notification C/SE/96/3501 – Adoption of the proposed implementing act concerning the placement on the market of the genetically modified starch potato Amflora

Dear President Barroso,

In relation to the above-mentioned authorisation procedure, the EU Commission has requested the European Food Safety Authority (EFSA) on 14 May 2008 to deliver a further scientific opinion on the use of antibiotic resistance genes as marker genes in genetically modified (GM) plants.

On 11 June 2009, EFSA published the results of its further evaluation of the use of antibiotic resistance marker (ARM) genes in GM plants entitled “Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the “Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants” and the Scientific Opinion of the GMO Panel on “Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants”.” This statement confirms again the safety of our GM potato Amflora. In detail, EFSA states that “...no new scientific evidence has become available that would prompt the Panel to change its previous opinions.” Two minority opinions were expressed and “...have already been extensively considered during the preparation of the joint Scientific Opinion...” and “...further clarification of this Scientific Opinion is not required, nor is further scientific work needed at this time.”

Based on such previous EFSA opinions stating that the use of the nptII gene in GM plants does not pose a risk to human or animal health or to the environment DG Environment in the past already submitted a positive draft decision authorising Amflora to the Regulatory Committee as well as to the Council.
In the letter dated 25 August 2008 addressed to Dr. Marcinowski as well as in the press release dated 7 May 2008 summarizing the College's orientation debate on GMOs, the EU Commission confirmed that the approval of the potato Amflora will be granted if and when EFSA reconfirms the safety of our product.

Since now the preconditions are fulfilled we expect the adoption of the implementing act in accordance with Article 18 (1) of Directive 2001/18/EC and with Article 5 (6) third paragraph of Council Decision 1999/468/EC and kindly ask for a fast decision process.

As you know, any further delay to the authorisation will delay the necessary preparation for the next planting season. This will result in significant negative financial consequences for BASF SE, BASF Plant Science and our partners in the European starch industry.

We would appreciate if you could acknowledge receiving this letter and inform us on the timing of the next steps of the EU Commission concerning the approval of Amflora.

Yours sincerely,

Dr. Stefan Marcinowski  
Board of Executive Directors  
BASF SE

Dr. Hans Kast  
President & CEO  
BASF Plant Science GmbH

CC:  
Günter Verheugen, Vice President, Commissioner for Enterprise & Industry  
Stavros Dimas, Commissioner for Environment  
Janez Potocnik, Commissioner for Science & Research  
Androulla Vassiliou, Commissioner for Health  
Mariann Fischer Boel, Commissioner for Agriculture & Rural Development  
Catherine Ashton, Commissioner for Trade  
Catherine Day, Secretary General, European Commission
Notification C/SE/96/3501 - Adoption of the proposed implementing act concerning the placement on the market of the genetically modified starch potato Amflora

Dear President,

First of all we would like to congratulate you on your renewed appointment as President of the European Commission.

On the other hand we are writing in relation to the above mentioned authorisation procedure and our attached letter of 15 June 2009, concerning the same matter (to which we have not yet received any reply).

On 11 June 2009 EFSA published its scientific opinion on the use of antibiotic resistance genes as marker genes in genetically modified plants, which once again confirmed the safety of the Amflora potato.

In the letter dated 25 August 2008 addressed to Dr. Marcinowski as well as in the press release dated 7 May 2008 the Commission confirmed that it would approve Amflora potato if EFSA gave a positive opinion. Although over three months have now elapsed since EFSA’s positive opinion was published, the Commission has so far failed to indicate what it has, is or intends to do in order to bring the Amflora approval procedure to a satisfactory conclusion.

Further delay to the authorisation will delay the necessary preparation for the next planting season. This will result in significant financial consequences for BASF SE, BASF Plant Science and our partners in the European starch industry.

Given that the Amflora approval procedure has now lasted for over 13 years, and given that it has been over three months since the publication of the EFSA opinion, you will

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Kurt Boek, Martin Brudermuehler,
Hans-Ulrich Engel, John Feldmann;
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hopefully understand that BASF would appreciate if you could acknowledge receiving this letter and inform us on the timing of the next steps of the Commission concerning the approval of Amflora.

Yours sincerely,

Dr. Stefan Marcinowski
Board of Executive Directors
BASF SE

Dr. Peter Eckes
President & CEO
BASF Plant Science Company GmbH

cc.
Günther Verheugen, Vice President, Commissioner for Enterprise & Industry
Stavros Dimas, Commissioner for Environment
Janez Potocnik, Commissioner for Science & Research
Androulla Vassiliou, Commissioner for Health
Mariann Fischer Boel, Commissioner for Agriculture & Rural Development
Catherine Ashton, Commissioner for Trade
Catherine Day, Secretary General, European Commission