Dear Sir or Madam,

Concerning: Response to Public Consultation regarding European Action in the field of Rare Diseases

The International Federation for Spina Bifida and Hydrocephalus (IF) is pleased to present to you a coordinated response to the above mentioned Public Consultation. Contributors to this response are members of a network of public, private and civic organizations dedicated to reduce the impact of Neural Tube Defects (NTDs) in Europe.

Introduction:
The Flour Fortification Initiative (FFI) is an international network of individuals and organizations working together to make micronutrient fortification of flour standard practice. The network is composed of representatives of private, public and civic organizations who combine their resources and collaborate to foster flour fortification. The representatives are non-governmental organizations, agencies of the United Nations, government agencies, groups with rare diseases, farmers, wheat procurement and marketing organizations, millers, mill manufacturers, producers and/or distributors of flour improvers and fortificants, and food industries that use flour.

Methodology of Response:
Following the publication of the European Commission stakeholder consultation on 27 November, IF requested input from all European members of the FFI, specifically addressing the point made in Question 7 of the consultation.

Responses were received from private, public and civic members in the UK, Germany, Italy, Romania, the Netherlands, Sweden and Belgium.

Input on the subject of prevention of NTDs by mandatory flour fortification was also received from leading scientists at a meeting of this network in Brussels, 8-9 November 2007.
The European Commission consultation on Rare Diseases: Europe’s Challenges published on 27 November 2007, highlights specifically the importance of primary preventative measures when possible – Question 7, page 11. It states:

“Primary Preventive measures when possible:......In addition, attention must be paid to women before conception and in early pregnancy in the management of chronic diseases such as diabetes, epilepsy and infertility. Among the possible interventions is raising folic acid intake of women before the time they conceived to prevent Neural Tube Defects (e.g. Spina Bifida) and other malformations. Many studies provide evidence that adequate folic acid intake, during the peri-conceptional period, can prevent more than half of the Neural Tube Defects. Action in this field should be the topic for a debate at EU level aiming to determine for which RD primary preventive measures may be successful. (emphasis added).

The purpose of our response is to support this specific point that a debate is needed at EU level to help determine for which Rare Diseases primary preventive measures may be successful, and explain why fortification of specific flours in Europe should be a primary preventive measure.

**Scientific assessment – folic acid and Neural Tube Defects:**

Neural Tube Defects are caused by a lack of adequate folic acid intake during the peri-conception period. The first scientific studies started in 1982 and identified precisely the vitamin connected to NTDs to be that of folic acid when published in 1991.

Maternal periconceptional use of folic acid has been found to reduce the risk of both recurrent and occurrent Neural Tube Defects (NTDs). This reduction occurs both in regions of high NTD rates and in regions of low NTD rates. Reductions of up to 70% can be achieved with the correct dosage.

Estimates suggest that over 300,000 babies globally develop a Neural Tube Defect per year. Whilst the solution is to increase the folic acid intake, there is not enough folic acid naturally occurring in the diet to reach the necessary dosage levels to have a positive impact. Voluntary consumption of supplements of folic acid for pre-planned pregnancies is only reaching a small part of the population. However, this does not have an impact for non-planned pregnancies. This is a reality of Europe today, and needs to be taken into account in discussing preventive measures for rare diseases.

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3 Berr et al. 1999
5 CDC Atlanta
Health inequities and fortification:
Health inequities, as defined by the European Commission, is a term referring to a broad range of inequali-
ties in health that are avoidable and unfair. Neural Tube Defects and other malignancies are avoid-
able through sufficient intake of folic acid. Well educated women tend to respond to the call for taking folic
acid supplements before and after conception where pregnancies are well planned. Less well-educated
women as well as those who do not plan their pregnancies do not take periconceptional folic acid and are
therefore at a higher risk of getting babies with NTDs. A primary preventive measure, fortification of wheat
flour with folic acid exists that would reduce the levels of NTDs. It is unfair that this measure is not avail-
able (yet) in most countries.

Global situation on fortification:
Over 50 countries around the world, including the USA and Canada, have fortified a staple food, flour, in
an effort to address as broad a population as possible, in order to improve public health. Fortification of a
staple food is a highly effective tool to improve public health. Wheat flour fortification offers a tremendous
opportunity to improve the vitamin and mineral status of populations because more than 400 million tons
of wheat is eaten each year.

Studies in the USA and Canada have demonstrated the subsequent positive effect of flour fortification with
folic acid.

Flour fortification – a primary preventative measure:
Rare diseases often do not have a means of prevention. However, for Spina Bifida and other malignan-
cies, there is strong scientific evidence over many years to demonstrate that fortification with folic acid
does prevent these rare diseases. Therefore, a debate at EU level on putting in place a primary preventa-
tive measure such as fortification of flour should be held, thereby allowing health equality for the whole of
the population in Europe.

More information can be obtained at the IF secretariat (lieven.bauwens@ifglobal.org).
Thank you for your consideration.

Yours sincerely,

Lieven Bauwens
Coordinator
International Federation for Spina Bifida and Hydrocephalus

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8 Philippe De Wals, Ph.D., et al. Reduction in Neural Tube Defects after Folic Acid Fortification in Canada. New Eng-
land Journal of Medicine, Volume 357:135-142, July 12, 2007, Number 2