

AseBio position on the Targeted review proposal of the General Block Exemption Regulation: The application of the “undertaking in difficulty” definition

Fostering innovation depends on investment in R&D, yet it is also essential to have a regulatory system that helps innovative companies. For innovative companies, and especially for biotechnology, a key sector in this health emergency caused by COVID-19, it is essential to have both **access to financing** and a **regulatory environment** that understands the particularities of a long innovation cycle which generates disruptive solutions often far from the market.

Within this context, in the past five years the Spanish Bioindustry Association, AseBio, has worked to spotlight how European regulations around State aid are damaging our innovative ecosystem, especially the definition of an “undertaking in difficulty” included in the General Block Exemption Regulation, which is making highly innovative companies in such strategic sectors as biotechnology ineligible for aid in R&D.

Scope of the Targeted review proposal of the General Block Exemption Regulation currently under public consultation from 6/10/2021 to 8/12/2021

The European Commission is currently carrying out a public consultation on a Targeted review proposal of the GBER, based on the results of the evaluations conducted in the context of the Fitness Check of the State aid rules adopted on July the 23rd 2021.

The targeted review includes modifications in article 2 (18), to adapt the GBER and its definitions to the modifications implemented in the Risk Finance Guidelines. Nevertheless, the modifications proposed for article 2(18) do not substantially alter the definition of undertaking in difficulties and as such, will not have a significant impact on innovative companies. The proposal does not either assess some of the main conclusions of the Staff Working document published on October the 30th 2020 about the definition of “Undertaking in Difficulty”

Accordingly, we consider that the proposal of the Commission is clearly insufficient and if finally adopted, would mean a missed opportunity to implement the changes the fitness check identified as necessary.

The impact of the “undertaking in difficulty” criterion in the biotech sector

The definition of undertaking in difficulty in the GBER states the older than 3 years which have lost more than half of their subscribed share capital as a result of accumulated losses should be considered undertakings in difficulty. The explicit definition of subscribed share capital states that it should include, when applicable, the share premium.

Soon after the GBER, the Commission issued a Communication on Guidelines on State aid for rescuing and restructuring non-financial undertakings in difficulty (2014/C 249/01) where it established that an undertaking is considered to be in difficulty when, without intervention by the State, it will almost certainly be condemned to going out of business in the short or medium term. Thereby the regulatory framework turned this definition into financial ratios, with huge impact on national innovation ecosystem.

Based on this definition, one interpretation of the GBER has gained ground in which those companies that burn half of their share capital plus the share premium shall be considered undertakings in difficulty. This interpretation has been supported by the Directorate General for Competition via the European Union’s tools to advise the Member States. Likewise, Spain has consolidated this interpretation through successive regulations of the calls for aid applications and the rules of the agencies that manage R&D aid.

Biotech companies are characterized by their high intensity of investment in R&D, long maturation periods of their projects and their technological risk profile. Because of this, this type of companies are typically financed with their own resources such as capital or hybrid instruments and subsidies, while bank loans tend to be minimal.

As a consequence of their business model based on R&D and the development of innovative products and services with long maturation periods, and therefore the absence of significant sales during this period, it is common for biotech companies to accumulate losses repeatedly for several years. These losses may at times consume half their share capital + share premium, and therefore, they may be considered undertakings in difficulty.

However, these are companies that totally comply with the business and corporate laws and are not in any way subjected to dissolution cases or bankruptcy proceedings. In fact, they **are fully viable, both technically and economically solvent companies** with ambitious, impactful projects. Additionally, the definition ignores that the Spanish Commercial Law considers share premiums as an unrestricted reserve, to which the company has access, and thus differs from subscribed share capital. Despite this, these companies are automatically excluded from the calls for application for public aid.

Since the regulation entered into force and was implemented in Spain by the different financing agencies via national regulations, the biotech sector has suffered from differences in the application of this criterion, which has gradually become standardized and more stringent.

Exclusion of Biotech Companies from R&D calls for grants

In consequence, **more and more biotech companies are being excluded from R&D support programs**. One recent example of this is the first decision by the general director of CDTI on *aid within the framework of the extraordinary call for aid applications for R&D and investment projects to deal with the health emergency declared over the COVID-19 disease*, in which 50% of the applications were rejected because they were considered undertakings in difficulty.

Another recent example is the **CDTI Mission Call for 2019**, where 22 applicants were excluded since at least a member of such consortia applying for funding fell in the definition of “Undertaking in Difficulty”. 25 consortia were successfully awarded a grant in this call.

Biotech companies have been increasingly discouraged from applying to national calls for grants

The effect of this regulation is to gradually discourage the ecosystem of Spanish biotech companies **from applying to national calls for applications**, since the effort needed to prepare a proposal for a competitive call for applications is significant, and given the certain risk of exclusion, they have simply ceased to apply. While 77 biotech companies applied in *the Agencia Estatal de Investigación’s 2017 Retos-Colaboración*, only 37 did in 2019 (52% fewer).

Hindering of public-private R&D partnerships

Furthermore, this is **hindering public-private R&D partnerships**, as well as partnerships between large and small companies, since the inclusion of a company affected by this definition could lead the proposal to be rejected. Therefore, this has prompted mistrust towards innovative SME’s, which makes the other stakeholders reluctant to jointly submit proposals with any SME that could be considered an undertaking in difficulty.

Therefore, the framework of State aid in the EU, and particularly the GBER, is acting as a major obstacle to achieving the overall goals of R&D policies and incentives. This regulation is stopping the instruments that support and promote R&D from reaching the companies that need them the most

because of their R&D intensity and size. This reality has been identified in the Study on the Practical Impact of R&D State Rules.¹

Arguments and evidence supporting the deficiencies and unsuitability of the definition of “Undertaking in Difficulties”

As previously stated, the Communication from the Commission 2014/C 249/01 on *Guidelines on State aid for rescuing and restructuring non-financial undertakings in difficulty*, defines that an Undertaking is considered to be in difficulty when, without intervention by the State, it will almost certainly be condemned to going out of business in the short or medium term. Subsequently, the guidelines develop said definition with criteria in the form of ratios and financial calculations.

Accordingly, the criteria used to classify an undertaking as being in difficulty should capture those companies which would almost certainly disappear in the short or medium term, and at the same time, leave out those that are viable under market conditions. However, plenty of companies that are, year after year, classified as Undertakings in Difficulties are able to continue to operate normally, and at the same time are not being beneficiaries of rescue or restructuring aid. Therefore, the way the definition was developed, and interpreted goes against the spirit of the definition and its objectives as stated in the GBER and in the referred rescue and restructuring guidelines. In our view, this clearly shows that the definition of Undertaking in Difficulties is being used to exclude companies that were not intended to be excluded from the good State Aid, and as such, the interpretation and use of the definition is going against the will of the legislator.

In January 2019, the European Commission launched an evaluation in the context of the Fitness Check of the State aid rules. On October 30, 2020, the European Commission published the Staff Working Document with the main conclusions of the fitness check. The Staff Working document assessed the definition of Undertaking in Difficulties (pages 74-77) and concluded that regarding Undertaking in Difficulty criteria, **the disappearing capital criterion is overly conservative on a stand-alone basis** as it may be met by companies with an investment grade rating which are not expected to default on their payments, and therefore, were not intended to be excluded from good aid. The report also refers to the fact that the definition is not fit for certain types

¹ EUROPEAN COMMISSION. 2019. Directorate-General for Competition. *Study on the practical impact of RDI State aid rules, Fact-finding inventory in selected Member States. Final report.*

of companies, particularly for start-ups, scale-ups, companies developing new technologies (especially when using venture capital financing).

The Staff Working Document also assessed the efficiency of the State Aid Framework to provide timely access to aid (page 97) and concluded that national authorities were concerned about the definition of Undertaking in Difficulty regarding the calculation of the financial criteria, in particular the calculation of the 50% share capital lost.

AseBio's proposals

According to what has been discussed above, we believe that the current legal framework needs to be modified to avoid its pernicious effects on the ability of companies that develop innovative technologies, start-ups and scale-ups, to gain access to national public financing in Europe.

Furthermore, the proposal of the Commission does not address some of the main concerns identified by the Staff Working Document regarding the rescue and restructuring guidelines and the definition of Undertaking in Difficulty. Consequently, the proposed revised definition would perpetuate a framework that is hindering Member States from promoting the development of their innovative businesses, damaging Europe's ability to foster the competitiveness of European economy. At a time when the European Union has decided to boost its Open Strategic Autonomy, and in the aftermath of a pandemic that has clearly shown the limitations of the current state aid framework, the proposal of the European Commission is clearly disappointing.

AseBio believes that the current legal framework should be changed to overcome the identified limitations. Consequently, we urge the Commission to review the GBER and its provisions according to the following principles:

1. Companies that are R&D-intensive because of their business models show losses repeatedly, and the undertaking in difficulty criterion does not reflect their solvency, meaning that the aid conferred on the R&D projects conducted by these companies does not conflict with the bailout and restructuring framework of undertakings in difficulty. Likewise, no factors that could distort competition would arise by granting aid to R&D projects in R&D-intensive companies in that this definition does not match their technical or economic solvency. Accordingly, R&D-intensive companies should be exempted from the exclusion stipulated by the GBER.
2. The definition of the undertaking in difficulty criterion could be changed to make it less harmful to R&D-intensive companies with long maturation

processes. In this sense, several alternatives could be considered, and some of them could even be implemented simultaneously:

- a. Equity loans and similar instruments should be considered as net assets and therefore as a balancing element that could offset the accumulated losses for the purposes of defining undertaking in difficulty.
- b. Similar to what occurs in the cases of dissolution or bankruptcy, the base of calculation should be share capital, thus excluding the share premium. In Spanish law, the share premium is fully available and is not part of the company's share capital. Therefore, the accumulated losses will be charged to reserves and the share premium (as the fully available reserve that it is), and once they have been fully burned down, the consumption of social capital would be calculated by the remaining accumulated losses, and this remaining social capital would have to be more than 50% of subscribed share capital not to be considered an undertaking in difficulty.
- c. In order to ensure that the definition includes companies with long maturation periods, the exception for companies less than 3 years old could be changed to define longer periods, as in the framework of aid for risk financing, of 7 years starting from the first commercial sale. This way, the definition would not be applied to companies whose business model consists in developing a product over long periods of time until they begin to generate income from sales.

About us

At AseBio, the Spanish Bioindustry Association, we bring together and represent the interests of companies, associations, foundations, universities, technology and research centres that work in the field of biotechnology in Spain.

Since 1999, we have worked to achieve positive political and economic changes that promote and boost the development of the Spanish biotechnology industry. In order to do this, AseBio works closely with regional, national and European legislative bodies, as well as with all those social organisations that are committed to using biotechnology to improve citizens' quality of life, environmental sustainability, economic development and skilled job creation.