EUROPEAN
COMMISSION

Brussels, 1.3.2022
C(2022) 1161 final

ANNEX

ANNEX

to the

COMMUNICATION FROM THE COMMISSION

Approval of the content of a draft for a Commission Regulation on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements

ANNEX

COMMISSION REGULATION (EU) …/…

of XXX

on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements

DRAFT

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union ('Treaty'),

Having regard to Regulation (EEC) No 2821/71 of the Council of 20 December 1971 on application of Article 85(3) of the Treaty to categories of agreements, decisions and concerted practices[1],

Having published a draft of this Regulation,

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Whereas:

(1) Regulation (EEC) No 2821/71 empowers the Commission to apply Article 101(3) of the Treaty on the Functioning of the European Union (*) by regulation to certain categories of agreements, decisions and concerted practices falling within the scope of Article 101(1) of the Treaty which have as their object (i) the research and development of products, technologies or processes up to the stage of industrial application, and (ii) exploitation of the results, including provisions regarding intellectual property rights.

(2) Article 179(2) of the Treaty calls upon the Union to encourage undertakings, including small and medium-sized undertakings, in their research and technological development activities of high quality, and to support their efforts to cooperate with one another.

(3) Commission Regulation (EU) No 1217/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements[2] defines categories of research and development agreements that the Commission regarded as normally satisfying the conditions laid down in Article 101(3) of the Treaty. In view of the overall positive experience with the application of that Regulation, which expires on 31 December 2022, and taking into account the results of the review procedure, it is appropriate to adopt a new block exemption regulation.

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1 OJ L 285, 29.12.1971, p. 46.

(*) With effect from 1 December 2009, Article 81 of the EC Treaty (previously Article 85 of the EEC Treaty) has become Article 101 of the Treaty. These provisions are, in substance, identical. For the purposes of this Regulation, references to Article 85 of the EEC Treaty or Article 81 of the EC Treaty should be understood as references to Article 101 of the Treaty where appropriate.

2 OJ L 335, 18.12.2010, p. 36–42.

(4) This Regulation intends to facilitate research and development while at the same time effectively protecting competition. This Regulation should also meet the requirement of providing adequate legal security for undertakings. The pursuit of those objectives should take account of the need to simplify administrative supervision and the legislative framework to as great an extent as possible.

(5) Below a certain level of market power, it can in general be presumed, for the application of Article 101(3) of the Treaty, that the positive effects of research and development agreements will outweigh any negative effects on competition.

(6) For the application of Article 101(3) of the Treaty by regulation, it is not necessary to define those agreements which are capable of falling within the scope of Article 101(1) of the Treaty. In the individual assessment of agreements under Article 101(1) of the Treaty, account has to be taken of several factors, and in particular the market structure on the relevant market.

(7) Agreements on the joint execution of research work or the joint development of the results of the research, up to but not including the stage of industrial application, generally do not fall within the scope of Article 101(1) of the Treaty. In certain circumstances, however, such as where the parties agree not to carry out other research and development in the same field, thereby forgoing the opportunity of gaining competitive advantages over the other parties, such agreements may fall within Article 101(1) of the Treaty and should therefore be included within the scope of this Regulation.

(8) The benefit of the exemption established by this Regulation should be limited to those agreements for which it can be assumed with sufficient certainty that they satisfy the conditions of Article 101(3) of the Treaty.

(9) Consumers can generally be expected to benefit from the increased volume and effectiveness of research and development through (i) the introduction of new or improved products, technologies or processes, or (ii) a quicker launch of those products, technologies or processes, or (iii) a reduction of prices brought about by new or improved technologies or processes.

(10) Cooperation in joint or paid-for research and development and in the exploitation of the results is most likely to promote technical and economic progress if the parties contribute complementary skills, assets or activities to the cooperation.

(11) The joint exploitation of results can take different forms such as production, distribution of products or application of technologies, assignment or licensing of intellectual property rights or communication of know-how required for such production or application that substantially contribute to technical or economic progress.

(12) In order to justify the exemption established by this Regulation, the joint exploitation should relate to products, technologies or processes for which the use of the results of the research and development is indispensable.

(13) Moreover, all the parties should agree in the research and development agreement that they will all have full access to the final results of the joint research and development, including any arising intellectual property rights and know-how, for the purposes of (i) further research and development and (ii) exploitation, as soon as the final results become available. Access to the results should generally not be limited as regards the use of the results for the purposes of further research and development. However, where the parties, in accordance with this Regulation, limit their rights of exploitation,

in particular where they specialise in the context of exploitation, access to the results for the purposes of exploitation may be limited accordingly. Furthermore, where (i) academic bodies, research institutes or (ii) undertakings that supply research and development as a commercial service without normally being active in the exploitation of results participate in research and development, they may agree to use the results of research and development solely for the purpose of further research.

(14) Depending on their capabilities and commercial needs, the parties may make unequal contributions to their research and development cooperation. Therefore, in order to reflect, and to make up for, the differences in the value or the nature of the parties' contributions, a research and development agreement benefiting from this Regulation may provide that one party is to compensate another for obtaining access to the results for the purposes of further research or exploitation. However, the compensation should not be so high as to effectively impede such access.

(15) Where the research and development agreement does not provide for any joint exploitation of the results, the parties should agree in the research and development agreement to grant each other access to their respective pre-existing know-how, as long as this know-how is indispensable for the purposes of the exploitation of the results by the other parties. The compensation (e.g. rates of any licence fee) charged should not be so high as to effectively impede access to the know-how by the other parties.

(16) The exemption established by this Regulation should be limited to research and development agreements that do not afford the undertakings the possibility of eliminating competition in respect of a substantial part of the products or technologies in question. It is necessary to exclude from the block exemption agreements between competitors whose combined share of the market for products or technologies capable of being improved, substituted or replaced by the results of the research and development exceeds a certain level at the time the agreement is entered into.

(17) The exemption established by this Regulation should also be limited to research and development agreements that do not afford the undertakings the possibility of eliminating competition in innovation, including the development of new products or technologies. It is necessary to exclude research and development agreements from the block exemption where there would remain less than three competing R&D efforts in addition to and comparable with those of the parties to the R&D agreement.

(18) However, there is no presumption that research and development agreements are either caught by Article 101(1) of the Treaty or that they fail to satisfy the conditions of Article 101(3) of the Treaty once the thresholds or other conditions set out in this Regulation are not met. In such cases, an individual assessment of the research and development agreement needs to be conducted under Article 101 of the Treaty.

(19) In order to ensure the maintenance of effective competition during the joint exploitation of the results, provision should be made for the block exemption to cease to apply if the parties' combined share of the market for the products or technologies arising out of the joint or paid-for research and development exceeds a certain level. The exemption should continue to apply irrespective of the parties' market shares for a certain period after the commencement of joint exploitation, so as to await stabilisation of their market shares, particularly after the introduction of an entirely new product, and to guarantee a minimum period of return on the investments involved.

(20) This Regulation should not exempt agreements containing restrictions which are not indispensable to the attainment of the positive effects generated by a research and development agreement. In principle, agreements containing certain types of severe restrictions of competition such as limitations on the freedom of parties to carry out research and development in a field unconnected to the agreement, the fixing of prices charged to third parties, limitations on output or sales, and limitations on effecting passive sales for the contract products or contract technologies in territories or to customers reserved for other parties, should be excluded from the benefit of the exemption established by this Regulation irrespective of the market share of the parties. In this context, field of use restrictions do not constitute limitations of output or sales, and also do not constitute territorial or customer restrictions.

(21) The market share limitation, the non-exemption of certain agreements and the conditions provided for in this Regulation normally ensure that the agreements to which the block exemption applies do not enable the parties to eliminate competition in respect of a substantial part of the products or technologies in question.

(22) The possibility cannot be ruled out that anti-competitive foreclosure effects may arise where one party finances several research and development projects carried out by competitors with regard to the same contract products or contract technologies, in particular where it obtains the exclusive right to exploit the results vis-à-vis third parties. Therefore, the benefit of this Regulation should be conferred on such paid-for research and development agreements only if the combined market share of all the parties involved in the connected agreements, that is to say, the financing party and all the parties carrying out the research and development, does not exceed 25 %.

(23) The benefit of this Regulation may be withdrawn pursuant to Article 29 of Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty.[3]

(24) As research and development agreements are often of a long-term nature, especially where the cooperation extends to the exploitation of the results, the period of validity of this Regulation should be fixed at 12 years.

HAS ADOPTED THIS REGULATION:

TITLE I

DEFINITIONS

Article 1 –Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(1) 'R&D agreement' means an agreement entered into between two or more parties which relates to the conditions under which those parties pursue:

(a) joint research and development of contract products or contract technologies which:

[3] OJ L 1, 4.1.2003, p. 1.

(i) excludes joint exploitation of the results of that research and development, or

(ii) includes joint exploitation of the results of that research and development; or

(b) paid-for research and development of contract products or contract technologies which:

(i) excludes joint exploitation of the results of that research and development, or

(ii) includes joint exploitation of the results of that research and development; or

(c) joint exploitation of the results of research and development of contract products or contract technologies carried out pursuant to a prior agreement falling under paragraph (1)(a) between the same parties; or

(d) joint exploitation of the results of research and development of contract products or contract technologies carried out pursuant to a prior agreement falling under paragraph (1)(b) between the same parties;

(2) 'agreement' means an agreement, a decision by an association of undertakings or a concerted practice;

(3) 'research and development' ('R&D') means activities aimed at acquiring know-how relating to existing or new products, technologies or processes, the carrying out of theoretical analysis, systematic study or experimentation, including experimental production, technical testing of products or processes, the establishment of the necessary facilities and the obtaining of intellectual property rights for the results;

(4) 'product' means a good or a service, including both intermediary goods or services and final goods or services;

(5) 'contract technology' means a technology or process arising out of the joint or paid-for research and development. This includes technologies or processes obtained through an R&D pole as well as new technologies or processes;

(6) 'contract product' means a product arising out of the joint or paid-for research and development or produced or provided applying the contract technologies. This includes products obtained through an R&D pole as well as new products;

(7) 'new product or technology' means a product, technology or process that does not yet exist at the time when the R&D agreement falling under paragraph 1(a) or (b) is entered into and that will, if emerging, create its own new market and not improve, substitute or replace an existing product, technology or process;

(8) 'R&D pole' means R&D efforts directed primarily towards a specific aim or objective. The specific aim or objective of an R&D pole cannot yet be defined as a product or a technology or involves a substantially broader target than products or technologies on a specific market;

(9) 'exploitation of the results' means the production or distribution of the contract products or the application of the contract technologies or the assignment or licensing of intellectual property rights or the communication of know-how required for such production or application;

(10) ‘intellectual property rights’ means industrial property rights, in particular patents and trademarks; as well as copyright and neighbouring rights;

(11) ‘know-how’ means a package of practical information, resulting from experience and testing, which is:

(a) ‘secret’, that is to say, not generally known or easily accessible;

(b) ‘substantial’, that is to say, significant and useful for the production of the contract products or the application of the contract technologies; and

(c) ‘identified’, that is to say, described in a sufficiently comprehensive manner so as to make it possible to verify that it fulfils the criteria of secrecy and substantiality;

(12) ‘joint’, in the context of activities carried out under an R&D agreement, means activities where the work involved is:

(a) carried out by a joint team, organisation or undertaking;

(b) jointly entrusted to a third party; or

(c) allocated between the parties by way of specialisation in the context of research and development or specialisation in the context of exploitation;

(13) ‘specialisation in the context of research and development’ means that each of the parties is involved in the research and development activities covered by the R&D agreement and they divide the research and development work between them in any way that they consider most appropriate; this does not include paid-for research and development;

(14) ‘specialisation in the context of exploitation’ means that the parties allocate between them individual tasks such as production or distribution, or impose restrictions upon each other regarding the exploitation of the results such as restrictions in relation to certain territories, customers or fields of use; this includes a scenario where only one party produces and distributes the contract products on the basis of an exclusive licence granted by the other parties;

(15) ‘paid-for research and development’ means research and development that is carried out by one party and financed by a financing party;

(16) ‘financing party’ means a party financing paid-for research and development while not carrying out any of the research and development activities itself;

(17) ‘undertaking competing for an existing product and/or technology’ means an actual or a potential competitor:

(a) ‘actual competitor’ means an undertaking that is supplying an existing product, technology or process capable of being improved, substituted or replaced by the contract product or the contract technology on the relevant geographic market;

(b) ‘potential competitor’ means an undertaking that, in the absence of the R&D agreement, on realistic grounds and not just as a mere theoretical possibility, would be likely to undertake, within not more than 3 years, the necessary additional investments or incur the necessary costs to supply a product, technology or process capable of being improved, substituted or replaced by the contract product or contract technology on the relevant geographic market;

(18) ‘undertaking competing in innovation’ means an undertaking that is not competing for an existing product and/or technology and that independently engages in or, in the absence of the R&D agreement, would be able and likely to independently engage in R&D efforts which concern:

(a) the research and development of the same or likely substitutable new products and/or technologies as the ones to be covered by the R&D agreement; or

(b) R&D poles pursuing substantially the same aim or objective as the ones to be covered by the R&D agreement;

(19) ‘competing R&D effort’ means an R&D effort in which a third party engages, alone or in cooperation with other third parties, or in which a third party is able and likely to independently engage, and which concerns:

(a) the research and development of the same or likely substitutable new products and/or technologies as the ones to be covered by the R&D agreement; or

(b) R&D poles pursuing substantially the same aim or objective as the ones to be covered by the R&D agreement;

These third parties must be independent from the parties to the R&D agreement.

(20) ‘not competing undertaking’ means an undertaking that is neither an undertaking competing for an existing product and/or technology nor an undertaking competing in innovation;

(21) ‘relevant product market’ means the relevant market for the products capable of being improved, substituted or replaced by the contract products;

(22) ‘relevant technology market’ means the relevant market for the technologies or processes capable of being improved, substituted or replaced by the contract technologies;

(23) ‘active sales’ means all forms of selling other than passive sales;

(24) ‘passive sales’ means sales in response to unsolicited requests from individual customers, including delivery of products to the customer or customers, without having initiated the sale through actively targeting the particular customer, customer group or territory; passive sales include sales resulting from participating in private or public procurement tenders.

2. For the purposes of this Regulation, the terms ‘undertaking’ and ‘party’ shall include their respective connected undertakings.

‘Connected undertakings’ means:

(a) undertakings in which a party to the R&D agreement, directly or indirectly:

(i) has the power to exercise more than half the voting rights;

(ii) has the power to appoint more than half the members of the supervisory board, board of management or bodies legally representing the undertaking; or

(iii) has the right to manage the undertaking’s affairs;

(b) undertakings which directly or indirectly have, over a party to the R&D agreement, the rights or powers listed in point (a);

(c) undertakings in which an undertaking referred to in point (b) has, directly or indirectly, the rights or powers listed in point (a);

(d) undertakings in which a party to the R&D agreement together with one or more of the undertakings referred to in points (a), (b) or (c), or in which two or more of the latter undertakings, jointly have the rights or powers listed in point (a);

(e) undertakings in which the rights or the powers listed in point (a) are jointly held by:

(i) parties to the R&D agreement or their respective connected undertakings referred to in points (a) to (d); or

(ii) one or more of the parties to the R&D agreement or one or more of their connected undertakings referred to in points (a) to (d) and one or more third parties.

TITLE II

EXEMPTION

Article 2 – Exemption

1. Pursuant to Article 101(3) of the Treaty and subject to the provisions of this Regulation, it is hereby declared that Article 101(1) of the Treaty shall not apply to R&D agreements.

2. The exemption provided for in paragraph 1 shall apply to the extent that R&D agreements contain restrictions of competition falling within the scope of Article 101(1) of the Treaty.

3. The exemption provided for in paragraph 1 shall also apply to R&D agreements which include provisions on the assignment or licensing of intellectual property rights to one or more of the parties or to an entity the parties establish to carry out the joint or paid-for research and development or joint exploitation, provided that those provisions:

(a) do not constitute the primary object of such agreements; and

(b) are directly related to and necessary for the implementation of such agreements.

TITLE III

CONDITIONS FOR EXEMPTION

Article 3 – Access to the final results

1. The R&D agreement must stipulate that all the parties have full access to the final results of the joint or paid-for research and development for the purpose of further research and development and for the purpose of exploitation.

(a) Access provided for in paragraph 1 shall include any resulting intellectual property rights and know-how.

(b) Access provided for in paragraph 1 shall be granted as soon as the results of the research and development become available.

2. The R&D agreement may state that the parties compensate each other for giving access to the results for the purposes of further research and development or for the purpose of further exploitation, but the compensation must not be so high as to effectively impede such access.

3. Research institutes, academic bodies and undertakings that supply research and development as a commercial service without normally being active in the exploitation of results, may agree to confine their use of the results for the purposes of further research.

4. Where the parties limit their rights of exploitation in accordance with this Regulation, in particular where they specialise in the context of exploitation, access to the results for the purposes of exploitation may be limited accordingly.

Article 4 – Access to pre-existing know-how

1. R&D agreements that exclude joint exploitation of the results of joint or paid-for research and development, must stipulate that each party must be granted access to any pre-existing know-how of the other parties if this know-how is indispensable for the purposes of its exploitation of the results.

2. R&D agreements that exclude joint exploitation of the results of joint or paid-for research and development may state that the parties compensate each other for giving access to their pre-existing know-how. The compensation must not be so high as to effectively impede such access.

Article 5 – Joint exploitation

1. Any joint exploitation may only pertain to results which are:

(a) indispensable for the production of the contract products or the application of the contract technologies; and

(b) protected by intellectual property rights or constitute know-how.

2. Parties charged with the production of the contract products by way of specialisation in the context of exploitation must be required to fulfil orders for supplies of the contract products from the other parties, except where:

(a) the R&D agreement also provides for joint distribution by a joint team, organisation or undertaking or by a third party jointly entrusted by the parties; or

(b) the parties have agreed that only the party producing the contract products may distribute them.

Article 6 – Thresholds, market shares and duration of exemption

1. Where the parties to the R&D agreement are not competing undertakings, the exemption provided for in Article 2 shall apply irrespective of market shares for the duration of the research and development.

2. Where two or more of the parties to the R&D agreement are undertakings competing for an existing product and/or technology, the exemption provided for in Article 2 shall apply for the duration of the research and development if, at the time the R&D agreement is entered into:

   (a) the combined market share of the parties to an R&D agreement involving joint research and development, as defined in Article 1 paragraph 1(1)(a) or (1)(c), does not exceed 25 % on the relevant product and technology markets; or

   (b) in case of an R&D agreement involving paid-for research and development, as defined in Article 1 paragraph 1 (1)(b) or (1)(d), the combined market share of the financing party and all the parties with which the financing party has entered into R&D agreements with regard to the same contract products or contract technologies, does not exceed 25% on the relevant product and technology markets.

3. Where two or more of the parties to the R&D agreement are undertakings competing in innovation, the exemption provided for in Article 2 shall apply for the duration of the research and development if, at the time the R&D agreement is entered into, there are three or more competing R&D efforts in addition to and comparable with those of the parties to the R&D agreement.

4. For R&D agreements where the results are jointly exploited, the exemption provided for in Article 2 shall continue to apply for seven years from the time the contract products or contract technologies are first put on the market within the internal market, if the conditions provided for in paragraphs 1, 2 or 3 are satisfied at the time the agreement falling under Article 1 paragraph 1 (1)(a) or (b) is entered into. For an agreement falling under Article 1 paragraph 1 (1)(c) or (d) to benefit from such a continued exemption, the conditions provided for in paragraphs 1, 2 or 3 must be satisfied at the point in time when the prior agreement pursuant to Article 1 paragraph 1 (1)(a) or (b) was entered into.

5. After the end of the seven year period referred to in paragraph 4, the exemption provided for in Article 2 shall continue to apply as long as the combined market share of the parties to the R&D agreement does not exceed 25 % on the markets to which the contract products or contract technologies belong. If, after the end of the seven year period, the market share rises above 25 % on one of these markets, the exemption provided for in Article 2 shall continue to apply for a period of two consecutive calendar years following the year in which the 25 % threshold was first exceeded.

Article 7 – Application of the thresholds

1. For the purposes of applying the market share thresholds provided for in Articles 6 paragraph 2 and 5, the following rules shall apply:

   (a) The market share shall be calculated on the basis of market sales value; if market sales value data are not available, estimates based on other reliable market information, including market sales volumes, expenditure in research and development or research and development capabilities, may be used to establish the market share of the parties;

   (b) The market share shall be calculated on the basis of data relating to the preceding calendar year; or, alternatively, when the preceding calendar year is not representative of the parties' position in the relevant

market(s), the market share shall be calculated as an average of the parties' market shares of the last three preceding calendar years;

(c) The market share held by the undertakings referred to in Article 1 paragraph 2 (e) shall be apportioned equally to each undertaking having the rights or the powers listed in Article 1 paragraph 2 (a).

2. For the purposes of applying the threshold provided for in Article 6 paragraph 3, the assessment of comparability of competing R&D efforts shall be made on the basis of reliable information concerning elements such as (i) the size, stage and timing of the R&D efforts, (ii) third parties' (access to) financial and human resources, their intellectual property, know-how or other specialised assets, their previous R&D efforts and (iii) the third parties' capability and likelihood to exploit directly or indirectly possible results of their R&D efforts on the internal market.

TITLE IV

HARDCORE AND EXCLUDED RESTRICTIONS

Article 8 – Hardcore restrictions

The exemption provided for in Article 2 shall not apply to R&D agreements which, directly or indirectly, in isolation or in combination with other factors under the control of the parties, have as their object any of the following restrictions:

1. The restriction of the freedom of the parties to carry out research and development independently or in cooperation with third parties:

(a) in a field unconnected with that to which the R&D agreement relates; or

(b) in the field to which the R&D agreement relates or in a connected field after the completion of the joint research and development or paid-for research and development.

2. The limitation of output or sales, with the exception of:

(a) the setting of production targets where the joint exploitation of the results includes the joint production of the contract products;

(b) the setting of sales targets, where the joint exploitation of the results:

(i) includes the joint distribution of the contract products or the joint licensing of the contract technologies, and

(ii) is carried out by a joint team, organisation or undertaking or is jointly entrusted to a third party;

(c) practices constituting specialisation in the context of exploitation; and

(d) the restriction of the freedom of the parties to produce, sell, assign or license products, technologies or processes which compete with the contract products or contract technologies during the period for which the parties have agreed to jointly exploit the results.

3. The fixing of prices when selling the contract product or licensing the contract technologies to third parties, with the exception of:

(a) the fixing of prices charged to immediate customers or the fixing of licence fees charged to immediate licensees where the joint exploitation of the results:

i) includes the joint distribution of the contract products or the joint licensing of the contract technologies, and

ii) is carried out by a joint team, organisation or undertaking or is jointly entrusted to a third party.

4. The restriction of the territory in which, or of the customers to whom, the parties may passively sell the contract products or license the contract technologies, with the exception of the requirement to exclusively license the results to another party.

5. The requirement not to make any, or to limit, active sales of the contract products or contract technologies in territories or to customers which have not been exclusively allocated to one of the parties by way of specialisation in the context of exploitation.

6. The requirement to refuse to meet demand from customers in the parties' respective territories, or from customers otherwise allocated between the parties by way of specialisation in the context of exploitation, who would market the contract products in other territories within the internal market.

7. The requirement to make it difficult for users or resellers to obtain the contract products from other resellers within the internal market.

Article 9 – Excluded restrictions

1. The exemption provided for in Article 2 shall not apply to the following obligations in R&D agreements:

(a) The obligation not to challenge:

(i) after completion of the research and development, the validity of intellectual property rights, which:

(1) the parties hold in the internal market, and

(2) are relevant to the research and development; or

(ii) after the expiry of the R&D agreement, the validity of intellectual property rights which:

(1) the parties hold in the internal market, and

(2) protect the results of the research and development.

The possibility to provide for termination of the R&D agreement in the event of one of the parties challenging the validity of the intellectual property rights referred to in (i) and (ii) shall remain unaffected;

(b) The obligation not to grant licences to third parties to produce the contract products or to apply the contract technologies unless the agreement provides for the exploitation of the results of the joint or paid-for research and development by at least one of the parties and such exploitation takes place in the internal market vis-à-vis third parties.

2. If the R&D agreement includes any of the excluded restrictions listed in this Article, the exemption provided in Article 2 continues to apply if the excluded restrictions are

severable from the remaining part of the R&D agreement and provided that the rest of the conditions of this Regulation are met.

TITLE V

WITHDRAWAL PROCEDURE

Article 10 – Withdrawal in individual cases by the European Commission

1. The Commission may withdraw the benefit of this Regulation, pursuant to Article 29(1) of Council Regulation (EC) No 1/2003, where it finds in any particular case that an R&D agreement to which the exemption provided for in this Regulation applies nevertheless has effects which are incompatible with Article 101(3) of the Treaty.

2. The benefit of this Regulation could be withdrawn pursuant to Article 29(1) of Regulation (EC) No 1/2003 in particular where:

   (a) the existence of an R&D agreement substantially restricts the scope for third parties to carry out research and development in the field(s) related to the contract products or contract technologies;

   (b) the existence of the R&D agreement substantially restricts the access of third parties to the market for the contract products or contract technologies;

   (c) the parties do not exploit the results of the joint or paid-for research and development vis-à-vis third parties without any objectively valid reason;

   (d) the contract products or contract technologies are not subject in the whole or a substantial part of the internal market to effective competition from products, technologies or processes considered by users as equivalent in view of their characteristics, price and intended use.

Article 11 – Withdrawal in individual cases by a competition authority of a Member State

1. The competition authority of a Member State may withdraw the benefit of this Regulation pursuant to Article 29(2) of Regulation (EC) No 1/2003, in respect of the territory of that Member State, or in a part thereof, where it finds in any particular case that an R&D agreement to which the exemption provided for in this Regulation applies nevertheless has effects which are incompatible with Article 101(3) of the Treaty in respect of the territory of that Member State, or in a part thereof, which has all the characteristics of a distinct geographic market.

2. The benefit of this Regulation could be withdrawn by a competition authority of a Member State pursuant to Article 29(2) of Regulation (EC) No 1/2003, in particular where any of the circumstances as set out in Article 10 paragraph 2(a) to 2(d) of this Regulation applies.

TITLE VI

FINAL PROVISIONS

Article 12 – Transitional period

1. Without prejudice to the specific transitional provision for R&D agreements between undertakings competing in innovation set out in paragraph 2, the prohibition laid down in Article 101(1) of the Treaty shall not apply during the period from 1 January 2023 to 31 December 2024 in respect of agreements already in force on 31 December 2022 which do not satisfy the conditions for exemption provided for in this Regulation but which satisfy the conditions for exemption provided for in Regulation (EU) No 1217/2010.

2. For R&D agreements between undertakings competing in innovation, Article 1 paragraph 1(18) and Article 6 paragraph 3 shall only apply to agreements that enter into force after 31 December 2022.

Article 13 – Period of validity

1. This Regulation shall enter into force on 1 January 2023.

2. It shall expire on 31 December 2034.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen