

Standing Committee on the Law of Patents

Sixteenth Session
Geneva, May 16 to 20, 2011

DRAFT QUESTIONNAIRE ON EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

prepared by the Secretariat

1. At its fifteenth session, held from October 11 to 15, 2010 in Geneva, the Standing Committee on the Law of Patents (SCP) requested the Secretariat to prepare a draft questionnaire on exceptions and limitations to patent rights for consideration by Member States at the sixteenth session of the SCP to be held from May 16 to 20, 2011 (see paragraph 12(i) of document SCP/15/5). Accordingly, the present document contains in the annex a draft questionnaire on exceptions and limitations to patent rights.
2. The draft questionnaire contains 11 Sections as follows:

Section I	General;
Section II	Private and/or non-commercial use;
Section III	Experimental use and/or scientific research;
Section IV	Preparation of prescribed medicines;
Section V	Prior use;
Section VI	Use of articles on foreign vessels, aircrafts and land vehicles;
Section VII	Acts for obtaining regulatory approval from authorities;
Section VIII	Exhaustion of patent rights;
Section IX	Compulsory licensing and/or government use;
Section X	Farmer's privilege and/or breeder's exception;
Section XI	Other exceptions and limitations.

[Annex follows]

Draft Questionnaire on Exceptions and Limitations to Patent Rights

The answers to this questionnaire have been provided on behalf of:

Country:
 Office:

Person to be contacted:

Name:
 Title:
 E-mail:
 Telephone:
 Facsimile:

Section I: General

This section is intended to obtain general information on exceptions and limitations to patent rights that are provided under the applicable laws. For the purpose of this questionnaire, the term “applicable law” refers to relevant national and regional statutory law and, where applicable, case law.

The terms used in the questionnaire are drafted in a general way aiming at providing a broad understanding of each concept used, assuming that the exact wording of these exceptions and limitations might differ under the applicable laws. More detailed explanations of the various exceptions and limitations may be found in the following documents: SCP/13/3, SCP/15/3 and CDIP/5/4.

1. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

- Private and/or non-commercial use;
- Experimental use and/or scientific research;
- Preparation of prescribed medicines;
- Prior use;
- Use of articles on foreign vessels, aircrafts and land vehicles;
- Acts for obtaining regulatory approval from authorities;
- Exhaustion of patent rights
- Compulsory licensing and/or government use
- Farmer’s privilege and/or breeder’s exception

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI “Other Exceptions”.

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

2. If the exception is contained in statutory law, please provide the relevant provision(s):
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3. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
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4. What is the rationale for providing the exception? Please explain:
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5. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):
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6. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):
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7. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
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8. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:
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Section III: Experimental use and/or scientific research ¹

9. If the exception is contained in statutory law, please provide the relevant provision(s):

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10. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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11. What is the rationale for providing the exception? Please explain:

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12. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

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13. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

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14. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

- determine how the patented invention works
- determine the scope of the patented invention
- determine the validity of the claims
- seek an improvement to the patented invention
- invent around the patented invention
- other, please specify:

¹ Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

15. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

- Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)
- Research and/or experimentation must be conducted with or using the patented invention (“research with”)
- Both of the above

Please explain by citing legal provision(s) and/or decision(s):

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16. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

- A non-commercial purpose
- A commercial purpose
- Both of the above
- The commercial intention of the experimentation and/or research is not relevant

17. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

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18. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

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19. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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20. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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Section IV: Preparation of prescribed medicines

21. If the exception is contained in statutory law, please provide the relevant provision(s):

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22. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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23. What is the rationale for providing the exception? Please explain:

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24. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

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25. Does the applicable law provide for any limitations on the amount of medicines that can be produced under the exception?

- Yes
- No

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

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26. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

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27. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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28. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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Section V: Prior use

29. If the exception is contained in statutory law, please provide the relevant provision(s):

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30. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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31. What is the rationale for providing the exception? Please explain:

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32. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

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33. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

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34. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

- Yes
- No

35. In case of affirmative answer to question 34, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

- Yes
- No

If yes, please explain what those conditions are:

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36. Does the prior use exception continue to apply in the situations where the prior user has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

- Yes
- No

If yes, please explain the conditions under which such use can continue to apply:

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37. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

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38. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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39. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

40. If the exception is contained in statutory law, please provide the relevant provision(s):

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41. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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42. What is the rationale for providing the exception? Please explain:

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43. The exception applies in relation to:

- Vessels
- Aircrafts
- Land Vehicles
- Spacecraft

44. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

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45. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

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46. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

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47. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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48. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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Section VII: Acts for obtaining regulatory approval from authorities

49. If the exception is contained in statutory law, please provide the relevant provision(s):

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50. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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51. What is the rationale for providing the exception? Please explain:

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52. Who is entitled to use the exception? Please explain:

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53. The exception covers the regulatory approval of:
any products
certain products. Please describe which products:
54. Please indicate which acts are allowed in relation to the patented invention under the exception?
Making
Using
Selling
Offering for sale
Import
Export
Other. Please specify:.....
55. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):
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56. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
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57. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:
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Section VIII: Exhaustion of patent rights

58. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:
National
Regional
International
Uncertain, please explain.....

If the exception is contained in statutory law, please provide the relevant provision(s):

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If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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59. What is the rationale for adopting the exhaustion regime specified above? Please explain:

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60. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

- Yes
- No
- Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

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61. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

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62. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

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Section IX: Compulsory licenses and/or government use

63. If the exception is contained in statutory law, please provide the relevant provision(s):

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64. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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65. What grounds for the grant of a compulsory license (CL) and/or government use (GU) does the applicable law provide in respect to patents (please indicate the applicable grounds):

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|----|----|---|
| CL | GU | |
| | | Non-working or insufficient working of the patented invention |
| | | Refusal to grant licenses on reasonable terms |
| | | Anti-competitive practices and/or unfair competition |
| | | Public health |
| | | National security |
| | | National emergency and/or extreme urgency |
| | | Dependent patents |
| | | Other, please specify: |

66. What is the rationale for providing compulsory licenses in your country? Please explain:

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67. What is the rationale for providing government use mechanism in your country? Please explain:

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68. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

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69. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

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70. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

Yes
No

If yes, what is the time period?

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

Yes
No

If yes, what are “legitimate reasons”?

72. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

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73. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

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74. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

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75. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

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76. If the applicable law provides for the grant of compulsory licenses and/or government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

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77. Please indicate how many times and in which technological areas compulsory licenses and/or government use have been issued in your country:

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78. Is the applicable legal framework for the issuance of compulsory licenses and/or government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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79. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system and/or government use provisions in your country? Please explain:

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Section X: Farmer’s privilege and/or breeder’s exception

80. If the farmer’s privilege in respect of patents is contained in statutory law, please provide the relevant provision(s):

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81. If the farmer's privilege in respect of patents is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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82. If the breeder's exception in respect of patents is contained in statutory law, please provide the relevant provision(s):

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83. If the breeder's exception in respect of patents is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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84. What is the rationale for providing the farmer's privilege in respect of patents? Please explain:

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85. What is the rationale for providing the breeder's exception in respect of patents? Please explain:

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86. If the applicable law provides for the farmer's privilege in respect of patents, please explain its scope by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

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87. If the applicable law provides for the breeder's exception in respect of patents, please explain its scope by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

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88. If the applicable law provides for the farmer's privilege in respect of patents, is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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89. If the applicable law provides for the breeder's exception in respect of patents, is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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90. Which challenges, if any, have been encountered in relation to the practical implementation of the farmer's privilege in respect of patents in your country? Please explain:

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91. Which challenges, if any, have been encountered in relation to the practical implementation of the breeder's exception in respect of patents in your country? Please explain:

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Section XI: Other Exceptions and Limitations

92. Please list any other exceptions and limitations that your applicable patent law provides:

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93. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

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(ii) the rationale of each exception and limitation:

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(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

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In addition, in relation to each exception and limitation, please explain:

(iv) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

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(v) if there have been any challenges encountered in the practical implementation of the exception in your country:

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[End of Annex and of document]