CIECA Report Medical Fitness to Drive Vision

Report covering the answers to the questionnaire

about medical fitness to drive and vision

final / May 2019

CIECA Topical Group on Fitness to Drive Sub group 2: Setting Standards for the Evaluation of Medical Fitness to Drive Andrea Demirtas, Åsa Ericson and Sara Magnusson

Avenue de Tervueren 36-38 | 1040 Brussels | info@cieca.eu



TABLE OF CONTENTS

1.	INTR	DUCTION
2.	ANSV	ER TO QUESTIONS IN THE QUESTIONNAIRE "VISION"
	2.1.	Question number 1 How are persons, applying for their first group I and group II
		icence assessed when it comes to visual function in your country?
		2.1.1. Medical assessment
		2.1.2. Vision test
		2.1.3. Self-declaration
	2.2.	Question number 2 How do you cover the different aspects of visual functions below in
		our country? If specified – what methods of measurement and cut off values are
		sed?5.
		2.2.1. Twilight vision
		2.2.2. Contrast sensitivity 5
		2.2.3. Glare
		2.2.4. Double vision
	2.3.	Question number 3 When assessing double vision – is a statement from the person
		hat they don't notice the double vision anymore (after the adaptation period) enough
		o consider them free from double vision?7
	2.4.	Question number 4 Visual field defects are of special importance. What are the medical
		assessment methods (like Esterman's, Humphrey's, Goldman's or Donder's method)
		used to assess that the criteria for group I or II licences are met?
		2.4.1. For the central part of the visual field
		2.4.2. For the part of the more peripheral visual field that should reach out to 120 or 160 degrees:
	2.5.	Question number 5 Does an on road assessment have a place in the assessment of
	2.5.	visual field defects?
		2.5.1. Group 1 licences
		2.5.2. Group I licences
	2.6.	Question number 6 Do you give exemptions in cases with visual field defects?
	2.0.	2.6.1. If yes – criteria for when this is allowed?
	2.7.	Question number 7 Do you give exemptions in cases with low visual acuity?
	2.7.	
	2.0	2.7.1. If yes – criteria for when this is allowed?
	2.8.	Question number 8 When it comes to progressive eye diseases – is the licence issued with a time limitation and on the condition of a periodic medical certificate?
	2.9.	Question number 9 Is the writing in the 2006 and 2009 Directives substantial or
	2.9.	specified enough to give equal results of medical fitness assessment in all European
		countries when it comes to visual functions?
	2.10.	Question number 10 When it comes to the criteria in the Directive 2006/126/EC, annex
		II and 2009/113/EC – should the medical methods for assessing visual field defects be
		specified?
	2.11.	Question number 11 Do you find the criteria for visual field defects sufficiently
		clinically-informed and evidence-based? 20
	2.12.	Question number 12 Do you find anything special in the Directives 2006/126/EC, annex
		II and 2009/113/EC on visual functions that you would like to see changed?21
2	CON4	
3.	CON	LUSION

ANNEX

1. INTRODUCTION

This report summarizes the answers in the questionnaire regarding "Vision" which was sent to 31 countries within Europe. The questionnaire was answered by 18 countries, although some of the countries did not answer all the questions. The countries who did not answer some of the questions or where the answers needed clarification was contacted again and in some cases an answer or clarification was received. The questionnaire was not answered at all by 13 countries.

Part two of this report lists the questions sent to the countries and the answers received. Part three contains a conclusion concerning fitness to drive and vision, based on the answers.

2. ANSWER TO QUESTIONS IN THE QUESTIONNAIRE "VISION"

2.1. Question number 1

How are persons, applying for their first group I and group II licence assessed when it comes to visual function in your country?

In this question, countries responded differently in the degree of detail provided. Some countries described the assessment in more detail and some countries responded more succinctly. Some countries did not specify whether the answers concerned group 1 or group 2 licence holders, while other countries described the assessment process for group 1 and group 2 separately. It is difficult to know if the countries that did not distinguish between group 1 and group 2 have the same standards for the groups or if their answers are intended for one of the groups. The various areas that the answers addressed are presented below. It is also difficult to know if answers such as "check within the general fitness to drive examination" include an assessment performed by a doctor or if an assessment performed by an optician is enough. Therefore, the number of countries has not been specified in the different areas described below.

2.1.1. Medical assessment

Some countries require a medical assessment performed by a doctor for both group 1 and group 2. Other countries requires a medical assessment only for group 2. One country answered that they require a medical assessment but did not specify if the requirement concerns both groups. Some countries specified that either an optician or a doctor can perform the assessment for group 1.

2.1.2. Vision test

Some countries require a vision test performed by an optician or optometrist instead of a medical assessment performed by a doctor. In some countries, the person needs to perform a vision test at the time of the driving test (either acuity chart or a visual number plate test). In these countries, no vision test performed by an optician or optometrist is required. The test performed at the time of the driving test is often used as a complement to the self-declaration.

2.1.3. Self-declaration

Some countries answered that a self-declaration is used for group 1 (in some of the countries this is complemented with a vision test at the time of the driving test).

Several answers indicate that if the self-declaration indicates any problems with vision the person may need to undergo a medical assessment or an assessment by an optician.

2.2. Question number 2

How do you cover the different aspects of visual functions below in your country? If specified – what methods of measurement and cut off values are used?

2.2.1. Twilight vision

Most of the countries who answered the question do not have any standardized method to measure twilight vision. Three countries gave example of a test. One test was described as 2/10 binocular with optical correction after 5 minutes adaptation to 1 lux. According to the answer, it is not clear whether this test is commonly applied in the country. Another test was described as a dark adaptation test with max cut off 1 log. The last test was specified as a Snellen chart test.

Many of the countries answered that there is no method used to investigate twilight vision, instead the doctor performs a medical assessment based on medical history and questions to the patient. If indicated, in some countries an opinion from a specialist is needed. Some countries specified that if the investigation indicates problems with twilight vision the patient needs to visit an ophthalmologist.

One country reported that they do not accept decreased twilight vision that results in a traffic safety risk for either group 1 or group 2 drivers. The answer also clarifies that if the vision is reduced corresponding to functional night blindness, it poses a road safety risk and the health requirements are not fulfilled. They do not specify a test, but they further conclude that the test used to measure twilight vision only provides indications, but no clear limits for normal variations. The conclusion of investigations carried out must therefore be based on whether the deterioration really constitutes a traffic safety risk. The country also answered that it must be considered whether driving assessment can help clarify whether the applicant can drive a motor vehicle safely. Therefore, in situations where there is decreased twilight vision, driving assessment may be applicable.

Two countries specified that they only perform investigation concerning twilight vision when it comes to group 2. Most of the countries did not specify any differences between group 1 and group 2.

2.2.2. Contrast sensitivity

All of the countries except for three answered that they do not have any standardized method to measure contrast sensitivity. One method mentioned by two countries was the Pelli Robson contrast sensitivity chart test. One of those two countries also mentioned that Sloan chart test could be used occasionally. The third country specified that contrast sensitivity can be measured with image and line tests.

Many of the countries reported that there is no method used to investigate contrast sensitivity, instead the doctor performs a medical assessment based on medical history and questions to the patient. If indicated, in some countries an opinion from a specialist is needed. Some countries specified that if the investigation indicate problems with contrast sensitivity the patient needs to visit an ophthalmologist. One country described that they do not accept decreased contrast sensitivity that results in a traffic safety risk for either group 1 or group 2 drivers. The country also clarify that contrast sensitivity is impaired with age, especially in relation to cataracts, contrast sensitivity usually becomes satisfactory after cataract surgery. Further, they answer that for glaucoma, macular degeneration and in case of refraction anomalies, contrast sensitivity may be significantly impaired, even though the visual strength is normal. They do not specify a test, but they further conclude that the test used to measure contrast sensitivity only provide indications, but no clear limits for normal variations. The conclusion of investigations carried out must therefore be based on whether the deterioration really constitutes a traffic safety risk. This country also highlighted that it must be considered whether driving assessment can help clarify whether the applicant can drive a motor vehicle in a traffic-safe way. Therefore, in situations where there is decreased contrast sensitivity driving assessment may be applicable.

Three countries indicated that they only have specific requirements regarding contrast sensitivity for group 2 drivers. Most of the countries did not specify any differences between group 1 and group 2 licence holders.

2.2.3. Glare

All of the countries except for one answered that they do not have any standardized method to measure glare. The method mentioned by one country was written in Spanish and was called Deslumbrómetro.

Many of the countries answered that there is no method used to investigate glare, instead the doctor performs a medical assessment based on medical history and questions to the patient. If indicated, in some countries an opinion from a specialist is needed. Some countries specified that if the investigation indicates problems with glare the patient needs to visit an ophthalmologist.

One country described that they do not accept increased glare that results in a traffic safety risk for either group 1 or group 2 licences. The country also answered that glare is the function that is least amenable to objective measurement and assessment. They also indicated that applicant's own description of driving out of tunnel towards low sun may provide useful information on the sensitivity of the lens and can be part of the optometrist's or ophthalmologist's assessment. Further, they concluded that the test used to measure glare only provide indications, but no clear limits for normal variations. The conclusion of investigations carried out must therefore be based on whether the deterioration really constitutes a traffic safety risk. The country answered that it must be considered whether driving assessment can help clarify whether the applicant can drive a motor vehicle safely. Therefore, in situations where there is increased glare sensitivity a driving assessment may be applicable.

Three countries specified that they only have specific requirements regarding contrast sensitivity for group 2. Most of the countries did not specify any differences between group 1 and group 2 drivers.

2.2.4. Double vision

Some of the countries reported that they do not perform any specific measurement, but instead look at the case history. One country specified that they use prism, Maddox, Hess screen or similar. One country indicated that they use a test, which includes visual movement exam and direction tracking. One country answered that they look at the case history and perform a neurology and ophthalmological assessment. Another country answered that the requirements for double vision applies within the viewing direction up to 30 degrees from midline directly forward and that a person with double vision needs to be examined by an optometrist or ophthalmologist.

Several countries reported that corrected double vision (for example patching) is acceptable for group 1 drivers. Some countries also stated that, when the double vision is uncorrected, an adaptation period is needed. Three of the countries specified the adaptation period to be six months. One of the countries specified the adaptation period to be three months provided that an optometrist or ophthalmologist certifies satisfactory compensatory measures, a positive driving assessment has been performed and no other impairment of the visual function that is covered by the health requirements, including the requirements for visual acuity and field of vision, exist. That country also clarified that compensatory measures may, for example, be prism glasses that eliminate double vision or permanent occlusion on one eye. This country further clarified that if double vision is eliminated with occlusion of one eye the country's regulation for loss of vision in one eye should apply. However, they did not specify the regulation for monocular vision.

One country has the requirement that no double vision is allowed in the central field.

Several countries answered that double vision is not acceptable for group 2 licence holders. One country clarified that prism glasses provide a limited field of view and the use of such glasses causes the person not to meet the health requirements for group 2.

2.3. Question number 3

When assessing double vision – is a statement from the person that they don't notice the double vision anymore (after the adaptation period) enough to consider them free from double vision?

Figure 1 presents how many of the countries that accept a statement from a person with double vision and how many of the countries that require further investigation. The results are clarified below.

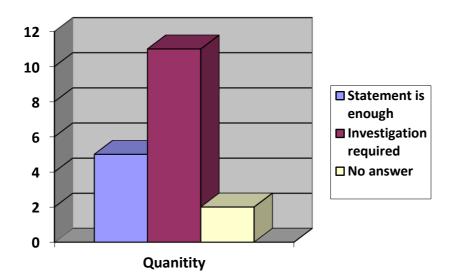


Figure 1. Requirements for assessing double vision.

Five countries answered that the statement from the driver is enough. One of those countries specified that this is only applicable for group 1 drivers. Another of those countries remarked that there also need to be a clinical judgement from a doctor, and a third country remarked that the doctor has to take into account the opinion from an eye specialist. Eleven countries answered that further investigation of some kind (e.g. ophthalmologic assessment) is needed. Two countries did not answer this question as either yes or no, but one of those countries remarked that the medical record is important and that the evolution over time including report from the ophthalmologist or neurologist should be taken into account.

2.4. Question number 4

Visual field defects are of special importance. What are the medical assessment methods (like Esterman's, Humphrey's, Goldman's or Donder's method) used to assess that the criteria for group I or II licences are met?

All but one of the 18 countries that participated in this survey responded to this question.

2.4.1. For the central part of the visual field

The different medical assessment methods used by the responding countries concerning the central part of the visual field are presented in Figure 2. The results are clarified below.

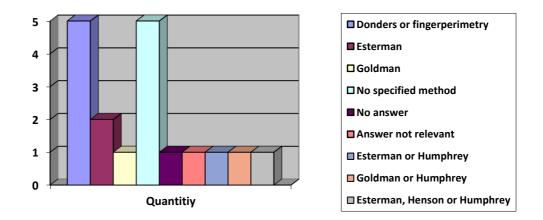


Figure 2. Methods used in the first place when assessing the central visual field.

Five countries reported that they use Donders or finger perimetry. One of those countries specified that they use Donders in the first place and then if necessary Esterman. Another of those countries specified that they use Donders in the first place and then if necessary Humphrey or another equivalent method.

Two countries answered that they use Esterman.

One country answered that they use Esterman or Humphrey.

One country answered that they use Esterman, Henson or Humphrey as a first choice.

One country answered that they use Goldman or Humphrey.

One country uses Goldman in the first place while other countries indicated that they use other tests in the first place and Goldman if required.

One country reported that the central field can be studied by keeping the normal text at 57 cm from the eyes of the subject. The person fixes a glance at the text and describes where the text curves, whether there is a shadow, whether the colours disappear somewhere. This country is included in the bar representing "no specified method" in Figure 2.

Five countries did not specify what type of method is used to measure the visual field. One of those countries reported that the visual field has to be tested with perimetry, Donders is not accepted. In several countries, an ophthalmologist performs the assessment if the doctor finds that necessary. In some countries the ophthalmologist choose what method to be used. The answer of one country was not relevant concerning this question.

2.4.1.1. How do you define "no defects" within this part of the visual field?

Some countries answered that it is up to the doctor or the ophthalmologist to decide whether the requirements are fulfilled or not. Two of those countries specified that no defects in the central area are acceptable, but the countries did not specify how they define a defect. One of these two countries explained that if the ophthalmologist finds it necessary to investigate the visual field, the investigation shall be binocular in order to assess scotomas coinciding in both eyes. The country also answered that computerized perimetry which analyses the central field can be a screening element for the general population. If more detailed studies are needed, classical campimetry should be used. Concerning professional driving licences, the author interpreted the answer from the country that no relevant absolute or relative scotomas are permitted in the monocular central field, nor significant reductions in any of the meridians of each monocular field. This country did not specify what type of categories are included in the term professional driving licences. Three countries who uses Esterman clarified how they define "no defects". One of those countries does not accept any missed points within the central 20 degrees for group 1 and no missed points within the central 30 degrees for group 2. Another of those countries indicated that they accept scattered missed points and also a single cluster of up to three adjoining missed points (the answer does not specify if it concerns group 1 and 2, or just one of the groups). The third country defined a defect concerning group 1 as being a cluster of 4 or more missed points centrally, or any defect (4 or more missed points) encroaching centrally. This country does not accept any missed points for Group 2.

One country who uses Esterman answered that every point that is not seen is a visual field defect. They clarify further that the extent to which this visual field defect is considered to affect the fitness to drive depends on the position of the defect. That is, if the defect is central it is of greater importance than if the defect is peripheral. The country indicated that other investigations that might be performed, also affect the decision whether the defect is part of an absolute or relative scotoma. The same country also clarifies that the result of the Esterman test needs to be reliable concerning false positive and false negative results. The country did not specify how many false positive and false negative results that is accepted in order to classify the test as reliable.

One country which uses Humphrey defined a defect for group 1 as one or more corresponding points under 20 dB within the central 10 degrees or two or more corresponding points under 10 dB between 10 and 20 degrees. Concerning group 2 a defect is defined as one or more corresponding points under 20 dB within the central 10 degrees or one or more corresponding points under 10 dB between 10 and 30 degrees. Another country reported that one missed point in Humphrey adapted full field assessment is considered as a scotoma.

One country who uses Esterman or Humphrey states that there must be absolutely no defects. One country who uses Goldman or Humphrey states that no absolute defects are allowed. One country who uses Donders or a similar confrontation method states that there should not be any defect within the central 20 degrees. These countries do not specify how they define a defect.

Three countries did not answer the question and the answers from some countries are not relevant concerning this question.

2.4.2. For the part of the more peripheral visual field that should reach out to 120 or 160 degrees:

The different medical assessment methods used by the responding countries concerning the peripheral part of the visual field are presented in Figure 3. The results are clarified below.

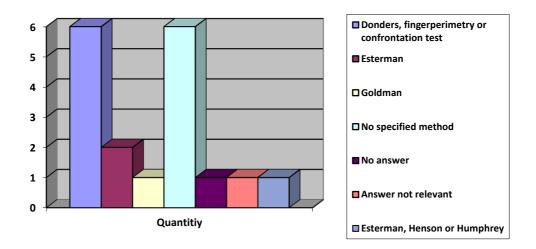


Figure 3. Methods used in the first place when assessing the peripheral visual field.

Six countries answered that they use Donders, finger perimetry or confrontation test. Two of those countries specified that they use Donders in the first place and then if necessary Esterman.

Two countries answered that they use Esterman.

One country answered that they use Esterman, Henson or Humphrey as a first choice.

One country use Goldman in the first place while other countries answered that they use other tests in the first place and Goldman if required.

Six countries did not specify what type of method that is used to measure the visual field. One of those countries specified that the visual field has to be tested with perimetry, Donders is not accepted. In several countries, an ophthalmologist performs the assessment if the doctor finds that necessary. In some of the countries, the ophthalmologist choose what method to be used. One country's answer is not relevant concerning this question.

One country using Esterman also described how many missing points they accept in the peripheral visual field. They accept a cluster of up to three adjoining missing points, unattached to any other area of defect, lying on or across the horizontal meridian; a vertical of only single point width but any length, unattached to any other area of defect, which touches or cuts across the horizontal meridian.

2.5. Question number 5

Does an on road assessment have a place in the assessment of visual field defects?

2.5.1. Group 1 licences

Figure 4 presents how many of the countries that have an on road assessment included in the assessment of visual field defects and how many of the countries that do not use an on road assessment when it comes to assess visual field defects. The results are clarified below.

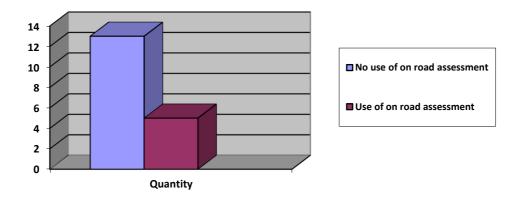


Figure 4. Use of on-road assessment when assessing visual field defects in group 1.

The responses to this question indicated that thirteen countries do not have an onroad assessment as part of the assessment of visual field defects for group 1. In five countries, an on-road assessment have a place in the assessment.

Three of the countries who answered yes and two of the countries who answered no specified that the on-road assessment has a place in exceptional cases under specific criteria. According to the answers above it can be assumed that these countries handle on-road assessment similarly when it comes to visual field defects although they answered differently. This suggests that this question could have been more detailed to avoid misunderstandings.

2.5.2. Group 2 licences

Figure 5 presents how many of the countries that have an on road assessment included in the assessment of visual field defects and how many of the countries that do not use an on road assessment when it comes to assess visual field defects. The results are clarified below.

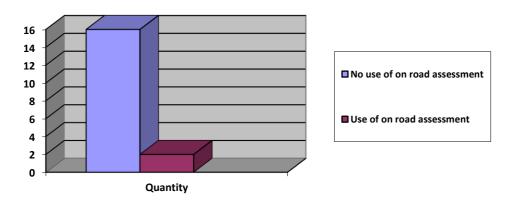


Figure 5. Use of on-road assessment when assessing visual field defects in group 2.

The results showed that sixteen countries do not have an on-road assessment as part of the assessment of visual field defects for group 2. In two countries, an on-road assessment have a place in the assessment.

The two countries who answered yes reported that the on-road assessment is used in exceptional cases under specific criteria. However, one of those countries, also reported that the on-road assessment is not an option when it comes to visual field defects for group 2, they clarified that they use the on-road assessment after a serious loss of vision in one eye.

2.6. Question number 6

Do you give exemptions in cases with visual field defects?

Figure 6 presents how many of the countries that give exceptions in cases of visual field defects. The results are clarified below.

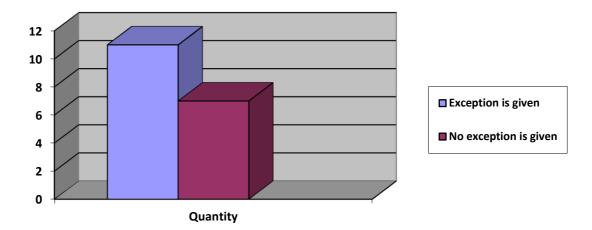


Figure 6. Exceptions in cases with visual field defects.

The responses to this question showed that eleven countries give exceptions in cases with visual field defects, seven countries do not give exceptions in those cases.

Six of those countries who answered yes, specified that they give exceptions only to group 1. One country specified that the exceptions are based on a medical certificate from a specialist (ophthalmologist or neurologist). Another country specified that as long as specific requirements are met exception can be given after a medical certificate from an ophthalmologist. Some countries clarified that exceptions are given within the legal limits.

2.6.1. If yes – criteria for when this is allowed?

The following criteria were clarified by the countries who give exceptions:

- Exceptions can be allowed if there are isolated visual field defects and good driving assessment.
- Exceptions can be allowed if there is an opinion from a doctor or specialist in eye diseases who have found that there is no other reduction of the visual function such as glare, contrast sensitivity or twilight vision. The applicant must also complete and pass an on-road assessment.
- Exceptions can be allowed if the following conditions are met:
 - defects have been present for at least 12 months.
 - defects are caused by an isolated event or a non-progressive condition.
 - there is no other condition or pathology regarded as progressive and likely to be

affecting the visual fields (panel's advice is that certain medical conditions, for example glaucoma and retinitis pigmentosa, would always be considered as progressive and so could not be considered as exceptional cases).

- binocular vision is present
- no uncontrolled diplopia exist.

- no other impairment of visual function, including no glare sensitivity, contrast sensitivity or impairment of twilight vision exist.

- clinical confirmation of full functional adaptation exist.

For exceptional cases considered to be potentially licensable under these criteria, a satisfactory practical driving assessment at an approved centre will be required.

- Exceptions can be allowed if the following criteria are met:
 - defects have been present for 12 month
 - defects are isolated and non-progressive
 - no other progressive pathology is present
 - binocular vision is present
 - no uncontrolled diplopia exist
 - no other impairment of visual function exists
 - there is a clinical assessment of full satisfactory functional adaptation
 - there is a satisfactory on-road assessment
- Exceptions are granted based on a positive on-road assessment.
- Exceptions can be allowed if the following circumstances are met:
 - defects should be permanent.

- there is no other condition or pathology regarded as progressive and likely to affect the visual field (for example glaucoma, macula degeneration, diabetic retinopathy and retinitis pigmentosa).

- no diplopia exist.

- no other impairment of visual function, including no glare sensitivity, contrast sensitivity or impairment of twilight vision exist.

- there is a statement from an ophthalmologist.

- there is a satisfactory on-road assessment.

- no defect should be present within or on the line of the circle with the radius of 20 degrees from the centre.

 Exception can be given in certain individual cases after an investigation based on type of disease and the size and location of the defects. In general, when using a Humphrey test, six scattered points below 20 dB within the central visual field can be accepted (depending on the position and values in these points). When using an Esterman program five adjoining missed points in the peripheral field can be accepted.

2.7. Question number 7

Do you give exemptions in cases with low visual acuity?

Figure 7 presents how many of the countries that give exceptions in cases of low visual acuity. The results are clarified below.

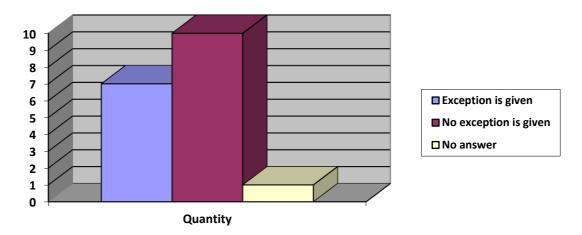


Figure 7. Exceptions in cases with impaired visual acuity.

The survey results showed that while seven countries give exceptions in cases with low visual acuity, ten countries do not. One country did not answer the question.

Three of those countries who answered yes, clarified that they give exception only to group 1. Some countries clarified that the exception is given within the legal limits.

One of the countries that answered no clarified what is stated in their regulation about visual acuity. Their regulation requires that applicants for group I shall have a binocular visual acuity of at least 0.5. For group 2 the visual acuity should be at least 0.8 in the better eye and at least 0.5 in the worse eye. If corrective lenses are used to attain these values, the minimum acuity without correction must achieve at least 0.05 in each eye.

2.7.1. If yes – criteria for when this is allowed?

The following criteria were clarified by the countries who give exceptions:

- Visual acuity above 0.3 and a satisfactory driving assessment.
- For group 1 licences there need to be an opinion from a doctor or specialist in eye diseases who has found that there is no other reduction of the visual function such as glare, contrast sensitivity and twilight vision. The applicant must also complete and pass an on-road assessment.
 For group 2 licences a serious loss of vision in one eye should be followed by an individually determined period when driving is not allowed. Driving can be resumed based on an opinion from a doctor or specialist in eye disease and on condition that the applicant completes and passes an on-road assessment.
- It is possible to give exception based on an individual ophthalmologic assessment.
- It is possible to give exception when twilight vision, contrast sensitivity and glare are normal.
- It is possible to give exception for group 1 licences when the visual acuity is between 0.4 – 0.5 if there is a positive on-road assessment. If visual acuity is

between 0.16 - 0.4 the driver has to use a bioptic device and perform a positive on-road assessment.

2.8. Question number 8

When it comes to progressive eye diseases – is the licence issued with a time limitation and on the condition of a periodic medical certificate?

Figure 8 presents how many of the countries that, when it comes to progressive eye disease, issue a licence with a time limitation and on the condition of a periodic medical certificate. The results are clarified below.

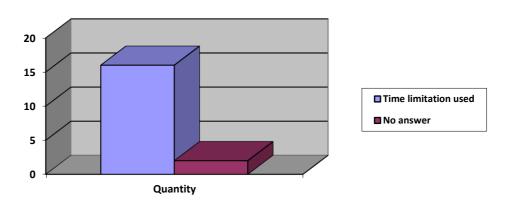


Figure 8. Progressive eye diseases - Driving licences issued with time limitation and on the condition of a periodic medical certificate.

The responses to this question showed that sixteen countries issue the licence with a time limitation when it comes to progressive eye diseases and on the condition of a periodic medical certificate. Two countries did not answer the question.

Many countries indicated that they issue the licence with a time limitation based on a medical certificate from a specialist.

Countries who answered that they issue a licence with a time limitation and on the condition of a periodic medical certificate, gave the following comments:

- Applies a time limitation of maximum ten years but in practice the maximum is five years.
- The requirement for visual acuity and visual field will normally be starting point for the assessment of the road safety consequences of an eye disease. If the applicant meets the requirements at the time of examination, a driving licence can be issued to both group 1 and 2 vehicles. Depending on the nature of the disease, issuance may be subject to a conditionally determined time limit. In that case, a time limit should usually be set based on the specific eye disease and the normal development of the disease. If the examination shows evidence of progressive eye disease that is of significance to the ability to see, the medical certificate should include a current assessment by a doctor or specialist in eye disease about the expected development of the disease. If driving licence has been time limited, a medical certificate must be attached when applying to renew the licence.

- Based on a physician's decision a time limitation can be suggested for the police requiring medical follow-up (as of course in other chronic or progressive diseases can be done).
- An ophthalmologist sets examination intervals.
- Medical certificate is not required, a visual test is required at reapplication.
- The time limitation is at the discretion of the clinician and depends on the nature of the disease.
- If progressive eye disease is detected or declared the driving licence may only be issued or revalidated for group 1, subject to annual periodic examination by an ophthalmologist.
- For group 1 licences, the validity time is limited to ophthalmological criteria. For group 2 licences a person can obtain or renew the licence as long as he/she meets the requirements of visual acuity, visual field etc. The period of validity will be reduced depending on ophthalmological criteria.
- In general the medical certificate is for a maximum duration of two years.

One of the countries which did not answer the question clarified under the remark section that the medical opinion issued by the doctor states whether a licence should be issued with a time limitation and on the condition of a periodic medical check. Another of those countries which did not answer the question clarified under the remark section that it is up to the competent doctor to assess medical fitness. The doctor decides the time limitation, which can be shorter than the required length in the regulation. The doctor also initiates an extraordinary medical fitness examination if needed.

2.9. Question number 9

Is the writing in the 2006 and 2009 Directives substantial or specified enough to give equal results of medical fitness assessment in all European countries when it comes to visual functions?

Figure 9 presents the results concerning if the countries think that the writing in the 2006 and 2009 Directives are specified enough to give equal results of medical fitness assessment in all European countries. The results are clarified below.

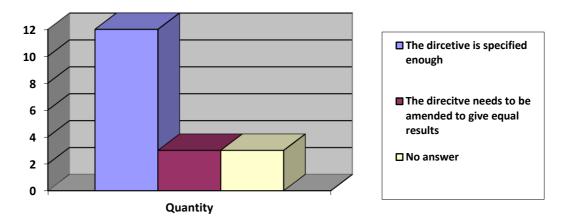


Figure 9. Does the EU Directive needs to be amended in order to give equal results when it comes to visual functions?

According to the answers, twelve countries believe that there is no need to amend the EU Directive when it comes to visual functions. They think the EU Directive is substantial and specified enough to give equal results of medical fitness assessments in all European countries. Three countries do not think that the EU Directive is detailed enough to give equivalent results of medical fitness when it comes to visual functions. Three countries did not answer the question.

Countries who think that the EU Directive is specified enough to give equal results provided the following comments:

- Note that many medical tests are not possible on a large scale and their efficiency has not been proved on that topic.
- Generally yes. However, it is acknowledged that while specified as a relevant vision problem that must be assessed, the lack of guidance and a measure for the assessment of glare and contrast sensitivity is problematic.
- Some minor internal inconsistencies.
- The authority has taken over and applies the corresponding provisions of the EU Directive with appropriate rigor.

Countries that believe that the EU Directive needs to be amended to give equal results gave the following comments:

- Contrast sensitivity is overemphasized. The EU Directive can be understood wrongly. We should keep in mind that mostly driver's fitness is assessed by "ordinary physicians" and only if needed by specialists.
- We think it is not possible because for some parameters it is very difficult to fix cut off points due to the absence of scientific evidences.
- Medical methods for assessing visual fitness to drive (diplopia, glare, contrast sensitivity, twilight vision and field of vision) aren't specified. It is only stated that

no defects should be present within the central area, but a definition what a defect is, is missing.

One country who did not answer yes or no gave the following comment:

- The minimum standards of the EU Directive for "sight", written in the Annex III, are not as detailed as the regulation in our country. In our country the regulation is very specific and differentiates in a lot of circumstances, so we cannot answer this question in an equitable way, because we don't know the regulations from other countries.

2.10. Question number 10

When it comes to the criteria in the Directive 2006/126/EC, annex III and 2009/113/EC – should the medical methods for assessing visual field defects be specified?

Figure 10 presents the results concerning if the countries think that the methods for assessing visual field defects should be more specified in the Directive 2006/126/EC. The results are clarified below.

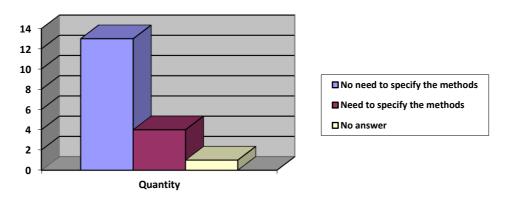


Figure 10. Is there a need to specify the methods to be used when it comes to assessing the visual field?

The responses showed that thirteen countries do not think that the medical methods for assessing visual field defects should be specified in the EU Directive. Four countries want the medical methods to be specified and one country did not answer the question.

Countries who think that there is no need to specify the methods gave the following comments:

- Not all countries and organisations can afford the fancy methods!
- Guidance is always welcomed on different methods but no obligatory methods should be demanded.
- We do not think this is necessary. We have Medical Advisory Panel on vision and driving and they provide advice on the appropriate medical methods for assessing visual field defects. To legislate for this would remove any flexibility and would prevent the considerations of innovative methods or equipment

developed.

- The professional protocols provide sufficient framework and security for the correct medical decisions.
- Clinical sciences change and adapt!
- We think that specific guides for each subject could be more practical and easier to change when needed.

One of the countries who think that there is a need to specify the methods gave the following comment:

- The methods we use today are good enough but must be carried out by an ophthalmologist or an optician.

2.11. Question number 11

Do you find the criteria for visual field defects sufficiently clinically-informed and evidence-based?

Figure 11 presents the results concerning if the countries think that the criteria for visual field defects are sufficiently clinically-informed and evidence-based. The results are clarified below.

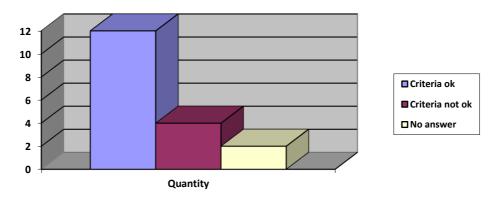


Figure 11. Are the criteria for visual field defects sufficiently clinically informed and evidence-based?

The results showed that twelve countries find the criteria for visual field defects sufficiently clinically informed and evidence based. Four countries do not find the criteria for visual field defects satisfactory. Two countries did not answer the question.

Countries who answered that they think the criteria for visual field defects are clinically informed and evidence based gave the following comments:

- There are the best there exist.
- They are necessary and sufficient to take into account during assessment of conditions of safe driving.

Countries who answered that they do not think the criteria for visual field defects are clinically informed and evidence based gave the following comments:

- Specification of requirements for the driving test is recommended in the EU Directive.
- The criteria are defined from expert opinion rather than from evidence specifically related to driving.
- 160 degrees for group 2 seems overly very strict.

One country, which did not answer yes or no, gave the following comment:

- When the EU experts prepared the latest report there was not enough evidence. At present, we are going to review recent studies together with the scientific community.

2.12. Question number 12

Do you find anything special in the Directives 2006/126/EC, annex III and 2009/113/EC on visual functions that you would like to see changed?

Figure 12 presents the results concerning if there is anything in the Directive 2006/126/EC, annex III and 2009/113/EC concerning visual functions that the countries would like to see changed. The results are clarified below.

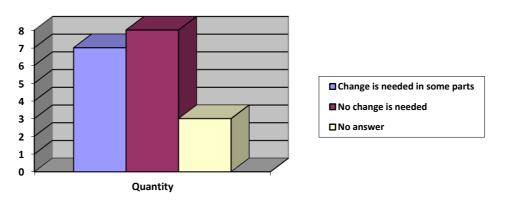


Figure 12. Is it need for anything special in the Directive to be changed?

Eight countries do not find it necessary to change the EU Directive. Seven countries indicated that there are things that they would like to see changed in the EU Directive. Three countries did not answer the question.

Countries who would like to see some specific things change in the EU Directive gave the following comments:

- Monocular drivers should also be allowed to drive group 2 vehicles.
- Contrast sensitivity testing requirements have no road safety value in practice. If there is some kind of visual problem further ophthalmologist assessment will tell what should be done.

- The assessment of the colour vision should be strengthened, twilight vision should be concretized.
- The lack of guidance and a measure for the assessment of glare and contrast sensitivity.
- When the vision acuity is not sufficient one should withdraw the driving licence without considering twilight vision, contrast sensitivity and glare.
- The requirements of 160 degrees for group 2 seems overly strict.
- The EU Directive should specify which method that should be used for examination of visual function.

One country who did not answer yes or no gave the following comment:

- As we have said for other pathologies, we think that certain criteria must be set in Annex III to be further developed in technical protocols. Our experience is that introducing numerous criteria in the standards leads to slow changes, when due to advances in treatments, techniques, etc., it is necessary to amend regulations.

3. CONCLUSION

In general, it is notable that it is very difficult to compile the answers into a readable report. There are several sources of error that needs to be considered before any final conclusion can be drawn.

For example, the countries may have used different wordings for the same things and the same wordings for different things. The countries have also provided different levels of detail. Some countries provided detailed explanations of what they do, while other countries responded more succinctly. It is likely that the countries often handle things in a similar way but it is not easy to conclude this based on the data that was provided. An example is the answers concerning how twilight vision is covered. Some of the answers are "case history", "not defined in law or guidelines, but referred to as other impairments to visual function", "no specific measurement, specialist opinion regarding fitness to drive is indicated". In this example, it is impossible to know whether the countries handle twilight vision in the same way or not.

Another source of error is the requirements for group 1 and 2. Some countries specified that they have different requirements for the two groups while other countries have not described anything about this. Thus it is difficult to know if it can be assumed that the requirements in those countries who have not specified between the groups are the same for the two groups or if the answers are intended for one of the groups.

In order to be able to compare the answers, complementary questions were sent to several countries, but not all of the countries answered the request.

Since the questions and the answers in several areas are complicated and can be interpreted in different ways it is important to point out that the charts presented in the report should only be seen as an indication of similarities and differences between countries and not as a precise description of how many countries that do things in one way or another. It is also important to keep in mind that 13 countries did not answer the questionnaire at all, and of those 18 countries who did respond, some countries did not respond to all the questions. Therefore, the response rate is quite low concerning several questions.

Despite what is written above concerning the sources of error and the response rate it can be concluded that the EU Directive has been interpreted differently within the EU concerning certain areas. One area where the requirements are handled in a different way is the area concerning visual field assessment. It is stated in the EU Directive under point 6.1 that *"the horizontal visual field should be at least 120 degrees, the extension should be at least 50 degrees left and right and 20 degrees up and down. No defects should be present within a radius of the central 20 degrees"*. In order to fulfil this requirement some countries use Donders, one country does not allow Donders, some countries use the Esterman program and some countries uses Goldman. It is hard to assess people in an equivalent way when using so many different methods. It should be noted that question number four concerning which medical assessment method that is used to measure the visual field was generally asked. Therefore, there is a possibility that some countries indicated how they measure the visual field in the first place when no eye disease or eye defect is known, while other countries described how they measure the visual field when there is an identified progressive eye disease that is known to affect the visual field.

Some countries reported on how they define "a defect". The definition of "a defect" is different in different countries. The conclusion of this is that a driving licence holder in one country may have the driving licence withdrawn as a direct consequence of central defects while a person with the same defects in another country may keep the driving licence. One of the countries pointed out that it would be good with a definition about what "a defect" is. However, one country is afraid that more specified requirements in the EU Directive would be hard to follow for countries which cannot afford expensive methods.

Several countries raised concerns regarding the lack of guidance when it comes to glare, contrast sensitivity and twilight vision. Some countries suggested a guide to describe how to handle those areas, another country thinks a guide to describe how to measure the visual field would be good.

Since the objectives of the EU Directive among other things are to contribute to road safety and facilitate the free movement of persons taking up residence in a Member State other than the one issuing the driving licence, it is important that the criteria in the EU Directive are interpreted in a similar way in the different Member States. Although several countries did not consider it necessary to amend the EU Directive since they are satisfied with the way they handle the criteria, this report demonstrates that the criteria in the EU Directive in some areas are difficult for the countries to follow in an equivalent way. Overall, there are many differences in the assessment concerning whether a driver licence holder fulfil the medical requirement about vision or not. Therefore, the conclusion of this report is that these differences needs to be highlighted and discussed further in order to increase the contribution of road safety and free movement.

Annex

Excel spreadsheet of responses.