



New RAPEX Risk Assessment Guidelines

Results of the public internet consultation

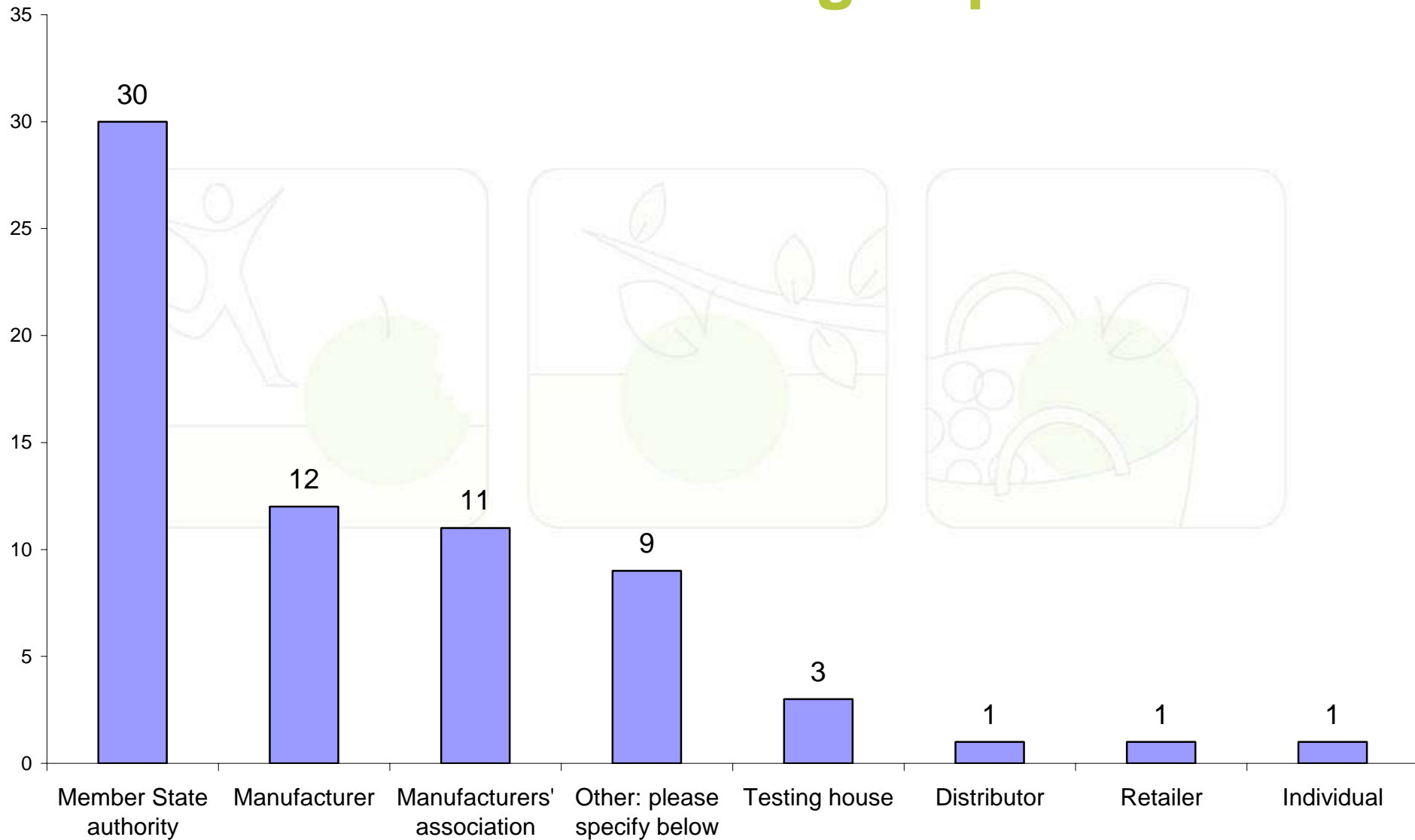
Meeting of the GPSD Committee
6 - 7 November 2008, Brussels

V. Povilaityte, J. Vogelgesang (SANCO.B.3)

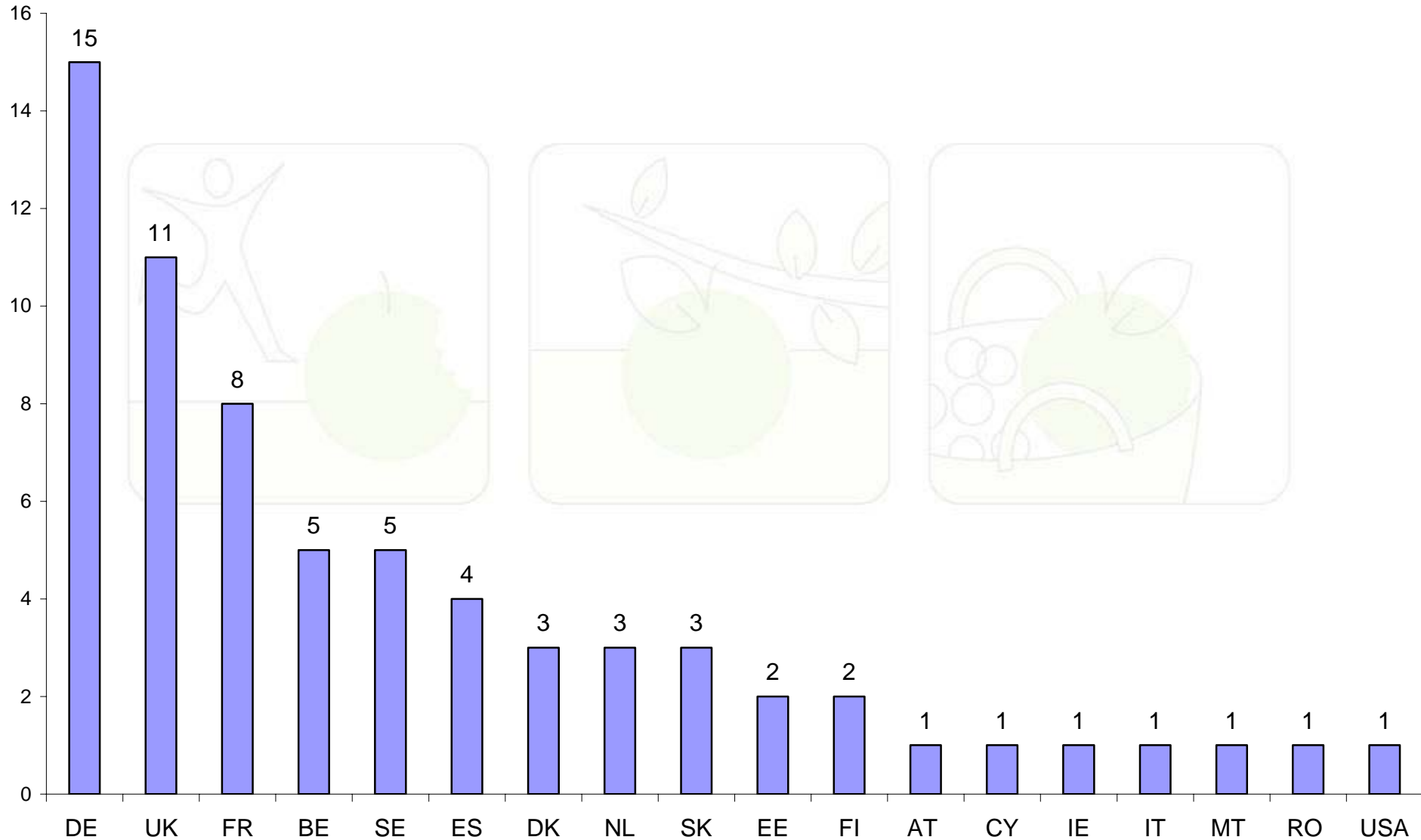
General information

- Public internet consultation on the draft RAGs:
open 15 July to 15 October 2008
- 25 questions
 - 9 questions on personal data and respondents' previous experience
 - 16 questions directly related to the RAGs
- Possibility to submit comments on all questions related to the RAGs
- 68 replies were received

Stakeholder group



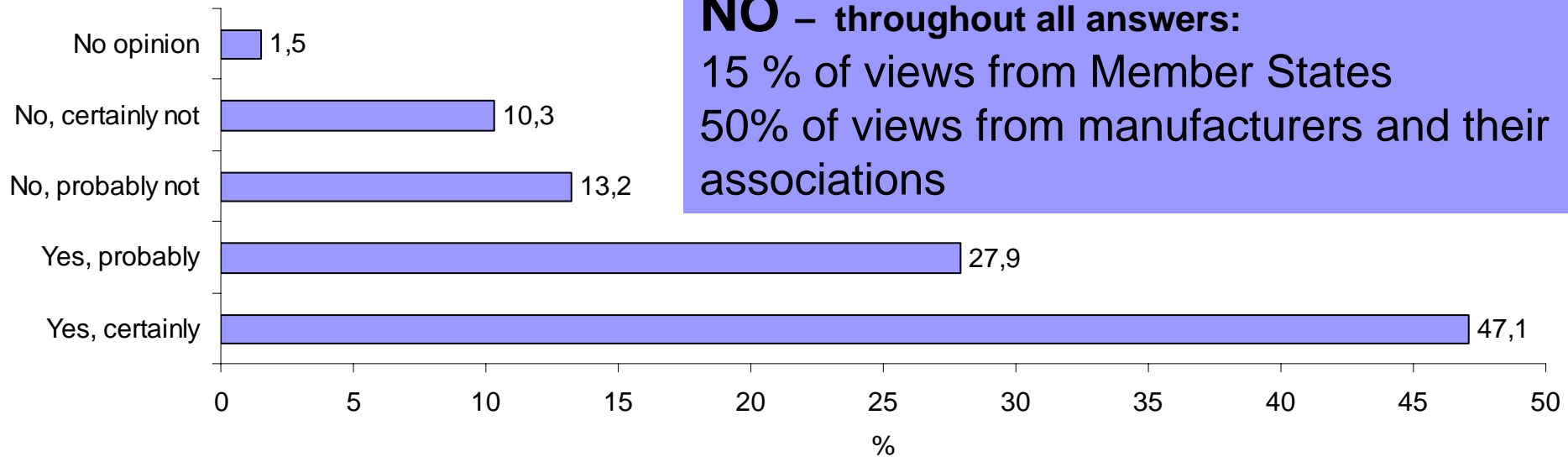
Countries of respondents



Awareness of RAGs and personal experience

- Awareness: **66%** of respondents knew that RAGs were in preparation
- Personal experience: **90%** of respondents carried out RA in the past and will so in the future

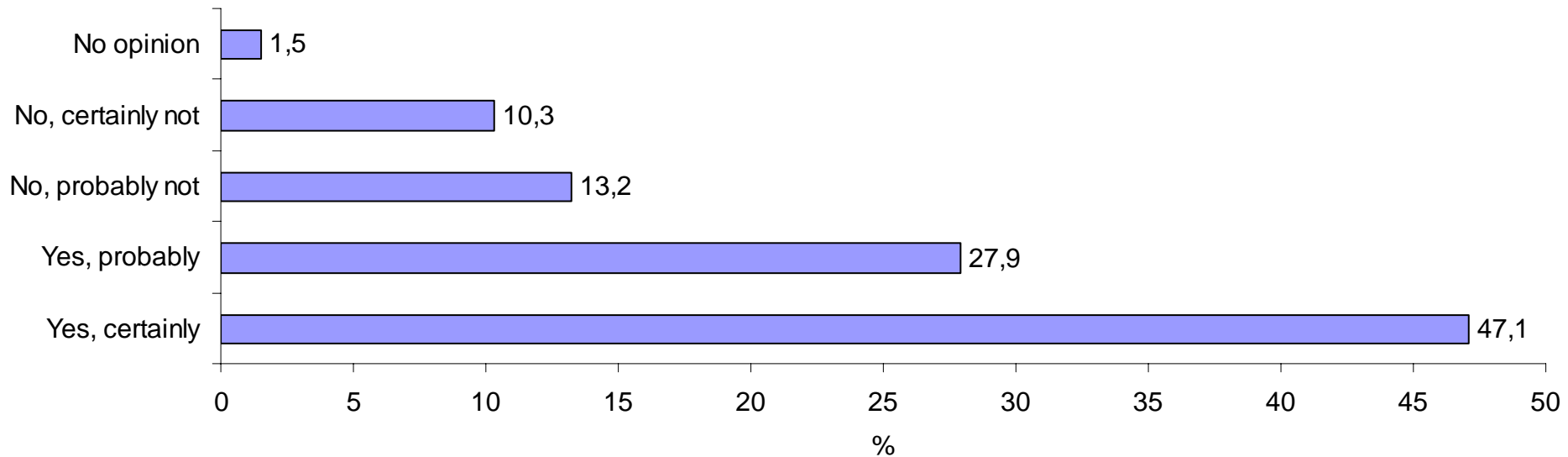
Are RAGs needed?



NO – throughout all answers:
15 % of views from Member States
50% of views from manufacturers and their associations

YES – throughout all answers:
85 % of views from Member States
50% of views from manufacturers and their associations

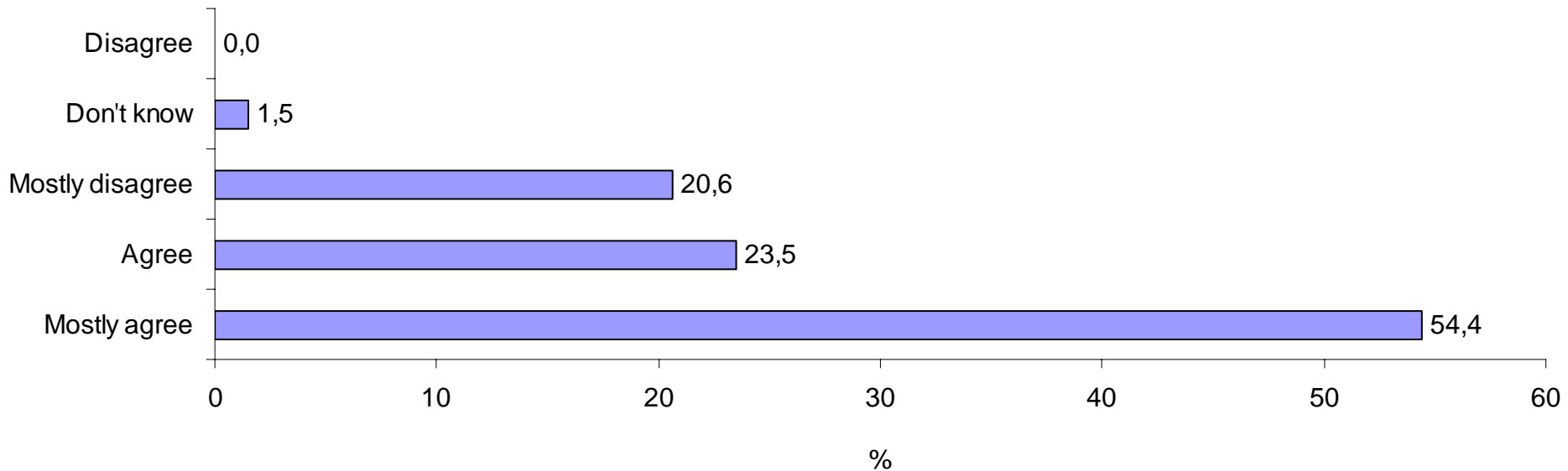
Are RAGs needed?



NO-views (throughout all slides):

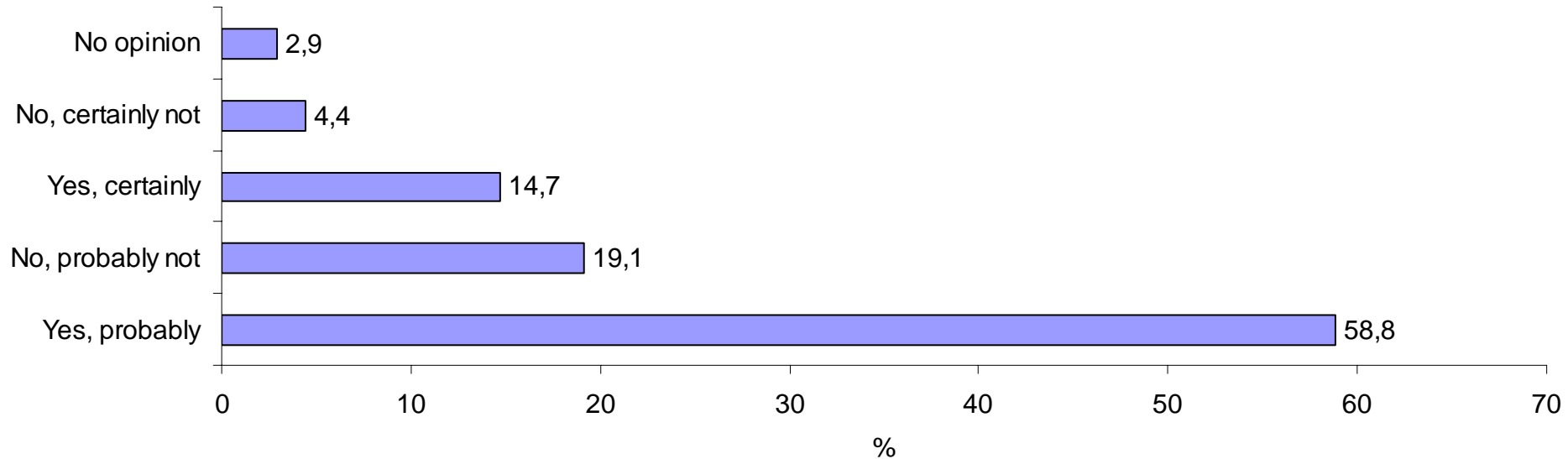
Product safety is ensured by harmonised standards

Do you agree with the proposed methodology?



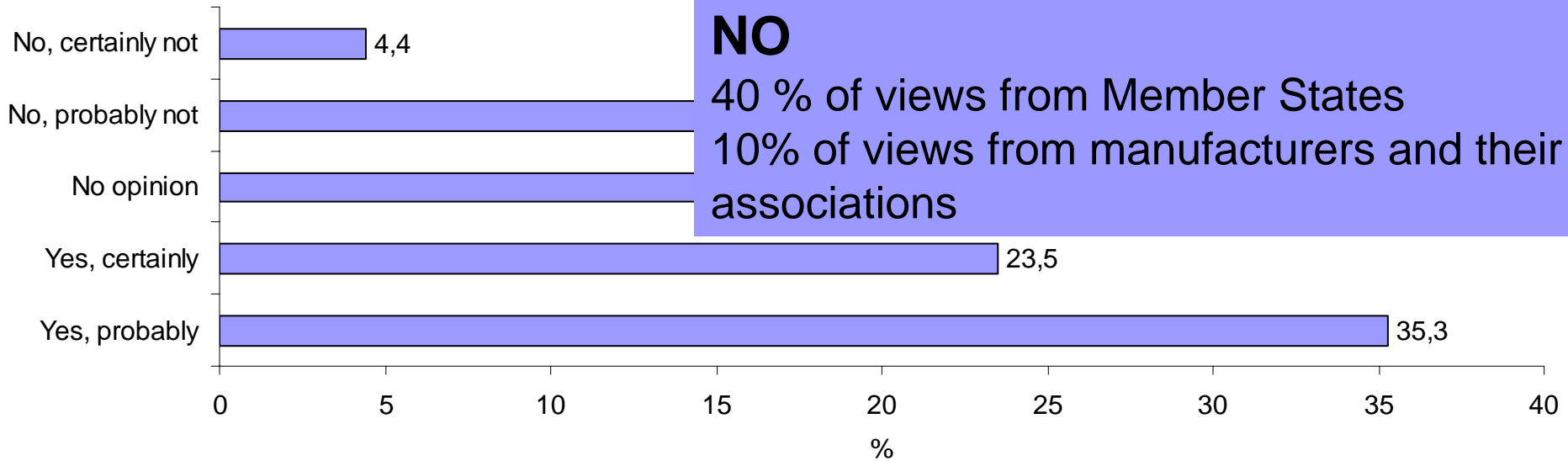
- The overall methodology is subject to personal interpretations (e.g. probability)
- Too complicated

Type of hazard easily identifiable ?



- Appropriate identification requires experience as well as accident statistics
- Proposal to differentiate between hazards that may lead to injury
 - after repeated exposure over a longer period
 - after a single contact

Chemical risks to be assessed according to the ECHA guidance?



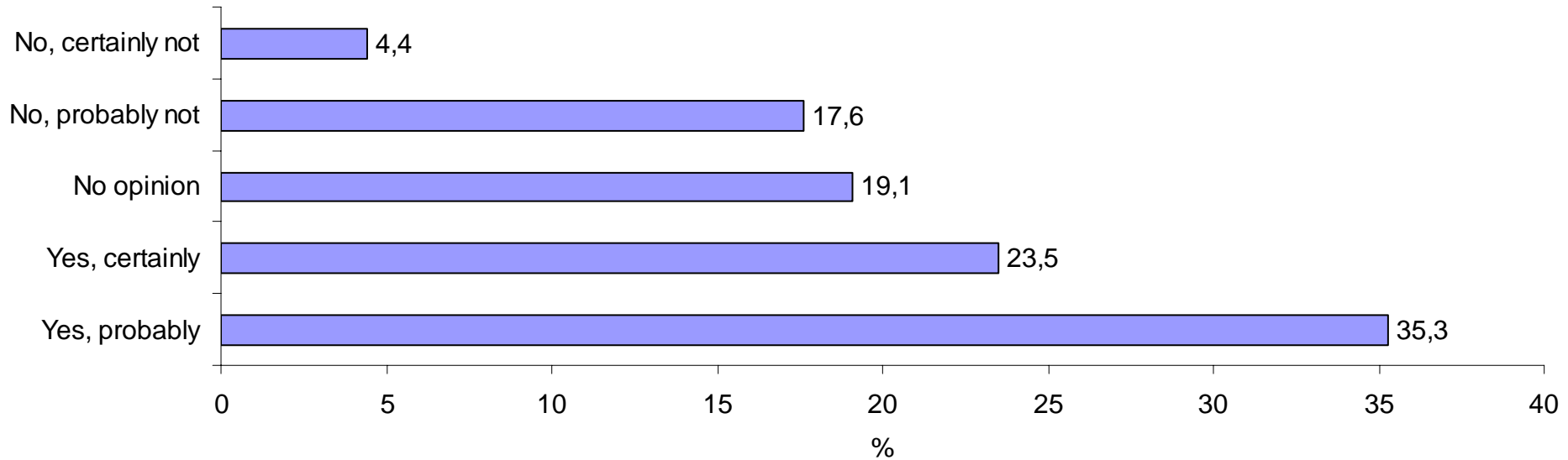
No Opinion

20 % of views from Member States

YES

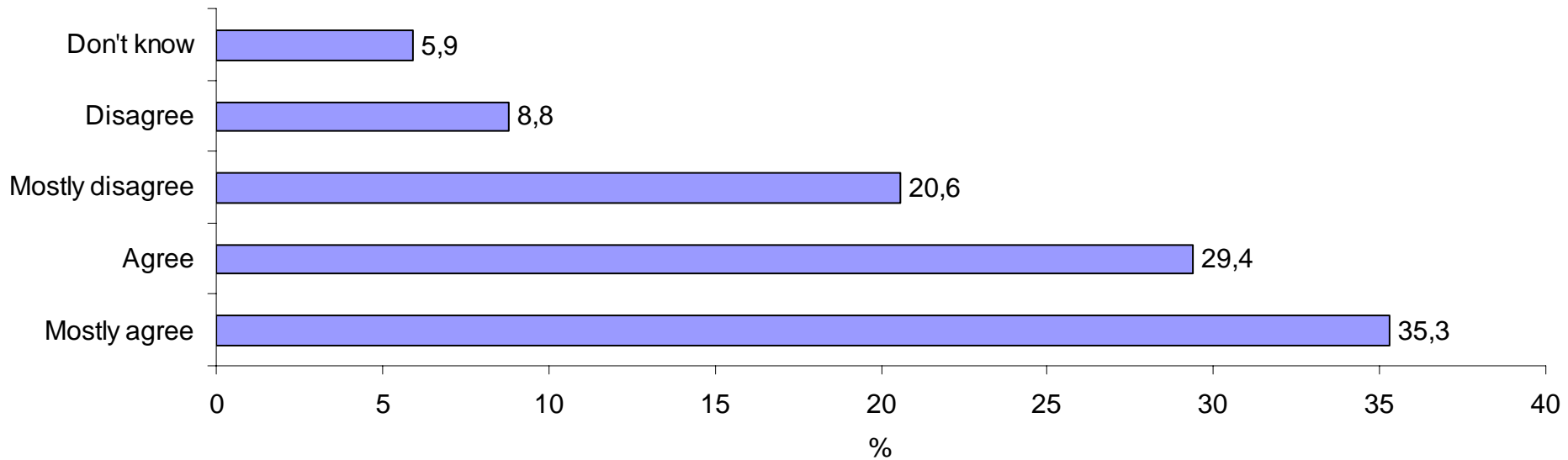
40 % of views from Member States
90% of views from manufacturers and their associations

Chemical risks to be assessed according to the ECHA guidance?



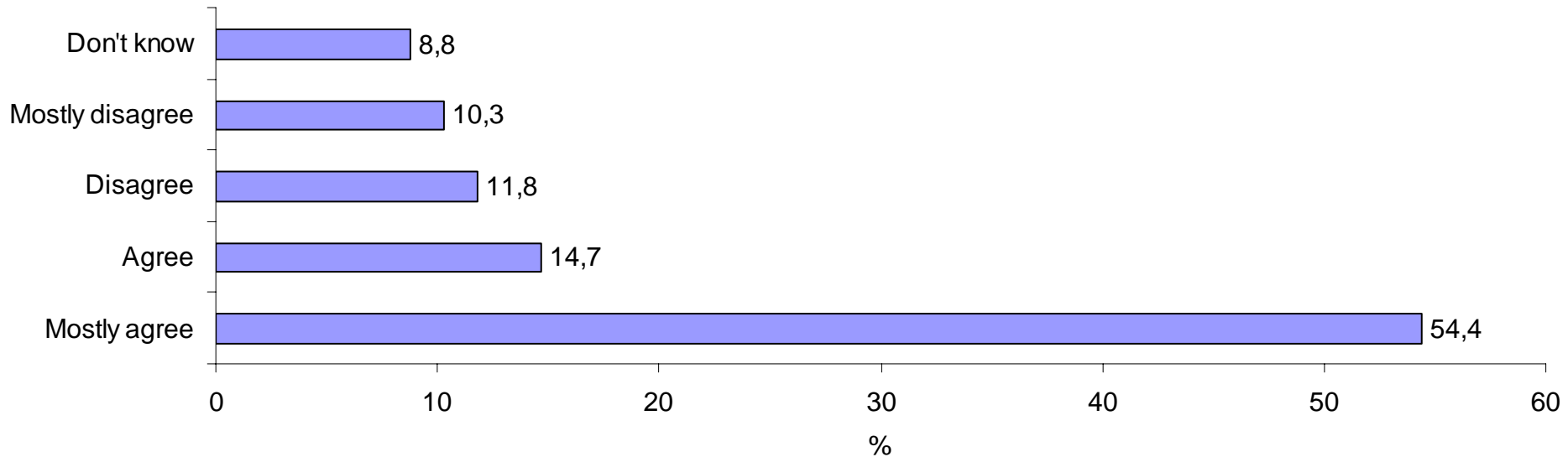
RAGs should be used only for non-chemical risks

Several injury scenarios in every risk assessment ?



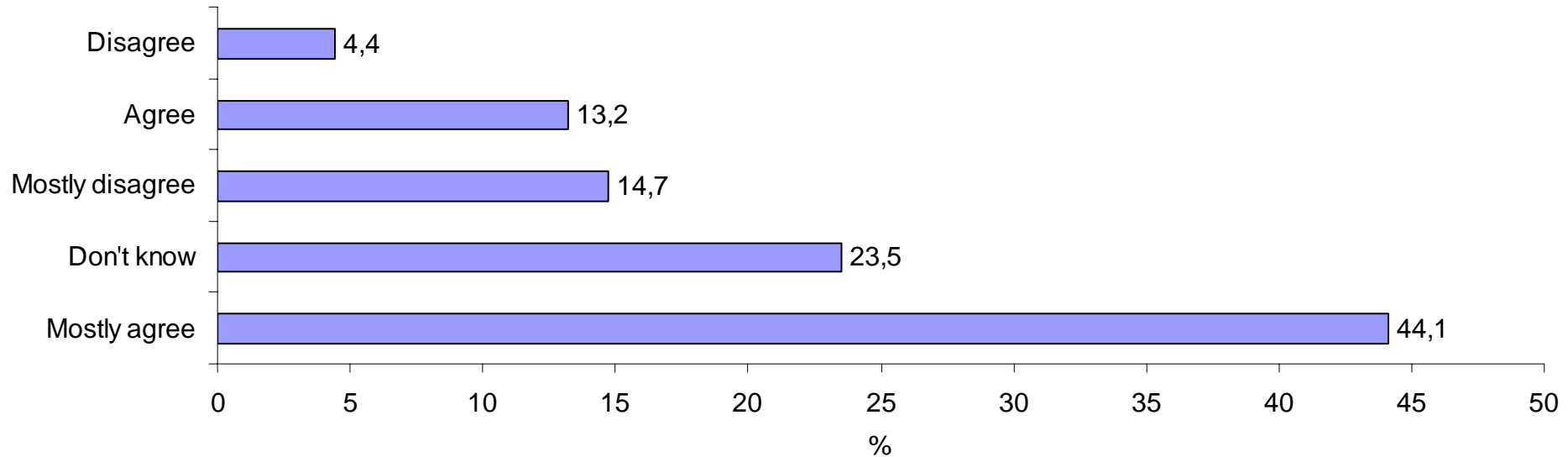
- Focus on the most severe scenarios with the highest likelihood
- When the highest risk can easily be identified, other scenarios are not necessary

Classification for the severity of injuries?



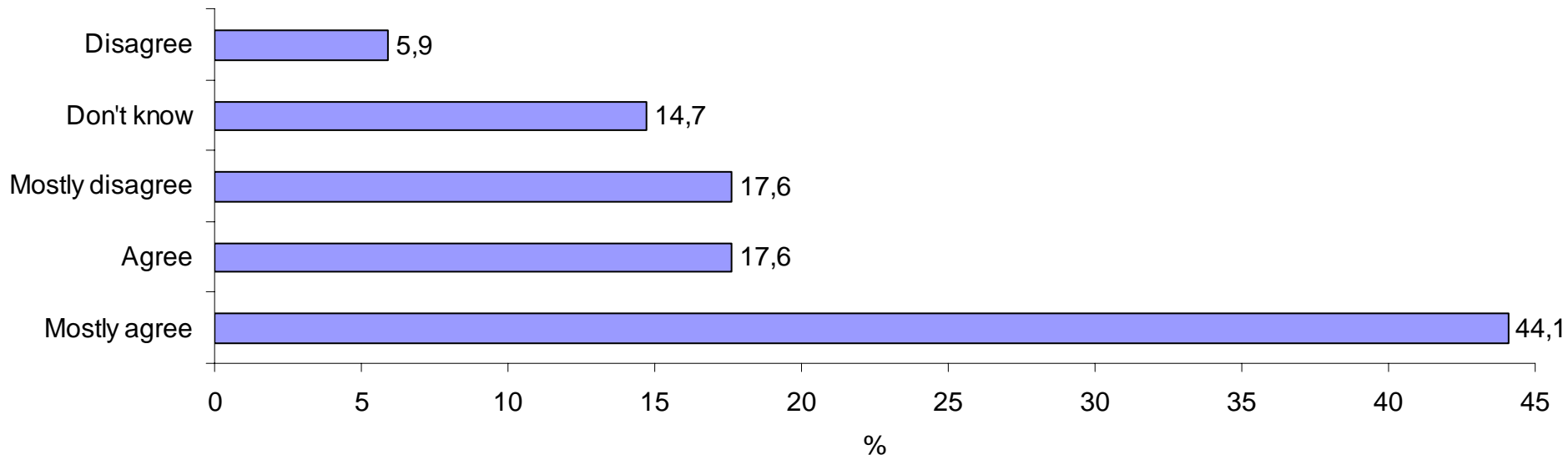
- The simple classification of an acute injury does not reflect its potential long-term severity
- The RAGs should refer to existing standards and guidelines

Classification for the probability?



- Is (too) subjective
- Difficult to apply in practice

Classification for the risk levels?



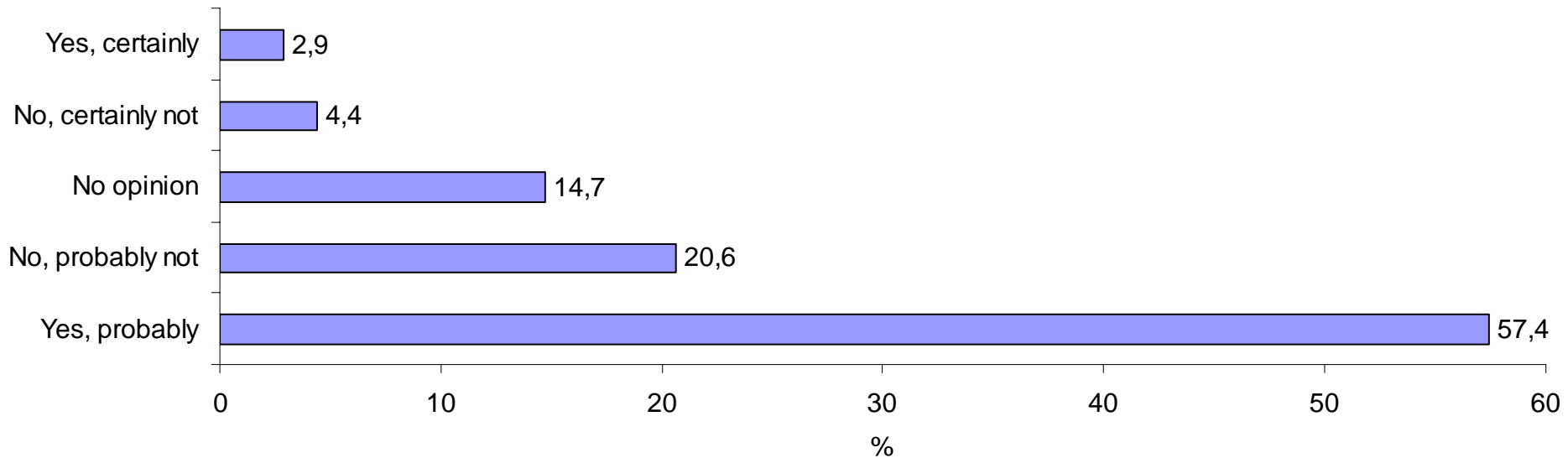
■ The proposed classification

- low, significant, high and serious risks (=1 low level, 3 high levels risk)

is more difficult to communicate than the previous one

- acceptable, low, moderate and serious risks

Are the Guidelines user-friendly and easy to apply?



- Yes, for trained risk assessors and experts
- The Commission should train the national CAs

☺ Some interesting statements ☺

It is reasonably foreseeable that consumers do not read the instructions.

Some never do, most have a look at them after meeting a problem.

Only old engineers and lawyers read all.

Products should be used safely without instructions for a basic use.

Dangerous misuses should be prevented by the design, not by instructions.

Conclusions

- 60-70% of respondents agreed or mostly agreed with proposed RA methodology
- Respondents stressed that
 - the RAGs should provide valuable assistance for RA
 - the RAGs should be improved
 - there are existing standards
- Not all respondents were aware about the context the guidelines are intended for

Next steps

- Comments are currently under evaluation by the Commission
- Inclusion into draft RAGs as far as possible
- Final discussion at a last IRAG WG meeting, planned for 9 December 2008

Please participate!



Thank you!