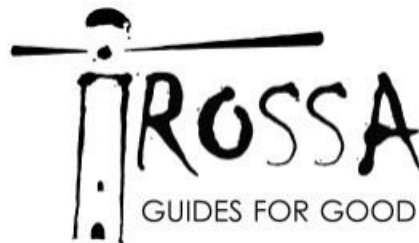


The view of the companies  
– opportunities and challenges

17<sup>th</sup> of April 2015, Charlotte Bergkvist



# The companies' views on the new requirements in the Biocide Regulation (EU)



# The companies' views on the new requirements in the Biocide Regulation (EU)

- An on-line survey with 10 questions
- 315 companies listed in the Swedish Chemicals Agency's Product Register
  - 8 companies - do not supply biocides
  - 2 companies - no email addresses
  - 12 companies - unsuccessfully delivery of email addresses
- 20% response rate (58 companies)
- Followed-up with phone calls

**Companies' views on some of the new requirements in the Biocide Regulation 528/2012**

According to the new requirements, anyone who wishes to place an active substance, as such or in a biocidal product, on the market need to be included on ECHAs list (Article-95 list) as of 1 September 2015.

Also, an application for product authorisation needs to be submitted for those biocidal products that include approved active substances.

\*Obligatorisk

4. If you intend to submit would you regard the document? Choose one or several alternatives. Markera alla som gäller.

We have the comp  
 We will need exten  
 We already have e  
 Don't know

5. Which of the following ) Choose one or several alternatives. Markera alla som gäller.

#1 - Human hygiene  
 #2 - Disinfectants ar  
 #3 - Veterinary hygie  
 #4 - Food and feed a  
 #5 - Drinking water  
 #6 - Preservatives fo  
 #7 - Film preservative  
 #8 - Wood preservati  
 #9 - Fibre, leather, rut  
 #10 - Construction ma  
 #11 - Preservatives fo  
 #12 - Silticides  
 #13 - Working or cuttin  
 #14 - Rodenticides  
 #15 - Avicides  
 #16 - Molluscicides, ve  
 #17 - Piscicides  
 #18 - Insecticides, acar  
 #19 - Repellents and att  
 #20 - Control of other vs  
 #21 - Antifouling product  
 #22 - Embalming and ta  
 Don't know

1. Which of the following alternatives will you choose/have you chosen in fulfilling the requirements of Article-95? \* Choose one or several alternatives. Markera alla som gäller.

Application to be included on the Article-95 list by submitting a dossier of our own on the active substance  
 Application to be included on the Article-95 list by submitting a Letter of Access existing dossier for which all data protection periods have expired  
 Our supplier or someone else in the distribution chain is already on the Article-95 list  
 Our supplier or someone else in the distribution chain intends to submit an application to be included on the Article-95 list  
 The product is withdrawn  
 Don't know

2. If you intend to submit a dossier of your own, how would you regard the competence within the company in conducting such a document? Choose one or several alternatives. Markera alla som gäller.

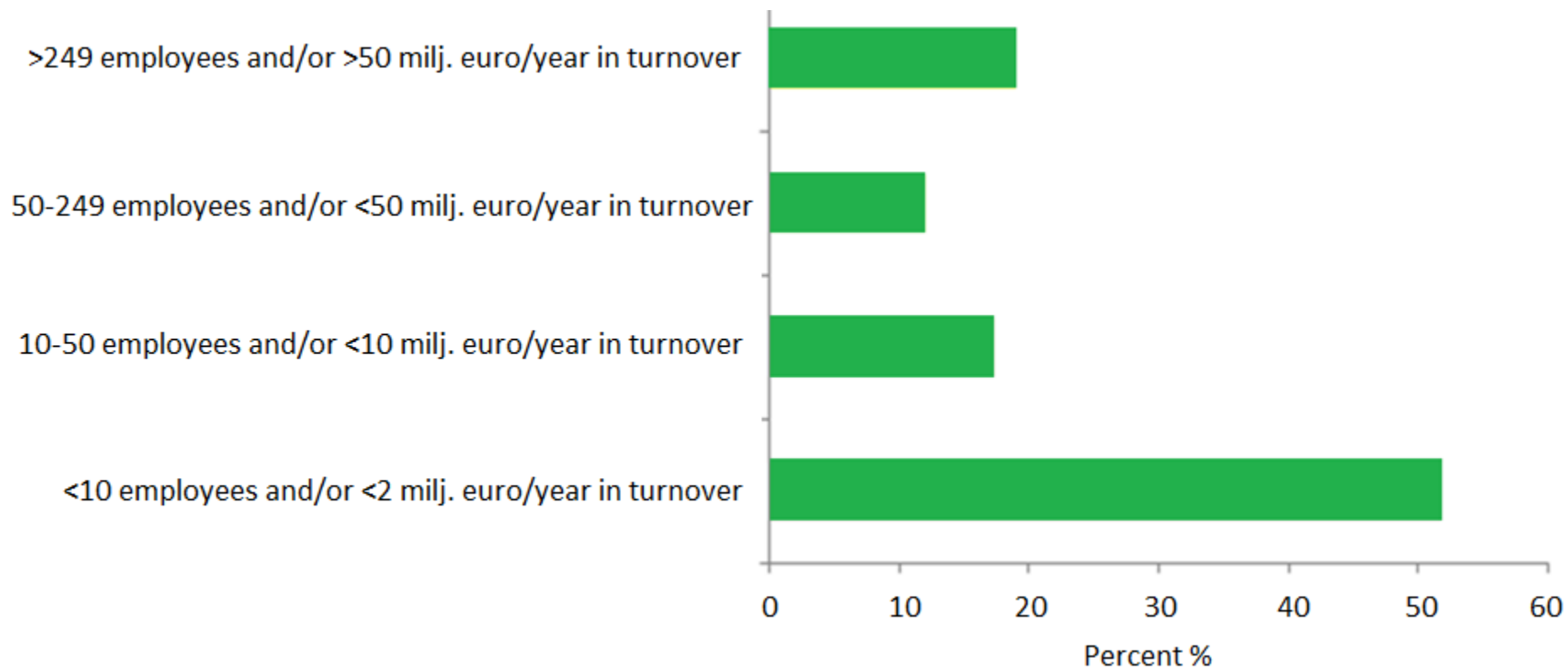
We have the competence and knowledge that we need internally  
 We will need external consultancy  
 We already have external consultancy  
 Don't know

3. Which role do you have/plan to have in regard to product authorisation of your biocidal products? \* Choose one or several alternatives. Markera alla som gäller.

We plan to apply for product authorisation ourselves  
 We plan to be a retailer of other's approved biocidal products  
 We will probably stop manufacturing/selling the product  
 Don't know

cs.google.com/forms/d/e/1FAIpQLSvYVGrFMcuu8n8GLD-ZfQoX01CkL3huljprstem


# COMPANY SIZE



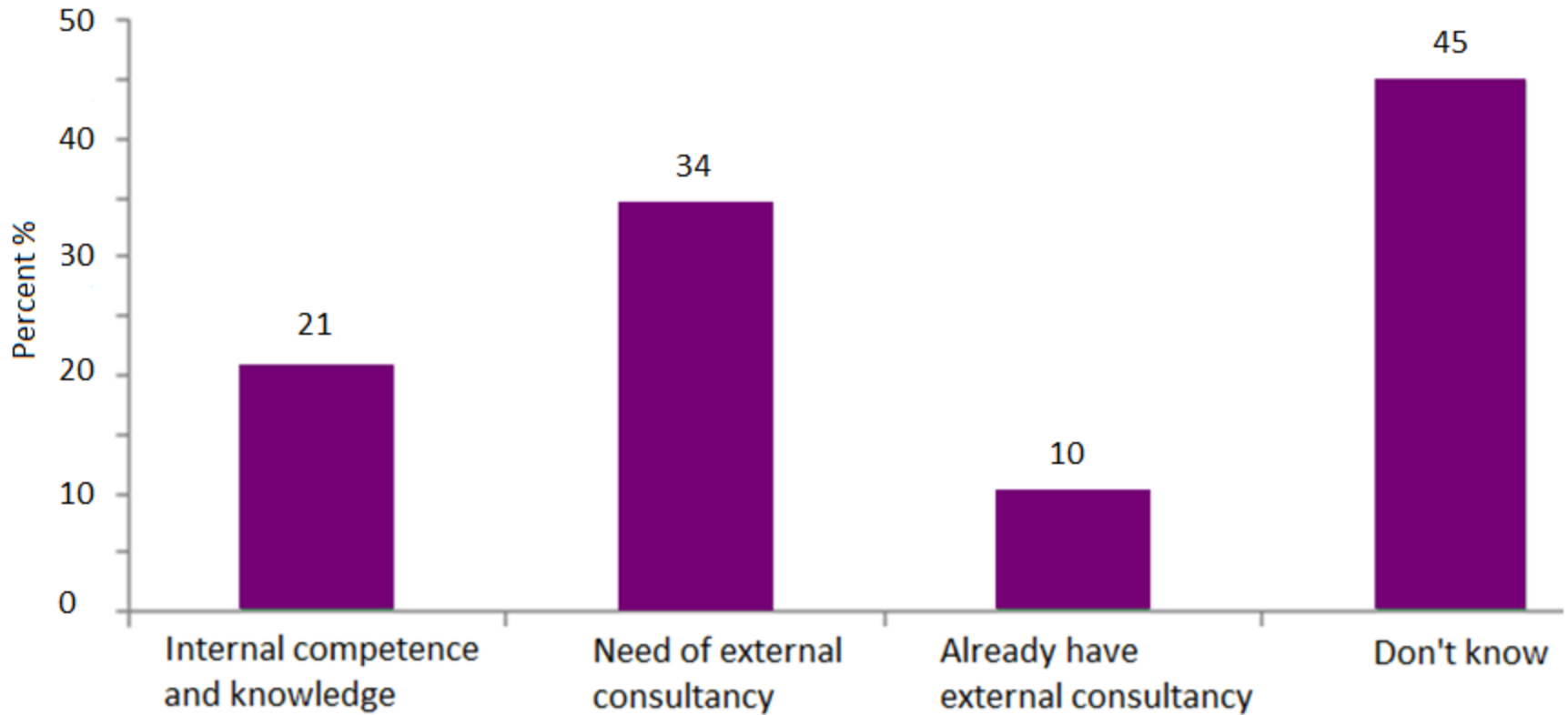
# TYPES OF BIOCIDAL PRODUCTS

Product type	Percent %
#2 Disinfectants and algaecides	47
#1 Human hygiene	22
#4 Food and feed area	21
#19 Repellents and attractants	17
#18 Insecticides, acaricides and products to control other arthropods	16
#11 Preservatives for liquid-cooling and processing systems	12
#3 Veterinary hygiene	9
#8 Wood preservatives	9
#6 Preservatives for products during storage	7
#14 Rodenticides	7
#5 Drinking water	5
#13 Working or cutting fluid preservatives	5
Don't know	5
#12 Slimicides	3
#7 Film preservatives	2
#9 Fibre, leather, rubber and polymerised materials preservatives	2
#10 Construction material preservatives	2
#15 Avicides	2
#16 Molluscicides, vermicides and products to control other invertebrates	2
#20 Control of other vertebrates	2
#21 Antifouling products	2
#17 Piscicides	0
#22 Embalming and taxidermist fluids	0

# Which of the following alternatives will you choose/have you chosen in fulfilling the requirements of Article-95?

- 
- 55 %** Our supplier or someone else in the distribution chain is already on the Article-95 list
  - 40 %** Our supplier or someone else in the distribution chain intends to submit an application to be included on the Article-95 list
  - 16 %** Application to be included on the Article-95 list by submitting a Letter of Access
  - 14 %** The product is withdrawn
  - 10 %** Don't know
  - 7 %** Application to be included on the Article-95 list by submitting a dossier of our own on the active substance
  - 3 %** Application to be included on the Article-95 list by submitting a reference to an existing dossier for which all data protection periods have expired

If you intend to submit a dossier of your own, how would you regard the competence within the company in conducting such a document?

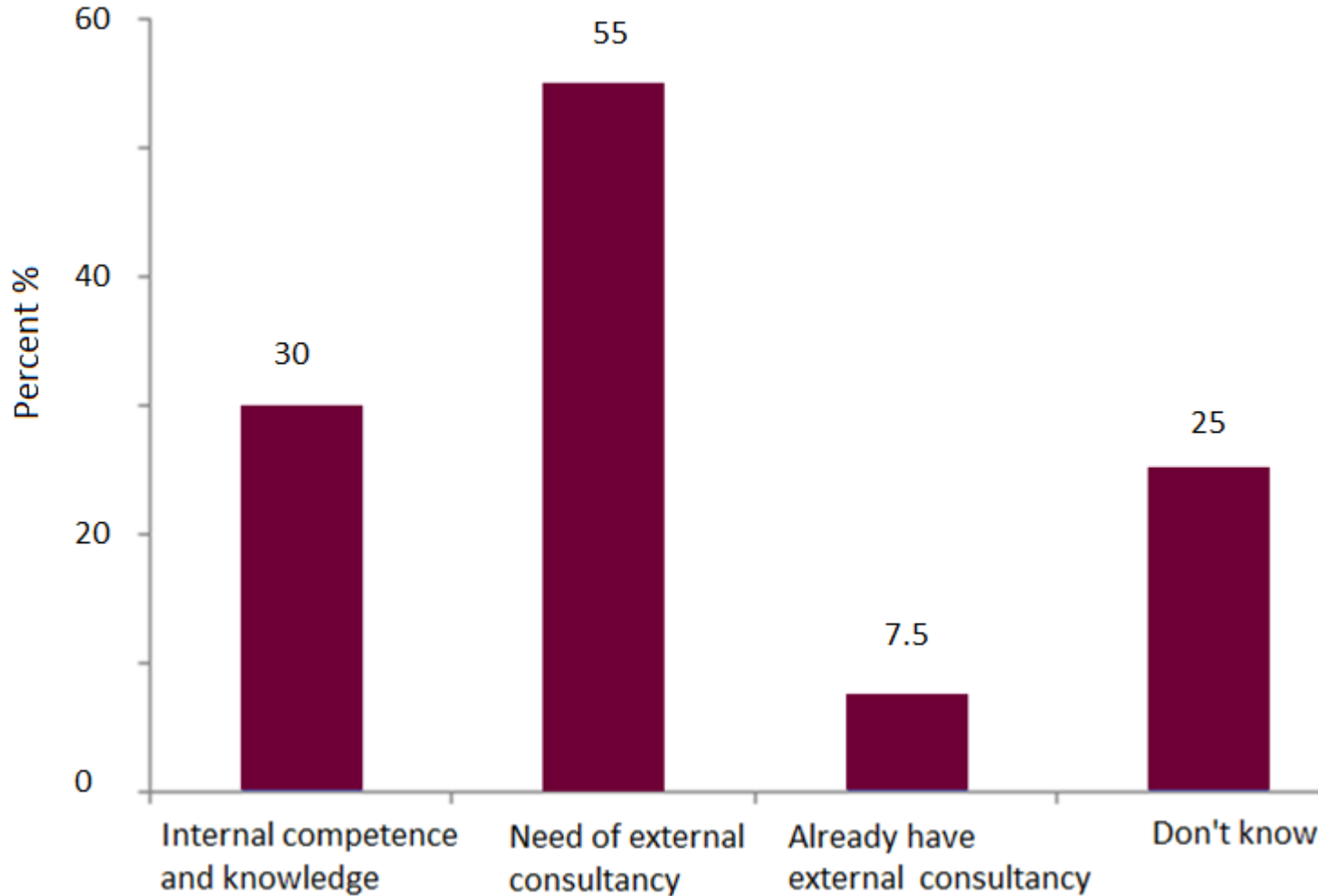


# Which role do you have/plan to have in regard to product authorisation of your biocidal products?

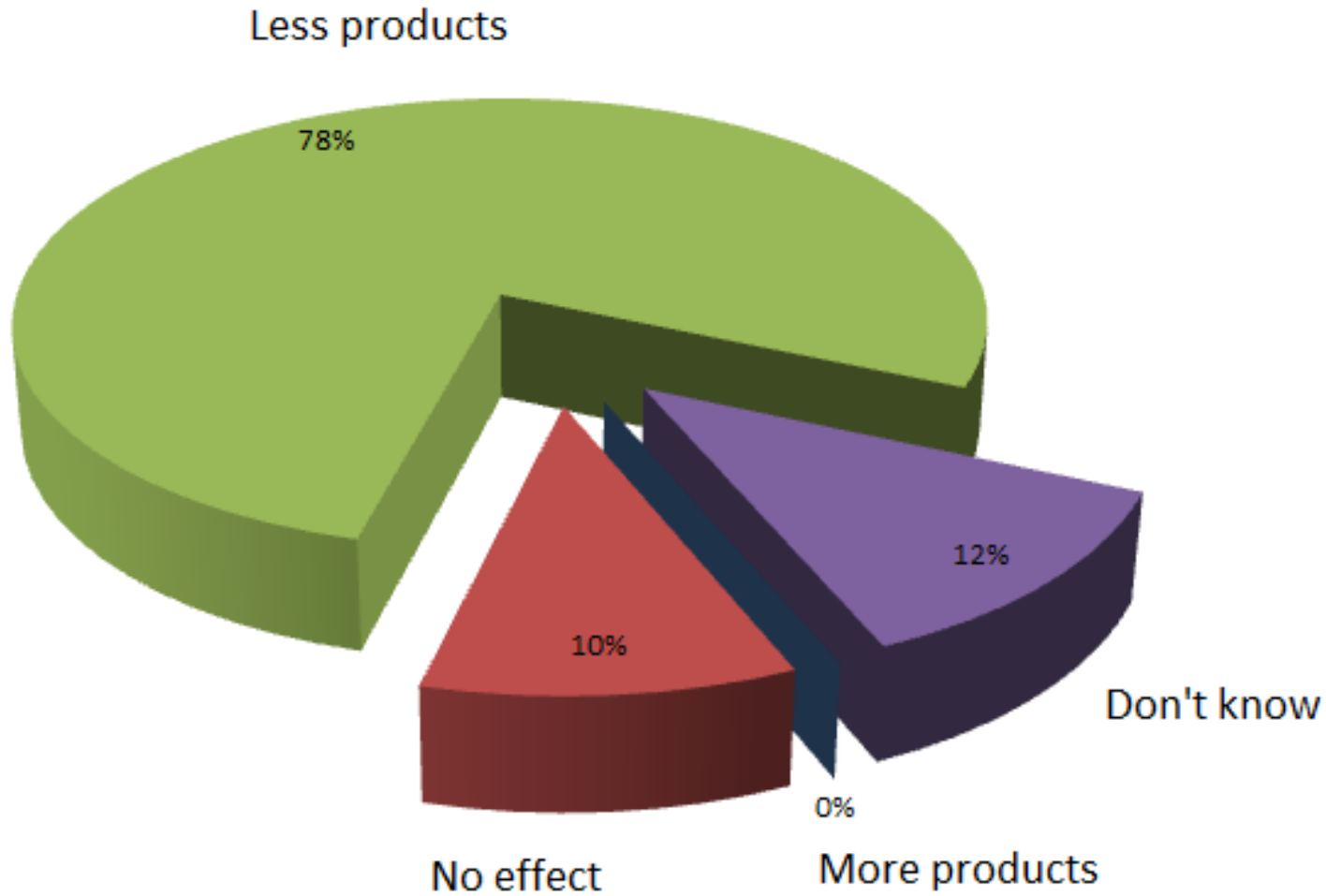




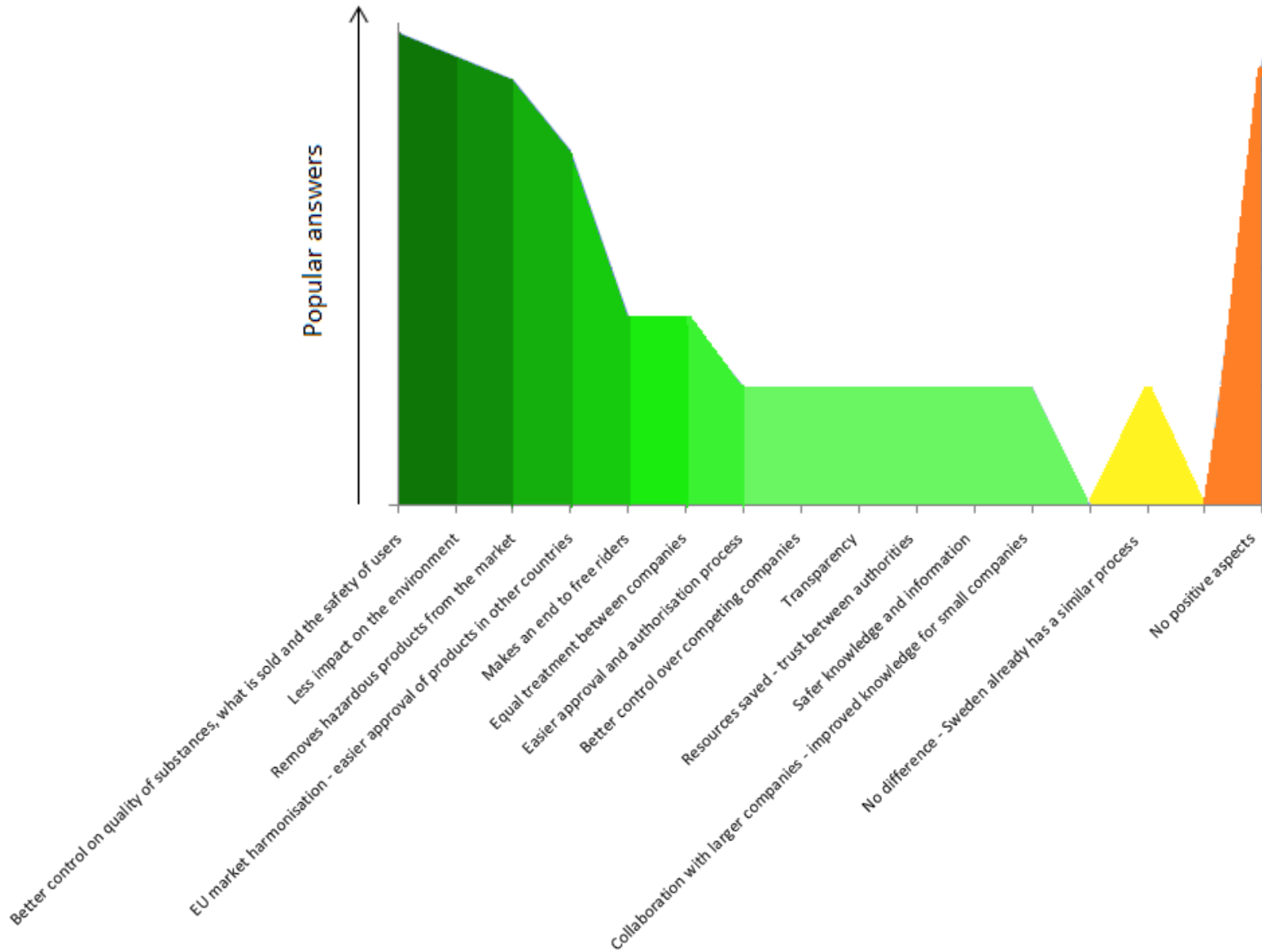
If you intend to submit an application for product authorisation yourselves, how would you regard the competence within the company in conducting such a document?



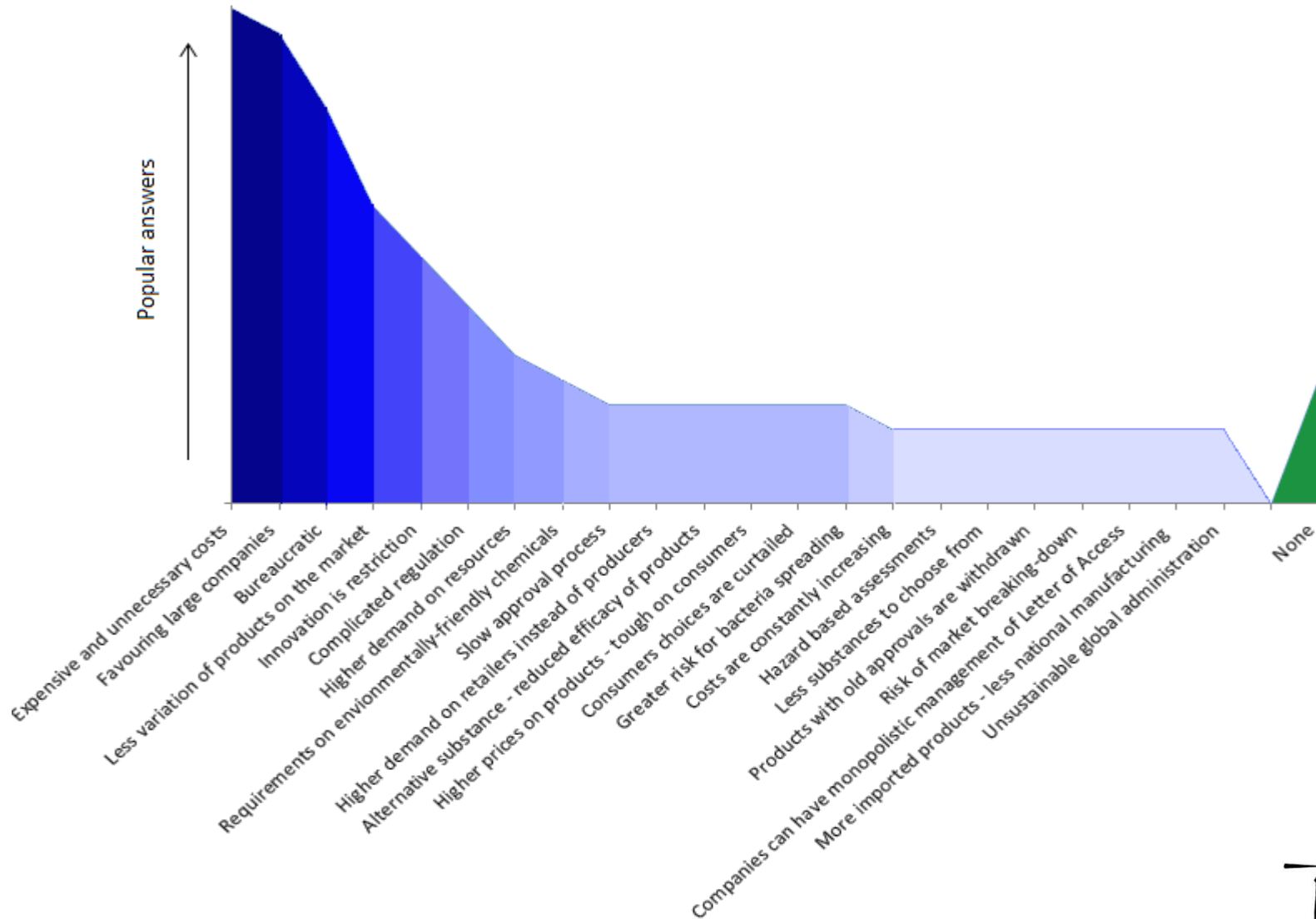
In what way do you think that the new requirements in the regulation will influence the market?



# What are the positive aspects of the new requirements in the regulation?



# What are the negative aspects of the new requirements in the regulation?



## ADDITIONAL COMMENTS

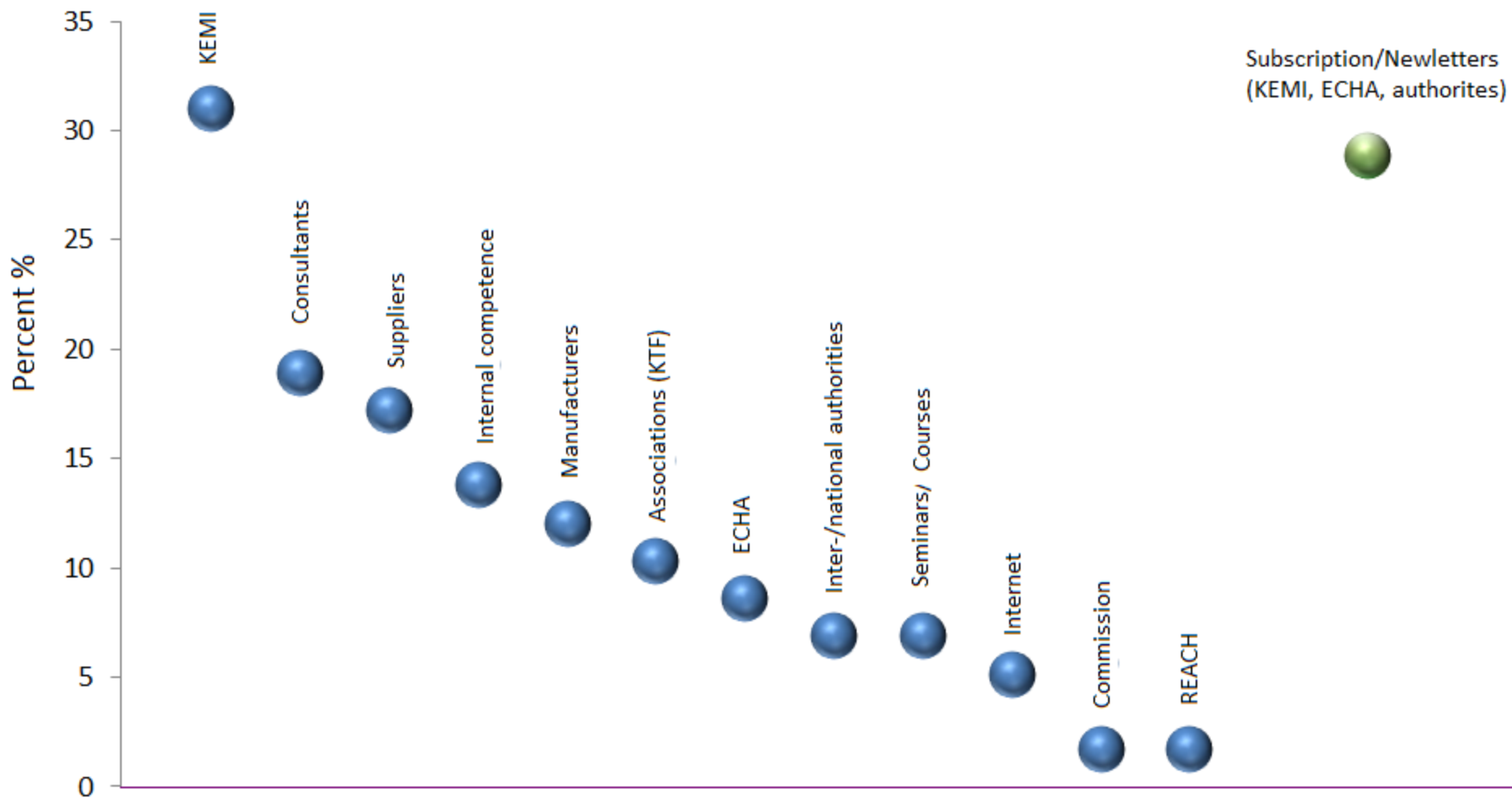
- *The procedure for applying to article-95 is difficult to understand*
- *The regulatory requirements for low-risk biocides should be reduced so that unnecessary costs and animal tests are avoided*
- *Both authorities and companies are far behind other countries (i.e. Germany, Netherlands, England, Belgium) in not fully taking advantage of the potential of regulations (incl. REACH)*
- *The regulation will lead to a generic market where the smaller companies have to choose among substances registered by larger companies – favouring large companies*
- *The regulatory demands should be on the manufacturer and also on the Swedish Chemicals Agency, and not the reseller*

## ADDITIONAL COMMENTS

The companies would like the Swedish Chemicals Agency to:

- *guide the companies through the regulation including IUCLID, R4BP and fees, as well as to make the submission process easier*
- *collaborate with trade and industry so that the Swedish companies can compete with the international companies*
- *make the information about the regulatory process clearer and easy-to-read instead of having to hire a consultant for the purpose of interpreting the regulation*
- *update manufacturers on any changes in the regulations by sending out the information*
- *give manufacturers of authorised biocidal products access to a quicker way of contact*

# How do you keep yourself updated on new regulations and requirements of biocides?



KEMI = The Swedish Chemicals Agency

KTF = The Swedish Cosmetics, Detergents and Toiletries Association

ECHA = The European Chemicals Agency

REACH = Regulation concerning Evaluation, Authorisation and Restriction of Chemicals

**THANK YOU!**

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