How to do a successful Union authorisation application

Biocides Stakeholders' Day

26 September 2017

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Overview

1. How did the process go so far
2. What is important for successful applications
3. Where are we heading to

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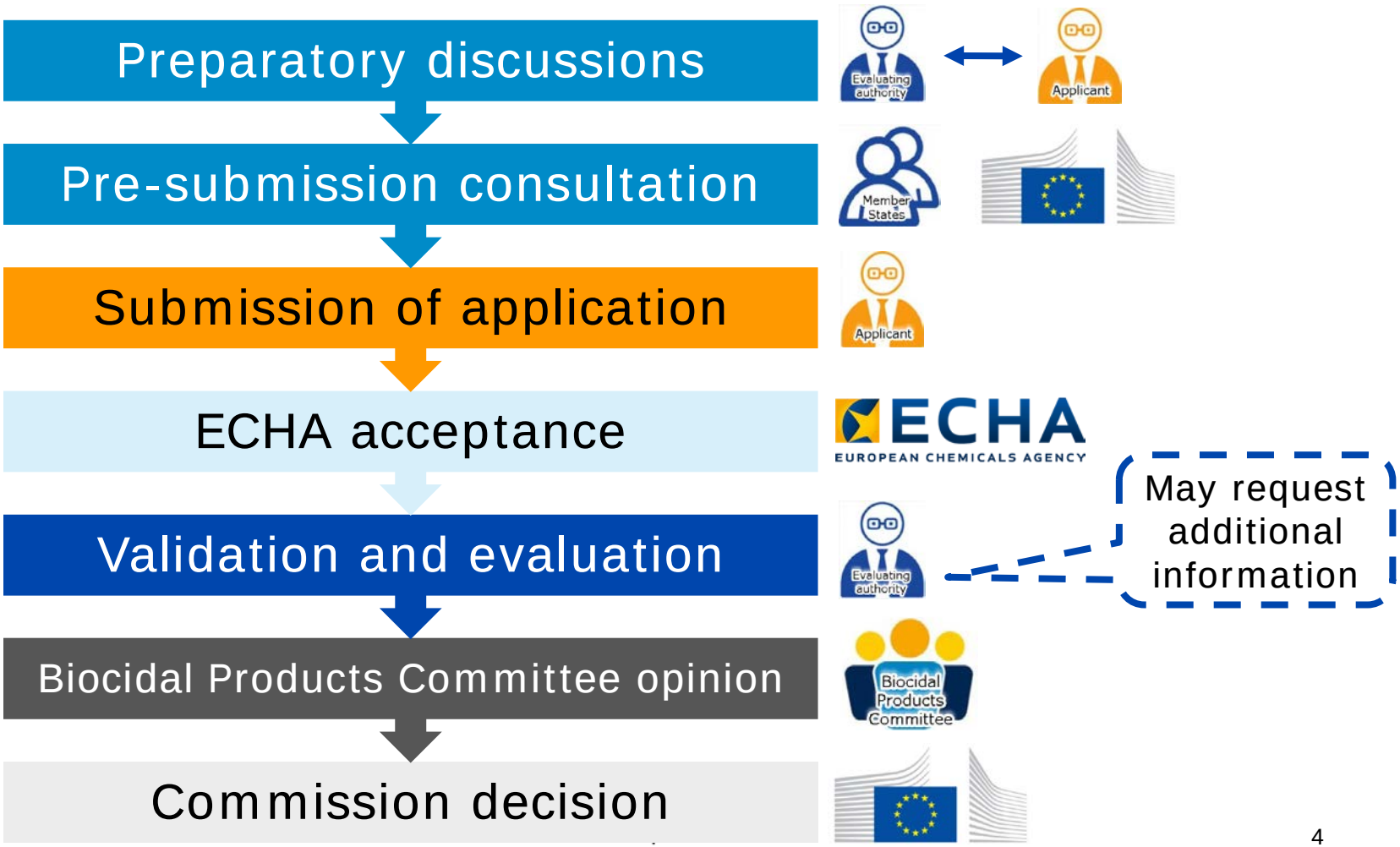
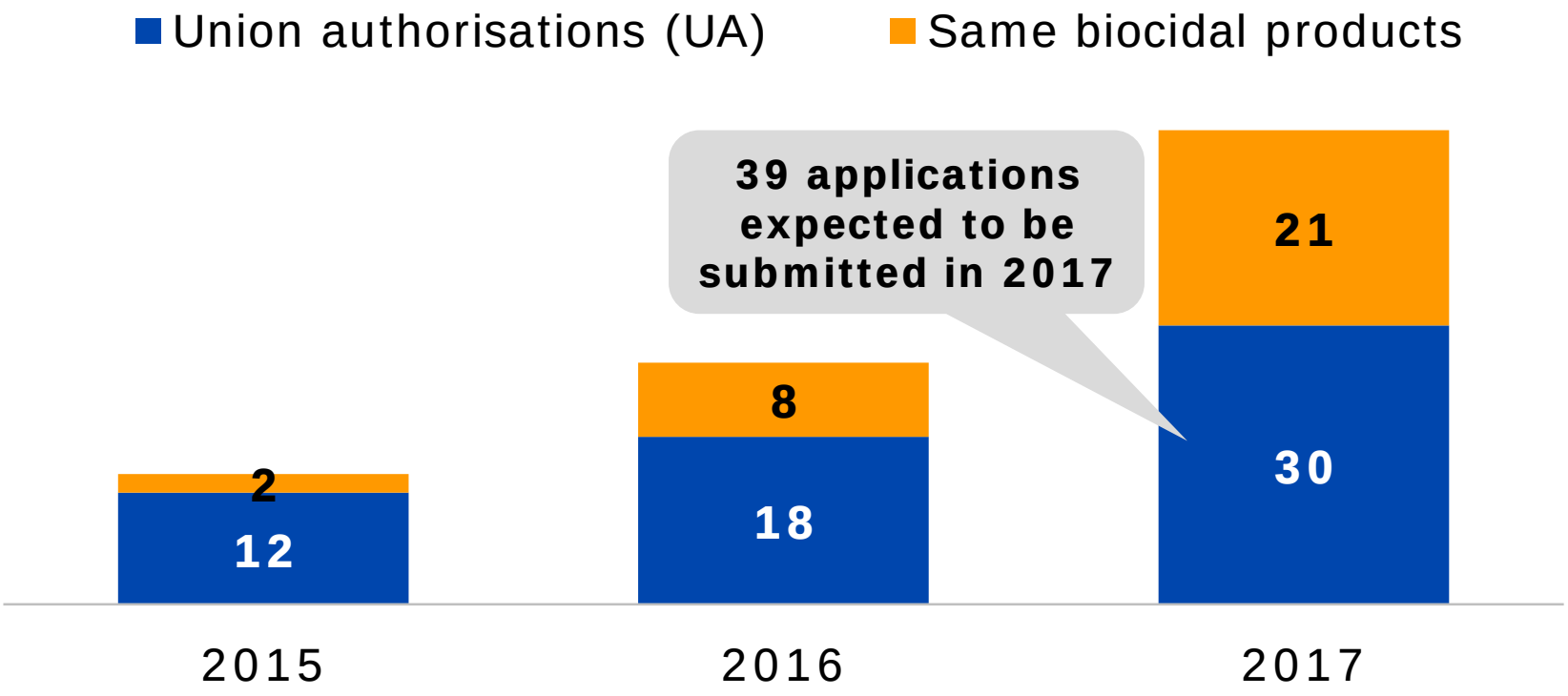
Overall timeline: at least 2.5 years

Steps and actors in the process



Applications in the ECHA's pipeline



Update 18 September 2017

- About 90% product families
- Disinfectants (>70%), insecticides and preservatives

How did the process go so far (1/2)

Pre-submission

- 92% of UA applications with pre-submission
- 95% of positive outcomes
- 93% of outcomes with additional comments

Submission and checks by ECHA

- Overall, smooth submissions of applications
- In general, applications passed ECHA checks

How did the process go so far (2/2)

Validation and evaluation

- Effective cooperation with evaluating authorities
- 3 evaluations submitted to ECHA

BPC opinion

- 3 working group discussions so far
- 2 BPC opinions foreseen in December 2017

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Tips for pre-submission

- **Discuss** technical or methodological questions with your evaluating authority
- **Describe** clearly the uses in the Summary of Product Characteristics (SPC)
- **Justify** that co-formulants do not contribute to efficacy
- **Make** a pre-submission at the latest 6 months before the intended date of submission

Requirements for pre-submission

Mandatory

☑ SPC (English; .xml)

☑ Supporting document

Recommended

☑ Agreement signed by the evaluating authority

R4BP 3

Where relevant

☑ Overview of the family

https://echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents

Tips for Union authorisation applications

- **Discuss** with the evaluating authority to prepare a good quality dossier
- Have your **SME status** verified before submission
- **Apply** as early as possible before the deadline
- **Monitor** your case in R4BP 3
- Pay attention to **deadlines**
  - Payment of the fees
  - Resubmission of requested information

Requirements for UA applications

Mandatory

- ☑ IUCLID dossier
- ☑ SPC (English; .xml)
- ☑ Agreement signed by the evaluating authority
- ☑ Outcome of pre-submission consultation or rationale about similar conditions of use

Where relevant

- ☑ Overview of the family
- ☑ Supporting document for provisional authorisation

R4BP 3

https://echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents

Tips for same product

- New possibilities after amendments to Same Products Regulation
- Only administrative changes accepted

Examples of administrative changes relevant for same product applications

- Change of the name of the product
- Addition of trade names
- Different authorisation holder

Requirements for same product

Mandatory

☑ Reference case number
☑ SPC (English; .xml)
☑ Supporting document

Where relevant

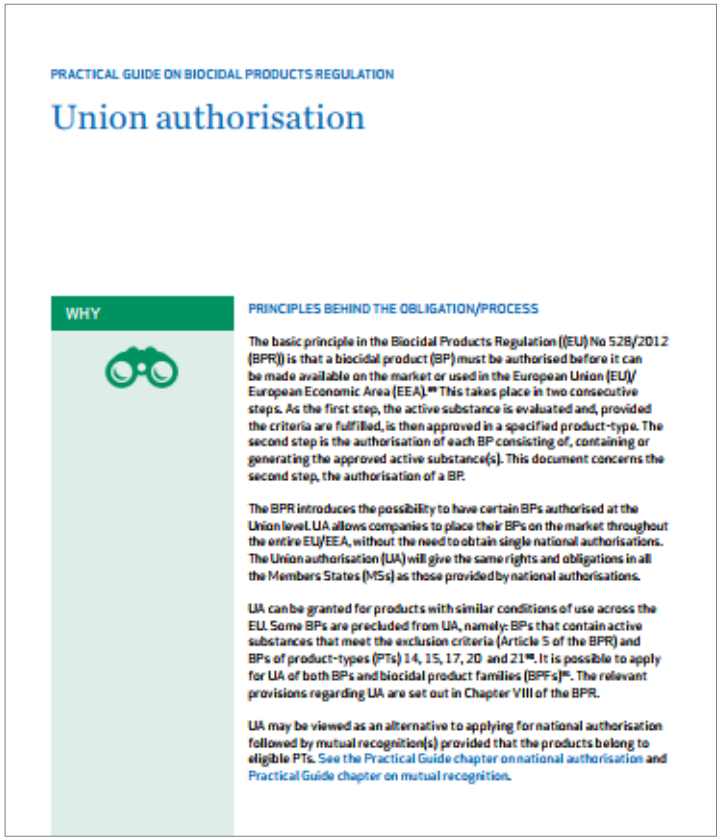
☑ Letter of access

Ensure consistency between supporting document and SPC

R4BP 3

https://echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents

Union authorisation



PRACTICAL GUIDE ON BIOCIDAL PRODUCTS REGULATION

Union authorisation

WHY

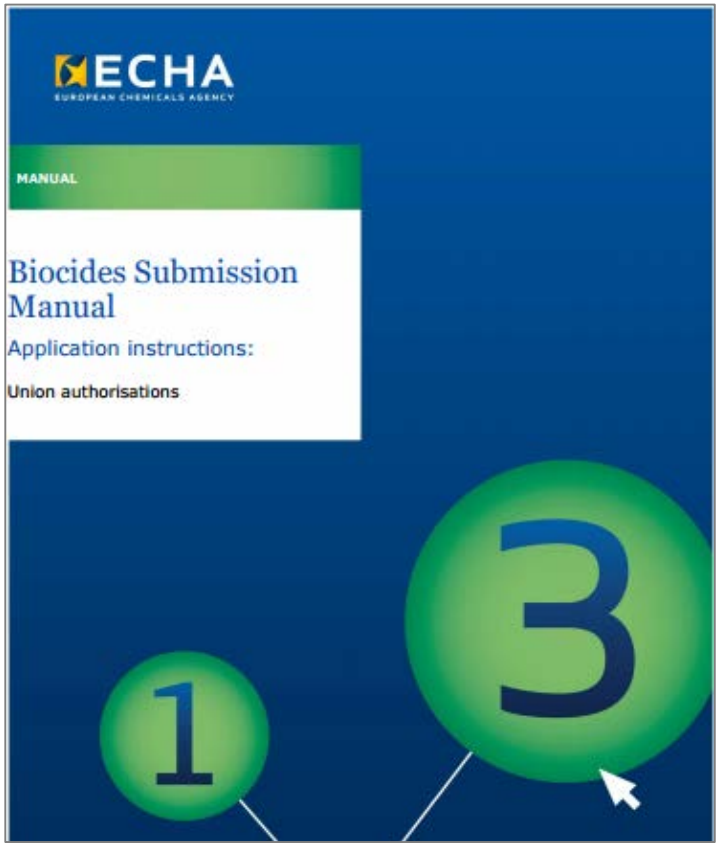
PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The basic principle in the Biocidal Products Regulation ((EU) No 528/2012 (BPR)) is that a biocidal product (BP) must be authorised before it can be made available on the market or used in the European Union (EU)/ European Economic Area (EEA).[1] This takes place in two consecutive steps. As the first step, the active substance is evaluated and, provided the criteria are fulfilled, is then approved in a specified product-type. The second step is the authorisation of each BP consisting of, containing or generating the approved active substance(s). This document concerns the second step, the authorisation of a BP.

The BPR introduces the possibility to have certain BPs authorised at the Union level. UA allows companies to place their BPs on the market throughout the entire EU/EEA, without the need to obtain single national authorisations. The Union authorisation (UA) will give the same rights and obligations in all the Members States (MSs) as those provided by national authorisations.

UA can be granted for products with similar conditions of use across the EU. Some BPs are precluded from UA, namely: BPs that contain active substances that meet the exclusion criteria (Article 5 of the BPR) and BPs of product-types (PTs) 14, 15, 17, 20 and 21[2]. It is possible to apply for UA of both BPs and biocidal product families (BPFs)[3]. The relevant provisions regarding UA are set out in Chapter VIII of the BPR.

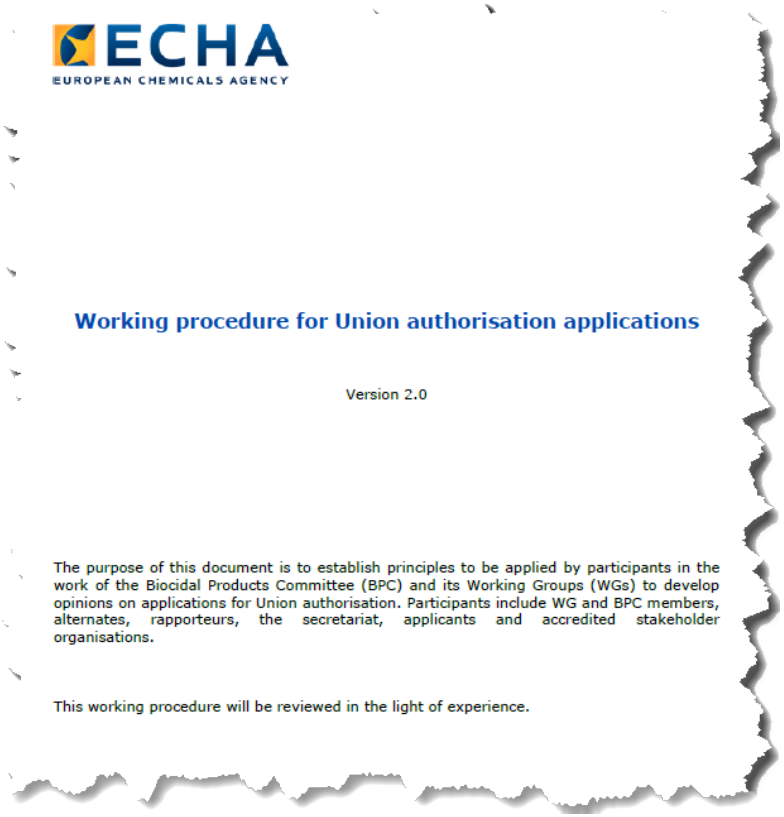
UA may be viewed as an alternative to applying for national authorisation followed by mutual recognition(s) provided that the products belong to eligible PTs. See the Practical Guide chapter on national authorisation and Practical Guide chapter on mutual recognition.



https://echa.europa.eu/practical-guides/bpr-practical-guides

https://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals

ECHA procedures



ECHA
EUROPEAN CHEMICALS AGENCY

Working procedure for Union authorisation applications

Version 2.0

The purpose of this document is to establish principles to be applied by participants in the work of the Biocidal Products Committee (BPC) and its Working Groups (WGs) to develop opinions on applications for Union authorisation. Participants include WG and BPC members, alternates, rapporteurs, the secretariat, applicants and accredited stakeholder organisations.

This working procedure will be reviewed in the light of experience.

Timelines for the peer review of Union authorisations applications

As indicated in section 3 of the Working procedure for Union authorisation applications, the dates given below are the actual binding dates for each step. The first column 'Step Ref' refers to the steps given in the working procedure.

Step Ref	Step description	Actors	Process flow 17			Process flow 18			Process flow 19		
			Days	Start	End	Days	Start	End	Days	Start	End
1	Submission	eCA	70	17/10/16	26/12/16	70	09/01/17	20/03/17	70	29/03/17	07/06/17
2	Accordance check	ECHA	21	26/12/16	16/01/17	21	20/03/17	10/04/17	21	07/06/17	28/06/17
5	Commenting phase	ECHA/ MSCAs/Applicant	35	16/01/17	20/02/17	28	10/04/17	08/05/17	28	28/06/17	26/07/17
6	Trilateral discussions and response to comments table (RCOM)	eCA/MSCA, Applicant	21	20/02/17	13/03/17	21	08/05/17	29/05/17	21	26/07/17	16/08/17
12	Disagreement in closing a point	MSCAs	7	13/03/17	20/03/17	7	29/05/17	05/06/17	7	16/08/17	23/08/17
13	Discussion table	ECHA, eCA	11	13/03/17	24/03/17	11	29/05/17	09/06/17	9	16/08/17	25/08/17
16	WG	ECHA, MSCA, ASOs, Applicant	4	03/04/17 *	07/04/17	4	19/06/17 *	23/06/17	4	04/09/17	08/09/17
23	WG minutes in the form of discussion table	ECHA	14	07/04/17	21/04/17	14	23/06/17	07/07/17	14	08/09/17	22/09/17
24	Commenting WG minutes	MSCAs	21	21/04/17	12/05/17	21	07/07/17	28/07/17	21	22/09/17	13/10/17
30	SECR-eCA dialogue	eCA, ECHA	45	07/04/17	22/05/17	66	23/06/17	28/08/17	59	08/09/17	06/11/17
31	Submitting the updated PAR and draft SPC	eCA	45	07/04/17	22/05/17	66	23/06/17	28/08/17	59	08/09/17	06/11/17
32	Checking updated PAR	MSCAs	14	22/05/17	05/06/17	14	28/08/17	11/09/17	14	06/11/17	20/11/17
33	Draft BPC opinion	ECHA, eCA	14	22/05/17	05/06/17	14	28/08/17	11/09/17	14	06/11/17	20/11/17
36	Commenting PAR and opinion	MSCAs, ECHA	14	05/06/17	19/06/17	14	11/09/17	25/09/17	14	20/11/17	04/12/17
37	Open issues	ECHA	2	19/06/17	21/06/17	2	25/09/17	27/09/17	2	04/12/17	06/12/17
38	BPC	ECHA, MSCAs, applicant, ASOs	4	26/06/17	30/06/17	4	02/10/17	06/10/17	4	11/12/17	15/12/17
39	Finalisation of the open issues document	ECHA	14	30/06/17	14/07/17	10	06/10/17	16/10/17	10	15/12/17	25/12/17
40	Opinion finalization	ECHA	14	30/06/17	14/07/17	10	06/10/17	16/10/17	10	15/12/17	25/12/17

https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

SPC

		SPC FIELD						
Sentence code	Sentence	4.1 Where relevant, an exact description of the authorised use	4.1 Field(s) of use	4.1 Application rate(s) and frequency	4.1 Pack sizes and packaging material	Instructions for use	Risk mitigation measures	Particulars of likely or indirect effects, aid instructions a emergency measur protect the environment
N-19	If discharging to municipal sewage treatment plant, provide the required onsite wastewater removal efficiency of [XX (%)]							
N-20	Freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.					X	X	
N-21	Hazardous to bees. Do not apply close to blooming plants/cultures.					X		
N-22	Do not apply near bodies of surface water or in the area of water protection zones. [where relevant provide for appropriate distance stipulations]					X	X	

https://echa.europa.eu/support/dossier-submission-tools/spc-editor

Linguistic review of the translations of the summary of product characteristics (SPC) for Union Authorisation applications

https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

R4BP 3.9

- New functionalities for Union authorisation
  - Grouped administrative changes
  - Notification of unexpected or adverse effects

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Outlook to 2018

First Union authorisations granted

First same product authorisations granted

18 BPC opinions adopted

Fine-tuning the process in light of experience

Conclusions

- Making the process as effective as possible
  - More templates and procedures available
  - More experience acquired by all the actors
  - Cooperation as the key to success
  - Continuous improvement thanks to your feedback

Thank you

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