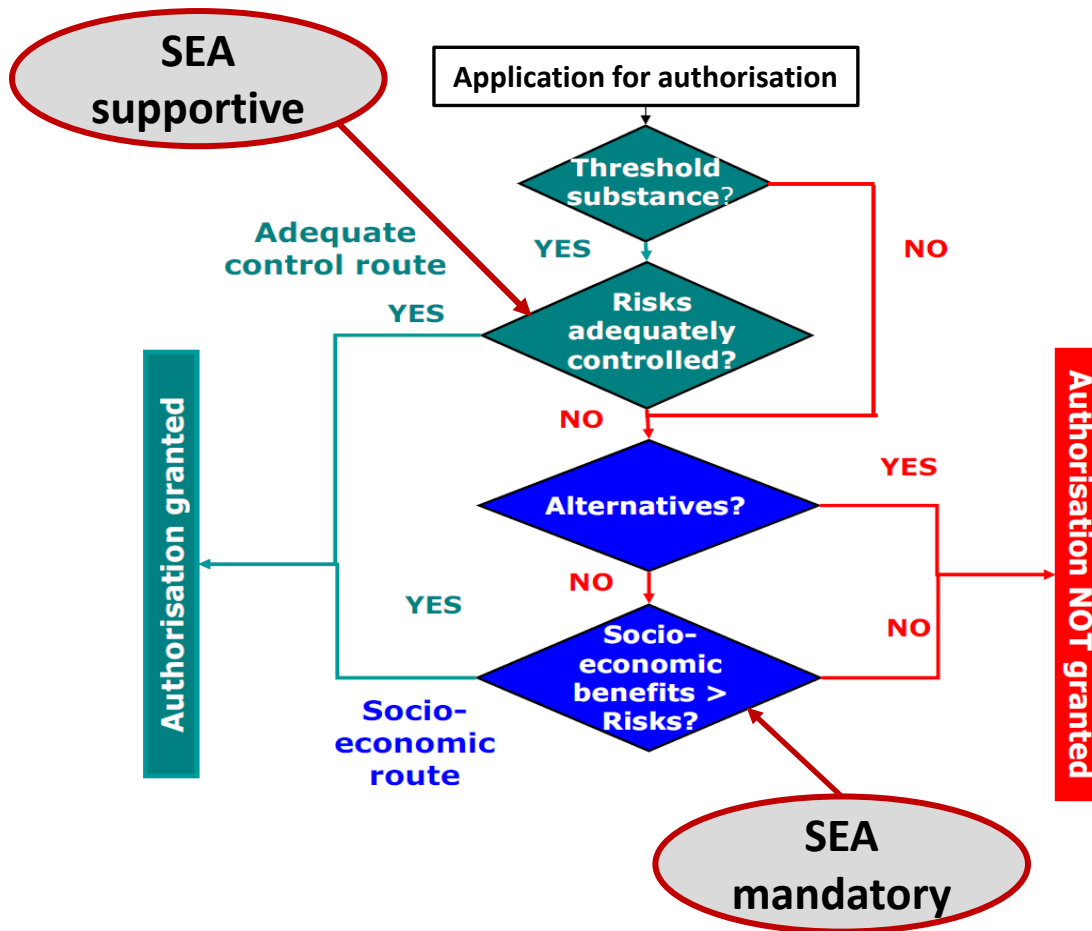


Application for Authorisation Socio-Economic Analysis (SEA)

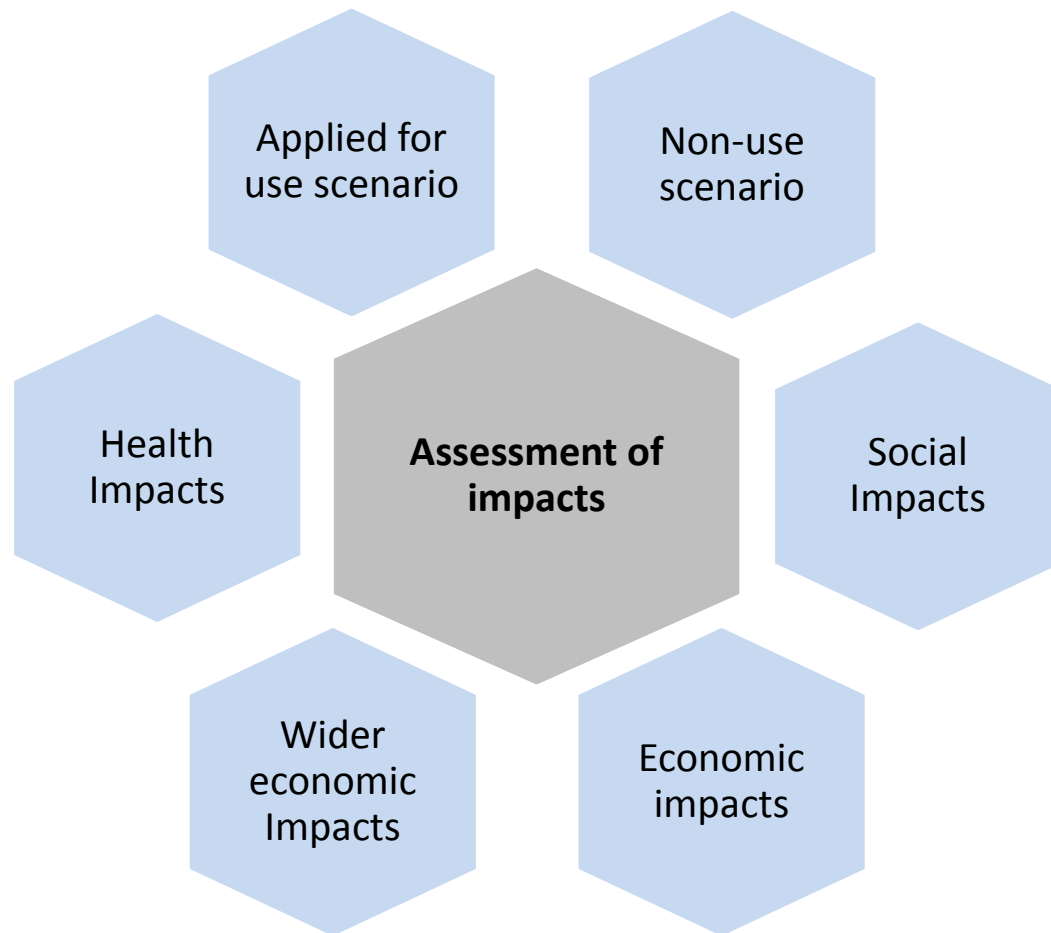
Dr. Reinhard Joas
BiPRO GmbH

Aim and background of the SEA

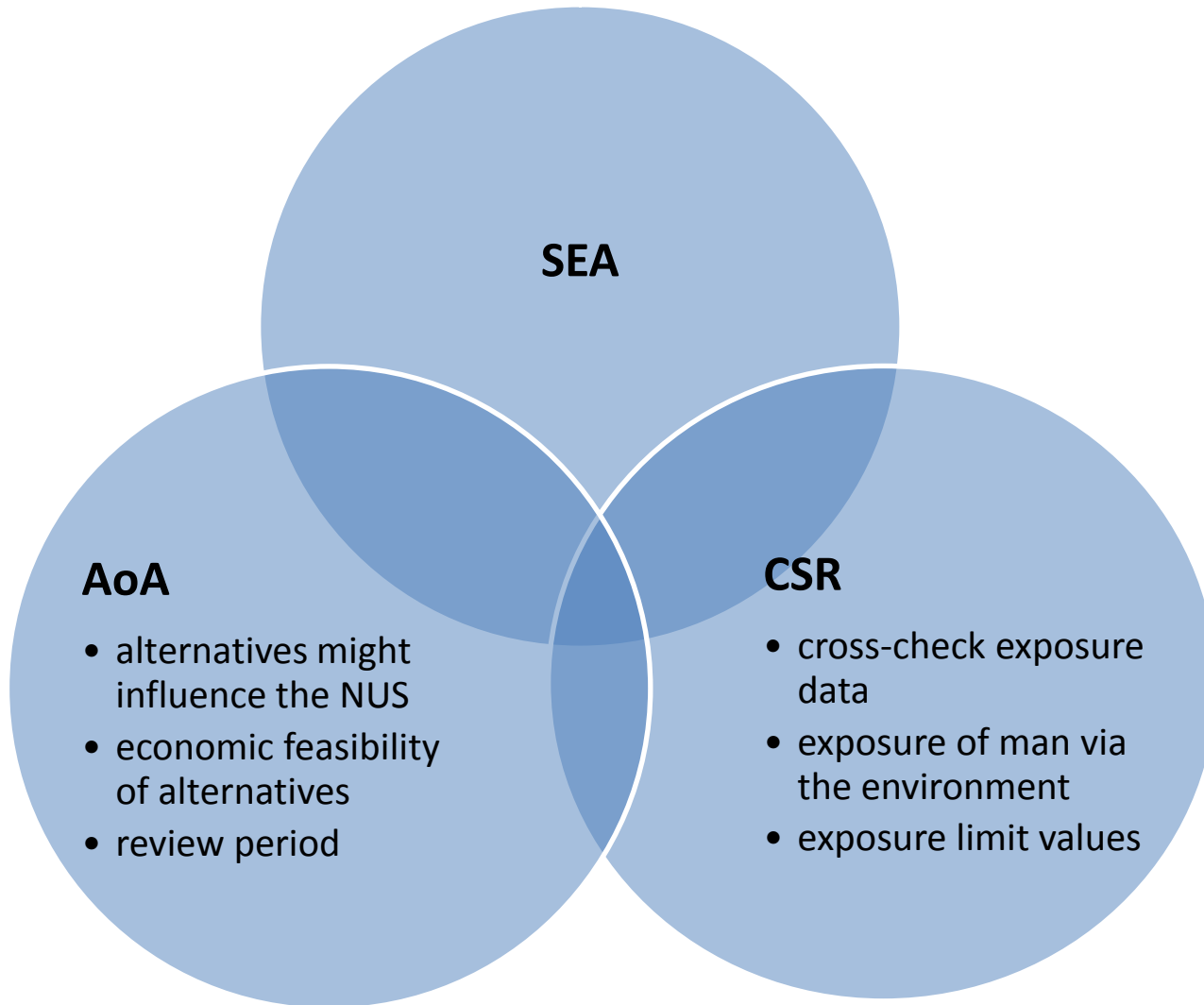
Background: Annex XIV substance that should be used after the „sunset date“



Elements of a SEA

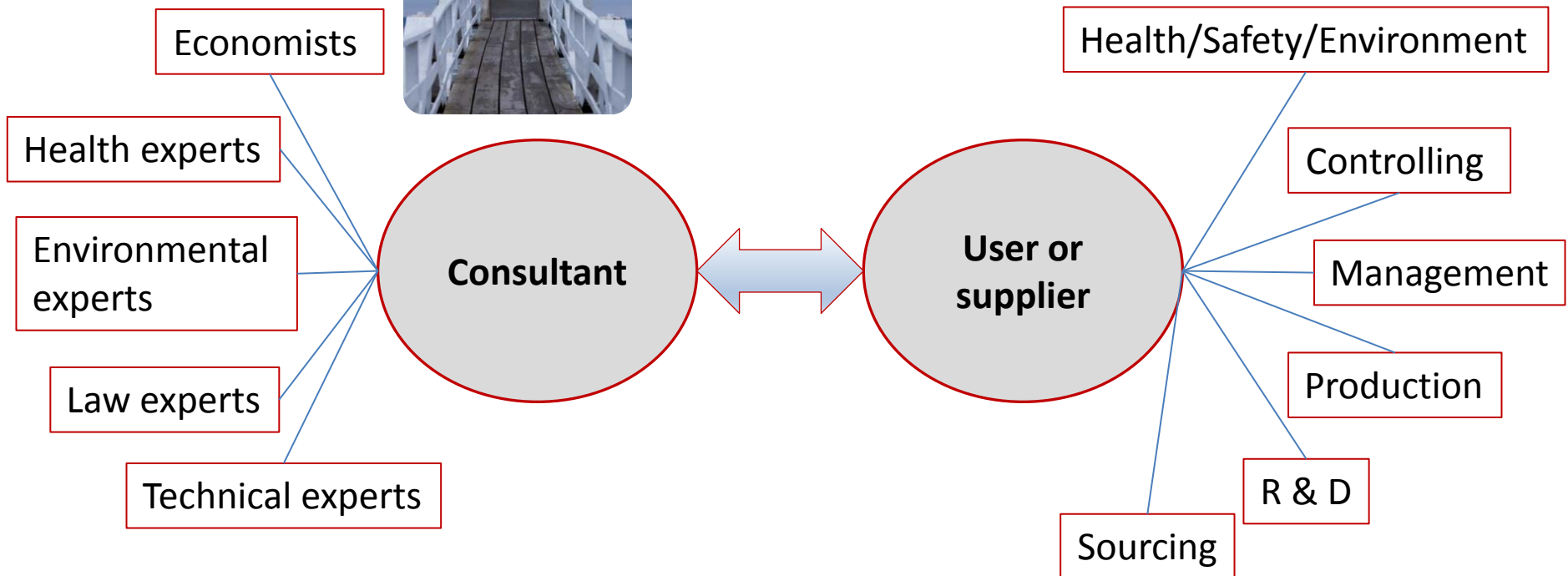
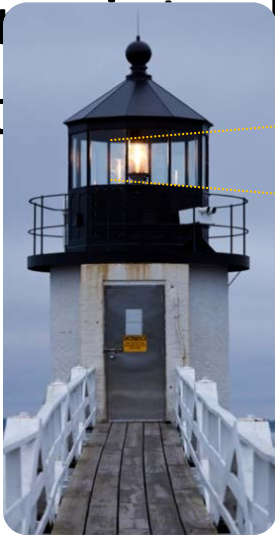


SEA links to AoA and CSR

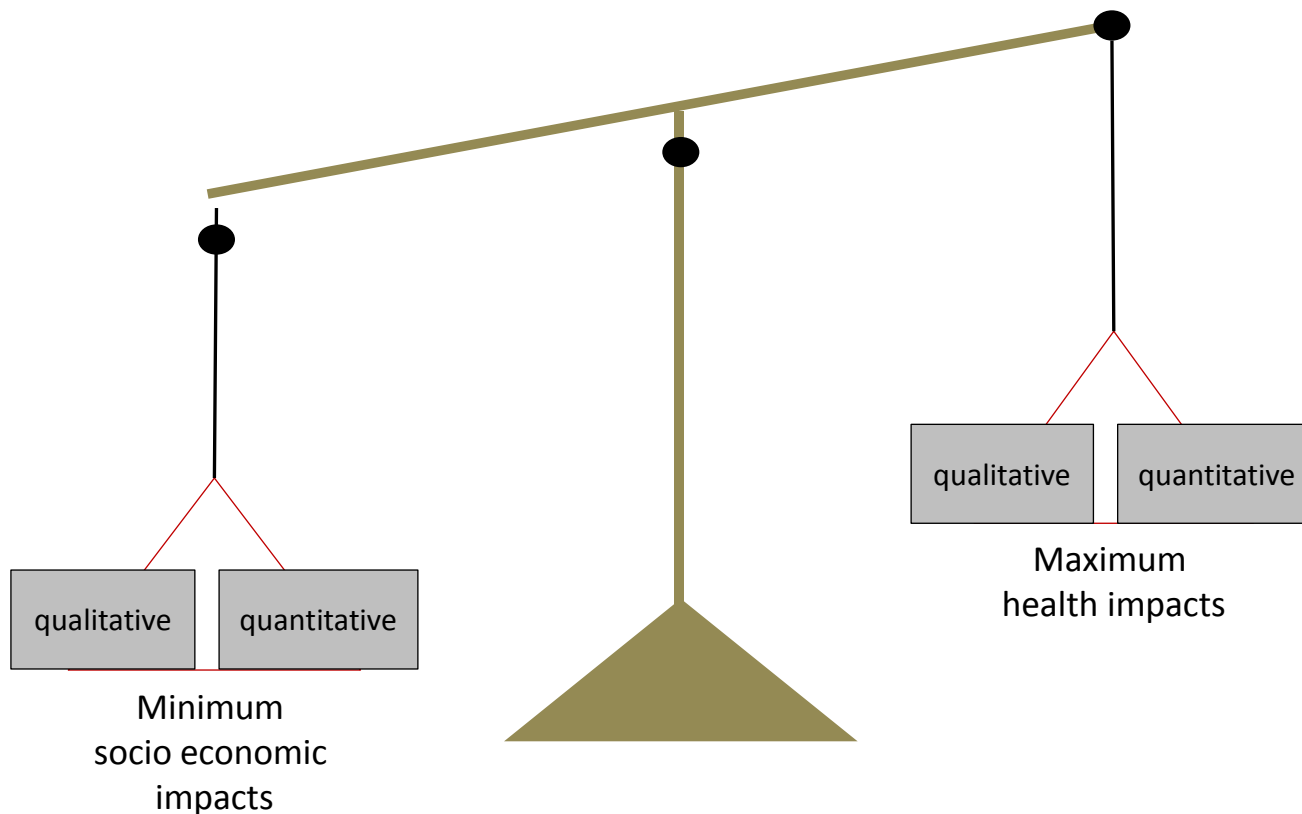


Lessons learned

- SEA requires interdisciplinary thinking, close collaboration and efficient data gathering
Experience required



Aim of the SEA



SEA reports intend to prove that even if economic impacts are underestimated, they outweigh overestimated health costs

Challenges in the SEA preparation

- Efficient data gathering
 - Firstly, easily accessible data with reliable causal chains are assessed quantitatively until the balance is stable
 - Supply chain data and wider economic impacts are assessed qualitatively
 - Interdepartmental information is necessary
 - Well-targeted dialogue needed to get the data assessment right

How we recognised and solved problems?

- Efficient data gathering

- Data is not available or data gathering requires high effort and time
- Confidential Business Information

→ Start the elaboration of application documents as soon as possible to close data gaps and to gather data step by step according to needs (starting from easy to assess and solid data)

- Individual vs. joint application

- Conflict of interest
- Confidential Business Information

→ Joint applications for the same use can save efforts as documents need to be prepared only once and submission fees can be saved

Challenges in the SEA preparation

- **Credible non-use scenario**
 - Define a credible and solid non-use scenario and explain why other scenarios are not realistic (taking into account AoA results)
 - If necessary discuss multiple non-use scenarios
 - If you use extrapolations choose adequate case studies and document that these case studies are representative for the whole market
 - Non-use scenario might accuse further and severe impacts within the supply chain which can be assessed either qualitatively or quantitatively

How we recognised and solved problems?

- Credible non-use scenario
 - Companies tend to overestimate their reaction in case of a non-use scenario and therefore weaken their case and credibility

→ Bilateral discussions and development of a credible non-use scenario with our experience of several projects

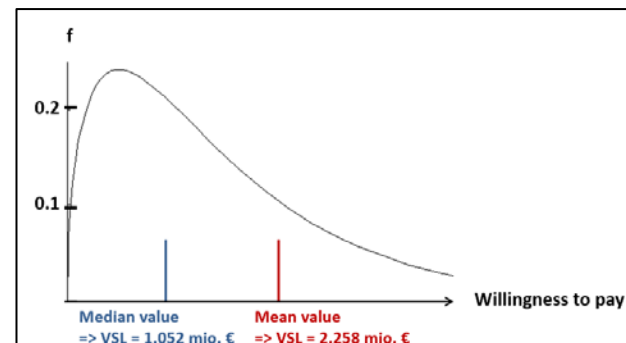
Challenges in the SEA preparation

- Balance between quantitative and qualitative assessment of impacts

Advantage Quantified impacts	Disadvantage Quantified impacts
In line with guidance and SEAC expectations for SEA. Present stronger case for authorisation. Cannot include new data once AfA submitted.	Concern that monetised (health) impacts data will be mis-used or abused.
Allows company to present the argument in a controlled manner (other applicants will likely present quantitative data).	Confidentiality concerns (Note: confidential data can be redacted in the publicly available version of the SEA).

Monetarisation of health impacts

- The approach will consist of the following four steps of the impact pathway:
 - Data gathering on work place exposure
 - Estimation of additional cancer cases in relation to baseline lifetime risk of developing the disease
 - Estimation of fatality rates in % for each relevant type of cancer, based on empirical data from EU
 - Monetary valuation of fatal and non-fatal cancer risks, based on the ECHA Guidance on the preparation of a SEA as part of an application for authorisation



SEA experiences so far

- Long lasting experiences of socio-economic assessments in consulting for policy makers (EU Commission) as background
- Experiences with SEA for non-threshold substances
 - TCE covering supplier and group approach, single company uses, e.g. Dow Chemicals
 - Cr(VI) containing substances (CTAC, CCST and COD consortia)
- Experiences with SEA for threshold substances
 - Example for an ongoing authorisation project: Diglyme
- Experiences with SEA before inclusion in Annex XIV
 - Example for an ongoing project: Coal tar pitch, high temperature, e.g. ECGA

Supporting SEA for threshold substances

- **Aim:**
 - SEA provides additional arguments for an authorisation
 - Strengthens argumentation for length of the review period

- **Your benefit:**
 - Increased chances for a successful authorisation
 - Providing a total picture of your case, also showing significance of your use and socio-economic impacts for the European Union in case of non granted authorisation
 - Risk reduction and early preparation, if substance is classified as non-threshold at a later stage (see TCE)

Supporting SEA for substances before inclusion in Annex XIV

- **Be proactive:**
 - Use the chances to comment during public consultations already when Annex XV dossiers are published
 - Provide detailed robust arguments for exclusion of your use when prioritisation of your substance is discussed with a supportive SEA
 - Communicate in advance with clients to avoid uncertainty in the market
- **Your benefit:**
 - Take the given chance to avoid inclusion in Annex XIV, by using a SEA to clearly demonstrate the impacts of an inclusion in Annex XIV
 - Even if the substance is included in Annex XIV you are well prepared with a first SEA
 - The SEA demonstrates that requirements for authorisation are fulfilled; this will strengthen the trust of your clients

Overview of business areas and services



Chemicals

- Registration, Evaluation and Authorisation of Chemicals (REACH)
- Hazard and Risk Assessment, Exposure Assessment
- Chemical Leasing Business Models
- Responsible Production Implementation
- Persistent Organic Pollutants (POPs)
- Safety Data Sheets



Sustainability & Innovation

- Sustainable Consumption and Production
- Sustainability Indicators (Environmental Commitments)
- Sustainability Policy Implementation



Health

- Human Biomonitoring
- Occupational Health



Environment, Climate & Energy

- Environmental Pollutants, Emission Reduction
- Permits
- Technology assessment, Resource Efficiency Improvement
- Environmental Monitoring Programmes
- Energy Efficiency
- Renewable Energy
- Climate Change
- Fluorinated Gases



Waste & Resource Management

- Waste Policy & Implementation
- Waste Management
- Waste Prevention
- Waste Technology



Support for Developing and Transition countries

- Optimisation of manufacturing plants
- Accident Prevention
- Innovative Business Models
- “Cleaner Production” and “Responsible Production”
- Technology Transfer
- Safety Data Sheets (SDS)

Contact details

Many thanks for your attention!

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