



EASA

European Aviation Safety Agency

The EASA System fit for addressing urgent safety issues

*The review of the rulemaking process and
the operational directives process*

Jean-Marc Cluzeau, Head of Strategy and Programmes Department

Michael Gerhard, Legal Adviser

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TE.GEN.00409-001



1. The Rulemaking Procedure

Forthcoming changes aiming to less, better and timely regulations

2. Corrective Action in Reaction to a Safety Problem

Operational Directives



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The Rulemaking Procedure

*Forthcoming changes aiming to less,
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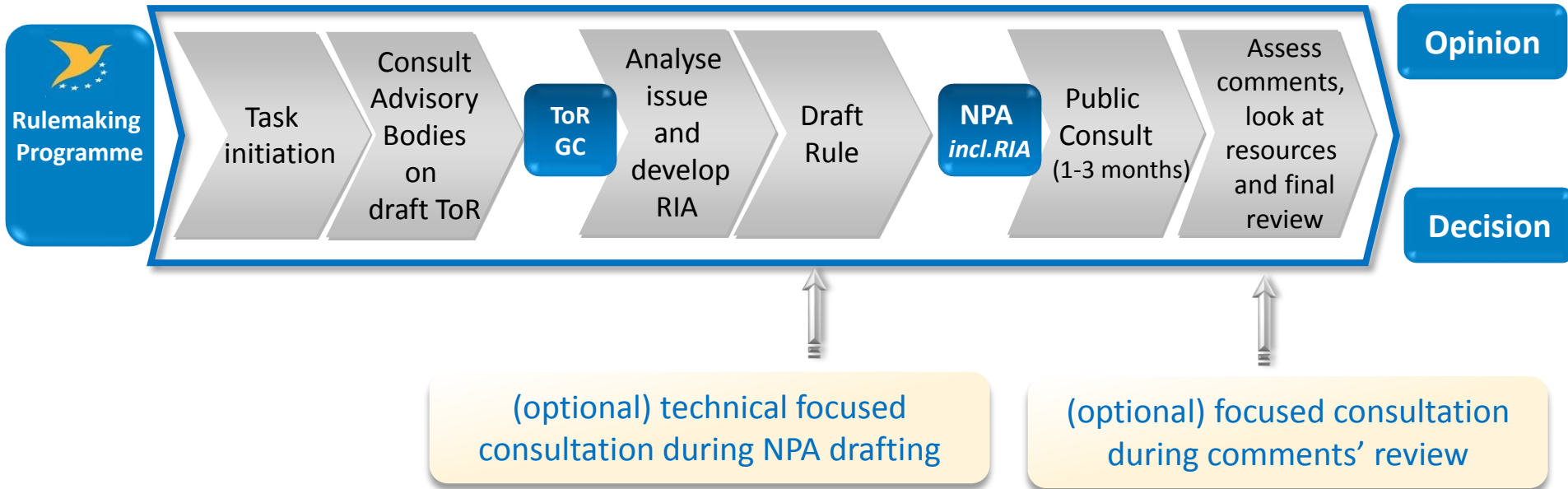


Agenda

- The current process for rules development
- The proposed changes



The current rule development phase





- Strengthened **Impact Assessments** for less and better rules
- A more **flexible consultation** for a tailor-made and thus more efficient and timely rulemaking process

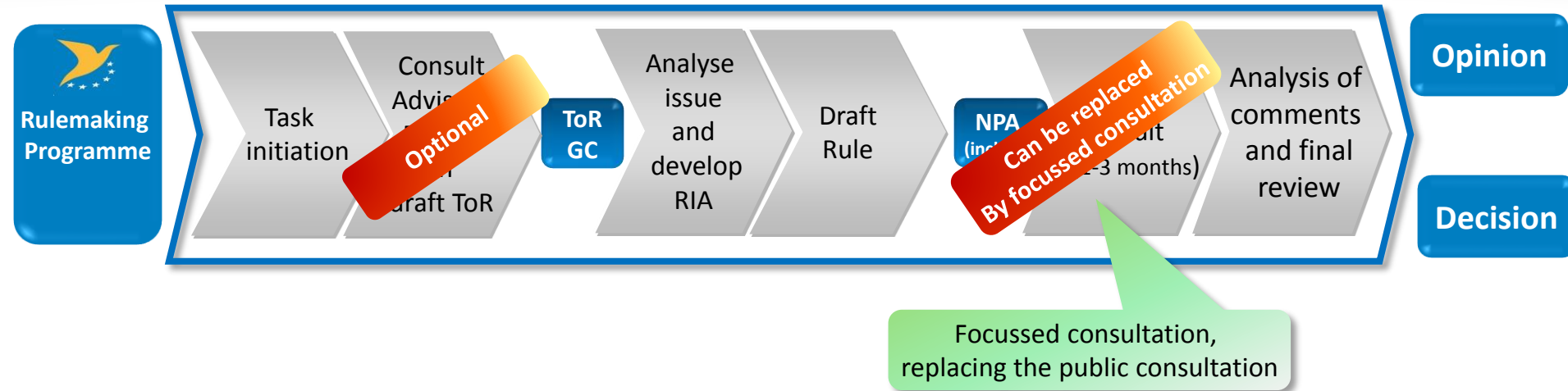


Strengthening Impact Assessment

- Paradigm shift: Impact Assessments at the core of the rulemaking activity
 - **Preliminary Impact Assessment during the programming phase**, to ensure a better use of alternative actions to rulemaking, in particular safety promotion and focussed oversight
 - **Regulatory Impact Assessment** involving stakeholders and Advisory Bodies, to assess the need for performance based approach and ensure rulemaking actions are based on evidence and sound analysis
 - **Ex-post evaluation**, as an explicit part of the rulemaking programme, to systematically assess the efficiency of rules



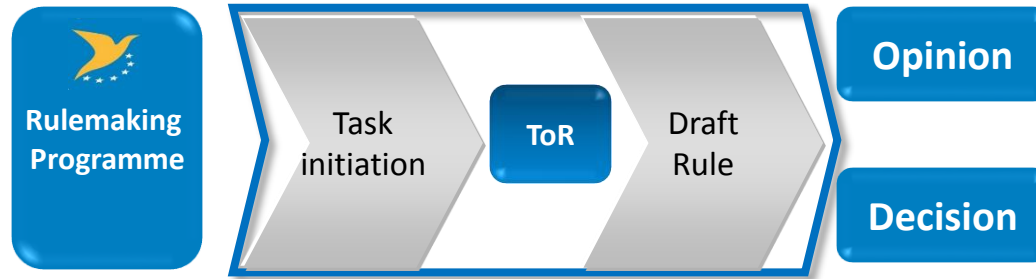
Flexible Consultation (1)



- **Optional** consultation of **ToR** with the Advisory Bodies
- Use of the **focussed consultation** (e.g. technical workshops, consultation of the Advisory bodies, a limited survey, etc.) **for replacing the public consultation of NPA**
 - Criteria for such “accelerated projects”: urgent safety issue, non-controversial or non-complex issue, size of the affected group of stakeholders, NAAs and interested parties’ consensus



Flexible Consultation (2)



➤ **Direct publication** of CS, AMC and GM or Opinion

- When? for urgent safety issues which require immediate reaction, non-controversial ICAO amendments consulted through State Letters, adoption of recognised foreign authority's advisory material, existing and agreed industry standard
- A short consultation of the Advisory Bodies (4-6 weeks) is envisaged prior to the publication of the final deliverable



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Corrective Action in reaction to a Safety Problem (Operational Directives)

Michael Gerhard
Legal Adviser

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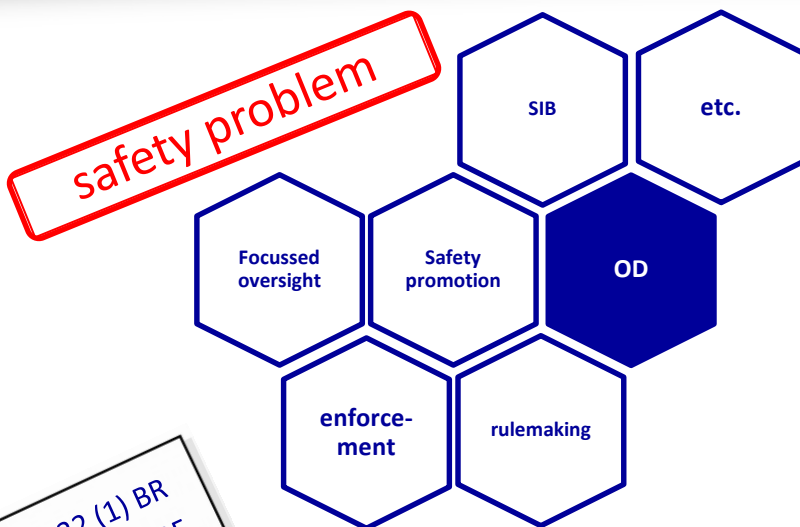


Background

- In certain cases EASA may have information on a safety problem in areas where EASA is not competent authority
- Urgent safety action may be needed, when the level of safety intended by existing rules is compromised
- EASA has issued in several occasions Safety Information Bulletins, which may not always be a strong enough tool



Proposal



EASA Operational Directive
OD No.: YYYY-XXXX
Issued: dd Month YYYY

The Operational Directive (OD) is issued in accordance with ARO.GEN.135(4), ARA.GEN.135(4), ADR.AR.A030, and is intended to be used by the Member States to take adequate measures to address the safety problem, to ensure compliance with ARO.GEN.135(4), ARA.GEN.135(4), ADR.AR.A030, and to ensure the safety of the aircraft.

Member States: (Text)
Products, Parts, Appliances, Persons or Organisations affected: (Text)

Effective Date: dd Month YYYY (standard: 30 days after OD issue date)
Supersede/Revision: (as appropriate)

Safety Problem / Corrective Action(s)

Applicability:
(Identify all product(s), part(s), appliance(s), person(s) or organisation(s) to which the OD applies.)

Background:
(Describe the safety problem and identify the proposed corrective actions.)

Corrective Action(s) and Compliance Time(s):
Requirements indicated, unless already accomplished:
Within (XX) days/months after the effective date of this OD, the competent authorities of the affected Member States shall take adequate measures to ensure that (corrective action(s) description).

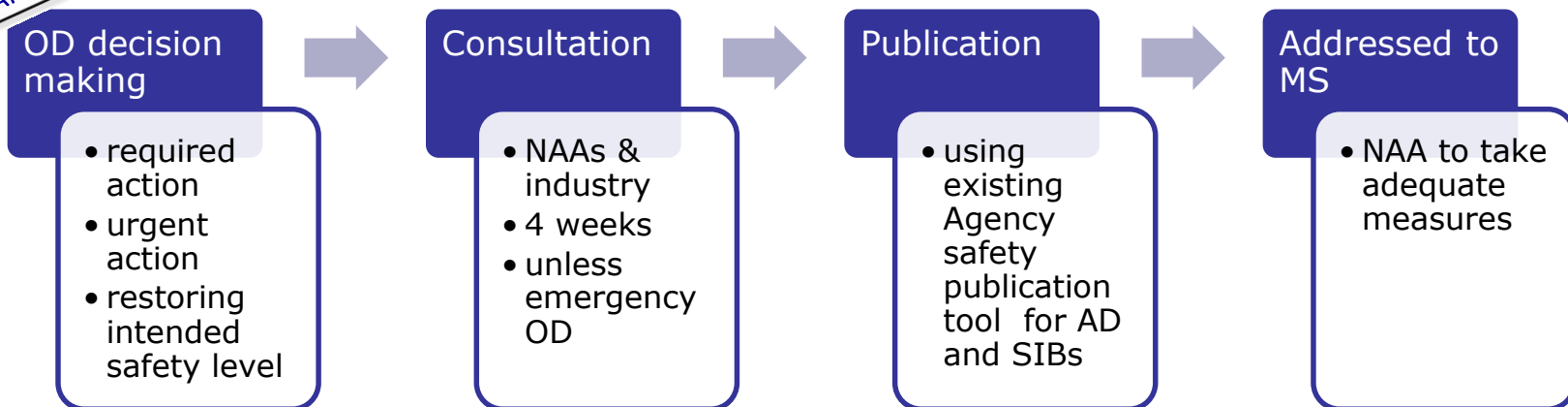
Ref. Publications:
(List (if any) each document which contains (further) instructions to accomplish the proposed corrective action(s) described by this directive.)

Remarks:

- Enquiries regarding this OD should be referred to the EASA Safety Information Section, Certification Directorate. E-mail: OD@easa.europa.eu
- The competent authorities shall notify to the Agency (E-mail: OD@easa.europa.eu) the measures taken.

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Examples for possible use of ODs

- Carriage of lithium batteries as cargo (SIB 2015-19)
- Unexpected autopilot behaviour on ILS approach (SIB 2014-07R1)
- Unreliable airspeed indication (SIB 2015-17R1; SIB 2009-17)
- Authorised persons in the flight crew compartment (SIB 2015-04)
- Fire risk of electronic cigarettes in checked baggage (SIB 2015-06R1)



Next Steps

Further discussions of the concept

- SSCC 10 December
- EASA Management Board 14/15 December



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Thank you for your attention

Comments and questions welcome!

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Legal framework (example)

ARO.GEN.135 Immediate reaction to a safety problem

- (a) Without prejudice to Directive 2003/42/EC of the European Parliament and of the Council, the competent authority shall implement a system to appropriately collect, analyse and disseminate safety information.
- (b) The Agency shall implement a system to appropriately analyse any relevant safety information received and without undue delay **provide to Member States and the Commission any information, including recommendations or corrective actions to be taken**, necessary for them to react in a timely manner to a safety problem involving products, parts, appliances, persons or organisations subject to Regulation (EC) No 216/2008 and its Implementing Rules.
- (c) Upon receiving the information referred to in (a) and (b), the competent authority shall take adequate measures to address the safety problem.
- (d) Measures taken under (c) shall immediately be notified to all persons or organisations which need to comply with them under Regulation (EC) No 216/2008 and its Implementing Rules. The competent authority shall also notify those measures to the Agency and, when combined action is required, the other Member States concerned.

similar: ARA.GEN.135; ADR.AR.A030