External Working procedure – ETA process & EAD Development Procedure
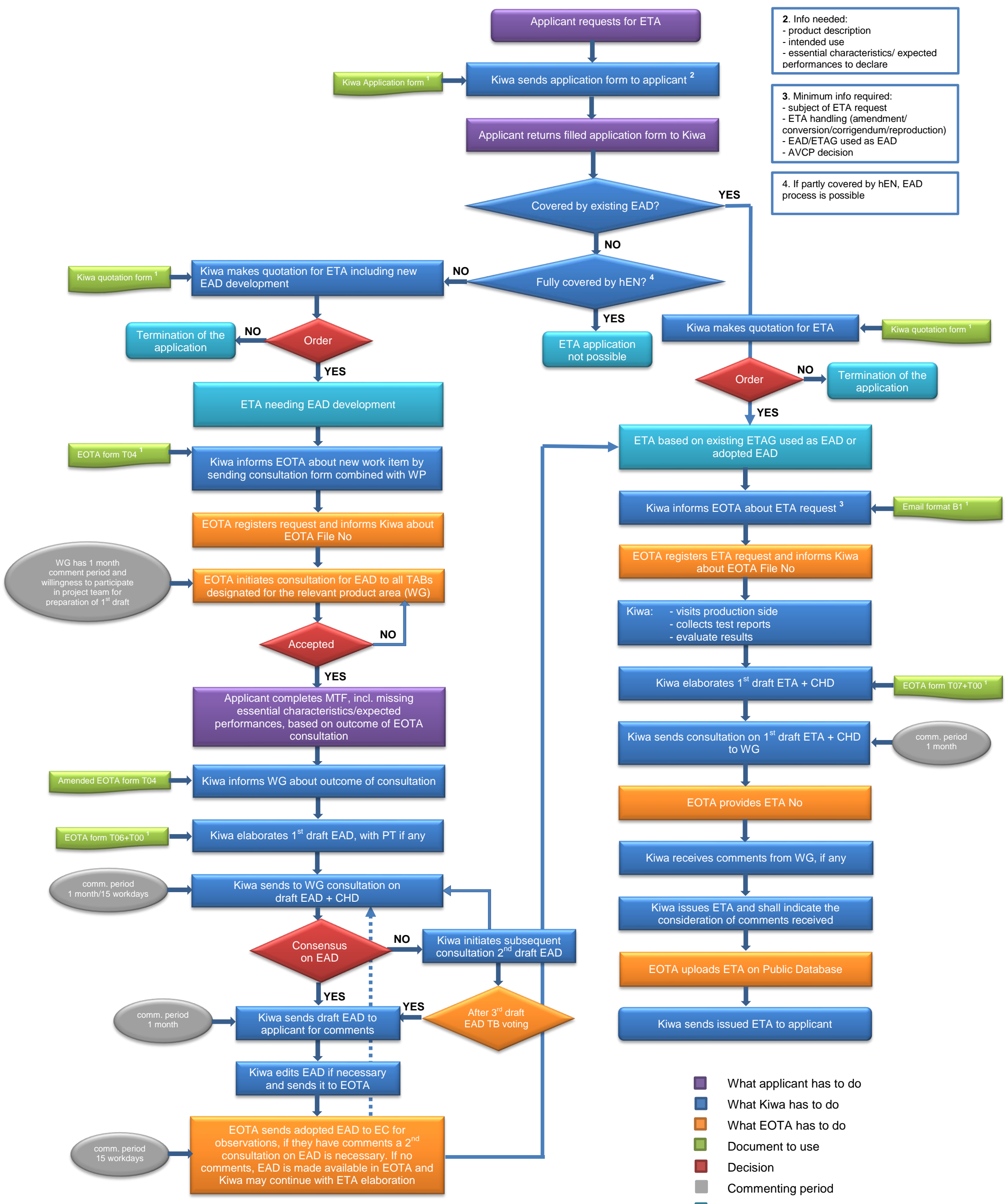
1. Request the form you need at Sharmila Bhagwat

2. Info needed:
- product description
- intended use
- essential characteristics/ expected performances to declare

3. Minimum info required:
- subject of ETA request
- ETA handling (amendment/ conversion/corrigendum/reproduction)
- EAD/ETAG used as EAD
- AVCP decision

4. If partly covered by hEN, EAD process is possible

```
Applicant requests for ETA
        │
Kiwa Application form [1] → Kiwa sends application form to applicant [2]
        │
Applicant returns filled application form to Kiwa
        │
Covered by existing EAD? ──YES──┐
        │ NO                     │
Fully covered by hEN? [4] ──NO──→ Kiwa makes quotation for ETA including new EAD development
        │ YES                    
ETA application not possible
```

Kiwa makes quotation for ETA ← Kiwa quotation form [1]

Order ──NO──→ Termination of the application
 │ YES

ETA based on existing ETAG used as EAD or adopted EAD

Kiwa informs EOTA about ETA request [3] ← Email format B1 [1]

EOTA registers ETA request and informs Kiwa about EOTA File No

Kiwa: - visits production side
      - collects test reports
      - evaluate results

Kiwa elaborates 1st draft ETA + CHD ← EOTA form T07+T00 [1]

Kiwa sends consultation on 1st draft ETA + CHD to WG ← comm. period 1 month

EOTA provides ETA No

Kiwa receives comments from WG, if any

Kiwa issues ETA and shall indicate the consideration of comments received

EOTA uploads ETA on Public Database

Kiwa sends issued ETA to applicant

Left branch (EAD development):

Kiwa quotation form [1] → Kiwa makes quotation for ETA including new EAD development

Order ──NO──→ Termination of the application
 │ YES

ETA needing EAD development

EOTA form T04 [1] → Kiwa informs EOTA about new work item by sending consultation form combined with WP

EOTA registers request and informs Kiwa about EOTA File No

WG has 1 month comment period and willingness to participate in project team for preparation of 1st draft → EOTA initiates consultation for EAD to all TABs designated for the relevant product area (WG)

Accepted ──NO──┐ (back to consultation)
 │ YES

Applicant completes MTF, incl. missing essential characteristics/expected performances, based on outcome of EOTA consultation

Amended EOTA form T04 → Kiwa informs WG about outcome of consultation

EOTA form T06+T00 [1] → Kiwa elaborates 1st draft EAD, with PT if any

comm. period 1 month/15 workdays → Kiwa sends to WG consultation on draft EAD + CHD

Consensus on EAD ──NO──→ Kiwa initiates subsequent consultation 2nd draft EAD

 │ YES   │
                          After 3rd draft EAD TB voting ──YES──┐

comm. period 1 month → Kiwa sends draft EAD to applicant for comments

Kiwa edits EAD if necessary and sends it to EOTA

comm. period 15 workdays → EOTA sends adopted EAD to EC for observations, if they have comments a 2nd consultation on EAD is necessary. If no comments, EAD is made available in EOTA and Kiwa may continue with ETA elaboration

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Legend:
- 🟪 What applicant has to do
- 🟦 What Kiwa has to do
- 🟧 What EOTA has to do
- 🟩 Document to use
- 🟥 Decision
- ⬜ Commenting period
- 🟦 Result

EAD: European Assessment Document
EC: European Commission
ETA: European Technical Assessment
CHD: Comments Handling Document
MTF: Manufacturer's Technical File
PT: Project team (participating in development of EAD)
TB: EOTA Technical Board
WG: all designated TABs for a product area
WP: Work programme

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