

Authority Paper

Committee:	Authority
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Paper Title:	Regulatory Enforcement and Sanctions Act, 2008
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For Information or Decision?	For Decision
Resource Implications:	To be established
Implementation:	To be agreed
Communication:	To be agreed
Organisational Risk:	Medium
Recommendation to the Committee:	This paper recommends the HFEA apply for three of the powers available under the RES Act: Discretionary Requirements, Stop Notices and Enforcement Undertakings.

1. Purpose of Report

- 1.1. This report sets out to advise the Authority on the enforcement powers for which it can apply under the Regulatory Enforcement and Sanctions Act, 2008 (RES Act). It considers the relative merits of these powers against the sanctions available to a Licence Committee under the current HFEA Act and HFE Bill and recommends that the Authority does apply. The intention is to ensure that a coherent suite of enforcement procedures is available to the Authority by April 2010.

2. Background: Why was the RES Act introduced?

- 2.1. The RES Act was introduced in response to the Hampton Review [Reducing Administrative Burdens: Effective Inspection and Enforcement, Hampton P., H M Treasury March 2005] and the Macrory review [Regulatory Justice: Making Sanctions Effective, Better Regulation Executive November 2006]. The RES Act is intended to deliver a regulatory system that is risk-based, consistent and proportionate, with access to a flexible set of sanctioning tools, without undue reliance on prosecution for effective enforcement.
- 2.2. Parts 1 and 2 of the RES Act relate to local authorities and do not concern HFEA. Part 3 gives regulators listed in Schedule 5 to the Act (including the HFEA) an “extended tool kit of alternative civil sanctions as a more proportionate and flexible response to cases of regulatory non-compliance normally dealt with in the criminal courts.” In particular, the...toolkit allows regulators to remove the financial benefit gained by businesses that deliberately seek an advantage through non-compliance while helping to secure increased compliance” [BRE Guidance to the RES Act].

3. How will the new powers be awarded?

- 3.1. The powers will be granted by ministerial order, once the Minister is satisfied that the regulator operates according to the principles of good regulation. Evidence for this will be generated through the Hampton Implementation Reviews (HIR), organised by the Better Regulation Executive (BRE). The HFEA will be reviewed in February 2009. Before making the order, the Minister must conduct a public consultation and the order itself is subject to the affirmative procedure for statutory instruments in parliament (See Figure 1 in the Appendix for greater detail).

4. Sanctions available in ‘the toolkit’

- 4.1. There is a range of sanctions available under the RES Act as an alternative to prosecution. These powers are not intended to replace informal means of enforcement, such as advice or warning letters, but rather are intended to add to the tools available for regulators to promote regulatory compliance. It is envisaged that each regulator will apply for a combination of powers appropriate to their needs.
 - a. Fixed Monetary Policy (FMP) notices will allow a regulator to impose monetary penalties of a fixed amount.

- b. Discretionary requirements will enable a regulator to impose, by notice, one or more of the following:
- a variable monetary penalty (VMP) determined by the regulator;
 - a requirement to take specified steps within a stated period to secure that an offence does not continue or happen again (compliance notice); and
 - a requirement to take specified steps within a stated period to secure that the position is restored, so far as possible, to what it would have been if no offence had been committed (restoration notice).
- c. Stop notices will prevent a business from carrying on an activity described in the notice until it has taken steps to come back into compliance.
- d. Enforcement undertakings will enable a business, which a regulator reasonably suspects of having committed an offence, to give an undertaking to the regulator to take one or more corrective actions set out in the undertaking.

5. How do the RES Act powers compare with the HFE Act powers?

5.1. The powers considered under this act, if granted, may only be applied to criminal offences and bear the same burden of proof – beyond a reasonable doubt. Section 41 of the HFE Act lists the activities that constitute criminal offences. In summary, these concern:

- Procuring, creating, distributing and storing embryos except in pursuance of a licence;
- creating, keeping or using an embryo or gametes except in pursuance of a licence;
- keeping or using an embryo in circumstances prohibited by Regulations listed in section 03(3)(c);
- knowingly providing materially false information;
- disclosing patient identifying information or breaches in confidentiality under s33;
- breaching Directions on the giving or receiving of money in respect of supply of gametes or embryos (2006/1);
- breach of Directions issued by licence committee under s24(7)(a) requiring information or materials to be transferred to the authority.
- obstructing an inspection;
- obstructing a warrant;
- failing to respond to summons issued by a Licence Committee (however, this will no longer be considered a criminal offence under the new bill).

5.2. These offences are listed roughly in descending order of legal gravity. Other offences include the following; however, these are presumably circumstances which would warrant immediate referral to the police to be investigated and possibly prosecuted.

- Implanting non-human or admixed embryos or gametes in a woman
- Using female germ cells taken or derived from an embryo or foetus to provide fertility services
- Creating keeping or using admixed embryo other than in pursuance of a licence
- Putting human or admixed embryos in animals
- Replacing the nucleus of an embryo

5.3. Currently, the powers the HFEA has to encourage compliance are informal or deal directly with the status of the licence. The Authority may issue directions to those concerned with the licence, but the only formal means for enforcement of these directions is to modify the conditions of a licence or to suspend or revoke a licence. To suspend a licence, the Committee must suspect that there are grounds for revoking a licence and must be of the opinion that immediate action is necessary. The licence committee may revoke a licence under Section 18 if information in the application is found to be false or misleading, the licensed premises are no longer suitable, the person responsible has failed to carry out their duties or is no longer suitable or there has been a material change of circumstances since the licence was granted. In the most serious of offences, the Chief Executive may refer the case to the police.

5.4. Action to revoke a licence has been initiated by the HFEA on ten occasions. Of these, only two instances involved a criminal breach and only in one case, which dealt with a non-criminal offence, was a licence actually revoked. This is demonstrative of an ongoing tendency to attach greater importance to non-criminal offences. For example, in Licence Committees, greater concern is devoted to justifications for three-embryo transfer in under-40 year olds, whereas the storage of embryos without consent seldom attracts censure. This may understandably arise out of concern for the health and safety of patients; however, this tendency does not fully recognise the innate seriousness of a criminal breach. Also, similar criminal breaches are handled differently. It may be possible to attribute this behaviour to the absence of a tariff of sanctions. While it is important the Authority has the flexibility to take into account factors other than the offence itself, such as the centre's record of previous offences and any mitigating actions offered by the centre, it seems necessary to enforce the gravity of non-compliance.

6. Powers available to the HFEA and their relative merits

6.1. In principle there seems a good case for the HFEA to apply for RES Act powers as a way to broaden its enforcement capabilities. However, when considered individually, not all the powers offered may be appropriate. This section considers each of the

RES Act powers in greater detail including advantages and disadvantages, and makes recommendations in respect of each power.

6.2. Fixed Monetary Penalty (FMP)

- 6.2.1 Fixed Monetary Penalties (FMPs) are intended to be used in the case of low level incidences of regulatory non-compliance and to avoid the stigma of criminal prosecution. In this case, the Minister fixes the amount of the fine, which may be set by offence and according to variable factors such as the size of the business, with a maximum usually set at £5,000.
- 6.2.2 To impose an FMP, the regulator must first serve the business with a 'notice of intent,' which includes the grounds for the penalty, timeline for action from both sides, the rights of the business and the obligations of the regulator. Once a notice is served, the business may make representations to the regulator, following which, if there is still dispute and following the issuance of a final notice, the business may appeal to an independent tribunal for a hearing. If the tribunal finds in favour of the regulator and payment is still withheld, the fine may be pursued as a civil debt. To ensure the sanctions issued are of a high quality, the regulator must have in place procedures for reviewing and monitoring the individual decisions (see Figure 2 in the Appendix for greater detail).

6.2.3 *Advantages*

Because the amount of the fine is already determined FMPs carry a lower administrative burden than Variable Monetary Penalties (VMPs), which will be discussed in the next section. Also, because the amount of these fines is pre-determined, FMPs create consistency in the penalties for violation.

6.2.4 *Disadvantages*

While the consistency that would be created by FMPs may be viewed as advantageous, it is also a disadvantage because it does not allow the issuing body to exercise discretion or to take into consideration the organisation's previous record of violations. Additionally, the processes for issuing and claiming FMPs are onerous and it is not possible to claim back any of the associated costs. Nor is it possible to retain the fines, which must be paid into the Consolidated Fund.

6.2.5 *Recommendation*

Given the administrative burden of FMPs and the inability to recover costs, **the prospective benefit gained from an FMP is not sufficient to recommend adoption.** Also, evidence suggests that the informal means of enforcement already applied through Licence Committee meetings is sufficient to correct the type of violations FMPs are intended to address.

6.3. Discretionary Requirements

6.3.1. Discretionary Requirements, which include, Variable Monetary Penalties (VMPs) and ‘Compliance’ and ‘Restoration Requirements’ are intended to be used individually or in combination to address mid to high level cases of regulatory non-compliance. These powers may be awarded separately, and if all three powers are granted, it is for the regulator to decide which combination of sanctions to use for each case. It is possible that both a monetary and non-monetary requirement may be issued and the organisation will be required to fulfil both. This gives the regulator the ability make the “punishment fit the crime” on a case-by-case basis.

- *Variable Monetary Penalty*

The VMP can be set by regulator at a level that removes financial gain resulting from the non-compliant activity and takes account of the gravity of the violation and the history of compliance. The regulator must consider aggravating (e.g. seriousness and history of non-compliance) and mitigating (previous good record) factors.

- *Compliance Requirements*

The purpose of ‘Compliance Requirements’ is to ensure that the licence holder takes appropriate steps, within a stated period, to return to compliance and to prevent recurrence by remedying failures, for example of equipment or training.

- *Restoration Requirement*

‘Restoration Requirements’ are intended to compel a business to take steps, within a stated period, to deal with the consequences of an offence, for example, reimbursing the customers’ money.

6.3.2. The procedure for issuing discretionary penalties is broadly similar to that for FMPs. It is also possible in the process of assigning the Discretionary Requirements to include opportunities for an organisation to mitigate the severity of the censure by offering enforcement undertakings, which are discussed later in this section. The acceptance and impact of these undertakings is determined by the regulator (see Figure 3 in the Appendix for greater detail).

6.3.3. Advantages

Discretionary Requirements allow regulatory authorities to exercise flexibility and creativity in taking enforcement action against non-compliant organisations. Alternatives to prosecution are particularly attractive to the HFEA, which cannot prosecute its own cases because it is not included in the Regulatory Investigative Powers Act (RIPA), and is not given a statutory duty before the HFE Act, therefore must work with police and request the Director of Public Prosecutions to prosecute non-compliant organisations. Having a greater range

of available sanctions might encourage Licence Committees to intervene in non-compliant action earlier, preventing the escalation of offences to those warranting more serious action, such as suspension or revocation of a licence. Unlike FMPs, the costs associated with investigation, administration and obtaining legal and other expert advice are recoverable. Also, the 'costs of and incidental to' tribunal proceedings may be awarded through tribunal procedures.

6.3.4. *Disadvantages*

As with FMPs the procedures are somewhat onerous for the regulator and the burden of proof is high – beyond a reasonable doubt. Although the direct costs may be recovered, necessary organisational investment, that would not be recovered, may include the need for enhanced staff training, engagement of new staff and retention of external solicitors for investigative purposes and setting up internal quality monitoring and review systems. However, such systems will be necessary to implement the changes proposed in the HFE Bill. As with FMPs, the fines may not be retained and must be paid into the Consolidated Fund.

6.3.5. *Recommendation*

The powers granted under Discretionary Requirements provide the Authority with the ability to take enforcement action regarding criminal offences that would fall in-between informal measures and taking away a licence. These powers are also flexible enough to be tailored to any situation. VMPs in particular could provide the Authority with the ability to impress upon non-compliant businesses the seriousness of their offence. Having a greater range of enforcement sanctions may generally encourage compliance by all clinics. **Therefore, it is recommended that the HFEA apply for the power to issue all three Discretionary Requirements.**

- 6.3.6. Two criminal offences are commonly discovered in inspections: storage without effective consent and breaches of confidentiality. Enforcement action is rarely taken by licence committees even when offences are repeatedly committed. The flexibility of the powers awarded under discretionary requirements would provide licence committees with proportionate sanctions for these breaches and would impress upon all licence holders the seriousness of a criminal breach.

6.4. **Stop notices**

- 6.4.1. A 'stop notice' requires a business to cease an activity that is causing or poses a serious risk of causing harm to human health, the environment, financial interest of consumers, or is likely to be committing an offence. This type of notice may either prohibit a business from carrying out an activity, or may prohibit an action until steps are taken to remove risk or return the business into

full legal compliance. In addition to being used to halt action which is or presents a significant risk of causing serious harm, stop notices may be used preventatively to prohibit a business from carrying on an activity which poses significant risk in the future. Stop notices may also be used to compel a business to cease trading altogether.

- 6.4.2. A 'stop notice' must be served by the regulator detailing the specific terms of the notice. Once a regulator is satisfied that the terms of a stop notice are fulfilled, the business will be issued a completion certificate, which the business may apply for at any point. If the tribunal finds that the notice was wrongly imposed, the business may apply to the regulator for compensation. However, a business that does not comply with a stop notice, that has been upheld, is guilty of a criminal offence and may be prosecuted appropriately (see Figure 4 in the Appendix for greater detail). Because of the potentially serious impact of a stop notice, they should only be used for the most serious offences.

6.4.3. *Advantages*

A 'stop notice' may be targeted at a specific area of trading, unlike the suspension of a licence and may be used preventatively. The issuance and terms of a stop notice, are aimed at securing improvement and compliance, rather than punishment. Also, the public is protected whilst changes and improvements are made. Of advantage to the business is the ability to appeal to an independent Tribunal, unlike the current situation when a licence is suspended or revoked.

6.4.4. *Disadvantages*

If the refusal of a business to comply with a stop notice becomes a criminal offence, as discussed earlier, the HFEA does not have the power to bring charges and would have to involve the police in order to do so.

6.4.5. *Recommendations*

It is recommended that the HFEA applies for the power to issue 'stop notices.' One of the particularly attractive aspects of 'stop notices' to the HFEA is the flexibility. Instead of shutting down an entire clinic through suspension or revocation of a licence, a 'stop notice' could be issued to halt breaches that were only occurring in one aspect of the clinic's business.

- 6.4.6. 'Stop notices' could be used to great effect in cases where an action was not directly jeopardising physical patient safety or clinical safety. A 'stop notice' could be used to good effect when a centre is found in non-compliance in an area that only effects a portion of their business, such as incorrect payment for donations. In this case a clinic could be compelled to cease collecting

donations until they revised their policies. Additionally, a stop notice could be used in instances when an organisation or individual does not have a licence, such as the online sale of gametes. Issuing a stop notice would carry more weight than simply ordering these businesses to stop because failure to comply would result in another criminal offence.

6.5. Enforcement Undertakings

6.5.1. 'Enforcement undertakings' are designed to originate with the business and not the regulator, enabling the business to own up to breaches and creating a creative way of addressing non-compliance. It is intended that in practice businesses will come to the regulator after having committed a breach, although it may happen that the regulator has reason to suspect an instance of non-compliance and discusses this with the business. But, in either instance it is the responsibility of the business to propose actions to cease and prevent recurrence, compensate those affected or restore original position.

6.5.2. Once action has been offered, it is up to the regulator to accept the terms of the undertaking. Once an undertaking has been accepted and the business has complied, the business may no longer be convicted for the original offence at any time. Because this is an agreement offered by the business and agreed to by the regulator, in general there should be no need for an appeal process. If a business fails to comply with its own undertaking, the regulator may either impose a different sanction or may bring criminal charges (see figure 5 in the Appendix for greater detail).

6.5.3. *Advantages*

'Enforcement undertakings' give businesses a good opportunity to take responsibility for actions and to use internal initiative to rectify any breach. This encourages organisations to become self-reliant in managing their own compliance. The ability to propose their own measures may also open better communication links between organisations and regulators and may mean that solutions are better fit to the specific circumstances of the breach because the initiative has come from within and not been imposed by an outside authority. This may also have the less-tangible effect of creating better working relationships between regulators and businesses.

6.5.4. *Disadvantages*

There is perhaps a danger that 'Enforcement Undertakings' will come to be viewed as a 'get out of jail free' card for non-compliant organisations. However, this would depend on how much scrutiny is exercised by the Licence Committees in accepting or rejecting enforcement undertakings.

6.5.5. Recommendation

‘Enforcement undertakings’ would fit well into the current self-reporting procedures of the HFEA and are recommended. Under the current ‘incident alert’ system, any adverse incident or near miss in relation to treatment involving a third party must be reported within 24 hours of discovery and must be followed by a review of procedures in order to minimise risk of recurrence. ‘Enforcement undertakings’ could work in parallel with this existing standard and add a new layer to the requirement of self-reporting. ‘Incident alerts’ are mainly intended for instances of accident or incompetence, whereas ‘enforcement undertakings’ would serve to address potential criminal offences.

6.5.6. A common cause of disclosure of information is human error, such as sending a letter to a different patient’s address. Often when there has been an accidental breach, it will be promptly reported to the HFEA and the centre will themselves propose measures to correct the incident and prevent recurrence. When this is a first offence, it may be appropriate to accept enforcement undertakings with a warning that further violations will risk fines or the issuance of other Discretionary Requirements.

6.6. Given the advantages of the powers discussed, what actual effect could be seen in the way the HFEA enforces compliance? Table 1 below shows fictitious examples of incidents of a criminal offence being committed and the actions that may be possible with RES Act powers. The adoption of the RES Act powers would not bar the use of informal measures, which, in many cases, have proved to be effective in encouraging compliance. But it would make available a new level of enforcement that can be applied proportionately. The appropriate use of these powers will demand clearer decisions about the weight of each offence. It is likely that the availability of the RES Act powers will enable Licence Committees to enforce compliance in a more robust and consistent manner.

Table 1: Fictional Criminal Breaches
Examples of possible action with RES Act powers

Incident	Mitigating / Aggravating Factors	Possible sanctions using RES Act powers
<i>Breach of Confidentiality</i>		
The centre reports to the Executive that on two occasions a patient has been sent information relating to a different patient.	The incident occurred during THE first week of work for the staff member responsible and the centre reported the mistake as soon as it was discovered.	Enforcement Undertakings could be offered by the centre. If accepted, the HFEA could choose to issue a VMP or Compliance Requirement in conjunction with the Enforcement Undertaking. Or, if not accepted, a VMP and/or Compliance Requirements could be issued.
<i>Operating Without a Licence</i>		

While research facilities are being refurbished, work was continued in temporary facilities without notifying the HFEA or applying for a licence for the temporary facilities.	The research team failed to apply because they did not believe they would be committing a breach because the temporary facilities are in a nearby building.	Stop order; VMP
When inspectors arrange an inspection it is discovered that the centre has moved to new premises without notifying the HFEA or applying for a new licence.	The Person Responsible is defensive and will not acknowledge fault.	Larger VMP; Restoration Requirement
<i>Keeping an embryo in the absence of effective consent</i>		
A centre is found to be storing a large number of embryos after the period of consent has expired.	The centre's procedures for contacting the consenting parties are not robust.	Stop order; VMP
<i>Paying donors more than allowed</i>		
During interim inspection, it is found that the centre is paying all egg donors a flat rate.		VMP and Compliance Requirements
<i>Knowingly providing materially false information</i>		
The centre provided the name of qualified consultant gynaecologist on its licence application, who at the time of the first inspection is found not to be, nor intending to be working at the centre	The named consultant gynaecologist turned down the job after the licence application was submitted.	VMP
<i>Breach of Directions requiring information</i>		
A centre is found to have falsified reported numbers of cycles started and live births.		VMP; stop order; Compliance Requirements
<i>Obstructing an Inspection</i>		
Inspectors are refused entry on the day previously arranged for inspection.	Centre staff are verbally aggressive in their refusal.	VMP; stop order

7. Resource implications for the HFEA

7.1. There are some significant organisational implications that would stem from the adoption of the RES Act powers, which would require greater internal clarification about the weight of legislation, policy and procedure. However, with the new HFE Bill looming and organisational refinements inspired by the Hampton review, the HFEA is currently ideally placed to reflect on its record as a regulator and develop a coherent strategy toward licensing and enforcement.

7.2. Once the Authority has made decisions about procedures under the HFE Bill, detailed consideration of how the RES Act powers will operate will be necessary. This will include consideration of who will have the authority to administer these sanctions and also how the various appeal structures demanded by the two pieces of legislation will fit together.

7.3. Other considerations will include the necessity to integrate the policy implications of the RES Act powers into existing guidance. Under the RES Act, each regulator will be required to publish guidance to the new sanctions and how it will enforce offences. This will require a revision of the current enforcement policy. Additionally, the regulator is required to publish details of all enforcement action taken. These could be appended to the annual report put on the website and/or included in the annual

thematic review of centres' performance. Additionally, a communications strategy to disseminate this information will need to be developed.

7.4. The greatest procedural significance will stem from the requirement that any action undertaken to use powers granted by the RES Act will require proof beyond a reasonable doubt. In practice this will require what in effect will amount to an internal mini-trial to prove the allegations to a criminal standard. In order to ensure the evidence collected in inspections is of sufficient quality and quantity it will be necessary for some inspectors to have Police and Criminal Evidence Act (PACE) training. There are, however, members of the inspection team who are already PACE trained and it seems appropriate that a specialised team of 'investigators' be formed within the Regulation department. The RES Act powers also demand that each regulator has the capacity for an internal review system. Although, at the moment, this does not formally exist, there is a system of internal review being established under the HFE Bill. Therefore a dedicated review system will not be necessary, only the addition of capacity to the system which is already being created.

8. Summary

8.1. The RES Act provides an opportunity for the HFEA to broaden its ability to ensure that clinics comply with standards. The internal organisational improvements that a successful application to the Secretary of State requires fit well with those being made in order to implement the HFE Bill. The current set of enforcement options is limited to informal actions, direct action in respect of a licence or referral to the police. While these strategies should continue to be exercised where appropriate it would be beneficial for the HFEA to have more flexible powers to be able to exercise enforcement proportionately. The HFEA has not yet developed consistent practices of enforcement and the leniency currently exercised in most cases, which may be attributed to an inability to exercise proportionality in sanctioning, runs the risk of undermining the reputation of the HFEA as an effective regulator. These new powers will benefit both the Authority and licence holders by encouraging clear policies and resulting in more robust, flexible and consistent enforcement.

9. Recommendations

9.1. It is recommended that the HFEA apply for Discretionary Requirements (including Variable Monetary Penalties, Compliance Requirements and Restoration Notices), Stop Notices and Enforcement Undertakings.

Appendix A

Please note, all figures are from the BRE, Regulatory Enforcement and Sanctions Act, 2008: Guidance to the Act. July 2008.

Figure 1: Process for awarding the new sanctioning

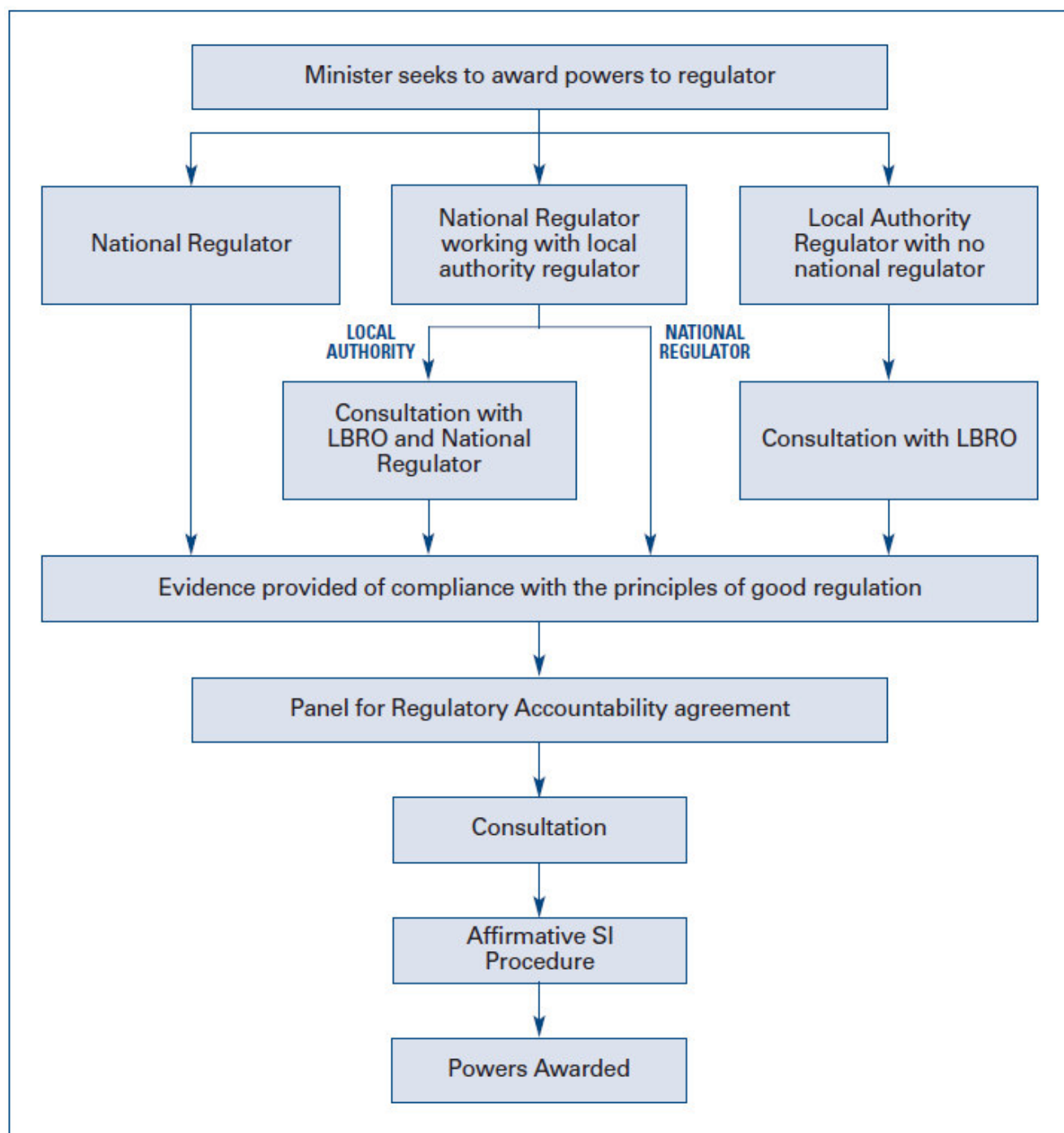


Figure 2: Issuing Fixed Monetary Penalties

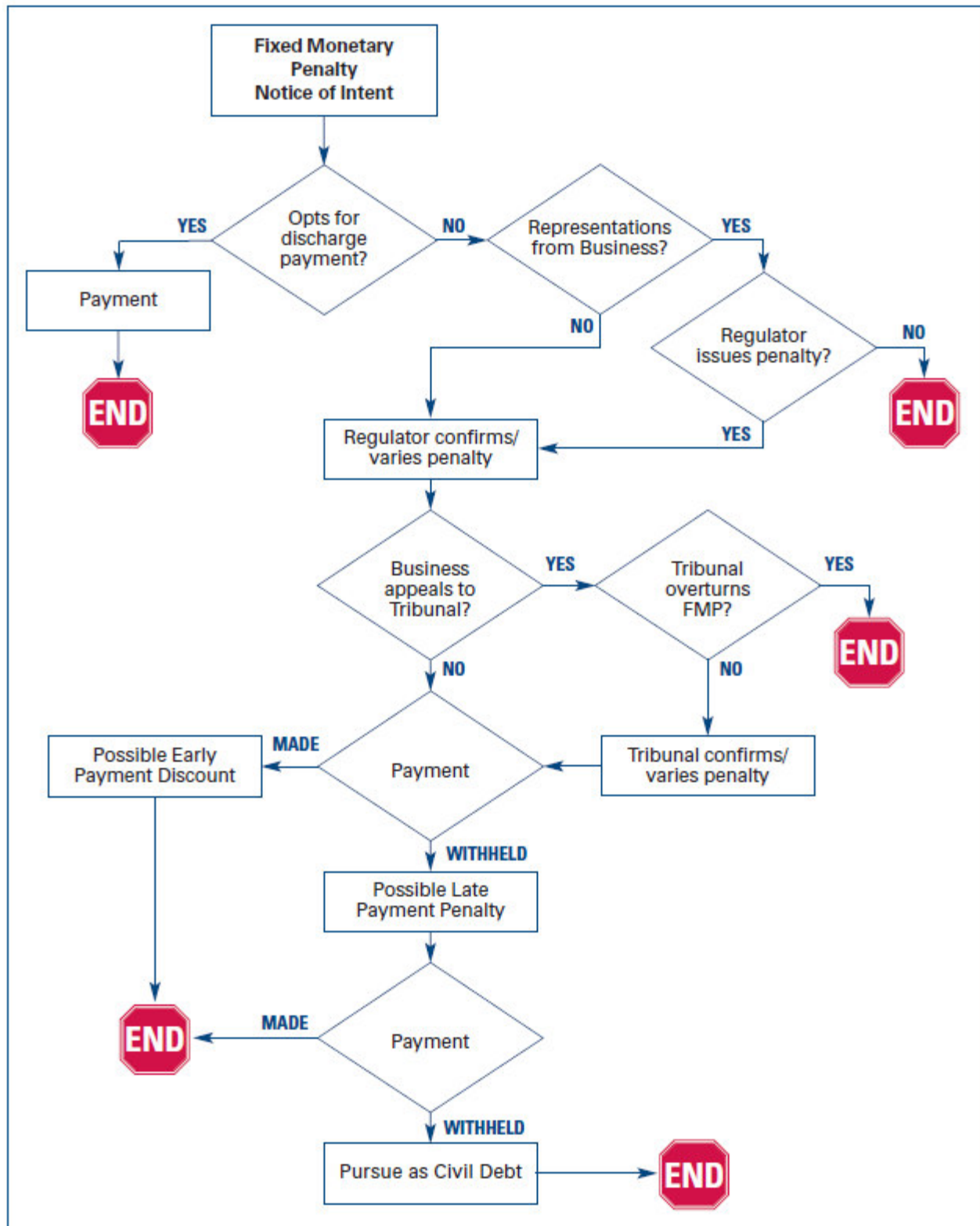


Figure 3: Issuing Discretionary Requirements

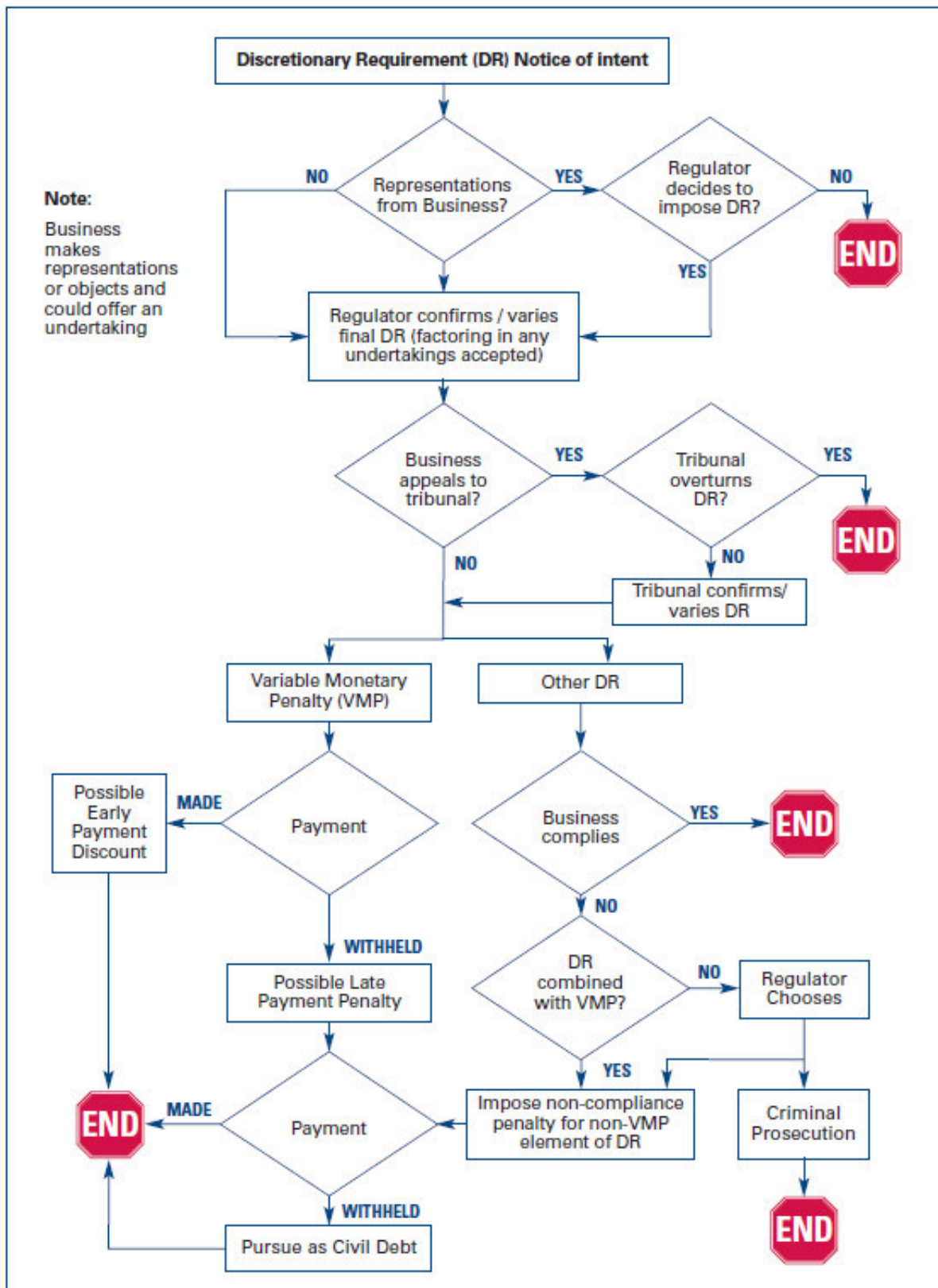


Figure 4: Issuing Stop Notices

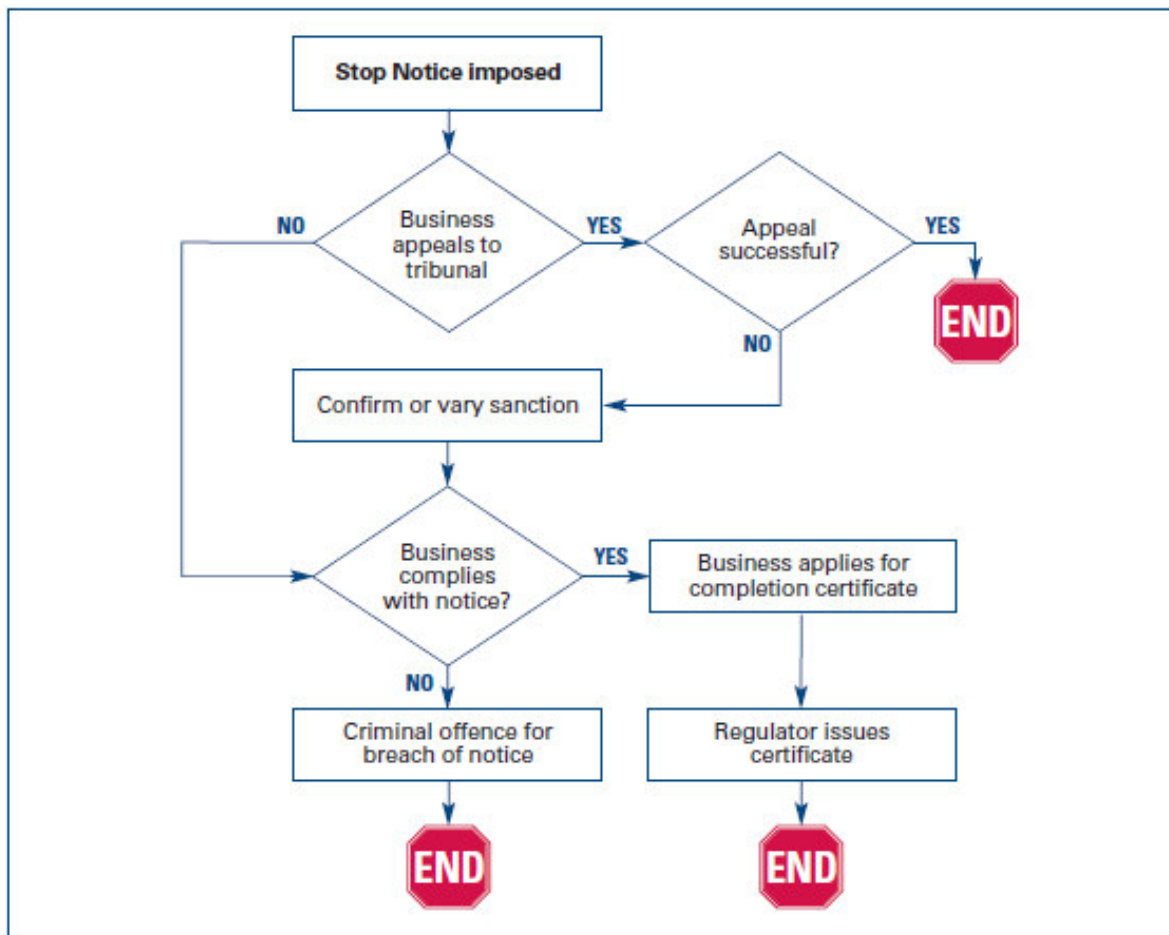


Figure 5: Issuing Enforcement Undertakings